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Understanding and enhancing approaches to quality improvement in small and medium-sized private facilities in Tanzania

Submission date
25/02/2016

Recruitment status
No longer recruiting

Registration date
09/03/2016

Overall study status
Completed

Last Edited
09/07/2024

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The private healthcare sector is steadily growing in low- and middle-income countries (LMIC), but there is considerable concern about the safety and quality of care. Recent years have seen an increase in the number of small and medium sized private clinics, but their regulation is often poor and relatively little is known about the effectiveness of studies trying to improve the quality of care they provide. This study has been designed to look at an innovative programme developed by the international NGO PharmAccess, which aims to improve the clinical standards of health facilities in low- and middle-income countries. The PharmAccess model seeks to improve the quality of care that facilities provide, as well as to shape the broader healthcare and finance markets and policy environment. Health facilities are assessed on a set of “SafeCare” structural quality standards, trained on quality improvement and business skills, and assisted in the development of a quality and business improvement plan. They receive regular mentoring visits and are also connected with the PharmAccess Medical Credit Fund, a social investment fund which facilitates access to bank loans to finance the prigramme. The aim of this study is to evaluate the impact of the PharmAccess model on quality of care given in private health facilities in Tanzania.

Who can participate?
Health facilities operating in the private for-profit and not-for-profit sectors in Tanzania.

What does the study involve?
Participating health facilities are randomly allocated to one of two groups. Those in the first group are assessed using SafeCare assessments at the start of the study and then again after two years. This involves comparing the practices of the health facility to a set of “SafeCare” standards, covering the way the facility is run and how it is structuired (e.g. staffing, equipment, systems and documentation). These facilities are then given a tailored quality improvement plan and receive training on quality and business systems. They are also connected with the PharmAccess Medical Credit Fund (MCF), a social investment fund which helps to access to loans to finance the quality improvement plan. Facilities are also given access to a call centre and online training portal. Those in the second group are assessed at the start of the study and then

again after two years with the SafeCare assessments. The results of the initial assessment are reported back to the facility but they are not advised to take any further action.
What are the possible benefits and risks of participating?
Participating health facilities could benefit from being able to improve the quality of care that they provide. There are no notable risks involved with taking part in the study.

Where is the study run from?
The study takes place in 240 private health facilities in Tanzania

When is the study starting and how long is it expected to run for?
January 2016 to December 2019

Who is funding the study?
1. Medical Research Council (UK)
2. Economic and Social Research Council (UK)
3. Department for International Development (UK)
4. Wellcome Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
MR/N015061/1

Study information

Scientific Title
Effect of approaches to quality improvement in small and medium-sized private facilities: A randomised controlled trial in Tanzania

Study objectives
The PharmAccess model will enhance the performance of participating private health facilities in terms of improved clinical quality, business performance and perceived quality of care by patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ifkakara Health Institute, Institutional Review Board, Dar Es Salaam, Tanzania, 09/03/2016, Ref: IHI/IRB/No: 04-2016
2. London School of Hygiene and Tropical Medicine, Interventions Research Ethics Committee, 05 /01/2016, Ref: 10493
3. Tanzania's National Institute of Medical Research, 17/02/2017, Ref: NIMR/HQ/R.8a/Vol.IX/2415

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
1. Clinical quality of care
2. Business performance

Interventions
Participating health facilities are randomly allocated to one of two groups.

Intervention group: Health facilities are assessed at two points in time (baseline and then one to two years later) using a set of “SafeCare” standards covering structural quality (e.g. staffing, equipment, systems and documentation). For example, the standard on infection control includes indicators on written policies, audit, handwashing facilities, protective clothing and waste management (www.safe-care.org). In between these assessment, facilities receive regular mentoring visits. In addition, the health facilities are provided with training on quality and business systems, and assisted in the development of a quality and business improvement plan. They are connected with the PharmAccess Medical Credit Fund (MCF), a social investment fund which facilitates access to loans to finance implementation of the plan. Loans are provided by local banks, with MCF guaranteeing all or part of the risk. Facilities are also given access to a call centre and online training portal.

Control group: Health facilities are assessed using the two SafeCare assessments, the baseline results of which will be reported back to the facility with no further action.

Intervention Type

Mixed

Primary outcome(s)
Current Primary Outcome Measures (as of 17/01/2018):
1. Correct treatment measured 18-24 months after the start of the intervention using standardised patients presenting four cases (suspected malaria, tuberculosis, asthma, and upper respiratory tract infection).
2. Compliance with infection prevention and control practices measured 18-24 months after the start of the intervention using observations of health worker-patient interactions

Previous Primary Outcome Measures:
Technical quality of patient care is measured two years after the start of the intervention in each health facility by:
1. Trained professionals present themselves unnanounced to a health provider as a genuine patient (the health providers are unaware that the standardised patient is acting)
2. Role-playing clinical vignettes (involving a fieldworker role-playing as a patient)
3. Observing doctor-patient interactions to assess patient safety and infection control practices using a structured questionnaire

Key secondary outcome(s))
Current Secondary Outcome Measures (as of 17/01/2018):
1. Perceived quality of care is measured using patient exit interviews at 18-24 months
2. Facility caseload is measured using the health facility questionnaire at 18-24 months
3. Facility revenue is measured using the health facility questionnaire at 18-24 months
4. User fees paid is measured using the standardised patients and patient exit interviews at 18-24 months
5. SafeCare assessment score is measured using the SafeCare assessment tool implemented by PharmAccess at baseline and at 18-24 months
6. Management practices score is measured in two different ways using: i) the health facility questionnaire at 18-24 months; ii) a sub-set of management-related criteria in the SafeCare assessment tool implemented by PharmAccess at baseline and at 18-24 months
7. History taking & examination, diagnosis, unnecessary and harmful care, dosing and advice measured using standardised patients at 18-24 months
8. Compliance with infection prevention and control practices by domain (hand hygiene, injection and blood draw safety, personal protective equipment safety, disinfection of reusable medical devices, and waste segregation) measured at 18-24 months using observations of health worker-patient interactions

Previous Secondary Outcome Measures:
1. Perceived quality of care is measured using exit interviews at two years
2. Facility caseload is measured using the health facility questionnaire at baseline and two years
3. Facility revenue is measured using the health facility questionnaire at two years
4. User fees paid is measured using the standardised patients at two years
5. Quality of management is measured using the hospital management tool at two years
6. SafeCare assessment score is measured using the SafeCare assessment tool implemented by PharmAccess at baseline and two years

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Inclusion criteria for health facilities:
1. Those operating within the study zones
2. Those operating under the umbrella organisations of APHFTA (Association of Private Health Facilities in Tanzania) and CSSC (Christian Social Services Commission)

Healthy volunteers allowed
No

Age group
Other

Sex
All

Total final enrolment
237

Key exclusion criteria
Exclusion criteria for health facilities:
1. Does not operate within the study zones
2. Does not operate under the umbrella organisations of APHFTA (Association of Private Health Facilities in Tanzania) and CSSC (Christian Social Services Commission)
3. Provides mental health services only
4. A referral hospital

Date of first enrolment
14/03/2016

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Tanzania

Study participating centre
Ifakara Health Institute
Kiko Ave
Dar es Salaam
Tanzania
PO Box 78373

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Economic and Social Research Council

Alternative Name(s)
Economic and Social Research Council (ESRC), ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name

Department for International Development, UK Government

Alternative Name(s)
DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/08/2021	09/08/2021	Yes	No
Results article	adoption of management practices and quality of care	18/09/2023	09/07/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes