Research Protocol - Assessing home based treatment and care of MDR-TB patients in northern Uganda

RESEARCH PROTOCOL

Assessing home based treatment and care of MDR-TB patients in northern Uganda.

Study Site: Location of interviews: Kitgum, Uganda – one month's duration.

Proposed start date of data collection for study: July 2011

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Glossary

DOT	Directly Observed Therapy
DR-TB	Drug-resistant TB
HBT&C	Home based care and treatment
MDR-TB	Multidrug-resistant TB
MoH	Ministry of Health
MSF	Médecins Sans Frontières
TB	Tuberculosis
WHO	World Health Organization

Background

MDR-TB is an emerging issue, with an estimated 0.5% of new TB cases in Uganda being MDR (WHO 2009). The actual figure could in fact be higher than this, with one study identifying MDR TB in 12.7% of TB patients (Temple et al, 2008). The National TB and Leprosy Programme is already stretched over capacity, with an extensive waiting list for treatment at the one identified treatment facility in Kampala. WHO also estimate that the MDR-TB incidence is higher than those diagnosed and treated (with just 1.4% of those with MDR-TB estimated to be diagnosed and treated), as drug susceptibility testing is not widely available. WHO have also recorded that 15% of new sputum smear positive patients defaulted from their treatment regime, highlighting the potential for new MDR-TB cases developing.

Assessing Medecins Sans Frontieres's HBT&C programme which began at the end of 2009 and investigating a patient-centred approach to MDR-TB could provide evidence which is of use towards the national response to MDR-TB. Analysis of this method of treatment & care, and identification of issues and strengths may enable development and implementation of a useful alternative and supportive model to hospital-based treatment, which could then be rolled out nationally. Issues raised by patients relating to hospital based care could also be fed back to improve this method of care in Uganda. This study could also be advocated internationally as an investigation into the 2009 WHO guidelines on MDR-TB, examining how these work in practice and recommending improvements if necessary.

The model of care used to manage MDR-TB globally has frequently been hospital based, where patients are admitted to specialist hospitals for at least the intensive phase of treatment. The arguments for hospital based care have included ease of management of complex drug regimes, increased adherence to treatment and reduced transmission within the community. However in reality this is not necessarily the case, there has been no evidence of an actual reduction in community transmission with hospital based care, as many patients will have been infectious whilst awaiting diagnosis or hospital admission. Nosocomial transmission is high with both health care workers and other patients being at risk of MDR-TB acquisition. The associated economic and social costs of isolating patients in hospitals for long durations of time and potentially long distances from their homes, has been found in one study to increase treatment default (Heller et al, 2010). Hospital based care has been associated with a lack of outpatient management after discharge, with many patients being lost to follow up (Griffith, 2004). Hospitalisation can comprise 50% of the total price of treatment in middle-income countries, with total care costs of MDR-TB treatment costing $30,000 in some places (Smart, 2010a). Lack of available beds and delays in commencement of hospital based treatment have been found to be associated with 45-55% of patients dying before treatment commences (Smart, 2010a).

Community based care has been found to be extremely effective in several settings such as Peru, Lesotho and South Africa (Smart, 2010a & Heller et al, 2010), with less opportunity for nosocomial transmission and with high cure rates such as 83% in a Peruvian study of a community based model (Smart, 2010a). Studies in South Africa have found that delivering MDR-TB treatment and care on a community level as opposed to hospital based is feasible and safe (Heller et al, 2010). It is possible to achieve a good level of health workers' expertise regarding drug provision and side effect management with focused training and sufficient exposure to clinical cases (Chalco et al, 2006), with programmes enabling rapid commencement of treatment (Smart, 2010a). Qualitative studies in Peru found that delivering MDR-TB treatment within the community enabled wider factors which influence health to be addressed including the family and community, as opposed to the clinical approach which does not account for psychosocial and economic factors which can negatively impact on health and treatment outcomes (Chalco et al, 2006).Community based approaches have been found to 'build local capacity for addressing the health and social problems which beset many communities in which tuberculosis is endemic' (Farmer & Kim, 1998).

There are currently few qualitative studies published on MDR TB, and the majority are not in Africa. There is little information about the acceptability of different models of care of MDR TB to patients with a recent qualitative programmatic review of 3 countries showing diverse programme implementation within 3 settings, with initial treatment ranging from community initiation at home, to hospital based initiation to a combination of community outpatient and hospital based (Furin 2011). Thus this research would provide vital insights towards enabling patient-centred treatment and care of MDR-TB. The Uganda National Tuberculosis and Leprosy programme in particular insists on gathering evidence within Uganda to best guide programme policy and practice.

Studies in Uganda have found patients may resist seeking TB treatment due to barriers such as lack of transport money, traditional healers being seen as more patient-centred and offering instant healing, fear of HIV testing and association of TB with HIV and enhanced stigma; as well as lack of friendliness perceived from health workers. It has been argued that these barriers could be overcome by bringing health services to the community level (Buregyeya et al, 2011), in which case home based treatment and care could potentially fill a gap in reaching those who may otherwise be missed.

Uganda's national model of treatment and care for MDR-TB is currently hospital based treatment for the initial phase when injections are provided (8 months), with Mulago hospital in Kampala being the sole provisory institution. However, funding for the delivery of MDR-TB treatment waned three years ago, leaving no current alternative model of care being provided nationally. There is thus urgent need for examination of a potential model of care which can address the growing numbers of MDR-TB

cases and which can provide treatment and care to those in need in an accessible, feasible and sustainable manner. MSF have successfully been delivering home based treatment and care for MDR TB in a pilot programme in collaboration with the ministry of health in the Kitgum district since 2009. Assessing this model of care in a patient-centred manner, considering the physical, emotional, psychosocial, material and spiritual needs should enable the improvement of health outcomes as well as improved quality of life and reduced suffering for those affected (Smart, 2010b). An analysis of this model could help inform development of a National MDR TB treatment model that could be rolled out country-wide.

Study sites

MSF programme in Kitgum and Lamwo districts in Northern Uganda.

A brief description of MSF and MoH collaborative TB/DR-TB programme

Kitgum was heavily affected by the fighting between Government forces and the Lord's Resistance Army in the early 2000s. However, more recently peace has returned, and the largely displaced population has returned to their villages. Despite this, the level of health care services remains very low, as the MoH has had to try to rebuild the health system.

MSF has been involved with TB care in Kitgum district since 2009 and has been working in collaboration with the ministry of health staff in 10 MoH facilities. The diagnosis and treatment of drug resistant TB was commenced in late 2009 due to a number of patients identified having failed 2 courses of TB treatment. Due to lack of hospital beds with acceptable infection control and concerns about patients tolerance of long stays in hospital, MSF commenced a home based drug resistant TB programme. Anecdotally acceptance rates have been high, however the programme has also encountered an number of difficulties during the implementation.

Collaborative Partnership

MSF has been developing a good collaboration with the Ugandan National TB and Leprosy Programme. It has however become clear that there is a difference in M SF's approach to MDR TB in Kitgum compared with the proposed Ugandan National programme that is due to start later in 2011. The Head of the National TB Programme, Dr Adatu, is keen for joint research into the MSF model to see what patients and families views of the programme are, and to see what potential negatives to the programme there may be. Dr Adatu has assigned the head of the MDR TB programme to collaborate with the research and hopes that information gained from this research may help inform whether ambulatory treatment for MDR TB is acceptable to patients, families and communities.

Overall aim:

To examine patients' experiences of home based treatment and care in order to learn lessons from the last 12 months of implementation using WHO 2009 guidelines and devise future strategies as a result.

Specific objectives:

1. To determine patients' perceptions, views and experience of treatment and care at home versus in hospital; and how best these patients could be supported
2. To examine what encourages HBT&C patients to adhere to treatment; and how this could be improved
3. To investigate families' experiences and views on home based treatment and care versus hospital based
4. To assess the views of various stakeholders of home based care of MDR-TB compared to hospital based care.

Methods:

This study will be conducted using a qualitative, descriptive research design and will take place in Kitgum, Uganda for a period of one month. This choice of methodology was decided to be most appropriate to answer the research question, which looks at patients' views on home based care; and how this interacts with that of their families and other stakeholders involved with tuberculosis.

This research uses a flexible participatory technique for which the researcher commences with a set of interview guides and then interacts with participants to tailor the research to local context. Thus the communities have not so far been involved except through anecdotal feedback from MSF health care workers in the programme related to issues of stigma and infection control. This is an external research project with a researcher from the UK. The study is taking place within the framework of existing MSF programmatic activities and will fit in with the day-to-day presence of MSF that participants will be familiar with.

Participation in the study will be voluntary and interviews/FGDs can be stopped at any point. Respondents' names will not be used and it will be ensured that individuals cannot be identified in the report (either by name, individual details or through use of job descriptions that are identifying). Tested interviews/FGDs will be recorded where possible, with permission being requested from respondents beforehand and tapes being destroyed once transcribed. Questions will be framed in a way which encourages honesty and openness of respondents. If possible participant observation will be undertaken of DOT delivery and a patient support session.

Sampling and recruitment strategy:

Two sampling methodologies are to be used to get variation in responses: both purposive sampling and snowball sampling. Purposive will allow for the researcher to use judgment about who will give the best perspective on home based treatment and care of MDR-TB and snowball sampling will allow for participants able to recommend useful potential candidates for study.

Participant selection[1] will cover MDR-TB patients on the MSF HBT&C programme, family members of these patients, a TB- related member of the Ministry of Health, a representative from the National TB & Leprosy Programme, NGOs working in the field of TB & HIV and health care professionals delivering DOTS. Participants will be recruited through routine programme activities.

In-depth semi-structured interviews with individual participants and focus group discussions (FGDs) will be used to collect data. This requires a flexible approach to research design in contrast with the design of quantitative studies, which makes accurate prediction of sample size difficult (Marshall, 1996). Examination of data occurs whilst the study is taking place, and the number of participants is only known finally when data saturation occurs, that is when new information is no longer being generated (Green & Thorogood, 2009), (OCA, 2007). Previous experience of similar studies with a focus on one specific phenomenon has established up to +/- 25 potential interviews as a working figure (Guest, G, Bunce, A and Johnson, L). 5 focus group discussions will be conducted with community members and general nurses (including governmental and NGO nurses) to compliment individual interviews and to gather from a group perspective the phenomenon under study. The intention for the FGD to include people with similar power levels, similar education levels and gender will be considered based on additional relevant information gathered during preparation in the field.

Data collection and analysis:

An interview guide with open-ended questions will be used to conduct the in-depth interviews and FGDs. Tape-recorded interviews will be transcribed. Before coding the data the researcher will read the typed field notes and interview transcripts word by word and initial coding will be placed in the margin of the scripts. During the coding process, data will be continually reviewed and revised with emerging patterns to be noted and relationships between constructs identified. Validation will be established by maximising validity with supporting evidence that includes cases that do not fit with conclusions (cases that deviate), testing emerging theory as opposed to only selecting examples which reiterate desirable points (Green & Thorogood, 2009). In addition transparency of interview transcripts so that they can be inspected will be done with ten per cent of the interview transcripts included as an appendix of the report, Removing respondents names and ensuring no details which

[1] The diversity of participants was known following a stakeholder analysis that filtered individuals or groups with a potential interest and/or influence in TB.

could link the response to the respondent are included to maintain confidentiality and anonymity, Reflection of the role of the researcher as a confounding factor will be considered throughout the analysis, acknowledging the potential for bias. Finally, triangulation as defined by searching for convergence among the different sources of information gathered to form themes or categories in the study is considered to be part of the validation procedure.

Interview Language

The interviews will be conducted in English when the person being interviewed feels comfortable doing the interview in English. Otherwise interviews will be conducted in Acholi with a translator. All interviews will be transcribed from tape into English or an English translation.

Limitations

This is a qualitative study, and as such the findings while informative may not be generaliseable to the whole of Uganda. There is always the risk of researcher bias and lack of methodological rigor in qualitative research, which we hope to minimise as much as possible through supervision by 2 supervisers with experience in qualitative research. Finally, the use of a translator may influence the quality of the research findings, however it is important that all patients have the opportunity to be interviewed which in this situation requires the use of a translator.

Inclusion criteria

1. All patients on drug resistant TB treatment will be potentially eligible
2. All adult family household members – with 1 member present at the time of visiting the patient randomly selected from each household
3. Staff members from MSF and MoH involved in TB care
    a. 3-10 staff members will be selected

Exclusion criteria

Patients

- Do not consent to interview
- Identified by treating team as too unwell to be interviewed

For family members

- If the patient does not give permission for a family member to be interviewed or if the family members do not consent

Staff members

- If MoH do not want particular staff members to be interviewed
- If staff members do not consent to interview

Fair Selection of Study Population

Selection of patients and family members is designed as much as possible to provide all with an equal chance of being selected, and given the small size of the programme all patients are likely to be asked if they would like to participate. There is currently no other research project that looks at TB or MDR TB in this programme, and therefore this population is not at risk of being overselected (with resulting burden on patients). For staff members they will initially be selected by involvement with the MDR TB programme, but through interviews and discussion with MoH other key stakeholders will be identified.

Supervision

The principle Investigator will have supervision and be able to discuss methodology issues for advice with both the London School of Hygiene and Tropical Medicine Superviser and with Bev Collins who is a trained Anthropologist.

Resources

This research will require the interviews to be performed by the principle investigator with 1 translator. Identification of some key stakeholders and of patients will be done by the MSF Team. Identification of key MoH staff will be done by the District TB Officer. The funding for the translator, tape recorder and the principle investigators trip are covered.

Data management, analysis and protection

After transcription all tapes will be destroyed.

Information will be stored without patient name and address identifying information and will be stored in a password protected format.

The student will sign a confidentiality agreement with MSF, and will also sign a data agreement – stating that data gathered may only be used for this research project, that all data must be kept in a manner that respects confidentiality and protection of data. Data collected may not be shared with others, presented or published without consent from the Medical Director of MSF OCA.

Informed Consent

The consent process will involve outlining the purpose of the study, stating that participation is voluntary and the respondent can change their mind about participating at any point. There is no right or wrong answer, we would like to learn about good and bad experiences and hear how it may be possible to strengthen TB services. Consent procedure will explicitly clarify that participation is in no way linked to receiving services. Consent will be briefly outlined verbally to ensure respondent comprehension, with voluntary written consent then being obtained. There will be two steps to the

written consent form – consent for the interview/FGD and consent for recording of the interview/FGD.

Confidentiality

Patients' names will not be included in any of the project write up, each respondent will be given a code which corresponds to the time they were interviewed so I can identify who they are; but no one else can. Computer stored data will be password protected and patients' files will not be left unattended. In Uganda adherence to treatment and hospitalization are two potential issues of public health concern, it will be discussed beforehand with the participant that the researcher will be obliged to discuss with the participants practitioner any disclosure of sensitive information detrimental to public health practice and or harmful to the patient. The joint MSF/ MoH programme in Kitgum is an approved pilot programme in the country and MoH staff are kept informed of programme performance, patients adherence and the fact that most patients are treated at home.

Social Value

This project has a number of potential benefits.

Project Level benefits:

This home based programme has not had any formal assessment of patient and family views of the service. This is likely to provide valuable information that may help improve the functioning of the programme.

Community Level Benefits:

It is currently known what community views of MDR TB and community management of MDR TB are. This study could help provide important information to provide to community leaders and key stakeholders that will be helpful for future scale up of effective TB care.

National Level Benefits:

There is little evidence currently about the best model of care for MDR TB in Uganda. The NTLP is planning on a hospital based programme with 6-8 months of hospitalisation in a centralised hospital. In making their final decision about how to structure the NTLP MDR TB programme research into patient and family acceptance of a community based model of care including home based care could be helpful and has been requested by the NTLP.

Potential Risks

It is perceived that MDR-TB patients face stigma, both externally enacted by members of the community and their families; as well as internally experienced accompanied with strong feelings of

guilt and fears of infecting others around them. Feelings of spoiled identity may be experienced by the patients, particularly with side effects of some drugs changing skin colour or changing personality, which can alter a patient's self image. It has been found that support of health workers such as nurses during home based care can counteract this stigma, by communicating with family and community members in order to reduce discrimination and raise awareness about the realities of MDR-TB (Chalco et al, 2006). However, the experience of stigma for tuberculosis and multi-drug resistant tuberculosis is thought to vary from community to community and country to country and for Uganda this has not been well described.

As patients are already receiving MSF treatment and care it is thought this study, which has been designed with input from MSF team members in Uganda, will not bring additional focus for stigma; visits to patients for interviews will be alongside daily health worker visits, fitting within the programmatic design, and therefore will not stand out to the community. Interviews and focus group discussions will be conducted with members of the community with and without MDR-TB and therefore will not be discriminatory. These will be conducted in a manner which is respectful, maintains dignity and considers each patients feelings regarding location and use of protective equipment.

This project is taking place alongside the organisation providing care, so if any issues do arise the patients can quickly be given any necessary support, particularly as interviews will take place in a private space within the health clinic.

The moral responsibility of inviting people for interviews/FGDs have been considered; and renumerations procedures will be as per the MSF standard. Patients, family members and those attending FGDs will be offered nutritional snacks/fruit to thank them for their time and we do not anticipate people needing to travel for these meetings.

Respect for Recruited Participants and Study Communities

Feedback mechanisms will be used to ensure participants are aware of the findings and outcomes of the study, for example via counsellors during patient visits to provide feedback about the findings to patients and families after the study. Respondents can choose to opt in or out of this feedback process prior to interview commencement. Summary findings of the study will also be made available to participants of the stakeholder and staff interviews.

Previous research work of the principle Investigator

I have conducted a qualitative research project evaluating a HIV education programme in Sierra Leone, examining whether education was changing young people's attitudes and practices and what

barriers existed to this change. I also conducted a qualitative research study into the proposed HIV law in Malawi, examining people's perceptions and views on this law and what potential effects it could have. This law has subsequently been postponed from being passed and recommendations for necessary amendments to the law included in my report are being proposed to the relevant ministers.

Independent Review

This protocol has been submitted to the Ugandan Ethics Review Board, The London School Ethics Review Board and the MSF Ethics Review Board.

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