BMJ Open

Combination adherence strategy to support HIV antiretroviral therapy and pre-exposure prophylaxis adherence during pregnancy and breastfeeding: protocol for a pair of pilot randomised trials

Friday Saidi ,[1] Wilbroad Mutale ,[2] Kellie Freeborn,[3] Nora E Rosenberg,[4] Lauren Aiko Graybill,[5] Suzanne Maman,[4] K. Rivet Amico,[6] Katie R Mollan,[5,7] Twambilile Phanga,[1] Beteniko Milala,[1] Lauren M Hill,[4] Allison M Gottwalt,[3] Sam Phiri,[8,9,10,11] Thoko Kalua,[12,13] Benjamin H Chi [3]

To cite: Saidi F, Mutale W, Freeborn K, *et al*. Combination adherence strategy to support HIV antiretroviral therapy and pre-exposure prophylaxis adherence during pregnancy and breastfeeding: protocol for a pair of pilot randomised trials. *BMJ Open* 2021;**11**:e046032. doi:10.1136/bmjopen-2020-046032

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-046032).

Received 19 October 2020
Accepted 11 June 2021

For numbered affiliations see end of article.

Correspondence to
Dr Friday Saidi;
fsaidi@unclilongwe.org

ABSTRACT

Introduction To realise the expected gains from prevention of mother-to-child HIV transmission initiatives, adherence to preventative and therapeutic antiretroviral regimens is critical and interventions deployable in busy programmatic settings with a high HIV burden are needed. Based on formative research, we developed an approach that integrates patient-centred counselling and engagement of an adherence supporter for pregnant and breastfeeding women initiating HIV treatment (ie, antiretroviral therapy (ART)) or biomedical HIV prevention (ie, pre-exposure prophylaxis (PrEP)).

Methods Tonse Pamodzi 2 is a pilot study designed to provide acceptability, fidelity and clinical outcomes data on a set of behavioural interventions for adherence support. The study comprises two parallel randomised trials, enrolling HIV-positive pregnant women initiating ART (Trial 1, n=100) and HIV-negative pregnant women with risk of HIV acquisition and willing to initiate PrEP (Trial 2, n=200). Within each trial, participants are randomised 1:1 to either the intervention or control group. The Tonse Pamodzi adherence intervention comprises patient-centred counselling (adapted Integrated Next Step Counseling(iNSC)) and external adherence support tailored to the clinical context (ie, for ART or PrEP). Participants randomly assigned to the control group receive standard counselling based on local HIV guidelines. Participants are followed for 6 months. To assess intervention acceptability, we will employ a mixed method approach to describe participant engagement, satisfaction, and discussion content. We will audit and score recorded counselling sessions to evaluate the implementation fidelity of iNSC sessions. We will also assess clinical outcomes at 3 and 6 months for both Trial 1 (retention in care and viral suppression of HIV) and Trial 2 (retention in care, and plasma and intracellular tenofovir drug concentrations).

Ethics and dissemination The study protocol was approved by the Malawi National Health Science Research Committee (19/05/2334) and the University of North Carolina at Chapel Hill Institutional Review Board (19-1060).

Trial registration number NCT04330989.

Strengths and limitations of this study

- We designed a status-neutral adherence intervention for pregnant and breastfeeding women that can be tailored to support adherence to either antiretroviral therapy for HIV-positive women or HIV pre-exposure prophylaxis for HIV-negative women at elevated risk of acquiring HIV.
- Our study is designed to evaluate the intervention's acceptability, fidelity and associated clinical outcomes.
- Study limitations include a relatively short follow-up period (ie, 6 months) and a targeted patient population; however, these features are consistent with other feasibility studies.
- Results from these pilot trials will inform the design of a larger study to assess the efficacy of the Tonse Pamodzi adherence intervention.

INTRODUCTION

Over the past two decades, services for prevention of mother-to-child transmission (PMTCT) of HIV have expanded rapidly in sub-Saharan Africa, resulting in dramatic reductions in paediatric HIV.[1–3] The progression of scientific, programmatic and policy advances have led to calls to eliminate mother-to-child transmission of HIV (EMTCT).[4–6] To achieve these ambitious benchmarks, 'status-neutral' approaches that offer universal services regardless of maternal HIV status are urgently needed.[7] Such an approach can

increase acceptability and reduce the stigma associated with HIV treatment and prevention services for pregnant and breastfeeding women.

In most African settings, PMTCT programmes have focused on the diagnosis, treatment, and retention of HIV-positive women within antenatal settings. The WHO and country-level policies support the provision of lifelong antiretroviral therapy (ART) for all HIV-positive pregnant and breastfeeding women (ie, the Option B+ strategy), which may reduce HIV transmission rates to less than 2%.[8–11] Nevertheless, challenges remain. ART uptake among pregnant and breastfeeding women is not universal and nearly 20% of women drop out of care in the first 6 months on treatment.[9–14] Further, poor adherence to ART can lead to antiretroviral drug resistance, treatment failure, and horizontal and vertical transmission.[15–18]

Incident maternal HIV infections—acquired during pregnancy and breast feeding—further contribute to the paediatric HIV burden,[18] with up to 45% of new paediatric HIV cases attributable to new maternal HIV infection during pregnancy and breastfeeding in countries like Malawi.[19] In 2018, the Joint United Nations Programme on HIV/AIDS estimated as many as 130 000 women acquired HIV during pregnancy and breastfeeding,[1] consistent with the high HIV incidence observed in clinical studies.[20 21] For most pregnant women who initially test HIV negative, few HIV prevention services are available, presenting a missed opportunity as these women are already engaged in care. Oral pre-exposure prophylaxis (PrEP) is recommended by the WHO to reduce horizontal HIV transmission and is considered safe and effective during pregnancy.[22–24] Although the acceptability and feasibility of PrEP in antenatal/postnatal settings are encouraging,[25–27] challenges to sustain uptake and adherence persist due to low risk of perception, perceived stigma and concerns about medication side effects.[28]

To reach the ambitious goals of EMTCT, effective and yet scalable approaches are needed to enhance current HIV services, including combination strategies that integrate proven biomedical and behavioural interventions. Given the critical role of medication adherence for both HIV treatment (ie, ART) and prevention (ie, PrEP), approaches that are adaptable and capable of being tailored to support antiretroviral use regardless of the context in which they are prescribed—treatment or prevention—may offer particular benefits in busy clinical settings. Such status-neutral interventions could broaden HIV services in maternal and child health settings. We developed an intervention combining patient-centred counselling (Integrated Next Step Counseling (iNSC)) and the inclusion of a participant-identified adherence supporter to enhance antiretroviral drug use during pregnancy and breastfeeding. In this protocol paper, we describe a pilot study to obtain data about the intervention's acceptability, fidelity and clinical outcomes.

METHODS AND ANALYSIS

Study overview

Tonse Pamodzi 2 (TP2) is a pair of pilot studies designed to evaluate an adherence support intervention for ART and PrEP. The term *tonse pamodzi* means 'all of us together' in Chichewa and Nyanja, signifying the importance of integrated facility-based and community-based adherence support. TP2 comprises two parallel randomised trials, evaluating an adapted integrated adherence support strategy for a different antenatal population. Trial 1 is enrolling HIV-positive pregnant women who have initiated ART; Trial 2 is enrolling HIV-negative pregnant women who meet local eligibility criteria to start PrEP (figure 1). The study enrolment began in March 2020 for Trial 1 and in June 2020 for Trial 2. The protocol is

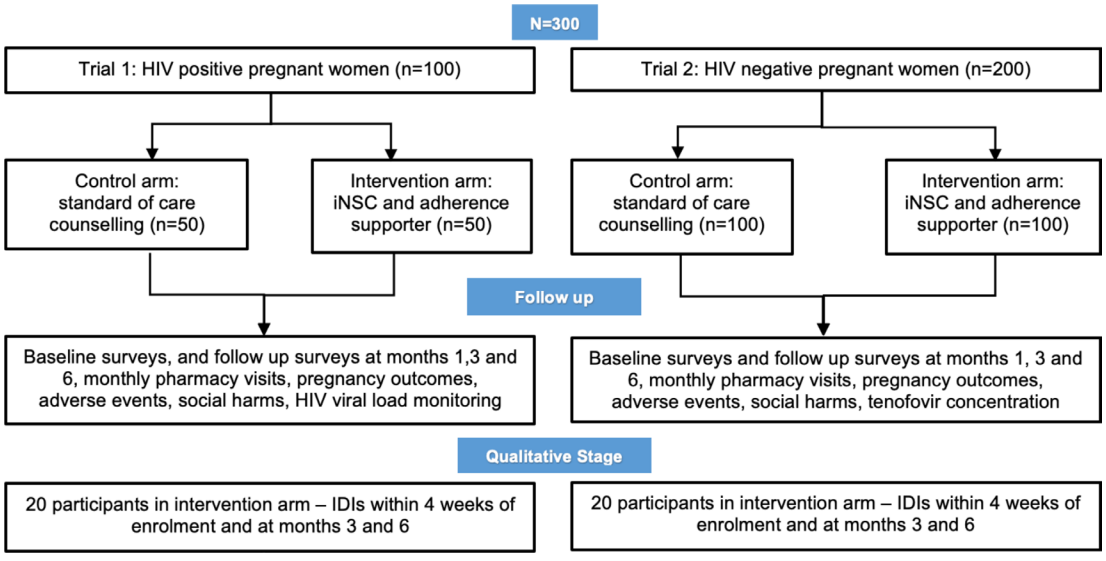


Figure 1 Consolidated Standards of Reporting Trials flow diagram. IDI, in-depth interviews; iNSC, Integrated Next Step Counseling.

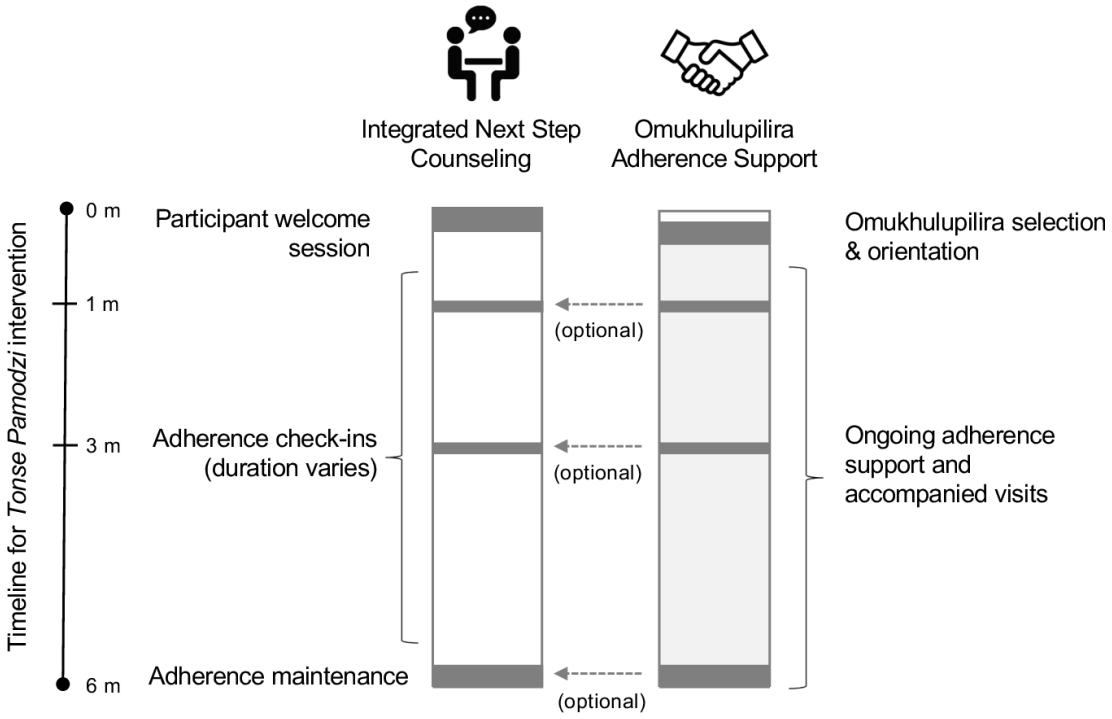


Figure 2 Overview of the Tonse Pamodzi 2 adherence intervention.

registered in ClinicalTrials.gov. Online supplemental appendix 1 gives as a summary of the trial registration details.

Study site

The Bwaila District Hospital is a district level public hospital serving approximately one million people in Lilongwe and surrounding rural villages. It is the busiest maternity hospital in Malawi, with approximately 150 pregnant women attending antenatal care every day and over 1200 deliveries every month. Bwaila District Hospital has been providing PMTCT services since April 2002. Similar to many parts of Lilongwe, the antenatal HIV prevalence is estimated as 12%.[29]

Adherence support: intervention group

The TP adherence intervention was developed following intensive formative research—including systematic reviews;[21 30] qualitative interviews with patients, healthcare workers and policymakers;[26 31] and mathematical modeling[32]—and expert consultation. It comprises two parts: an adaptation of iNSC and the optional inclusion of an adherence supporter who is from the patient's social network. Figure 2 provides an overview of the intervention session activities; a detailed description is included in online supplemental appendices 2 and 3.

A core component of our adherence support intervention is iNSC, a patient-centred counselling approach that adopts a systematic process or flow of conversation to promote patient engagement and autonomy as counsellors guide the conversation towards the identification of needs related to health and well-being, sexual health protection, and/or adherence (table 1).

iNSC has been used in several studies and programmes to support adherence for PrEP in different populations, but has never been tested among pregnant women.[24 33 34] The goal of iNSC is to foster a collaborative problem-solving environment that allows the participant to identify their individual needs to create, enhance or sustain overall well-being, sexual health through non-biomedical approaches, and adherence to antiretroviral drugs. iNSC frames the counselling sessions as a non-judgmental discussion to explore one's current experiences; one's vision for an alternative experience that would make health promotion easier/easiest to manage; and the facilitators, challenges and needs for progressing towards that improved situation. Although the content of these discussions is entirely tailored to the specific participants' situation, clinical context and priorities, the process of the conversation is identical across participants. Participants in the intervention arm receive iNSC at study enrolment and their visit at months 1, 3 and 6.

All individuals receiving the intervention are also invited to identify an adherence supporter or Omukhulupilira ('close confidant' in Chichewa and Nyanja) from their own social network. As part of the approach, this individual is trained to support the participant's use of ART or PrEP and may accompany the participant to study visits. The Omukhulupilira may be a partner, family member or friend chosen by the participant who can provide emotional, instrumental and informational social support. Selecting an Omukhulupilira is recommended, but not mandatory. Once nominated, an Omukhulupilira receives a brief in-person orientation training on how to provide positive support to the participant. This includes

Table 1 Steps and content for Integrated Next Step Counseling

Step	Content
Introduce	Explain what you want to discuss, why and ask permission
Frame discussion	Frame discussion to two components, first about general well-being and then about adherence. Steps below will be repeated for each component.
Review	Check in on previous goals/discussions, close and move into current experiences (follow-up visits only)
Explore	Discuss socioecological factors that challenge or could optimise a specific behaviour
Tailor	Reflect on context and experiences shared to tailor remainder of the discussion
Identify	Ask what would be needed to happen for the situation (identified above) to be slightly better, easier to handle or be more manageable
Strategise*	Ask how the participant might consider addressing this need
Agree*	Ask the participant if she would agree to try out one or more strategies to address the identified need
Transition/close*	Move to a new topic and repeat the flow or close the discussion

*These steps may be repeated in a joint discussion with the adherence supporter (ie, Omukhulupilira), if he/she is present and the participant agrees.

basic HIV knowledge, the importance of antiretroviral adherence, potential drug side effects, and practical strategies for supporting adherence. This intervention component is based on the premise that social support provides access to essential information and resources to encourage specific health behaviours.[35]

Adherence support: current standard of care

Participants randomly assigned to the control group receive standard counselling in PMTCT, safe obstetrics and newborn care, based on the Malawi Ministry of Health guidelines.[36] In addition, all participants receive education regarding HIV/AIDS—including HIV treatment and prevention—when they initiate either ART or PrEP. The content of this education comprises the basics of HIV transmission and prevention, stages of HIV infection, the role of ART or PrEP for PMTCT and their mechanisms of action, dosing and adherence guidance, and drug safety and side effects.

Recruitment and retention procedures

Participants are recruited from the antenatal clinic at Bwaila District Hospital in Lilongwe, Malawi. Study staff provide educational talks about the study in the antenatal waiting areas. Pregnant women interested in the study are booked for screening at the research clinic and undergo informed consent before study procedures begin. Once participants are enrolled in the trial, the study team uses a multipronged strategy—including telephone contact, community outreach and peer engagement—to retain those in both arms to minimise losses to follow-up. The study team closely monitors retention and addresses any issues prospectively.

Randomisation

Participants are randomised separately within each trial and the randomisation procedures are similar between the two parallel studies. Within each trial, participants are randomly assigned 1:1 to either the intervention or control arm using a permuted block randomisation design.[37] The study statistician (KRM) independently generated the randomisation assignments using SAS V.9.4 software. Opaque, sealed randomisation envelopes for Trial 1 and Trial 2 were numbered in advance of enrolment by an independent data staff member and stored in sequential order in separate boxes. Team members preparing these envelopes are not involved in ascertaining eligibility or assessing outcomes. Once eligibility is confirmed and the participant provides informed consent (online supplemental appendix 4), the research nurse obtains the next sequential envelope from the box for the randomisation assignment, enters the randomisation identification number on the envelope into the participant's linkages form and then opens the envelope to determine randomisation assignment. Due to the nature of the intervention and data collection instruments, it is not possible to blind clinic staff, study statisticians or participants on the assigned randomisation arm. However, the laboratory technicians responsible for measuring biological endpoints are blinded to the randomisation assignment.

Considerations for Trial 1 (ART adherence support)

Eligibility criteria for Trial 1: We are enrolling HIV-positive women 18 years of age or older with documented pregnancy by urine pregnancy test or physical examination. Other eligibility criteria include initiation on first-line ART within the past 30 days, for the first time or after treatment interruption of 6 months or longer (if previously started, but stopped ART). HIV-positive women initiating ART may be enrolled on the same day if they meet the eligibility criteria. The women should be willing to provide written informed consent, remain in the study site's catchment area throughout study follow-up, and comply with the visit schedule. Women with risk for intimate partner violence (IPV) or social harms resulting from participation as assessed by study personnel are excluded.

Table 2 Schedule of evaluations for Trial 1—ART adherence support for pregnant women living with HIV

	Clinic visits				Adherence assessment
	Enrolment	Month 1	Month 3	Month 6	Monthly
Laboratory studies					
HIV RNA (viral load)	X		X	X	
Haemoglobin	X				
Syphilis screening	X*				
Urine dipstick	X		X	X	
Medical examination					
Medical history	X				
Obstetric examination	X	X	X	X	
Questionnaires					
Social and demographic information	X				
Pregnancy history	X		X	X	
Sexual partners	X		X	X	
Social harms	X	X	X	X	X
Intimate partner violence	X		X	X	
Substance abuse	X			X	
HIV status disclosure	X	X	X	X	
COVID-19 questionnaire	X	X	X	X	X
LifeWindows—ART adherence[46]	X		X	X	
Multidimensional Scale of Perceived Social Support	X		X	X	
Pregnancy and delivery status		X	X	X	X
ART adherence questionnaire		X	X	X	X
Drug dispensation and adherence assessment					
Participant-specific dispensing record	X	X	X	X	
Intervention assessment (intervention arm only)					
Overall intervention acceptability		X	X	X	
Integrated Next Step Counseling acceptability		X	X	X	
Adherence supporter acceptability		X	X	X	
Qualitative interviews (subset)	X†		X†	X†	

*Will perform test if no results available in the medical record.
†Schedule additional procedures within 30 days of visit for subset of participants enrolled in this component.
ART, antiretroviral therapy.

Study activities for Trial 1: Visits occur at enrolment, and at months 1, 3 and 6 (table 2). The study procedures at these scheduled visits include collecting blood and urine specimens for the following laboratory tests: HIV RNA (viral load), haemoglobin, syphilis screening (if not available in the antenatal record) and urine dipstick (table 2). These specimens are collected for safety monitoring and outcome measurement. Urine dipstick is collected per local standard of care. HIV viral load is measured onsite using the HIV RNA PCR on M2000 platform (Abbott Laboratories, Lake Forest, Illinois, USA) at the University of North Carolina Project Malawi Central Laboratory (Lilongwe, Malawi). Most index pregnancies are expected to end prior to the participant's 6-month study visit, and we collect obstetric and neonatal information when the pregnancy outcome is available. In the event that the index pregnancy is ongoing at the participant's 6-month study visit, we schedule additional monthly follow-up visits until the participant can report an obstetrical outcome. ART regimens are prescribed according to local HIV guidelines:[36] tenofovir disoproxil fumarate (TDF) and lamivudine with either dolutegravir or efavirenz. The dispensation of ART is coordinated with the local PMTCT/ART programme at the study facility. We collect information about prescribed ART drugs, pharmacy dispensations and adherence evaluations at short visits every month, timed with routine clinic visits.

Considerations for Trial 2 (PreP adherence support)

Eligibility criteria for enrolment in Trial 2: In Trial 2, we enrol HIV-negative pregnant women 18 years of age or older willing to initiate and continue daily oral PrEP, coformulated as TDF and emtricitabine (TDF/FTC; 200/300 mg). To be eligible, candidates must report one or more of the following risk factors for HIV acquisition in the past 12 months: known positive or unknown partner HIV status, multiple sexual partners, diagnosis of a sexually transmitted infection, use of postexposure prophylaxis, use of shared injection material or equipment, or an unspecified concern about HIV acquisition. Other eligibility criteria include documented pregnancy by urine pregnancy test or physical examination, a documented negative HIV status within the past 3 months, plans to remain in the study site's catchment area throughout study follow-up, willingness to provide informed consent and comply with the visit schedule, and interest in initiating and continuing PrEP throughout study follow-up. We exclude women who test positive for hepatitis B surface antigen at the time of screening, have renal insufficiency (defined as creatinine clearance <90 mL/min), have a history of known renal parenchymal disease or have a known single kidney at the time of screening. Women with risk for IPV or social harms resulting from participation as assessed by study personnel, are excluded.

Activities for Trial 2: In Trial 2, participants undergo screening procedures to confirm their HIV and hepatitis B status, both of which must be negative before enrolment and randomisation. Study visits will occur at enrolment and at months 1, 3 and 6 (table 3). We use oral PrEP coformulated as TDF/FTC, to be dosed on a once-daily basis. The packaged product is dispensed for Trial 2 participants by onsite study staff. Participants begin daily administration of TDF/FTC on the day of randomisation and this will continue through month 6. PrEP is dispensed for 1–3 months at a time, depending on local control measures for COVID-19 (see COVID-19 considerations below). Study laboratory tests at baseline include rapid HIV antibody screening, alanine transaminase, creatinine, syphilis screening (if not available in the antenatal record) and urine dipstick. At follow-up visits, tests include HIV antibody screening, urine dipstick, creatinine, tenofovir (TFV) concentrations, and intracellular TFV-diphosphate (TFVdp) measurements. These specimens are collected both for routine safety monitoring for PrEP and as outcome measurements. As in Trial 1, if the index pregnancy is ongoing at the 6-month study visit, we will schedule monthly follow-up visits until the participant reports a pregnancy outcome. Specimens for TFV concentration and TFVdp measurements are stored at the local site laboratory and then shipped for processing at the University of North Carolina at Chapel Hill by the Clinical Pharmacology and Analytical Chemistry Core of the Center for AIDS Research.

For women who test HIV positive during the study, TDF/FTC will be discontinued while the diagnosis is confirmed. We will also collect a specimen for HIV RNA (ie, viral load) and storage for HIV resistance testing. If the HIV diagnosis is confirmed, the participant completes exit study procedures (ie, analogous to the 6-month visit) and receives a guided referral to the HIV care and treatment clinic at the study site.

Acceptability and fidelity endpoints

Mixed methods assessment of intervention acceptability: Among those randomised to the intervention group, we assess the acceptability of the integrated intervention and its component parts (ie, adherence supporter and iNSC) at each study visit. This includes questions about overall satisfaction and, if the intervention were to be made available again, likelihood of continued use. We inquire about aspects of the iNSC experience, including the discussion content, counsellor engagement and perceived effect on adherence behaviours. We also ask about whether they are working with an Omukhulupilira and, if so, his/her level of engagement in adherence support and perceived effect on adherence behaviours. Questions are structured with binary outcomes (eg, yes/no) or using a five-point Likert scale. To complement these quantitative assessments, individual semi-structured interviews (SSIs) are conducted to further explore participant experiences with the TP intervention. We are interested in individual-level engagement (including satisfaction with the different components), as well as barriers and facilitators to participation. With three interviews planned (ie, following enrolment, and at 3-month and 6-month visits), our approach provides a longitudinal assessment of the intervention. We are recruiting a subset of 40 study participants, all from the intervention group, divided equally between the two trials.

Quantitative assessment of iNSC fidelity: We conduct detailed audits of iNSC sessions for all participants assigned to the intervention arm from both trials (n=150 total). A case report form is used to document fidelity to each component of the iNSC session. Two reviewers independently rate the iNSC session according to key domains, providing both objective and subjective measures about the quality of the counselling. Through this process, our audit staff also assess the appropriateness of documentation in the primary case report forms, including misinformation and missing data. This exercise provides critical feedback loops to improve counselling over time.

Clinical endpoints

In addition, we collect longitudinal participant outcomes data at 3 and 6 months for both trials. In Trial 1 (HIV-positive women), we will examine an endpoint of retention in care with viral suppression of HIV (<40 copies/mL). In Trial 2 (HIV-negative women), we will examine retention in care with adherence to PrEP as measured by plasma and intracellular TFV drug concentrations at 6 months following study enrolment. Using published algorithms,[38] results from the plasma and upper layer of packed cells assays are combined to develop a composite adherence score (table 4). Our Trial 2 clinical outcome is

Table 3 Schedule of evaluations for Trial 2—PrEP adherence support for HIV-negative pregnant women

		Clinical visits				Adherence assessment	HIV confirmatory testing
	Screening	Enrolment	Month 1	Month 3	Month 6	Monthly	(if rapid HIV test is positive)
Laboratory studies							
Rapid HIV antibody test	X	X		X	X		
Hepatitis B antigen	X						
Alanine aminotransferase		X					
Creatinine	X			X	X		
Syphilis screening		X *					
Urine dipstick		X	X	X	X		
Tenofovir concentration				X	X		
HIV RNA (viral load)							X
Storage for HIV resistance testing							X
Medical examination							
Medical history	X						
Obstetric examination	X	X	X	X	X		
Questionnaires							
Social and demographic information		X					
Pregnancy history		X		X	X		
Sexual partners		X		X	X		
COVID-19 questionnaire		X	X	X	X	X	
Social harms		X	X	X	X	X	
Intimate partner violence		X		X	X		
Substance abuse		X			X		
Motivating factors for PrEP use		X					
Perceived HIV risk assessment		X			X		
PrEP use disclosure		X	X	X	X		
LifeWindows—PrEP adherence[46]		X		X	X		
Multidimensional Scale of Perceived Social Support		X			X		
PrEP adherence questionnaire			X	X	X	X	
Pregnancy and delivery status			X	X	X	X	
Drug dispensation and adherence assessment							
Participant-specific dispensing record		X	X	X	X	X	
Intervention assessment (intervention arm only)							
Overall intervention acceptability			X	X	X		
Integrated Next Step Counseling acceptability			X	X	X		

Continued

Table 3 Continued

	Screening	Clinical visits				Adherence assessment	HIV confirmatory testing
		Enrolment	Month 1	Month 3	Month 6	Monthly	(if rapid HIV test is positive)
Adherence supporter acceptability			X	X	X		
Qualitative interviews		X†		X†	X†		

*Will perform test if no results are available in the medical record.
†Schedule additional procedures within 30 days of visit for subset of participants enrolled in this component.
PrEP, pre-exposure prophylaxis.

based on functional adherence, defined as 4–5 or more doses/week (scores of 4 or 5).

In line with pilot designs, our study is not formally powered to detect clinically meaningful differences between study arms (see the Sample size section). Instead, these data will be used to assess the feasibility of future trials, including in the areas of recruitment and retention. These preliminary endpoint data will also provide baseline estimates for future studies, especially for PrEP use among pregnant and breastfeeding women, where adherence data remain scarce.

Safety monitoring

At each study visit, the study staff will evaluate participants for social harms, IPV and AEs (Adverse Events). We will use standardised instruments to screen for social harms and IPV. Social harms involve problems with other people as a result of study participation. IPV involves physical or sexual violence experienced with a partner. An AE will be defined as any untoward medical occurrence in a study participant, including an abnormal physical examination or laboratory finding, symptom or disease, temporally associated with the individual's participation in the research, whether or not considered related to participation in the research. The severity of events will be graded using the National Institute of Health's Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events. Participant deaths will be recorded along with the contributing cause(s) of death. We will also record information on all serious adverse events occurring in participants, whether or not they are related to study participation or the study drug. Because our combination intervention is designed to enhance adherence—and because the Malawi Ministry of Health already recommends the prescribed antiretroviral regimens—a data monitoring committee has not been convened.

Sample size

In Trial 1, we plan to enrol 100 HIV-positive pregnant women, randomised 1:1 between the intervention and control arms (n=50 each). In Trial 2, we plan to enrol 200 HIV-negative pregnant women, randomised 1:1 between the intervention and control arms (n=100 each). Similar to other pilot studies, these sample sizes were selected based on practical considerations, including recruitment ability, participant flow, and budgetary constraints. We enrolled larger number of HIV-negative women in Trial 2 because assessments of PrEP adherence during pregnancy and breastfeeding are limited in the medical literature. These sample sizes were deemed sufficient to evaluate the acceptability and fidelity endpoints described above. We also conducted exploratory precision and power calculations for our clinical endpoints over a range of potentially meaningful effect sizes.

Data management

Clinical and behavioural data collected during this study are collected on case report forms and through REDCap

Table 4 Adherence composite scores based on TFV and TFVdp concentrations, with doses estimated/interval

Score	TFV in plasma	TFVdp in ULPC	Estimates doses per interval
0	None detectable	<10 000 fmol/mL	Low number or no doses in the interval
1	Detectable	<10 000 fmol/mL	A few doses in the entire interval
2	Any level	10 000–100 000 fmol/mL	1–2 doses/week
3	<10 ng/mL	>100 000 fmol/mL	Several doses early in the interval, followed by a stop in the 1–2 weeks leading up to sampling visit
4	10 ng/mL or higher	100 000–1 000 000 fmol/mL	4–5 doses/week
5	10 ng/mL or higher	>1 000 000 fmol/mL	Approximately daily dosing

Adapted from Corneli *et al*.[38]
TFV, tenofovir; TFVdp, tenofovir diphosphate; ULPC, upper layer packed cells.

software.[39] Access to study data is restricted to a limited number of team members (data coordinator, study coordinator and study investigator). For the qualitative interviews, the SSI audio recordings are transcribed and translated for analysis. All identifiers are redacted from the interview transcripts before analysis. Weekly data monitoring reports, including the performance indicators, are generated to monitor study progress. Deidentified data will be made available via existing online data repositories once the planned analyses are completed and data sharing agreements are established with proposed investigators and institutions.

Confidentiality

Measures are being taken to ensure the safety of data and confidentiality of all our study participants. All participants are assigned a unique coded study identification numbers (ID) number. The interview guides will not capture names of the participants, but only coded study ID. No participants will be identified in any report or publication about this study. Clinical information with individual identifiers will not be released without the written permission of the participant. We expect these procedures to protect participant confidentiality adequately.

Data analysis

In our assessment of intervention acceptability, we will tabulate participant responses about engagement, satisfaction and discussion content. Only participants in the intervention group will be included in these analyses and the results will be stratified by trial. Outcomes will be reported as a proportion, with precision quantified using 95% CIs. We will examine the responses to our five-point Likert scale and, depending on their distribution, report them as either categorical or binary variables. To complement these qualitative data, we will analyse SSI data to gain additional insights about intervention acceptability. Data will be analysed using established techniques that include coding, memoing and matrices to summarise and interpret key patterns in the data. Comparative and thematic analyses will be used to provide an in-depth understanding of the experiences related to HIV testing.

To assess fidelity, each iNSC session will be scored (range 0–100) and then stratified by individual participant, type of study visit, staff member providing iNSC and calendar time. This will allow us to describe trends in fidelity over the course of participant follow-up time and calendar time. We will describe scores overall and by steps within iNSC.

Analyses of clinical endpoints will be conducted separately for each trial. Given the nature of these pilot studies, emphasis will be placed on estimation and precision. In Trial 1, we will assess ART adherence by evaluating the viral suppression status of each study participant at 3 and 6 months after randomisation. Participants not lost to follow-up will be classified as either virally suppressed (<40 copies/mL) or not virally suppressed (≥40 copies/mL). The proportion of women retained in care with viral suppression will be compared between randomisation arms by estimating the risk difference and corresponding 95% CI. In Trial 2, we will assess PrEP adherence by evaluating retention in care and functional PrEP use for each study participant at 3 and 6 months. Mirroring our approach in Trial 1, the proportion of women retained in care with functional PrEP use will be compared between randomisation arms using a risk difference and corresponding 95% CI. Women who do not attend the month 6 visit will be counted as failures and contribute to the analysis denominator.

The incidence of social harms, IPV and other AEs will be estimated by randomisation arm and, where possible, by individual event types. Study retention will be described for each scheduled visit using frequency tables, and reasons for attrition will be described. Adherence to ART and PrEP will also be measured both by self-report and pharmacy measures. A medication possession ratio will be estimated and described using summary statistics, using established thresholds to dichotomise this endpoint.[40 41] We will compare these composite adherence outcomes between randomisation arms using a risk difference and corresponding 95% CI.

Patient and public involvement

Prior to commencing recruitment, the local Community Advisory Board (CAB) was engaged to review the study aims and recruitment procedures. The CAB consists of local community and religious leaders, community representatives and adolescents representing the youth. CAB meetings were held bimonthly to review progress in enrolment and retention, and to solicit feedback about ongoing successes and challenges with study implementation.

COVID-19 considerations

Due to the ongoing COVID-19 pandemic,[42] we have modified our activities to increase the safety of staff and participants. All study personnel practice personal safety measures when interacting with others, including personal protective equipment, frequent handwashing and physical distancing.[43] All participants wear face masks when being attended to on the study site. To minimise the number of clinic visits, we dispense study drugs (either ART or PrEP) for longer durations—aligned with study activities—and conduct monthly adherence assessments via phone. All directives from the Malawi Ministry of Health are followed and an information sheet is used to provide participants with up-to-date information on COVID-19 preventive measures.

Ethics and dissemination

The study protocol has been reviewed and approved by the Malawi National Health Science Research Committee (19/05/2334) and the University of North Carolina at Chapel Hill Institutional Review Board (19-1060). Any protocol modifications are submitted to and approved by these committees before any change in implementation.

Study findings will be disseminated through appropriate local channels, including academic and public health research symposia.

DISCUSSION

The TP2 study comprises two parallel trials to support antiretroviral adherence in the setting of antenatal and postnatal care, both for ART (Trial 1) and PrEP (Trial 2). This pilot study will provide important data on intervention acceptability, fidelity and clinical outcomes. Our overarching goal is to assess these attributes, while evaluating the feasibility of the TP2 adherence intervention for future efficacy trials.

Our trial focuses on two different pregnant and breastfeeding populations that may benefit from adherence interventions—HIV-positive women on ART and HIV-negative women on PrEP. For the HIV-positive group, we focused on those who had recently initiated HIV treatment or restarted following a prolonged (ie, greater than 6 months) interruption. We reasoned that the timing of our combination behavioural intervention may be most relevant during this start/restart window. However, we also recognise the importance of adherence support for those on long-term ART, even in shorter periods. If shown to be acceptable in our pilot study, we would look to expand the eligibility criteria in follow-on studies.

Similar to other settings in sub-Saharan Africa, the provision of PrEP during pregnancy and breastfeeding in Malawi remains limited. This study will provide important acceptability data about PrEP use, including self-reported and objective measures of adherence. Although we considered common challenges to PrEP delivery in the design of our study, some barriers were difficult to address. For example, the integration of PrEP dispensation with routine antenatal/postnatal visits may promote adherence and persistence.[27 44] However, such evaluation schedules did not align with our adherence assessments or our relatively short (ie, 6 month) follow-up period. Nevertheless, as part of our acceptability assessments, we will gather data that can inform future PrEP delivery strategies.

While we expect to gain insights into antiretroviral adherence during pregnancy and breastfeeding, the design of this pilot study emphasises the former period. All participants are enrolled during pregnancy, with the expectation that most will deliver prior to the 6 months and continue in follow-up. The vast majority of new mothers in Malawi opt to breastfeed their children[45] and, as such, we did not make the intention to breastfeed a separate eligibility criterion for the trial. Our assessments of acceptability and fidelity will consider a women's pregnancy status (ie, antenatal or postnatal) and allow us to evaluate the intervention across these related, but distinctly different time periods. The study will also provide some descriptive data about PrEP safety in pregnancy and breastfeeding, both for the participant and her newborn.

In summary, the TP2 study evaluates a new combination intervention to support antiretroviral adherence. This pilot study will provide important data about the intervention's acceptability, fidelity and clinical outcomes promoting consistent ART and PrEP use. Once completed, our study will provide insight into broad strategies for HIV prevention and treatment that are status neutral, and able to support both HIV-positive and HIV-negative pregnant women in sub-Saharan Africa.

Author affiliations
[1]University of North Carolina Project-Malawi, Lilongwe, Malawi
[2]Department of Health Policy and Systems, University of Zambia School of Medicine, Lusaka, Zambia
[3]Department of Obstetrics and Gynecology, School of Medicine, University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, North Carolina, USA
[4]Department of Health Behavior, University of North Carolina at Chapel Hill Gillings School of Global Public Health, Chapel Hill, North Carolina, USA
[5]Department of Epidemiology, University of North Carolina at Chapel Hill Gillings School of Global Public Health, Chapel Hill, North Carolina, USA
[6]Department of Health Behavior and Health Education, University of Michigan School of Public Health, Ann Arbor, Michigan, USA
[7]Center for AIDS Research, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, USA
[8]Lighthouse Trust, Lilongwe, Malawi
[9]Department of Medicine, School of Medicine, University of North Carolina, Chapel Hill, North Carolina, USA
[10]Department of Global Health, University of Washington, Seattle, Washington, USA
[11]School of Public Health and Family Medicine, College of Medicine University of Malawi, Blantyre, Malawi
[12]Department of HIV and AIDS, Ministry of Health Malawi, Lilongwe, Malawi
[13]Institute for Social and Preventive Medicine (ISPM), University of Bern, Bern, Switzerland

Twitter Friday Saidi @DrFridaySaidi

Acknowledgements We acknowledge the research team members at University of North Carolina Project-Malawi for their commitment and preparatory work to see the study open to enrolment. We thank the Bwaila District Hospital management and staff for their support. We would like to also thank the management and staff at Lighthouse Trust for their support.

Contributors BHC and WM are the trial's protocol chairs. In Malawi, FS is the lead investigator, TP is the study coordinator, and BM is the data coordinator. BHC, WM, FS, KF, AMG, NER, SP, LAG, KM and LMH developed the study protocol. KRA, FS, BHC, KF, NER, SM, LMH and WM developed the intervention manual and KRA and KF developed the participatory workbook for Integrated Next Step Counseling. KF, SM and LMH developed the qualitative component. TK and SP advised the study team and contributed scientific expertise. FS, TP, LAG, LMH and BM oversaw data collection and data management activities. KRM, LAG, BHC and FS planned the analyses. BHC, WM, FS, KF, KRA and TP oversaw implementation of study procedures. All the authors have contributed to the development of this manuscript. They have read and approved the final version for publication.

Funding The US National Institute of Allergies and Infectious Diseases (NIAID, R01 AI131060) funds the Tonse Pamodzi 2 trial. Additional investigator, trainee and administrative support is provided by NIAID (K24AI120796, P30 AI050410), National Institute of Mental Health (K01 MH121186 and R00 MH104154) and Fogarty International Center (D43 TW009340, D43 TW010060).

Disclaimer Funders were not involved in the study design development, writing of the protocol and in the decision to submit this article for publication.

Competing interests None declared.

Patient consent for publication Not applicable

Provenance and peer review Not commissioned; externally peer-reviewed.

ORCID iDs
Friday Saidi http://orcid.org/0000-0003-1190-1499
Wilbroad Mutale http://orcid.org/0000-0002-4891-6750
Benjamin H Chi http://orcid.org/0000-0002-1435-8455

REFERENCES

1 UNAIDS. *Fast-Track - Ending the AIDS epidemic by 2030*. Geneva, Switzerland: UNAIDS, 2014. https://www.unaids.org/en/resources/documents/2014/JC2686_WAD2014report
2 Joint United Nations Programme on HIV/AIDS, editor. *Countdown to zero: global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive, 2011-2015*. Geneva, Switzerland: UNAIDS, 2011: 44.
3 Joint United Nations Programme on HIV/AIDS. *Together we will end AIDS. Geneva*. Switzerland: Joint United Nations Programme on HIV/AIDS (UNAIDS), 2012.
4 Chi BH, Adler MR, Bolu O, *et al*. Progress, challenges, and new opportunities for the prevention of mother-to-child transmission of HIV under the US president's emergency plan for AIDS relief. *J Acquir Immune Defic Syndr* 2012;60 Suppl 3:S78–87.
5 Chi BH, Stringer JSA, Moodley D. Antiretroviral drug regimens to prevent mother-to-child transmission of HIV: a review of scientific, program, and policy advances for sub-Saharan Africa. *Curr HIV/AIDS Rep* 2013;10:124–33.
6 Joint United Nations Programme on HIV/AID. *2015 progress report on the global plan towards the elimination of new HIV infections among children and keeping their mothers alive*. Geneva, Switzerland: UNAIDS, 2015. https://www.unaids.org/sites/default/files/media_asset/JC2774_2015ProgressReport_GlobalPlan_en.pdf
7 Myers JE, Braunstein SL, Xia Q, *et al*. Redefining prevention and care: a Status-Neutral approach to HIV. *Open Forum Infect Dis* 2018;5:ofy097.
8 Schouten EJ, Jahn A, Chimbwandira F, *et al*. Is option B+ the best choice? *The Lancet* 2013;381:1272–3.
9 Kalua T, Tippett Barr BA, van Oosterhout JJ, *et al*. Lessons learned from option B+ in the evolution toward "Test and Start" from Malawi, Cameroon, and the United Republic of Tanzania. J Acquir Immune Defic Syndr 2017;75 Suppl 1:S43–50.
10 Tippett Barr BA, van Lettow M, van Oosterhout JJ, *et al*. National estimates and risk factors associated with early mother-to-child transmission of HIV after implementation of option B+: a cross-sectional analysis. *Lancet HIV* 2018;5:e688–95.
11 Haberer JE, Sabin L, Amico KR, *et al*. Improving antiretroviral therapy adherence in resource-limited settings at scale: a discussion of interventions and recommendations. *J Int AIDS Soc* 2017;20:21371.
12 Rollins NC, Essajee SM, Bellare N, Doherty M, Hirnschall GO, *et al*. Improving retention in care among pregnant women and mothers living with HIV: lessons from INSPIRE and implications for future who guidance and monitoring. *J Acquir Immune Defic Syndr* 2017;75 Suppl 2:S111–4.
13 Chimbwandira F, Mhango E, Makombe S. Impact of an innovative approach to prevent mother-to-child transmission of HIV--Malawi, July 2011-September 2012. MMWR Morb Mortal Wkly Rep 2013;62:148–51.
14 Tenthani L, Haas AD, Tweya H, *et al*. Retention in care under universal antiretroviral therapy for HIV-infected pregnant and breastfeeding women ('Option B+') in Malawi. *AIDS* 2014;28:589–98.
15 Nachega JB, Uthman OA, Anderson J, *et al*. Adherence to antiretroviral therapy during and after pregnancy in low-income, middle-income, and high-income countries. *AIDS* 2012;26:2039–52.
16 Kirsten I, Sewangi J, Kunz A, *et al*. Adherence to combination prophylaxis for prevention of mother-to-child-transmission of HIV in Tanzania. *PLoS One* 2011;6:e21020.
17 Haas AD, Msukwa MT, Egger M. Adherence to antiretroviral therapy during and after pregnancy: cohort study on women receiving care in Malawi's option B+ program. Clin Infect Dis 2016;63:1227–35.
18 UNAIDS. *improving UNAIDS' paediatric and adolescent estimates*. Geneva, Switzerland: UNAIDS, 2020. https://www.unaids.org/sites/default/files/media_asset/improving-unaids-paediatric-and-adolescent-estimates_en.pdf
19 UNICEF. Last-mile-to-emtct_whitepaper_unicef2020.Pdf, 2020. Available: http://www.childrenandaids.org/sites/default/files/2020-02/Last-Mile-To-EMTCT_WhitePaper_UNICEF2020.pdf
20 Drake AL, Wagner A, Richardson B, *et al*. Incident HIV during pregnancy and postpartum and risk of mother-to-child HIV transmission: a systematic review and meta-analysis. *PLoS Med* 2014;11:e1001608.
21 Graybill LA, Kasaro M, Freeborn K, *et al*. Incident HIV among pregnant and breast-feeding women in sub-Saharan Africa: a systematic review and meta-analysis. *AIDS* 2020;34:761–76.
22 WHO. *Preventing HIV during pregnancy and breastfeeding in the context of prep*. Geneva, Switzerland: WHO, 2017. http://www.who.int/hiv/pub/toolkits/prep-preventing-hiv-during-pregnancy/en
23 Baeten JM, Donnell D, Ndase P, *et al*. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med* 2012;367:399–410.
24 Grant RM, Lama JR, Anderson PL, *et al*. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med Overseas Ed* 2010;363:2587–99.
25 Pintye J, Beima-Sofie KM, Kimemia G, *et al*. "I Did Not Want to Give Birth to a Child Who has HIV": Experiences Using PrEP During Pregnancy Among HIV-Uninfected Kenyan Women in HIV-Serodiscordant Couples. J Acquir Immune Defic Syndr 2017;76:259–65.
26 Zimba C, Maman S, Rosenberg NE, *et al*. The landscape for HIV pre-exposure prophylaxis during pregnancy and breastfeeding in Malawi and Zambia: a qualitative study. *PLoS One* 2019;14:e0223487.
27 Pintye J, Drake AL, Kinuthia J, *et al*. A risk assessment tool for identifying pregnant and postpartum women who may benefit from preexposure prophylaxis. *Clin Infect Dis* 2017;64:751–8.
28 Sidebottom D, Ekström AM, Strömdahl S. A systematic review of adherence to oral pre-exposure prophylaxis for HIV – how can we improve uptake and adherence? *BMC Infect Dis* 2018;18:581.
29 Ministry of Health and Population, Malawi. Malawi population-based HIV impact assessment MPHIA 2015–2016. Available: https://phia.icap.columbia.edu/wp-content/uploads/2018/10/MPHIA-SS_2018_FINAL.pdf
30 Graybill L, Freeborn K, Kasaro M. A systematic review of risk factors for HIV acquisition during pregnancy and breastfeeding in sub-Saharan Africa. *10th International AIDS Society Conference on HIV Science* 2019.
31 Hershow RB, Gonzalez M, Costenbader E, *et al*. Medical providers and harm reduction views on pre-exposure prophylaxis for HIV prevention among people who inject drugs. *AIDS Educ Prev* 2019;31:363–79.
32 Powers KA, Orroth K, Rosenberg NE. A mathematical modeling analysis of combination HIV prevention in antenatal clinics. In 2019 Conference on Retroviruses and Opportunistic Infections Seattle, WA 2019.
33 Amico KR, Miller J, Balthazar C, *et al*. Integrated next step counseling (iNSC) for sexual health and PreP use among young men who have sex with men: implementation and observations from ATN110/113. *AIDS Behav* 2019;23:1812–23.
34 R Amico K, McMahan V, Goicochea P, *et al*. Supporting study product use and accuracy in self-report in the iPrEx study: next step counseling and neutral assessment. *AIDS Behav* 2012;16:1243–59.
35 Berkman LF, Glass T. Social integration, social networks, social support, and health. Social epidemiology 2000;1:137–73.
36 InMinistry of Health and Population, Malawi. *2018 clinical management of HIV in children and adults. 4th ed*. Lilongwe: Ministry of Health and Population, Malawi, 2018.
37 Doig GS, Simpson F. Randomization and allocation concealment: a practical guide for researchers. *J Crit Care* 2005;20:187–91.
38 Corneli AL, Deese J, Wang M, *et al*. FEM-PrEP: adherence patterns and factors associated with adherence to a daily oral study product for pre-exposure prophylaxis. *J Acquir Immune Defic Syndr* 2014;66:324–31.
39 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.

40 Chi BH, Cantrell RA, Zulu I, *et al*. Adherence to first-line antiretroviral therapy affects non-virologic outcomes among patients on treatment for more than 12 months in Lusaka, Zambia. *Int J Epidemiol* 2009;38:746–56.
41 Goldman JD, Cantrell RA, Mulenga LB, *et al*. Simple adherence assessments to predict virologic failure among HIV-infected adults with discordant immunologic and clinical responses to antiretroviral therapy. *AIDS Res Hum Retroviruses* 2008;24:1031–5.
42 World Health Organization. WHO announces COVID-19 outbreak a pandemic. Available: https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/novel-coronavirus-2019-ncov
43 Chu DK, Akl EA, Duda S, *et al*. Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. *The Lancet* 2020;395:1973–87.
44 Kinuthia J, Pintye J, Abuna F, *et al*. Pre-Exposure prophylaxis uptake and early continuation among pregnant and post-partum women within maternal and child health clinics in Kenya: results from an implementation programme. *Lancet HIV* 2020;7:e38–48.
45 The DHS Program ICF. Malawi demographic and health survey 2015-16, 2021. Available: https://dhsprogram.com/pubs/pdf/FR319/FR319.pdf
46 LifeWindows Project Team. The LifeWindows information motivation behavioral skills art adherence questionnaire (LW-IMB-AAQ), 2006. Available: http://www.chip.uconn.edu/int/F_LWIMBARTQuestionnaire.pdf

TRIAL REGISTRATION—DATA ELEMENTS

NCT Number	NCT043309
Status	Recruiting
Study Results	Study ongoing
Conditions	HIV/Antenatal Care
Interventions	Combination intervention to promote antiretroviral drug adherence for HIV antiretroviral therapy (Trial 1) and pre-exposure prophylaxis (Trial 2)
Outcome Measures	Trial 1 (ART adherence support) The primary outcome measure is retention in care with HIV viral suppression, defined as <40 copies/ml. [Time Frame: 6 months following study enrolment] Trial 2 (PrEP adherence support) The primary outcome is retention in care with functional adherence to PrEP, categorized according to plasma and intracellular tenofovir drug concentrations. [Time Frame: 6 months following study enrolment]
Sponsor/Collaborators	University of North Carolina, Chapel Hill UNC Project-Malawi
Gender	Female
Age	18 Years and older (Adult, Older Adult)
Phases	Not Applicable
Enrolment	300 participants – 100 for Trial 1 and 200 for Trial 2
Funded by	The US National Institute of Allergies and Infectious Diseases (NIAID, R01 AI131060)
Study Type	Interventional
Study Designs	Allocation: Randomized Intervention Model: Parallel Assignment Intervention Model Description: This is a parallel pilot randomized trial in which participants randomly assigned to the control arm will receive educational material about HIV treatment and prevention. Those randomized to the intervention arm will additionally receive an adherence support strategy comprising integrated next-step counselling (iNSC) and adherence supporter training. Masking: None (Open Label)
Other IDs	19-1060 , UNCPMZ 41901, 19/05/2334
Start Date	March 1, 2020
Primary Completion Date	December 2021 (anticipated)
Completion Date	June 2022 (anticipated)
First Posted	April 2, 2020
Results First Posted	Not applicable
Last Update Posted	August 18, 2020
Locations	Bwaila District Hospital; UNC Project Malawi; Central Region, Malawi
URL	https://clinicaltrials.gov/ct2/show/NCT04330989

TONSEPAMODZI

ADHERENCE SUPPORT INTERVENTION MANUAL

Contents

Acknowledgements

We would like to acknowledge the following individuals for their roles in creating this training manual: Friday Saidi, Lauren Hill, Benjamin Chi, Kellie Freeborn, Nora Rosenberg, Suzanne Maman, and Wilbroad Mutale. We would also like to thank K. Rivet Amico for her valuable guidance and many reviews of the manual. The development of the Tonse Pamodzi adherence support intervention was funded by the National Institutes of Health (R01AI131060).

This training manual was developed using formative data from the Tonse Pamodzi study; input from the co-investigators listed above; and training materials for Integrated Next Step Counseling, an approach developed by Amico, et al. for the iPrEx Study ("Iniciativa Profilaxis Pre-Exposición"). We have adapted these materials to fit the Malawian and Zambian settings, as part of a broader adherence support package that includes self-selected adherence supporters.

INTRODUCTION

If the anticipated gains for the biomedical prevention of mother-to-child HIV transmission (PMTCT) programs are to be realized, adherence to antiretroviral regimens for both treatment and prevention of HIV are critical. Adherence can be defined as the extent to which a patient follows a treatment plan, takes prescribed medicines as directed, and follows any related restrictions regarding food and other medications. There are other important factors that go into successful outcomes—like coming in for recommended care or medication refills (retention in care), the length of time someone is committed to a given treatment (persistence), or a mix of all of these (patient engagement).

Over the years, different models and frameworks for how and why people may struggle with adherence particularly have been developed and so have different approaches to trying to optimize outcomes for antiretroviral therapy (ART) and pre-exposure prophylaxis (PrEP). Humans are ultimately social creatures, so it is not surprising that partner, friend, and/or family support can be very valuable for women and improve adherence and retention in antenatal and HIV programs. Adherence support from team members trained in patient-centered, person-facing counselling and communication can also help individuals to optimize medication adherence.

This workbook describes an intervention that is a combination approach to improve adherence for women initiating antiretroviral therapy (ART) or pre-exposure prophylaxis (PrEP) during pregnancy. It has been designed for the Tonse Pamodzi 2 study (TP-2). This combination intervention includes Integrated Next Step Counselling (iNSC) and an adherence supporter model (Omukhulupilira) that helps pregnant and breastfeeding women to develop their own strategies to improve adherence in the context of their overall well-being.

Women receiving this combination intervention will have dedicated time with a specialized counselor at their enrollment, Month 1, Month 3 and Month 6 study visits. In addition, they will be given the opportunity to identify an *omukhulupilira* (“close confidant” in Chichewa and Nyanja), an individual who will be educated and trained to support the participant’s use of ART or PrEP, and may accompany the participant to study visits. Over the course of the four study visits, study counselors will provide iNSC and—if a support person is identified—support omukhulupilira interactions, in ways that encourage adherence to antiretroviral medications in the context of general well-being. This is described in greater detail in this manual.

INTERVENTION COMPONENTS

1. Integrated Next Step Counselling (iNSC)

iNSC is a two-phase discussion opened with an invitation to explore experiences and intentionally framed as a process rather than a series or set of messages. Although steps are articulated to guide implementers through the iNSC process, the driving goal is to engage participants in a non-judgmental discussion of their experiences surrounding protection of sexual health. iNSC is a process for having a conversation. It draws from the Information, Motivation, Behavioral Skills model situated within a socio-ecological context. The iNSC discussion assumes that the participant is the expert of their own experiences, that experiences are influenced by multiple factors, that there are diverse pathways to adherence and engagement in sexual health, that these pathways can be identified through exploration, and that facilitated exploration can lead to clients identifying their own needs and strategies. iNSC training emphasizes the importance of engaging in a genuine, as opposed to formulaic or predetermined, conversation framing the discussion around the specific context and needs of the participant. Communication is intentionally neutral (non-judgmental), avoids telling participants what they must or should do, and draws on strengths, resources, and facilitators.

2. Adherence supporter model (Omukhulupilira)

A recommended but optional component of the intervention, the omukhulupilira, will be a person chosen by each participant who can provide emotional, instrumental, and informational social support to help the participant adhere to their ART/PrEP regimen. In Chichewa and Nyanja, “omukhulupilira” means a close confidant. If and once selected by the participant, the omukhulupilira will receive a brief in-person training on how to provide positive support to the participant during a structured orientation visit. At the participant’s

invitation, they will have the opportunity to join portions of the iNSC sessions after they have completed the orientation visit. In these sessions, the counselor and participant may call on the omukhulupilira to help discuss barriers to adherence, strategies to overcome these barriers, and their role in helping the participant to implement these strategies as appropriate. The role of the omukhulupilira outside of these sessions will be determined by this discussion and the needs and preferences of the participant.

OVERVIEW OF INTERVENTION SESSIONS

Visit	Participant activities	Omukhulupilira activities
Welcome Orientation (Day 0)	I. Welcome & education debrief II. iNSC • Health in context: sexual health (PrEP) or general well-being (ART) • PrEP/ART adherence III. Exploration & selection of omukhulupilira IV. Close session	N/A not yet selected
Omukhulupilira orientation (As early as possible, but not restricted)	Encouraged to attend, but not mandatory	I. Education about HIV and PrEP/ART II. Social support for adherence III. Coaching to provide support IV. Closing the session & next steps
Adherence check-in (Month 1 and Month 3)	I. iNSC session • Health in context: sexual health (PrEP) or general well-being (ART) • PrEP/ART adherence *If the omukhulupilira is present, determine whether the participant would like to discuss further in a joint session*	If present, participate in discussion of selected adherence strategies and potential role to support these strategies
Maintaining adherence (Month 6)	I. iNSC session • Health in context: sexual health (PrEP) or general well-being (ART) • PrEP/ART adherence • Discussion of future steps, including links to the standard of care *If the omukhulupilira is present, determine whether the participant would like to discuss further in a joint session*	If present, participate in discussion of selected adherence strategies and potential role to support these strategies

FACILITATOR/COUNSELOR PREPERATION

All counselors must have completed training on procedures and received confirmation from the supervisory team that he/she is ready to implement the intervention. Additionally, counselors should not only be facile with the intervention approach (iNSC) but should also have had the opportunity to gain knowledge and feel confident in any of the education material that the participant will have received prior to the iNSC session (in case there are questions and to identify potential misinformation). Finally, awareness of crisis counseling techniques for those working with newly diagnosed pregnant women is required. Ongoing supervision and training are provided throughout the study by the supervisory team.

NOTES ABOUT THIS MANUAL

An important goal of this intervention is to learn from the participant and tailor counseling messages in their individual context. As such, it is critical that the conversation flows freely and is directed to the participant's own experiences, needs, and obstacles. In this manual, we include sample text in blue italicized font. These examples are meant as guides only and *should not* be recited verbatim.

ENROLLMENT VISIT

After consent and enrollment, participants will be randomized to intervention or standard of care. ALL participants will have engaged in [ART/PrEP] education before meeting with the intervention counselor, as required by the study protocol. As such, participants may feel tired, overwhelmed or otherwise distracted by the time she meets with the intervention counselor. We will deliberately include comfort check-ins and efforts to promote participant engagement in intervention conversations. Welcoming participants and providing an overview of the session, while checking in on their current state of mind, is essential to this and must be attempted before getting into exploration of sensitive topics like sex and health. This is particularly critical for women who only recently learned of their HIV status.

SESSION COMPONENTS

Participants assigned to the intervention condition will go from receiving the standard education information about [ART/PrEP] and clinic visits to meeting with trained intervention counselors. During this part of the visit, participants will be asked to engage in the following 4 general phases of interaction:

1. Welcome and education debrief
2. iNSC
3. Exploration and selection of omukhulupilira
4. Close session with plan for next steps

1. WELCOME AND OVERVIEW

The enrollment session begins with an overview of the intervention package.

Introducing yourself, the intervention and this session

> *My name is _____. Thank you for meeting with me today! Thank you joining the study. You have been selected to take part in the study intervention, which will help you with [ART/PrEP]. I will be checking with you each time you come to clinic to see how things are going. For this first conversation together, I am hoping to spend some time getting to know you better, share information with you and explore your thoughts, feelings and plans for your journey with [ART/PrEP].*

Check in on comfort

> *Before we begin, I want to check in with you. You have been here a while today [and for newly diagnosed "and no doubt this has been challenging"]. We will spend about 30-45 minutes talking together today. Before we begin, do you need to use the rest room or take a break? Can I get you a snack or beverage? [list whatever amenities you have at the site]*

Explain the program and your role

> *This program works with people starting [ART/PrEP] with the goal of helping people to feel confident and motivated to follow their regimen to the best of their ability. Moreover, it gives people the space to talk frankly about their experiences, even when those experiences may involve challenges- like missing doses or just not feeling like taking doses. Our conversations are about your needs, and we do not share this information with your medical care providers. It is private. The only thing I cannot keep private are situations where you may be in danger. If that is the case, then you and I will work together with other members of the care team here to ensure your safety. Sound OK?*
>
> *Thank you. Each time you come in for [ART/PrEP], I will be checking with you to see how things are going. For this first conversation together, I am hoping to spend some time getting to know you better, share information with you and explore your thoughts, feelings and plans for your journey with [ART/PrEP].*

Ask permission to carry on

Does that sound OK to you? Do you have any questions before we begin?

Education debrief – before moving further, check in on information the participant received already today

You have received a lot of information from the clinic staff today. What did you find most meaningful in all that was shared?

[Reflect]

Are there any pieces of information you heard that were not so clear or seemed hard to understand or believe?

[Process]

Any time you have questions about the information you receive, please let me or other members of the study staff know. We can help to clarify or explain further. The more informed people are, the better!

2. iNSC

The iNSC component of the session includes two parts.

The first part is a broader discussion about general well-being. This initial phase provides some information about the situational context for adherence behaviors and helps to build rapport with the participant. For individuals on ART, the emphasis is on general well-being; for individuals on PrEP, the focus is on sexual health.

The second part focuses in on use of [ART/PrEP], including challenges and facilitators of adherence. This is a direct discussion about how to achieve and maintain medication adherence.

All intervention counselors will be trained in the conduct of iNSC, using the iNSC Workbook (see Appendix). The iNSC discussion structure is shown in the table below. This follows with usual steps of iNSC, with the exception of the *Review* step, which may be skipped in first sessions because there are no previous goals or iNSC discussions to review with the participant yet.

Step	Description
Introduce	Explain what you want to discuss, why, and ask permission
Frame discussion	Frame discussion to two components, first about general well-being and then about adherence. *Steps below will be repeated for each component.*
Review	Check in on previous goals/discussions, close and move into current experiences (follow-up visits only)
Explore	Discuss socio-ecological factors that challenge or could optimize a specific behavior
Tailor	Reflect on context and experiences shared to tailor remainder of the discussion
Identify	Ask what would be needed to happen for the behavior (identified above) to be easier to handle or be more manageable
Strategize	Ask how the participant might consider addressing this need
Agree	Ask the participant if she would agree to try out one or more strategies to address the identified need
Transition / close	Move to a new topic and repeat the flow OR close the discussion

3. EXPLORATION AND SELECTION OF OMUKHULUPILIRA OPTION

The intervention counselor introduces the role of the omukhulupilira and how he/she may help to support ART/PrEP adherence. Below is an example of how this discussion may start.

> *Part of this program is to talk together when you come in for your [ART/PrEP]. Another service that we offer involves what we call an omukhulupilira, someone outside of the clinic who supports you and helps you to take [ART/PrEP]. Being able to take a medication every day can be hard. Many people find it helpful to have a family member or friend that they can rely on to help them remember to take their medicine, attend medical appointments, keep their spirits up, or just be there to talk about things. Research suggests that people who have someone important to them help out with adherence and their efforts to [treat/prevent] HIV may have better chances of being able to do so.*
>
> *For this study, we recommend that participants select an omukhulupilira. This may be a partner, family member, or friend who can support your adherence both during and outside of study counseling visits. Their exact role will be determined by your preferences and needs. You also do not have to select an omukhulupilira if you do not want to. You can select someone today, or at any other study visit.*
>
> *If you desire, your omukhulupilira can attend study counseling sessions with you. If you wish, your omukhulupilira can join us at the end of the counseling session to discuss ways to support your adherence. Outside of the counseling sessions, she/he can help you to implement these adherence strategies and may be a helping hand or someone to lean on for emotional support. The exact support they provide will depend on your needs, but some things that are often helpful include:*
>
> - *Helping you remember to take your medication*
> - *Helping you get to the clinic or refill prescriptions*
> - *Providing encouragement or emotional support*
> - *Providing child care so you can attend clinic appointments*
>
> *Some people have important others in their lives that they want to involve in their efforts to use [ART/PrEP] as recommended. We also know that not everyone has or wants that. If you do have someone you could see being your supporter, we are able to work them into parts of our sessions so that your plans, goals or strategies can be supported by that person.*
>
> *Just knowing what you know right now, and how you feel right now, what is your reaction to/thoughts about an omukhulupilira?*

If the participant is uninterested in identifying an *omukhulupilira*, thank her and ask for permission to revisit this topic at the next session and skip to Part 4 (Close the Session) below.

> *Thank you. I understand that an omukhulupilira is not for everyone. When you think about it, what are the main reasons you do not want that right now? Thank you. I respect your careful consideration on this. I will check in with you at your next visit about this service—and periodically throughout the study—just in case something changes. Is this okay?*

If the participant is interested in selecting an omukhulupilira (or exploring further), cover the remaining sections below as appropriate.

Material Needed: the Omukhulupilira Orientation Visit Invitation Card, the Omukhulupilira Agreement Form.

A. Important considerations when selecting an omukhulupilira

> *As we've discussed, the support that you will receive from the omukhulupilira will depend upon your needs, your relationship with them, and their capacity to provide support. It will be slightly different for each person. There are few things to consider when deciding on the appropriate supporter for you:*

1) *In most cases, it will be helpful if the omukhulupilira is someone you can see regularly outside of the counseling sessions so they can provide the support that you agree upon together.*
2) *If you have not done so already, you will need to disclose your [if applicable: HIV status] and [ART/PrEP] use to the person you select as your omukhulupilira (if you choose one).*
3) *Once you have selected an omukhulupilira, we will ask them to come in for an orientation session so that we can coach them on how to support you outside of study counseling sessions. Your [if applicable: HIV status] and [ART/PrEP] use will be discussed during this orientation session.*
4) *Omukhulupilira may come with you to our clinic counseling sessions, but this is entirely up to you. If they come, they can join us after the counseling session to discuss how they can support your adherence.*

Is there someone you can think of—a friend or family member you trust, [if applicable: who knows your HIV status], and who you see often—who might be appropriate and willing to be your omukhulupilira?

Allow person time to think and respond.

If not ready, let participant know that you can check in again next time they come in or they can simply bring the person with them to the next visit. Then go to Part 4 (Close the Session).

If the participant remains interested, continue to the next section.

B. Explore possible candidates

Work with the participant to reflect on the possible advantages and disadvantages of approaching potential people for this role. Gauge their interest and comfort in approaching each possible candidate.

- *Are you currently staying with [candidate's name]?*
- *Do you feel comfortable informing [candidate's name] that you have started [ART/PrEP]? What will you tell them?*
- *Can you ask [candidate's name] to come in for an orientation visit? What words might you use?*
- *Do you see any problem(s) having [candidate's name] come here for the next visit? If yes, how so?*
- *Would you like [candidate's name] to join us after the counseling sessions to talk about how they can support your adherence?*

Allow participant to continue exploring advantages and disadvantages—and different considerations—for each of the potential omukhulupilira candidates. When the conversation feels ready to move forward, continue to the next section.

C. Nominating an omukhulupilira

Ask the participant if she feels ready to identify an omukhulupilira. If no, remind participant you will check in again or if she does identify someone between visits, she can just let you know or bring in the person to her next visit. Then move to Part 4 (Close the Session).

For participants who are ready to nominate an omukhulupilira, review and complete the Omukhulupilira Nomination Form with them and ask them to sign and date the form. If the participant is unable to sign their name, ask them to provide a fingerprint instead. Read the form aloud to the participant and help them to complete and sign the form

On this form we will record identification information about the omukhulupilira you named, and any alternate individuals who might participate if that person is not available. This information will help us to make sure that we have the right person in the case that you are not able to come to the Orientation Visit. We also want to make sure that you understand what will be discussed with the omukhulupilira if they attend this visit.

D. Scheduling a visit with the omukhulupilira

If the participant is able to attend the visit, find a day and time for the visit that works for them, and complete the invitation card accordingly, otherwise simply provide the card. Instruct them to provide the card to the person they have determined is able to serve as their omukhulupilira. If they have nominated multiple potential omukhulupilira, ask them how they will determine which person to provide the invitation card to. Thank the participant before transitioning to closing the visit.

Now that you've selected a potential omukhulupilira, he/she will need to come in to this clinic for an orientation visit to learn how to work with you and the counselor to support your use of [ART/PrEP]. While not mandatory, we encourage you to take part in this orientation visit along with the omukhulupilira. Do you think you will be able to attend the visit with your omukhulupilira?

4. CLOSE THE SESSION WITH PLAN FOR NEXT STEPS

Provide a summary of what was discussed, thank the participant and remind her of the next visit.

We have covered a lot today. Thank you for sharing with me. Before you go, I just want to summarize some important parts of our conversation. OK? You mentioned that you need _____ to feel [well, motivated to protect yourself, committed to your health and wellbeing, to feel using condoms works, so on] and _____ would be a strategy you would be willing to try out to help with that. And for [ART/PrEP], you need _____ and you are going to try [strategy] to see if that can be addressed.

You also [identified/decided against] selecting an omukhulupilira at this time. [If applicable] We will schedule a time to meet with this individual, as previously described.

Thank you for talking with me. I look forward to asking you about how things went. It is OK to give something a try and feel it is not quite right. Something that sounds perfect here may feel not so perfect once you leave this space and get into your daily life. If that happens, keep trying. Keep thinking of ways you might work with [repeat needs] just like we did here together. Thank you!

iNSC CHECKLIST – EXAMPLE

STANDARD iNSC Tracking Forms (2 pages)

ID:

Visit Date:	Completed by:

PrEP/ART Status (as of today's visit	Support Discussion
☐ on or getting PrEP ⟶	Full iNSC
☐ on or getting ART⟶	Full iNSC

Sexual Health Promotion/Wellbeing Counseling – iNSC

1 INTRODUCE / FRAME: Introduction to session provided? ☐ yes ☐ no

2 REVIEW: The participant's experiences/goals reviewed ☐ yes ☐ no ☐ NA (first visit, no goals from last visit)

3 EXPLORE: Experiences with sexual health protection through behavioral strategies. What strategies are used/considered? What promotes those (makes it easy)? What challenges use of protection strategies (makes it hard)?

Facilitators (said by participant)	Challenges (said by participant)
☐being well informed	☐not feeling well informed
☐partner(s) supports strategies	☐partner(s) unwilling/reluctant/against to practice strategies
☐personal commitment (motivation) to staying HIV negative	☐ fearful of rejection or missed opportunity (ruining the mood)
☐confidence in negotiating strategies with sexual partner(s)	☐specific incentives to not use strategies (pay or trade)
☐having intimacy (closeness) with partner	☐not thinking that getting HIV would be bad
☐fits well into what I do sexually	☐thinking partners are HIV-negative without really knowing their status
☐feeling "at risk"	☐feeling down/sad (not caring about protecting self)
☐**none could be identified**	☐interferes with intimacy
☐other, specify:	☐drug or alcohol use (making decision making difficult)
	☐caught up in the moment
	☐**none could be identified**
	☐other, specify:

4 TAILOR: Level of engagement in this part of counseling: ☐low ☐medium ☐high

5 IDENTIFY or **confirm** needs: **Needs** (What would make using protection strategies or sustaining ones that work "easier"? Select all)	
☐feel better informed	☐have better concrete skills around negotiating strategies with partners
☐have access to strategies (condoms, HIV testing, lube)	☐gain partner support
☐be assertive/confident	☐basic living needs met (housing, food, safety)
☐have strategies that are sexy/fit into sexual life	☐**none could be identified**
☐feel more motivated	☐other, specify:

6 STRATEGIZE: How to meet needs discussed? ☐ yes ☐ no

Sexual Health / Well-being Goal:

7 AGREE on: Strategy and Action Plan? ☐ yes ☐ no

Medication adherence – iNSC

3 EXPLORE: Experiences with adherence. What has made adherence manageable/well integrated (PrEP easy)? What has challenged consistent PrEP use?

Facilitators (said by participant)	Challenges (said by participant)
☐match with routine/events	☐partying/drugs/alcohol
☐mobile/carry tools (e.g., pill box)	☐medication (too big, tastes bad)
☐personal commitment (motivation) to staying HIV negative	☐disruption in routine
☐memory aids/tools (e.g., alarm, calendar)	☐lack privacy
☐access	☐scared others will think HIV+
☐social support (partner(s), family)	☐side effects
☐feeling "at risk"	☐feeling down/sad (not caring about protecting self)
☐**none could be identified**	☐feeling not at risk
☐other, specify:	☐memory or organization problems
	☐Partner or family member taking PrEP away
	☐PrEP being stolen
	☐**none could be identified**
	☐other, specify:

4 TAILOR: Level of engagement in this part of counseling: ☐low ☐medium ☐high

5 IDENTIFY or **confirm** needs: **Needs** (What would make PrEP "easier"/manageable? What do current successful strategies DO for participant- what **need** do they meet? Select all)	
☐more information	☐manage side effects
☐have access to PrEP when needed	☐social support
☐remember dose times	☐basic living needs met (housing, food, safety)
☐motivation (to feel like taking it, positive reasons to take it)	☐**none could be identified**
☐have privacy	☐other, specify:

6 STRATEGIZE: Strategies discussed? ☐ yes ☐ no

7 AGREE on: Strategy and Action Plan ☐ yes ☐ n

Adherence Goal:

OMUKHULUPILIRA INVITATION CARD (SAMPLE)

Invitation

Dear _____:

At [Clinic Name] we are providing integrated services for pregnant women involving their partners, family members, or other loved ones who are supporting them in their pregnancy. We ask you to visit the antenatal clinic so that we can provide you with important information to ensure the best care for your partner, family member, or friend.

TONSEPAMODZI

Date: _____Time: _____
Room: _____

You may come on another day (Mon to Fri)/time ([CLINIC HOURS]).

Bring this card and you will be attended to right away.

INVITATION #: _____

OMUKHLUPILIRA NOMINATION FORM (SAMPLE)

TRIAL 1 PARTICIPANTS:
I, _____, wish to nominate an individual to serve as my omukhulupilira, to help support my adherence to medicines for HIV treatment. I understand that, in order to serve in this role, the omukhulupilira will need to know my HIV status and that I am currently using antiretroviral medicines.

TRIAL 2 PARTICIPANTS:
I, _____, wish to nominate an individual to serve as my omukhulupilira, to help support my adherence to medicines for HIV prevention. I understand that, in order to serve in this role, the omukhulupilira will need to know that I am currently using pre-exposure prophylaxis (PrEP) for HIV prevention.

I expect to invite the following person as my omukhulupilira, who I will ask to attend the Omukhulupilira Orientation Session:

ID information for omukhulupilira	
Name/Nicknames	
Relationship to participant	
Gender	
Age (approximate)	
Brief physical description (optional)	
Phone number (optional)	

If this person is unavailable, I may send the following alternate person(s) to attend:

ID information for omukhulupilira: alternate 1	
Name/Nicknames	
Relationship to participant	
Gender	
Age (approximate)	
Brief physical description (optional)	
Phone number (optional)	

ID information for omukhulupilira: alternate 2	
Name/Nicknames	
Relationship to participant	
Gender	
Age (approximate)	
Brief physical description (optional)	
Phone number (optional)	

_____ _____
PARTICIPANT SIGNATURE OR FINGERPRINT DATE

INVITATION # ISSUED: _____

OMUKHULUPILIRA ORIENTATION VISIT

Lay support for each participant's adherence to ART or PrEP is an integral component of the Tonse Pamodzi intervention. Social support from an important person in the participant's life can greatly reinforce their own individual efforts to take their medication by the prescribed schedule. The omukhulupilira is a partner, family member, or friend selected by the participant to support their adherence to ART/PrEP outside of study visits. They may also take part in adherence strategy-building following iNSC sessions at the clinic, depending on the participant's preference. Prior to this visit, the participant will nominate someone to attend this orientation visit (see Section 3 in Enrollment Visit section).

To help the omukhulupilira in this role, this orientation session is designed to educate them about ART/PrEP and their role in supporting the participant's use of ART/PrEP, and to coach them in the best ways of providing this support. This section includes the orientation visit procedures and the orientation visit checklist

The scripts provided below are examples only. The Orientation Visit Checklist and the corresponding headers provided in the text indicate the necessary components of the session.

1. INTRODUCING THE ORIENTATION VISIT

Check in and build rapport

[Begin by checking in and building rapport with the person. Then introduce yourself and the session].

Confirm omukhulupilira identity (if participant not present)

The participant is encouraged to accompany the omukhulupilira to the site for this orientation. This is to reduce problems with proper identification and issues around HIV status or ART/PrEP use disclosure. However, if they were unable to accompany the omukhulupilira, be sure to begin by verifying the omukhulupilira's identity using the instructions below.

If the participant *is not* present, ask the person to state the name of the participant who sent them, their name, and their relationship to the participant. Verify this information as well as their physical description, approximate age, and gender against the omukhulupilira ID information provided by the participant. Only proceed with the visit if you are able to verify their identity as one of the possible supporters named by the participant.

If the participant *is* present, you do not need to verify the identity of the omukhulupilira as above, but check with the participant first that the person they have brought with them is the individual they want to be their omukhulupilira. This can be done privately when the participant first arrives.

Once the person is confirmed by the participant as the intended omukhulupilira, record the omukhulupilira's gender and relationship to the participant in the appropriate fields of the Orientation Visit Checklist.

Confirm disclosure of HIV status (if applicable) and ART/PrEP use

Ascertain if participant has disclosed HIV status (if applicable) and ART/PrEP use to the supporter. Be careful not to disclose any information about HIV status or medications on behalf of the participant.

If participant is present, in private conversation to confirm omukhulupilira selection:

- Ask if she has already disclosed her [if applicable] HIV status and ART/PrEP use with the omukhulupilira.
- If she HAS NOT disclosed, make sure the woman is aware the counselor cannot disclose on her behalf

I do not have the right to disclose your HIV status or ART/PrEP use, but I can help to guide the conversation to help you disclose. Do you want to disclose in my presence?

If participant *is not* present, ask the person to explain what they understand about the purpose of their visit to the clinic. Probe on whether support for health or medication was mentioned. If disclosure has not occurred, conduct brief discussion of pregnancy support and close session (see below).

Would you tell me what [Name of Participant] told you about the purpose of this visit today?

If the participant has not disclosed and is either not present or does not wish to disclose the above, explain to the prospective omukhulupilira that this is a check in to see how the pregnancy is going. Engage them in a discussion regarding:

- Their understanding of issues the participant may be facing in their pregnancy
- If there is any way that they can help to support the participant in their pregnancy
- If there is anything the clinic can do to better support the participant in their pregnancy

Provide session overview

When HIV status and/or ART/PrEP use disclosure is confirmed, proceed:

So, as we've discussed, [Name of Participant] asked you to support her in taking [ART/PrEP]. We are calling people like you in this role "omukhulupilira."

Would you tell me a little bit about your relationship with [Name of Participant]?

How do you feel about being asked to play this role and help [Name of Participant] in this way?

Thank you for sharing. It's important to me to know your questions and concerns about being an omukhulupilira for your [family member/partner/friend], and we will take the time to address these issues over the course of our conversation today. We'll begin the session by providing you with information about [ART/PrEP], and why taking it every day as prescribed is so important. Then we'll talk about what is expected of you as an omukhulupilira, and talk about the ways that you can best support [Name of Participant]. Finally, we'll talk about what happens next after this visit, and the steps you can take between this visit and the next to support [Name of Participant].

Before we begin, are there any questions you have for me?

Discuss importance of confidentiality

Ask supporter to agree to confidentiality and allow questions before proceeding

In this session we'll be discussing [Name of Participant]'s [ART/PrEP] use and ways that you may support her to take this medication every day. It is very important that you do not share the information we discuss today with anyone besides [Name of Participant] unless she gives you permission. Specifically, it is extremely important that you do not disclose [Name of Participant]'s [if applicable: HIV status] or [ART/PrEP] to anyone else unless she says it is okay.

Sometimes, this disclosure can be accidental; you may be excited about what you learn here about [ART/PrEP] and want to share this information with others. If this is the case, it is imperative that you don't share the context in which you learned this information. That is, do not disclose that you learned this information in connection with [Name of Participant]'s care or this program.

Using [ART/PrEP] or [if applicable: living with HIV] is nothing to be ashamed of, but sharing this information with people can lead to reactions that someone may not want or may not be ready to deal with. For these reasons, it's extremely important that [Name of Participant] be able to choose if she wants to share this information with anyone else, and who to share it with.

Do you agree to keep this information confidential?

Do you have any questions about this before we move on?

2. EDUCATION ABOUT HIV AND ART/PREP

Review ART/PrEP information table

*Refer to participant education materials and procedures. Note to the participant (if present) that this will be a review for them. Examples from the Tonse Pamodzi 2 trial are included in the Appendices.

Afterwards, ask if the omukhulupilira has any questions before moving on.

3. THE ROLE OF THE OMUKHULUPILIRA

Define expectations of omukhulupilira

Now that you know about [ART/PrEP] and why it's so important to take it every day, let's talk about what you are being asked to do to support [Name of Participant]'s adherence to [ART/PrEP].

There is no one right way to support adherence to [ART/PrEP], and so you are being asked to be part of a collaborative process to find the best strategies for [Name of Participant] to maintain adherence centered around her individual needs and preferences. Because every person is different, these strategies will look different for each person. So, while we can't tell you exactly what the strategies will be, we can tell you what the basic expectations will be of you as an omukhulupilira. These are:

- *To help [Name of Participant] put into practice the adherence strategies she develops with the study counselor, and provide any other support appropriate to help her take [ART/PrEP] every day.*
- *Depending on [Name of Participant]'s needs, she may invite you to participate in up to 3 adherence counseling sessions to help her develop strategies to overcome problems she might be having with adherence.*

Seek agreement to serve in this role

I want to take this opportunity to see if you think you are able to play this role:

- *Do you think you will be able to meet with [Name of Participant] regularly outside of these sessions to provide this support?*
- *Do you think you will be able to meet with her in a private location?*
- *What types of places/times might you meet?*

Given what we've discussed, are you willing to serve as [Name of Participant]'s omukhulupilira?

Discuss importance of adherence support and common adherence barriers

The following includes additional education, to be conducted in a participatory manner. Try to engage the omukhulupilira through a series of questions and answers to better engage them in the topics covered.

First let's talk about why your support is so important to help [Name of Participant] adhere to [ART/PrEP]. Can you tell me about something that you have to do or have had to do on a daily basis that might seem simple but is actually difficult to keep doing every day?

[If participant has no ideas, prompt to think about common tasks. For example, for men, this may include finding work in order to provide for the family. For women, this may focus on cooking for the family.]

Would you tell me why it [is/was] difficult to do every day?

What do/did you do to make it easier, if anything? Did anyone help you?

As you can see just because a task might seem simple, like taking a pill, if we have to do it every day it might become difficult to maintain. Finding ways to overcome these difficulties, often with the help of family or friends, is essential to being able to complete the task every day.

While everyone is different, there are many common difficulties that people may face in being able to take [ART/PrEP] on a daily basis include [give examples from table below]*:*

Common barriers to PrEP adherence	Common barriers to ART adherence
• Disruption in routine • Dislike of medication (too big, tastes bad) • Lack privacy • Scared others will think HIV+ • Side effects • Feeling down/sad (not caring about protecting self) • Feeling not at risk • Memory or organization problems • Alcohol/drugs	• Disruption in routine • Dislike of medication (too big, tastes bad) • Lack privacy • Scared others will find out HIV+ • Side effects • Feeling down/sad (not caring about protecting health) • Memory or organization problems • Alcohol/drugs • Feel sick • Feel healthy

Now let's talk about how support from a [family member/partner/friend] like you would help someone overcome these barriers. First let's take the example of forgetting – if [Name of Participant] were having trouble remembering to take her medication on time every day, what are some things you would do to help her, or advice you would give her?

Thank you, now let's take the example of feeling sad, down, or discouraged – if [Name of Participant] were feeling this way, what are some things you would do to help her?

Allow for questions

Do you have any questions about this before we move on?

4. WAYS OF PROVIDING SUPPORT FOR PrEP/ART ADHERENCE

The right way to support someone will depend on their needs and the relationship you have with them, but it may be helpful to think through some of the basic ways you can provide meaningful support. These fall into 3 basic categories:

1) *Emotional support, or providing expression of empathy, acceptance, love, trust, or care*
2) *Instrumental support, or providing tangible aid or service*
3) *Informational support, or providing advice, suggestions, or information*

Let's talk about each of these in more detail:

Discuss emotional support and empathy

Emotional support (Expressions of empathy, acceptance, love, trust, and care)

Before we talked about one example of providing support for someone who is feeling sad, depressed, or discouraged. Can you think of any other ways of providing emotional support to help [Name of participant] maintain adherence to [ART/PrEP]? [Allow person time to respond]

Thank you for sharing that, there are a lot of ways of providing emotional support to help with adherence, but some of the most common ways include:

- *Emotional support for any source of distress*
- *Providing encouragement to take medication when the person is feeling discouraged*
- *Letting them know that you care about their health and wellbeing*

- *Letting them know that you accept them regardless of their HIV status*

Empathy

*An important principle to keep in mind when providing emotional support is **empathy**, or seeking to understand rather than judge. [Name of Participant] may share person problems and emotions with you not only as part of your existing relationship, but in your new role as omukhulupilira. When she shares these sensitive topics with you, it's important that you try to receive the information with empathy, or understanding of and sympathy for the feelings and problems that she is sharing rather than disinterest or judgement.*

- *Say for example that [Name of Participant] tells you that her husband is angry with her and has been yelling at her a lot.*
  - *Here are some examples of unhelpful ways of responding:*
    - [Disinterested] *"That happens to me all the time it's part of life, you just have to deal with it."*
    - [Judgmental] "*You must have done something to make him angry, you should be more careful in the future."*
  - *Would you tell me what is wrong with both of these responses?* [Allow person time to respond]
- *Can you think of a more positive and empathetic way of responding?* [Allow person time to respond] *Thank you for sharing that example, here are a couple of others:*
  - *I'm so sorry to hear that you're going through that. I'm here to help.*
  - *This must be really difficult, thank you for sharing with me.*

Discuss instrumental support and non-punitive support

Instrumental support (Tangible aid and service)

Before we talked about one example of providing support for someone who has difficulty remembering to take their medication every day, on time. Can you think of any other ways of providing day to day, practical support to help [Name of participant] maintain adherence to [ART/PrEP]? [Allow person time to respond]

Thank you for sharing that, there are a lot of ways of providing instrumental support to help with adherence, but some of the most common ways include:

- *Help with transport or transport money to medical appointments*
- *Help picking up prescriptions if you are their guardian*
- *Providing childcare so person can attend medical appointments*
- *Bringing someone water to take their pills with*

Non-punitive support

There are some ways of encouraging [Name of Participant]'s adherence to [ART/PrEP] that may seem like good ideas but should be avoided. Specifically, using punishments like you might use for a child to encourage [Name of Participant] to take [ART/PrEP] every day is not a good approach because it may hurt her own motivation to use [ART/PrEP] by making her feel powerless. The most extreme approaches like this, such as threatening or using physical violence, will cause much more harm than good and must be avoided. Some examples of other things not to do:

- *Saying mean or hurtful things if she does not take her medication*
- *Expressing anger or yelling*
- *Threatening to or actually withholding food or other material needs if she does not take her medication*
- *Not talking to her because she did not take her medication*

- *Asking other family members for advice or to tell her that she is wrong for not taking medication*

Discuss informational support and patient-centeredness

Informational support (Advice, suggestions, and information)

The last kind of support we'll talk about is informational support, or providing advice, suggestions, or information to help a person. One major way you can help with informational support is by participating in adherence counseling sessions with [Name of Participant] to help her think of strategies to help her take [ART/PrEP] every day and on time. Can you think of any ways that you could provide advice or suggestions to her outside of these counseling sessions that could help with her adherence? [Allow person time to respond]

Thank you for sharing that, there are a lot of ways of providing informational support to help with adherence, but some of the most common ways include:

- *Medication taking reminders*
- *Daily check-in to see if took medication*
- *Reminding the person of why it is important to them to take the medication every day*
- *Help acquiring information from clinic staff regarding medication taking between appointments*

Participant-centeredness

When you provide instrumental or informational support, always keep in mind that while we may each have our own ideas about the best way to do things, it is important that we put the needs, perspective, and opinions of [Name of Participant] before our own. While your role as omukhulupilira is to help [Name of Participant] develop strategies to be able to take [ART/PrEP] every day, and help her to carry out these strategies after the counseling sessions, it's important to allow [Name of Participant] to determine with your assistance how she wants to be helped to rather than deciding on your own how you might be most helpful.

Let's talk about one example: [Name of participant] tells you she hasn't taken her medication for the past few days.

- *Here is an example of a handling the situation that puts your ideas before hers: "That's not good, I know that taking your medication every day can be hard but what you really need to do is be sure to take your pill every day when you eat dinner so you will not forget." What's wrong with this response?* [Allow person time to respond]
- *In contrast, here's a way of supporting the person that puts their needs and ideas first: "What are the reasons that you weren't able to take your medication? I'm sorry to hear that, what do you think would make this easier? What can I do to help you?"*

Allow for questions

Do you have any questions about this before we move on? [Give the person time to respond]

5. FACILITATING INITIATION OF SUPPORT

At this point I hope you understand the basic ways that you can help [Name of participant] as an omukhulupilira. Do you have any questions for me at this point?

Plan for private meetings between omukhulupilira and participant

Meeting with participant and confidentiality

Before we talked about the importance of confidentiality, or keeping sensitive information private. Would you tell me what you remember about this? [Allow person time to respond]

Yes, it's very important to not talk about the following things to other people unless [Name of Participant] gives you permission

- *HIV status*
- *Her use of [ART/PrEP]*
- *Her and your participation in this program*
- *Discussions related to these topics*

To preserve the confidentiality of this information, it's important to think through if and how you will be able to meet with [Name of Participant] privately so you can talk about [ART/PrEP] without anyone hearing your conversation who she would not want to have hear it.

[Involve participant in discussion if present]

- *Where do you think you can meet to speak comfortably in private, so that people will not overhear?*
- *When would you be able to meet in private?*

[If participant not present]

- *How do you think you will make a plan with her for these private meetings?*
- *When will you do this?*

Develop action steps for first support discussion with participant

Having the first support conversation (if participant present)

Now that you have a meeting plan, let's talk about how you can get started supporting [Name of participant]

Desired support: [Ask of participant]

- *Do you have any initial ideas of how [Name of Supporter] could be most helpful to support your adherence to [ART/PrEP]?* [Allow person time to respond, provide suggestions if needed]
- *How have you provided support to each other in the past?*
- *How could you apply that to this situation?*

Support to offer: [Ask of Supporter]

- *What do you think are the main ways, including or in addition to those already mentioned, that you feel able to support [Name of participant]?*

Planning future check-ins: [To both]

- *Now that you have this understanding, what do you think it would be most helpful to talk about next time you are able to speak to each other comfortably about [Name of participant] taking [ART/PrEP]?*

Planning the first support conversation (if participant *not* present)

Now that you have a good idea of how and when you will meet with [Name of Participant], let's talk about how to have the first conversation about supporting her use of [ART/PrEP].

Questions to ask:

- *What questions would you ask of [Name of participant] to better understand how she would want to be supported?*
- *Those are all great ideas; which two questions do you think will be the most important for you to ask [Name of participant] first?*

Support to offer:

- *Great, these questions will help you figure out how you can best help [Name of Participant]. What are some types of support that you could offer to her during this conversation?* [Allow person time to respond, provide suggestions if needed]

Planning future check-ins:

- *Once you understand how [Name of Participant] wants to be supported, how will you decide when to talk next at a private setting and time?*

Allow for questions

Do you have any concerns about having your [first/next] conversation? [Allow person time to respond, trouble-shoot issues that arise]

6. CLOSING THE SESSION

Thank for participation

Thank you very much for coming today and for your active participation in our session today.

Allow for final questions

Before we close the session, do you have any other questions or concerns? [Allow person to ask questions and provide responses, for questions that you are unable to answer, ask for their contact information and say that you will follow-up with an answer, or you can provide the response at the next visit]

Provide contact information

Don't hesitate to contact us if you have any other questions or concerns about your role as omukhulupilira [Provide contact information]. *You can also discuss any questions or concerns if you come with [Name of Participant] to her next counseling session.*

Thank you again for your participation and for agreeing to serve as an omukhulupilira*. Please discuss with [Name of Participant] if you should attend the first counseling session on* [*date and time of scheduled appointment*]*. This decision will be based on her needs and your availability.*

ORIENTATION VISIT CHECKLIST

Date (DD/MMM/YYYY) |___|___|/|___|___|___|/|___|___|___|___| Start time ___ ___: ___ ___

Participant ID |___|___|___|___|___| Staff ID |___|___|___|

Omukhulupilira gender: □ Male □ Female

Omukhulupilira relationship with participant: _____

Participant present? □ Yes □ No

◯ **1. Introducing the counseling visit**
- □ Check in and build rapport
- □ Confirm omukhulupilira identity (if participant not present)
- □ Ascertain disclosure of HIV-status (if applicable) and ART/PrEP use
- □ Provide session overview
- □ Discuss importance of confidentiality
- □ Allow for questions

◯ **2. ART/PrEP education**
- □ Review ART/PrEP information table
- □ Allow for questions

◯ **3. Role of the omukhulupilira**
- □ Define basic expectations of omukhulupilira
- □ Seek assent to play this role
- □ Discuss importance of adherence support and common adherence barriers
- □ Allow for questions

◯ **4. Ways of providing support for PrEP/ART adherence**
- □ Discuss Emotional support, empathy
- □ Discuss Instrumental support, non-punitive support
- □ Discuss Informational support, person-centered support
- □ Allow for questions

◯ **5. Facilitating initiation of support**
- □ Plan for private meeting omukhulupilira and participant
- □ Develop action steps for first support discussion with participant
- □ Allow for questions

◯ **6. Closing session**
- □ Thank for participation
- □ Allow for final questions
- □ Provide contact information

Brief description of the mood, content, and dynamics of the session; things to remember for next visit:
_____
_____
_____
_____

End time ___ ___: ___ ___

ADHERENCE CHECK-IN VISITS (MONTHS 1 & 3)

SESSION COMPONENTS

Participants assigned to the intervention condition will have follow-up iNSC sessions during Month 1 and 3 visits. The aim of these visits is to follow up on the goals set during the previous iNSC sessions, first individually and then—if the participant is accompanied—with the omukhulupilira. During this part of the visit, participants will be asked to engage in the following four general phases of interaction:

1. Welcome
2. iNSC
3. Joint session with omukhulupilira (if accompanying participant)
4. Close session with plan for next steps

1. WELCOME

The session begins with a general welcome and an overview of the discussion.

> *Welcome and thank you for coming to this follow up visit. I look forward to hearing about how things went these past weeks! I also want to learn more about your journey on ART/PrEP.*

The intervention counselor should note whether the participant has chosen an omukhulupilira and whether this individual has accompanied her to the visit. This will help to frame the discussion in the iNSC component. The participant should also be given the option of inviting the omukhulupilira to join the counseling session following the individualized iNSC discussion.

2. iNSC

Similar to the enrollment visit, the iNSC component of the session includes two parts. The first part is a broader discussion about general well-being. The second part focuses in on use of [ART/PrEP], including challenges and facilitators of adherence. This is a direct discussion about how to achieve and maintain medication adherence. All intervention counselors will train in the conduct of iNSC, using the iNSC Workbook (see Appendix). The iNSC discussion structure is shown in the table below.

Step	Description
Introduce	Explain what you want to discuss, why, and ask permission Ask if it is okay to split the discussion into two parts -- first about general well-being and then about adherence. *Steps below will be repeated for each component.*
Review	Check in on previous goals/discussions, close and move into current experiences
Explore	Discuss socio-ecological factors that challenge or could optimize a specific behavior
Tailor	Reflect on context and experiences shared to tailor remainder of the discussion
Identify	Ask what would be needed to happen for the behavior (identified above) to be easier to handle or be more manageable
Strategize	Ask how the participant might consider addressing this need
Agree	Ask the participant if she would agree to try out one or more strategies to address the identified need
Transition / close	Move to a new topic and repeat the flow OR close the discussion

3. JOINT SESSION WITH OMUKHULUPILIRA

Participants accompanied by their omukhulupilira will be given the option of a joint session following the individualized iNSC session. This is voluntary. The purpose of this joint session is to engage the omukhulupilira in identifying and addressing challenges to medication adherence.

Participants who elect to have this joint session are asked—at the end of the iNSC session—to identify the issues they would like to discuss with their omukhulupilira in the room. These should be issues they are comfortable discussing with the omukhulupilira. This will serve as a guide for the session.

The joint session with omukhulupilira will be condensed to only three steps of the iNSC framework: review, strategize, and agree (see below). The intervention counselor encourages engagement of the omukhulupilira and ensures that he/she is given the opportunity to share observations and experiences in a manner that fosters joint problem-solving.

Step	Description
Review	Review the main issues identified by the participant for discussion regarding medication adherence
Strategize	Ask the *omukhulupilira* and participant how this issue might be addressed
Agree	Ask the *omukhulupilira* and participant if they would agree to try out one or more strategies to address the identified need

For participants who **did not** previously select an omukhulupilira, the option should be presented again.

> *Last time you were here we talked about the option to train someone to help you with your medication adherence. This person is called the omukhulupilira. Do you remember what this is?* [re-explain role if needed]
>
> *I know that last time you were here it didn't make sense to pick an omukhulupilira at that time. You still don't have to select an omukhulupilira but we want to give you the opportunity again each time you come in. Would it be okay with you if we take a few minutes now to discuss this option again to consider if you want to select an omukhulupilira today?*

If participant expresses interest in choosing an omukhulupilira, refer to **Enrollment Visit Section 3**. If permission not granted, then continue to closing the session.

4. CLOSE THE SESSION WITH PLAN FOR NEXT STEPS

Provide a summary of what was discussed, thank the participant and remind her of the next visit.

> *You noticed that [reiterate a key strategy from iNSC discussion] would really make it feel easier to work [ART/PrEP] into your life and that [reiterate a key strategy from iNSC discussion] is something that will help with that. You'll give that a try between now and the next time we meet.*
>
> *Thank you for talking with me. I look forward to talking again when you come in next time.*

ADHERENCE MAINTENANCE VISIT (MONTH 6)

SESSION COMPONENTS

The aim of this final visit is to identify new barriers to medication adherence and how to address them. It is also to summarize those strategies that have been used and provide the participant with some insights into continued engagement in this problem-solving approach.

1. Welcome
2. iNSC
3. Joint session with omukhulupilira (if accompanying participant)
4. Close session with plan for next steps

1. WELCOME

The session begins with a general welcome and an overview of the discussion.

> *Welcome and thank you for coming to this follow up visit. For this conversation together, I am hoping to spend some time getting to know how things have been going since the last visit. I also want to learn more about your journey on ART/PrEP.*

The intervention counselor should note whether the participant has chosen an omukhulupilira and whether this individual has accompanied her to the visit. This will help to frame the discussion in the iNSC component. The participant should also be given the option of inviting the omukhulupilira to join the counseling session following the individualized iNSC discussion.

2. iNSC

Similar to the enrollment visit, the iNSC component of the session includes two parts. The first part is a broader discussion about general well-being. The second part focuses in on use of [ART/PrEP], including challenges and facilitators of adherence. This is a direct discussion about how to achieve and maintain medication adherence. All intervention counselors will train in the conduct of iNSC, using the iNSC Workbook (see Appendix). The iNSC discussion structure is shown in the table below.

Step	Description
Introduce	Explain what you want to discuss, why, and ask permission Ask if it is okay to split the discussion into two parts -- first about general well-being and then about adherence. *Steps below will be repeated for each component.*
Review	Check in on previous goals/discussions, close and move into current experiences.
Explore	Discuss socio-ecological factors that challenge or could optimize a specific behavior
Tailor	Reflect on context and experiences shared to tailor remainder of the discussion
Identify	Ask what would be needed to happen for the behavior (identified above) to be easier to handle or be more manageable
Strategize	Ask how the participant might consider addressing this need
Agree	Ask the participant if she would agree to try out one or more strategies to address the identified need
Transition / close	Move to a new topic and repeat the flow OR close the discussion

3. JOINT SESSION WITH OMUKHULUPILIRA

Participants accompanied by their omukhulupilira will be given the option of a joint session following the individualized iNSC session. This is voluntary. The purpose of this joint session is to engage the omukhulupilira in identifying and addressing challenges to medication adherence.

Participants who elect to have this joint session are asked—at the end of the iNSC session—to identify the issues they would like to discuss with their omukhulupilira in the room. These should be issues they are comfortable discussing with the omukhulupilira. This will serve as a guide for the session.

The joint session with omukhulupilira will be condensed to only three steps of the iNSC framework: review, strategize, and agree (see below). The intervention counselor encourages engagement of the omukhulupilira and ensures that he/she is given the opportunity to share observations and experiences in a manner that fosters joint problem-solving.

Step	Description
Review	Review the main issues identified by the participant for discussion regarding medication adherence
Strategize	Ask the *omukhulupilira* and participant how this issue might be addressed
Agree	Ask the *omukhulupilira* and participant if they would agree to try out one or more strategies to address the identified need

4. CLOSE SESSION WITH PLAN FOR NEXT STEPS

Provide a summary of what was discussed. Remind the participant that this is the last scheduled intervention session and review the main issues identified and addressed through the counseling sessions. Discuss ways in which these could be applied for continued medication adherence following the study.

> *As you know, this is the final scheduled visit for the intervention part of this study. Through this process, you identified strategies that could improve your adherence. These include [reiterate key strategies from the iNSC discussions] that would make it feel easier to work [ART/PrEP] into your daily routine. I would encourage you to continue trying these ways to ensure that you take medicines on a daily basis.*

Discuss future steps for continuing ART/PrEP use, including transition to the standard of care. Details of this discussion and guidance will be site-specific but should include:

- For women living with HIV on ART:
  - Encourage women to discuss their perceived challenges about transitioning to standard of care and how those issues might be addressed.
  - Provide information and resources about continuing support for ART adherence as appropriate.
- For HIV-negative women on PrEP:
  - Discuss desire to use PrEP after study close, either in the immediate or future. Provide information about local PrEP resources.
  - Encourage women to discuss their perceived challenges about transitioning to standard of care PrEP services and how those issues might be addressed.
  - Provide information and resources about continuing support for PrEP adherence as appropriate.

Close by thanking them for their participation.

> *I hope your participation has been helpful. Thank you again for talking with me.*

Next Step Counseling
Integrated Next Step Counseling

AN INTERACTIVE WORKBOOK
For Tonse Pamodzi Facilitators

TONSEPAMODZI

Saidi F, *et al. BMJ Open* 2021; 11:e046032. doi: 10.1136/bmjopen-2020-046032

Contents

Using this Workbook

Welcome to the Next Step Counseling workbook. Here, we review the basic and advanced ideas underlying Next Step Counseling (NSC) and integrated Next Step Counseling (iNSC). After an introduction to what Next Step Counseling does, and doesn't do, and how it was developed, we review the communication skills needed to engage in NSC or iNSC discussions. This workbook has suggestions for trying these out in **TRY IT** spaces. Each step in NSC is then unpacked, with examples in italics and **TRY IT** opportunities. We then expand NSC to its use with multiple health-related topic areas. With integrated Next Step Counseling facilitators can engage people in conversations that include related but unique topics- like general well-being and adherence to a prescribed medication, sexual health and persistence with a given therapy, or decision making and maintaining health. We intentionally try to adopt a general explanation of the approach which can be applied to any number of health-related behaviors and strategies to promote well-being. Concrete examples are provided in the areas of HIV prevention and treatment. We encourage learners to use the workbook **EXERCISES** to adapt the approach to be most useful to their particular areas of interest. Because all person-facing approaches are highly context driven and dynamic (always changing), we provide recommendations for monitoring how NSC and iNSC is delivered and received in practice.

Learners

NSC and iNSC facilitators have to be willing and open to working with people "where they are at", which involves giving up relational power, adopting shared decision making, and doing a whole lot of listening. Depending on people's beliefs, views about their role, and views about the people they work with and for, this can be more or less challenging. In this workbook, we assume no formal training in counseling or communication. That is why we use many **TRY IT** and **EXERCISE** opportunities throughout. We **DO** however recommend that learners work with each other to refine skills and connect with NSC or iNSC facilitators who have some experience using the approach. No matter what your background is or where you are using NSC or iNSC, we believe anyone can implement parts of or the complete approach. Commitment, practice and willingness to learn are the core determinants for learning the approach.

Learning Objectives

People completing this workbook in full, including the activities, should:

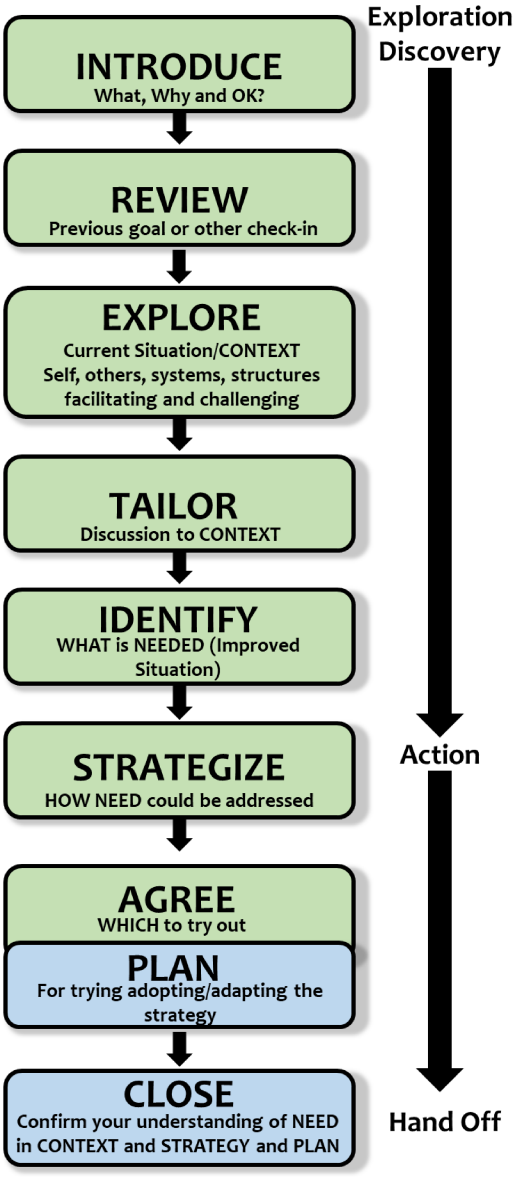
- Feel confident in their understanding of the underlying rationale for NSC and iNSC
- Be able to use basic and advanced communication skills
- Be able to facilitate NSC and iNSC discussions
- Use the self-monitoring tool
- Gather implementation feedback from people engaged with them in NSC or iNSC discussions

A NOTE ON LANGUAGE

This workbook is written in American English. We use **facilitator** to identify the person/people implementing NSC/iNSC, **learner** to identify the person/people using the workbook, and **person/people engaged** in NSC/iNSC discussions to identify those facilitators are working with (eg., participants, patients, participants, so on).

What is Next Step Counseling?

Next Step Counseling is a guided, conversational approach to engaging people in discussions about their health and wellbeing. It uses an approach where the base of the conversation is all about understanding the context in which someone is negotiating or experiencing something. As in the figure below, we do a lot of exploring before moving to action and ultimately handing things off to the person we are working with. There are 8 steps described that unpack the person's current situation and a relevant, meaningful next step. **We believe you can't engage with someone about what might improve or strengthen a situation if you don't have a shared understanding of what that situation is.**



We cannot assume someone's "next step" is aligned with what we, as health promoters, think it should be. We cannot assume the person has the same vision we have for what an "improved situation" would even look like. We need the person's opinions and insights to understand their situation and what they desire in relation to those. Genuine respect towards and valuing of each person's story is essential in NSC. You literally CANNOT do NSC without it. No matter how well-informed you are about a community, an issue, a disease, a treatment or a condition, you are **not** the expert on the person's life context. In NSC, we guide people through an exploration of their current situation in relation to some important issue. It is through that exploration that facilitators can help people to unpack important influences on their lives on specific health behaviors. We draw from theory and social determinants to help people fully appreciate that all health behaviors are heavily situated in socio-ecological contexts. Ultimately, **we facilitate identification of** what **this person's "next step" towards an improved situation** may be.

NSC uses a series of "steps" that reflect different phases of a conversation that are intended to help facilitators to build a strong, shared understanding of someone's current situation, from a socio-ecological perspective, guide people through considering their specific needs in a given situation, and consider what improving a situation may look like. Then the conversation shifts for the last few steps by focusing on that identified "need" to brainstorm possibly strategies that could be appropriate in making the desired improvement and action planning around trying out one of those strategies.

So, **NSC is** really just **a format to having a person-facing, strengths-based**, health-promoting **discussion that is specific to someone's lived experiences and** the **context** in which that health-promoting issue is actually negotiated **and what that person is** hoping, willing and **interested in trying out to improve some aspect** of **that experience**/context **that is meaningful and relevant to them**.

How is it any different than other kinds of health-related discussions?

NSC should share a number of similarities with patient-centered, strengths-based counseling, and draws heavily from the tenets of Motivational Interviewing (MI) and some of the strategies used in MI. Basic and advanced communication skills are also part of NSC. Exploring barriers and coming up with strategies to address those is common in many brief counseling approaches. NSC is unique from some approaches that prescribe specific content. NSC is a process approach, a format to a conversation and, as such, can be applied to any number of issues or areas. While we see considerable synergies with other approaches, we feel the following have been identified by practitioners and learners as offering specific value:

(1) **Supports flexibility in discussions**- the process of exploration to something more concrete like a specific strategy or action plan is recommended, but what that looks like, skills you may use, communication styles, and content, are all tailored to the person.

(2) **Supports use and dissemination of theory**- Exploration draws on the Socio-ecological model and the situated Information, Motivation, Behavioral Skills model and aspects of Motivational Interviewing concepts and skills are used in training facilitators and can also be explicitly shared with the people they engage during exploration and strategizing.

(3) **Shares power with people engaged-** Conversational power and a person's autonomy feature prominently in the approach and are highlighted as reasons for a number of the steps, including the identification of a "next step"

(4) **Emphasizes that people engaged can and do come up with their own needs, strategies and plans-** Facilitators "hold-back" on recommending courses of action, preferring to guide people towards their own identification of needs, strategies and plans

(5) **Works specifically with "needs" not barriers-** Facilitators help people to identify one or more need- an underlying condition that facilitates or even drives a downstream behavior.

(6) **Is a guided conversation versus message delivery or providing "counsel"-** Facilitators talk with people. There is an exchange of information and expertise. Power is shared in this regard. Counsel (telling someone what they should do) is not part of the approach.

(7) **Acknowledges limits of discussion-based person-facing approach-** NSC depends on open engaged communication. If people do not want to share or want to share only parts of their realities or experiences, that is their decision and we cannot force people to be open, or engaged or even honest. We rely on the person to share- so creating welcoming and conducive environment for this is our first job and responsibility. We cannot, however, control whether or not people want to use those environments. The level at which someone engages in up to them. We do not know the truth of someone's experiences, only what they decide to share.

Saidi F, *et al. BMJ Open* 2021; 11:e046032. doi: 10.1136/bmjopen-2020-046032

What does NSC sound like?

Below is an example NSC discussion about a person's HIV medication adherence.

I would like to spend a little time talking with you specifically about your experiences with your HIV meds. Is that OK?

You have been prescribed these medications for a while. How would you describe your experiences trying to take them?

What would you say are the main things, situations, ways you think or feel that have helped you stick with your meds?

What are the things, situations, times or ways you think or feel that make it hard to do?

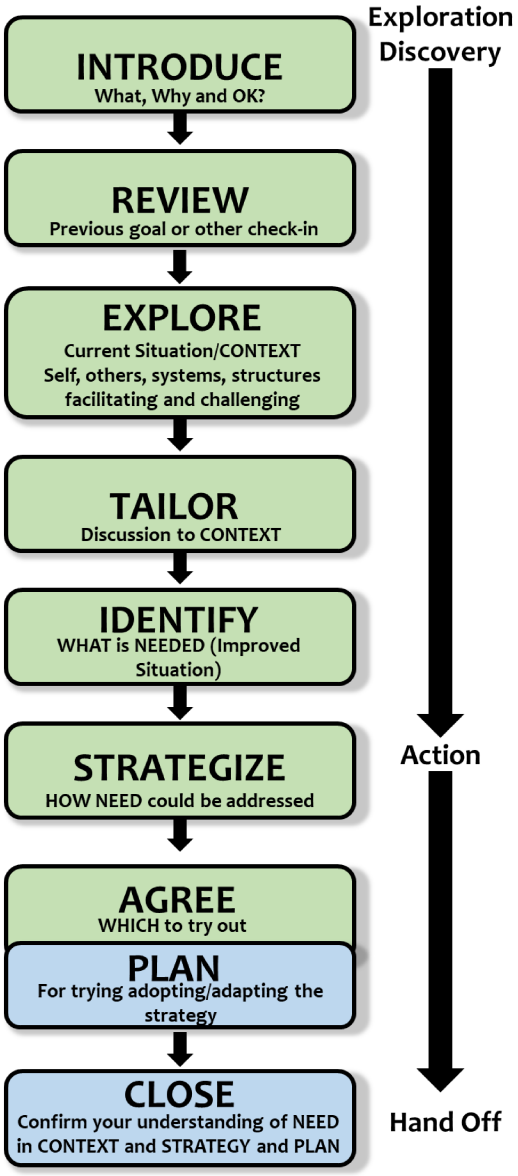
Thinking about that, what would need to happen for it to feel just a little easier or more manageable to take your meds, given [CONTEXT]*?*

How could you see that actually happening?

Would you be willing to try any of those out?

What would that plan look like?

You said that taking your medications would be easier when [CONTEXT] if [NEED] could be addressed, which you think maybe [STRATEGY] could do. You are going to [PLAN] between now and the next time we meet. Does that sound right? Thank you. I look forward to checking in with you on that.



What is person-facing anyway?

You may have noticed that we have used this phrase a few times now- "person-facing". We do not mean patient centered- that is an important kind of service provision that places the patient in the center of care delivery. When we say person-facing, we literally mean "facing the person" you are engaging. It is an approach that explicitly considers how messages, services, communication and structures are ***received*** and ***experienced*** by the person/people they reach. We may have learned there are common barriers or helpful strategies at a community or population level—so we deliver messages about them just in case they might be relevant. They may or may not be. The risk, however, is that when the message misses the mark, we end up communicating that we don't know someone's actual story. We don't 'see' the person. We may see the disease, the therapy, the epidemiology and outcomes, but not so much the person.

Have you hear people say- *I feel you, I hear you, I see you*. Feeling heard and understood have deep value. Think of the absence of these- *I don't feel you, I don't hear you, I don't see you.* Definitely **not** the feelings that most of us would want to create.

Go ahead and **TRY IT**- try experiencing these messages. How person-facing are they? Do they connect with the person's lived experience in a meaning way? If the situation of the receiver was appreciated, would the communication change? How?

If you are person-facing, you are **mindful to tailor your communication to the needs and issues that are relevant and germane to the person** or people you are engaging. You recognize the value of the person and their autonomy in making health related decisions. That doesn't mean you don't have an agenda- You do! But you appreciate that you are joining someone on *their* exploration- a guest or guide.

TRY IT
Person-Facing Engagement

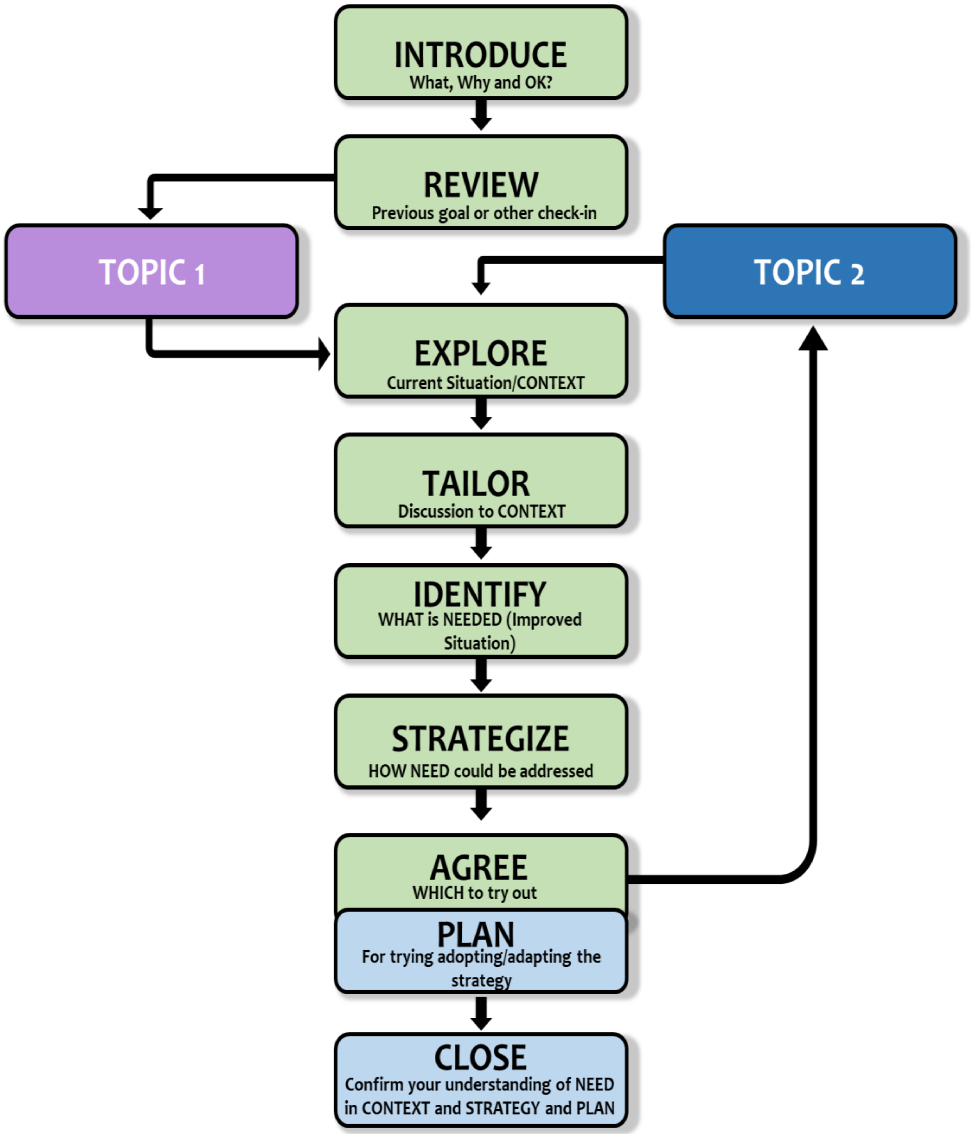
Consider the communications below delivered to someone (the receiver of the communication) in the different situations presented. These are not "bad" or uncommon messages but may not be person-facing. Consider how the communication may be interpreted by the receiver. What is implied by the information or request? What is the underlying message conveyed? Does that "fit" the situation, engage the receiver or create feelings of being seen and heard? Why and why not?

Communicator	Receiver (person)
"Anyone can be healthy"	• Has struggled to be healthy and feels considerable shame over it • Has worked hard to become healthy and feels successful and motivated
"Let's talk about reasons you are not taking you medicine every day."	• Is concerned about rumors in the community about medications being poison and prescribers getting money for prescribing them • Husband recently became angry and violent over use of the medicine
"Tell me about your sexual history. When did you last have an STI?"	• Sexual trauma survivor • Sex educator in the community- very knowledgeable about STIs and related risks • Is struggling with sexual identity
"You must use condoms each time."	• Does use condoms "each time" • Does not use condoms at all • Wants to use condoms but partner will not
"Checking blood sugar levels is very serious."	• Very serious about checking blood sugar and does so regularly • Teaches others in the community how to check blood sugar

Saidi F, *et al. BMJ Open* 2021; 11:e046032. doi: 10.1136/bmjopen-2020-046032

What is integrated Next Step Counseling?

Often, facilitators are in a situation where they are hoping to speak with someone about two or more related but unique health-topics. They are related in some important way- maybe they relate to one another, one facilitates the other, or each contributes to some larger outcome. They are unique in important ways- maybe they involve very different behaviors, strategies or goals.



Consider medication adherence and management of stigma for people on TB treatment; adjustment and wellbeing while living with HIV and engagement in medical care; well-being in gender minority youth and HIV testing; diet and exercise; attending antenatal care and self-care; so on. These are all related topics and likely draw on the same kinds of motivation but often involve very different skill sets, barriers, resource, navigation and strategies.

iNSC was developed to facilitate discussions that recognize the inter-relatedness while also separating the topics into their own NSC discussions. We originally developed this for people on Pre-Exposure Prophylaxis (PrEP) to have a combined conversation about sexual health and wellness more generally (all things not including PrEP) and then looping into a conversation focused specifically on PrEP fit, adherence and continuity. Each topic has the features of NSC through to planning and the final plan contains a review of needs in each topic, all of the strategies selected, and a master plan for actioning these between the current and next session. Before we go into iNSC, we will cover NSC and then consider expansions of it.

Models Underlying NSC

Why do health behaviors happen at all, ever, especially when they are hard to do? We all have working models (our own sets of beliefs and assumptions) about the causes, supports and challenges to health promoting decisions, behaviors and life-styles. Before we get into how NSC looks at this, take a minute to unpack your working model. **TRY IT**. You can go back to it later to see if it still fits after mastering some of the NSC approach.

TRY IT
What is your working model?

For the health related topic you work with most closely, what do you think CAUSES the behavior or outcome? What things FACILITATE those? What things CHALLENGE those?

TOPIC?	HOW THEY WORK TOWARDS SOME OUTCOME
CAUSES (DRIVERS)	
HELPERS (Facilitators)	
HINDERERS (Challenges)	

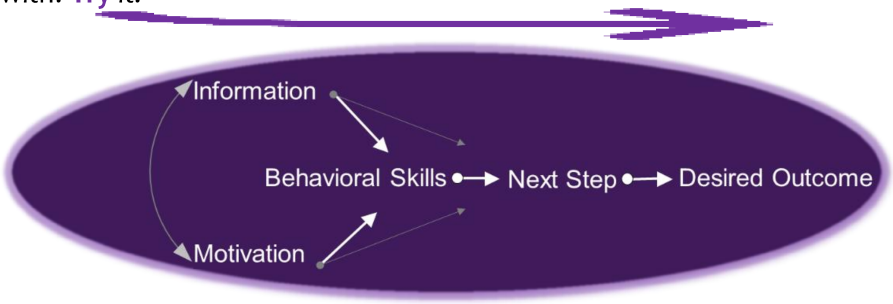
Think of a case where the outcome is reached. How did the person do it or get there? Think of a case when the outcome is NOT reached. What happened?

CASE SCENARIO

CASE: Successfully reached outcome	
CASE: Did not reach outcomes	

Given the case, would you change your model? Did it explain things well?

NSC draws from a number of models. We use the Information Motivation Behavioral Skills model situated to the socio-ecological context in which someone would have to negotiate, sustain or avoid any given health behavior. This situated IMB model assumes that being well informed, socially and personally motivated and in possession of required skills drives reaching someone's next step. The next step is what the person identifies as important to making progress towards some desired outcome. In thinking about your particular area, can you identify what some 'next steps' might be for people you work with? **Try** it.



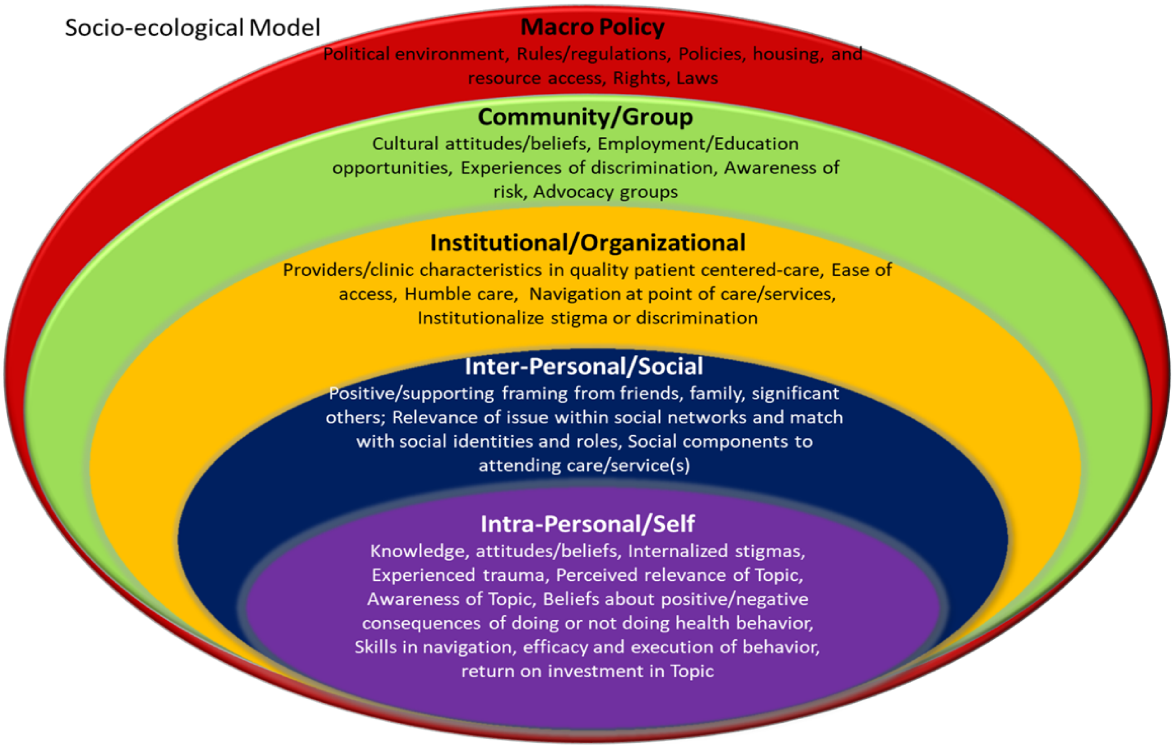
TRY IT
Given your health area, describe the smaller steps it takes for someone to go from a current to an ideal situation.

IDEAL SITUATION

CURRENT SITUATION

We unpack factors influencing progress or maintenance of whatever the 'next step' may be for a person- a step towards some important but more distant goal. When thinking about the kinds of knowledge, motivation and skills needed, we position them in reference to a socio-ecological perspective of lived experiences.

That means that most, if not all, next steps exist in a context of multiple and interacting influences that range from personal to what may feel like distant 'macro' factors.



We also draw from Motivational Interviewing when considering not only a next step but also in the way in which we try to engage people in discussions. A next step represents some form of movement or momentum on a journey from a current situation to one that is more desired, improved or "better" from the perspective of the person we are working with. That is very similar to MI's 'change talk' where discourse suggesting a discrepancy between now and where someone would like to be forms an important area of exploration.

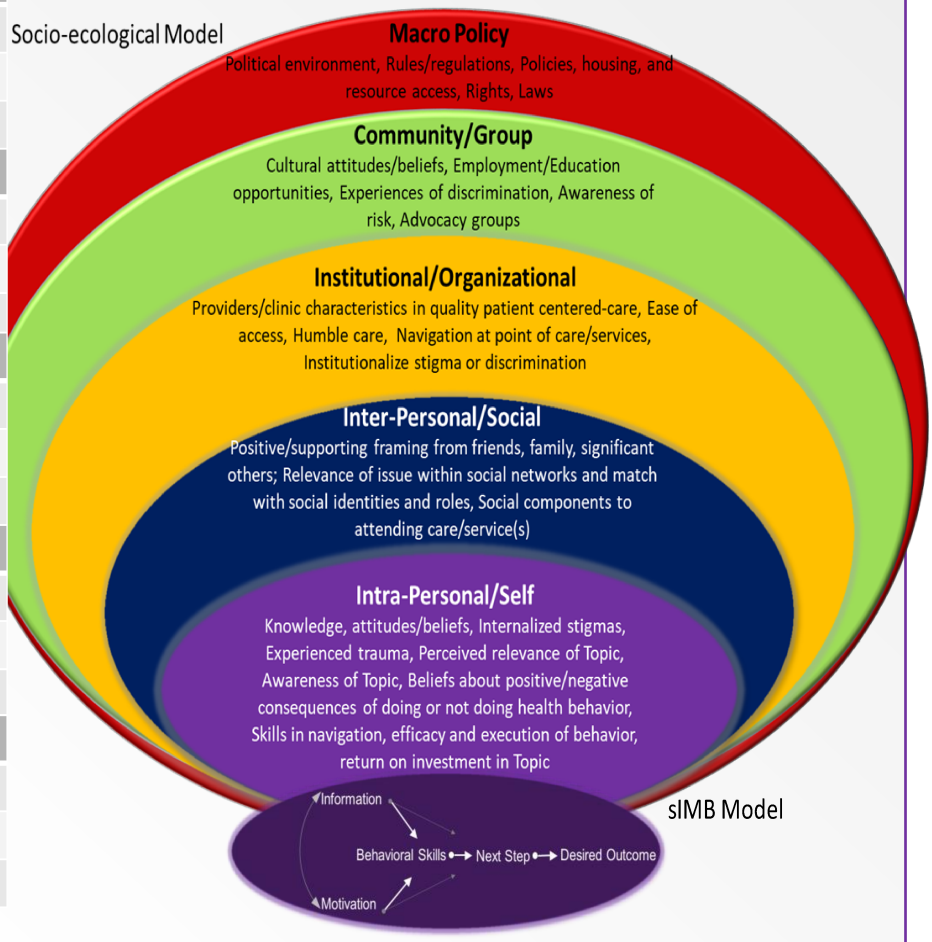
After reviewing these models, return to your TRY IT working model. Now how would you describe the topic you work in? Did you identify factors at all of the levels? Did you consider how knowledge, motivation and skills? Did you consider the series of steps that may get someone from present to a desired situation? In your cases, did you think about what the person desired as an outcome? Take another **TRY** and challenge yourself to unpack all aspects of factors that drive and influence that outcome.

TRY IT

Expand your working model?

Thinking about information, motivation and skills, situated to a socio-ecological framework, complete the table below with factors, situations, relationships and other influencers of the health behavior or outcome.

Influential Factors



Facilitation Skills

Before getting into the steps of NSC, we want to take a short look at different skills people can use to facilitate discussions. NSC is dialogue-based. You can have the most comprehensive working models and appreciation for where someone is at and still struggle with creating an engaging, genuine, person-facing conversation. Look over each of the different kinds of strategies and techniques used in a number of different counseling and communication models below. Read over each and give them a try. We recommend considering the use of each of these where appropriate as you implement NSC.

Active listening Active Listening refers to the facilitator's ability to communicate listening through eye contact, facial expressions and other forms of non-verbal communication. • Sitting in a relaxed posture, leaning forward occasionally, and using natural hand and arm movements that are responsive and encouraging. • Be aware of the participant's non-verbal communications, non-verbal cues are important forms of communication.	**Open-ended questions** Open-ended questions are not easily answered with a one-word response ("yes" or "no"). • Open-ended questions invite further discussion and help to build rapport and trust. • What the facilitator asks and how it is asked can demonstrate positive regard for the participant and interest in knowing how the participant feels. • Example: *"What has your experience been like at this clinic?"* versus *"Do you like this clinic?"*
Summarizing Summarizing refers to highlighting the most important aspects of the discussion – this can occur topic to topic and at the end of a session. • Summarizing often will touch on one's context (situation), needs, strategies, and goals. • This is an important way of modeling and empowering problem-solving.	**Pausing** Pausing provides opportunities for participants and facilitators to digest material and to make room for feelings or thoughts to emerge. • Allowing silence to happen is a sign of respect for the power of the participant's thoughts and feelings. • Sometimes the facilitator's discomfort with silence can interrupt the participant's process.
Process Comments Process comments are observations the facilitator makes about what is going on in the session. The comment may be about the exchange, discussion, or the process of communication between the facilitator and participant. Process comments are typically followed with a question about the observation. • If the participant suddenly crossed his arms and looked away, you could ask, "Your body looks tense right now, I'd like to take a moment and check in with you . . . How are you feeling right now?" • When a discussion feels "stuck," consider whether or not there is a process comment that might help to move the discussion forward.	**Third-personing** Third-personing refers to a facilitator noting what "others" have done, experienced, or found helpful in similar situations. The facilitator refers to someone outside the session as a way to normalize the participant's experiences. • When third-personing, explain you've worked with other people in the participant's situation and request permission to share more. • "I have worked with a few people struggling with this, and they have found some interesting approaches to deal with it. Obviously, everyone is different, but would you be interested in hearing about what worked for them?"
Reframing Reframing refers to offering an alternative way of looking at something that the participant has just said, usually one that is more constructive and positive. • A participant might say, *"I get so frustrated with myself because I often miss my HIV-medications on the weekends."* The facilitator may reframe this by saying, *"Which means that, you often remember your medications, especially during the week."*	**Roll with Resistance** This Motivational Interviewing strategy avoids persuading or correcting participant communication that reveals thoughts, beliefs or reasons NOT to change or adopt a healthy behavior. • Facilitators go with the content and direction of the participant • Facilitators avoids a situation where the participant must defend their reasons not to change or not consider change.

Facilitators use skills and approaches that make NSC/iNSC...

- **Client-Centered**
  - The person is the expert on her life and behaviors.
- **Comprehensive (Multi- targeted)**
  - Providing accurate information is necessary but insufficient to produce behavior change or promote engagement in discussions about product use. Motivation (personal and social) and skills are also critical to help produce change.
- **Context-Driven**
  - The session explores the context in which one negotiates next-steps. It is not focused on 'failure' events (e.g., times when the person did not exercise, did not dose, or did not show up to care) or on the identification of barriers (e.g., attributions or reasons for failures). The focus is on the aspects of a topic that contextualize one's experiences with it which can elicit the identification of some needs people may have that when addressed could move the person from their present to an improved situation through some identified strategy.
- **Genuine**
  - The facilitator maintains a genuine interest in the person and reflects that interest through exploration of the person's experiences. Facilitators seek to remain aware of their bias and judgments and seek to be responsive to the person and their engagement in the conversation.
- **Guided**
  - The facilitator guides the discussion through questioning, and *does not* do most of the 'talking'. The person should have the majority of 'talk time' in any given session.

- **Individualized**
  - The discussion is individually tailored to the levels of engagement and context of a given person at a given point in time.
- **Neutral (In Stance)**
  - The facilitator maintains a supportive but neutral stance throughout the session to convey acceptance of both the person and their disclosures of positive and negative aspects around adopting or trying to adopt certain behaviors.
- **Recognizes Limited Role**
  - The facilitator recognizes that their impact is in the immediate session and that they cannot "make" people do anything. They can, however, ensure that a safe environment is consistently provided for people to engage and discuss their experiences.
- **Strengths Based**
  - Discussions about experiences, needs and strategies are appropriate across the full spectrum of behavior adoption. Someone need not have challenges for the discussion to proceed. The conversation is flexible to promoting behavior change or promoting maintenance of an established strategy/strategies.

The Mindful Facilitator

One of the most important skills is to become aware of yourself… your reasons for asking participants specific questions, your body language, your expectations and biases, and your 'session planning'. Often, we engage in a process- it is not one question and one answer (that is assessment or interviewing). Asking a question, reflecting or summarizing should have a reason in your mind. Take your time. Think about why you would go some particular direction in a conversation rather than other directions. Watch yourself and ask others to watch you. Being mindful of your own processes, as well as the participants, distinguishes good from excellent facilitators.

NSC Overview

At the most basic level, NSC is a facilitated discussion that explores experiences, identifies needs, strategized on meeting needs, and agrees on an actionable goal. Each part listed below is generally structured as an exploration, guiding participants towards identifying specific needs, generating strategies that help to address those needs, and narrowing in on a strategy or strategies that the participant identifies as feasible, relevant, and worthwhile to try out (the Next Step on someone's journey).

Next Step Counseling STEP BY STEP

Each step or phase of an NSC conversation is unpacked. For each, we recommend first reading about the purpose or point of the step, each has a goal. Then look over some wording examples and what the intentions for the phase of the discussion ARE (IS intended to be) and ARE NOT (IS NOT intended to be). We suggest reading through and saying aloud the first few steps before stopping to practice. Look for the **TRY IT** boxes. Use the notes area to mark down your observations and experiences. We present each step generically, and offer examples of them in general and specific to different health topics/areas.

Get ready to see these words a lot as we go through the NSC steps

Current Situation

- Where someone is at with a given topic/health behavior. Place on a continuum and/or "stage of change". How they would describe their current thoughts and feelings about something.

Next-step

- Where someone is willing to consider moving to relative to their current situation- what a slightly improved situation might look like? A situation that is a little further on a continuum or stage of readiness for change. at with a given topic/health behavior. Place on a continuum and/or "stage of change". Given their current situation, the next step is the situation that is slightly changed to be a little better, easier, or manageable, or a good situation that is largely sustained.

Need

- Given the current situation and the next-step, this is the persons assessment of what would need to be different anywhere in the IMB model situated in the socio-ecological framework for movement from current next-step to be made.

Strategy

- Given the current situation, next-step, and the need that, if addressed, can free someone up to move from here to there, HOW will movement be made? What strategy is used to actually move forward? What will the action be? A strategy is something you do or someone does. A need is why you would do it in the first place.

STEP 1: INTRODUCE [Frame] . . . the discussion.

Goal: Invite the person (people) to join a discussion about a specific topic and ask for permission to continue.

Share what you would like to do and discussion and ask if that is OK with the person. Doing so creates an opportunity to share power and balance the discussion that could otherwise unfold more like a teacher-student dynamic, where you are the teacher. By being transparent about your "ask" and allowing someone to determine if it goes further, you are intentionally proving some correction to the imbalance.

I am hoping to take a few minutes to talk with you about your experiences with HIV medications. Is that OK?

Can we take a few minutes to talk about how it has been managing you blood sugar?

Every time you come in, I will be checking in with you about how things are going with your sexual health. Is that OK?

Critical Components
Explain what you hope to talk about
Ask permission

IS intended to be
- ✓ A sincere invitation
- ✓ An opening toa frank conversation
- ✓ An opportunity for people to exercise choice
- ✓ Genuine

IS NOT intended to be
- × A long explanation
- × A directive or instruction
- × Reading from a sheet
- × Non-responsive (people can say "no")

NOTES:

STEP 2: REVIEW . . . Anything to check in on? Information or education from other people they have met with today, experiences with 'counseling', or past goals from previous sessions? If no, skip this step.

Goal: An opportunity for "checking in" on goals set at last session (where appropriate). Also can be used to check in on the person's experiences with counseling in the topic area, looking for things that helped and things that did not, checking in on information or education they have received thus far or on how their clinic and center visit has been so far. If NSC is part of a larger conversation and these check-ins are redundant, it is OK to skip this for the first session as there are no specific goals to review.

Thank you. Can we first talk a little about how things have gone for you so far today?

You have already talked with a few people about how and when to take medications. Do you have any questions that did not get answered or concerns that you want to address?

Last time we talked, you said you needed [need] *and you were going to try* [strategy]. *How did that go?*

This is a **brief** check in. The facilitator should transition from this check to exploring the participant's current situation rather than using this to determine today's conversation.

Thanks for sharing that. I want to switch to talking about how things are going with [TOPIC] *as you are feeling about it now. OK?*

Critical Components

Check-in on goal(s) from previous session. Can be used to check-in on other things if appropriate. Can be skipped.

IS intended to

- ✓ Distinguish this discussion as separate from other exchanges or experiences the person may have had at clinic or center prior to NSC
- ✓ Provide assurance that this is a safe place to discuss feelings, behaviors, and concerns
- ✓ Check in on progress and experiences from last session (where appropriate)

IS NOT intended to

- × Be long or overly detailed
- × An evaluation of success or failure

NOTES:

STEP 3: EXPLORE . . . the context of the person's current situation, facilitators and barriers.

Goal: Ask about the person's current situation/context surrounding the health topic. This will require establishing that the person is the expert on their behaviors, thoughts, and feelings. The exploration will include facilitators and barriers to the desired health behavior, but first you need a shared understanding of where someone is at with that. Different people can be in different phases and stages and working on a "next-step" needs to be in relation to that. Having this discussion will lead to a shared understanding of the context in which the participant is navigating.

Tell me about the times, situations, thoughts, or feelings that make self-care feel easy or manageable.

Tell me about the times, situations, thoughts and feelings, or people you're around that makes taking your medications harder.

This exploration is meant to touch on the layers and nuance of the participant's experience. There are often many things that aid and distract from achieving a desired health behavior – these are experienced as internal and external facilitators and barriers. Recall the IMB model situated in within and across those socio-ecological levels? THAT is that you are getting at through exploring.

When you are finished exploring **summarize** the participants concerns

Critical Components

The participant is the expert on their behaviors, thoughts, and feelings. Help them explore multiple layers and levels of influencers and barriers

IS intended to

- ✓ Build a shared understanding of the natural, realistic context in which this participant approaches adherence
- ✓ Explores from a socio-ecological perspective
- ✓ Delays action to model mindfulness

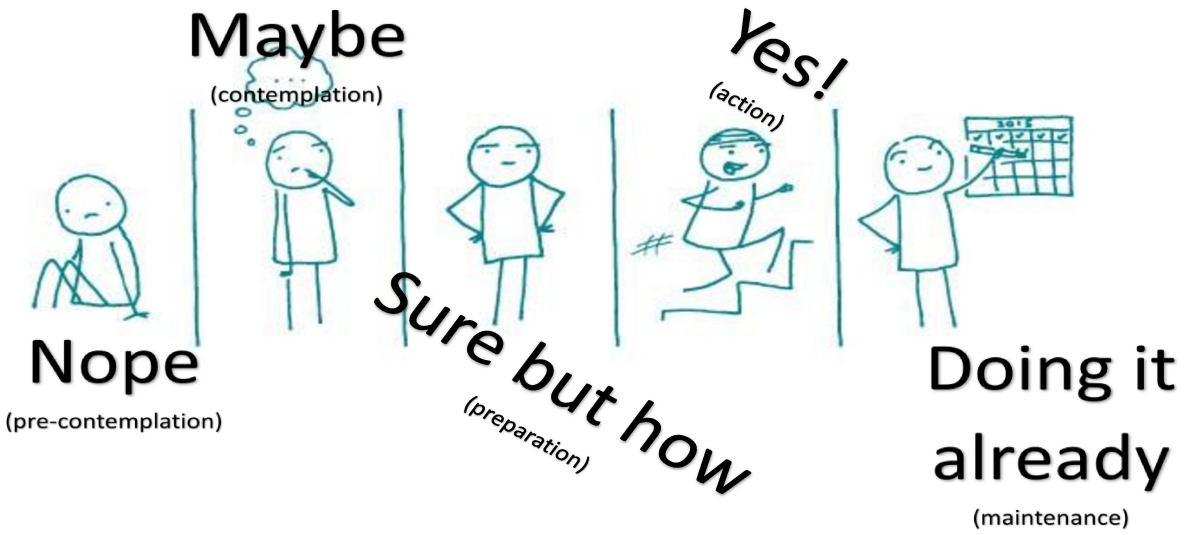
IS NOT intended to

- × Identify barriers to "fix"
- × Focus exclusively on barriers

NOTES:

CURRENT SITUATION?

Depending on the topic you are discussing, there may be stages and phases to consider. When Motivational Interviewing was first developed, there was an emphasis on considering Stage of Change, from a model called the Transtheoretical Model. The basic idea is that different people are in different places when it comes to behavior change and the same person can go back and forth in these stages at different times.



To add a bit more complexity, many health-related outcomes, like suppressed viral load, low A1C, good asthma control, prevention of malaria, HIV prevention through PrEP, are the result of a series of accomplishments or stages on a continuum. The HIV-care continuum below is one way of thinking about where someone may be at (their "situation" in our approach) on the journey to suppressed viral load. A NSC facilitator would want to gain an understanding from the person about where they

Continuum of Engagement in HIV Care

Not in Care ⟷ Fully Engaged					
Unaware of HIV infection	Aware of HIV infection (not in care)	Receiving some medical care but not HIV care	Entered HIV care but lost to follow-up	Cyclical or intermittent user of HIV care	Fully engaged in HIV medical care

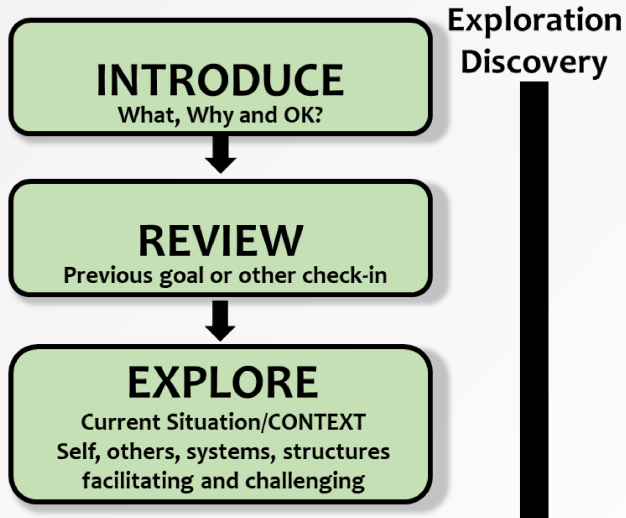
are in this continuum (current place on the continuum) and how they are feeling about their movement towards the next phase (current place on "stage of change"). By the completion of NSC EXPLORE, a facilitator should have a good, shared understanding of these factors.

TRY IT

Try this exercise. DO NOT move on to strategies or actions or ask your role play partner to do or change ANYTHING yet!! This is just about getting permission and exploring.

TRY IT

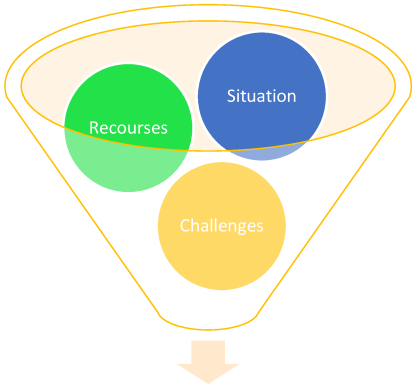
Get into pairs. Your partner should role play a person you realistically could be working with and you are a facilitator. Decide with your partner if you are going to check in on something at REVIEW. If not, go right to EXPLORE.



What is the issue you discussed?
Did you explain what you wanted to discuss and why?
Did you ask permission to continue?
For this person, what was the context they shared?
What kinds of things, feelings, situations, relationships, structures (so on) were shared as FACILITATORS for this health behavior or issue?
What kinds of things, feelings, situations, relationships, structures (so on) were shared as FACILITATORS for this health behavior or issue?
What are you ***thinking*** presently about in terms of the most relevant or meaningful aspect of their situation that may be open to change? Don't move to change! Just be mindful of it.

STEP 4: TAILOR . . . . . take a moment to specifically think about the discussion and how to guide it towards identifying an important need.

Goal: Leveraging your judgment, tailor the remainder of the conversation on this participant's experiences with, and context of achieving or maintaining the health behavior or improvement to a current situation. This step is internal to the facilitator, and does not include dialogue with the participant. Rather, this step is a check point for facilitator to survey the interaction and prepare their approach for the next step.



What would need to happen for...

Critical Components
Reflect on the conversation thus far

IS intended to
- ✓ Promote person-facing direction to conversation
- ✓ Promote flexibility and responsiveness of approach

IS NOT intended to
- × Focus the discussion on one particular barrier or skill
- × Find ways to 'make' participants do a desired behavior more often or more regularly

TRY IT
For the conversation you just had using the first 3 steps of NSC, reflect on your understanding of the person's current situation, what they found helpful and what they found challenging. Think of a few different **TAILORED** ways you could ask about someone's **needs**- for improvement to a situation going poorly or sustaining a situation that is working well. Try to think about possible manageable next-steps given what you have learned about this person. Remember- different people will be in different places when it comes to reaching a health related outcome. You want to stay focused on changes or improvements that are relevant (shared as important) and close enough to where someone is now for the changed situation to feel possible.

NOTES:

STEP 5: IDENTIFY . . . work with the person to identify their *need* – inquire, reframe, or reflect on *WHAT* this person feels they need to change or maintain their situation

Goal: Work with person to identify (name) the underlying or core ***need*** when it comes to their health goals the context of their life. Help to consider what would need to be different from any or several of the socio-ecological levels for the health behavior or outcome to be a little more manageable. While the facilitator provides the specific context (reflecting back the situation, strengths and challenges the person just shared) it is up to the person to tell the facilitator what they envision needing.

Thinking about [reflect back the content/situation shared], ***what would need to happen for*** *it to feel just a little easier to* [manageable improvement, shared challenge, your understanding of a small 'next step']?

Thinking about your desire to reduce the anxiety you feel around going to clinic, ***what could you envision happening or being different*** *in that situation that would make it even a little bit more manageable?*

Critical Components
Identify relevant needs that the person believes would help to make the health behavior or outcome feel more manageable or approachable (or sustainable) in their specific life-space.

IS intended to
- ✓ Promote mindful reflection
- ✓ Acknowledge and support self-care
- ✓ Promote appreciation of health in context and in relation to multiple levels

IS NOT intended to
- × Fix or strategize on reported barriers

Keep moving through to Step 6 before trying this one out. It is important to understand the difference between helping someone narrow down on a "need" and helping someone consider actual things that may help to satisfy or address a need. Things you do to address a need are strategies. The reason you do any strategy should be because it helps with some specific need. Keep going and this will become clearer over the next few pages.

NOTES:

STEP 6: STRATEGIZE . . . with the person on *HOW* the need could be addressed, met, or further supported

Goal: Identify HOW the person might see that need addressed, worked on, improved, so on. Try to encourage brainstorming around meeting a need for those who are working towards an improved situation. If the person feels that their situation is good and their needs are well-met, just summarize your understanding of that. To promote maintenance of successful approaches ask the participant how they can maintain motivation for the strategy (or strategies) and to identify any foreseeable threats to the effectiveness of the strategy (or strategies). Now is when we get to engage in exploring actual strategies! It is OK for you to suggest or offer strategies (we recommend doing that with asking permission and framing these as options others have considered) but give the person the opportunity to come up with their own first.

So you've identified that in order to take your medications, you need to feel like you can manage your time better. How can you see that actually happening?

For you to feel really motivated towards showing up for your care visit when your family is visiting, you said you need to prioritize your own needs a little more. How could you see that happening? Are there times in the past where you were able to do that? What did that look like?

I have talked with a few other people in a similar situation. Can I share some of the ideas they had with you?

Critical Components

Promote the participant's identification of things they can consider doing
Encourage brainstorming
Remain neutral and supportive

IS intended to

- ✓ Link health needs to behaviors or actions (strategies) that help address the need(s)
- ✓ Move the conversation towards action
- ✓ Offer those who cannot identify a fitting strategy to remain open to continuing the exploration on their own in between visits

IS NOT intended to

- × Create new strategies when one or more strategies are already working well for someone's specific needs
- × Become uncomfortable for the facilitator or participant- it is not an inquisition
- × Force a strategy on a participant

NOTES:

The Difference between Needs and Strategies
Steps 5 and 6

Steps 5 and 6 can be confusing. The difference between ***WHAT*** someone **needs** to make a health behavior feel as easy/manageable as possible and ***HOW*** someone can see themselves addressing that need can be difficult to separate.

When you ask what is needed and the person tells you they **NEED** to do this or that (basically, they are giving you a strategy not a need), you want to clarify the need underlying the action.

- *You say that you need to take your meds at lunch for it to feel easy, but can you help me to understand what taking it at lunch does for you? Does it help you remember when to take it? Does it help with not feeling stomach-sick? Is it a time when you have privacy? What does that strategy do for you?*
- *You said that you need support from your partner to exercise. Just curious… is that because you're more likely to exercise with someone else, because your partner already has an exercise routine, or because of something else?*

When needs are identified, behaviors that can feel overwhelming and complicated can feel more manageable. Things people do or don't do (actions and strategies) should have roots in what someone needs. If something you do does not address something you need, then it probably is not really helping much.

Need	**Strategy**
What must happen for the person to incorporate a health behavior into their life	*Strategies are things people do to achieve a desired health behavior*
I need support from my partner to exercise more often	*I will ask my partner to invite me to the gym with them*
I need to be calm to take my medicine	*I will take my medicine at lunch*
I need to have access healthy foods when I come home from work	*I will go grocery shopping on Sundays*

STEP 7: AGREE ON. . . WHICH strategy (strategies) discussed the person is willing to try or continue with between now and the next time you meet. Explore the ACTION PLAN for how that strategy will be executed.

Goal: Move from brainstorming hypothetical or possible strategies to address a relevant need into an executable, accomplishable goal – a strategy or strategies to try, continue with, or consider doing between now and the next time you meet. Promote the person's identification of what seems most reasonable to commit to doing. This may include maintaining a strategy the person uses now that is working well, adopting a new strategy, considering something different, or continuing to explore strategies.

Acknowledge that making an agreement together does not take away from or underestimate the fact that this is the person's choice, their health, their efforts, and their commitment. You will be handing off the process to the person after this. Whether or not they do something will be up to them. The agreement is simply a tentative agreement. Make sure you check in on how they will implement the goal.

It can be useful as well to ask how they will know if the strategy was helpful? This is especially the case when there will be a good amount of time before you see the person again. Help them consider what to do if the strategy works well and what they will do if they try it and it does not help. That will build capacity for them to do the same kind of exploration and thinking you just did with them on their own.

Of the ideas we just talked about, is there one that you would be willing to try before we meet again? What needs to be in place to do that?

How will you know if that worked for you?
What will you do if it does work well? What about if you try it and it just wasn't what you wanted?

Critical Components
The person determines the plan
Make a verbal agreement
Explore possible outcomes

IS intended to
- ✓ Promote an extension of the discussion, which prioritizes the participant and their context, experiences, and problem solving
- ✓ The participant agrees to a concrete action/strategy that continues to prioritize their health

IS NOT intended to
- × Take away from the recognition that the person is a free agent- making an agreement with you should not undermine his or her feeling of ownership or autonomy

NOTES:

STEP 8: CLOSE

Goal: To close the conversation summarize your discussion and the plan, thank the person for engaging with you, and confirm that they are all set.

After the person leaves, complete the necessary end of session documentation.

Thank you so much for engaging in this conversation! From what we talked about, you mentioned that [**reflect resources**] *is helpful and* [**reflect challenges**] *get in the way when you consider* [**reflect specific situation and next-step change to it**] *but also thought that* [**NEED**] *would make that a little easier. In the past you found* [brainstormed **STRATEGIES**] *to work with* [**NEED**] *so you are going to try* [selected **STRATEGY**]. *You'll check in with whether or not it helped by* [monitoring and adapting as needed]. *Does that sound about right?*

Critical Components
Review discussion highlights
Gratitude towards person

IS intended to
- ✓ Summarize the goals discussed
- ✓ Confirm the goals are relevant and achievable
- ✓ Document the interaction **AFTER THEY LEAVE**

IS NOT intended to
- × Introduce new strategies or ideas that the facilitator wants the person to do

I look forward to meeting again on [next meeting] *to check in on how things went!*

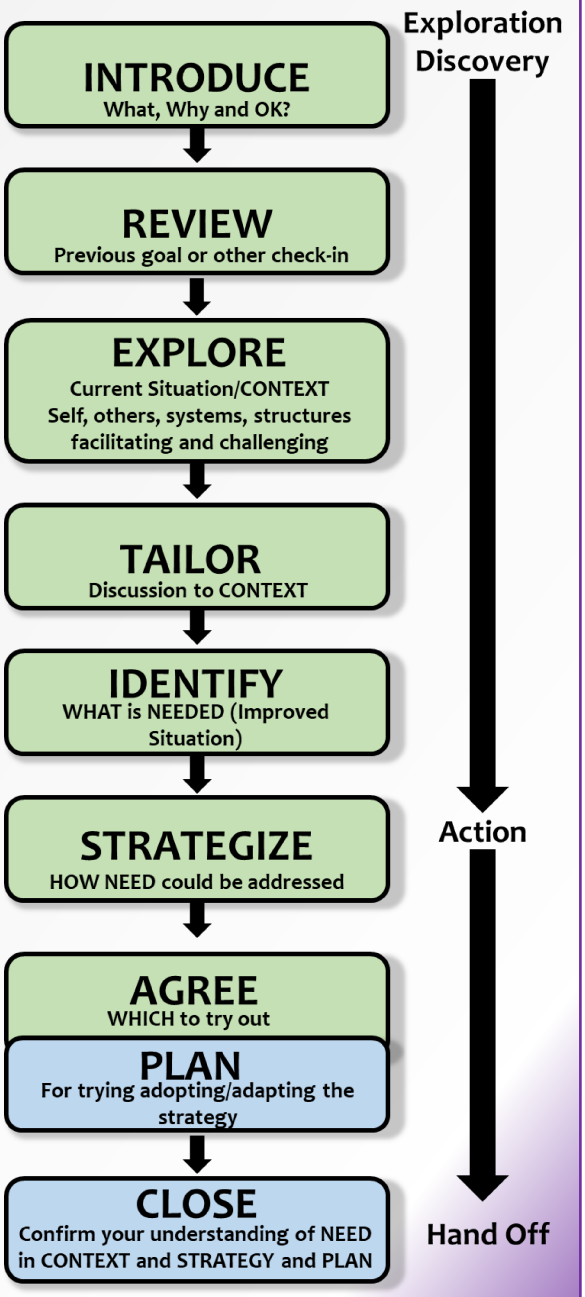
NOTES:

YOU MADE IT TO THE END OF NSC STEPS. NOW LET'S FINISH UP OUR ROLE-PLAY!

TRY IT

Get back to your partner. You already did the first 3 steps. Add in the rest. Start with the summary at the end of EXPLORE and move all the way through.

What is the issue you discussed?
For this person, what was the context they shared? What is their "current" situation? Where on they on the journey to the health outcome?
Facilitators/strengths?
Challenges/barriers?
What did you focus your "need" question on? Health behavior? Change to current situation? A way to achieve something is in specific situation?
What did they need? Check that this is not a strategy.
What strategies were brainstormed?
Which strategy did they pick? Was there a plan for implementing it?
How will they know it works well or not and what would they do either way?



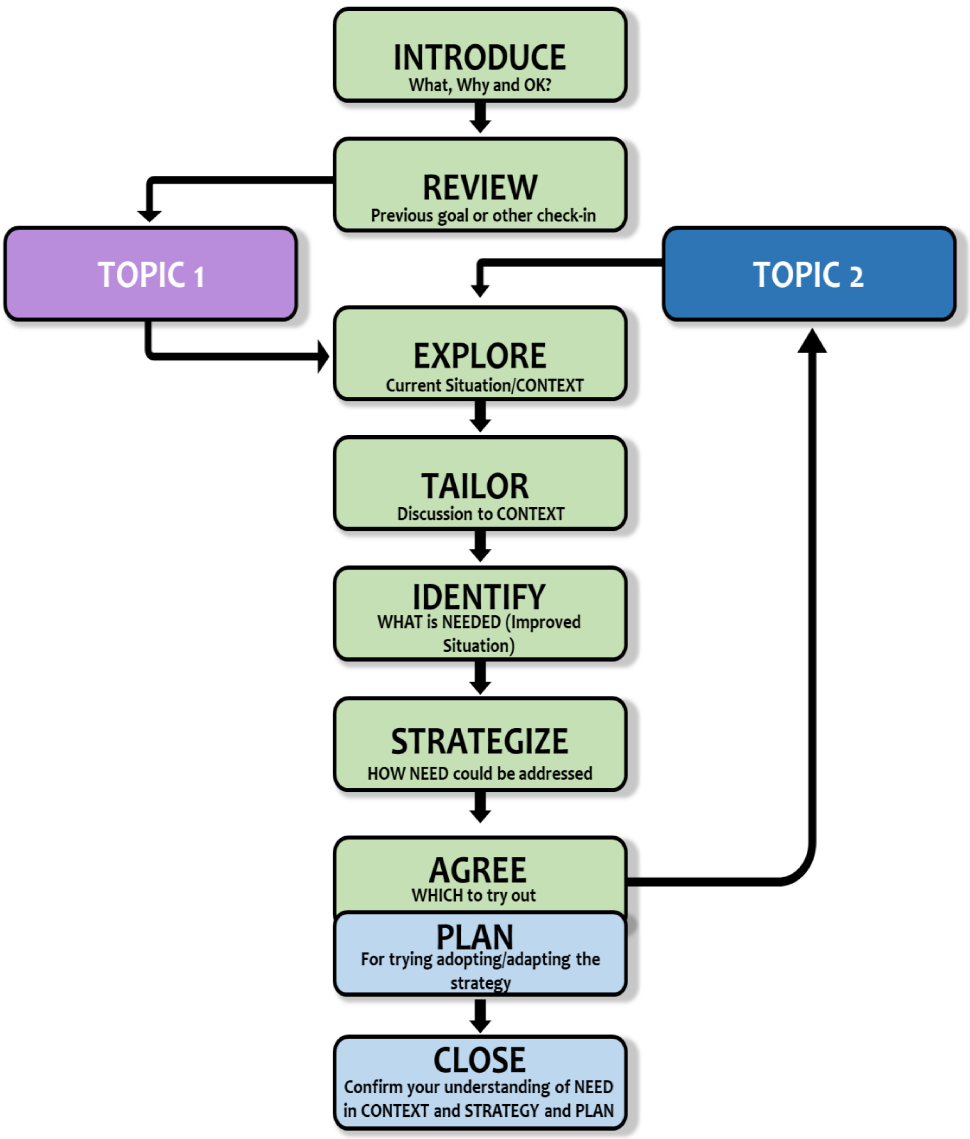
EXAMPLES OF NSC FACILITATOR PROMPTS

STEP	FEATURE	HIV Medication Adherence	Diabetes Self-Care
Introduce	Promote shared decision making and balance of power by sharing what you are hoping to discuss and asking permission	*Now I'd like to talk about your medication use. Is that okay?*	*Are you comfortable talking about nutrition and exercise now?*
Review	Anything to check in on? Information or education from other people they have met with today, experiences with 'counseling', or past goals from previous sessions?	*Last time we talked a lot about what makes taking your meds easy and challenging. You came up with some strategies to make it easier. What, if anything, have you tried?*	*Last time you shared that you would feel more confident managing your diabetes if you were eating more colorful meals and getting more physical activity. What, if anything, have you tried?*
Explore	Things, situations, ways you feel, thoughts you have, your beliefs, other people's beliefs, ways your community feels or treats people, resources available, systems of care, economics, political environment so on (all levels of Socio-ecological model) that help with *TOPIC* … that make it hard to *TOPIC*	*What kinds of things or ways you feel seem to make dosing feel manageable, or like something you can or want to do?* *What kinds of situations, thoughts or feelings make dosing feel really hard or like something you just can't or don't want to do?*	*What kinds of situations, thoughts or feelings make preparing your own meals feel manageable, or like something you can or want to do?* *What things or ways you feel making preparing your own meals feel hard or like something you just can't or don't want to do?*
Tailor	Facilitator factors in the person's context and constructs a question that will focus the discussion on this person's specific needs		
Identify	Facilitator asks an appropriate question "**WHAT** would **need** to happen for TOPIC to feel just a little more manageable"	*What would need to happen for it to feel just a little more manageable to take your meds when you feel depressed?*	*What would need to happen for it to feel just a little more manageable to prepare your meals during busy work weeks?*
Strategize	Facilitator guides exploration of **HOW** the person could see the need identified being met, in part or in full	*How could you incorporate more movement into your day, especially when you're depressed?*	*How could you imagine receiving more support from those around you?*
Agree	Facilitator guides identification of **WHICH** of the strategies the person is willing to try out and explores an action plan- checking in on how to monitor success of the strategy and adapt strategy explored. Remind person of NEED and that lots of other strategies may help with a given NEED.	*So you've come up with a few ideas – to walk your family dog each morning, to do at-home yoga videos, and to walk your sibling to the park – what would you like to try between now and the next time we meet? Great. When you do try that, how will you know if it is helping? What will you do if it does not feel like it really is helping?*	*So you've come up with a few ideas – splitting meal prep duties with your partner, making a list of healthy take out options, and reducing your weekend commitments to make more time for meal prep. What would you like to try between now and next time we meet?*
Close	Facilitator provides a summary of the discussion (here are the things that help, here are challenges, here is the main need you identified, here is what you said you would try, using this specific plan), confirms, thanks and plans for next conversation.	*Ok, so you'd like to try taking the dog for a walk every morning and then take your meds when you return. Is that right?*	*Alright. So it sounds like you want to start by asking your partner to cook dinner two nights a week and creating a list of healthy take out options so that you can still have a colorful meal when you're in a time crunch.* *Is that right?*

Integrated Next Step Counseling

For iNSC, we essentially combine two NSC discussions together. To do that, you need a couple of new steps- you need to let someone know that you are hoping to touch on two (or more) related but unique health issues or behaviors and ask if that is OK, and you need to transition between the two NSC discussions in a smooth way.

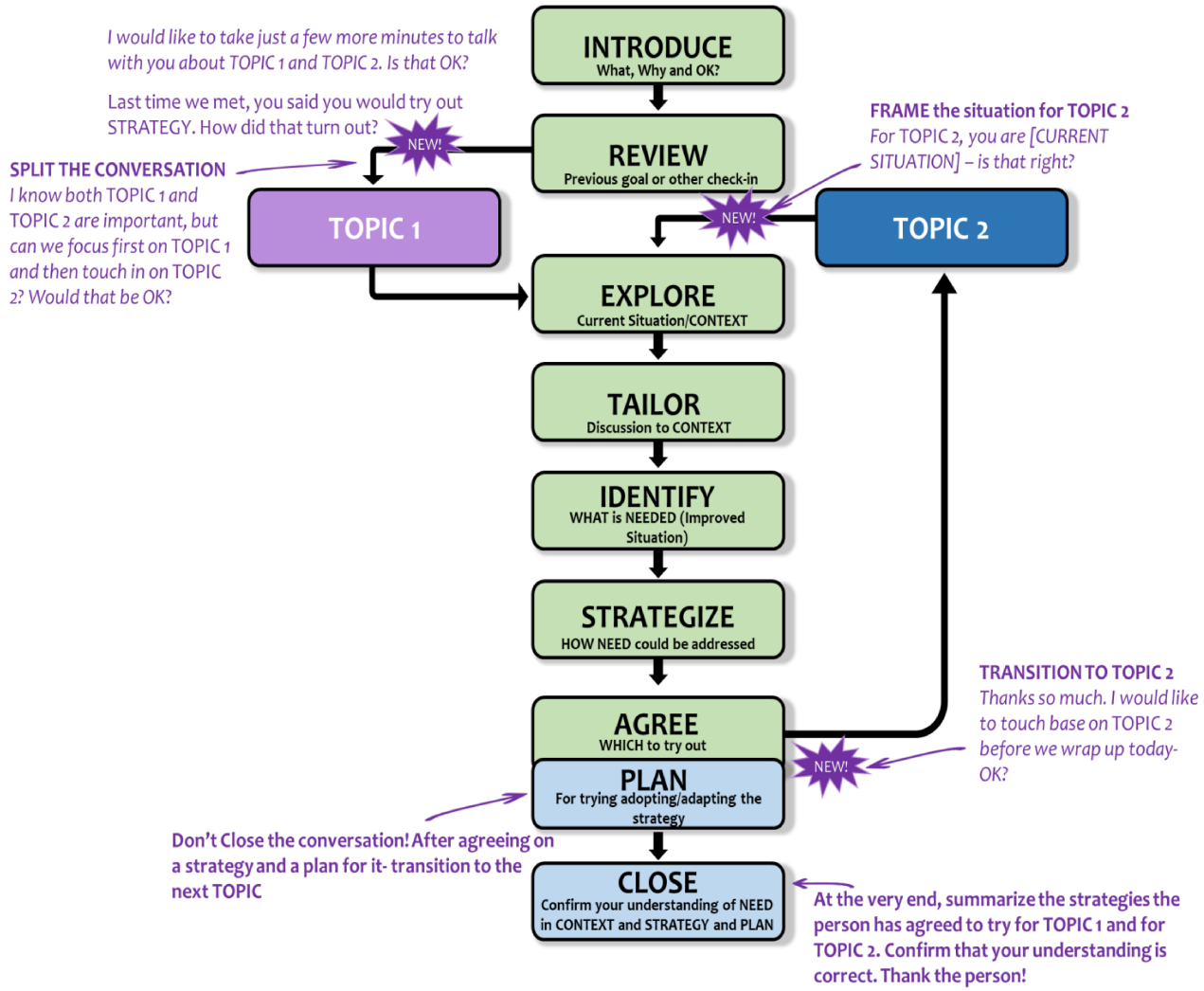
Notice that we now have two topics for the figure for iNSC. We still introduce and review (as appropriate) but we then cover one topic with EXPLORE, TAILOR, IDENTIFY, STRATEGIZE, and AGREE.



Once we reach an agreement and check in on their action plan for whatever that first topic area is, we then go into EXPLORE through AGREE for the second topic with a transition statement (*Thank you. I am hoping we can take just a few more minutes to talk about* [TOPIC 2]. *Is that OK?*).

Depending on the topics, the transition can be an opportunity to check in on where someone it at with TOPIC 2, which is important if people can be in different stages of adoption or implementation of a health behavior.

New Parts Included in iNSC



Notice the new pieces to the NSC conversation. Now when you INTRODUCE, you need to include that you are hoping to talk about a couple things, not just one thing. REVIEW is the same. After that though, you need to tell the person that you recognize both topics are important, but you want to talk about TOPIC 1 and then TOPIC 2. After that, it is basically an NSC discussion for TOPIC 1 and then for TOPIC 2.

Remember, iNSC is recommended for topics that are related but have certain unique aspects to them that would warrant exploring the situation, facilitators, barriers, needs and strategies separately. When first developed, iNSC was used to talk with people who were using pre-exposure prophylaxis for prevention of HIV. The interest was to have two important conversations- one about sexual health and well being considering what people were doing or considering doing to promote that *besides* PrEP, and then ask about where someone was at with PrEP (current PrEP situation) and do NSC on next-step in that domain. That could be considering PrEP, prescribed PrEP and trying to take it, or prescribed and taking it just fine. We wanted to be able to encourage thinking about health and well-being, and about adherence and persistent. These two topics related to HIV prevention but have different kinds of facilitators, barriers, needs and strategies. So, we integrate two different but related conversations.

What does Integrated Next Step Counseling Sound Like?

Let's consider the example of working with someone who is coming to your clinic for PrEP services. You are using iNSC to introduce discussions about sexual health generally and PrEP adherence specifically. Read through the facilitators comments and questions. The step is noted at the end of the facilitators statement.

I would like to take just a few more minutes to talk with you about sexual health and where you are at with PrEP. Does that sound OK? [**INTRODUCTION**]

Last time we met, you said you would talk to your partner about agreements to be just with each other and also you were just starting with PrEP. How did that go for you? [**REVIEW**]

Thank you. Let's focus in on how things are going now.

I want to learn more about how PrEP went for you, but can we focus first for a few minutes on the other things you are doing or thinking of doing to protect your sexual health besides PrEP? [**SPLIT THE CONVERSATION**]

Can you share with me again – what your thoughts are about protecting your sexual health? Are there things you do for that, not including PrEP? [**Establish current situation for TOPIC 1**]

I hear you saying that you are considering condoms with outside partners and also considering entering a monogamous arrangement with your boyfriend. What kinds of things, situation, things going on in the relationship or ways you think or feel make you feel like protecting your sexual health is someone accomplishable- not easy to do but easier? [**EXPLORE TOPIC 1**]

And what would you say are the times, situations, thoughts or feelings that make protecting your sexual health feel hard to do or like something that just isn't possible or gonna happen? [**EXPLORE TOPIC 1**]

Facilitator reflects internally on the situation (that the person does use condoms in situations and is considering monogamy with a partner he cares a lot about), the facilitators reported (person reported feeling motivated towards condom use with outside partners when the relationship with his partner is strong and going well) and barriers (when he is in an argument with his boyfriend, when work is overwhelming, and when drinking he cares less about protecting his health in general). The facilitator decides to center a question about needs on motivation towards protecting himself as that seemed like a common theme. [**TAILOR TOPC 1**]

In thinking about the situations you shared, what would you say would need to happen or be different for you to feel consistently motivated to protect your sexual health? If you could change anything, what would it be? What would be there or not there? What would need to be a little different? [**IDENTIFY NEED TOPIC 1**]

So, for you, feeling happier seems to be an important need. If you could feel happier more consistently, you feel you would be more motivated. How could you see that happening? How could you be happier more consistently? [**STRATEGIZE TOPIC 1**]

You mentioned being in a more committed relationship would provide you happiness, and also said that when you are working out and eating well, you feel happier overall. Of those, is there one you could plan to address? [**AGREE TOPIC 1**]

You said going to the gym. What are the steps that go into that? What sequence of events leads to going to the gym? [**ACTION PLAN for TOPIC 1**]

So you have a plan for going to the gym to try to see if that helps with more consistent feelings of happiness, and from that motivation to take care of yourself. When you try that, how will you know if it is working as you wanted it to? What will you do if it feels like it is not doing what you thought it would? [**CONFIRM plan and explore monitoring and adapting for strategy**]

Thanks so much. I know you got PrEP last visit and have been trying to take it I think? Where are you at with it right now- does it feel like a good choice for you? [**TRANSITION AND ESTABLISH SITUATION FOR TOPIC 2**]

OK- so you are feeling good about the decision. Can you share with me what situations or feelings seem to make taking a dose a day feel like it is easy- or easier- to do? [**EXPLORE TOPIC 2**]

Thank you. What about things that make it feel like a challenge- even if you do it- things that make it just feel hard? [**EXPLORE TOPIC 2**]

Facilitator reflects internally on situation shared (on PrEP, engaged and continuing with it), facilitators (shared partner is on PrEP as well and they dose together, reported no side effects), and barriers (lamented over needing PrEP as it seems to represent that the relationship is open and he is looking for more commitment, sometimes has trouble remembering dose times when family visits). Facilitator is not sure about the relationship dynamics the person is reporting and worries that asking about needs for higher commitment in the relationship may be too far outside the person's control. The facilitator decides to center a question about needs on consistent dosing when family visits. The facilitator believes if the relationship part is more pressing, the person will return to it and bring it up.

What do you feel would need to happen for you to feel more consistent in taking PrEP when family visits? [**IDENTIFY NEED TOPIC 2**]

I hear you saying that you would need some access to privacy. How does access to privacy help? [**IDENTIFY NEED TOPIC 2**]

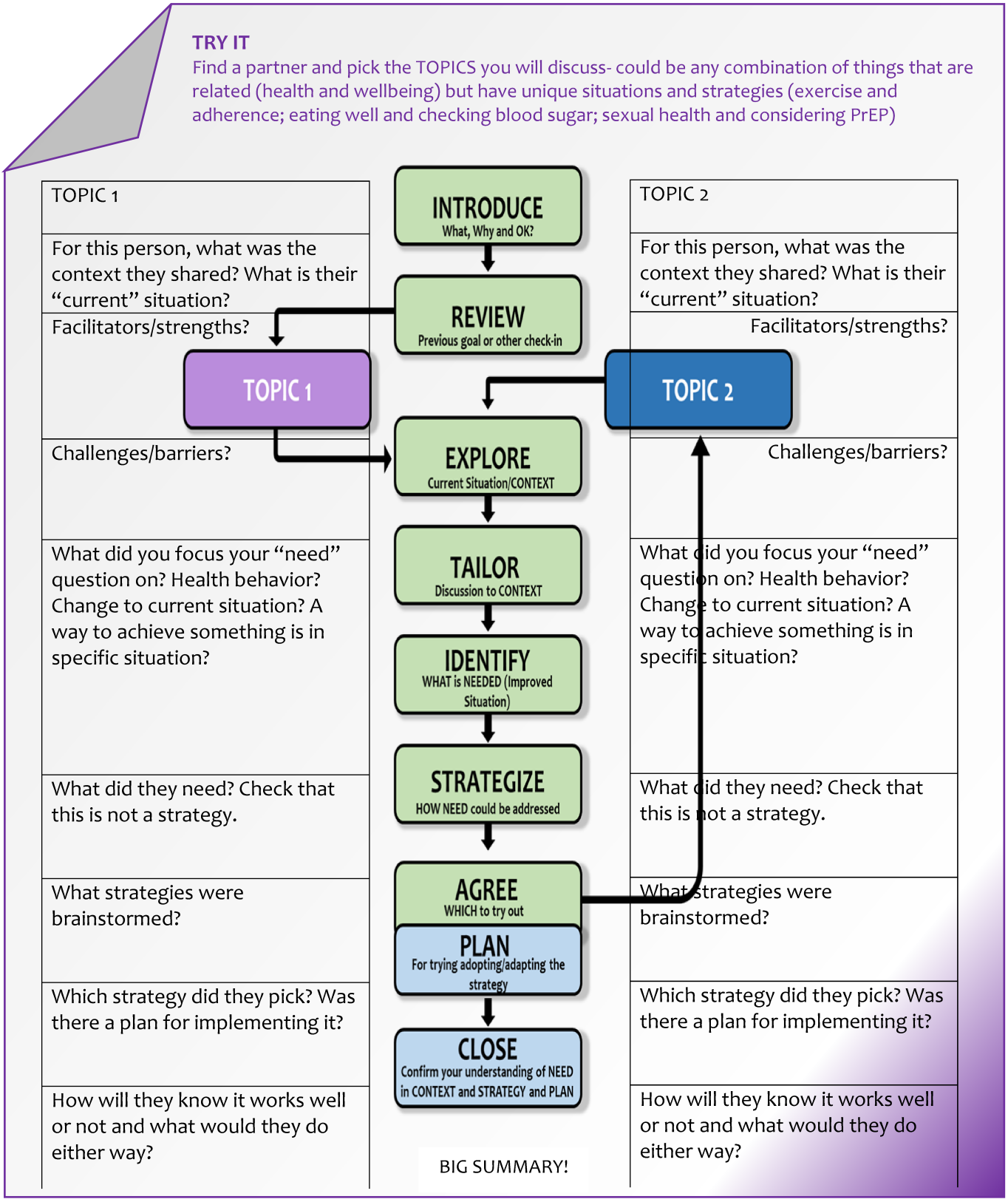
So privacy is not so much for confidentiality but because you want to have a minute to yourself, away from the loud talking and occasional arguing and that is the situation you want for taking your dose. Right? [**IDENTIFY NEED TOPIC 2**]

How could you see getting a moment to yourself when family visits? [**STRATEGIZE TOPIC 2**]

So, "taking a shower" seems to be a time when no one bothers you and you have peace. Would trying to use the "taking a shower" idea be something you want to try out? Great. [**AGREE TOPIC 2**] *Quick question though- if you try that- how will you know it worked? OK- so it you took every dose the week they are here- that would be your "proof". OK.* [**CONFIRM plan and explore monitoring and adapting for strategy**]

We have talked about a lot today. To confirm I have it right- you mentioned that you would feel more motivated around protecting your health if you felt happier more consistently and going to the gym is a way to get there- so you are trying that. And for taking PrEP you are going to try to use the "shower time" excuse to get a few minutes away from family and be able to take your time and take your dose. Sound right? Great- I can't wait to check in again when you come back. Thank you! [**Confirm full PLAN and CLOSE**]

YOU TRY- IF YOU KNOW NSC YOU CAN DO iNSC!! FOLLOW THE DIAGRAM



ADAPTING NSC and iNSC TO YOUR TOPIC(s)

ADAPT AND CHANGE

Flesh out the NSC or iNSC conversations to your specific health area. Use the workbook and exercises to help with that. In role plays, create different scenarios where people are in different stages along a continuum (if appropriate) and different spaces and places in terms of where they are at with contemplating change.

We have provided the basic approach, but how it looks and sounds depends on your own style, the areas you are discussing and the people you are engaging. That is OK. It should sound unique – it is supposed to be genuine and organic. What is discussed and the facilitation style is meant to be flexible.

DON'T ADAPT (CHANGE)

The only aspects of NSC and iNSC that are not so flexible are (1) the FLOW (explore→ needs→ strategy) and (2) the "spirit" of the conversation.

THE FLOW is recommended to always lead with exploration- meaning the person you are working with should have the chance to share their vision and experience of things before any action or strategy is discussed. The biggest learning point in NSC for many facilitators is NOT jumping in and offering suggestions for how to solve what **they** have decided is the issue. To be person-facing, you need to let the person you are working with tell you what is pressing to them. You want to let them think through it and come to realize their specific need(s) and strategies. We guide, they solve. That flow of going from exploration to needs to strategies to action is very important.

The "SPIRIT" (from Motivational Interviewing) is about the relationship you work to establish with people. We want people to fee they have a lot of control in the conversation- that they are the focus and their needs are respected. If the exchange feels like the facilitator is doing all the talking, is doing one-way messaging (you must do this or that, you should try this or that), is filling out some form or sheet, or is casting opinions and judgements on the person's choices or circumstances, when it is NOT NSC. The relationship and related dynamics are critical.

PRACTICE

As with any skill, you have to practice.
Use the monitoring sheets for practice in Appendix E. The self-assessment tool can be used after role-plays and after sessions to review the important communication and facilitation skills and parts of NSC and iNSC, and to identify areas where you may want to improve.

When possible, record your role-plays or sessions. Listen to the recording with the self-evaluation form. Always have something to be working on!

Working with fellow facilitators can be extremely beneficial. It not only gives you great practice opportunities, but when practicing NSC or iNSC, having regular meetings to debrief on cases and experiences can be rewarding, re-energizing, and skills building.

We HIGHLY recommend forming a team when possible – a group of facilitators with a supervisor when possible—that can review each other's implementation of NSC or iNSC and debrief regularly (weekly ideally and monthly at minimum).

APPLYING iNSC TO TONSE PAMODZI

For the Tonse Pamodzi project, we use the iNSC approach. iNSC- integrated Next Step Counseling- was developed during the iPrEx open label study as a way to check in with people trying to use PrEP. It prioritizes 'Next Steps' instead of ideal outcomes (100% adherence every day!) to change the conversations from telling people what they must do to asking people to share where they really are at with adherence in the context of their current resources and limitations. While an ideal outcome might be dosing daily every day, a next step might be figuring out how to keep medication on hand when traveling because that is what someone says would be helpful. **Making PrEP or ART as easy or manageable as possible is the goal, but how someone gets there depends on where they are now, what matters to them, how they feel about PrEP or ART in the first place, and what their own goals are with adherence.**

The approach is called 'integrated' because that process of exploring where people are at and working with them to identify their own needs and next steps is done twice in one conversation- once in relation to sexual health and wellbeing in general and once in relation to adherence specifically. So, the topics are integrated in their common approach (exploration, identifying needs, discussing strategies and agreeing on goals) but happen in two different steps because while the two topics are related, the facilitators, barriers, needs and strategies for dosing daily can be unique from those that relate to sexual health and well-being.

For the Tonse Pamodzi project, iNSC is applied to two groups of women- all of whom are expecting at the time of enrollment, but who differ in terms of current HIV status. Some women will be living with HIV and starting ART (or restarting after a gap) and others will not have HIV but rather will be starting PrEP for prevention of HIV during pregnancy and breastfeeding. The content that arises from the discussions with each group will have unique features, but the process and flow of iNSC will be consistent between the groups.

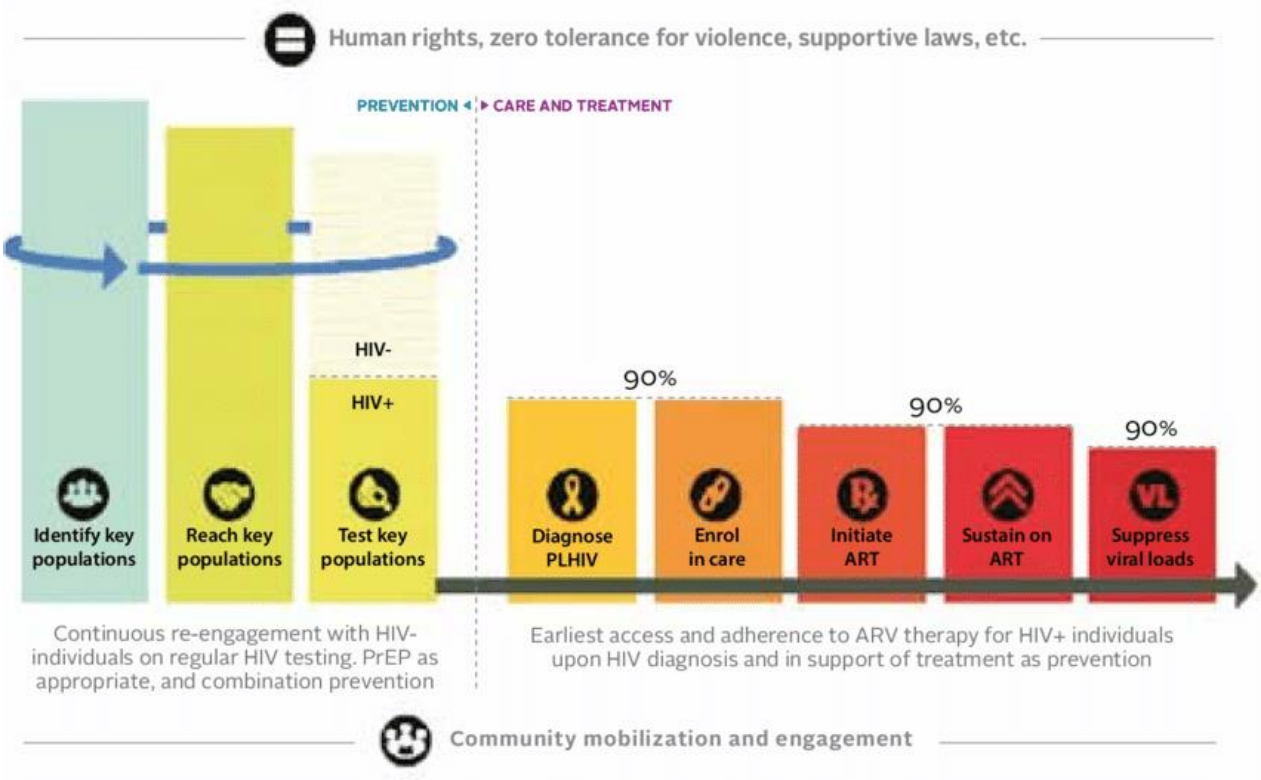
Where iNSC notes TOPIC 1 and TOPIC 2, that will be informed by whether the woman is starting or restarting ART to treat HIV or the woman is in some phase of consider, using, coming off or re-starting PrEP. For Tonse Pamodzi, the EXPLORE part of iNSC where we learn about the woman's specific lived experiences around HIV treatment or prevention *is critical* to guiding the conversation towards person-facing outcomes.

Each woman is different. Her HIV status and reasons she is using ARVs will also be part of her unique story. Counselors work with each woman to learn her story and help her on what can be a difficult journey. As such, listening skills, reflection, and being present are as essential as following the session steps.

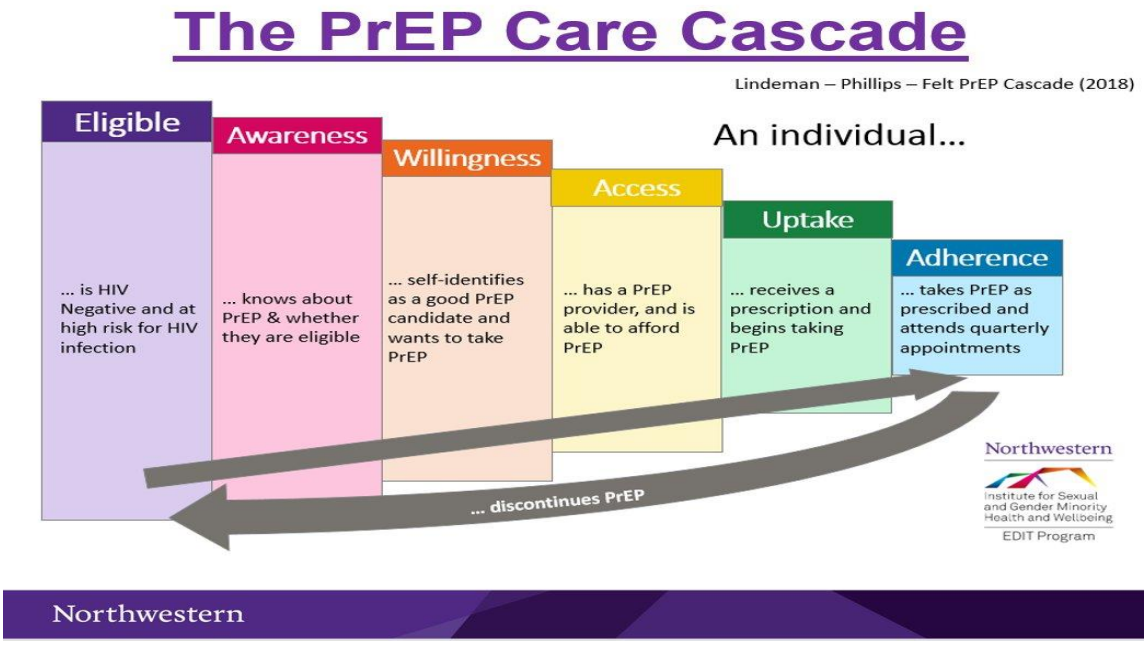
Facilitators have already read through the standard workbook with the women in Tonse Pamodzi in mind. Over the next section, we add a little more to the background for our project, and provide examples for implementing the approach in the diverse situations facilitators will encounter.

A LITTLE MORE BACKGROUND FOR TONSE PAMODZI FACILITATORS

Recall the cascade of care for HIV we presented earlier? For Tonse Pamodzi, women living with HIV are likely to be around initiation and sustaining on ART in the cascade, but we need to check in with them about how they are feeling about it when we EXPLORE with them.

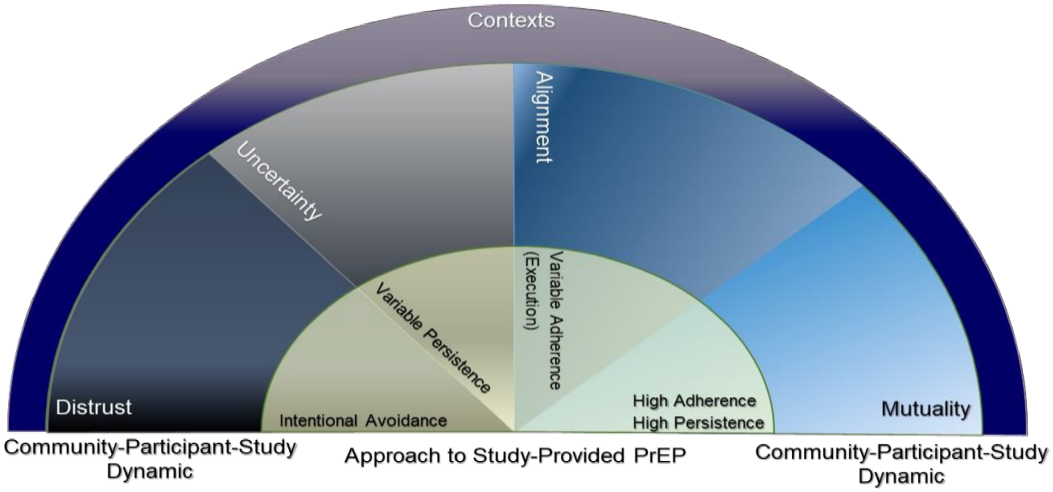


For women who are considering or using PrEP to prevent HIV, they can be anywhere on the continuum below.



GETTING A PRESCRIPTION DOES NOT MEAN SOMEONE IS IN ACTION AT A GIVEN STEP TOWARDS TREATMENT OR PREVENTION!

The Mutuality Framework identifies different dynamics that may be going on with people as they engage with our project. Each of the "dynamics" explained below suggest a distinct situation and relationship between the person, the biomedical prevention strategy (PrEP) and the facilitator or service providing PrEP. These can be adapted to reflect relationships with ART among women living with HIV as well as they negotiate using it during and after pregnancy.



Distrust	**Uncertainty**	**Alignment**	**Mutuality**
• Rejection of integrity of stated goals of study or its benefits to community • Active avoidance of study- provided product. • Avoidance of disclosure of concerns to study; may manage tension by dissuading others. • **Try to build and earn trust**	• Skeptical kind of exploration; is the study and/or the study products good for self or community? • Variable persistence (e.g., on /off). • Discomfort while weighing options; may not disclose concerns to study. • **Try to support exploration with credible information**	• Provisional acceptance that the study and product as a benefit self and community • Variable success with adherence. • Maintaining alignment with study while improving execution. • Try to invite discussions about challenges and potential strategies • **Build skills**	• Alignment of study goals and vision are seen as mutual; the vision is shared, and a kind of ownership of the work and advocacy in the community takes place • Good persistence/good adherence. • **Try to create opportunities to lead and advocate**

Take some time to consider how iNSC might LOOK or SOUND to appreciate where someone is at in terms of steps in the cascade, relationships with PrEP or ART, and how this all may impact your conversations about next steps.

TRY the Mutuality Model! A number of scenarios are offered below. Think about each one. Talk it over with a partner. You can't really know what you would say or do in the real situation, but imagining what may happen can help you to prepare.

TRY IT

YOU ARE EXPLORING WITH SOMEONE WHO IS STARTING PREP… HOW DO YOU LEARN ABOUT HER FEELINGS ABOUT IT? HOW DO YOU LEARN ABOUT HER DYNAMIC? HOW WILL UNDERSTANDING HER CURRENT SITUATION INFORM YOUR FACILITATION?

TRY IT

YOU ARE EXPLORING WITH SOMEONE WHO IS STARTING ART FOR THE FIRST TIME… HOW DO YOU LEARN ABOUT HER FEELINGS ABOUT IT? HOW DO YOU LEARN ABOUT HER DYNAMIC? HOW WILL UNDERSTANDING HER CURRENT SITUATION INFORM YOUR FACILITATION?

TRY IT

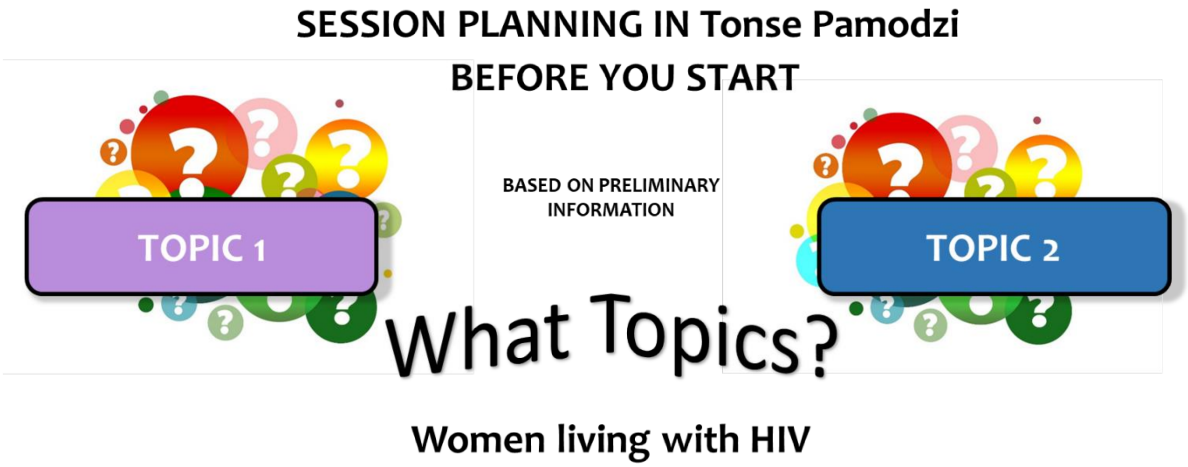
YOU ARE EXPLORING WITH SOMEONE WHO IS STARTING ART AFTER BEING ON IT FOR A FEW MONTHS AND COMPLETELY STOPPING. HOW DO YOU LEARN ABOUT HER FEELINGS ABOUT IT? HOW DO YOU LEARN ABOUT HER DYNAMIC? HOW WILL UNDERSTANDING HER CURRENT SITUATION INFORM YOUR FACILITATION?

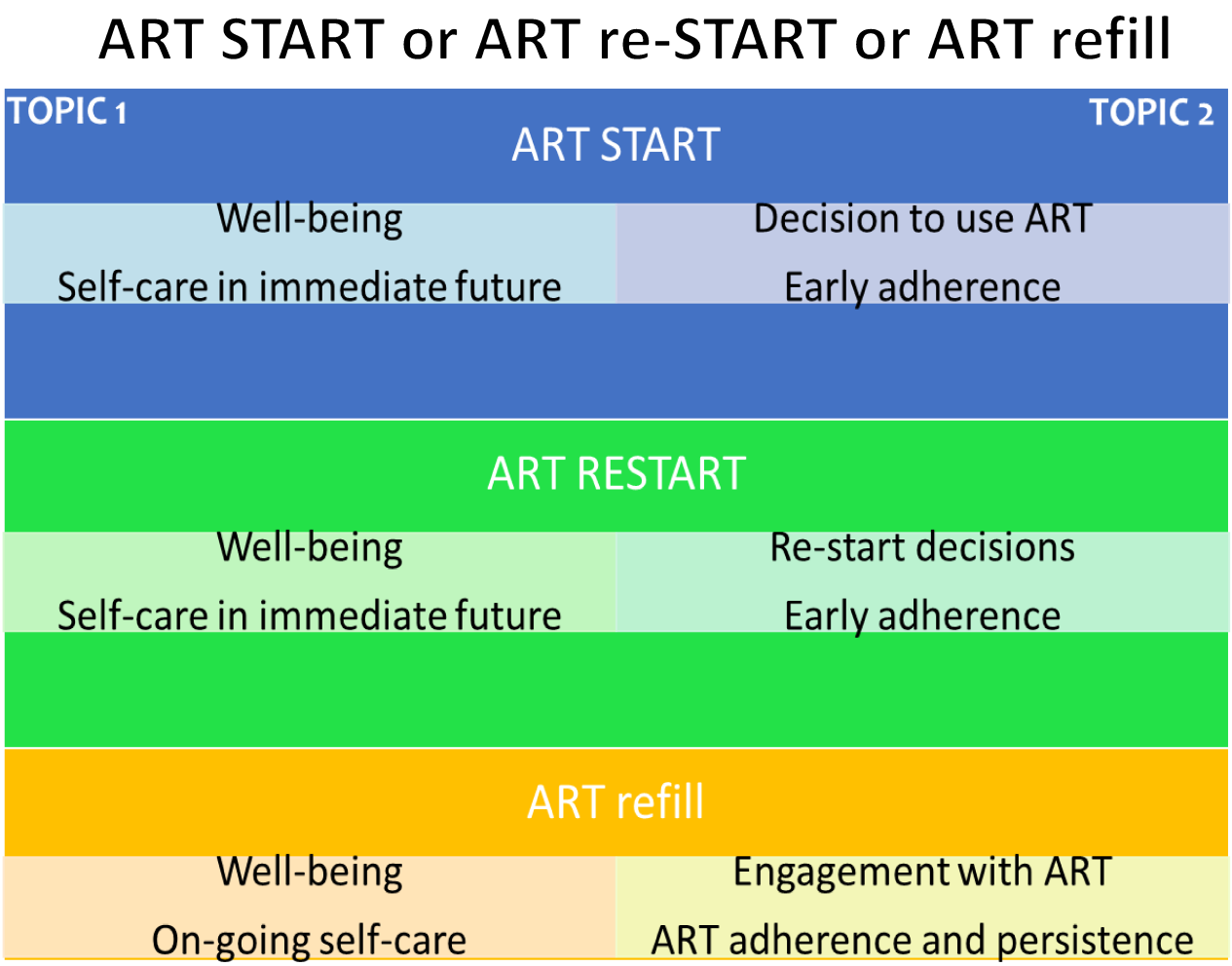
TRY IT

YOU ARE EXPLORING WITH SOMEONE WHO HAS BEEN PRESCRIBED PREP FOR 1-MONTH. SHE IS BETWEEN DISTRUST AND UNCERTAINTY. HOW DO YOU ENGAGE HER IN A CONVERSATION THAT WOULD INVITE HER TO SHARE THAT? HOW WILL THAT INFORM YOUR FACILITATION?

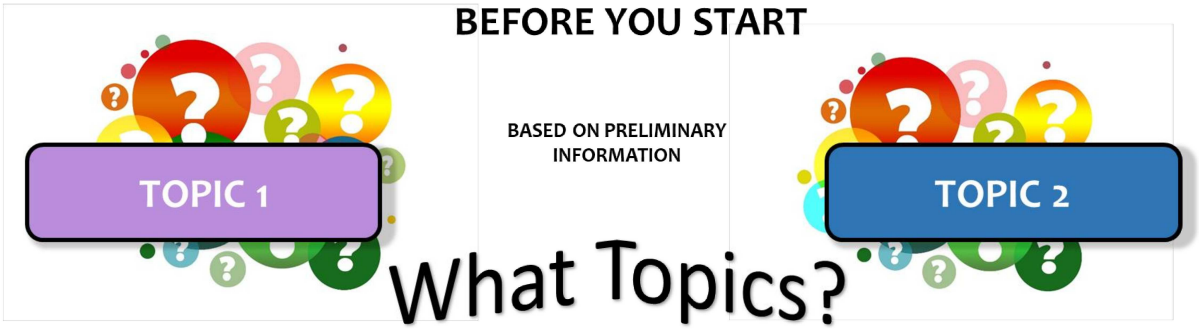
TONSE PAMODZI Session PLANNING

In Tonse Pamodzi, women will have already gone through quite a bit before reaching the iNSC facilitator. Depending on what their situation is, you will be working with pregnant women who are starting ART , restarting it, or (in follow-up) continuing with it. For HIV prevention, you may have someone starting PrEP, and over time, continuing with it, stopping or re-starting. Before you meet with her, think about the TOPICS you will start the conversation with in INTRODUCE and SPLIT the discussion.





SESSION PLANNING IN Tonse Pamodzi

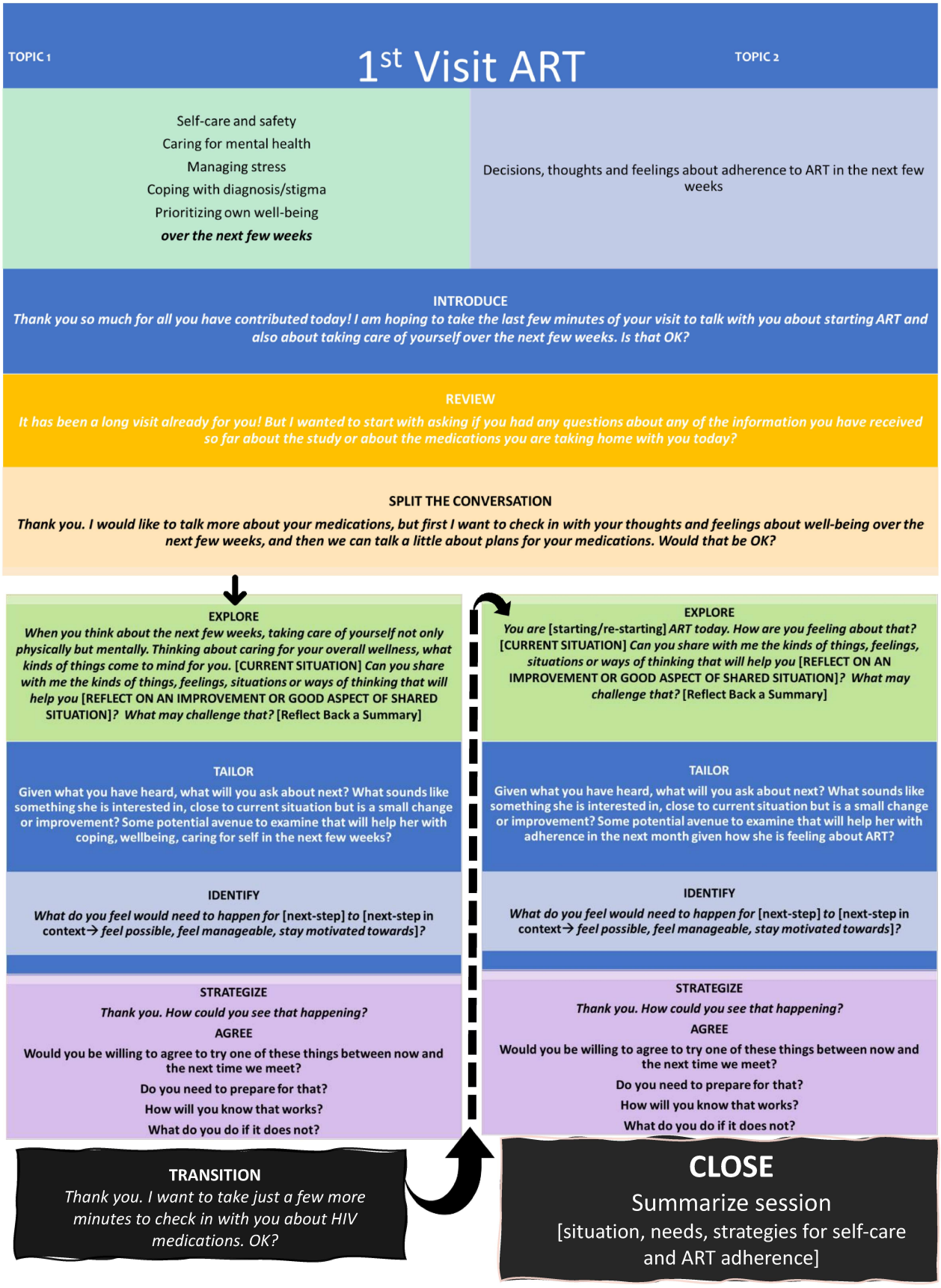


Women preventing HIV

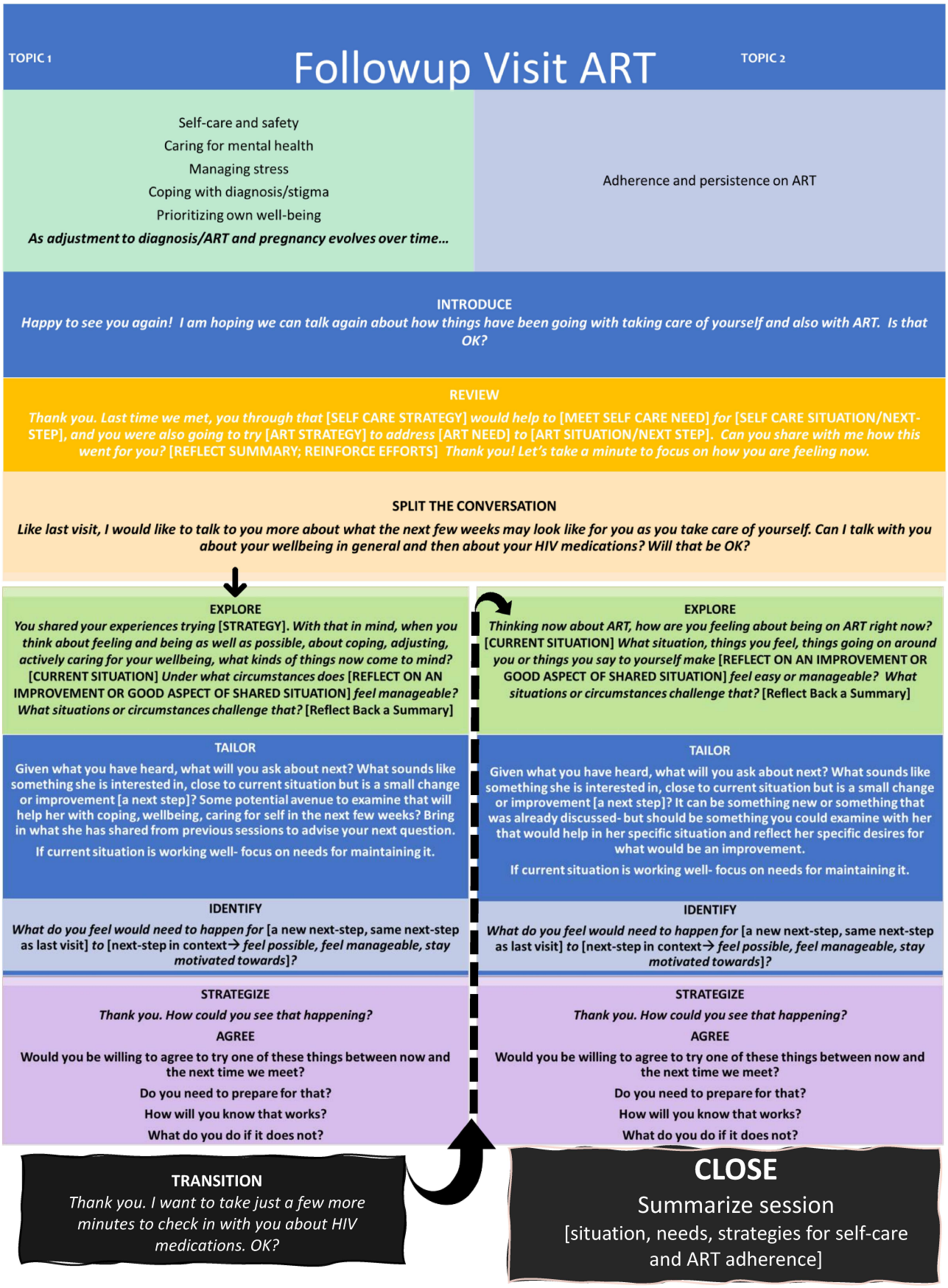
PrEP START or PrEP re-START or PrEP refill or PrEP stop

TOPIC 1		TOPIC 2
PrEP START		
Sexual Health Well-being		Decision to use PrEP Early adherence
PrEP RESTART		
Sexual Health Well-being		Decision to re-start Early adherence
PrEP refill		
Sexual Health Well-being		Continuity with PrEP PrEP adherence
PrEP Stop		
Sexual Health Well-being		Decision to stop Plans for ongoing re-evaluation

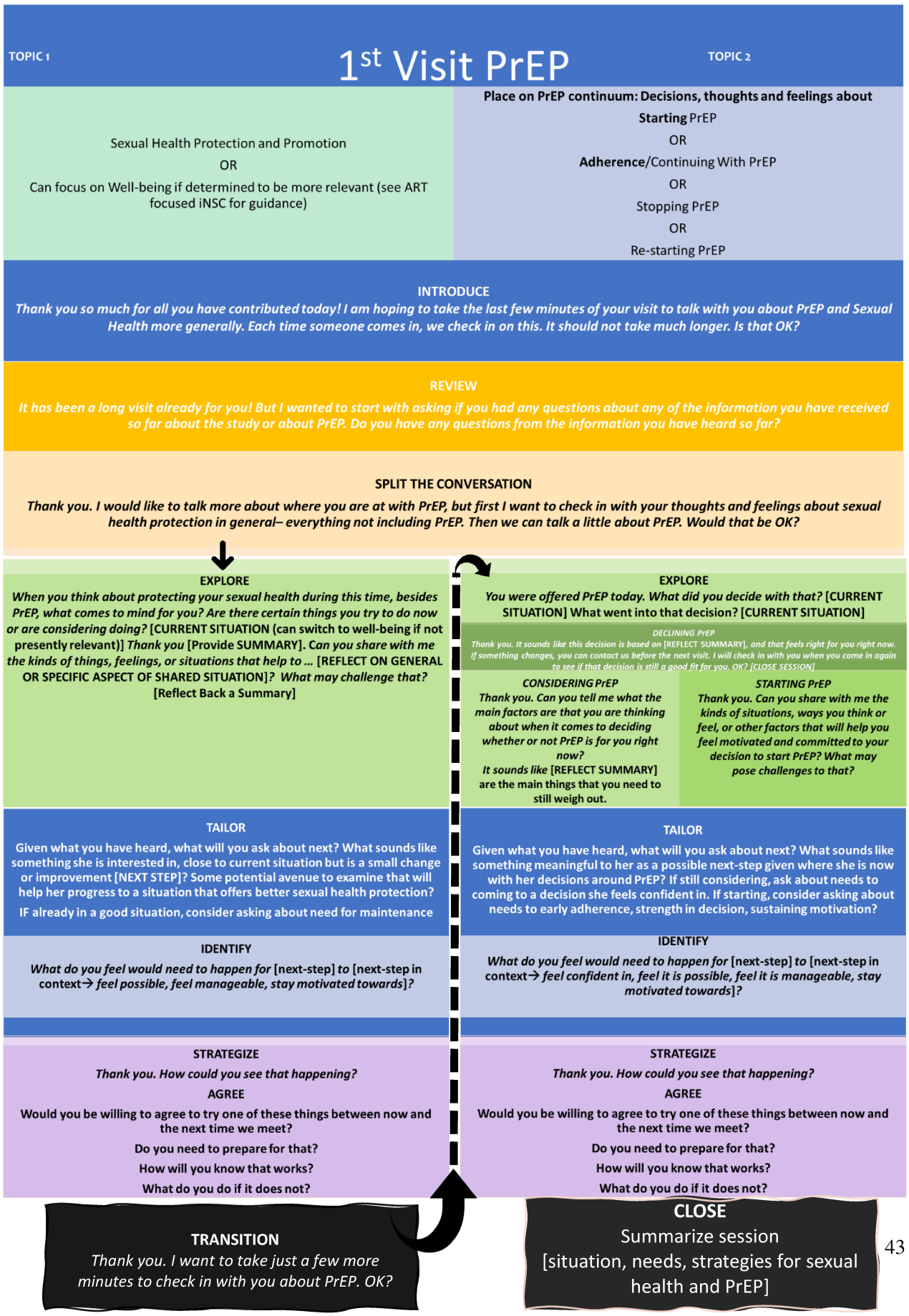
TONSE PAMODZI 1st iNSC FOR WOMEN STARTING OR RESTATING ART



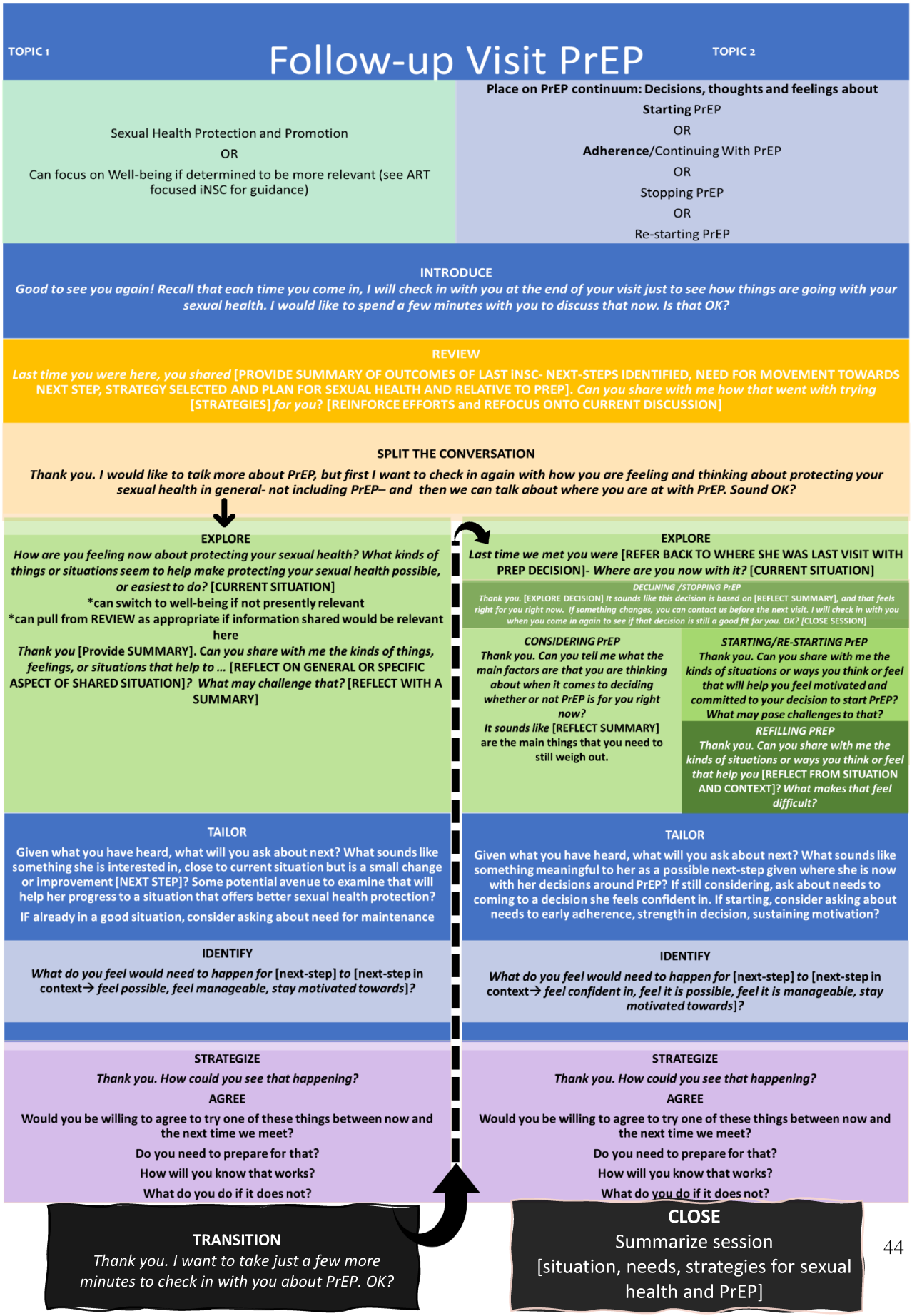
TONSE PAMODZI Followup Session iNSC FOR WOMEN ON ART



TONSE PAMODZI 1st iNSC FOR WOMEN OFFERED PrEP



TONSE PAMODZI Followup iNSC FOR WOMEN OFFERED PrEP



CASE SCENARIOS TONSE PAMODZI

Use this sheet to write out some case scenarios you want to role-play or prepare for.

APPENDIX

APPENDIX A

Primer on communication and facilitation skills

APPENDIX B

IMPLEMENTING NSC/iNSC OVER TIME

APPENDIX C

PLANNING FOR WHEN ALL IS FINE

APPENDIX D

PLANS

APPENDIX E

Self-monitoring and supervisory tool implementation and fidelity

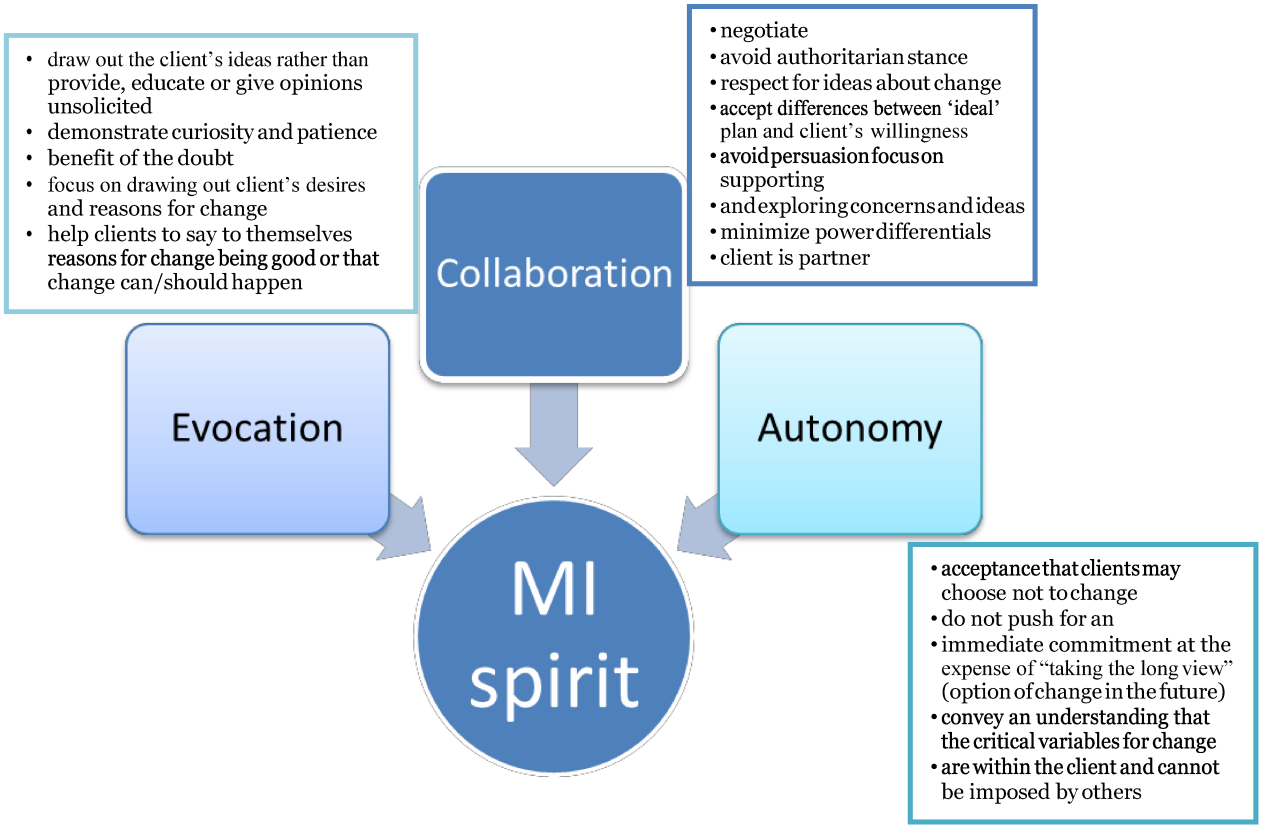
APPENDIX A

Primer on communication and facilitation skills

Key Aspects of Motivational Interviewing

Three Pillars of Motivational Interviewing

The elements of MI "spirit" are (1) Collaboration; (2) Evocation; and (3) Autonomy



CHANGE TALK

Client discourse that implies, suggests or states that where he/she is now is not really where he/she want to be.

Client consideration, reasons or arguments for change.

Listen for….

Problem Recognition Concern

Intent to Change Optimism

Ambivalence

Guide towards…

Recognition of dissatisfaction with status quo

Noticing possible advantages of change Feeling optimistic/confident about change

Expression of intentions to change

MI METHODS

[asking Open questions, providing affirmations, Reflective listening, and Summarizing: OARS][1]

Ask Open Ended Questions

Cannot be answered with a yes or no (or other "pick an option" kind of response)
Is *respectful* of where client might be willing to go Fits into the context of discussion- can be used to guide conversation in change-talk direction

Provide Affirmations

Statements or gestures that build confidence and self-efficacy for change by recognizing someone's strengths, abilities or efforts. In many ways, this is a complement – but it should *not* be about you (the counselor). Avoid "I'm proud of you" and go with statements that are genuine and focused on the client …"It is really impressive how…" "What you are doing shows respect for yourself and partners" or "It's really amazing how…". Cannot be answered with a yes or no (closed response)

Reflective Listening

Reflective listening requires reflective thinking- which is mostly driven by an investment in and desire to understand what the speaker is really saying. Several kinds of questions or statements help in reflective listening and also can be used to guide the conversation. Repeating, paraphrasing (using different words then the client to convey what you understood the client to say), and reflecting feelings (feeding back the emotional parts of what a client is sharing) are used to check-in with clients to make sure that the counselor is truly understanding what the client is sharing.

Summarizing

A special kind of reflective listening, summarizing is used to synthesize what someone has shared, with special emphasis on "change talk". These are always framed as a question- not a statement of facts. Allow clients the opportunity to correct your understanding.

Eliciting Change Talk

Uniquely MI – these strategies are meant to help move people towards change.
Ask evoking questions, for elaboration or explore extremes, goals and values [what worries you most, what else, example, what's the worst of it, what would the best scenario look like; what is most important to you]

- Use an importance ruler [with 0 not at all important and 10 extremely important...how important is…]
- Explore decisional balance [what do you like about {present behavior}; what concerns you about it]
- Look back/forward [what was it like before; what changed; what do you want to be different in a year]

[1] http://peer.hdwg.org/sites/default/files/MotivationalInterviewing-ContinuingEducation-Peer_Training.pdf

REFLECTIONS

Good Reflections

Use person's own words when possible
Highlight any change talk
Highlight discrepancies between wants and current behaviors
Roll with resistance
Are statements- not questions or commentary
"You notice that you would like things to be different but feel really confused about how you could possibly change right now."

http://www.michigancancer.org/bcccp/WiseWomanProgram/PDFs/Tutorials/MotivationalInterviewing.pdf

These are NOT Reflections

Ordering, directing or commanding
Warning, cautioning or threatening
Giving advice, making suggestions or providing solutions
Persuading with logic, arguing, lecturing
Telling people what they should do
Disagreeing, judging, criticizing or blaming
Agreeing, approving, praising
Shaming, ridiculing or labeling
Interpreting or analyzing
Reassuring, sympathizing, consoling
Questioning or probing
Withdrawing, distracting, humoring or changing the subject

http://www.michigancancer.org/bcccp/WiseWomanProgram/PDFs/Tutorials/MotivationalInterviewing.pdf

DISCRETE COMMUNICATION/FACILITATION SKILLS

We covered several of these earlier in the workbook. Look over each situation or exchange presented in the table below. We include an abbreviation here because these are also things we use in self-monitoing and supervisory tools- so have a shorthand to refer to a strategy is helpful when marking up transcripts. The important part is to think about the exchange or interaction presented and consider if it is something you do well, do unconsciously, want to work on or consider valuable, in all or certain circumstances. Most are not good or bad, they simply are strategic ways of communication that facilitators should use with awareness. Mindfullness over what you communicate and how is critical to being an excellent facilitator. Go through each description and think about how or when you might choose to use or avoid them and when.

TERM	Additional context	Description
Advise (AD)	With Permission (ADP)	Asking before providing advice/recommendation
	Without Permission (ADW)	Giving advice unsolicited or without permission (note: may be appropriate depending on context)
Affirm (AF)	Appreciation, expressed confidence, reinforcement for spec beh/thought	Reinforcing client comments/reflections on positive things/insights (note: does not include general praise or positive comments)
Confront (CO)	Challenge ideas, confrontation	Expressing opposing ideas or overt debating with client (note: may be appropriate depending on context)
Contingencies (CT)	Praise, punishment, disapproval, moralizing in response to client discourse	Use of praise, disappointment or concern to motivate adoption of change resulting in direct or implied contingencies for client to "earn" counselor respect or positive regard. (note: typically inappropriate in most situations)
Emphasize Control (EC)	Emphasis on client personal control, choice, and responsibility.	Reflections or comments that reinforce or introduce client choice and power in discourse or in general
Evocation (EV)	Question, reflection or strategy to foster alternative viewpoints/change talk	Introducing or steering conversation towards alternatives or inconsistencies in views or behaviors (note: distinct from confrontation by counselor's use of reflection and questions that target change talk)
Facilitate (FA)	Verbiage that supports exploration or unfolding issue more	Questions, reflections and non-verbals that move client towards continued or deeper exploration of an issue
Filler (FI)	Chit chat/report building	Generic conversation- often promoting a sense of history between client and counselor or commonality or courtesy
Follow Change Talk (FC)	Counselor focus/reflection on change talk	Counselor notes and explores client verbiage that reflects desire, ability, reasons for change, need for change, commitment towards change, action or taking steps
	Missed opportunities to explore change talk	Client expressed desire, ability, reasons, need, commitment, action or taking steps and counselor does not reflect or explore
Giving Information (GI)	General information (GI)	Provision of general information
	Protocol (intervention) specific information (PI)	Information about sexual risk, risk management, adherence, or PrEP (or other material related to protocol/study)

Question (QU)	Closed Question (QUC)	Questions with answers that resemble response options or yes/no
	Open Question (QUO)	Questions that cannot be answered with a simple option or reply- choices for response not provided or implied
Raise Concern (RC)	With Permission (RCP)	Asking to share a concern, worry or fear typically in relation to what the client just shared
	Without Permission (RCW)	Stating a concern, worry or fear about something the client shared without asking/permission (note: may be appropriate depending on context)
Redirection (RD)	Focus/refocusing conversation intentionally (RDI)	Changing topics or shifting conversation to different content intentionally (eg., to close a topic, refocus an unproductive discussion, or manage conversation length)
	Changed topic unintentionally or producing missed opportunity (RDU)	Topic shifts or changes introduced that were not intentional-questions that redirect conversation from one area to a different one for unclear reasons
Reflect (RE)	Simple (RES)	Reflecting back client statements or experiences in a way that maintains client's content or level of insight (echo, repeat, rephrase, reword)
	Complex (REC)	Statements that paraphrase to emphasize connections, new insights or offer potential for deeper understanding/meaning or feeling
Reframe (RF)	Providing alternative explanations/view points	Offering an alternative and typically more functional or empowering way of looking at something the client has shared
Righting (RT)	Advocating for prevention/health rather than joining in ambivalence (RT)	Statements or questions that emphasize what the client should think or do that are pro-health or pro-self-care.
Roll with resistance (RR)	Joining client in reflecting on/feeling negatively about pro-health/pro-self-care options	Statements, questions, reflections that join client's negative feelings/thoughts about adopting/maintaining a health behavior-specific avoidance of touting the "should do" point of view
Silence (SI)	Strategic use of silence (vs filling silence or unintentional interruption of it)	Allowing for silence in an appropriate manner- productive silences- and using silence to learn about client

GLOBAL RATINGS	Basic Definition
Acceptance	Counselor demonstrates openness to client and discourse-willing to discuss difficulties without judging or correcting them.
Empathy/Understanding	Counselor demonstrated ability to "sit with" difficult content, positions client experiences within the context of his/her life and genuinely engages with client.
Spirit	Overall presence of counselor promotes a supportive environment. Counselor appears engages in conversation and mixes his or her own expressions and affect to create a positive productive working alliance with client.

Additional facilitation strategies

All of the developing discrepancy strategies can be used when exploring possible challenges, strengths and strategies for change. These can be incorporated into iNSC or t-iNSC. These strategies allow for added exploration and tailoring of intervention strategies through open discussions.

Asking evoking questions

These are questions that prompt the client to reflect on where he or she is presently in terms of promoting their health may not be where he or she would like to be. These evoke thoughts of potential differences between now and what could be.
What concerns you most about [current behavior]?
Why change at all?
When would change be something to consider? At what point? What indicators?

Asking for elaboration or examples …

when clients focus either on benefits of current behavior or mention possibility for change

If someone is stuck talking mostly about why change is not a good thing because there are lots of benefits to staying the same, stay with that line of thinking. Ask the client to say more about it. Ask for examples of how no-change is better. This is one way of "rolling with resistance" that can feel counter intuitive but often leads clients to their own discovery of reasons why change may in fact be preferable to remaining the same.

If a client mentions something, anything, about change or adopting a healthier behavior, ask the client to say more about it or provide examples. This fosters the client's own realization that change may be possible and preferred.

Guide client towards exploration of extremes

Sometimes, pushing thoughts or beliefs to extremes can help someone see behaviors and attitudes in a different way. In doing so, you want to consider both sides of extremes, summarize what you hear, and ask client to reflect on how it all makes sense to him or her. Let the client come to his or her own conclusions.
What would be the very worst of that? What would be the absolute best?

Look back/Look Forward

This involves asking the client to either (or both) look back to how things were at some point prior to now and how he or she would like things to be in the future.
What is different now from what you did before? How did that change for you?
If you look ahead a year from now or 5 years from now, what do you see? What would be different?

Explore decisional balance

Decisions to change or stay the same come, in part, from considering the pros and cons of adopting a behavior and pros and cons of keeping the old/current behavior. Walk the client through a decisional matrix for PrEP non-adherence and adherence. With the completed grid, explore client's reactions and thoughts about what can and cannot be changed/addressed.

Tell me some good things about NOT taking a dose a day. Tell me the bad things about NOT taking a dose a day.
Tell me some potential benefits about making sure you take PrEP each day. Tell me the possible bad things about taking PrEP every day.

http://www.wpro.who.int/hiv/documents/docs/HIVtoolkit19Janfinal_CA4F.pdf

Fill in the table below. When you are finished, review your answers and weigh your reasons for change. Which way does your decisional balance tip?*

** Note: If the client cannot clearly identify reasons for change, the counsellor may ask additional questions to identify reasons and assess the advantages and disadvantages of each.*

Changing your current (*write down targeted behaviour*)	
What's good about it?	What's not so good about it?

Changing your current behaviour	
What's good about it?	What's not so good about it?

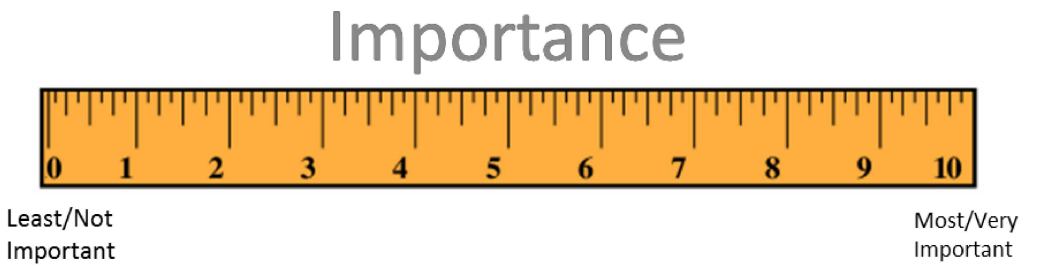
Rate IMPORTANCE and CONFIDENCE

Importance and confidence ratings are a common strategy to foster a discussion about change and readiness for thinking about changing a behavior and/or adopting a new one. First ask for a rating of importance (of taking all doses in the situations most challenging to client) and then have the person rate confidence in doing so, using the same scale.

MOVE DOWN THE RULER
Then you ask [for scores that are not 0]
"Why this score and not something a little lower?"
Summarize and reflect
on strengths.

MOVE UP THE RULER
Then you ask [for scores that
are not 10] *"Why this score
and not a little bit higher?"*
Summarize challenges.

NEEDS AND STRATEGIES
What would need to happen for your score to more from this (score) to this (score+1 or 2).
Use discussion to identify strategies to consider adopting as goals.



APPENDIX B

IMPLEMENTING NSC/iNSC OVER TIME

iNSC over the long haul

The following are some tips for performing iNSC over time.

- **Context.** Use the history and context of the counseling relationship as it develops. Talk with clients about things you have shared in past conversations, including things you know about the client and his or her life. This will help build rapport between you and the client. Counselors can also establish trust and convey genuine regard through what some might call "small talk". But often it is the small talk that makes the big talk feel genuine! In fact, the kind of calm and openness someone has when asking about the client's friend or family or work is the same kind of non-judgmental, supportive, open conversation that is the intended to characterize the entire tone of iNSC discussions.

- **Avoiding fatigue.** As soon as discussions feel routine or like you are just going through the motions to get to the next step, then fatigue has likely set in. If you are bored, it is likely that the client is bored too. iNSC recommends a rhythm to a conversation, but using your own words and changing those up over time is critical to keeping the conversation from being "stale" or predictable. We want conversations to feel natural and genuine. Responsiveness, flexibility, spontaneity, and genuineness are all critical to keeping conversations "fresh" over time.

- **Avoiding "forced" exploration.** When clients share a lot, the counseling sessions can feel really energized, with lots of potential for change and possibilities. When clients don't share much in terms of what gets in the way, or about what helps, it can feel like you are up against a wall. How do you continue the conversation when you don't have anything to work with?

  There are many reasons clients may not report challenges: they may not be aware of their challenges, they may know their challenges but not want to share them, they may feel that a behavior (pill taking, condom use) is a habit ("just something they do"), or they may have a strategy they use that meets their needs "perfectly." We ask counselors to value and trust the *process* of the discussion. While it may be tempting to try to "make" the client "talk" by asking a lot of questions, resist the temptation!
  Respect the resistance and do not try to attack it head on. Instead, work with it…join the client in discussing the things that help it to feel so "easy". You may have concerns that

the client is painting an overly positive picture, but try to remain open to exploring what the client is willing to explore and see what happens.

- **Maintenance.** This term comes largely from concepts in stages of change, where someone who has adopted a behavior for a certain amount of time is thought to be in the process of "maintenance." They are not changing but are maintaining. As a process, maintenance often draws from different skills sets than adopting a new behavior or trying to change a behavior. When working with someone in maintenance on some behavior, reinforcement can be helpful, but a focus on efforts rather than outcomes is worthwhile here because you don't want to create a situation where they would be fearful of disappointing you if they slip or return to an old behavior. The iNSC goals in this case are often to 'continue doing what you have been doing'. Because you don't know for sure if someone is in maintenance, versus wanting to present him or herself in maintenance, it is important *not* to assume that a check-in is not necessary. It is important to provide support to those sustaining PrEP use and/or sexual health strategies over time.

APPENDIX C

PLANNING FOR WHEN ALL IS FINE

All good!

EXAMPLE OF iNSC when people are "FINE" (from iPrEx OLE)

Integrated Next-Step Counseling
Case Scenario: Client Reports no Barriers

Step 3 in Integrated Next Step Counseling (iNSC) involves exploring clients' experiences with sexual health promotion and PrEP-use behaviors. We do this in an open-ended way because we want to learn how people integrate these behaviors into their lives and the challenges they may face. It is not uncommon for someone to share that they do not have challenges, barriers, or difficulties with a behavior.

Using iNSC does not depend on someone reporting a barrier.

iNSC is a strengths-based approach. The goal of each conversation is to offer clients the opportunity to talk about sexual health promotion and PrEP use, and to enhance and support clients' knowledge, motivation and skills. iNSC does not "hunt" or probe for problems to fix. For clients reporting a feeling of confidence and/or ease around a behavior, iNSC helps to identify what strategies facilitates that confidence, why it is that those strategies work for this person, and asks clients if they feel that they can continue to use these strategies over the next several months. This includes understanding what needs are satisfied by the client's strategies.

We know that some people will say everything is fine and that sexual health promotion and/or PrEP use is "easy," when in fact it is not. This may be because the client is in a hurry or they just are not comfortable openly discussing their experiences. **That is OK. Continue with the approach.**

Some counselors may find it appealing in these situations to probe, assess, challenge or push to try to find something to work on…some barrier to address; this is highly unlikely to "open-up" the conversation and may actually distance the client. Other counselors may feel drawn to simply reinforcing "achievements" and end the discussion quickly; this is not expected to have long-term benefit since clients may report only experiences that gain your praise.

The general process of exploration, identification of needs, and agreeing on a strategy are the keystones of iNSC discussions.

We ask that counselors continue with the approach regardless of whether or not a client reports any barriers. Below is a case scenario of how one may work with a client reporting no barriers while implementing iNSC.

iNSC when behaviors are reported as well-integrated

PrEP use conversation example [note that the sexual health promotion discussion has already occurred for this client and now the counselor is transitioning into the PrEP use part of the discussion]

<<transition>>
Counselor (C): *You are getting PrEP again today and before we talk about how things have been going with the PrEP pills, I want to check-in with you about this choice. Does getting PrEP still feel like something that is a good fit for you? Something you want to try to do?*
Client (X): *Yeah. For sure.*

STEP 3: EXPLORE
C: How have things been going with daily PrEP?
X: Really well. It's pretty easy to do really. I have no complaints.
C: What are the things that make it feel so easy for you?
X: You know, it's just easy. Like a habit now. I just do it.
C: Can you help me to understand, because I work with a lot of people who struggle with taking a pill every day and it would be really helpful if you could share what makes it or made it a habit for you?
X: I take supplements in the morning. I always have. I take my tablet at the same time. I almost never miss. So it's just something I do now. I don't even think about it really. I mean, I think about being on PrEP but I don't worry about 'did I take it' or 'this is so hard'. I just do it. You know.

STEP 4: TAILOR

STEP 5: IDENTIFY
C: So, by taking it with your supplements you found a way to fit the pills into your life rather than trying to change your life to fit in taking the pills. Does that sound right?
X: Yeah. If you fit it into something you already do it's easier
C: And that feels like it works for you most of the time.
X: Yeah. Not all the time but most of it.
C: Well most of the time sounds like something you feel good about. Yes?
X: Yeah. That works for me.

STEP 6: STRATEGIZE
C: OK. Do you see any situations that might come up in the next few months that would make matching-up PrEP to taking your supplements difficult or impossible to do?
X: Hmm. No. I don't think so.
C: Any concerns about keeping this something that feels easy you want to talk about?
X: Not right now.

STEP 7: AGREE ON
C: You have figured a way to make pill-taking feel more manageable. Are you willing to keep going with this for the next few months?
X: Definitely.

STEP 8: CLOSE/RECORD
C: Just to let you know, I or one of the other counselors will be checking in with you again each time you come in on how things are going with protecting your sexual health and using PrEP. So I'll be checking in on how things went with talking to your partner about using condoms when you do have sex with other people (this was the sexual health protection goal selected by this client)*, the strategy you came up with for promoting your sexual health, and also with how you are feeling about PrEP and experiences around using it daily. OK?*
X: Yeah. Sounds good. OK.

iNSC when behaviors are reported as well-integrated

<<transition>>
Counselor (C): *You are getting PrEP again today and before we talk about how things have been going with the PrEP pills, I want to check-in with you about this choice. Does getting PrEP still feel like something that is a good fit for you? Something you want to try to do?*
Client (X): *Yeah. For sure.*

At the transition the C checks in on choice. We want to emphasize choice at

STEP 3: EXPLORE
C: How have things been going with daily PrEP?
X: Really well. It's pretty easy to do really. I have no complaints.
C: What are the things that make it feel so easy for you?
X: You know, it's just easy. Like a habit now. I just do it.
C: Can you help me to understand, because I work with a lot of people
day and it would be really helpful if you could share what makes it or
X: I take supplements in the morning. Always have. I take my tablet at
it's just something I do now. I don't even think about it really. I mean,
don't worry about 'did I take it' or 'this is so hard'. I just do it. You know.

C listens and guides, but does not doubt, challenge or probe for barriers. Nor does the C just praise and close the conversation. Here the C encourages exploration of strengths.

STEP 4: TAILOR

C decides to focus on supporting the continued use of this reported strategy

STEP 5: IDENTIFY
C: So, by taking it with your supplements you found a way to fit the pills into your life rather than trying to change your life to fit in taking the pills. Does that sound right?
X: Yeah. If you fit it into something you already do it's easier
C: And that feels like it works for you most of the time.
X: Yeah. Not all the time but most of it
C: Well most of the time sounds like something you feel good about. Ye
X: Yeah. That works for me.

C frames how the strategy is satisfying an adherence-related need (PrEP use fitting into an existing routine). C respects P's assessment that it works "good enough" for him but offers the opportunity for P to say he needs more.

STEP 6: STRATEGIZE
C: OK. Do you see any situations that might come up in the next few months that would make matching up PrEP to taking your supplements difficult or impossible to do?
X: Hmm. No. I don't think so.
C: Any concerns about keeping this something that feels easy you want to talk about?
X: Not right now.

C confirms that this is a strategy that will continue to meet this P's need(s).
C offers opportunity to explore further and respects P's decision *not* to.

STEP 7: AGREE ON
C: You have figured a way to make pill-taking feel more manageable.
for the next few months?
P: Definitely.

P agrees to continue to use this strategy.

STEP 8: CLOSE/RECORD
C: Just to let you know, I or one of the other counselors will be checking in with you again each time you come in on how things are going with protecting your sexual health and using PrEP. So I'll be checking in on how things went with talking to your partner about using condoms
people, the strategy you came up with for promoting your sexual healt
about PrEP and experiences around using it daily. OK?
X: Yeah. Sounds good. OK.

C confirms of all goals agreed upon for the full iNSC discussion which includes the goal from the sexual health protection part of the discussion.
C reminds P that each visit will involve this kind of check-in.

This example shows how the counselor was able to guide a discussion around experiences, needs and strategies for someone who has a strategy they are reporting works most of the time. The counselor sets the stage for continued open conversations and also conveys respect for and engagement with this client.

APPENDIX D

PLANS

Behavioral Strategies for Sexual Health

Behavior	Need	Strategies

Strategies for Daily ART Use

Need	Strategies

EXAMPLE SEXUAL HEALTH PLAN

Behavioral Strategies for Sexual Health

Behavior	Need	Strategies
Condom use	*Access to a condom*	*Get condoms at clinic*
		Keep 4 condoms in purse
	Feel more comfortable asking partner to wear one	
Discuss importance of HIV testing and knowing ones status with new partners	*Feel more comfortable bringing it up*	*Discuss self-testing* *Discuss attending ANC visits* *Discuss health and wellness of partner and baby*

ART Use

Need	Strategies
Remember each day	*Cell phone alarm*
	Pill bottle in bathroom
	Take pill in the morning
Swallowing pill	*Take pill in the morning*
Privacy	*Hide pills in prenatal vitamin bottle*
Access to a pill each day	*Keep two pills in handbag*

APPENDIX E

Self-monitoring and supervisory tool implementation and fidelity

SELF ASSESSMENT TOOL (general and fidelity to iNSC)

SPECIFIC SKILLS		To work on… (goal for building skills) 1 2 3 4 5 6 7 Increase No change Decrease
Advise (AD)	With Permission (ADP)	1 2 3 4 5 6 7
	Without Permission (ADW)	1 2 3 4 5 6 7
Affirm (AF)	Appreciation, expressed confidence, reinforcement for spec beh/thought	1 2 3 4 5 6 7
Confront (CO)	Challenge ideas, confrontation	1 2 3 4 5 6 7
Contingencies (CT)	Praise, punishment, disapproval, moralizing in response to client discourse	1 2 3 4 5 6 7
Emphasize Control (EC)	Emphasis on client personal control, choice, and responsibility.	1 2 3 4 5 6 7
Evocation (EV)	Question, reflection or strategy to foster alternative viewpoints/change talk	1 2 3 4 5 6 7
Facilitate (FA)	Verbiage that supports exploration or unfolding issue more	1 2 3 4 5 6 7
Filler (FI)	Chit chat/report building	1 2 3 4 5 6 7
Follow Change Talk (FC)	Counselor focus/reflection on change talk (FC)	1 2 3 4 5 6 7
	Missed opportunities to explore change talk (MO)	1 2 3 4 5 6 7
Giving Information (GI)	General information (GI)	1 2 3 4 5 6 7
	Protocol (intervention) specific information (PI)	1 2 3 4 5 6 7
Question (QU)	Closed Question (QUC)	1 2 3 4 5 6 7
	Open Question (QUO)	1 2 3 4 5 6 7
Raise Concern (RC)	With Permission (RCP)	1 2 3 4 5 6 7
	Without Permission (RCW)	1 2 3 4 5 6 7
Redirection (RD)	Focus/refocusing conversation intentionally (RDI)	1 2 3 4 5 6 7
	Changed topic unintentionally or producing missed opportunity (RDU)	1 2 3 4 5 6 7
Reflect (RE)	Simple (RES)	1 2 3 4 5 6 7

SPECIFIC SKILLS		To work on… (goal for building skills) 1 2 3 4 5 6 7 Increase No change Decrease
	Complex (REC)	1 2 3 4 5 6 7
Reframe (RF)	Providing alternative explanations/view points	1 2 3 4 5 6 7
Righting (RT)	Advocating for prevention/health rather than joining in ambivalence (RT)	1 2 3 4 5 6 7
Roll with Resistance (RR)	Joining client in reflecting on/feeling negatively about pro-health/pro-self-care options	1 2 3 4 5 6 7
Silence (SI)	Strategic use of silence (vs filling silence or unintentional interruption of it)	1 2 3 4 5 6 7
Support (SU)	General support for efforts	1 2 3 4 5 6 7
Other:		1 2 3 4 5 6 7
Other:		1 2 3 4 5 6 7

GLOBAL RATINGS	Low 1 2 3 4 5 6 7 High
Acceptance	1 2 3 4 5 6 7
Empathy/Understanding	1 2 3 4 5 6 7
Spirit	1 2 3 4 5 6 7

FIDELITY MOTINORING TOOL

iNSC	REVIEW IMPLEMENTATION OF THESE AND COMMENT
1. Introduction and Rapport-building. □	
2. Review □	
SPLIT THE CONVERSATION	
iNSC TOPIC 1	
3. Explore □ (Situation? Words used? Ideas for next time?)	
a. Facilitators □ (Wording for this? Non-judgmental? Assist in pushing for deeper understanding?)	
c. Challenges □ (Wording for this? Non-judgmental? Assist in pushing for deeper understanding?)	

4. Tailor □ (What insights/observations did you use? What did you under-use?)	
5. Needs □ (What does client need to make progress towards a "next-step" improvement?)	
6. Strategies □ (How might client address/continue to address needs/wants/desires? What questions did you ask or not ask?)	
7. Agree/Goal setting □ (Which strategy will client try? How did you work with client to get this? Collaborative decision making?)	
TRANSITION TO TOPIC 2 □ (How to you switch gears? Smooth?)	
iNSC-TOPIC 2	
3. Explore □ (How did you frame this? What is current situation? Where is the person at? Words used? Ideas for next time?)	
a. Facilitators □ (Wording for this? Non-judgmental? Assist in pushing for deeper understanding?)	
c. Challenges □ (Wording for this? Non-judgmental? Assist in pushing for deeper understanding?)	
4. Tailor □ (What insights/observations did you use to tailor?)	
5. Needs □ (What does client need to make progress towards their next step- light improvement to their current situation)? How did you inquire about this?)	
6. Strategies □ (What questions did you ask for her to generate her own strategies?)	
7. Agree/Goal setting □ (Which strategy will client try? Collaborative decision making?)	
CLOSE. Thank Participant and summarize main insights and goals for next contact/next visit □	

NOTES:

REFERENCES AND RECOMMENDED READING

Basic Counseling/Communication Skills

- Schillinger, D. (2010). *An Introduction to Effectiveness, Dissemination and Implementation Research.* P. Fleisher and E. Goldstein, eds. From the Series: UCSF Clinical and Translational Science Institute (CTSI). Resource Manuals and Guides to Community- Engaged Research, P. Fleisher, ed. Published by Clinical Translational Science Institute Community Engagement Program, University of California San Francisco. http://ctsi.ucsf.edu/files/CE/edi_introguide.pdf
- Egan G. *The Skilled Helper: A problem management and opportunity development approach to helping.* 2009. Cengage Learning.
- Nelson-Jones R. *Basic Counseling Skills: A Helper's Manual.* 2008. Sage Publications.

Culture Communities and Health

http://www.cdc.gov/healthycommunitiesprogram/tools/
http://www.who.int/water_sanitation_health/hygiene/emergencies/em2002chap15.pdf

- Stokols D. (1992). Establishing and maintaining healthy environments: Toward a social ecology of health promotion. *American Psychologist,* 47, 6-22.
- Garcia A. Is Health Promotion Relevant Across Cultures and the Socioeconomic Spectrum?
- *Family Community Health*, 2006, s1 26(1s), 20s-27s.
- Kreuter MW et al. Achieving cultural appropriateness in health promotion programs: targeted and tailored approaches. *Health Education Behavior.* 2003, 30(2):133-46.

IMB and sIMB Model

- Amico KR. (2011). A situated IMB model for care initiation and maintenance in chronic medical conditions: sIMB-CIM. *Journal of Health Psychology*. DOI: 10.1177/1359105311398727. Published online April 1 2011.
- Amico, K. R., Barta, W., Konkle-Parker, D. J., Fisher, J. D., Cornman, D. H., Shuper, P. A., & Fisher,
- W. A. (2009). The Information-Motivation-Behavioral Skills model of ART adherence in a Deep South HIV+ clinic sample. *AIDS and Behavior, 13*(1), 66-75.
- Fisher JD, Amico KR, Fisher WA, Harman JJ. The Information-Motivation-Behavioral Skills model of antiretroviral adherence and its applications. Curr HIV/AIDS Rep. 2008; 5(4): 193-203.
- Fisher, J. D., & Fisher, W. A. (1992). Changing AIDS-risk behavior. *Psychological Bulletin, 111*(3), 455-474.
- Fisher JD, Fisher WA, Amico KR, Harman JJ. An Information-Motivation-Behavioral Skills Model of Adherence to Antiretroviral Therapy. Health Psychol. 2006; 25(4): 462-473.
- Fisher, J. D., Fisher, W. A., & Shuper, P. A. (2009). The Information-Motivation-Behavioral Skills Model of HIV preventive behavior. In R. DiClemente, R. Crosby, & M. Kegler (Eds.), *Emerging theories in health promotion practice and research model of HIV preventive behavior* (2nd ed., pp. 22-63). San Francisco, CA: Jossey Bass Publishers.

iPrEx

http://iprexole.com/

- Amico KR, McMahan V, Goicochea P, Vargas L, Wolf E, Lama J, Grant R, Liu A. (2010, May).
- Developing an Innovative Approach to Adherence Counseling and Assessment in a Pre- Exposure Prophylaxis (PrEP) Trial: Next Step Counseling and Neutral Assessment in the iPrEx Study. Oral presentation at the 5th International Conference on Treatment Adherence, Miami, FL.
- Grant RM, Lama JR, Anderson PL, McMahan V, et al. Pre-exposure chemoprophylaxis for HIV prevention in men who have sex with men. NEJM. 2010; DOI 10.1056/NEJMoa1011205
- Grant R, Lama J, Glidden D et al. Pre-exposure Chemprophylaxis for Prevention of HIV among Trans-women and MSM: iPREx Study. 18th Conference on Retroviruses and Opportunistic Infections (CROI). Boston, US, 2011.

Motivational Interviewing

http://motivationalinterviewing.org/

- Rollnick S, Miller WR, Butler CC. Motivational Interviewing in Health Care: Helping Patients Change Behavior. New York, NY: Gilford Press; 2008.

Options Intervention

- Manual http://www.chip.uconn.edu/chipweb/documents/interventions/Options%20intervention%20protocol% 20manual.pdf
- Centers for Disease Control and Prevention. Compendium of Evidence-Based HIV Behavioral Interventions (2012). http://www.cdc.gov/hiv/topics/research/prs/subset-best- evidence-interventions.htm
- Cornman, D. H., Christie, S., Shepherd, L. M., MacDonald, S., Amico, K. R., Smith, L. R., Shuper, P. A., Adelaja, A., Mahlase, G., Fröhlich, J. A., Pillay, S., Lalloo, U. G., Fisher, W. A., & Fisher,
- J. D. (2011 December). Counsellor-delivered HIV risk reduction intervention addresses safer sex barriers of people living with HIV in KwaZulu-Natal, South Africa. *Psychology and Health,* 26(12), 1623-1641.
- Fisher JD, Fisher WA, Cornman DH, Amico KR, Bryan A, Friedland GH. Clinician-delivered Intervention during routine clinical care reduces risky sexual behavior of HIV infected patients. . *J Acquir Immune Defic Syndr.* 2006; 41(1): 44-42.

Centers for Disease Control and Prevention. Compendium of Evidence-Based HIV Behavioral Interventions (2012). http://www.cdc.gov/hiv/topics/research/prs/subset-best- evidence-interventions.htm

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants - Trial 1 English

Consent Form Version Date: 15 June, 2020
IRB Study # 19-1060 NHSRC #19/05/2334
Title of Study: UNCPMZ 41901 - An integrated strategy to support antiretroviral therapy and pre-exposure prophylaxis adherence for HIV prevention in pregnant and breastfeeding women: a pilot study

Protocol Version 1.3, dated 15 June, 2020

Malawi Principal Investigator: Dr. Friday Saidi, MD - UNC Project Malawi. **US Principal Investigator**: Dr. Ben Chi, MD, University of North Carolina at Chapel Hill (UNC-CH).
Zambia Principal Investigator: Dr. Wilbroad Mutale, MBChB, PhD, University of Zambia.

UNC-Chapel Hill Department: Obstetrics and Gynecology
Funding Source and/or Sponsor: National Institutes of Health (NIH)
Study Contact telephone number: +265 995 403 113

CONCISE SUMMARY

The purpose of this study is to find the best ways to help support women who are pregnant and breastfeeding with HIV treatment and prevention. To do this, we are testing the use of next-step counseling and adherence supporters during pregnancy and breastfeeding to help with medication adherence. Participation in the study is 6 months and includes 4 clinic visits and a postpartum visit. There are also other adherence assessments timed with pharmacy visits. Individuals could benefit from the study if this strategy helps them take their medication for HIV every day. The main risks include breach of confidentiality and embarrassment/discomfort with the personal nature of the questions that will be asked during study visits.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the local clinic. You do not have to be in the research study in order to receive health care.

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be offered a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
Women who become infected with HIV during pregnancy and breastfeeding have a high chance of transmitting the infection to their babies. Adherence to HIV medication is needed to prevent transmission of HIV, but some patients find it difficult to remember to take their drugs every day. In this study, we want to find out whether support for adherence can increase a women's adherence to HIV medications during pregnancy and breastfeeding. The package of services includes a special kind of counseling, called integrated next step counseling (iNSC), and training of an adherence supporter selected by the participant.

Are there any reasons you should not be in this study?
You should not be in this study if you are under 18 years old, or do not plan on staying in this area for the next 6 months, or if you have concerns that your partner may harm you.

How many people will take part in this study?
A total of 100 women will take part in this study.

How long will your part in this study last?
Participation in the study is for 6 months. This includes the visit today, 3 additional clinic visits, a pharmacy visit each month and a final end of study visit. In addition, you will be asked to have adherence assessments done on a monthly basis, around the time of your pharmacy visits for antiretroviral drugs.

Today's enrollment visit will take approximately 1 hour. Clinic visits at months 1, 3 and 6 take from 30 minutes to 1 hour, depending on which group of the study you are assigned. In addition, six weeks after your pregnancy ends we will collect information about your delivery. This visit will take about 30 minutes.

What will happen if you take part in the study?
During the study you will continue to take your medication for HIV as prescribed. If you decide to take part in the study, at today's visit we will:

- Ask you questions about yourself, your partners, your home environment, your emotional wellbeing, and some of your behaviours. You may choose not to answer any questions you do not want to answer
- Ask questions and review your medical records to collect information about your medical history, including your pregnancy history and HIV history
- Collect urine to check for any kidney problems, including infection
- Collect approximately 1-2 tablespoons of blood from your arm. The blood will be tested for your HIV viral load, your blood counts (hemoglobin), and a syphilis test (if not

already in your medical record). Some blood will be stored for future testing to check for HIV resistance.
- Collect a sample of vaginal fluid. This will be done by a research nurse who will use a soft swab to collect a sample from the vagina.
- Ask you for your contact information

Half of the women in this study will receive integrated next step counseling (iNSC) at each clinic visit. The counseling sessions are designed to help you identify and solve problems that you face around adherence. They also help you to consider your medication adherence and how it relates to other health issues. The length of these sessions will depend on the issues you face, but are expected to be approximately 30 min. These sessions will be audio-recorded, so we can make sure the counseling is performed correctly. These audio-recordings will be identified by your study number and not your name.

Women getting iNSC will also be asked to choose someone to help them remember to take their HIV medications every day. For example, this may be a partner, family member, or friend who you are willing to tell you are HIV-positive. If you prefer you may choose someone from the clinic to help you remember to take your HIV medications every day. This supporter will undergo a short training about supporting adherence for antiretroviral therapy.

The choice about who receives these support activities and who does not will happen at random/by chance (like flipping a coin). Neither you nor the study staff will be able to choose which group you are placed in.

How often will I be seen for this study?
You will also come to the clinic for visits at 1, 3, and 6 months after the first visit. Each visit will take about 30 minutes to one hour. At these visits we will:

- Ask you questions about your pregnancy and your health, and perform a physical exam
- Ask questions about your well-being and sexual behavior. This will include questions about your partner(s) and any social harms (including intimate partner violence) that you may have experienced.
- At the one-month visit you will have a vaginal swab.
- At the three and six-month visits you will also have blood drawn for an HIV viral load test and urine collected to assess kidney function.
- If you are assigned to the group of study participants that also receives counseling, you will meet with the counselor at each visit. You will also be asked questions about the services being offered as part of the study.

In addition, some blood that is collected will be stored for future testing. The blood sample will be labeled with a code so your identity will not be known. The samples will be stored at UNC Project and will not be kept for more than 5 years. The samples will not be used for any purpose outside of this study.

In addition to the 4 scheduled visits you will visit the pharmacy to get your medication for HIV the same way you would if you were not in this study. These visits will include counting your

pills and answering questions about how many days you have taken your medicines in the past month.

After your pregnancy has ended, we will also collect information about the outcome of your pregnancy.

In addition to the above study activities, you may be asked to have a separate interview to talk about your experiences in the current study. You will be asked to sign a separate consent form to participate in this part of the study.

You may also be contacted about future research projects as well. If you are contacted, you will receive information about the study and, if you wish to join, you will be asked to sign a separate consent form.

Will I receive test results from the study?
You will be notified about test results that may help to guide your clinical care.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. The benefits to you include taking your HIV medication every day, which will help you to be healthy and prevent HIV transmission to your baby and partner(s). It is also possible that you will not benefit from taking part in this study.

What are the possible risks or discomforts involved from being in this study?
Taking part in this study involves the following risks:

The collection of blood from your arm may cause some discomfort, light-headedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting, or infection. The staff collecting the blood will be trained and will try hard to minimize these problems.

You may become embarrassed, anxious or worried when we ask you personal questions about your pregnancy, sexual behaviors, or HIV history. You are free not to answer any question that you do not want to. The staff involved in the counseling are trained specifically to provide integrated next step counseling.

There is also the risk of breach of confidentiality. The study staff will take precautions to ensure the confidentiality of all study data. All participants will be assigned a unique study ID number, and this number will be used on all study documents and specimens. Consent forms will be kept in a locked cabinet

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

How will information about you be protected?

Every effort will be made to keep your personal information confidential. It will be your decision whether you share any information about this study with others in your home or community. We will not do so. Your study information will be identified by a code to protect your privacy. Any publication about the results will not use your name or identify you personally.

Your records may be reviewed by representatives of the ethical and regulatory committees in Malawi-National Health Sciences Research Committee (NHSRC) and the University of North Carolina Institutional Review Board, the study sponsor (NIH), the U.S. Office for Human Research Protections, study staff, or study monitors. This is for quality control and safety purposes.

We may use gather data from this project to study other important research questions; however, all information will be removed so you cannot be personally identified.

Any recordings of the counseling sessions will be deleted after they have been transcribed (written down), and any identifying information will be deleted.

What is a Certificate of Confidentiality?

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. It is unlikely that you will be injured as a result of study participation. If you are injured, the UNC Project will give you immediate necessary treatment for your injuries. You will not have to pay for this treatment. You will be told where you can get additional treatment for your injuries. There is no program to pay money or give other forms of compensation for such injuries either through this institution or the United States National Institutes of Health. You do not give up any legal rights by signing this consent form.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, for any reason. The investigators also have the right to stop your participation at any time.

Will you receive anything for being in this study?

You will be receiving the Malawi Kwacha equivalent of $10 for each study visit you complete. This amount is to cover the costs of your transport expenses to and from the clinic.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

Who is sponsoring this study?
This research is funded by the National Institutes of Health (NIH). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact, , the Chairman, Dr. Matias Joshua 0999397913.

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

SIGNATURE PAGE

IRB # 19-1060

Title of Study: UNCPMZ 41901 - An integrated strategy to support antiretroviral therapy and pre-exposure prophylaxis adherence for HIV prevention in pregnant and breastfeeding women: a pilot study

Principal Investigator: Drs. Ben Chi and Wilbroad Mutale

Participant's Agreement:

If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please sign your name or place your thumbprint** in the signature area at the bottom of this page**.**

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

Saidi F, *et al. BMJ Open* 2021; 11:e046032. doi: 10.1136/bmjopen-2020-046032

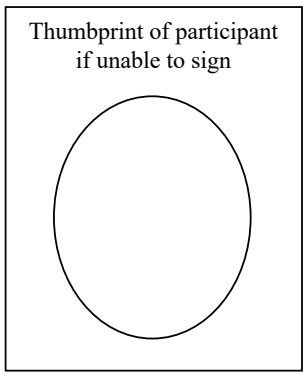
IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

PART B : ILLITERATE PARTICIPANT

Participant is illiterate: ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The **study staff must write participant's name and date of consent** on the **SHADED AREA.**



Participant Name (print)	Participant Thumbprint	Date

Participant Name and Date Written By…….on…...……

Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date
Impartial Witness Name (print)	Impartial Witness Signature	Date

Saidi F, *et al. BMJ Open* 2021; 11:e046032. doi: 10.1136/bmjopen-2020-046032

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants - Trial 2 English.

Consent Form Version Date: 15 June, 2020
IRB Study: UNC# 19-1060; NHSRC #19/05/2334
Title of Study: UNCPMZ 41901 - An integrated strategy to support antiretroviral therapy and pre-exposure prophylaxis adherence for HIV prevention in pregnant and breastfeeding women: a pilot study

Protocol Version 1.3, dated 15 June, 2020

Malawi Principal Investigator: Dr. Friday Saidi, MD - UNC Project Malawi. **US Principal Investigator**: Dr. Benjamin Chi, MD, University of North Carolina at Chapel Hill (UNC-CH).
Zambia Principal Investigator: Dr. Wilbroad Mutale, MBChB, PhD, University of Zambia.

UNC-Chapel Hill Department: Obstetrics and Gynecology
Funding Source and/or Sponsor: National Institutes of Health (NIH)
Study Contact telephone number: +265 995 403 113

CONCISE SUMMARY

The purpose of this study is to find the best ways to help support women who are pregnant and breastfeeding with HIV treatment and prevention. This part of the study focuses on prevention of HIV infection in women who are HIV-negative. All participants must be willing to take the combination drug, tenofovir disoproxil fumarate and emtricitabine (TDF-FTC), on a daily basis to prevent HIV infection. This is called oral pre-exposure prophylaxis, or PrEP, and is approved for use among people at higher risk for getting HIV. In this study, we are testing the use of integrated next-step counseling and adherence supporters during pregnancy and breastfeeding to help pregnant and breastfeeding women take PrEP. Participation in the study is 6 months and includes 4 clinic visits and a postpartum visit. There are also other adherence assessments timed with pharmacy visits. Individuals could benefit from the study if this strategy helps them take their medication for HIV prevention. The main risks include breach of confidentiality and embarrassment/discomfort with the personal nature of the questions that will be asked during study visits. There are also risks associated with taking TDF-FTC.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people

in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the local clinic. You do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be offered a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
Women who become infected with HIV during pregnancy and breastfeeding have a high chance of transmitting the infection to their babies. Certain antiretroviral medicines can be taken by HIV-negative pregnant and breastfeeding women to prevent new HIV infections. When taken daily, the combination drug TDF-FTC can be used in this way, also known as pre-exposure prophylaxis (or PrEP). Adherence to PrEP is needed to prevent HIV, but some patients find it difficult to remember to take their drugs every day. In this study, we want to find out whether support for adherence can increase a women's adherence to PrEP during pregnancy and breastfeeding. The package of services includes a special kind of counseling, called integrated next step counseling (iNSC), and training of an adherence supporter selected by the participant..

Are there any reasons you should not be in this study?
You should not be in this study if you are under 18 years old; are unwilling to take PrEP; have been told you have hepatitis B, kidney disease, or osteoporosis; do not plan on staying in this area for the next 6 months; or if you have concerns that your partner may harm you. We will also perform some blood tests to make sure PrEP is safe for you.

How many people will take part in this study?
A total of 200 women will take part in this study.

How long will your part in this study last?
Participation in the study is for 6 months. This includes the visit today, an enrollment visit, 3 additional clinic visits, a pharmacy visit each month and a final end of study visit. In addition, you will be asked to have adherence assessments done on a monthly basis, around the time of your pharmacy visits for PrEP.

If you choose to participate, today's screening visit will take about 1 hour. The enrollment visit, which will take place within 3 weeks and will take approximately 1 hour. Clinic visits at months 1, 3 and 6 take from 30 minutes to 1 hour, depending on which group of the study you are assigned. In addition, six weeks after your pregnancy ends we will collect information about your delivery. This visit will take about 30 minutes.

What will happen if you take part in the study?
At today's visit we will:

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

- Ask you questions about your medical history
- Perform a physical exam
- Collect blood to test for HIV, hepatitis B and kidney function.
- Ask you for your contact information

You will be asked to come back to review your lab test results and confirm your eligibility for the study. If qualify for the study, you will be formally invited to participate in the study. At this enrollment visit, we will again collect blood to test for HIV. We will also:

- Ask questions about yourself, your partners, your home environment, your emotional wellbeing, and some of your behaviors. You may choose not to answer any questions you do not want to answer
- Ask questions and review your medical records to collect information about your medical history, including your pregnancy history and HIV history
- Collect urine to check for any kidney problems, including infection
- Collect approximately 1-2 tablespoons of blood from your arm. The blood will be tested for syphilis (if not already in your medical record) and to make sure your liver is functioning normally.
- Collect a sample of vaginal fluid. This will be done by a research nurse who will use a soft swab to collect a sample from the vagina.

Half of the women in this study will receive integrated next step counseling (iNSC) at each clinic visit. The counseling sessions are designed to help you identify and solve problems that you face around adherence. They also help you to consider your adherence in the context of other health issues. The length of these sessions will depend on the issues you face, but are expected to be approximately 30 min. These sessions will be audio-recorded, so we can make sure the counseling is performed correctly. These audio-recordings will be identified by your study number and not your name.

Women getting iNSC will also be asked to choose someone to help them remember to take their PrEP medications every day. For example, this may be a partner, family member, or friend who you are willing to tell you are taking PrEP. If you prefer you may choose someone from the clinic to help you remember to take your HIV medications every day. This supporter will undergo a short training about supporting adherence for PrEP.

The choice about who receives these support activities and who does not will happen at random/by chance (like flipping a coin). Neither you nor the study staff will be able to choose which group you are placed in.

How often will I be seen for this study?

You will also come to the clinic for visits at 1, 3, and 6 months after enrollment. Each visit will take about 30 minutes to one hour. At these visits we will:

- Ask questions about your pregnancy and your health, including possible side effects from PrEP medicines, and perform a physical exam

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

- Ask questions about your well-being and sexual behavior. This will include questions about your partner(s) and any social harms (including intimate partner violence) that you may have experienced.
- At the one-month visit you will also have a vaginal swab.
- At the three- and six-month visits you will also have blood drawn to test for HIV and check the levels of TDF-FTC (the drugs in PrEP) in your blood.
- Collect samples to make sure your kidneys are working properly. This includes blood tests at three and six months. Urine tests will be done at one-, three-, and six-month visits.
- If you are assigned to the group of study participants that also receives counseling, you will meet with the counselor at each visit. You will also be asked questions about the services being offered as part of the study.

In addition to these four scheduled visits you will visit the study pharmacy to get your PrEP medication. These visits will include counting your pills and answering questions about how many days you have taken your medicines in the past month.

After your pregnancy has ended, we will also collect information about the outcome of your pregnancy.

If you become HIV-positive while in the study, we will perform additional tests to confirm the diagnosis. We will stop you from taking PrEP and will collect blood to test for HIV drug resistance. You will have your study exit visit and will be referred to your local clinic for HIV care and treatment.

Leftover specimens may also be stored for future testing. The blood sample will be labeled with a code so your identity will not be known. The samples will be stored at UNC Project and will not be kept for more than 5 years. The samples will not be used for any purpose outside of this study. In addition to the above study activities, you may be asked to have a separate interview to talk about your experiences in the current study. You will be asked to sign a separate consent form to participate in this part of the study.

You may also be contacted about future research projects as well. If you are contacted, you will receive information about the study and, if you wish to join, you will be asked to sign a separate consent form.

Will I receive test results from the study?
You will be notified about test results that may help to guide your clinical care.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. Participation in this study could lower your risk of contracting HIV. By doing this, it may also lower the chances your baby may get HIV. It is also possible that you will not benefit from taking part in this study.

What are the possible risks or discomforts involved from being in this study?
Taking part in this study involves the following risks:

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

The most common risks and discomforts associated with TDF-FTC are: nausea, headache, abdominal pain, and weight decrease. These side effects are uncommon and usually resolved within the first month of taking these medicines. The less common risks and discomforts associated with TDF-FTC are decreases in bone density and moderately reduced kidney function. Rare but possible risks may include severe kidney problems. If this were to occur, we would stop the drug and closely monitor closely monitor your kidneys with blood tests.

TDF-FTC is widely regarded as safe during pregnancy. Any medication taken while pregnant will come in contact with the baby. The baby will be exposed to the medicines in PrEP, but there are no studies that have shown an increased chance of birth defects. Most pregnant women who take PrEP in the form of TDF-FTC tolerate it well.

The collection of blood from your arm may cause some discomfort, light-headedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting, or infection. The staff collecting the blood will be trained and will try hard to minimize these problems.

You may become embarrassed, anxious or worried when we ask you personal questions about your pregnancy, sexual behaviors, or HIV history. You are free not to answer any question that you do not want to. The staff involved in the counseling are trained specifically to provide integrated next step counseling.

There is also the risk of breach of confidentiality. The study staff will take precautions to ensure the confidentiality of all study data. All participants will be assigned a unique study ID number, and this number will be used on all study documents and specimens. Consent forms will be kept in a locked cabinet

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

Every effort will be made to keep your personal information confidential. It will be your decision whether you share any information about this study with others in your home or community. We will not do so. Your study information will be identified by a code to protect your privacy. Any publication about the results will not use your name or identify you personally.

Your records may be reviewed by representatives of the ethical and regulatory committees in Malawi-National Health Sciences Research Committee (NHSRC) and the University of North Carolina Institutional Review Board, the study sponsor (NIH), the U.S. Office for Human Research Protections, study staff, or study monitors. This is for quality control and safety purposes.

We may use gather data from this project to study other important research questions; however, all information will be removed so you cannot be personally identified.

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

Any recordings made as part of our counseling sessions will be deleted after they have been transcribed (written down), and any identifying information will be deleted.

What is a Certificate of Confidentiality?
Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. It is unlikely that you will be injured as a result of study participation. If you are injured, the UNC Project will give you immediate necessary treatment for your injuries. You will not have to pay for this treatment. You will be told where you can get additional treatment for your injuries. There is no program to pay money or give other forms of compensation for such injuries either through this institution or the United States National Institutes of Health. You do not give up any legal rights by signing this consent form.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, for any reason. The investigators also have the right to stop your participation at any time.

Will you receive anything for being in this study?
You will be receiving the Malawi Kwacha equivalent of $10 for each study visit you complete. This amount is to cover the costs of your transport expenses to and from the clinic.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

Who is sponsoring this study?
This research is funded by the National Institutes of Health (NIH). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact, the Chairman, Dr. Matias Joshua 0999397913.

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

SIGNATURE PAGE

IRB # 19-1060

Title of Study: UNCPMZ 41901 - An integrated strategy to support antiretroviral therapy and pre-exposure prophylaxis adherence for HIV prevention in pregnant and breastfeeding women: a pilot study

Principal Investigator: Drs. Ben Chi and Wilbroad Mutale

Participant's Agreement:

If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please sign your name or place your thumbprint** in the signature area at the bottom of this page**.**

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

PART B : ILLITERATE PARTICIPANT

Participant is illiterate: ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The **study staff must write participant's name and date of consent** on the **SHADED AREA.**

	Thumbprint of participant if unable to sign	
Participant Name (print)	Participant Thumbprint	Date

Participant Name and Date Written By…….on…...……

Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date
Impartial Witness Name (print)	Impartial Witness Signature	Date

Saidi F, *et al. BMJ Open* 2021; 11:e046032. doi: 10.1136/bmjopen-2020-046032

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants – English Qualitative Interviews.

Consent Form Version Date: 15 June, 2020
IRB Study: UNC# 19-1060; NHSRC 19/05/2334
Title of Study: UNCPMZ 41901 - An integrated strategy to support antiretroviral therapy and pre-exposure prophylaxis adherence for HIV prevention in pregnant and breastfeeding women: a pilot study

Protocol Version 1.3, dated 15 June, 2020

Malawi Principal Investigator: Dr. Friday Saidi, MD - UNC Project Malawi. **US Principal Investigator**: Dr. Benjamin Chi, MD, University of North Carolina at Chapel Hill (UNC-CH).
Zambia Principal Investigator: Dr. Wilbroad Mutale, MBChB, PhD, University of Zambia.

UNC-Chapel Hill Department: Obstetrics and Gynecology
Funding Source and/or Sponsor: National Institutes of Health (NIH)
Study Contact telephone number: +265 995 403 113

CONCISE SUMMARY

The purpose of this study is to find the best ways to help support women who are pregnant and breastfeeding with HIV treatment and prevention. This part of the study involves three in-depth interviews to collect more information about women's opinions of a combination adherence support package. This includes integrated next-step counseling and adherence supporter training. Each interview is expected to take approximately 1 hour, and will occur at enrollment, 3 and 6 months after enrollment. There is no expected benefit to you for participating in this part of the study. The main risk is breach of confidentiality.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the local clinic. You do not have to be in the research study to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be offered a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

What is the purpose of this study?
The main purpose of this study is to evaluate how well the strategies used in this study work at helping women adhere to HIV treatment and prevention. By interviewing women who participated in the main study, we are hoping to understand how people felt about these different services. You are being asked to be interviewed because you participated in the main study and we would like to collect information about your experience.

Are there any reasons you should not be in this study?
You should not be in this study if you are under 18 years old, or you do not wish to talk about your experience in the study.

How many people will take part in this study?
A total of 40 women from the main study will take part in the interviews.

How long will your part in this study last?
There are three interviews; each is expected to take approximately 1 hour.

What will happen if you take part in the study?
If you consent to participate, you will be interviewed by a member of the study staff. You will be asked to talk about your opinions and experiences with the study intervention, what made it difficult and what you found helped.

The interviews will be conducted in a private room and will be recorded to help us have an accurate record of the information you provided.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. There are no expected benefits to you from participating in the interviews.

What are the possible risks or discomforts involved from being in this study?
Participation in clinical research includes the risks of loss of confidentiality and discomfort with the personal nature of questions, particularly when discussing HIV infection or sexual behaviors. Investigators will make every effort to protect participant privacy and confidentiality. You may choose not to answer questions during the interview if you do not want, and you may end the interview at any time. Data that could identify you will not be collected during the interview. There may also be uncommon or previously unknown risks. You should report any problems to the researcher.

If you choose not to be in the study, what other treatment options do you have?
You do not have to be in this research study in order to receive antenatal care.

How will information about you be protected?
Every effort will be made to keep your personal information confidential. It will be your decision whether you share any information about this study with others in your home or community. We

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

will not do so. Your study information will be identified by a code to protect your privacy. Any publication about the results will not use your name or identify you personally.

Your records may be reviewed by representatives of the ethical and regulatory committees in Malawi-National Health Sciences Research Committee (NHSRC) and the University of North Carolina Institutional Review Board, the study sponsor (NIH), the U.S. Office for Human Research Protections, study staff, or study monitors. This is for quality control and safety purposes.

Audio recordings of the interviews will be deleted after the information has been reviewed. Any information that could identify you will not be used.

What is a Certificate of Confidentiality?

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

What if you want to stop before your part in the study is complete?

There is no penalty if you do not give permission to join the study. You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time.

Will you receive anything for being in this study?

If you receive a separate trip to the clinic for this interview, you will receive the equivalent of 10 USD for transportation costs.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is funded by the National Institute of Health. This means that the sponsor will pay for all of the costs associated with the study. The research team will not gain any financial benefit from this study or the results of this study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the investigators listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you

IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

would like to obtain information or offer input, you may contact, the Chairman, Dr. Matias Joshua 0999397913.

SIGNATURE PAGE

IRB # 19-1060

Title of Study: UNCPMZ 41901 - An integrated strategy to support antiretroviral therapy and pre-exposure prophylaxis adherence for HIV prevention in pregnant and breastfeeding women: a pilot study

Principal Investigator: Drs. Ben Chi and Wilbroad Mutale

Participant's Agreement:

If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please sign your name or place your thumbprint** in the signature area at the bottom of this page**.**

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

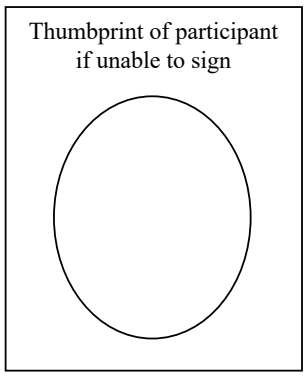
IRB TEMPLATE Version 2.0 - 12/5/2018 - Do not alter this text box

PART B : ILLITERATE PARTICIPANT

Participant is illiterate: ☐

The study staff must complete this section, ONLY if an impartial witness is available.

The **study staff must write participant's name and date of consent** on the **SHADED AREA.**



Participant Name (print)	Participant Thumbprint	Date

Participant Name and Date Written By…….on…...……

Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date
Impartial Witness Name (print)	Impartial Witness Signature	Date