



**Research Protocol - Evaluating the effectiveness
and burden of diabetes care in a complex
humanitarian emergency setting in Mweso, North
Kivu, Democratic Republic of the Congo (DRC), 2015**

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*Evaluating the effectiveness and burden of diabetes
care in a complex humanitarian emergency setting in
Mweso, North Kivu, Democratic Republic of the
Congo (DRC), 2015*

Research Study Protocol
(8 July 2015)

Key data

Version	v.5
Study design	Mixed methods (cohort, cross-sectional survey, qualitative)
Study period	March 2015 to March 2017
Study sites	Mweso Hospital, North Kivu, Democratic Republic of the Congo (DRC)
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List of acronyms

BMI	Body Mass Index
BP	Blood Pressure
CHW	Community Health Worker
DRC	Democratic Republic of Congo
FPG	Fasting Blood Glucose
IEC	Information, Education, Counselling
MoH	Ministry of Health
MSF-OCA	Médecins sans Frontières – Operational Centre Amsterdam
MSF-UK	Médecins sans Frontières – United Kingdom office
RPG	Random Plasma Glucose
WHO	World Health Organisation

Executive summary

Background: Since 2008 Médecins Sans Frontières-Operational Centre Amsterdam (MSF-OCA) has been working in Mweso health zone, North Kivu, Democratic Republic of the Congo (DRC). In collaboration with the local Ministry of Health (MoH), MSF-OCA supports the Hospital in Mweso and 4 out of 23 Primary Health Care clinics. Mweso Hospital routinely treats diabetic patients presenting with acute complications and in need of treatment (insulin and/or oral treatment). Since 2011, this has been extended to the out-patient clinic, but without clinical guidance or standard operating procedures (SOP), nor specifically trained staff. The Mweso project reports increasing numbers of patients with diabetes and diabetes-related complications, and requested from MSF-OCA to implement a formal diabetes service to improve quality of care for Diabetics.

Rationale: A new model of diabetes care was implemented by MSF-OCA in Mweso in March 2015. The model (Integrated Diabetic Clinic within an Outpatient Department (IDC-OPD)) is based on simplified context-adapted clinical guidelines, clinical SOPs, adapted patient counselling & support materials, medications from World Health Organization(WHO) Essential Medicines list, and one-off staff training by a Diabetologist. This represents an opportunity to evaluate and refine this model of diabetes care to support its application in comparable settings. Furthermore there is an opportunity to benchmark diabetes burden in the MSF Catchment area and measure its diabetes care coverage in the area.

Overall aim: To evaluate IDC-OPD in Mweso health zone, North Kivu, DRC.

The specific objectives are to examine:

- The *reach* (coverage) of the diabetes service to the intended target population.
- The *effectiveness* of IDC-OPD in improving diabetes outcomes (fasting blood glucose and complications)
- *Adoption / acceptance* of IDC-OPD by staff and patients
- *Implementation* of IDC-OPD in terms of consistency/fidelity, adaptation and costs
- *Maintenance* of IDC-OPD in patients and programme over time.

Methods:

Design: A mixed-methods design will be used, based upon the RE-AIM framework (see Annex 7.3) and <http://www.re-aim.hnfe.vt.edu/>). Objective 1 (Reach) will use a randomised cross-sectional population-level household survey design to measure the prevalence of diabetes and coverage of the diabetes service; routine cohort data will be used to compare numbers receiving and requiring care. Objective 2 (Effectiveness) will use a cohort study

design of all diabetes patients at the MSF run hospital in Mweso. It will use routine clinic data to assess the effectiveness of the new diabetes care model implemented by MSF-OCA in Mweso. It will also include cost-effectiveness analysis. Objective 3 (Adoption): This will use qualitative data to explore issues around adoption and acceptance of the model components. Objective 4 (Implementation) will use cohort, costing and qualitative data. Objective 5 (Maintenance) uses cohort and qualitative data.

Study participants: For the cohort study, all patients with confirmed diabetes attending Mweso hospital Outpatient department will be included (using patient records from January 2013 to March 2017). For the household survey, respondents will be randomly selected in the study catchment area using a cluster sampling design. For the qualitative research, respondents will be purposively selected patients and health workers in Mweso hospital.

Data collection: Cohort data will be collected and from routine patient records by trained data clerks, who will input this data into a predesigned database on a weekly basis. Cost data will be obtained from accounting records and supply orders. For the household survey, teams of nurses, enumerators, Community Health Workers, and Supervisors will collect data. Qualitative data will be collected by trained interviewers.

Data analysis: For the cohort study, Interrupted Time Series segmented analysis will be used to evaluate the impact of the new model on treatment outcomes and complications. Economic analysis will compare the level and trend of cost per clinical outcome at pre and post intervention time period and estimate the effect of the intervention. The household survey research will use descriptive and multivariate analysis. The qualitative research will use thematic analysis.

Ethical considerations: This study protocol will be submitted to the MSF Ethics Review Board for ethics clearance, and also the LSHTM Ethics Committee. Written authorisation to implement the study will also be obtained from the MoH of North Kivu.

Dissemination: Findings from the study will be shared with local, national and international stakeholders every 6 months in order to inform and improve the delivery of diabetes care by MSF and other public health agencies in the study area. Outputs will include reports and peer-reviewed academic publications and presentations at key conferences and workshops.

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1 Background

Diabetes is a non-communicable disease (NCDs) characterized by chronic hyperglycaemia. The mortality and morbidity from diabetes is significant, both from acute events and from the long-term micro vascular and macro vascular complications that arise from the disease. By 2030, Africa is expected to have the largest proportional increase (90.5%) in the number of adult diabetics among the six WHO Regionsⁱ.

In the Democratic Republic of the Congo (DRC), NCDs and diabetes are estimated to account for 21% and 1% of all deaths respectively.ⁱⁱ However those estimates have a high degree of uncertainty. Data from the International Diabetes Federation (IDF) estimates prevalence at 5.4% for DRC.ⁱⁱⁱ Similar estimates (4.0-4.2%) were observed by other authors in the country ^{iv}, with high mortality rates within 5 years after diagnosis due to acute complications associated with diabetes (e.g. ketoacidosis).^v

Since 2008, Médecins Sans Frontières Operational Centre Amsterdam (MSF-OCA) has offered primary and secondary health care in Mweso health zone which is located in the Health District of Masisi, North Kivu Province, in DRC. Mweso health zone is a rural, low income and conflict-affected area with an estimated catchment area of 145,000 people which includes 17 camps for Internally Displaced Persons (IDPs). MSF-OCA, in collaboration with the local Ministry of Health (MoH), supports health services in the hospital in Mweso and 4 out of 23 Primary Health Care clinics.

1.4 MSF diabetes activities prior to implementation of IDC-OPD

Since 2011, MSF-OCA in partnership with the MoH has provided diabetes care through the hospital in Mweso. The hospital provides care for the people who live in the catchment area of Mweso health zone. To date 140 patients (age 11-60 years) have been treated for diabetes, although data on patient outcomes is limited.

MSF-OCA has been the only provider of treatment for patients presenting with decompensated diabetes at the hospital in Mweso since 2011. Initially the medical team focused on short-term survival and the management of keto-acidosis, and relied on guidelines that were minimally adapted for the field-setting; they lacked therapeutic objectives, data collection tools, quality indicators, and model of care to ensure patient care and follow-up.

Notably, patients were generally treated with Insulin monotherapy, despite the fact that the majority were suspected to be type 2 Diabetics.

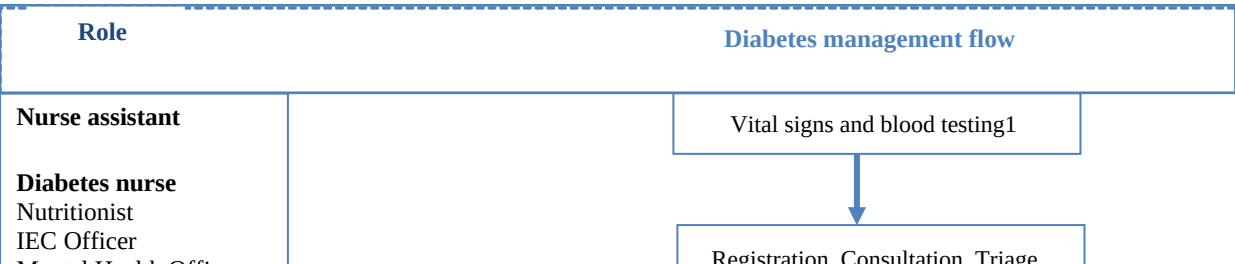
A patient file and system of registration was introduced in January 2014, and the new model of care (IDC-OPD) was implemented in March 2015, at which point the patient file was modified to reflect the new clinical procedures.

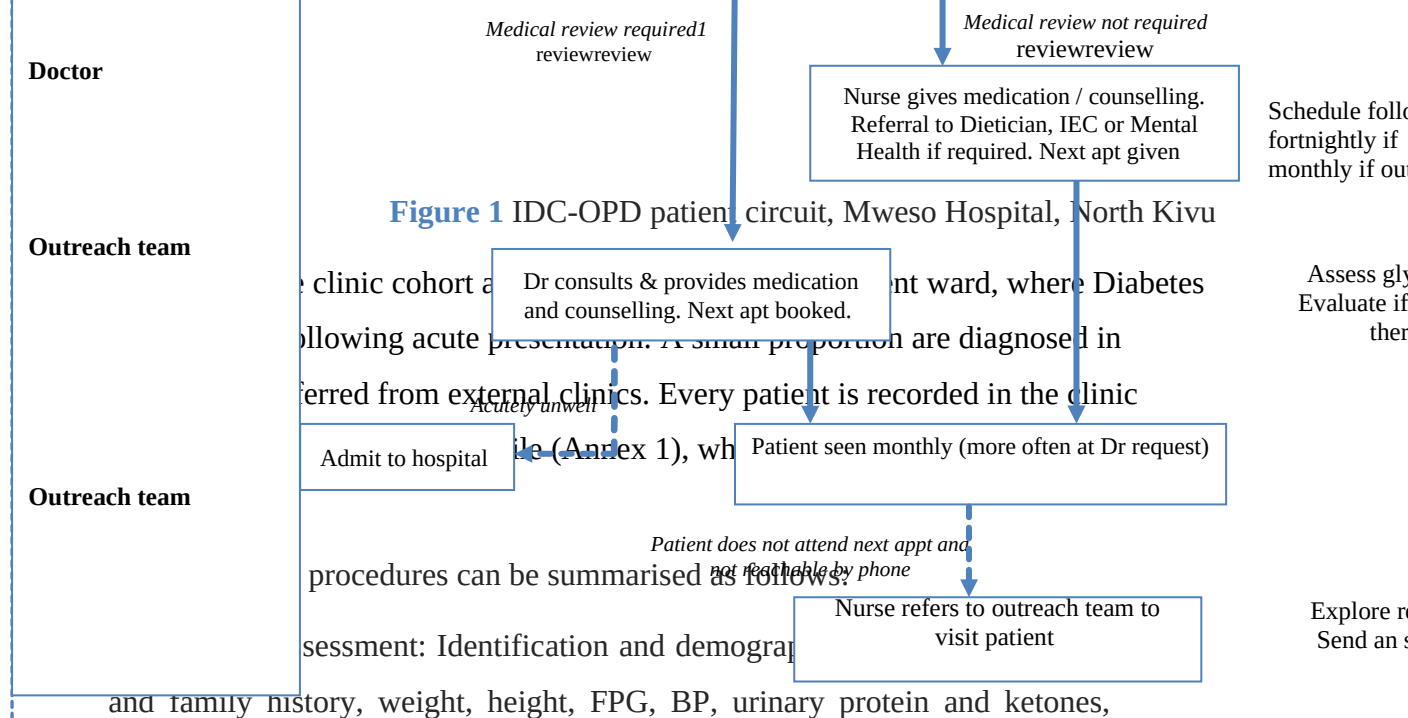
1.5 The new Diabetes model of care for Mweso Hospital

IDC-OPD is a nurse-led, multi-disciplinary model of care adapted to the specific setting of Mweso Hospital. The service is managed by a Nurse Supervisor who oversees the running of the clinic (including orders of drugs and materials, coordination of staff involved, M&E and quality assurance) and ensures that hospitalised patients receive appropriate follow-up. The Nurse Supervisor is the sole member of staff dedicated to the service (although at the time of writing, this person had not yet been recruited); all other staff have other roles in the hospital:

- Nurses: two nurses and one nursing assistant are allocated to the Diabetes clinic on clinic days, and are responsible for clinic consultations
- Doctors: two doctors provide medical support for the clinic when called on, and see all patients referred by the nurse
- Nutritionist: the nutritionist visits the clinic on clinic days to provide brief (15-30 mins) nutrition education, and to see referred patients (BMI<15)
- Information, Education and Counselling (IEC) officer: visits the clinic on clinic days to provide group education sessions
- Psycho-social support officer: visits the clinic on clinic days to facilitate peer support sessions (30 mins), and to see referred patients.

Patient circuit





creatinine, visual acuity and eye check, foot examination, symptom review, diagnosis, treatment initiation, counselling and arranging next appointment.

- Follow-up appointment: FPG, BP, weight, infection and pregnancy screen, brief foot inspection, documentation of any hospitalisations, urine analysis if unwell or hyperglycaemic, referral to doctor if unwell or poor glucose control, who may modify treatment, referral to nutritionist of psychosocial team as required, treatment education as required.
- 6 month medical review: visual acuity and eye check, foot examination, urinary protein, plasma creatinine, symptom check, treatment modification if required and counselling.

1.5.1 Clinical Guidelines and clinical SOPs

Specific clinical guidelines were developed for the Mweso setting, based on World Health Organisation (WHO), International Diabetes Association, National Institute of Clinical Excellence and MSF guidelines, with input from a Diabetes specialist and experienced clinicians within MSF. These guidelines cover diagnosis of diabetes, out-patient care for diabetics, insulin initiation and adjustment, management of diabetic emergencies, management of surgical and other hospitalised patients with stable diabetes, and management of gestational diabetes. These guidelines were converted into clinical SOPs which are displaced in hospital departments. An important element of these guidelines was the emphasis on distinguishing type 1 from type 2 Diabetes, and prioritising treatment with oral hypoglycaemic (OHG) therapy for type 2 Diabetics, moving on to Insulin therapy only if

acceptable glycaemic control (FPG<200mg/dl) is not achieved on OHGs (typically after 6 months).

Diagnosis of Diabetes Mellitus is based on WHO Guidelines. Either:

- Random Plasma Glucose (RPG) > 11.1mmol/l (200 mg/dl) on a minimum of two occasions. Random is defined as the glucose concentration any time of the day without regard to the time since the last meal. OR
- Fasting Plasma Glucose (FPG) > 7.0 mmol/L (126 mg/dl) on two occasions. Fasting is defined as no caloric intake for at least the past 8h. If the results are discordant, the test should be repeated, and the diagnosis will be made on basis on this value

1.5.2 Patient education and supportive counselling

Diabetes educational tools were developed for Mweso based on tools developed by Diabetsante (Mali), adapted to the context of North Kivu . These tools are mostly visual and cover diabetes self-management, acute and chronic complications, diet, treatment (insulin and tablets), pregnancy, daily foot care, how to recognise symptom of hyperglycemias and hypoglycaemia, store insulin and safe injection technique. Since literacy levels are very low in Mweso zone, the tools are designed for use by medical and IEC staff rather than for patient self-education. Therapeutic education is provided by the Diabetes nurse and the IEC team on a group and 1:1 basis on every clinic day.

The Diabetes nurse also coordinates the activities of the Psycho-social team who can provide 1:1 support for patients referred by the nurse, as well as support groups at the weekly clinics. At these groups, patients are asked to describe what is concerning them; the facilitator may ask about available family support and resources that will help the participants and the facilitator to design a realistic self-management plan. Patients with severe coping problems, signs of mental illness, substance misuse or cognitive decline, are followed up on a 1:1 basis.

A nutritionist attends the clinic each week, also providing group education and focused 1:1 education for patients referred by the nurse. The nutritionist advises a balanced and affordable diet based on locally available foods and matched to the individual needs of patients; visual support tools have been developed specifically for the setting. The nutritionist also sees any patient with a Body Mass Index (BMI)<16, for provision of food support according to standard hospital procedures.

2 Study rationale, aim and objectives

There is a lack of data on models of diabetes care and limited evidence on implementation, effectiveness and feasibility of diabetes care in rural contexts where MSF is working. The increase in diabetes patient load in Mweso (and elsewhere) promoted MSF-OCA to strengthen diabetes care by developing and implementing the new model of diabetes care in the outpatient department (IDC-OPD) of Mweso hospital. The introduction of new model of care provides an opportunity to evaluate it's the effectiveness of diabetes care in Mweso. Lesson learned from Mweso can be adapted for MSF's programmes in other contexts where diabetes is present.

The overall aim is to evaluate IDC-OPD in Mweso health zone, North Kivu, DRC.

The specific objectives are to examine:

- The *reach* (coverage) of the diabetes service to the intended target population.
- The *effectiveness* of IDC-OPD in improving diabetes outcomes (fasting blood glucose and complications)
- *Adoption / acceptance* of IDC-OPD by staff and patients
- *Implementation* of IDC-OPD in terms of consistency/fidelity, adaptation and costs.
- *Maintenance* of IDC-OPD in patients and programme over time.

3 Methods

3.4 Overall design

A mixed-methods design will be used, based upon the Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework (see Annex 7.3) and <http://www.re-aim.hnfe.vt.edu/>). RE-AIM is a validated and widely used framework to evaluate the impact of a public health interventions by assessing five key indicators: reach, effectiveness, adoption, implementation, and maintenance. The research methods will include a cohort design, a cross-sectional survey, qualitative research, and use of routine service data. This mixed methods approach is being used in order to address the study objectives based upon the overarching RE-AIM framework used for the evaluation.

The Reach (R) component of the evaluation study will provide information about the diabetes services as a whole by using a cross-sectional household survey on diabetes prevalence; whereas the remaining components (E-AIMS) will focus more specifically on the IDC-OPD intervention.

The study indicators and data sources are summarised in Table 3.

Objective		Indicator	Methods
Reach		<ul style="list-style-type: none"> Glycaemia levels Population prevalence of diabetes Number of people eligible for diabetes care Number of people receiving care Representativeness of those reached Access and barriers to care 	<ul style="list-style-type: none"> Cross-sectional survey Cohort data Qualitative research
Effectiveness (% of diabetic patients)	Outcomes	<ul style="list-style-type: none"> Trend in confirmed diabetes-related deaths Trend in defaulters Optimal glycaemia <150 mg/dl (average last 3m) Acceptable glycaemia <200 mg/dl (average last 3m) Hypoglycaemia symptoms reported in last 3m Hyperglycaemia symptoms reported in last 3m Blood pressure control <140/90 mmHg Hospitalization due to diabetes complications BMI < 25 Creatinine <1.3 Proteinuria absent No decline in visual acuity No new neuropathy No new foot ulcers/ amputation Perceived benefits/unintended consequences 	Cohort study data Costing data (for cost-effectiveness analysis) Qualitative research
Adoption	Participation	# of staff correctly using guidelines (to break down by activities and staff type) Sources and perceptions of information and support	Cohort data Qualitative data
Implementation	Availability of key services/ activities	<ul style="list-style-type: none"> Staff (e.g. number, ratio of staff per patient) Dedicated room Treatment continuity/rupture Number of support groups organised and attended 	Qualitative data
	Cost	<ul style="list-style-type: none"> Staff time Implementation costs 	Costing data
	Acceptability	<ul style="list-style-type: none"> Staff Patients Community MSF Government Perspectives on acceptability and accessibility of services 	Qualitative research
Maintenance	Supplies (e.g. insulin)	Key challenges in maintaining medical treatment Key challenges in altering diet Types of support Strengths and challenges in the support	Qualitative research
	Money		
	Support		

Table 1. List of main indicators and data method/source based on RE-AIM

3.5 Study setting

The study setting will be Mweso health zone in the Health District of Masisi, North Kivu Province, in DRC. Mweso health zone is a rural, low income and conflict-affected area with an estimated catchment area of 145,000 people which includes 17 camps for Internally Displaced Persons (IDPs). MSF-OCA, in collaboration with the local Ministry of Health (MoH), supports health services in the hospital in Mweso and 4 out of 23 Primary Health Care clinics. The cohort study, qualitative research, and use of routine service data will take place in the MSF-MoH hospital in Mweso. The cross-sectional survey will take place in Mweso health zone.

3.6 Cohort study

The objective of the cohort design is to assess the effectiveness of the intervention of the new diabetes model of care introduced by MSF-OCA in March 2015. This will include cost-effectiveness analysis.

3.6.1 Study area and study population

The study location will be the MSF-OCA supported hospital providing diabetes in Mweso health zone. To date (April 2015), 140 patients (age 11-60) have been registered in the diabetes cohort, since patient registration was introduced in January 2014. All diabetic patients with at least two recorded visits (to enable evaluation of outcomes) will be included in the study cohort. This includes any new patients presenting with a new or existing diagnosis of DM confirmed by blood glucose measurement since implementation of IDC-OPD.

3.6.2 Intervention and comparison

The intervention is the new model of care developed by MSF-OCA in Mweso which was introduced week beginning 23 March 2015 (with revised care provided from 26 March 2015 onwards). This includes new treatment protocols, standard operating procedures, data entry forms, and training for nurses and doctors.

The comparison will be changes in outcomes compared to prior to the intervention. The start date for data collection was when the diabetes programme began collecting routine data (January 2014). The end date for the analysis will be March 2017.

3.6.3 Main outcomes measures

The principal clinical outcome measures for patients in the Diabetes cohort are:

- Mean fasting Plasma Glucose (FPG) < 150mg/dl, and < 200mg/dl
- Death, default or hospitalisation due to diabetic complications.

Death is defined as confirmed inpatient death or death reported by family or community health worker

A defaulter is defined as a patient who has not attended any Diabetes clinic appointments within the last 90 days, is not known to have died or moved out of the area, and has not been successfully traced by CHW.

Hospitalisation due to diabetic complications is defined as self-reported history of hospitalisation due to hyperglycaemia, hypoglycaemia or another diabetes- associated complication; but excluding elective admission for insulin initiation.

Other outcome measures are listed in table 1.

3.6.4 Data sources

The cohort will use a combination of retrospective data already collected (since January 2014), and prospective data collected from 26 March up to March 2017. A dedicated diabetes form was used for all diabetes patients in the hospital. The form was amended in March 2015 to capture additional key data for the new model of diabetes care. Nurses and doctors were provided training on completing the new form. Data on costs for the economic analysis will be obtained from accounting records and supply.

3.6.5 Data management

Paper data from the new form will be collected on a weekly basis by existing MSF data clerks and any abnormal or missing values will be discussed with the nurse or doctor and paper and electronic data updated accordingly. Data entry clerks will be provided training on entering the data. Single data entry will be performed on a password-protected using an Excel software database developed for the cohort. The study doctor (Dr. Augustin) will be the lead person in Mweso for the cohort study, and will ensure the quality of data collection and entry through weekly checks. The data will also be emailed to London-based staff on a monthly basis for further quality checks.

Data from the old form will be entered into a separate Excel database March/April 2015 and quality checked by Dr. Augustin and London-based staff.

All data are fully anonymous, with unique identifiers used instead of names/addresses. The data are held on password protected databases and PCs in a secure location. Data on costs for the economic analysis will be held on a secure excel file.

3.6.6 Data analysis

The study time can be divided in three periods: pre-intervention (P0), a period of gradual implementation of the new system (P1) and a period when the new system is fully implemented (P2). Not all variables recorded under the new system were recorded in the old system (see figure 2).

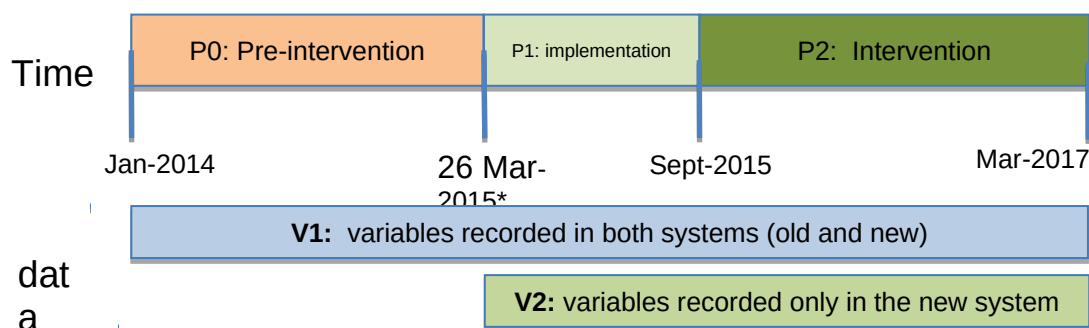


Figure 2 Split of periods and data: *index date for roll-out of new system.

Before-after comparison between pre-intervention (P0) and intervention (P2): With variables V1 we will compute the main outcomes for each patient. These will include: glycaemia control, blood pressure control, hypoglycaemia and hyperglycaemia symptoms, diabetes related deaths, defaults and unplanned hospitalisations due to diabetes complications. We will model the association of each of these outcomes with the period in which the patient was recruited, using suitable statistical models depending on the specific nature of the outcome (logistic regression for binary outcomes, linear regression for continuous outcomes and Cox regression for time-to event outcomes). All these models allow for the adjustment by other variables (age, baseline values of glycaemia and blood pressure, comorbidities, etc...). In this analysis we will include only patients from periods P0 (pre-intervention) and P2 (intervention fully implemented) to avoid the dubious effect of period P1 where the intervention is being implemented.

Change of outcomes from implementation (P1) to intervention (P2) phase: With V2 variables recorded only in the new system we cannot compare the outcomes in pre-intervention patients. But we might be able to see improvement in these variables as the implementation of the new system is improved. We will compute outcomes for each patient recruited in P1 and P2 using variables in V2 and V1. We will model the association of these outcomes with the time since roll out of the new system (26 March 2015) using suitable statistical models depending on the specific nature of the outcome as before. All these models allow for the adjustment by other variables.

A cost-effectiveness analysis will be undertaken to compare the costs and outcomes of new diabetes model of care (i.e., post-intervention model of care) versus pre-intervention model of care. The cost-effectiveness analysis will assess whether additional costs of implementing new model of diabetes care (drugs and supplies, staff time, staff training) are justified by subsequent reduction in morbidity costs and/or improvement in clinical outcomes. The cost analysis will take a health services perspective and will consider direct costs of alternative models of diabetes care. The cost-effectiveness analysis will use suitable regression method (e.g., linear regression for costs, logistic regression for mortality) to report incremental costs, incremental effects (as discussed in clinical analysis above), and incremental cost-effectiveness (e.g., costs per death averted, costs per chronic complications avoided) of post-versus pre-intervention model of diabetes care. The health outcome data will be taken from the routine data collected for the main cohort study (see above). The cost data for the diabetes drugs and supplies will be collected from routine accounting records and supply orders held by the MSF office in Mweso. Estimates of staff time spent on diabetes care and training will be collected by research staff through observation of diabetes care services in Mweso hospital and discussions with relevant staff using a standardised methodology for calculating time estimates. These time estimates will then be converted to monetary values based on salary data held by the MSF office in Mweso.

3.7 Cross-sectional survey

The primary objective of the cross-sectional survey will be to measure population-level prevalence of diabetes in Mweso health zone. This will provide important background information for the diabetes service and also enable an assessment of its reach/coverage. The secondary objective will be to measure key diabetes risk-factors and knowledge. This

secondary objective lies outside of the RE-AIM evaluation framework but will provide important background information for the diabetes programme.

The survey is planned to take place in August 2015 (subject to ethics approval and local permissions). A dedicated epidemiologist will oversee the design, preparation and implementation of the survey.

3.7.1 Survey location, population and sampling

The survey will take place in Mweso health zone. The population of interest will be adults > 16 (in Mweso Hospital presentation prior to the age of 16 is very rare; the only cases reported by staff were acute presentations with Diabetic Keto-Acidosis following a rapid onset of symptoms, hence these patients would be unlikely to remain asymptomatic and be identified by the survey). Exclusion criteria will include people who are too physically or mentally frail to attend the data collection, children < 16, or those that are under the influence of alcohol or drugs during the data collection.

The sample size required is estimated to be 1375 persons (assuming diabetes prevalence of 7%, 95% Confidence, a required precision of 2%, a Design Effect of 2, and a 10% non-response rate). Provisional planning and costings have been based on this sample size.

Multi-stage random sampling will be used following a cluster sampling design. In Stage One, clusters (villages) will be randomly selected using probability proportion to size technique from a sample frame of a complete list of villages in Mweso health zone provided by Bureau Central des Zones de Santé (BCZ) (the list was last updated in 2012 but is adjusted each year based on overall demographic trends in the region). In Stage 2, within the selected villages, households will be randomly selected by trained CHWs using the random walk method by selecting a random starting direction from a central location in the village/cluster, with households lying on this transect from the centre to the border of the cluster counted and one of them is then chosen at random and the next nearest households subsequently visited. In Stage 3, one individual currently living in the household (i.e. a resident of the house for >12 months) will then be randomly selected (e.g. based on nearest come birthday). That individual will be given information on the study and asked to give written consent to participate in the study. If the individual is illiterate, they can give verbal consent provided

that a witness who is appointed by that individual can sign the consent form on their behalf). If the individual is under the age of 18 but over the age of 16, (s)he can normally give consent on his/ her own behalf. Any individual deemed by the nurse not to be competent to give consent on their own behalf, will only be included if a parent or legal guardian gives written consent on their behalf, and the individual gives verbal assent for their participation. If they accept, key identification data for the individual (e.g. name, age) will be taken and an identifying card/number will be given to that individual. The selected individuals will then be asked to attend the data collection point on a given date (most likely within the next few days), and to fast for the blood glucose test. The data collection point is likely to be the closest health clinic or health post to the selected cluster but these will be chosen when the clusters have been selected.

If the selected person is not present in the household (a household being defined as a person or a group of persons, related or unrelated, who live together and who share a common source of food) the house will be revisited on up to two more occasions. If a respondent agrees to participate, but fails to show up on the data collection date, the CHW will phone the participant, and if unable to reach them will re-visit that household to arrange for another data collection day. If the household is derelict, a replacement house will be found (nearest household)

Community sensitisation will take place prior to the research through community leaders and health area leaders to try and ensure community support for the survey.

3.7.2 Survey data collection

Around 5 or 6 sites will be selected in Mweso Health Zone for the data collection (to be determined once sample size calculations and logistical/security issues are finalised). As noted above, the data collection points will most likely be health posts/health centres but alternative sites such as schools could also be used if required. A dedicated research team will collect the demographic, lifestyle and health data, physical and biochemical measurement (i.e not health workers at the health posts/health centres). The research team members are noted in Figure 2.

The collected data will be based on the WHO Steps approach and will include:

- (i) Demographic and socio-economic data.

- (ii) Lifestyle factors (tobacco, alcohol, diet, activity levels).
- (iii) Health history (diabetes, blood pressure, cardiovascular disease, malnutrition) and awareness of diabetes and if and where they receive diabetes care
- (iv) Physical measurement: blood pressure; weight, height, waist circumference, neuropathy, visual acuity.
- (v) Biochemical measurement Clinical data (collected by the nurse): fasting plasma glucose and urinalysis for ketonuria.

The draft questionnaire (in annex) will be translated into French and field tested, and then adjusted if required, prior to the survey. Biological samples will be analysed on site and destroyed immediately after analysis.

Respondents with FPG >126 mg/dl or RPG>200 mg/dl will be asked to return to the data collection point for retesting the next day. If their repeat test remains above the threshold defined, the nurse will explain the diagnosis of diabetes (based on WHO guidelines) and will provide basic education and dietary counselling consistent with that provided at Mweso hospital. The nurse will inform the patient about the service offered at Mweso Hospital, and will encourage the patient to attend one of the clinic days. Likewise, if the nurse's evaluation yields any other evidence of undiagnosed pathology (e.g. hypertension, proteinuria), the nurse will explain this to the patient and advise them to attend the out-patient department at Mweso hospital for further evaluation.

At either visit, if the patient is acutely unwell or the urinalysis shows marked Ketonuria (++ or more), the survey team will arrange transfer of the respondent to Mweso hospital with their consent.

The data collection flow is outlined in Figure 3.

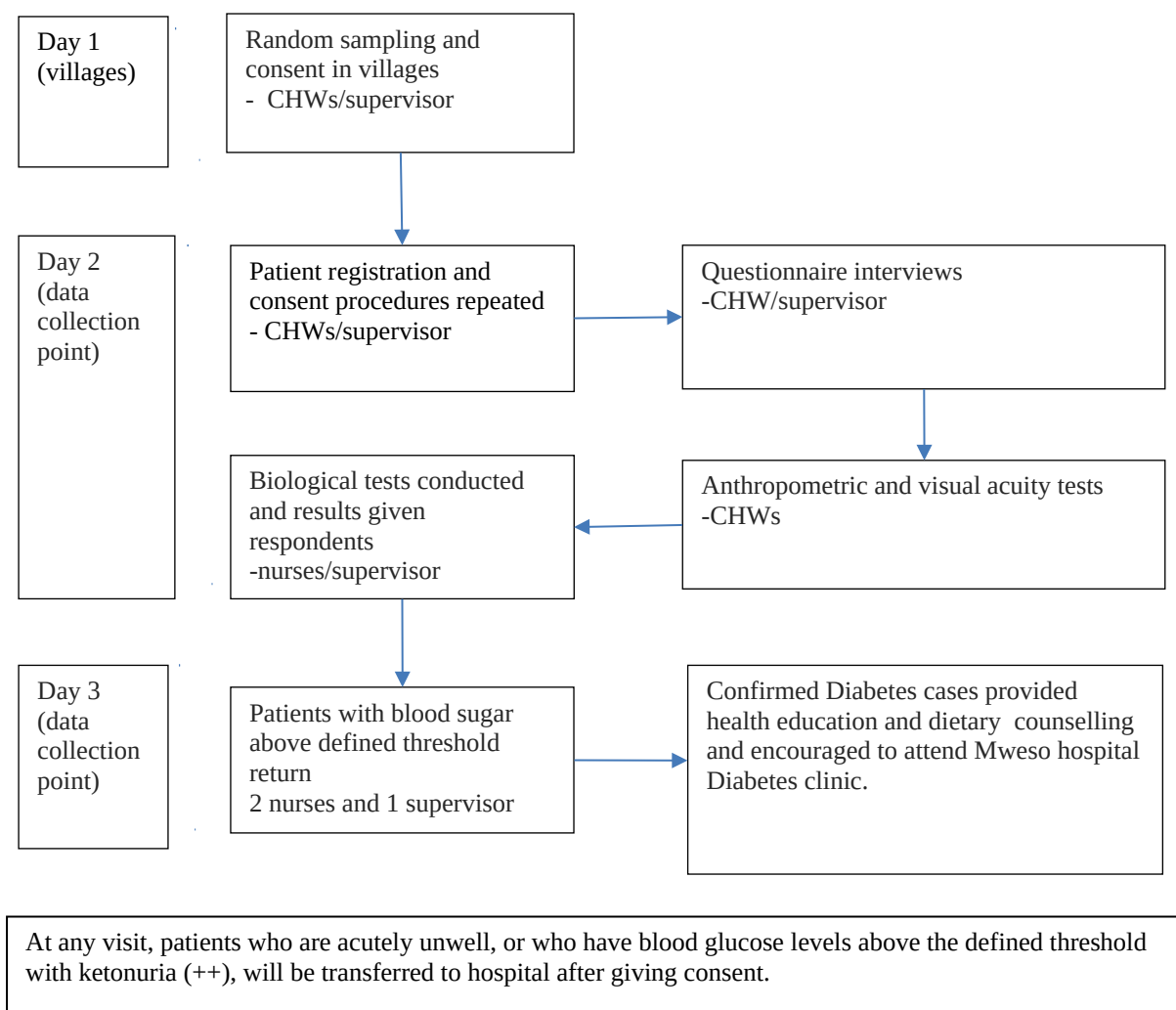


Figure 3: Data collection flow at the data collection point

Data will be collected by trained CHW enumerators for the questionnaire items and by nurses for the physical and biochemical tests. The number of enumerators and nurses required will be determined once the sample size and logistical arrangements have been further developed. For the sake of planning, a sample size of around 1400 respondents would require approximately 5 nurses, 8 CHWS, 1 supervisor, and 4 data entry clerks and the data collection would take approximately 3 weeks to complete (please see separate Excel document on local research costs). Training will be provided to the supervisors, nurses, enumerators and data entry clerks, with the training length and content will be determined once existing capacity is established.

3.7.3 Survey data management

Data will be double-blind entered using appropriate software (e.g. Epidata) by up to four trained data entry clerks. This will be password protected. Hard copies of questionnaires will be securely stored at the MSF base in Mweso.

3.7.4 Survey data analysis

Data analysis will include descriptive and inferential analysis, and will be crude and age standardized. The analysis will be led by staff from London School of Hygiene and Tropical Medicine.

3.8 Qualitative research

The objective of the qualitative research is to explore key issues related to adoption, implementation and maintenance of the intervention.

3.8.1 Qualitative study design

Focus group discussions and semi-structured interviews will be used. The focus groups will be conducted with diabetes patients. These will explore the reach and implementation of the diabetes model (e.g. perceived benefits, acceptability, barriers, unintended consequences). It will include examination of specific components of the diabetes care (e.g. service provision, nutrition advice, psychosocial counselling, outreach support). These focus groups will then be followed at a later date (e.g. the following week) by semi-structured interviews with purposively selected participants from the focus groups in order to explore further key issues raised in the focus groups.

Semi-structured interviews will also be conducted with health care staff involved in the diabetes services (both MSF and BCZ). These will focus particularly on issues related to: (i) reach (e.g. available resources and support, perceived benefits versus costs, barriers, suggestions for improvement; and (ii) adoption and implementation (e.g. values and capacity, challenges of implementation, compatibility with values, resources, complexity); (iii) maintenance: support, activities to support sustainability, perceived benefits vs. costs. The interviews will include a focus on specific components of the diabetes care (e.g. service provision, nutrition advice, psychosocial needs and counselling, outreach support).

3.8.2 Qualitative research study population and sampling

Two focus groups will be conducted with a cross-section of diabetes outpatients at Mweso hospital. Information about the study will be provided to all patients attending the diabetes outpatient department; participants for the focus groups will be selected based on diabetes type and severity, age, gender and occupation type. These focus groups will be followed by individual semi-structured interviews with purposively selected participants (to include participants with good and poor glycaemic control) of the focus groups who had particularly insightful perspectives in order to follow-up on key issues raised. Approximately 6-8 individual interviews with diabetes patients will be conducted, but this is subject to principles of saturation.

Approximately 12 to 15 semi-structured interviews will be conducted with key staff involved in the provision of diabetes care in Mweso hospital. These staff will be purposively selected to reflect the range of activities, organisations and staff functions involved. They will include the lead doctors for diabetes care, the lead nurses involved, nutrition advisor, psychosocial workers, field co-ordinator, BCZ staff, and expat MSF Medical and research staff in Mweso, Goma, Amsterdam, and London either currently or previously involved in the diabetes programme.

All participants in the qualitative study will be asked to give written consent to participate. If the individual is illiterate, they can give verbal consent provided that a witness who is appointed by that individual can sign the consent form on their behalf. If the individual is under the age of 16, or is deemed by the nurse not to be competent to give consent on their own behalf, that individual will only be included if a parent or legal guardian gives written consent on their behalf, and the individual gives verbal assent for their participation.

3.8.3 Qualitative data collection

The focus groups will last approximately two hours, and the individual semi-structured interviews approximately one hour. Separate topic guides will be developed for the focus groups and interviews with patients and service providers. These will seek to provide guidance and structure to the interviews, but not to restrict the discussion.

The qualitative research will take place in two phases. The first phase will consist of the focus groups and individual interviews with diabetes patients, and interviews with key health

staff. This first phase is expected to take approximately 4 weeks, and will take place in August 2015.

The second phase of the qualitative research will take place towards the end of the cohort study (e.g. February/March 2017) and this will focus specifically on health staff involved in diabetes care and could be completed in around two weeks.

The focus groups and interviews will be conducted either at the MSF base or Mweso hospital, or by telephone or skype for expatriate workers who have left Mweso. The focus groups and interviews with diabetes patients will be conducted in Swahili. They will be audio recorded and then translated written transcripts typed up. The interviews with health staff will be conducted in French or English and audio recorded where possible (unless conducted by telephone or skype where notes will be used instead).

Training will be provided to the local researcher/facilitator of the focus groups and interviews with diabetes patients and some health care staff.

The qualitative research will be led by an expatriate qualitative researcher who will help finalise the study design and instruments, be involved in the focus groups and interviews, and lead the analysis and write-up of outputs. This will be conducted in collaboration with national researcher/facilitator (ideally from within MSF). Advisory support will be provided by Beverley Stringer (MSF) and Bayard Roberts (LSHTM).

3.8.4 *Qualitative data analysis*

Thematic analysis will be used to detect key emerging themes arising from the data, while using the overall RE-AIM framework to help structure it. Where appropriate, the qualitative data will also be compared and contrasted with the other data sources to triangulate study findings.

4 Ethical considerations

4.4 Social Value

Potential patient benefits from the cohort include improved continuity and quality of diabetes care and reduced risk of acute and chronic complications. Survey participants will benefit from access to testing services and earlier treatment if found to have diabetes, than would otherwise have been the case; they may also benefit from earlier diagnosis of other conditions (e.g. hypertension) by virtue of the standard tests offered. Community-level benefits include access to improved diabetes care, and potentially increased awareness of diabetes as a result of the survey process. Potential programme benefits include provision of new information to help understand the strengths and weaknesses of the new diabetes model of care and its potential for use in other settings. National level benefits include access to new information about the burden of diabetes and the effectiveness and cost-effectiveness of diabetes programmes in DRC.

4.5 Potential risks from the study

Potential risks include potential emotional distress for newly diagnosed diabetes patients on the survey. The focus groups could also discuss emotional challenges of having diabetes which could possibly cause distress. Overall, these risk are expected to be low and the study has experienced psychosocial workers to respond to any distress. The study will also provide referral information to Mweso hospital for treatment for diabetes and psychosocial support.

4.6 Respect for recruited participants and study communities

Survey respondents diagnosed with diabetes will be provided necessary information and referral advice, including transfer to the diabetes clinic at Mweso hospital if in an acute condition (see above).

Prior to the survey data collection, the research team will meet with community leaders to discuss the survey with them (including its aims, objectives, methods and process) and gain their support for the survey.

4.7 Informed consent

All survey participants and qualitative research participants will be given verbal and written information and then asked to give written informed consent (or verbal consent if illiterate, as long as a witness chosen by the participant is able to sign on their behalf). Since the cohort study is based on analysis of routine patient data it will not involve any additional procedures and patients in the cohort study will not be asked to give written consent for use of their routine data. However, information sheets on the walls of the Diabetes clinic will inform patients about the study.

4.8 Data management and protection

All paper and electronic data will be held securely, with the paper data held securely at the MSF base in Mweso. Electronic data will be password protected, with only identified team members given access to the data and password.

4.9 Confidentiality

All cohort data, survey data, and qualitative data will be treated confidentiality with no names recorded in datasets. Survey interviews and qualitative semi-structured interviews will be conducted in a private space. The focus group discussions content will be treated as confidential and all participants will be requested to agree and adhere to the confidential nature of the discussions.

4.10 Independent review

This study protocol will be submitted to the Ethics Review Board instituted by MS, and also the LSHTM Ethics Committee. Written authorisations to implement the study will also be obtained from the Ministry of Health of North Kivu..

5 Study implementation

5.4 Collaborative partnership

This will be a collaborative partnership between the Manson Unit, MSF-OCA, the MoH of North Kivu, and London School of Hygiene and Tropical Medicine.

5.5 Timeline

The time period of the prospective research is 24 months. The proposed timeline is shown below. For more detailed time-plans, please see the research plans for the individual research methods.

	Month																							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Finalise protocol	X																							
Ethics approval			X																					
Implementation																								
Cohort study	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Survey			X	X	X																			
Qual research			X																				X	
Data analysis				X	X																			
Dissemination							X	X															X	X

5.6 Dissemination plan

Findings from the cohort study will be shared with local, national and international stakeholders every 6 months in order to inform and improve the delivery of diabetes care by MSF and other public health agencies in the study area. Outputs from the rest of the study such as survey findings and qualitative research will include briefing papers, reports and peer-reviewed academic publications and presentations at key conferences and workshops. Community dissemination meetings will be conducted to share the key findings from the survey.

5.7 Financial resources

All costs relating to the study will be covered by the Manson Unit (MSF-OCA).

6 Annexes

6.4 Consent statement for participation in the diabetes survey

Before collecting any information from the participants, administer the following consent statement and ask for written consent:

In this form, there may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, please ask me or another member of staff.

Diabetes is a chronic disease that needs treatment and continuity of care.

In order to improve diabetes care in Mweso we would like to ask you some questions about you, your health history, your health lifestyle, and carry out some tests (urine tests, blood tests, height, weight, bloody pressure, and eyesight tests). This survey is being conducted by Medecins sans Frontieres (MSF) in collaboration with the Ministry of Health of North Kivu.

During the visit MSF medical staff will gather from you the following:

- 1) Information on clinical symptoms, medical examination, laboratory test and treatment;*
- 2) Blood and urine samples.*

If you have Diabetes, these tests will help to diagnose it. If the Diabetes test is positive, we will ask you to return to the same place on the following day to repeat the test. If the repeat test is positive, this means that you have Diabetes, which can be treated with medicines available at Mweso hospital. The nurse will explain how to obtain this.

The data will be used to better understand diabetes needs in Mweso to help improve our services, and also for research – including publication by MSF. All data will be completely confidential and anonymous – your name will not appear on any reports using these data.

Participating in the discussions will not benefit you in any way. Refusal to participate will not harm you in any way, and will NOT affect the medical treatment that you will receive.

You can also withdraw your consent at any time before OR during the discussion, or afterwards until the study is complete, by contacting the MSF clinic staff ([name, address/telephone number/e-mail]). In this event, your data will be withdrawn from the database (however, once data collection is complete and analysis is underway, it is no longer possible to withdraw data.)

I have read the following information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.

Respondent survey number: _____

Date (Day/month/year)

I, _____, consent voluntarily.

(patient's name/guardian's name)

(Signature)

(Print) _____

Designation, ie. parent/guardian: (Print) _____

If parent or guardian is signing this form, does the individual give verbal assent?

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team).

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

(Signature) _____

(Print) _____

6.5 Consent statement for diabetes patients for the qualitative research

Before collecting any information from the participants, administer the following consent statement and ask for written consent.

In this form, there may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, please ask me or another member of staff.

In order to evaluate our diabetes services in Mweso we would like to ask you some questions about your experience of managing diabetes, accessing diabetes care, and the care you've received here in the hospital. This will be in a group with other diabetes patients or individually. We will use the findings to help with evaluating and improving the diabetes services, research and scientific publication by MSF.

All the findings from this discussion will be confidential and anonymous. The interviews will be audio recorded. The recordings will only be heard by the research team and translator. All the transcribed written records of the recording will be kept privately and anonymously so that no one can link anything you say in the interview back to you. The recording and written transcriptions will be securely stored and only accessible by approved study team members.

Participating in the discussions will not benefit you in any way. Refusal to participate will not harm you in any way, and will NOT affect the medical treatment that you will receive. You can also withdraw your consent at any time before OR during the discussion, or afterwards until the study is complete, by contacting the MSF clinic staff ([name, address/telephone number/e-mail]). In this event, your data will be withdrawn from the database (however, once data collection is complete and analysis is underway, it is no longer possible to withdraw data.)

BCZ and MSF have given their approval for these interviews to be conducted.

I have read this information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.

Respondent number: _____

Date (Day/month/year)

I, _____, consent voluntarily.

(patient's name/guardian)

_____ (Signature)

Designation, ie. Patient/parent/guardian: (Print) _____

If parent or guardian is signing this form, does the individual give verbal assent?

If illiterate

A literate witness must sign (if possible, this person should be selected by the patient and should have no connection to the research team).

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

(Signature) _____

(Print) _____

6.6 Consent statement for health experts for the qualitative research

Before collecting any information from the expert participants, administer the following consent statement and ask for written consent.

In order to evaluate our diabetes services in Mweso we would like to ask you some questions about your experience of supporting diabetes care in Mweso. This will cover subjects such as patient access to diabetes care, sources of information and support for diabetes patients, challenges and benefits of the diabetes programme for patients. This will be through a one-to-one interview. We will use the findings to help with evaluating and improving the diabetes services, research and scientific publication by MSF.

All the findings from this discussion will be confidential and anonymous. The interviews will be audio recorded. The recordings will only be heard by the research team and translator. All the transcribed written records of the recording will be kept privately and anonymously so that no one can link anything you say in the interview back to you. The recording and written transcriptions will be securely stored and only accessible by approved study team members.

Participating in the discussions will not benefit you in any way. Refusal to participate will not harm you in any way. You can also withdraw your consent at any time before OR during the discussion, or afterwards by contacting the MSF clinic staff ([name, address/telephone number/e-mail]).

BCZ and MSF have given their approval for these interviews to be conducted.

If you have questions later, please ask me or another member of staff.

I have read this information. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.

Respondent number: _____

Date (Day/month/year)

I, _____, (Print) consent voluntarily.

_____*(Signature)*

6.7 Data collection forms

6.7.1 Qualitative data collection forms

Topic guide: Focus groups discussions with diabetes patients:

Key area	Themes	Question
Introduction	Study aim and agencies involved Why invited to participate Consent & any questions?	
Participant Background	Getting to know each other + building rapport	Could you tell us a bit about yourself? <i>Prompt: e.g. profession, what area live in, when you were first diagnosed with diabetes?</i>
Reach	Access Barriers to testing and diagnosis Ways of reducing barriers	What do you know about diabetes? <i>Prompt – e.g. causes, types, who gets it, treatment</i> Could you tell me about how you came to learn about diabetes? <i>Prompt – e.g. from friends/family, from the radio (or other media), when diagnosed at hospital.</i> What were you told about diabetes when you were diagnosed through the hospital diabetes service? <i>Prompt – probe understanding of diabetes such as causes, risks and its management (medication and diet).</i> What do you think might prevent people testing for diabetes? <i>Prompt: lack of knowledge, lack of services, costs, time, quality of services, stigma etc.</i> How could knowledge of diabetes be improved among the populations? <i>Prompt – outreach, radio, health workers etc</i> How could access to testing for diabetes be improved?
Adoption and implementation	Information Support	How did you feel when you got the diabetes test result? <i>Prompt: counselling/support experience. Prompt: subsequent days/weeks experience</i> Who did you talk to about the result? <i>Prompt: E.g. family members, friends.</i> What were you told about diabetes care after your result (by the diabetes staff)? <i>Prompt: medicine types and usage, managing medicines, diet changes, risks and symptoms, frequency of check-ups etc.</i> What sources of support did you receive? <i>Prompt: emotional support from family/friends, information support from health workers, psychosocial support from health workers.</i> What made it easy or difficult for you to access care?

		How acceptable do you find the diabetes treatment. <i>Prompt: e.g. logistically, socially, culturally etc.</i>
Maintenance	Challenges Supportive factors To support adoption and implementation	What have been the main challenges in maintaining your medical treatment for diabetes? <i>Prompt: time, costs, information, drug supply, stigma/shame etc.</i> What have been the main challenges for altering your diet? <i>Prompt: information, costs, support</i> What could have made accessing care easier for you? <i>Prompt: e.g. information given – content and way it was delivered; costs; type and quality of care and support; focus on role of the diabetes programme/services.</i>
Effectiveness	Unintended consequences Benefits	What have been the negative consequences of taking diabetes treatment? <i>Prompt: physical, psychological, costs, time.</i> What have been the benefits of receiving diabetes treatment? <i>Prompt: e.g. physical, psychological, social, economic.</i>
Thanks and close	Anything else to add Questions Thanks, feedback info	Anything else to add on topic that we haven't discussed today? Any questions for me? Feedback again on how the discussion will be used and fed back.

Topic guide: semi-structured interviews with diabetes health care providers:

Key area	Themes	Question
Introduction	Study aim and agencies involved Why invited to participate Consent & any questions?	
Participant Background	Getting to know each other + building rapport	Could you us a bit about yourself? <i>Prompt: e.g. professional, involvement in the diabetes service at Mwezo (and previously if relevant), what area live in, when you were first diagnosed with diabetes?</i>
Reach	Access Barriers to testing and diagnosis Ways of reducing barriers	What are the key challenges to accessing testing for diabetes <i>e.g. knowledge, costs, time, availability of care, quality of care [expand], stigma etc.</i> How could access to testing for diabetes be improved? <i>Prompt: improve knowledge (e.g. outreach, radio, health workers etc), improve availability of services, quality of services etc.</i>
Adoption and implementation	Information and support	What types of information are provided to patients when they are diagnosed with diabetes? What sources of support are offered to patients when they are diagnosed with diabetes? How acceptable do you think the diabetes treatment is for patients? <i>Prompt: e.g. quality, responsiveness, socially, culturally etc.</i>
Maintenance	Challenges Supportive factors To support adoption and implementation	What do you think are the main challenges facing diabetes patients here in terms of managing their diabetes? <i>Prompt: medicines/testing - time, costs, information, drug supply etc; dietary factor – knowledge, social/cultural pressures etc.</i> What could be done to make it easier for diabetes patients to access care? <i>Prompt: e.g. information given – content and way it was delivered; costs; type and quality of care and support; [note: focus on role of the diabetes programme/services].</i>
Effectiveness	Unintended consequences Benefits	What are the benefits of the strengthened diabetes care programme in Mwezo? <i>Prompt: more efficient, less complications etc.</i> What are negative consequences of the strengthened diabetes care programme in Mwezo? <i>Prompt: time, complexity, costs etc.</i> What particular aspects of the revised programme have helped or hindered diabetes care?
Thanks and close	Anything else to add Questions Thanks, feedback info	Anything else to add on topic that we haven't discussed today? Any questions for me? Feedback again on how the discussion will be used and fed back.

6.7.2 Household survey data collection form

SURVEY NUMBER:

Survey Information					
Location and Date	Response				Code
Cluster/Centre/Village ID _____					
Cluster/Centre/Village name _____					
Registering ID _____					
Date of completion of the instrument _____					
<div style="text-align: center;"> _____ dd mm year </div>					
Consent, Interview Language and Name					
Consent has been read and obtained	Yes 1				
	No 2 If NO, END				
Interview Language [Insert Language]	Swahili 1				
	[Add others] 3				
	[Add others] 3				
Time of interview (24 hour clock)					
<div style="text-align: center;"> _____ hour min _____ </div>					

1. Demographic Information		
Question	Response	Code
Interview ID	<div><div></div><div></div><div></div></div>	
Sex (Record Male / Female as observed)	Male 1	

	Female 2	
What is your date of birth? <i>Don't Know 77</i>	<div> <div> <div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div> </div> <div>dd mm year</div> </div>	
How old are you?	Years	
What is the highest level of education you have completed? <i>[INSERT COUNTRY-SPECIFIC CATEGORIES]</i>	No formal schooling 1 Less than primary school 2 Primary school completed 3 Secondary school completed 4 High school completed 5 College/University completed 6 Refused 88	
What is your <i>[insert relevant ethnic group / racial group / cultural subgroup / others]</i> background ?	<i>[Locally defined]</i> 1 <i>[Locally defined]</i> 2 <i>[Locally defined]</i> 3 Refused 88	
What is your marital status ?	Never married 1 Currently married 2 Separated 3 Divorced 4 Widowed 5 Cohabiting 6 Refused 88	
Which of the following best describes your main work status over the past 12 months? <i>(USE SHOWCARD)</i>	Manual laborer 1 Officer worker 2 Non-paid 3 Student 4 Retired 5 Unemployed (able to 6 Unemployed (unable to 7 Refused 88	
How many people older than 16 years, including yourself, live in your household?	Number of people:	
Displacement Status	Permanent resident: Internally displaced person: 1 2	
Question	Response	Code
Taking the past year , can you tell me what the normal earnings of the household have been? <i>(RECORD ONLY ONE, NOT ALL 3)</i>	Per week _____ OR per month _____ OR per year _____ Refused 88	

2. Lifestyle Factors

Tobacco Use			
Now I am going to ask you some questions about tobacco use.			
Question	Response		Code
Do you currently smoke any tobacco products, such as cigarettes? (USE SHOWCARD)	Yes	1	
	No	2 If No, go to X	
Do you currently smoke tobacco products daily ?	Yes	1	
	No	2	
How old were you when you first started smoking?	Age (years)		
	Don't know 77	<div> <div></div> <div></div> <div></div> </div>	
On average, how many cigarettes do you smoke each day Don't Know 77	Number of cigarette s per day	<div> <div></div> <div></div> <div></div> </div>	
In the past, did you ever smoke daily ?	Yes	1	
	No	2	
How old were you when you stopped smoking?	Age (years)	<div> <div></div> <div></div> <div></div> </div>	
Alcohol Consumption			
The next questions ask about the consumption of alcohol.			
Have you ever consumed any alcohol such as beer, wine, spirits or [add other local examples]? (USE SHOWCARD OR SHOW EXAMPLES)	Yes	1	
	No	2 If No, go to X	
Have you consumed any alcohol within the past 12 months ?	Yes	1 If Yes, go to X	
	No	2	
Have you stopped drinking due to health reasons, such as a negative impact on your health or on the advice of your doctor or other health worker?	Yes	1 X	
	No	X	
During the past 12 months, how frequently have you had at least one standard alcoholic drink? (READ RESPONSES, USE SHOWCARD)	Daily	1	
	5-6 days per week	2	
	3-4 days per week	3	
	1-2 days per week	4	
	1-3 days per month	5	
	Less than once a month	6	
Have you consumed any alcohol within the past 30 days ?	Yes	1	
	No	2 If No, go to X3	
During the past 30 days, on how many occasions did you have at least one standard alcoholic drink?	Number Don't know 77	<div> <div></div> <div></div> <div></div> </div>	
During the past 30 days, when you drank alcohol, how many standard drinks on average did you have during one drinking occasion? (USE SHOWCARD)	Number Don't know 77	<div> <div></div> <div></div> <div></div> </div>	

During the past 30 days, what was the largest number of standard drinks you had on a single occasion, counting all types of alcoholic drinks	Largest number Don't Know 77	<input type="text"/>	
During the past 30 days, how many times did you have six or more standard drinks in a single drinking occasion?	Number of times Don't Know 77	<input type="text"/>	
During the past 12 months , how often have you found that you were not able to stop drinking once you had started?	Daily or almost daily	1	
	Weekly	2	
	Monthly	3	
	Less than monthly	4	
	Never	5	
During the past 12 months , how often have you failed to do what was normally expected from you because of drinking?	Daily or almost daily	1	
	Weekly	2	
	Monthly	3	
	Less than monthly	4	
	Never	5	
During the past 12 months , how often have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Daily or almost daily	1	
	Weekly	2	
	Monthly	3	
	Less than monthly	4	
	Never	5	
During the past 12 months , have you had family problems or problems with your partner due to someone else's drinking?	Yes, more than monthly	1	
	Yes, monthly	2	
	Yes, several times but less than monthly	3	
	Yes, once or twice	4	
	No	5	

Diet

The next questions ask about the fruits and vegetables that you usually eat. I have a nutrition card here that shows you some examples of local fruits and vegetables. Each picture represents the size of a serving. As you answer these questions please think of a typical week in the last year.

In a typical week, on how many days do you eat fruit ?	Number of days Don't Know 77	6.7.2.1.1.1.1.1.1 <input type="text"/> If Zero	6.7.2.1.1.1.1.1.2
How many servings of fruit do you eat on one of those days? <i>(USE SHOWCARD)</i>	Number of servings Don't Know 77	<input type="text"/>	6.7.2.1.1.1.1.1.1
In a typical week, on how many days do you eat vegetables ? <i>(USE SHOWCARD)</i>	Number of days Don't Know 77	6.7.2.1.1.1.1.1.1.4 <input type="text"/> If Zero	
How many servings of vegetables do you eat on one of those days? <i>(USE SHOWCARD)</i>	Number of servings Don't know 77	<input type="text"/>	

Physical Activity

Next I am going to ask you about the time you spend doing different types of physical activity in a typical week. In answering the following questions 'vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate, 'moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.

Question	Response		Code
Work			
Does your work involve vigorous-intensity activity that causes large increases in breathing or heart	Yes	1	6.7.2.1.1.1.1.1.5

	No	2 If No, go to X	
In a typical week, on how many days do you do vigorous-intensity activities as part of your work?	Number of days	<input type="text"/>	6.7.2.1.1.1.1.1.6
How much time do you spend doing vigorous-intensity activities at work on a typical day?	Hours : minutes	<input type="text"/> : <input type="text"/> hrs mins	
Does your work involve moderate-intensity activity, that causes small increases in breathing or heart rate such as brisk walking <i>[or carrying light loads]</i> for at least 10 minutes continuously?	Yes	1	
	No	2 If No, go to X	
In a typical week, on how many days do you do moderate-intensity activities as part of your work?	Number of days	<input type="text"/>	
How much time do you spend doing moderate-intensity activities at work on a typical day?	Hours : minutes	<input type="text"/> : <input type="text"/> hrs mins	
Travel to and from places			
The next questions exclude the physical activities at work that you have already mentioned.			
Now I would like to ask you about the usual way you travel to and from places. For example to work, for shopping, to market, to place of worship. <i>[Insert other examples if needed]</i>			
Do you walk or use a bicycle (<i>pedal cycle</i>) for at least 10 minutes continuously to get to and from places?	Yes	1	
	No	2 If No, go to X	
In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days	<input type="text"/>	
How much time do you spend walking or bicycling for travel on a typical day?	Hours : minutes	<input type="text"/> : <input type="text"/> hrs mins	

3. Health History			
History of diabetes			
Before this survey, were you aware of the disease of diabetes?	Yes	1	
	No	2	
Have you ever had your blood sugar measured by a doctor or other health worker?	Yes	1	
	No	2 If No, go to X	
If not, what was the reason you have not?	I was not aware it could be a	1	
	It was too expensive to get it	2	
	It was too far to go and get it	3	
	Other	4	
Have you ever been told by a doctor or other health worker that you have raised blood sugar or diabetes?	Yes	1	
	No	2 If No, go to X	
Have you been told in the past 12 months?	Yes	1	
	No	2	
In the past two weeks, have you taken any drugs (medication) for diabetes prescribed by a doctor or	Yes	1	
	No	2	

other health worker?		
Are you currently taking insulin for diabetes prescribed by a doctor or other health worker?	Yes 1 No 2	
Have you ever seen a traditional healer for diabetes or raised blood sugar?	Yes 1 No 2	
Are you currently taking any herbal or traditional remedy for your diabetes?	Yes 1 No 2	
Has a family members ever been diagnosed with diabetes (i.e. a parent, brother, sister, uncle, aunt or child).	Yes 1 No 2	
History of Raised Blood Pressure		
Question		
Have you ever had your blood pressure measured by a doctor or other health worker?	Yes 1 No 2 <i>If No, go to X</i>	
Have you ever been told by a doctor or other health worker that you have raised blood pressure or hypertension?	Yes 1 No 2 <i>If No, go to X</i>	
Have you been told in the past 12 months?	Yes 1 No 2	
In the past two weeks, have you taken any drugs (medication) for raised blood pressure prescribed by a doctor or other health worker?	Yes 1 No 2	
Have you ever seen a traditional healer for raised blood pressure or hypertension?	Yes 1 No 2	
Are you currently taking any herbal or traditional remedy for your raised blood pressure?	Yes 1 No 2	
History of Cardiovascular disease		
Have you ever had a heart attack or chest pain from heart disease (angina) or a stroke (cerebrovascular accident or incident)?	Yes 1 No 2	
Are you currently taking aspirin regularly to prevent or treat heart disease?	Yes 1 No 2	
Are you currently taking statins (Lovastatin/Simvastatin/Atorvastatin or any other statin) regularly to prevent or treat heart disease?	Yes 1 No 2	
Malnutrition		
Have you ever suffered from malnutrition?		
If yes, approximately, how old were you?		

4. Physical Measurements

Blood Pressure		
Question	Response	Code

Interviewer ID		
Device ID for blood pressure		
Cuff size used	Small 1 Medium 2 Large 3	
Reading 1	Systolic (mmHg)	
	Diastolic (mmHg)	
Reading 2	Systolic (mmHg)	
	Diastolic (mmHg)	
Reading 3	Systolic (mmHg)	
	Diastolic (mmHg)	
During the past two weeks, have you been treated for raised blood pressure with drugs (medication) prescribed by a doctor or other health worker?	Yes 1 No 2	
Height, weight and waist circumference		
For women: Are you pregnant?	Yes 1 <i>If Yes, go to X</i> No 2	
Device IDs for height and weight	Height Weight	
Height	in Centimetres (cm)	
Weight <i>If too large for scale 666.6</i>	in Kilograms (kg)	
Waist circumference	in Centimetres (cm)	
Peripheral neuropathy		
Peripheral neuropathy	Yes 1 No 2	
Visual acuity		
Visual acuity – left eye	3/6 1 3/18 2 3/60 3 Fingers 4 Blind 5 Cataracts 6	
Visual acuity – right eye	3/6 1 3/18 2 3/60 3 Fingers 4	

	Blind 5	
	Cataracts 6	

5. Biochemical Measurements		
Blood Glucose		
Question	Response	Code
Nurse ID	<input type="text"/>	
During the past 12 hours have you had anything to eat or drink, other than water?	Yes 1 No 2	
Technician ID	<input type="text"/>	
Device ID	<input type="text"/>	
Time of day blood specimen taken (24 hour clock)	Hours : minutes <input type="text"/> : <input type="text"/> hrs mins	
Fasting blood glucose [CHOOSE ACCORDINGLY: MMOL/L OR MG/DL]	mmol/l <input type="text"/> . <input type="text"/> mg/dl <input type="text"/> . <input type="text"/>	
Today, have you taken insulin or other drugs (medication) that have been prescribed by a doctor or other health worker for raised blood glucose?	Yes 1 No 2	
Urine analysis		
Had you been fasting prior to the urine collection?	Yes 1 No 2	
Technician ID	<input type="text"/>	
Device ID	<input type="text"/>	
Time of day urine sample taken (24 hour clock)	Hours : minutes <input type="text"/> : <input type="text"/> hrs mins	
Urinary outcome 1	mmol/l <input type="text"/> . <input type="text"/>	
Urinary outcome 2	mmol/l <input type="text"/> . <input type="text"/>	

7 References

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ⁱⁱⁱ International Diabetes Federation. IDF Diabetes Atlas (6th Edition). 2013. www.idf.org

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^v Muyer M et al, Mortality of young patients with diabetes in Kinshasa, DR Congo. *Diabet Med.* 2010 Apr;27(4):405-11