Research Protocol

Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)

Short title: DSD models at Malawi sentinel sites

January 20, 2021

Version 1.0

NHSRC Protocol Number: _____ (Malawi)
BUMC IRB Protocol Number: H-XXXXX (United States)
Wits University HREC Protocol Number: XXXXXX (South Africa)

Federal-Wide Assurance Numbers:
FWA00005976 (National Health Sciences Research Committee)
FWA00000301 (Boston University Medical Campus)
FWA00000715 (University of the Witwatersrand)

Contents

1. SUMMARY OF SENTINEL-MALAWI

To achieve global goals for the treatment of HIV, many countries are piloting and scaling up differentiated service delivery models (DSD). A handful of efforts have been formally described and evaluated in the literature; many others are being implemented formally or informally under routine care, without a research or evaluation goal. For most countries however, we have little evidence on progress and challenges at the facility level—the number of patients actually participating in DSD models, health outcomes and non-health outcomes, effects on service delivery capacity and clinic efficiency and operations, and costs to providers and patients.

AMBIT is a set of data synthesis, data collection, and data analysis activities aimed at generating information for near- and long-term decision making and creating an approach and platform for ongoing evaluation of differentiated models of HIV treatment delivery. The first AMBIT protocol, "Gathering Records to Evaluate Antiretroviral Treatment" (GREAT, Malawi NHRC 2376), collects and analyzes comprehensive patient medical record data, allowing us to assess the effect of DSD models on patients' clinical outcomes and to evaluate uptake of DSD models at scale.

The **Sentinel-Malawi** study, the second AMBIT protocol, will examine the effect of DSD models on patient and provider satisfaction, service delivery capacity and quality, costs to patients, and other outcomes for which data are not routinely collected in patient-level medical records. We will collect clinic aggregate data, conduct surveys of patients and providers, and observe operations at a selected set of 12 healthcare facilities in Malawi and their affiliated DSD models. Results are expected to inform Malawian policy makers and other local and international stakeholders on the actual implications of DSD models for patients, health system operations, and healthcare budgets.

2. INVESTIGATORS

This evaluation will be conducted by investigators from the Clinton Health Access Initiative (CHAI) in Malawi, Boston University in the U.S., and Wits University in South Africa. Individual investigators are:

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3. BACKGROUND, RATIONALE AND OBJECTIVES

a. Background

To achieve global goals for the treatment of HIV, many countries are experimenting with and scaling up differentiated service delivery (DSD) models. These models alter key characteristics of service delivery, such as location, provider cadre, or visit frequency. Common DSD models include facility-based "fast track" services, community- or home-based drug distribution, multi-month dispensing of medications, and adherence clubs. In Malawi, where this study will take place, the Ministry of Health (MOH) and its implementing partners are currently supporting the scale-up of multimonth dispensing, fast track medication refills, nurse led community ART, and teen club models of HIV treatment. A few other models are also being piloted at small numbers of sites in Malawi, at the initiative of NGO partners.

In the published literature and in policy documents, DSD models are assumed to generate a wide range of potential benefits. These include increased clinic efficiency and capacity, lower costs to providers and patients, better health outcomes for HIV and non-HIV patients, and improved access and greater satisfaction with healthcare for patients. Despite a high level of confidence on the part of DSD advocates that at least some of these benefits will materialize, however, there is still relatively little evidence to support their assumptions. A few DSD programs have been formally described and evaluated in the literature[1–5]; many others are being implemented formally or informally under routine care, without a research or evaluation goal. Models that have been rigorously evaluated have often been implemented in the course of randomized trials, rather than routine practice[6]. Even evaluations of routine practice, as have been done in Malawi[7], Uganda[8], Zambia[9], and South Africa[10,11] have been limited in scope, have relied on assumptions due to missing data, or are already outdated. For most countries and models, we have little evidence of the impact of routinely-implemented DSD models on clinic efficiency and capacity; quality of care for HIV and non-HIV patients; or patient or provider satisfaction.

b. Rationale

The AMBIT project, supported by the Bill & Melinda Gates Foundation, is a set of data synthesis, data collection, and data analysis activities aimed at generating information for near- and long-term decision making and creating an approach and platform for ongoing evaluation of differentiated models of HIV treatment delivery. The first protocol developed for the AMBIT project, "Gathering Records to Evaluate Antiretroviral Treatment" (GREAT, Malawi NHRC 2376, BU IRB H-38822, Wits HREC M190451), collects and analyzes patient medical record data, allowing us to assess the effect of DSD models on patients' clinical outcomes and to evaluate uptake of DSD models at scale. GREAT includes patient-level data collection from the national ART electronic medical record system (previously managed by the Baobab Trust and now by EGPAF) and other paper and electronic sources, such as patient files and paper DSD model registers kept on site and the Laboratory Information Management Systems (LIMS).

While GREAT will answer some questions about DSD models in Malawi, one reason for the dearth of rigorous evaluations of DSD models in many African countries, including Malawi, is that medical records that we will rely on for the GREAT study do not capture the details of individual patients' participation in DSD models. Implementation of the models preceded efforts to adapt national paper and electronic record systems to include DSD-related data fields. While some countries have recently added such fields to their data capturing forms, as Malawi has done for fast track refills, completion of the fields by clinic staff remains incomplete and inaccurate. Even in the instances where a specific model of care is reported or can be inferred from medical record data, the variables available tell us little beyond simple clinical outcomes, such as retention in care or viral suppression.

In addition to the limitations of existing medical records, patient- and facility-level data on the impact of DSD models on service delivery and non-clinical outcomes are not routinely collected in any country. Such data can therefore only be obtained by generation of new data through surveys and other methods and new analysis of aggregate data. Without this information, the impact of DSD models on the health system, individual healthcare facilities, or patients themselves cannot be ascertained. In combination with the GREAT-Malawi protocol, therefore, the Sentinel-Malawi study, the second AMBIT protocol, will examine the effect of DSD models on patient and provider satisfaction, service delivery capacity and quality, costs to patients, and other outcomes for which data are not routinely collected in medical records.

In Malawi, we will collect aggregate facility-level data, conduct surveys of patients and providers, and observe operations at a selected set of 12 sentinel healthcare facilities and their affiliated DSD models. The goal of the study, called Sentinel-Malawi, is to complement medical record data with primary information not currently available to policy makers through existing monitoring and evaluation procedures. Results are expected to inform Malawian policy makers and other local and international stakeholders on the actual implications of DSD models for patients, health system operations, and healthcare budgets.

c. Objectives and research questions

Sentinel-Malawi is a multi-faceted evaluation of the impact of differentiated service delivery for HIV treatment on health facilities and patients in Malawi. Specific research questions for each model of care in use at each site, including standard or conventional care, and for the full cohort of ART patients, fall into four general domains, as shown below.

(i) Domain 1: Provider time utilization

DSD models are expected to reduce the average amount of time that clinicians spend per stable ART patient, which is in turn expected to increase the time they have available for non-stable ART patients and patients with other conditions. We ask the following questions:

1. What is the allocation of clinicians' and other staff time at the facility level, by staff cadre and type of patient, and how is it affected by the number and uptake of models at the site? This question will be answered using time-and-motion observations.

2. How has the introduction of DSD models affected quality of care for HIV patients and, if data allow, non-HIV patients, defined as provider (clinical and non-clinical) time spent per patient?

(ii) Domain 2: Provider experiences

DSD models are expected to improve healthcare providers' quality of professional life, by reducing the patient/provider ratio and allowing providers to spend more time with patients in need. It is likely that the scaleup of DSD models has also changed facility procedures in other ways. We ask the following questions:

3. How has the introduction of DSD models affected individual providers' perceived workloads?

4. How has the introduction of DSD models affected individual providers' job satisfaction?

5. What were the major facility-level procedural and other changes entailed in introducing and maintaining DSD models and how can implementation be improved in the future?

(iii) Domain 3: Patient experiences

A major goal of DSD models is to make ART delivery more "patient-centred," thus improving patients' experiences and reducing their costs of seeking ART and potentially increasing long-term adherence and retention in care. We ask the following general questions:

6. How much time do patients spend at facilities and at other DSD model venues for each model of care?

7. What are the direct and indirect costs to patients of participation in each model?

8. What do patients like and dislike about each model, how satisfied are they with their healthcare, and what would their preferences be for different model characteristics in the future?

(iv) Domain 4: Resource utilization (non-human subjects data)

A number of questions about the scale-up of DSD models for ART can be answered using aggregate, non-human subjects data that facilities typically collect for reporting purposes, such as number of patients and visits, staff availability, funding sources, etc. These data do not pertain to individual human subjects but are included here because they are integral to the overall goals of the study. We will ask the following questions:

9. Has the total number and/or mix of patients seen at the healthcare facility overall, including HIV and non-HIV patients, changed as the number of patients in DSD models has increased?

10. Has the total number or mix of providers at the healthcare facility overall, including for HIV and non-HIV services, changed as the number of patients in DSD models has increased?

11. Have standard operating procedures at the facility, such as how patients are scheduled for visits or the internal allocation of space or other resources, changed over the time period of observation?

12. What is the contribution of external (donor/NGO) resources to the operation of DSD models?

Responses to all of these 12 questions will be estimated for individual models of care and compared among the models in use at each study site. Questions may be revised, refined, removed, or added based on data availability, Ministry of Health priorities, and other factors. The protocol will be amended whenever additional data, not described below, are needed.

4. STUDY DESIGN AND PROCEDURES

a. Overview

To answer the broad range of research questions listed above, the study will include surveys of patients and providers; a time and motion study of providers and observation of patient time use; and collection of non-human subjects indicators such as aggregate patient numbers, unit costs, and staff allocation records. With written informed consent of participants, data provided directly by patients (patient survey responses) will also be linked to their medical record data.

For purposes of this study, we will define each separate approach for interacting with ART patients that we observe at the study sites as a model of care. This will include conventional care (similar to the pre-differentiation model of care) for patients eligible for other models but not enrolled in them; conventional care for patients not eligible for other models, such as those with detectable viral loads; and each additional model of care offered by each study site. Common additional models of care currently in use in Malawi include six-month dispensing, community outreach, and teen clubs. Several less common models have also been implemented at the study sites, as shown in Table 1 below.

b. Study sites

Sentinel-Malawi will be conducted at 12 sites (healthcare facilities with their associated DSD models) in 3 districts of Malawi. The majority of the current HIV treatment burden in Malawi is in the Southern Region (62%), with less than a third (28%) in the Central Region. We thus chose two Districts in the Southern Region and one in the Central Region. Within each district, a preliminary set of 6 potential study sites was purposively selected based on availability of EMR systems, ART patient volume, facility ownership (only public facilities were selected), and the variety of DSD models implemented. After brief site evaluations and in consultation with the MOH, the final 12 sites (4 per District) were selected, as shown in Table 1. We note that these sites are intended to capture the variation among Malawian ART sites in terms of DSD model implementation, uptake, outcomes, costs, etc. They are not intended as a nationally representative group of facilities.

Table 1. Study sites for Sentinel-Malawi

District	Facility	Setting	ART patients	Current DSD models (preliminary)
Lilongwe	Malingunde Health Center	Rural	1,025	6MD*, Community ART group, Community outreach
Lilongwe	Kawale Health Center	Urban	4,200	6MD, Community outreach
Lilongwe	Bwaila Hospital	Urban	24,247	6MD, Nurse outreach community ART, Fast track, Teen club, Late shift
Lilongwe	St. Gabriel Mission Hospital	Rural	2,728	6MD, Teen club, Mother infant pairs, High viral load clinic
Blantyre	Mlambe Hospital	Rural	6,592	6MD
Blantyre	South Lunzu Health Center	Urban	2,925	Teen club, Welcome back model, High viral load clinic, 6MD
Blantyre	Limbe Health Center	Urban	8,400	6MD, Teen club, Intensified care ART clinic
Blantyre	Ndirande Health Centre	Urban	6,178	6MD, Teen club, Mother infant pairs
Chiradzulu	Namadzi Health Centre	Rural	5,288	6MD, Teen club, Mother infant pairs
Chiradzulu	Mbulumbuzi Health Centre	Rural	2,633	6MD, Teen club
Chiradzulu	Chiradzulu DHO	Rural	6,520	6MD, Teen club
Chiradzulu	Milepa Health Centre	Rural	3,944	6MD, Teen club

*6MD, six-month dispensing

c. Domain 1 (Provider time)

Questions in Domain 1 pertain to the allocation and efficiency of provider time use within the study clinics, which are expected to change as result of the scaling up of DSD models. These questions will be answered with a time-and-motion study. Written informed consent will be sought from providers for the time-and-motion observations. The data collection instrument and consent information sheet and form are included as appendices to this protocol.

What is the allocation of clinicians' and other staff time at the facility level, by staff cadre and type of patient, and how is it affected by the number and uptake of models at the site?

How has the introduction of DSD models affected quality of care for HIV and non-HIV patients, defined as provider (clinical and non-clinical) time spent per patient?

(i) Sample selection

A sample of up to five clinical providers will be selected at each study site, for a total sample size of up to 60 for the 12 sentinel sites. The providers involved will include nurses, lay counsellors and/or community health workers, doctors/medical officers, and/or DSD model-specific staff, based on their role in providing HIV treatment. The participants will be purposively selected from within the site's staff cadre and invited to participate, in agreement with the individual serving as facility in-charge or facility manager.

Different calendar days will be observed during the study period, with days selected based on when each site schedules ART care and to represent typical patient care days for each cadre of provider. To minimize the burden on participants, no provider will be observed for more than two days.

(i) Inclusion and exclusion criteria

Inclusion criteria for provider interviews are:

- Direct or indirect service provider at the study site (indirect providers include supervisors, technical advisors, etc.)
- Directly or indirectly involved in the site's implementation of ART and DSD models
- Employed in current role at the study site for at least six months
- Provides written informed consent to participate

Exclusion criteria for provider interviews are:

- None.

(ii) Data collection

We will collect the data fields listed below. We will also record non-patient-facing time, such as non-patient-facing duties (e.g. record-keepping, outreach activities, or administration) and other time (breaks and idle time).

For each participant interaction with a patient over the course of the day, we will record:
- Date
- Provider cadre (professional rank) and role at site
- Start time of observation (beginning of working day)

- Start time of interaction
- End time of interaction
- Patient type (e.g. HIV, ART, other)
- Reason for visit/services provided at visit (e.g. consultation, counseling, rescripting)
- End time of observation (end of working day)

Depending on patient volume and provider role, the data set may include up to several dozen interactions over the course of a day, along with start and end times for non-patient facing duties and other time. As mentioned, no individual identifiers will be recorded.

(iii) Implementation of the study

A research assistant will first request written informed consent from each individual provider identified as a potential participant. For participants who provide consent, the research assistant will be assigned to the participant for the entire working day. The research assistant, equipped with a tablet, will observe the start and end times of each interaction and the other data fields listed above. For this purpose, we may use TimeCAT software loaded onto tablets (https://lopetegui.net/timecat/39/login/) or may find that REDCap is easier for research assistants to use, with each interaction as a separate record. Research assistants will be stationed in inconspicuous locations in the study sites, where they can make the required observations without causing disruption to clinic operations or inconveniencing patients. The research assistants will not be in the same space as the patients and will not directly observe any patient-provider interactions. No identifiers will be collected with these observations.

(iv) Data analysis

We will analyze the time-and-motion data to generate mean time intervals, in minutes, for each combination of provider cadre/patient type/interaction type in the data set (and to the extent that data allow). For example, it is likely that at each site, one combination observed will be a nurse/stable ART patient/annual consultation and prescription refill. We will estimate the mean time required for this combination by pooling observations across all 12 sentinel sites. We will repeat this exercise for all the common combinations observed, including for non-patient facing time. If data are not available for all three of the variables (provider cadre/patient type/interaction type) we will define types of interactions based on data we do have. Results will be used to estimate and compare staff time allocations per patient per year for each DSD model and determine whether DSD models are associated with an increase or decrease the potential number of patients who can be managed with the existing staff complement. We will also look for associations between staff time use and the overall proportion of ART patients enrolled in DSD models. Finally, results will be used to estimate the staff component of treatment costs, with provider fully loaded salaries (total cost to company) multiplied by the time spent per patient.

(v) Informed consent

Written informed consent will be sought from each provider participating in the time-and-motion study. Potential participants will be referred to the research assistant by the facility in-charge. The research assistant will explain that we are conducting a study to understand time use and would like to record the timing of the potential participant's interactions with ART and non-ART patients throughout the day. Potential participants will be assured that we will not observe actual interactions with patients, only

record staff provider cadre (e.g. “nurse”), patient type (e.g. ART, non-ART HIV, non-HIV), interaction type (or reason for consultation) (e.g. “scheduled medical visit and medication prescription extension”), and start and end times for each interaction.

Potential participants will also be informed that participation is completely voluntary and that observation can be halted at any time, if they do not feel comfortable. Participants will remain completely anonymous; no individual identifiers of any kind will be recorded for the participants or the patients they interact with, and facility names, while recorded, will not be reported in a way that allows respondents to be identified by their provider cadre.

d. Domain 2 (Provider experiences)

Questions in Domain 2 pertain to providers’ experiences with DSD models. These questions will be answered through a survey of providers at the study sites. Questionnaires will include both closed- and open-ended questions about the strengths and weaknesses of the models; how the advent of DSD models has changed provider responsibilities, work burden, and time allocation; and the effect of DSD models on job satisfaction. Written informed consent will be sought for provider interviews.

How has the introduction of DSD models affected individual providers’ perceived workloads?

How has the introduction of DSD models affected individual providers’ job satisfaction?

What were the major facility-level procedural and other changes entailed in introducing DSD models and how can implementation be improved in the future?

(ii) Questionnaire

We will administer a questionnaire to a sample of up to 10 providers per study site, with questions addressing providers’ views on how the advent of DSD models has changed 1) individual job responsibilities and challenges; 2) facility operations in general; and 3) the respondent’s job satisfaction. We will also ask participants to comment on challenges faced in implementing DSD models, the impact of DSD models on provider time allocation and efficiency (average time spent treating each patient) while caring for ART or non-ART patients, and other related topics. The questionnaire and consent information sheet and form are included as appendices to this protocol. No identifiers will be collected for any participant in the provider survey.

(iii) Sample selection

For the survey, we will enroll up to 10 providers per facility, preferentially including all staff who manage ART patients and the site’s operations manager, one or more lay counselors or community health workers, a pharmacist or pharmacy assistant, and any other cadre that is relevant to the DSD model program, as identified by the site. To select participants, we will ask the facility in-charge (facility manager) to choose the individuals in each cadre who are most involved in DSD model implementation. At some sites, each cadre will have only one representative on staff, and in some cases the cadre may be missing entirely. For facilities that have fewer than 10 providers in total, we will enrol as many as are

involved in DSD model implementation and meet other enrollment criteria. At each site, we will work with the operations manager to select the most relevant individuals.

(iv) Inclusion and exclusion criteria

Inclusion criteria for provider interviews are:

- Direct or indirect service provider at the study site (indirect providers include supervisors, technical advisors, etc.)
- Directly or indirectly involved in the site's implementation of ART and DSD models
- Employed in current role at the study site for at least six months
- Provides written informed consent to participate.

Exclusion criteria for provider interviews are:

- None.

(v) Implementation of survey

A Sentinel-Malawi study research assistant will administer the surveys in person in a private location at the clinic at a convenient time for the clinic staff member. We anticipate that each survey will take 45-60 minutes to complete.

(vi) Data analysis

We will first estimate and report simple frequencies of responses to each closed question on the provider survey, by provider cadre. We will then summarize responses to open-ended questions. If data allow, we will stratify results by the models of care in use at the site and/or by the proportion of patients enrolled in non-conventional models of care.

(vii) Informed consent

Providers identified for potential survey participation will be asked for written informed consent. The consent form will explain the purpose of the survey and assure participants that 1) they are not required to answer any questions they do not wish to and can stop the survey at any time; 2) they may decline to participate in the study entirely without any harmful consequences; and 3) no individual identifiers will be collected—we will not record names or any other identifying information. Those who provide consent will then be administered the survey.

(viii) Distress protocol

If a provider exhibits distress reflective of what would be expected in an interview about a sensitive topic, study staff will offer support and extend the opportunity to: (a) stop the interview; (b) regroup; (c) continue. If a participant's distress reflects acute emotional distress beyond what would be expected in an interview about a sensitive topic, study staff will take the following actions: (a) stop the interview; (b) give the provider a quiet private space and time interval to regroup if desired; (c) encourage the

participant to contact his/her mental health provider, if they have one; (d) if the participant does not have a mental health provider, refer the participant to the clinic operations manager for more information on resources available to health care providers experiencing burnout or challenges related to workplace stress.

e. Domain 3 (Patient experiences with service delivery)

A quantitative, structured questionnaire will be administered to patients to understand patients' satisfaction with their current model of care, motivation for enrolling in that model, and direct and indirect costs of accessing care. The focus will be on treatment service delivery, not on clinical aspects or outcomes of HIV treatment itself. Written informed consent will be sought for patient surveys.

How much time do patients spend at facilities and at other DSD model venues for each model of care?

What are the direct and indirect costs to patients of participation in each model?

What do patients like and dislike about each model, how satisfied are they with their healthcare, and what would their preferences be for different model characteristics in the future?

(i) Questionnaire

A structured questionnaire, designed for quantitative analysis, will be administered to a sample of patients at each site. Questions will address:

(i) Costs to patients of seeking care (transport, time, lost wages, child care, etc.)
(ii) Time required for seeking care (travel, time at healthcare facility, time participating in DSD interactions)
(iii) Patient satisfaction with their current model of care
(iv) Patient's preferences as to best and worst aspects of seeking care

Identifiers will be collected to allow questionnaire responses to be linked to respondents' clinical records. Written informed consent will be sought from all participants, including consent to link questionnaire responses to clinical records and to collect data from clinical records. The questionnaire and consent information sheet and form are included as appendices to this protocol.

(ii) Sample selection

We will recruit adult ART patients who are enrolled in a defined model of care and present at the study sites during the recruitment period. At the study sites, clinic staff will inform potentially eligible patients about the study during routine visits. Patients who agree will be referred to a research assistant, who will explain to each potentially eligible subject that a study is underway and that patients who voluntarily enroll in the study will be asked questions about their feelings about the care at the clinic, costs incurred for care, and feelings about being enrolled in their DSD model. They will be told that the study will have no effect on the care they receive; that they do not have to participate to continue to receive care at the site as they usually would; and that they do not have to answer any questions they

do not wish to. The research assistant will enter the patient in the screening register and administer written informed consent; those who consent will then be administered the survey.

We will aim to enroll up to 10 patients per site per model of care, with conventional care defined as one model and including patients eligible for but not enrolled in a differentiated model other than conventional care and, defined as a separate model, patients not eligible for DSD models. Patients will be recruited consecutively as they complete their visits to the facility or other DSD model venue, based on availability of study interviewers. Study interviewers will await potential participants at locations convenient for each model of care (for example, for teen clubs held at facilities, the interviewer will be available near the club's meeting place as soon as club activities have ended for a group of potential participants). We anticipate that each of the 12 sites will include an average of 5 models of care, including the two conventional care models described above.

(iii) Inclusion and exclusion criteria

Inclusion criteria for the patient survey are:

- Living with HIV and on ART for at least six months at the study site
- ≥ 16 years old (16 and older considered adult for research purposes in Malawi)
- Enrolled in a specified model of care (including conventional care) up to the target number of participants for that model and have received at least one medication refill under this model
- Presented at the clinic for routine HIV-related care
- Provide written informed consent to participate.

Exclusion criteria for the patient survey are:

- Unable to communicate in any of the languages into which the questionnaire has been translated or that is known to the research assistant
- Not physically, mentally, or emotionally able to participate in the study, in the opinion of the investigators or study staff.
- Unwilling to take the time required to complete the questionnaire on the day of consent.

Eligibility based on these criteria will be determined through completion of a survey screening form. The screening form will also allow us to compare the sex and age distribution of the population enrolled in the survey with those of the full potentially eligible population. The screening form is included as an appendix to this protocol.

(iv) Implementation of survey

A trained Sentinel-Malawi research assistant will administer the survey in person in a private location at the clinic either while the patient is waiting for services or after the patient has completed the clinical visit. We anticipate that each interview will last 60 minutes, including the consent process. The questionnaire will document the subject's basic demographic and socioeconomic characteristics, details about their HIV care, their understanding of and satisfaction with aspects of the DSD or conventional care, and costs incurred while obtaining care, such as transport and lost wages.

(v) Data analysis

We will first estimate and report simple frequencies of responses to each question on the patient survey, by site, model, and patient type. For patient costs of seeking care, we will estimate total cost/healthcare system interaction and then multiply by the number of interactions per patient year to estimate a cost/patient/year. Monetary and time costs for patients will be estimated separately; time costs will also be converted to a monetary value using the local minimum wage or another appropriate metric. Questions on patient satisfaction, barriers, preferences, etc. will be reported as frequencies, stratified by model of care, patient type, age group, and sex as data allow.

(vi) Informed consent

Upon referral to the research assistant, patients will receive a more complete description of the study, including the details of why it is being done, the types of questions that will be asked, and the need for written informed consent. Patients will be assured that participation is voluntary and that they can withdraw from the study at any time, without affecting the quality of care provided by the site. They will also be offered the opportunity to ask questions. If all inclusion/exclusion criteria have been met, the patient will be asked to provide written informed consent to participate. The research assistant will complete a screening form to record study eligibility for each patient screened. The screening form will not collect any identifiable information pertaining to individual patients prior to receipt of written informed consent. For patients who decline to participate in the study (consent refused), the study interviewer will indicate the refusal and, if offered, reason for refusal in the screening form.

The patient survey information sheet and consent form will be translated into Chichewa, which is most commonly spoken by patients at the study site. Translated consent documents will be submitted to required ethics committees for review prior to use with any study subjects.

(vii) Distress protocol

If a patient exhibits distress reflective of what would be expected in an interview about a sensitive topic, study staff will offer support and extend the opportunity to: (a) stop the interview; (b) regroup; (c) continue. If a patient's distress reflects acute emotional distress beyond what would be expected in an interview about a sensitive topic, study staff will offer support and take the following actions: (a) stop the survey; (b) give the participant a quiet private space to regroup; (c) encourage the participant to contact his mental health provider, if they have one; if the participant does not have a mental health provider, provide the participant with a list of resources available including appropriate hotlines and referral to the appropriate person at the local clinic.

f. Domain 4 (Resources)

In addition to the human subjects' data described above, we will collect facility-level, aggregate data on patient volumes, reasons for visits for HIV and non-HIV patients, staff complements, and other operational indicators.

Has the total number or mix of patients seen at the healthcare facility overall, including HIV and non-HIV patients and HIV patients in different stages of treatment, changed over the time period of observation?

Has the total number or mix of providers at the healthcare facility overall, including for HIV and non-HIV services, changed over the time period of observation?

Have standard operating procedures at the facility, such as how patients are scheduled for visits or the internal allocation of space or other resources, changed over the time period of observation?

What is the contribution of external (donor/NGO) resources to the operation of DSD models?

The data to be collected for Domain 4 include routine reports and records generated by the facilities, District Health Offices, and nongovernmental partners. We will aim to collect the number of HIV, ART, and non-HIV patients presenting at the site in each time period and the number of full-time equivalent staff at the site in each time period, by cadre, including lay counselors, community health workers, and staff paid by external partners. We will also describe in detail the site's operating procedures with relevance to models of HIV treatment.

5. SAMPLE SIZE

The sample size for the study is 1000. Table 2 presents the sample size for each data collection activity described above. All sample sizes are based on pooled analysis across all 12 study sites. We do not have preliminary data for any of the outcomes we intend to estimate, the study does not test a hypothesis, and all study procedures are minimal risk. We have therefore chosen to enroll a number of each type of participant that is feasible based on site characteristics and study resources and will generate a large enough data set to analyze using standard methods.

Table 2. Sample size

Study population	Sample size
Domain 1: Time and motion study	Up to 60 providers (Up to 5 providers/site x 12 sites)
Domain 2: Providers surveyed	120 providers (Up to 10 providers/site x 12 sites)
Domain 3: Patients surveyed	600 patients (Up to 10 patients/model x 5 models/site x 12 sites)
Total study subjects	=60 + 120 + 600 = 780 study subjects maximum

To account for withdrawal after consent and/or the possibility of a site having more than 5 models, we will increase this to a maximum of 1000 study subjects for all of Sentinel-Malawi.

6. DATA ENTRY AND STORAGE

Data entry and storage for each data set are described in Table 3.

Table 3. Data entry and storage

Data set	Data entry and storage

Domain 1: Time and motion study	Data will be collected either on a cloud-based tool called TimeCat 3.9 or on REDCap loaded onto tablets. In cases of power failures or difficulties with the tablets, data will be entered onto paper study forms and then transcribed into a database at a local study office. These forms will be stored in a locked cabinet at the study sites, with access limited to the study team. Electronic data files will be stored on secure, protected drives at the Health Economics and Epidemiology Research Office (HE^2RO) in Johannesburg, Clinton Health Access Initiative (CHAI) offices in Lilongwe, and at Boston University in Boston, with access limited to relevant study staff. All subjects will be assigned a seven-digit, sequential identification number. The study ID number will not be linked to any identifiers, which will not be collected for this domain of the study. TimeCAT and REDCap both require secure log-in and access and the final dataset will be accessible only to the study team.
Domain 2: Provider survey	Provider survey responses will be entered into electronic databases at the time of interview, using tablets. If there are power failures, data will be entered onto paper study forms and then transcribed into a database at the local study office. Forms will be stored in a locked cabinet at the study sites, with access limited to the study team. Electronic data files will be stored on secure, protected drives at the Health Economics and Epidemiology Research Office (HE2RO) in Johannesburg, Clinton Health Access Initiative (CHAI) offices in Lilongwe and at Boston University in Boston, with access limited to relevant study staff. Provider survey records will not contain any individual identifiers. REDCap or a similar software program requiring secure log-in and access by invitation will be used to create an electronic database to manage quantitative study data. On a regular basis, the data will be converted to SAS, STATA or SPSS for final cleaning and data analysis. All analytic databases will be password protected with access restricted to the members of the study team.
Domain 3: Patient survey	A screening register will be kept by the study interviewers to record the consent process and keep track of those who do not consent, to allow us to determine if our sample is biased by patient characteristics due to differential consent. The screening register will not contain any individual identifiers. It will request age category, sex, and information required to determine survey eligibility only. The register will be kept as a form on the screeners' tablets. Patient survey responses will be entered into electronic databases at the time of interview, using tablets. If there are power failures, data will be entered onto paper study forms and then transcribed into a database at the local study office. Forms will be stored in a locked cabinet at the study sites, with access limited to the study team. Electronic data files will be stored on secure, protected drives at the Health Economics and Epidemiology Research Office (HE2RO) in Johannesburg, Clinton Health Access Initiative (CHAI) offices in Lilongwe and at Boston University in Boston, with access limited to relevant study staff. All subjects will be assigned a seven-digit, sequential identification number. The study ID number will be used to identify individual subjects in the study databases and for all data analysis. REDCap or a similar software program requiring secure log-in and access by invitation will be used to create an electronic database to manage quantitative study data. On a regular basis, the data will be converted to SAS, STATA or SPSS for final cleaning and data analysis. All analytic databases will be password protected with access restricted to the members of the study team.

Domain 4: Resources	Data for Domain 4 will consist of aggregate indicators which will be collected using a standard template at each site. This will not be human subjects-related data and confidentiality will not be required.

7. DISSEMINATION OF FINDINGS

The primary audience for this evaluation is the Malawian Ministry of Health and its partners, which will use the results to improve, target, and budget for the national implementation of DSD models. Many of the findings, however, will likely be of broader interest in Malawi and other countries, where more information about DSD model costs and impacts are eagerly sought. Results of the evaluation will be made as widely available as possible, through journals, websites, and conferences. Only aggregated, stratified data will be presented; it will not be possible to identify any individual patients from any of the data that is presented.

8. ETHICAL CONSIDERATIONS

The evaluation will require ethical approval from the National Health Sciences Research Committee of Malawi, the Institutional Review Board of Boston University, and the University of the Witwatersrand's Human Ethics Research Committee.

a. Potential risks and protections

The study team will not collect any biomedical samples specifically for this study. Data for the study will be drawn from provider questionnaires, patient questionnaires, and direct observation. We therefore believe that our study poses no physical risks to subjects. We will request written informed consent for the three study populations with whom study staff will interact.

(i) Population 1: Providers to be observed for time-and-motion study

We have identified one potential risk for providers participating in the time-and-motion study.

Risk 1: Loss of confidentiality

Study staff will observe providers starting and ending each interaction with a patient in order to record the amount of time required for each type of interaction. Providers participating in the time-and-motion study will be asked for written informed consent. No identifiers of any kind will be collected about the provider. We will, however, collect the provider's staff cadre (e.g. enrolled nurse, pharmacy assistant, etc.). At some study sites, only one individual will be in the cadre for which we collect data, making it potentially possible for someone with access to the data to identify that individual. If the person gaining access were a supervisor, knowledge of time spent on different types of interactions could be used to judge the individual's performance.

Protection against Risk 1:

Data from the time and motion study will be recorded on password protected tablets held by the study research assistants. The tablets will be kept in locked cabinets when not in use, with data transferred to the central database and removed from the tablets regularly. Data pertaining to individual staff members will not be provided to site managers or supervisors, who will receive only aggregate results.

During analysis, data from all 12 study sites will be pooled, preventing any single individual from being identified.

(ii) Population 2: Providers who participate in the provider survey

We have identified two potential risks for providers participating in the provider survey.

Risk 1: Emotional distress

The provider survey will ask questions about job satisfaction and challenges that could cause emotional distress among participants.

Protection against Risk 1:

Study staff will be trained to identify distress among respondents. The distress protocol described above will be followed should any occur. We repeat it here for convenience.

> If a provider exhibits distress reflective of what would be expected in an interview about a sensitive topic, study staff will offer support and extend the opportunity to: (a) stop the interview; (b) regroup; (c) continue. If a participant's distress reflects acute emotional distress beyond what would be expected in an interview about a sensitive topic, study staff will offer support and take the following actions: (a) stop the interview; (b) give the provider a quiet private space to regroup; (c) encourage the participant to contact his/her mental health provider, if they have one; (d) if the participant does not have a mental health provider, refer the participant to the clinic operations manager for more information on resources available to health care providers experiencing burnout or challenges related to workplace stress.

Risk 2: Loss of confidentiality

Providers participating in the provider survey will be asked for written informed consent. No identifiers of any kind will be collected about the provider. We will, however, collect the provider's staff cadre (e.g. enrolled nurse, pharmacy assistant, etc.). At some study sites, only one individual will be in the cadre for which we collect data, making it potentially possible for someone with access to the data to identify that individual. If the person gaining access were a supervisor, responses could be used to judge the individual's performance or affect his or her employment in other ways.

Protection against Risk 2:

Data from the provider survey will be recorded on password protected tablets held by the study research assistants. The tablets will be kept in locked cabinets when not in use, with data transferred to the central database and removed from the tablets regularly. Data pertaining to individual staff members will not be provided to site managers or supervisors, who will receive only aggregate results. During analysis, data from all 12 study sites will be pooled, preventing any single individual from being identified.

(iii) Population 3: Patients who participate in the patient survey

We have identified two potential risks for patients participating in the patient survey.

Risk 1: Emotional distress

The patient survey will ask questions about health and other topics that could cause emotional distress among participants, who will have HIV and may have encountered obstacles in navigating the treatment process. Interacting with them in order to explain the study and confirm eligibility before requesting written informed consent may cause some emotional distress for some potential subjects.

Protection against Risk 1:

Study staff will be trained to identify distress among respondents. Site staff who introduce the study to potential subjects will be trained to assure potential subjects that referral to study staff and enrolling in the study are completely voluntary and that those who do not wish to enroll will receive exactly the same care as the study site would otherwise have provided. Potential subjects will also be told that they can discontinue participation even after consenting without any effect on their care. The distress protocol described above will be followed should any occur. We repeat it here for convenience.

> If a patient exhibits distress reflective of what would be expected in an interview about a sensitive topic, study staff will offer support and extend the opportunity to: (a) stop the interview; (b) regroup; (c) continue. If a patient's distress reflects acute emotional distress beyond what would be expected in an interview about a sensitive topic, study staff will offer support and take the following actions: (a) stop the survey; (b) give the participant a quiet private space to regroup; (c) encourage the participant to contact his mental health provider, if they have one; if the participant does not have a mental health provider, provide the participant with a list of resources available including appropriate hotlines and referral to the appropriate person at the local clinic.

Risk 2: Loss of confidentiality

Patients participating in the patient survey will be asked for written informed consent. We will collect data indicating individuals' HIV status, their opinions on the quality of the services received, and some sensitive health information. A breach of confidentiality, for example through inadvertent loss of a storage device or paper files, would thus pose a risk to subjects.

Protection against Risk 2:

To protect patients against this risk, patient identifiers will be collected and stored separately from all other individual data. Identifiers will be entered on site and stored in encrypted, password protected files, so that no paper records containing identifying information are removed from the sites. Names, national identification numbers, and other identifying information will be used only for the purposes of linking disparate sources of data for the same patient (e.g. electronic medical record information to paper clinical records). As soon as a specific source document has been linked to the patient of interest, data from it will be entered in a record containing the Study ID number only. Analytic data sets will not contain any identifiers, and the linking files containing the identifiers will be destroyed after linking is complete.

All study data, whether in electronic or paper format, will be stored in secure locations. Password-protected laptops or tablets used on site will be kept in locked and secure cabinets and rooms when not in use. Files will be transferred to the study office on a regular basis and stored on secure servers and in locked cabinets. Study staff will not be permitted to download de-identified data sets for cleaning or analysis except with the explicit permission of a co-investigator, and data sets will not be stored on individual hard drives when not in use. Upon completion of the study, computer files and any data collection forms containing study data will be retained for seven years and then destroyed.

All study staff will be trained in Good Clinical Practice, Research Ethics, and study procedures to ensure that they understand both research confidentiality requirements and study confidentiality procedures. Study investigators will monitor data collection on an ongoing basis. They will report to the Malawi NHSRC, the BU IRB, and the Wits HREC any breaches in confidentiality identified. In the event that a breach in confidentiality does occur, staff will be retrained on human subjects' protection and confidentiality if possible or removed from the study if either the breach is too serious or if the PIs feel the staff member cannot be sufficiently retrained. Staff will be made aware of this condition on employment.

b. Direct benefits

There are no direct benefits to study subjects enrolled in this study.

c. Indirect (societal) benefits

The indirect benefits of this study are expected to be large. Government of Malawi is embarking on scale up of some DSD models that will ultimately affect hundreds of thousands of patients. Generating early evidence of the expected patient and provider impact and patient cost of these interventions has the potential to make DSD models more effective and less expensive nationwide. The evaluation will also assist the government to prioritize models that are more preferable for providers and patients, as well as those that are most efficient.

Because the indirect benefits of the study are large and the risks to human subjects are minimal, we are confident that the benefits justify the risks.

d. Informed consent

Written, informed consent will be sought from all participants in the time-and-motion study, provider survey, and patient survey. The informed consent information sheet will describe the nature and goals of the study and assure subjects their information will be kept confidential. It will explain to subjects what will occur in the study and the procedures to be followed and/or questions to be asked. It will indicate that after the study has been completed, fully dis-identified data may be posted to a public research repository, as is typically required for journal publication.

The consent form will be administered by a trained study research assistant. Participants will be assured that data collected for our study will be kept strictly confidential and will never be reported to clinic staff or anyone outside the study team. For the patient survey, the full informed consent information sheet and form will be translated into the languages most commonly used by patients at the study sites. For providers all interviews will be conducted in English.

e. Subject confidentiality

As explained above, we will take multiple steps to protect subject confidentiality. These are detailed in the paragraph entitled "Potential Risks and Protections."

f. Costs and payments

Study subjects will not incur any costs from study participation. Participants in the time-and-motion study will not receive any payments for their participation. Participants in the provider and patient surveys will receive compensation valued at USD 10 ($10) to thank them for their time and willingness to participate.

g. Access to data

As is often required by journals for publication of research manuscripts, we will post completely anonymized data sets to a public repository after all analysis and publication has been completed. The informed consent forms will alert participants to this and indicate that in providing consent to participate in the study, they are also consenting to the posting of completely de-identified data to a research repository.

9. COVID-19 CONSIDERATIONS

In light of COVID-19 and the need to adhere to safety protocols to protect study staff and participants, we will implement the following precautions:

- Fieldwork will only commence when permitted according to the country's lockdown regulations.
- Training plans for the study team will be evaluated at the time and if COVID risk is too high, training will be done remotely via Zoom.
- We will supply Personal protective equipment (PPE) material including masks, hand sanitizers, and/or other applicable PPE to the study team
- Regular screening of study team members for COVID-19 symptoms will be conducted
- If any team members show COVID-19 symptoms, he/she will immediately report it to the study PI and action will be taken as specified in the COVID-19 SOP
- Study interviewers will capture responses directly in REDCap during the interview – therefore alleviating the need for printed questionnaires.
- Study interviewers will practice physical distancing (minimum of 1.5 meters apart) at all times while conducting fieldwork
- A separate COVID-19 SOP will provide detailed guidance on safety protocols that need to be followed while conducting fieldwork
- We will provide training on the COVID-19 SOP and procedures that need to be followed at the clinics/facilities, including infection prevention control measures and PPE use.

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11. APPENDICES

Data collection instruments

1. Time and motion study data collection form
2. Provider survey instrument
3. Patient survey instrument
4. Patient survey eligibility screening form

Consent forms and information sheets

5. Time and motion study information sheet
6. Time and motion study consent form
7. Provider survey information sheet
8. Provider survey consent form
9. Patient survey information sheet
10. Patient survey consent form

Time and motion instrument for AMBIT Sentinel-Malawi (single day observation)

For each provider observed:

1. Observation ID number (record number)
2. Provider code (to use to link all the observations for a single provider)
3. Facility name and code
4. Research assistant name and code
5. Date (DD/MM/YY)
6. Day of week (drop down)
7. Assigned clinic (e.g. ART, HIV general, chronic, general)
8. Provider cadre (drop down)
9. Starting time of observation
10. Ending time of observation

For each patient consultation during the day:

11. Start time
12. End time
13. Patient cohort (stable on ART, not yet on ART, initiating ART, first six months on ART, advanced disease, etc.)
14. Consultation primary purpose (scheduled medical exam, prescription refill, ART initiation, counseling, unscheduled cause, other)
15. Patient model of ART delivery (DSD model)

For each non-consultation time interval during the day:

16. Start time
17. End time
18. Main activity (patient-related tasks, DSD-model related tasks, general administration and meetings, external outreach, personal breaks, training, other) (Note: for staff working specifically on DSD models, we may want to specify model-related activities, like leading a group or delivering medications.)

RESEARCH INFORMATION FORM FOR TIME AND MOTION STUDY

Title of Project: Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)

Principal Investigators: Sydney Rosen, Andrews Gunda, Sophie Pascoe

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Study Number:

Study Title:	**Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)**
Sponsor:	Bill & Melinda Gates Foundation
Investigators:	Prof Sydney Rosen (Boston University); Mr. Andrews Gunda (Malawi); Dr. Sophie Pascoe (South Africa)

Good day. My name is _____, and I am a Research Assistant at CHAI-Malawi. I would like to invite you to consider participating in a research study entitled "Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)."

What Is this research study about?

CHAI-Malawi, Boston University in the United States, and Wits University in South Africa are conducting a research study about different models of HIV treatment delivery in Malawi and how these models of care affect both the clinics and their staff and the patients who are receiving treatment. In particular, today we would like to measure how much time each step in providing treatment to HIV takes, in the different models of care that this clinic offers.

We are asking you to participate in this study because you work at this clinic as a provider who has regular contact with the patients who access ART here. If you choose to participate, we will collect information on how much time you spend with different kinds of patients and for the various services you provide. We will not interact with you or the patients directly, only observe the times at which consultations and other events start and end.

This study is being conducted by Professor Sydney Rosen from Boston University in the U.S., Mr. Andrews Gunda from CHAI-Malawi, and Dr. Sophie Pascoe from Wits University in South Africa. Other investigators involved in the study are Mr. Clement Banda and Mr. Timo Tchereni from CHAI-Malawi and Ms. Idah Mokhele from Wits University. This study is being sponsored by the Bill & Melinda Gates Foundation in the United States.

I would like to provide you with some more information about the study, so that you can decide whether you would like to take part in it. Taking part in this study is voluntary. You can choose not to take part and if you join, you may quit at any time. If you decide not to participate, it will have no effect on your position at the clinic. Please ask the study staff to explain anything you do not understand.

What is the purpose of this research study?

In many countries, including Malawi, Ministries of Health and healthcare providers are trying to find easier ways to provide ART to the many thousands of patients who need it. This effort has led to the development of what are called "differentiated service delivery" models (DSD models), which adjust the timing, location, and other aspects of ART for different kinds of patients. The goal of DSD models

is to make treatment more accessible to patients so that they can more easily adhere to treatment and be more satisfied with the services they received and to reduce the burden of the national ART program on clinics and healthcare workers.

In Malawi, the Ministry of Health has rolled out three main models of care, known as multi-month dispensing, teen clubs, and community outreach. Some individual clinics and partner organizations have created other models as well. Now that clinics and patients have some experience with these different models, it is important to find out how many patients are participating in each model, how well the models are performing, how much they cost both the clinics and patients, and whether patients and healthcare providers are satisfied with them. This study is being conducted in collaboration with the Ministry of Health to try to find answers to these questions, so that models can be improved in the future.

What happens in this research study?

This study is taking place in 12 clinics in Malawi. You will be one of 60 providers to be asked to participate in this study. If you participate in the study, a study research assistant will observe how much time you spend with each patient and the services that are provided to that patient over the course of two full working days. The research assistant will have a stopwatch and will record the start and end times for each of your interactions with patients. We will not record your name or other personal identifiers, only your position (job title) and role in the ART program. Any reports that are written using information from this study will combine information for many providers and it will not be possible to identify any individual participant from the information that is presented.

Are there risks or discomforts from participating?

The only risk to participating in this study is the small risk of loss of confidentiality, i.e., that your name and study results may become known to others. The study team will take every measure to ensure that this does not happen, however, and to keep the data we collect confidential and will not tell or show anyone what you have said. None of your answers will be shared with others at this facility. Your participation and your answers will not affect your work at this health facility in any way. You may choose to stop the observation at any time if you prefer not to continue.

Are there potential benefits from participating?

You will receive no direct benefit from taking part in this study. However, the information that you provide may help us to understand ways to improve healthcare services Malawi and how to appropriately support both patients and providers.

What other choices do I have?

Your alternative is not to participate in this study.

Are there any costs or payments to me?

There are no costs to you for participating in this study. ART is free at this clinic. There are no payments to you for participating in this study.

How will my information be protected?

The information that we collect from this research project will be kept private. Once you agree to

join the study, we will assign you a study number in order to protect your privacy. We will not record your name or other personal identifiers. All consent forms, questionnaires, and notes from the study will be stored in a locked unit, and only study staff and designated officials will have access to them. We will not report whether you have participated in the study to any others at the clinic, community members, or health facilities or health care staff. However, complete confidentiality cannot be guaranteed.

Also, upon signing this consent you give designated officials from the Institutional Review Boards at the Malawi National Health Sciences Research Committee, the University of the Witwatersrand, Boston University, and the Office of Human Subject Protection in the U.S. Department of Health and Human Services consent to look at your study records. They are ensuring that everything happening in this study is ethical. They would only review the study records to ensure that your privacy and integrity is being maintained and protected. A description of this study will be available on http://www.ClinicalTrials.gov. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

In addition, the final data set containing your responses may be posted in a public data repository as a part of the research publication process. The posted data set will have all identifiers removed so that it is not possible to identify any individual respondent.

Participant's rights

Taking part in this study is voluntary. You have the right to refuse to take part. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. If you choose to take part, you have the right to stop at any time without losing any of your rights as a healthcare worker here in any way. The researchers may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

If you want any information regarding your rights as a research participant, or complaints regarding the research study, you may contact the National Health Science Research Committee, Ministry of Health P.O. Box 30377, Lilongwe 3, Malawi, Tel: +265994063425, Email: mohdoccentre@gmail.com.

RESEARCH CONSENT FORM FOR TIME AND MOTION STUDY

Title of Project: Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)

Principal Investigators: Sydney Rosen, Andrews Gunda, Sophie Pascoe

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INFORMED CONSENT SIGNATURE PAGE

Signing this consent form indicates that you have read the consent form information sheet (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this consent form to keep.

_____	_____	_____	_____
Participant (Signature or Thumbprint)	(Printed Name)	Date	Time

_____	_____	_____	_____
Person Obtaining Consent (Signature)	(Printed Name)	Date	Time

_____	_____	_____	_____
Witness* (Signature)	(Printed Name)	Date	Time

*Witness signature required if patient provides mark or thumbprint rather than signature

Participant Survey ID Number

SENTINEL-Malawi Providers' Survey

Survey ID

Introduction

Ask the participant for a few minutes of their time. Introduce yourself and the study. Begin to provide information on the study as per the training, and provide the participant with the information sheet for the study. If the provider agrees to participate, allow the participant to sign and date the informed consent and then sign and date the consent form yourself. After the consent form has been signed, leave the information sheet with the participant.

If consent has been obtained, continue to Question 1. If consent has not been obtained, thank the provider for their time and end the interaction with the provider.

Surveyor ID _____ Facility Name _____

Date (DD/MM/YYYY) _____

Q#	Question	Responses
1	**Respondent description and position at facility**	
1.1	What is your current role at this facility?	(1) Site Operations Manager (2) Doctor/Medical Officer/Clinical Officer (3) Lay Counselor (on site) (4) Professional Nurse (5) Site Nurse (6) Outreach Worker or Community Health Worker (off site) (7) Pharmacist (8) Pharmacy Assistant (9) Other (specify)
1.2	What is your employment status?	(1) Full time (2) Full time – rotating (3) Part-time (4) Contract (5) Partner secondment (6) Other (specify)
1.3	How many years have you worked in your current role/capacity?	Years, months
1.4	How many years have you worked at this facility?	Years, months
1.5	In a typical five-day work week, how much of your work time do you spend on HIV-related service delivery?	Number of days, decimal allowed
1.6	In a typical five-day work week, how much of your work time do you spend providing HIV treatment?	Number of days, decimal allowed
2	**Involvement in DSD models**	
Surveyor: Explain to respondent what you mean by "other models of treatment delivery"		
2.1	When did this facility first start offering other models of treatment delivery, such as (examples at that site)?	Year
2.2	Do you have any responsibilities for other models of treatment delivery, such as helping to organize clubs, provide services in the community, etc.?	Yes/no
2.3	If yes, which models are you involved in? (Check all that apply)	☐ 6MMD ☐ 3MMD ☐ Adherence club ☐ Teen club

Q#	Question	Responses
		☐ Community adherence groups (CAG) ☐ Community outreach ☐ Teen club ☐ Intensified care ART clinic (ICAC) ☐ Fast track ☐ Late shift ☐ Nurse led community ART (NCAP) register ☐ High viral load clinic ☐ Mother infant pair ☐ Advanced HIV disease ☐ Other (specify)
2.4	If yes, for each model you mentioned, what exactly do you do?	Open ended, one answer for each model
2.5	In a typical five-day work week, how much of your work time do you spend on other models of treatment delivery?	Number of days, decimal allowed
3	**Effect of DSD models on job responsibilities**	
3.1	Were you working at this facility before any other models of treatment delivery were offered?	Yes/no
3.2	Have the other models of treatment delivery offered here affected your job, such as your responsibilities, work load, hours, schedule, etc.?	Yes/no
3.3	If yes, in which of the following ways has your job changed since patients began participating in other models of treatment delivery? (Check all that apply)	☐ I see fewer patients each day ☐ I see more patients each day ☐ The queues are shorter ☐ The queues are longer ☐ I can spend more time with individual patients ☐ I can spend less time with individual patients ☐ I spend time involved in the other models themselves (e.g. leading a group or delivering medications) ☐ I work shorter hours ☐ I work longer hours ☐ I have more management/administrative responsibility ☐ I have less management/administrative responsibility ☐ I spend more time in training ☐ I spend less time in training ☐ Other (specify)
3.4	Please briefly explain the changes to your job you indicated in the previous question.	Open ended
3.5	Does having some patients in other models of treatment delivery “free up” some of your time?	Yes/no/don’t know
3.6	If yes, what exactly do you do with the extra time?	Open ended

Q#	Question	Responses
3.7	Do you receive different compensation (salary, benefits) as a result of having other models of treatment delivery? (E.g. overtime payments for weekends)	Yes/no/don't know
3.8	If yes, how has your compensation changed	Open ended
3.9	Have the models of treatment delivery offered here led to changes in how the clinic is managed (including management of personnel, resources, space, etc.)?	Yes/no/don't know
3.10	If yes, what specifically has changed with how the clinic is managed?	Open ended
3.11	Do you think that the other models of treatment delivery make your job harder or easier?	Harder/easier/no change/don't k now
3.12	In what specific ways do they make your job harder or easier?	Open ended
3.13	In your view, have other clinic procedures, policies, resources, attitudes or other aspects of working here changed as a result of having other models of treatment delivery?	Yes/no
3.14	If yes, what specifically has changed?	Open ended
4	**Effect of DSD models on job satisfaction**	
Surveyor: Explain to respondent that each of these questions compares what his or her job was like before the clinic started to offer other models of treatment delivery to what it is like now. If the respondent was not at this site or in this position before other models started, ask him or her to imagine the position at that time.		
4.1	Please say how much you agree with the following statements.	These are all Likert scales 1-5 (strongly disagree, mildly disagree, neither agree or nor disagree, mildly agree, strongly agree, no response/don't know)
a.	I like my job more now	
b.	I prefer how my time is spent now, compared to before	
c.	My work schedule is not as stressful	
d.	I am able to spend more time with individual patients	
e.	I see fewer patients each day than I used to	
f.	Patients who are in other models of treatment are more polite or more friendly than those who are not	
g.	Having other models of treatment delivery available has improved my relationship with patients	
h.	I get more time to myself (breaks, etc.)	
i.	I have to work harder to get everything done	
j.	I am more satisfied with my job than I was	
k.	I work shorter hours than I used to	
l.	Having other models of treatment delivery has made my relationships with colleagues in the facility better	
m.	Having other models of treatment delivery has made my relationships with senior management better	
n.	I feel happier overall (in my life) than I used to	
o.	Because of the other models of treatment delivery, I am more likely to stay in my current position than I was before	
4.2	Please describe your personal level of satisfaction with your job and how it has been affected by having other models of treatment delivery at this clinic. *(Surveyor: if any*	Open ended

Q#	Question	Responses
	of the items above received Leikert scores of 1 or 5, please ask respondent to explain these answers as well.)	
5	**Views of DSD models**	
5.1	Do you think that having other models of treatment delivery available improves or worsens the care that this facility's ART patients receive?	Improve/worsen/no change/don't know
5.2	Please explain your answer.	Open ended
5.3	How confident are you that you understand the requirements for each other model?	Likert scale
5.4	From your perspective, what are the most valuable aspects of other models?	Open ended
5.5	From your perspective, what are main challenges to having other models?	Open ended
5.6	Are you aware of targets set by the Ministry of Health or others for getting more patients into other models?	Yes/no
5.7	Do you feel pressure to enroll patients in other models?	Yes/no
5.8	If yes, please describe what kind of pressure you feel.	Open ended
5.9	How do you think this clinic's offering of other models of ART delivery can be improved?	Open ended
5.10	What else would you like to see changed to improve this clinic's overall ART program?	Open ended
6	**Is there anything else you'd like to tell me before we finish?**	**Open ended**

Surveyor: "Thank you sincerely for your time. We have completed this interview and are grateful for your help in improving our understanding of how other models of HIV treatment delivery affects healthcare providers' jobs."

RESEARCH INFORMATION FORM FOR PROVIDER SURVEY

Title of Project: Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)

Principal Investigators: Sydney Rosen, Andrews Gunda, Sophie Pascoe

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Study Number:

Study Title:	**Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)**
Sponsor:	Bill & Melinda Gates Foundation
Investigators:	Prof Sydney Rosen (Boston University); Mr. Andrews Gunda (Malawi); Dr. Sophie Pascoe (South Africa)

Good day. My name is _____, and I am a Research Assistant at CHAI-Malawi. I would like to invite you to consider participating in a research study entitled "Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)."

What Is this research study about?

CHAI-Malawi, Boston University in the United States, and Wits University in South Africa are conducting a research study about different models of HIV treatment delivery in Malawi and how these models of care affect both the clinics and their staff and the patients who are receiving treatment.

We are asking you to participate in this survey because you work at this clinic as a provider who has regular contact with the patients who access ART here. We would like to discuss the models of ART this clinic offers, your experiences with these models, and how the different models have affected the clinic's procedures and your workload and job satisfaction. If you choose to participate, you will be asked to answer a set of questions today.

This study is being conducted by Professor Sydney Rosen from Boston University in the U.S., Mr. Andrews Gunda from CHAI-Malawi, and Dr. Sophie Pascoe from Wits University in South Africa. Other investigators involved in the study are Mr. Clement Banda and Mr. Timo Tchereni from CHAI-Malawi and Ms. Idah Mokhele from Wits University. This study is being sponsored by the Bill & Melinda Gates Foundation in the United States.

I would like to provide you with some more information about the study, so that you can decide whether you would like to take part in it. Taking part in this study is voluntary. You can choose not to take part and if you join, you may quit at any time. If you decide not to participate, it will have no effect on your position at the clinic. Please ask the study staff to explain anything you do not understand.

What is the purpose of this research study?

In many countries, including Malawi, Ministries of Health and healthcare providers are trying to find easier ways to provide ART to the many thousands of patients who need it. This effort has led to the development of what are called "differentiated service delivery" models (DSD models), which adjust the timing, location, and other aspects of ART for different kinds of patients. The goal of DSD models is to make treatment more accessible to patients so that they can more easily adhere to

treatment and be more satisfied with the services they received and to reduce the burden of the national ART program on clinics and healthcare workers.

In Malawi, the Ministry of Health has rolled out three main models of care, known as multi-month dispensing, teen clubs, and community outreach. Some individual clinics and partner organizations have created other models as well. Now that clinics and patients have some experience with these different models, it is important to find out how many patients are participating in each model, how well the models are performing, how much they cost both the clinics and patients, and whether patients and healthcare providers are satisfied with them. This study is being conducted in collaboration with the Ministry of Health to try to find answers to these questions, so that models can be improved in the future.

What happens in this research study?

This study is taking place in 12 clinics in Malawi. You will be one of 120 providers to be asked to participate in this study. If you participate in the study, it will take about 45-60 minutes of your time today. We will ask you questions about clinic and DSD model procedures, your professional responsibilities and experiences, changes as a result of DSD model scaleup, and your job satisfaction. We will not ask you questions about yourself outside your job, your beliefs or behaviors, or any other personal information. We will not record your name or other personal identifiers, only your position (job title). Any reports that are written using information from this study will combine information for many providers and it will not be possible to identify any individual participant from the information that is presented.

Are there risks or discomforts from participating?

- The only risk to participating in this study is the small risk of loss of confidentiality, i.e., that your name and questionnaire results may become known to others. The study team will take every measure to ensure that this does not happen, however, and to keep your answers confidential and will not tell or show anyone what you have said. None of your answers will be shared with others at this facility. Your participation and your answers will not affect your work at this health facility in any way. You may refuse to answer any questions or choose to stop the interview at any time. You do not have to respond to any question unless you feel comfortable doing so. We can stop at any time if you prefer not to finish the interview.

- The other risk of this study is that some of the questions you are asked may make you feel uncomfortable or emotionally distressed. The study staff will make every effort to reduce your distress. You do not have to respond to any question unless you feel comfortable doing so. We can stop at any time if you prefer not to finish the questionnaire.

Are there potential benefits from participating?

You will receive no direct benefit from taking part in this study. However, the information that you provide may help us to understand ways to improve healthcare services Malawi and how to appropriately support both patients and providers.

What other choices do I have?

Your alternative is not to participate in this study.

Are there any costs or payments to me?

RESEARCH INFORMATION FORM FOR PROVIDER SURVEY

Title of Project: Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)

Principal Investigators: Sydney Rosen, Andrews Gunda, Sophie Pascoe

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There are no costs to you for participating in this study. ART is free at this clinic. If you consent to participate in this study and complete study procedures, you will receive compensation equivalent to USD 10 to thank you for your time and any inconvenience of being in the study.

How will my information be protected?

The information that we collect from this research project will be kept private. Once you agree to join the study, we will assign you a study number in order to protect your privacy. We will not record your name or other personal identifiers. All consent forms, questionnaires, and notes from the study will be stored in a locked unit, and only study staff and designated officials will have access to them. We will not report whether you have participated in the study to any others at the clinic, community members, or health facilities or health care staff. However, complete confidentiality cannot be guaranteed.

Also, upon signing this consent you give designated officials from the Institutional Review Boards at the Malawi National Health Sciences Research Committee, the University of the Witwatersrand, Boston University, and the Office of Human Subject Protection in the U.S. Department of Health and Human Services consent to look at your study records. They are ensuring that everything happening in this study is ethical. They would only review the study records to ensure that your privacy and integrity is being maintained and protected. A description of this study will be available on http://www.ClinicalTrials.gov. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

In addition, the final data set containing your responses may be posted in a public data repository as a part of the research publication process. The posted data set will have all identifiers removed so that it is not possible to identify any individual respondent.

Participant's rights

Taking part in this study is voluntary. You have the right to refuse to take part. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. If you choose to take part, you have the right to stop at any time without losing any of your rights as a healthcare worker here in any way. The researchers may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

If you want any information regarding your rights as a research participant, or complaints regarding the research study, you may contact the National Health Science Research Committee, Ministry of Health P.O. Box 30377, Lilongwe 3, Malawi, Tel: +265994063425, Email: mohdoccentre@gmail.com.

RESEARCH CONSENT FORM FOR PROVIDER SURVEY

Title of Project: Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)

Principal Investigators: Sydney Rosen, Andrews Gunda, Sophie Pascoe

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INFORMED CONSENT SIGNATURE PAGE

Signing this consent form indicates that you have read the consent form information sheet (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this consent form to keep.

_____	_____	_____	_____
Participant (Signature or Thumbprint)	(Printed Name)	Date	Time

_____	_____	_____	_____
Person Obtaining Consent (Signature)	(Printed Name)	Date	Time

_____	_____	_____	_____
Witness* (Signature)	(Printed Name)	Date	Time

*Witness signature required if patient provides mark or thumbprint rather than signature

Provider Survey ID Number

Survey ID

Sentinel-Malawi Patients' Survey

Surveyor ID _____ Facility name _____

Date (DD/MM/YYYY) _____ Location within facility _____

Surveyor notes:

Introduction

Surveyor: Read the following statement. Please repeat the statement translated into the local language based on primary languages.

"Thank you for agreeing to participate in this survey. My name is _____. I will be asking you the questions. Most of the questions require that you select one of the options as your answer, although some questions you can select all the answers that apply. I will specify the options and instructions for you as I ask each question. If your answer is not one of the specified options please tell me and I will write your answer down. Please feel free to tell me whatever you are comfortable sharing. You should also remember that you do not have to share anything that you are not comfortable sharing and that you can stop this interview at any time without any risk to your rights or treatment and care. There are no right or wrong answers, so please be honest and help us to understand what is true for you and your community. Are you ready to begin?

Part 1.

Surveyor: "I'm going to start by asking you some basic questions about who you are, where you live, and your education and employment."

Q#	QUESTION	RESPONSES
Respondent demographics and socio-economic status		
1.	Patient study ID	
2.	Patient ART number	
3.	What is your gender?	0= Male 1= Female 2= Other
4.	What is your nationality/country of origin?	1= Malawi 2= Botswana 3= Lesotho 4= Mozambique 5= South Africa 6= Namibia 7= Swaziland 8= Zambia 9= Zimbabwe 10=Tanzania 11=Burundi 12= Other African country (specify) 13= Other (specify)
5.	If you are not Malawian, how long have you lived in Malawi?	1= < 1 yr 2= 1-2 years 3= 2-5 years 4= >5 years 5= Seasonal work
6.	How old were you at your last birthday?	Age (years)

Q#	QUESTION	RESPONSES
		Don't know
7.	What is your marital status?	1= Never married 2= Married (customary/traditional or legal/civil) 3= Divorced 4= Separated 5= Widowed
8.	Is there someone who you have a relationship with and who you call your partner?	1= No 2= Yes
9.	Do you currently live with your husband/wife or your partner?	1= No 2= Yes, married or living together
10.	Do you think of the house you currently live in as your main house?	1= Yes 2= No, my main house is somewhere else in Malawi 3= No, my main house is in another country
11.	Do you know how to read and write?	1= No 2= Yes – read and write 3= Yes – read only
12.	What was the highest level of school that you completed?	1 = No schooling 2= Primary 3= Secondary 4= Certificate/Diploma/ Post-secondary 5= Graduate degree
13.	What is your occupation?	1= Farming (my own or my family's farm) 2= Farm worker (someone else's farm) 3= Domestic worker or carer (paid) 4= Informal sector job (not farming or domestic) (e.g. trader, day service provider) 5= Formal sector job (salaried) 6= Household work and/or childcare (my own house, not paid) 7= Unemployed but looking for work 8= Student or trainee 9= Retired 10= Other (specify)
14.	Do you have any living children?	0= No 1= Yes
15.	How many living children do you have?	Specify number
16.	How many adults age 15 or older are living in your household, including yourself? By "living in," I mean they spend most nights of the week sleeping in your household.	Specify number
17.	How many children age 14 or younger are living in your household, including yourself? By "living in," I mean they spend most nights of the week sleeping in your household.	Specify number
18.	Do you have electricity in your house?	0= No 1= Yes
19.	Do you have access to piped water?	0= No 1= Yes – to house 2= Yes – community tap/pipe
20.	Do you or the people in your household go without food often, sometimes, seldom, never?	1= Never 2= Seldom 3= Sometimes 4= Often

Q#	QUESTION	RESPONSES
21.	Do you or does anybody in your household, currently receive any support from National Social Support Programme (MNSSP II)? Tick all that apply)	0= No 1= Child grant 2= Partial disability / illness grant / temporary grant 3= Pension grant 4= Disability grant 5= Other (specify)
22.	If a person in your household became ill and 2000 Kwacha was needed for treatment or medicines, would you say it would be very easy, easy, difficult, or very difficult to find the money?	1= Very difficult 2= Difficult 3= Easy 4= Very easy
23.	**Healthcare access and cost**	
24.	How long have you been coming to this facility for any kind of HIV treatment?	Months/years
25.	How long have been taking ART?	Months/years
26.	Which diseases are you currently being treated for at this facility in addition to HIV? (Tick all that apply)	0= No other diseases 1= TB 2= Diabetes 3= Hypertension 4= Asthma 5= Mental health 6= Malaria 7= Other (specify)
27.	What is the main reason for you coming to this facility today?	1= Scheduled HIV treatment visit 2= Unscheduled HIV treatment visit 3= HIV medication refill only 4= Other (specify)
28.	In the past 12 months have you sought health care from any other health care provider outside this facility? (Tick all that apply)	0= No 1= Hospital 2= Private doctor 3= Traditional healer 4= Community health worker 5= Local NGO/FBO 6= Other (specify)
29.	How do you usually get to the clinic? (Tick all that apply)	1= Walk 2= Mini-bus/common taxi 3= Motor bike taxi 4= Hired taxi 5= Brought by family/friends in their vehicles 6= Other (specify)
30.	How long does it take you to get to the clinic? (One way – from home to the clinic)	Hours/minutes one way
31.	What expenses/costs do you incur for each clinic visit? (Tick all that apply)	0= No costs 1= Transport 2= Loss of income due to missing work 3= Child care 4= Food/drinks 5= Other (specify)
32.	If you pay for transport, please estimate how much does public transport cost you in Kwacha each time you visit the clinic (Return trip – to the clinic and back home)	Amount in Kwacha
33.	Please estimate how much does unpaid time off work cost you in Kwacha each time you visit the clinic	Amount in Kwacha
34.	Have there been occasions where you missed your facility visits in the past year by more than 2-3 days?	0= No 1= Yes

Q#	QUESTION	RESPONSES
35.	If so, why did you miss the visit?	1= Forgot pick up date 2= Ill health 3= Nobody else to go for me 4= Buddy forgot 5= Buddy unwell 6= No money for transport 7= Could not leave work 8= Afraid HIV status will get known 9= Other (specify)
36.	**Questions for patients in standard care**	
37.	For your HIV treatment, how many visits to this clinic where you both see a nurse and collect your medication do you attend per year?	Number
38.	For your HIV treatment, how many visits to this clinic where you do not see a nurse but do collect your medication do you attend per year?	Number
39.	How long does it take total, on average for each HIV clinic visit where you see a nurse and pick up medications (counting from when you arrive at the clinic to when you leave)?	Hours and minutes
40.	How long does it take total, on average for each ART medication pick-up (visits where you only pick up medications, do not see a nurse)?	Hours and minutes
41.	How would you rate your overall satisfaction with the care that you receive at this facility?	1= Extremely dissatisfied 2= A little dissatisfied 3= Neither satisfied nor dissatisfied 4= Satisfied 5= Very satisfied
42.	Please explain your satisfaction rating above	Open ended
43.	Please state how much you agree or disagree with the following statements	These are all Likert scales 1-5 (strongly disagree, mildly disagree, neither agree or nor disagree, mildly agree, strongly agree, no response/don't know)
a.	I receive enough information about HIV and ART	
b.	Nurses and other clinicians at this facility spend enough time with me	
c.	When I arrive, the clinic can find my file promptly	
d.	My laboratory test results are available when I come back for them	
e.	People at this clinic are always nice and friendly	
f.	I trust the healthcare providers I see at this clinic	
g.	I would like to come to this clinic more often than my current appointments	
44.	How could HIV services in this facility be improved? (select all that apply)	☐ More staff ☐ More information provided by staff ☐ Better, more polite, or friendlier staff attitude/manner ☐ Better location ☐ Open different days ☐ Open different times of day ☐ Open outside of work hours ☐ Shorter waiting time ☐ More counselling when there are problems ☐ More counselling overall ☐ Less counselling

Q#	QUESTION	RESPONSES
		☐ Being able to pick up ARVs at different and more convenient sites ☐ Being able to have someone else pick up your ARVs ☐ Having somebody to support you take your ARVs ☐ Tracing when missed an appointment ☐ Reminders via phone ☐ More months of ARVS given at each visit ☐ Fewer months of ARVS given at each visit ☐ Better access to a nurse or clinic staff ☐ Treatment/support for other illnesses(specify) ☐ Other (specify and elaborate)
Questions for patients in DSD models		
45.	When were you first enrolled in Model X?	Month/year
46.	Did you ask to be enrolled in Model X?	Yes/no
47.	Did you have to provide consent to be enrolled in Model X?	0= No 1= Yes – written consent 2= Yes – verbal consent 99= Not sure/don't know/can't remember
48.	Were you given a choice about joining Model X?	0= No 1= Yes 99= Not sure/don't know/can't remember
49.	Were you happy to be enrolled in a DSD model?	0= No 1= Somewhat 2= Yes 3 = Neither happy nor unhappy (did not care)
50.	How would you rate your overall satisfaction with your ART care <u>before</u> you started Model X?	1= Extremely dissatisfied 2= Not satisfied 3= Neither satisfied nor dissatisfied 4= Satisfied 5= Very satisfied
51.	How would you rate your overall satisfaction with your ART care now that you are in Model X?	1= Extremely dissatisfied 2= Not satisfied 3= Neither satisfied nor dissatisfied 4= Satisfied 5= Very satisfied
52.	Please explain your satisfaction rating for Model X	Open ended
53.	Please state how much you agree or disagree with the following statements pertaining to Model X	These are all Likert scales 1-5 (strongly disagree, mildly disagree, neither agree or nor disagree, mildly agree, strongly agree, no response/don't know)
a.	I receive enough information about HIV and ART	
b.	Nurses and other clinicians at this facility spend enough time with me even though I'm in another model	
c.	When I arrive, the clinic can find my file promptly	
d.	My laboratory test results are available when I come back for them	
e.	People at this clinic are always nice and friendly	
f.	I trust the healthcare providers I see at this clinic	
g.	People who manage my model of care are always nice and friendly	
h.	I trust the healthcare providers who manage my model of care	

Q#	QUESTION	RESPONSES
i.	I would like to come to this clinic more often than my model of care allows	
54.	For your HIV treatment, how many visits to this clinic where you both see a nurse and collect your medication do you attend per year?	Number/year
55.	For your HIV treatment, how many visits to this clinic where you do not see a nurse but do collect your medication do you attend per year?	Number/year
56.	How many out-of-facility HIV events do you attend per year? By "event" we mean anything involving your treatment that is not at this facility, including club meetings, picking up medications outside the clinic, etc.	Number/year
57.	If you have a question about your HIV treatment, what would you most likely do?	1= Make a special visit to this clinic 2= Wait and ask during a regular visit to this clinic 3= Wait and ask during a regular out-of-facility HIV event 4= Other (specify)
58.	How do you usually get to the out-of-facility Model X events (Tick all that apply)	1= Walk 2= Mini-bus/common taxi 3= Motor bike taxi 4= Hired taxi 5= Brought by family/friends in their vehicles 6= Other (specify)
59.	How long does it take you to travel to the out-of-facility Model X events? (One way – from home to the clinic)	Hours and minutes (one way)
60.	What expenses/costs do you incur for each out-of-facility Model X event? (Tick all that apply)	0= No costs 1= Transport 2= Lost income due to missed work 3= Child care 4=Food/drinks 5= Other (specify)
61.	If you pay for transport, please estimate how much does transport cost you in Kwacha each time you make an out-of-facility Model X visit. (Return trip – to the clinic and back home)	Amount in Kwacha
62.	Please estimate how much income (wages or salary) you lose in Kwacha each time you attend a Model X event.	Amount in Kwacha
63.	How long does it take total, on average for each out-of-facility Model X event	Hours and minutes, including travel time and time at event
64.	How would you rate your overall satisfaction with your out-of-facility Model X events?	1= Extremely dissatisfied 2= Not satisfied 3= Neither satisfied nor dissatisfied 4= Satisfied 5= Very satisfied
65.	Have you been referred back to regular (standard of care) HIV services by the Model X staff for any reason? (Tick all that apply)	0= No 1= Ill health 2= Missed a visit 3= Missed ARV doses 4= Blood draw 5= Screened positive for TB 6= Diabetes complication 7= Hypertension complication 8= Don't know why

Q#		QUESTION	RESPONSES
66.		Have there been occasions in the past year where you missed your out-of-facility Model X event by more than 2-3 days?	0= No 1= Yes
67.		If so, why did you miss the visit?	1= Forgot pick up date 2= Ill health 3= Nobody else to go for me 4= Buddy forgot 5= Buddy unwell 6= No money for transport 7= Could not leave work 8= Afraid HIV status will get known 9= Other (specify)
68.		Please state how much you agree or disagree with the following statements	These are all Likert scales 1-5 (strongly disagree, mildly disagree, neither agree or nor disagree, mildly agree, strongly agree, no response/don't know)
	a.	I am concerned about transport cost to get to the clinic	
	b.	I am concerned about transport cost to get to my model events (e.g. club meetings, medication pickups)	
	c.	I cannot take time off work to get to the appointments	
	d.	I am unsure about how the DSD model works	
	e.	I don't receive enough information about HIV and ART	
	f.	I have to wait for a long time to receive care	
	g.	I am concerned about safely carrying and storing ARVs at home	
	h.	I am concerned about other people finding out that I am HIV positive	
	i.	I am concerned about having to interact with other patients in my treatment model	
	j.	I am concerned about the quality of care in my treatment model	
	k.	I have other concerns about my HIV treatment or model of treatment delivery (specify)	
	l.	I have no concerns about my HIV treatment or model of service delivery	
	m.	I have trouble taking time off work to get to clinic visits	
	n.	I have trouble taking time off work to get to model events	
	o.	I prefer to come to the clinic as few times per year as possible	
	p.	I'd like to come to the clinic regularly, at least once every 3 months	
	q.	I like being able to connect with other HIV-positive patients at the clinic	
	r.	I like being able to connect with other HIV-positive patients in my model of care	
69.		Would you recommend Model X to another patient who is on ART treatment?	0=No 1=Yes
70.		Why or why not?	Open ended
71.		How could services on this Model X model be improved? (select all that apply)	☐ More staff ☐ More information provided by staff ☐ Better, more polite friendlier, staff attitude

Q#	QUESTION	RESPONSES
		☐ Better location for model events ☐ Events on different days ☐ Events at different times of day ☐ Events outside of work hours ☐ Shorter waiting time ☐ More counselling when there are problems ☐ More counselling overall ☐ Less counselling ☐ Being able to pick up ARVs at different and more convenient sites ☐ Being able to have someone else pick up your ARVs ☐ Having somebody to support you take your ARVs ☐ Contacting you when you miss an appointment ☐ Reminders via phone or SMS ☐ More months of ARVs given at each visit ☐ Fewer months of ARVs given at each visit ☐ Better access to a nurse or clinic staff ☐ Treatment/support for other illnesses (specify) ☐ Other (specify and elaborate)
72.	In conclusion, what is the best thing for you about Model X?	Open ended
73.	And what is the worst thing for you about Model X?	Open ended

Surveyor: Please thank the participant for their time and ask if they have any additional questions about the study.

Was payment provided to the participant, per protocol?

YES _____ | Payment confirmation number

NO _____

If NO, why not? |

Surveyor initials _____

Supervisor initials _____

Date reviewed by supervisor _____

Screening number

Sentinel-Malawi Patients' Survey Eligibility Screening Form

Surveyor ID _____Facility Name _____

Date (DD/MM/YYYY) _____

I. Introduction

Ask the patient for a few minutes of their time. Introduce yourself and the study. Provide information on the study as per the training and give the patient the information sheet for the study. If the patient expresses interest in being in the study, proceed to section II below and then complete the eligiblity screening in section III. If the participant is not interested in being in the study, thank them for their time, end the interaction, and answer the questions in section II below.

II. Demographic description

1. Sex Male____ Female ____ Other/unknown ____

2. Approximate age <30____ 30-50 ____ >50 ____

III. Eligibility screening

3. Are you currently enrolled in HIV care at this facility?

   YES _____ (Proceed with next question)

   NO _____ (STOP! Thank the participant for their time but do not proceed with the survey)

4. Are you currently age 16 or older?

   YES _____ (Proceed with next question)

   NO _____ (STOP! Thank the participant for their time but do not proceed with the survey)

5. Have you been taking ART for at least 6 months?

   YES _____ (Proceed with next question)

   NO _____ (STOP! Thank the participant for their time but do not proceed with the survey)

6. Which HIV care model are you currently enrolled in? (Multiple responses possible for integrated models) (*Note: this question provides the basis for question 5.*)

   - ☐ Standard or conventional care, not in an alternative model
   - ☐ 6MMD
   - ☐ 3MMD
   - ☐ Adherence club
   - ☐ Teen club
   - ☐ Community adherence groups (CAG)

- ☐ Community outreach
- ☐ Teen club
- ☐ Intensified care ART clinic (ICAC)
- ☐ Fast track
- ☐ Late shift
- ☐ Nurse led community ART (NCAP) register
- ☐ High viral load clinic
- ☐ Mother infant pair
- ☐ Advanced HIV disease
- ☐ Other (specify)

7. Have you had at least one medication collection visit under the model of care you said you are enrolled in?

YES _____ (Proceed with next question)

NO _____ (STOP! Thank the participant for their time but do not proceed with the survey)

IV. Eligibility decision

If all answers to the screening questions 1-3 and 5 above are "YES", proceed to administer the informed consent process. If any answers were "NO", thank the patient for their time and end the interaction.

This patient was

ELIGIBLE _____ (Proceed with consent process)

NOT ELIGIBLE _____(Thank the participant for their time but do not proceed with the survey)

This patient

CONSENTED TO PARTICIPATE____ (Fill in survey instrument ID number below and proceed with survey)

DID NOT CONSENT TO PARTICIPATE ____ (Thank the participant for their time and end the interaction)

For patients eligible for and consenting to the study, please indicate study survey ID number here:

SURVEY INSTRUMENT ID NUMBER

RESEARCH INFORMATION FORM FOR PATIENT SURVEY

Title of Project: Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)

Principal Investigators: Sydney Rosen, Andrews Gunda, Sophie Pascoe

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Study Number:

Study Title:	**Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)**
Sponsor:	Bill & Melinda Gates Foundation
Investigators:	Prof Sydney Rosen (Boston University); Mr. Andrews Gunda (Malawi); Dr. Sophie Pascoe (South Africa)

Good day. My name is _____, and I am a Research Assistant at CHAI-Malawi. I would like to invite you to consider participating in a research study entitled "Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)."

What is this research study about?

CHAI-Malawi, Boston University in the United States, and Wits University in South Africa are conducting a research study about different ways that clinics are delivering treatment for HIV in Malawi and how these different ways of delivering treatment, which are called "models of care", affect both the clinics and their staff and the patients who are receiving treatment.

From patients like you, we would like to find out whether the model of care you are participating in has changed your access to treatment, the costs you incur for seeking treatment, and your satisfaction with the services you are receiving. We are inviting adult patients in this clinic who are receiving HIV treatment (antiretroviral therapy, or ART) in any of the models of care offered by this clinic to participate in the study. If you choose to participate, you will be asked to answer a set of questions today, and we will also look at your clinic records.

This study is being conducted by Professor Sydney Rosen from Boston University in the U.S., Mr. Andrews Gunda from CHAI-Malawi, and Dr. Sophie Pascoe from Wits University in South Africa. Other investigators involved in the study are Mr. Clement Banda and Mr. Timo Tchereni from CHAI-Malawi and Ms. Idah Mokhele from Wits University. This study is being sponsored by the Bill & Melinda Gates Foundation in the United States.

I would like to provide you with some more information about the study, so that you can decide whether you would like to take part in it. Taking part in this study is voluntary. You can choose not to take part, and if you join, you may quit at any time. If you decide not to participate, you will receive the same care from this clinic that you would have received otherwise. This information sheet may have some words that you do not understand. Please ask the study staff to explain any words or information that you do not understand.

What is the purpose of this research study?

In many countries, including Malawi, Ministries of Health and healthcare providers are trying to find easier ways to provide ART to the many thousands of patients who need it. This effort has led to the development of what are called "differentiated service delivery" models (DSD models), which adjust

the timing, location, and other aspects of ART for different kinds of patients. The goal of DSD models is to make treatment more accessible to patients so that they can more easily adhere to treatment and be more satisfied with the services they received and to reduce the burden of the national ART program on clinics and healthcare workers.

In Malawi, the Ministry of Health has rolled out three main models of care, known as multi-month dispensing, teen clubs, and community outreach. Some individual clinics and partner organizations have created other models as well. Now that clinics and patients have some experience with these different models, it is important to find out how many patients are participating in each model, how well the models are performing, how much they cost both the clinics and patients, and whether patients and healthcare providers are satisfied with them. This study is being conducted in collaboration with the Ministry of Health to try to find answers to these questions, so that models can be improved in the future.

What happens in this research study?

This study is taking place in 12 clinics in Malawi. You will be one of approximately 600 patients to be asked to participate in this study. Patients in this study must be at least 16 years old and receiving ART in any of the models of care offered by your clinic, including conventional care. If you participate in the study, it will take about 60 minutes of your time today.

If you agree to participate in this study, I will ask you a set of question about you, your household, your health, and your experience of being treated at this clinic and the model of care you are participating in, and your satisfaction with the services at this clinic. The questions will take about 30-45 minutes to complete and will be conducted in Chichewa or English.

We will also link your answers to the questions today to your clinic medical records. The reason that we need to do this is so we can see whether patients with different characteristics and experiences and in different models of care have different outcomes in their medical records. To make this link, we will ask you your name and information needed to find your individual medical record. After we link your clinic records to the question responses, all links between your answers and your clinic records will be made anonymous—they will not include your name or any other identifiers. We would like to ask your permission to link the answers you give today with your clinic medical records starting when you initiated ART and continuing for the next twenty-four (24) months, including if you transfer to another clinic.

Any reports that are written using information from this study will combine information for many patients and it will not be possible to identify any individual patient from the information that is presented. If you do not wish to give us permission to link your answers with your clinic records, unfortunately you will not be able to participate in this study, but this will in no way influence the health care, treatment or services that you receive at this clinic.

Are there risks or discomforts from participating?

- This study will not affect the care and treatment you will receive. The main risk to participating in this study is the small risk of loss of confidentiality, i.e., that your name and questionnaire results may become known. The study team will take every measure to ensure that this does not happen, however, and to keep your answers confidential and will not tell or show anyone what you have said. Your name and other identifying information will be used only to locate your clinic records, and not for any other purpose.

- The other risk of this study is that some of the questions you are asked may make you feel uncomfortable or emotionally distressed. The study staff and clinic staff will make every effort to reduce your distress. You do not have to respond to any question unless you feel comfortable doing so. We can stop at any time if you prefer not to finish the questionnaire. We can also arrange for you to spend time in a private room or space if you feel that you need to time to recover from your distress. Please inform any member of the staff if you feel that you do not want to remain in the clinic to participate in the study or would like to speak individually with someone on the study or clinic staff.

Are there potential benefits from participating?

You will receive no direct benefit from taking part in this study. However, the information that you provide may help us to understand ways to improve healthcare services in Malawi and how to appropriately support patients who are taking long-term treatment.

What other choices do I have?

Your alternative is not to participate in this study.

Are there any costs or payments to me?

There are no costs to you for participating in this study. ART is free at this clinic. If you consent to participate in this study and complete study procedures, you will receive compensation equivalent to USD 10 to thank you for your time and any inconvenience of being in the study, including travel and refreshments.

How will my information be protected?

The information that we collect from this research project will be kept private. Once you agree to join the study, we will assign you a study number in order to protect your privacy. Your real name will not be used in any report coming from this study. All consent forms, questionnaires, and notes from the study will be stored in a locked unit, and only study staff and designated officials will have access to them. We will not report whether you have participated in the study to any community members or health facilities or health care staff. However, complete confidentiality cannot be guaranteed.

Also, upon signing this consent you give designated officials from the Institutional Review Boards at the Malawi National Health Sciences Research Committee, the University of the Witwatersrand, Boston University, and the Office of Human Subject Protection in the U.S. Department of Health and Human Services consent to look at your study records. They are ensuring that everything happening in this study is ethical. They would only review the study records to ensure that your privacy and integrity is being maintained and protected. A description of this study will be available on http://www.ClinicalTrials.gov. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

In addition, the final data set containing your responses may be posted in a public data repository as a part of the research publication process. The posted data set will have all identifiers removed so that it is not possible to identify any individual respondent.

Participant's rights

Taking part in this study is voluntary. You have the right to refuse to take part. If you decide to be in the study and then change your mind, you can withdraw from the research. Your participation is completely up to you. If you choose to take part, you have the right to stop at any time without losing any of your rights as a patient here in any way. Your decision will not affect your being able to get health care at this clinic or any other health benefits to which you are entitled.

The researchers may decide to discontinue your participation without your permission because he/she may decide that staying in the study will be bad for you, or the sponsor may stop the study.

If you want any information regarding your rights as a research participant, or complaints regarding the research study, you may contact the National Health Science Research Committee, Ministry of Health P.O. Box 30377, Lilongwe 3, Malawi, Tel: +265994063425, Email: mohdoccentre@gmail.com.

RESEARCH CONSENT FORM FOR PATIENT SURVEY

Title of Project: Outcomes of Differentiated Models of Service Delivery for HIV Treatment at Sentinel Sites in Malawi (Sentinel-Malawi)

Principal Investigators: Sydney Rosen, Andrews Gunda, Sophie Pascoe

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INFORMED CONSENT SIGNATURE PAGE

Signing this consent form indicates that you have read the consent form information sheet (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this consent form to keep.

_____	_____	_____	_____
Participant (Signature or Thumbprint)	(Printed Name)	Date	Time

_____	_____	_____	_____
Person Obtaining Consent (Signature)	(Printed Name)	Date	Time

_____	_____	_____	_____
Witness* (Signature)	(Printed Name)	Date	Time

*Witness signature required if patient provides mark or thumbprint rather than signature

Participant Survey ID Number