FINAL REPORT

HIV Sentinel Surveillance among Key Populations in Bhutan, 2021

Detection of HIV infection and indicators of preventive and risk behaviors among high-risk women (HRW), men who have sex with men (MSM), transgender women (TGW), and transgender men (TGM)

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Contents

List of acronyms and definitions

CSW	Commercial sex worker
HISC	Health Information Service Center
HIV	Human immunodeficiency virus
HRW	High risk women
KP	Key population
MoEA	Ministry of Economic Affairs
MoH	Ministry of Health
MSM	Men who have sex with men
NACP	National AIDS/HIV and STI Control Program
NGO	Non-governmental organization
NSB	National Statistics Bureau
STI	Sexually transmitted infection
TGM	Transgender men
TGW	Transgender women
UNAIDS	Joint United Nations Programme on HIV and AIDS

EXECUTIVE SUMMARY

An HIV Sentinel Surveillance (HSS) system for key populations was developed and launched in Bhutan in 2021. The General Objective was to pilot test the methods for ongoing rounds of collecting data relevant to the control and elimination of HIV among high-risk women (HRW, including commercial sex workers [CSW]), men who have sex with men (MSM), transgender women (TGW), and transgender men (TGM). Additional Specific Objectives were the detection of HIV and measurement of risk and preventive behaviors among key populations in Bhutan. Methods included recruitment of key populations through peer-driven recruitment, a risk behavioral questionnaire, and HIV testing.

HSS successfully recruited 119 HRW, 133 MSM, 29 TGW, and 66 TGM in 2021. The sample was apportioned to three Groups comprised of: Thimphu/Paro/Punakha/Wangdue (Group 1), Phuentsholing-Chukkha/Gelephu (Group 2), and Bumthang/Monggar/Samdrup Jongkhar (Group 3). Due to venue and district closures during the COVID-19 pandemic, projected sample sizes were not attained in the border districts of Phuentsholing/Chukkha, Gelephu, and Samdrup Jongkhar. In the field rapid HIV testing offered by lay counselors was accepted by 97% of participants. The clients were either offered supervised rapid self-testing or referred to HISC counsellors for testing.

One HIV test was positive for an MSM who was previously unaware of being infected. As per HSS protocol, the sample size for MSM in the Group 1 districts along with partner notification testing. The resulting prevalence of HIV among MSM in Group 1 was 0.9% (95% confidence interval [CI] 0% - 2.6%). Zero HIV infections were detected in all other key population groups, supporting a conclusion of HIV prevalence being below 4% for all key populations in Bhutan. Interview data also found multiple partners were common among HRW, MSM, and TGW despite COVID-19. Meanwhile access and use of HIV/STI prevention services was low. Reported stigma and discrimination were high, particularly among transgender people.

Overall, the HSS methods were found to be feasible, acceptable, and efficient despite COVID-19 restrictions. Recognized limitations include the potential anomalous behaviors resulting from COVID-19 restrictions (e.g., closure of dryangs, clubs, borders), possible participation bias among key populations at highest risk, and small and unmet sample sizes.

Recommendations stemming from the lessons learned and data of this first round of HSS include:

- Restart HSS in Group 2 districts (Phuentsholing, Gelephu) and Samdrug Jongkhar when COVID-19 restrictions are lifted.
- Conduct the second round of HSS in 2023 as part of a biennial cadence.
- Increase the sample size for future HSS rounds to lend more certainty to the evidence for low HIV prevalence and to be more sensitive to small increases in transmission and risk.
- Dissemination of findings with public health officials, non-governmental organizations, and community members.
- Promote more HIVST self testing both assisted and unassisted to increase the uptake of tests and make HIVST freely available and accessible

Sharing if information and lessons learned will strengthen interpretation of the data, identify underlying causes of findings, and appropriate responses to help Bhutan achieve HIV elimination goals by 2030.

BACKGROUND AND NEED

The HIV Epidemic in Bhutan and the Need for HIV Sentinel Surveillance among Key Populations

Historically, Bhutan has experienced a low-level HIV epidemic [1]. Compared to other counties in the region, Bhutan's HIV epidemic started later, with the first case diagnosed in 1993, and progressed more slowly. Sporadic cases appeared between 1993 and 2000. From 2000 to 2013, the number of new HIV diagnoses rose from 9 to 51. Since 2013, there has been a plateau in the number of new HIV diagnoses, fluctuating between 49 and 58 annually. To June 2019 there were a cumulated 663 HIV diagnoses, 505 of whom are known to be alive, and 450 of whom are on antiretroviral treatment provided by the Ministry of Health. UNAIDS models place the number of people living with HIV in Bhutan at 1,265. The national response to HIV is geared to end the epidemic by 2030. Targets to achieve this vision include increasing the proportion of persons living with HIV who are diagnosed to >95%, the proportion of those diagnosed on antiretroviral treatment at 100%, and the proportion with sustained viral suppression at >95%.

Bhutan may stand in contrast to other countries in South and South East Asia in its pattern of HIV epidemiologic progression. Typically, key populations (KP) at elevated risk acquire infection early in an epidemic, when the conditions for rapid spread were already present (e.g., high sexual partner turn-over, multiple concurrent partnerships, low condom use). These KP include men who have sex with men (MSM), transgender women (TGW), and high risk women (HRW) who work or frequent venues and hotspots were commercial sex and casual partnering are initiated. Transgender men (TGM) are also a sexual/gender minority group for whom there are few studies assessing their risk for HIV. HIV incidence rises fast in these populations, often accelerating after a threshold of 5% prevalence is surpassed. HIV transmission to the sexual partners of key populations becomes substantial, raising the overall prevalence of HIV for the nation. At this point, the epidemic has moved from low-level to concentrated.

Several factors are cause for concern that conditions are present for greater spread of HIV among key populations in Bhutan. First, with a passive surveillance system, under-reporting of HIV cases

is possible. Second, UNAIDS projections and low CD4 counts among persons newly diagnosed with HIV indicate that many infections go undiagnosed for long periods of time. Therefore, the number of people living with HIV may be under-estimated and the potential for onward transmission from persons who are untreated may be high. Third, MSM, TGW, TGM, and HRW status has not been systematically recorded in surveillance or program data. A disproportionate burden of infection in these populations may be unrecognized. Fourth, indicators of risk suggest high potential for increased sexual transmission of HIV. These include rising incidence of sexually transmitted infections (STIs), low condom use in all types of partnerships, high levels of multiple sex partners, and the apparent emergence of commercial and transactional sex [1-5]. Finally, there is increasing concern that the prevention needs of KP have been inadequately addressed in Bhutan [3,6,7].

Whether Bhutan will follow a progression from a low level to concentrated epidemic, similar to other countries in the region, or start on a trajectory towards eliminating HIV by 2030 may hinge upon reaching KP with effective programs. The Ministry of Health of Bhutan has embarked on a nationwide HIV prevention and awareness program with targeted interventions for MSM, TGW, TGM, and HRW. Unfortunately, there is a scarcity of data on these populations in Bhutan – particularly the current prevalence of HIV, risk behaviors that lead to HIV acquisition and transmission, and access to and uptake of prevention programs including HIV testing. To guide the national effort to end the epidemic, an efficient approach to HIV Sentinel Surveillance (HSS) for KP is needed that is adapted to Bhutan's specific epidemic, demographic, and cultural context.

A recent population size estimation exercise conducted among MSM, TGW, TGM, and HRW in Bhutan [8] laid the groundwork for an HSS system. The exercise applied multiple methods to arrive at robust population size estimates, mapped the venues where KP can be reached, and gauged their levels of risk and preventive behaviors through face-to-face interviews. The study successfully recruited 948 KP (including 517 HRW, 273 MSM, 34 TGW women, and 124 TGM) using a hybrid venue- / peer-referral sampling approach. Synthesis of the several population size estimates and extrapolation arrived at an estimated 1,726 MSM, 1,221 HRW, 76 TGW, and 302

TGM. Interview data found high levels of risk behaviors (e.g., sex for money, multiple partnering, early sexual debut, sex with alcohol) coupled with low levels of preventive behaviors (e.g., condom use, HIV testing, receiving prevention outreach) and wide experiences of discrimination and stigmatization of KP. The exercise had the added benefit of building capacity for outreach worker/peer teams to conduct the methods needed for a community-based HSS system.

Unfortunately, HIV testing was not done in the population size estimation leaving the data gap of HIV prevalence among KP in Bhutan. Community member input at the formative phase cautioned against adding HIV testing as threatening the primary aims of population size estimation, venue mapping, and frank disclosure of risk behaviors. The requirements of written informed consent and health professional delivery of counseling and testing were considered barriers to participation. Stigma, discrimination, and fear of learning one's HIV serostatus were also cited as reasons not to include HIV testing in the mapping and size estimation exercise.

In recent months, Bhutan's MOH trained and certified peer outreach workers to conduct counseling and initial rapid HIV testing using rapid supervised HIV Self Test kits (oral swap) in the field with the option of blood-based finger prick rapid test kits. This new policy can partially address barriers to testing among KP. With any initial positive or indeterminate results in the field, the peer counselors can bring the participant to the local HISC or other health facility for confirmatory testing, further counseling, and linkage to care if confirmed positive. The new process provides a potentially acceptable means to integrate community-based HIV prevalence measures into HSS. With the inclusion of HIV prevalence among KP, a critical data gap in understanding the epidemic in Bhutan will be filled.

The current report describes the principles, procedures, and findings of an HSS system develop to detect HIV and measure related risk and preventive behaviors among MSM, HRW, TGW, and TGM in Bhutan. The approach builds on the capacities and lessons learned during the Population Size Estimation exercise with the addition of HIV testing. The sampling method used the peer-driven recruitment (PDR) approach successfully deployed for the size estimation. Following

verbal informed consent, peer outreach workers conducted a detailed interview on risk and preventive behaviors followed by counseling and an observed rapid oral HIVST. These certified peer counselors were equipped to escort any participant with a reactive or indeterminate result to the nearby HISC or approved testing site for confirmatory testing and linkage to care and social services. Considering that it is the first time, we rolled out HIVST, a more cautious approach was taken. A dedicated trained HISC counselor was stationed with peer counsellors to provide emergency services or to provide testing services that were directed to them.

The HSS sites proposed included 9 dzongkhag (Thimphu, Paro, Punakha, Wangdue, Chhukha, Sarpang, Bumthang, Mongar, and Samdrup Jonghkar). However, the COVID-19 epidemic restricted activities from several districts (described below). The sample size of 133 HRW, 139 MSM, 30 TGW, and 90 TGM was gauged to have sufficient power to determine that HIV prevalence is below 4% using a Lot Quality Assurance approach [9]. Any HIV-positive result in a lot indicates a threshold has been passed whereby HIV prevalence may be greater than 5%. Finding any HIV-positive in the lot triggers further investigation, including increased sample size for that KP, enhanced partner notification, mobilizing community support for information and testing, and testing within hotspot areas. HSS is proposed to be implemented on biennial basis.

The described HSS approach for KP is envisioned as only one part of a comprehensive surveillance system that also includes case-based reporting data, detailed profiles of all newly diagnosed cases, partner notification, updated KP population size estimates, programmatic data from clinics and prevention services for KP, and epidemic modeling. Taken together, data will help track changes in the epidemic and its determinants over time, gauge successes and shortfalls in epidemic control, set targets for prevention programs, and identify points for HIV interventions to end the epidemic in Bhutan.

OBJECTIVES

General objective:

1. To establish an HIV Sentinel Surveillance system for key populations in Bhutan.

Specific objectives:

1. To determine HIV prevalence and track trends in HIV prevalence over time among MSM, TGW, TGM, and HRW in Bhutan.
2. To measure and track indicators of HIV risk and preventive behaviors among MSM, TGW, TGM, and HRW.
3. To assess the reach, uptake, and trends in HIV care and prevention programs for MSM, TGW, TGM, and HRW.

METHODS

Conceptual Framework and Characteristics of HIV Sentinel Surveillance

UNAIDS defines surveillance is the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice [10]. No single source of information can provide a complete picture of the HIV epidemic; several complementary data collection systems are needed. These data systems include the reporting of diagnosed HIV infections, reporting of sexually transmitted infection (STI) diagnoses, clinic data on patients receiving anti-retroviral treatment (ART) and other HIV-related program data. Sentinel surveillance is one component of a comprehensive public health surveillance system for HIV. Sentinel surveillance entails the short-term and periodic tracking of HIV prevalence among populations at highest risk for infection, such as key populations (KP), to serve as an early warning system for emerging trends in the epidemic [10].

Sentinel surveillance has several pragmatic characteristics. First, the methods are consistent over person, place, and time. Truly representative surveys of KP at high risk for HIV are difficult and costly. Sentinel surveillance therefore relies on approaches that may not be representative of the

whole population, but are simple and consistently implemented to enable interpretation of relative differences in HIV prevalence between groups and locations and changes in the epidemic over time. Second, sentinel surveillance targets populations at highest risk for HIV to obtain early warning signals. Sentinel surveillance seeks to identify HIV among populations where infection may first appear, for example sampling at hotspots, within sexual networks, or among clients of STI clinics, drug treatment centers, jails, or services with high proportions of key populations among their clientele. Third, sentinel surveillance is designed to be resource efficient in order to be sustainable over time. Sentinel surveillance may therefore be based in facilities that already collect blood that can be used for HIV testing (e.g., antenatal clinics, STI clinics, NGOs providing outreach and mobile HIV testing). Trade-offs in efficiencies with facility-based sentinel surveillance, however, entail potential biases in who does or does not access services and limited amounts of behavioral data.

Alternative approaches to sentinel surveillance entail recruitment of community-based samples (i.e., reaching persons not accessing services) outside of facilities. State-of-the-art community-based sampling methods include respondent-driven sampling or RDS (by peer referral) and time-location sampling or TLS (by intercepting at venues) [11]. However, RDS and TLS have high cost, practical limitations, and theoretical assumptions that are difficult to meet. These include having numerous venues where KP congregate, for TLS, and for RDS a large enough target population size, highly connected social networks, accurate assessment of personal network sizes, and random recruitment from one's network. Adaptations, modifications, and hybrid designs of RDS and TLS that relax assumptions have also been used for HSS, including targeted interventions, snowball sampling, stratified snowball sampling, and starfish sampling [12]. If systematically implemented, diversified using multiple sources, and consistent over time and place, the practical advantages of these adapted sampling methods may outweigh the potential loss of rigor of conventional RDS and TLS.

Unique Challenges to HIV Sentinel Surveillance for Key Populations in Bhutan

Several factors unique to Bhutan make conventional RDS and TLS or facility-based approaches for HSS challenging. First is Bhutan's small and sparse population. The recent population size estimation exercise projects 1,726 MSM, 1,221 HRW, 76 TGW, and 302 TGM. Second, HIV prevalence among KP in Bhutan is likely low. Sample sizes for precise estimates of HIV prevalence typical for HSS are not viable. For example, a survey found only 0.83% HIV prevalence among women in entertainment sites [13] and no cases detected in a survey of 30 MSM [3]. To estimate HIV prevalence at 1% even with a wide 50% relative margin of error, a sample size of 865 is required. Third, facilities serving many KP do not ask or record KP status, making a facility-based HSS system not possible unless these practices change. Fourth, access to KP is difficult. Not all HRW work from venues and not all women working at entertainment venues are HRW. Moreover, MSM do not congregate at physical venues as in other countries worldwide. Further, the population size estimation exercise found social network sizes of KP were small and diffused throughout Bhutan. These factors indicate that HSS based on TLS, or and RDS is not theoretically appropriate or practically feasible. Therefore, a pragmatic approach to HSS is needed for contexts such as Bhutan's where HIV prevalence is low, KP are highly hidden and diffuse, and facilities and services do not record KP status. The described HSS system sought to balance these factors through a "Lot Quality Assurance" statistical approach using a hybrid venue-/peer-referral sampling method.

HIV Sentinel Surveillance Using a "Lot Quality Assurance" Approach

The lot quality assurance (LQA) approach is based on assuring a high degree of confidence that signal events are not missed, such as product defects in manufacturing, when it is not feasible to obtain large sample sizes. LQA has also been adapted for malaria surveillance [9]. In epidemiological terms, the LQA approach chooses high statistical power to reduce the risk of a type II error. That is, the sample size is geared to avoid falsely concluding there is no or low HIV infection in a population when in fact prevalence is higher. LQA also sets a "threshold" for case detection that when exceeded, further investigation is conducted. Thus, the LQA approach provides a sentinel signal for initiating responses for further data collection and prevention interventions.

The present HSS approach set a threshold of a single HIV-positive case detected in any grouping of 30 participants by KP type. If this threshold is breached, a two-pronged response is launched. First, additional data are gathered at the site where the case was detected using rapid assessment methods and adaptive sampling. Second, an outbreak investigation type response is initiated. For example, if one HIV-positive HRW is detected, then the sample size is increased by re-visiting venues and recruiting more HRW in that area. Qualitative data is also gathered to assess the risk environment and identify potential reasons for increased HIV prevalence. The single case detection would also trigger a prevention response for HRW in the area, such as partner notification, outreach education, mobilization of peers, mobile testing at HRW hotspots, STI screening, and referral to treatment.

The calculations for the LQA sample size are presented below. The total sample size for all nine study sites was set at 133 HRW, 139 MSM, 30 TGW, and 90 TGM.

Peer-Driven Recruitment (PDR) Sampling Design

The PDR sampling approach developed for the recent Population Size Estimation exercise [8] was used for the HSS. A formative assessment was first done to map the venues where KP congregate and to also establish the willingness of peers to refer friends and acquaintances from their social networks. The PDR method entails peer outreach workers contacting their networks to make introductions to the study. After the participation of their contacts, participants are asked to refer other eligible KP to the outreach worker or bring the outreach worker to venues where their peers can be found. Additional recruitment is done by visiting venues to enroll eligible participants with further snowballing at the venues or by later referral. A further mechanism of recruitment used peer outreach workers intercepting individuals on LGBT-oriented online sites including geo-locating dating apps and inviting them to participate. The resultant PDR surveys obtain diverse samples of KP members who are not directly affiliated with hotspots, as required by TLS. The PDR approach is also not dependent upon large social networks for long-chains of peer referrals self-presenting at a fixed study site as required by RDS. The hybrid PDR approach

is similar to other sampling methods employed for HSS such as targeted interventions, stratified snowball sampling, and starfish sampling [12].

Procedures

- **Study field teams:** Study field teams consisted of peer outreach workers, an HISC health worker, and a team lead. The peer outreach workers conducted recruitment, eligibility screening, interviews, and pre- and post- test counseling. The HISC health worker supervised the peer outreach workers and was available to conduct HIV counseling and testing as appropriate. The team lead oversaw all study operations, including data quality. Three field teams were constituted to match peers with the target populations: one team for HRW, one team for MSM, and one team for TGW and TGM.
- **Initial contact:** Once a peer outreach worker approached or referred to a prospective participant, an initial explanation of the study was provided. Outreach contact and referrals were made in person, by phone, or by online contact through a social media app. If the person was willing to participate, the peer identified a place and time that the participant was comfortable to meet in private. The peer explained that the team was working in pairs, a peer outreach worker and health care worker.
- **Eligibility and informed consent:** The peer outreach worker conducted eligibility screening and informed consent, and answered any questions the KP participant had.
- **Interview:** If eligible and providing informed consent, the peer administered the standardized HIV risk questionnaire (see appendix). To ensure autonomy, participants could terminate the interview at any time. Due to COVID-19, there were two options to complete the risk questionnaire.
    1. The first option was to meet in person at a place of the participant's choice.
    2. The second option was to complete the risk question online using a media app of the participant's choice.
- **HIV counseling and testing:** All HIV testing was done after completing the questionnaire. Peer outreach workers trained and certified for HIV counseling offered an approved oral, rapid HIV test. Participants could choose one of three options for HIV testing:

1. Participants who completed the risk questionnaire with the peer outreach worker in person may be offered HIV testing immediately following the interview. Observed, assisted, rapid, oral self-testing for HIV in the presence of the peer outreach worker and HISC worker was done. The peer outreach worker provided pre-test counseling, guided the participant through the self-test procedures, read the result of the test, conduct post-test counseling, and referrals. A negative result was disclosed by the peer outreach worker along with health education messages on HIV prevention. A reactive (positive) or indeterminate result would be referred to the HISC worker (see below). Throughout the process, the HISC worker was available to supervise, provide assistance as needed, and if the test is HIV positive, to bring the participant to the HISC for HIV confirmatory testing.
2. Participants who completed the risk questionnaire online may be asked to make an appointment with the peer outreach worker at a time and location of their choice to conduct HIV testing. The participant was informed that an HISC worker was on hand to provide supervision and assist with referrals as needed. At the designated appointment, HIV counseling and testing was conducted as described per option 1 above.
3. Participants who do not wish to do HIV counseling and testing with the peer outreach worker were offered the opportunity to test with the HISC worker. This may occur when the participant may recognize or know the peer outreach worker as part of their social circle. The option to test with the HISC worker can be done as part of options 1 and 2 above, or a separate appointment will be made for the participant to visit the HISC.

- In agreement with the principle of autonomy, the participant may decline to be tested for HIV at any point during the study procedures.
- **Confirmatory testing and linkage to care:** A reactive or indeterminate result was referred to the HISC health care worker. The health care worker explained the meaning of the preliminary result and the need for confirmatory testing. The peer outreach worker and health care worker together escorted the participant to the local HISC or agree upon a

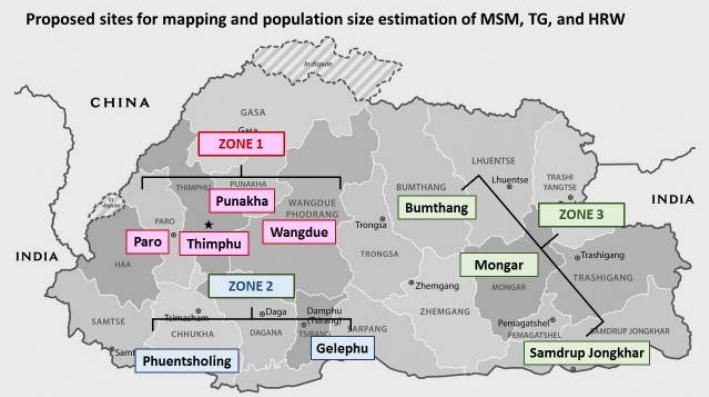
time and means to re-connect for follow-up. The HISC worker provided linkage to care and ART for participants confirmed positive for HIV.

- **Reimbursement and further peer referrals:** Upon completion of the interview and testing, the participant was given reimbursement incentives in consideration of their time, use of airtime, and transport needed for their participation and referral of peers. For their own participation, participants were given Nu 500 in cell phone airtime. Participants were also asked to refer potentially eligible acquaintances to the study. To make referrals and introductions of peers, participants made calls, went online, met with acquaintances in person, or met with peer outreach workers together. To reimburse their airtime, online, or transportation, Nu 200 in airtime were given for each recruit. Referrals could be done in person (e.g., making introductions at venues) or through providing their friends with study contact information.
- **Response to HIV-positive cases.** In addition to direct linkage of HIV positive cases to the HISC for confirmatory testing and care, the detection of a new HIV-positive case triggered several measures. First, the targeted sample size for the KP in the particular area was expanded beyond the minimum of 30. This entailed continuing peer referrals and venue-based recruitment. Second, partner notification efforts engaged the index case to find sexual partners to offer counseling and testing. Third, mobile testing could be implemented in the hotspots and areas of the index case, including both HIV and STI testing. Fourth, the study team (peer and health care worker) worked with local community stakeholders (e.g., venue owners, NGOs) to disseminate health education information on HIV testing and prevention. This could entail, for example, mobilization events at venues or local HISC or information through online sites, such as Rainbow Bhutan. Fifth, qualitative rapid assessment through in-depth interviews with KP members and other stakeholders and participant observation could be done to identify the patterns and sources of infection and propose additional response measures.

Analysis and Interpretation

The LQA approach has the primary function of establishing an early warning system that HIV prevalence may have exceeded 5% in a particular KP. In the low HIV prevalence setting of Bhutan, a precise estimate of HIV prevalence would require an infeasibly large sample size. Similarly, changes in prevalence between waves is not feasible. Rather, analysis focused on the detection of HIV cases and data on indicators of HIV risk and preventive behaviors. Although HIV prevalence is expected to be low, related risk and preventive behaviors can be measured with sufficient precision. The sample size calculation was based on a reasonable the margin of error expected for key risk and preventive behaviors as indicated from the results of the population size estimation exercise.

Study setting



Justification for Study Sites Selected. HSS will be implemented in 9 dzongkhag study sites. For logistical purposes, these 9 study sites are organized into 3 groups or zones (see map). The 9 study sites are Thimphu, Paro, Wangdue, Punakha, Phuentsholing (Chhukka), Gelephu, Bumthang, Mongar, Samdrup Jongkhar. The sites were selected considering several criteria: 1) participation in the Population Size Estimation exercise that demonstrated the feasibility of reaching the sample size, 2) the sites cover ~80% of the urban population of Bhutan, 3) HISC and partnering NGOs provide services to key populations and persons living with HIV in these locations; and 4) the sites cover a substantial part of the geographic and cultural diversity of the country, including the capital and largest city, the major border, and eastern, central, and western regions.

Definitions and study eligibility criteria

Four key populations were included in the HSS proposal: high risk women (HRW), men who have sex with men (MSM), transgender women (TGW), and transgender men (TGM). These populations bear a disproportionate burden of HIV infection in many parts of the world, including South and Southeast Asia. The recent Population Size Estimation exercise also demonstrated high risk behaviors among these KP in Bhutan, such as multiple partners, inconsistent condom use, and low levels of testing for HIV.

Definitions of these key populations vary greatly, taking into account multiple factors such as identity vs. behavior, recent vs. lifetime timeframe, rapidly changing communities and cultures, and comparability with definitions used by prior studies, programs, and public health surveillance. Recognizing definitions of these populations are complex and contextual, we adopted a public health response perspective. The target populations were those at risk for HIV due to their current behaviour. The target populations were also those who can be contacted through peers, outreach to venues, or through social media. We acknowledge this definition may not include persons with distant past behaviours, persons whose situations may be temporary (e.g., worksites, barracks), persons who may not recognize or express their gender identity or sexual orientation, and persons who are not connected to other members of the key populations.

The following operationalize the eligibility criteria for HSS:

- **High risk women (HRW):** Bhutanese or non-Bhutanese women age 18 years and above who work or visit hotspot environments where high risk sexual behaviors are frequently initiated (e.g., commercial sex work, transactional sex, multiple and concurrent partnering, high partner turn-over, and sexual networking within and between KP).
- **Men who have sex with men (MSM):** Bhutanese or non-Bhutanese males age 18 and above, who report anal or oral sex with another male in the past 12 months, regardless of their sexual orientation.

- **Transgender women (TGW) and men (TGM):** Bhutanese or non-Bhutanese persons age 18 and above who were assigned male sex at birth and now self-identify as "transgender" or "woman" or a gender other than male. TGW may or may not have undergone gender transition procedures (e.g., sex reassignment surgery, breast augmentation, facial implants), take hormones, or dress in women's clothes or present as female all the time. TGM follow a parallel definition, reversing the gender in the above definition for TGW.

Sample size

The total sample size target was 133 HRW, 139 MSM, 30 TGW, and 90 TGM. The table below describes how these samples are distributed across the 9 study site dzongkhag in the three operational groups. TGW may be recruited from any dzongkhag.

Table: Targeted sample sizes for 9 study site districts (by grouping) for HSS in Bhutan.

Group	HRW sample size	MSM sample size	TGW sample size	TGM sample size
Group 1: Thimphu, Paro, Punakha, Wangdue	73	54	--	30
Group 2: Phuentsholing, Gelephu	30	55	--	30
Group 3: Bumthang, Gelephu, Monggar, Samdrup Jongkhar	30	30	--	30
Total	**133**	**139**	**30***	**90**

*Sample may be recruited from any grouping.

The above sample sizes are based on having sufficient statistical power to achieve the objectives of HSS in Bhutan, meeting several considerations:

- HIV prevalence is unknown among these key populations in Bhutan, but likely rare at present. Of 663 HIV cases reported to date, only a few have been recorded as MSM, TGW or HRW. Moreover, few persons recorded as MSM, TGW, or female entertainment employee have been identified as HIV-positive in the HISC testing system. A conventional sample size to measure a low prevalence would be infeasible. For example, one published survey of HRW recruited at venues found HIV prevalence to be 0.83% [Khandu et al, 2019]. At this prevalence, a sample size of 471 HRW would be needed to ensure that the lower bound of the 95% confidence interval is above 0. That is, the sample size would be exceedingly difficult to recruit and would still not provide a usable estimate of HIV prevalence.
- A method to address this challenge is to use a Lot Quality Assurance (LQA) approach that sets a threshold for detection as a sentinel signal to investigate further. For LQA, minimum sample size of 30 is needed to have >90% power (beta 0.90) to determine that HIV prevalence remains below 4% (in the event of no HIV-positive participants) or a substantial chance (alpha 0.05, or 1 in 20) that HIV prevalence may exceed 5% in the event that the threshold of 1 infection detected is breached.
- The one HIV infection detection threshold for an enhanced response was set for each 30 samples. If an infection is detected within any grouping of 30, the response protocol is triggered to conduct further investigation. Further investigation includes increasing the sample size at that site, conducting enhanced partner notification, mobilizing community support for information and testing, and/or testing around hotspot areas.
- The total sample was apportioned to be “population per size” based on the 2019/2020 Population Size Estimation exercise. The smallest estimated population size is set to 30 (for the LQA minimum) while the remaining sample is proportionately distributed to the other groupings based on relative estimated population sizes. In this manner, the total sample is approximately representative of the key populations in the whole target area and does not require sampling weights for analysis.
- The target sample sizes were deemed feasible to achieve based on the recruitment achieved by the peer-directed sampling (PDS) method used during the Population Size

Estimation exercise. For HRW, the PDS method recruited 94 HRW in group 1 dzongkhag, 72 in group 2 dzongkhag, and 29 in group 3 dzongkhag. For MSM, the PDS approach recruited 98 MSM in group 1, 108 MSM in group 2, and 67 MSM in group 3. A total of 34 TGW were recruited by PDS over all dzongkhag; 124 TGM were recruited approximately balanced across the dzongkhag groupings.

- The pooled sample sizes provide sufficient statistical power (beta >80%) to measure key indicators of risk and preventive behaviors with acceptable precision (i.e., margin of error, see table below). For HRW and MSM, this level of precision is sufficient to detect meaningful improvements or deteriorations in indicators over successive rounds of HSS, achieving or failing to meet set targets (e.g., HIV testing), or significant differences between groups. Point estimates in the table are from the Population Size Estimation exercise.
- Sample size estimates take into consideration a finite population correction factor based on the Population Size Estimation exercise. The net effect is a greater precision is achieved for small sample sizes given the small total key population sizes. The table below shows high precision for a wide range of HIV indicators.

Recruitment

The study used peer-driven recruitment (PDR) to enroll the sample size. PDR entails peer outreach workers contacting their networks to make introductions to the study. After their participation, they were asked to refer other eligible KP to the outreach worker or bring the outreach worker to venues where their peers can be found. Additional recruitment was done by visiting venues to enroll eligible participants with further snowballing at the venues or by later referral. A further mechanism of recruitment used peer outreach workers intercepting individuals on LGBT-oriented online sites including geo-locating data apps and inviting them to participate. The resultant PDR surveys obtain diverse samples of KP members who were not directly affiliated with hotspots nor did it depend upon long-chains of peer referrals self-presenting at a fixed study site. The hybrid PDR approach was similar to other sampling methods

employed for HSS such as targeted interventions, stratified snowball sampling, and starfish sampling [12].

Data Collection, Variables, Data Sources/Measurement, Data Management

Data collection was through face-to-face interviews and through the results of the HIV testing. Variables collected were those included in the questionnaire used for the population size estimation exercise, presented in the appendix. The source of the questionnaire instrument is from a study of HIV risk among dryang women in Bhutan [13]. Questions were adapted for the MSM, TGW, and TGM populations through a focus group discussion with community stakeholders. The adapted questionnaire was pilot tested by peers for reliability and comprehension. The final questionnaire was field tested during the Population Size Estimation in Bhutan in 2019-2020 that included all four target populations (HRW, MSM, TGW, and TGM). Domains include demographic characteristics, use of alcohol, sexual orientation, sexual risk behaviors, contact with HIV prevention programs, STI history, experiences of stigma and discrimination, HIV testing history, results of last HIV test, and engagement in HIV care. The results of the oral fluid rapid HIV test were recorded on the final page. To preserve confidentiality, verbal informed consent was sought.

Data were initially entered on the paper questionnaires by the peer interviewer/counselor. Data were reviewed by the project coordinator on a daily basis for the initial week at each field site and then weekly thereafter. Reviews resolved errors, omissions, discrepancies, and standardize interview methods for all peers. Upon completion of the study, data were entered by two people into an Excel database by the project coordinator and one health care worker. Initial analysis examined the data for completeness, out of range responses, and other inconsistencies. The databases are stored on password protected computers with access limited to the project coordinator, health care worker, and principal investigators. In some cases, the questionnaire could be completed online but appointment made of HIV testing in person.

Analysis and Dissemination

Analysis was primarily descriptive. As discussed above, HIV prevalence is expected to be low and therefore a precise, population-based estimate is not feasible. The primary analysis was therefore based on the LQA approach to conclude whether there is evidence that HIV prevalence remains below 4% for each KP. For other key indicators, such as risk and preventive behaviors, point estimates and 95% confidence intervals are presented, with stratification by KP.

To ensure the highest transparency, buy-in, and ultimate use of the HSS Data, we envision multiple avenues to disseminate findings of this study in addition to this present report:

1. **Forums with partnering institutions, NGO, and other government of Bhutan agencies.** We propose the rapid dissemination of preliminary results in meetings with select representatives of the different agencies who have a stake in the findings of this study. Their input at an early stage will help identify biases and challenges not previously considered with potential modifications to conclusions and recommendations. Their early input will also foster transparency, ownership, and ultimate buy-in on findings.
2. **Forums reaching KP community members and their representatives.** With agreement from the above stakeholders, early dissemination of findings will be done through public forums with KP community members and their representatives. These may include in-face public meetings inviting key persons, or online by posted results on websites reaching the KP (e.g., Rainbow Bhutan) using PowerPoint presentations. These forums can elicit public commentary that can be included in the final comprehensive report.
3. **Factsheets, posters, and abstracts.** Once the comprehensive report is accepted, further dissemination can occur through written materials, such as factsheets for distribution by the HISC and peer outreach workers, posters to hang in HISC, DiC, and NGO offices, and abstracts submitted to present in national, regional, and international conferences.
4. **Publications in the scientific literature.** We envision that this study's findings will contribute to the scientific literature by sharing methodological adaptions, lessons

learned, and conclusions with researchers and public health officials facing similar challenges. Under the leadership of the PI, the team will decide upon topics for publication, authorship, and timelines for submission. The *Bhutan Health Journal* is likely to be an important vehicle for reaching the local and regional audience. Other international journals will be considered.

Ethical considerations

Ethical review. This protocol was reviewed and monitored by the Research Ethics Board of Health (REBH) of Bhutan.

Informed consent. Verbal informed consent was obtained from all participants for this study for the interview to complete the questionnaire and for HIV counseling and testing. Verbal consent was sought instead of written consent to ensure the privacy and confidentiality of participants by having no identifying information appearing on any forms or databases. Consent was obtained by the study field staff by reviewing the consent form with the participant. The staff reviewed the purpose of the study, the procedures, the potential harms, potential benefits (including incentives), who is the PI and investigators, and who to contact if they have complaints. Sufficient time was given to answer participant questions.

Confidentiality. We take several measures to reduce the risk of inadvertent disclosure of sensitive information about participants:

- Questionnaires and electronic databases will not include any personally identifying information. Informed consent will be verbal only.
- Any temporarily or accidentally obtained contact information (e.g., phone numbers called, email contact, IP addresses, rendez-vous to meet participants) were destroyed after their use. Only persons who have a need to know had such information.

- Data collection was done by health professionals working with trained peer outreach workers. These staff underwent training on research ethics and professional conduct concerning privacy of information.
- Given the small size of the communities, participants could opt to be interviewed and counseled by a professional HISC health worker rather than a peer outreach worker.
- We implemented a refresher training on research ethics and privacy to the study staff in preparation for field work.
- Interviewers ensured privacy when interviewing key informants and survey respondents in the field.
- An oath of confidentiality before collecting or accessing to any study-related information, was required of personnel to sign agreeing to protect the security and confidentiality of participants interviewed or persons seen in the field.
- Computer based files will only be made available to personnel involved in the study through the use of access privileges and passwords.
- Records will be kept in a secured location and only accessible to personnel involved in the study.
- Staff will receive ethical training prior to data collection, including protections for special populations and maintaining confidentiality.
- Dissemination materials will not include information that may identify or appear to identify individuals (e.g., no data with less than 5 participant will be shown).
- Any breach of confidentiality will be reported to the REBH along with measures to ensure such occurrences do not happen in the future.

RESULTS

Recruitment Outcomes

Due to the COVID-19 pandemic, HSS activities could not occur in several border districts (i.e., Phuentsholing, Gelephu, Samdrup Jongkhar). Therefore, HSS recruitment was done in 6 of the 9 study districts, including 4 of 4 districts for Group 1 (Thimphu, Paro, Punakha, and Wangdue), and 2 of 3 districts for Group 3 (Bumthang and Monggar but not Samdrup Jongkhar). None of 2 districts were open for recruitment in Group 2 (Phuentsholing and Gelephu).

The table below shows the targeted and attained (i.e., interviewed) sample sizes by key population and Group. For HRW, the targeted sample size was exceeded in Group 1 (127%) and nearly achieved (87%) for Group 3, despite no recruitment permitted in Samdrup Jongkhar. For MSM, the targeted sample size was exceeded in Group 1 (213%) because the occurrence of an an HIV-positive test result triggered increasing the sample size as per protocol. For Group 3, the sample attained fell short (60%) of the target, due in part to lack of recruitment in Samdrup Jongkhar. For TGW, the targeted national sample (i.e., the sample was not targeted by Group) the targeted sample size was nearly attained (97%). For TGM, the sample size attained exceeded the target for Group 1 (143%) and fell short in Group 3 (77%).

Table: Targeted and achieved sample sizes for 9 study site districts (by grouping) for HIV Sentinel Surveillance in Bhutan, 2021.

Group	HRW target	HRW attained	MSM target	MSM attained	TGW target	TGW attained	TGM target	TGM attained
Group 1: Thimphu, Paro, Punakha, Wangdue	73	93	54	115	--	24	30	43
Group 2: Phuentsholing*, Gelephu*	30	0	55	0	--	--	30	0

Group 3: Bumthang, Monggar, Samdrup Jongkhar	30	26	30	18	--	5	30	23
Total	133	**119**	139	**133**	30**	**29**	90	**66**

*Districts not open for recruitment during the COVID-19 pandemic.

**Sample may be recruited from any district for national estimate.

Demographic Characteristics

The table below shows demographic characteristics of the sampled key populations for the combined districts. All participants were Bhutanese. Of note, divorced status was high among HRW and educational attainment low among HRW and TGW. Unemployment was high for all key populations.

Table: Demographic characteristics of key populations sampled, Bhutan, 2021.

Variable	**HRW % (N=119)**	**MSM % (N=133)**	**TGW % (N=29*)**	**TGM % (N=66)**
Sex assigned at birth:				
Male	0	100	100	2
Female	100	0	0	98
Current gender identity:				
Male	0	98	0	0
Female	100	0	0	3
Trans woman	0	0	100	3
Trans man	0	0	0	92

Other	0	2	0	2
Age in years (mean)	26.8	26.7	26.5	24.2
Marital status:				
Married, official	27	10	0	0
Living together as if married	15	5	14	55
Single never married	16	78	86	45
Divorced	39	7	0	0
Widowed	3	0	0	0
Current district of residence:				
Thimphu	52	63	79	61
Paro	12	17	3	3
Wangdue	3	2	0	0
Punakha	10	4	0	1
Bumthang	18	8	7	18
Monggar	3	4	3	17
Other	2	2	8	0
Education level completed:				
No formal education	15	1	7	2
Primary	13	5	14	3
Middle secondary	47	16	48	30
Higher secondary	24	39	24	58
University	1	39	7	8
Other	0	1	0	0
Occupation:				
Unemployed	36	25	24	41
Entertainment	20	0	24	0
Student/trainee	0	18	14	19
Civil servant	0	19	3	3
Other	44	38	35	37

*Caution with small sample sizes, especially for TGW.

HIV Prevalence

As described in the methods above, the design of the HSS was to ensure that HIV prevalence has not crossed the critical threshold of 4% as signaled by the critical outcome of 1 or more positive results occurring in a sample of 30 participants in any key population in a Group of districts. If any HIV-positive test result occurs, the HSS design is to increase the sample size to provide a more precise estimate of HIV prevalence and its associated 95% CI. As noted above, some samples fell short of 30 participants. For MSM and HRW in Group 1, the sample size achieved was sufficient to provide a point estimate of HIV prevalence with a reasonably precise 95% CI.

Of note, 10 participants interviewed declined HIV testing (97% acceptance rate). Few provided reasons for declining to test, with some mentioning not being interested, wanting to test with a private provider, or intending to self test. The table below provides the results of HIV testing.

Table: HIV prevalence and estimated likely upper limit of HIV prevalence among key populations in Bhutan, 2021.

Group	Key population	No. tested	No. HIV+	HIV prevalence % (uncertainty measure)
1	HRW	93	0	0 (97.5% CI 0 – 3.9)
	MSM	108	1	0.9 (95% CI 0 – 2.6)
	TGW	24	0	0 (likely <4% nationally)
	TGM	42	0	0 (likely <4%)
2	na	na	na	(unknown)
3	HRW	26	0	0 (uncertain)

	MSM	17	0	0 (uncertain)
	TGW	5	0	0 (likely <4% nationally)
	TGM	23	0	0 (uncertain)

The prevalence of HIV among MSM in Group 1 districts is 0.9%, with a 95% CI of 0 – 2.6% corrected for the finite population size of MSM in the Group 1 districts. In the field, 1 MSM was determined to be HIV positive in Group 1. Following the HSS protocol, the sample size was increased to 115 MSM with 108 being tested in total (see table above). In addition, 2 partners of the case were interviewed and tested negative for HIV. Therefore, no additional HIV infections were detected. Of note, the participant reported not previously being diagnosed or aware of his HIV infection.

HIV prevalence is estimated at 0% for all other key populations in Group 1 and Group 3 districts. For all other key population groups, no HIV infections were detected. The point estimate for HIV prevalence is therefore 0% with varying levels of uncertainty on the upper limit of the likely prevalence. The data in the table above can be cautiously interpreted as follows:

- The prevalence of HIV among HRW in the Group 1 districts (n=93 for Thimphu, Paro, Punakha, Wangdue) is 0% with a 97.5% one-sided CI of 0 – 3.9. There is reasonable certainty that the prevalence of HIV among HRW in this area is under 4%. This is consistent with the HIV prevalence of 0.6% (95% CI 0 – 3.3) found by Khandu et al in Thimphu / Paro in 2015 [Khandu, 2019], suggesting no increased in HIV prevalence among HRW to 2021.
- The prevalence of HIV among TGW nationally (n=29) is likely below <4%, given the sample size is close to 30 when combining Group 1 and Group 3. As per HSS protocol, the TGW sample is national as there are too few TGW in any of the Group groups separately.
- The prevalence of HIV among TGM in the Group 1 districts (n=42) is likely <4%.
- The prevalence of HIV among HRW in Group 3 districts (n=26 for Bumthang and Monggar) is uncertain due to falling below the sample size of 30 and not recruiting from Samdrup Jongkhar due to COVID-19.

- The prevalence of HIV among MSM in Group 3 districts (n=17 for Bumthang and Monggar) is uncertain due to falling below the sample size of 30 and not recruiting from Samdrup Jongkhar due to COVID-19.
- The prevalence of HIV among TGM in Group 3 districts (n=23 for Bumthang and Monggar) is uncertain due to falling below the sample size of 30 and not recruiting from Samdrup Jongkhar due to COVID-19.
- The prevalence of HIV in Group 2 districts (Phuentsholing and Gelephu) is unknown due to the inability to recruit in these districts during the COVID-19 pandemic.

Risk Behaviors

Indicators of HIV risk behaviors were measured for each key population in the combined Groups 1 and 3 data and presented in the table below. Notable findings include:

- Exchanging sex for money (commercial sex work) was acknowledged by 97% of HRW. Although exchanging sex for money was not an eligibility criterion, the high level found in the HSS is likely due to increased reliance on peer referral by other women who are current or former FSW. A majority of TGW (59%) had engaged in commercial sex work.
- Early all HRW, TGW, and TGM reporting being “straight” as their sexual orientation. MSM reported diverse sexual orientations, with 60% as “gay” and 35% as “bisexual”. Sexual orientation largely aligned with reported lifetime gender of partners.
- Despite COVID-19, the average number of different sexual partners in the last 30 days was high for HRW (6.4), TGW (5.4), and MSM (1.8).
- HRW had the highest level of unprotected sex in the last 30 days (76%).

Table: Indicators of HIV/STI risk behavior among key populations in Bhutan, 2021.

Variable	HRW %	MSM %	TGW %	TGM %

	(N=119)	(N=133)	(N=29*)	(N=66)
Provided sex for cash in lifetime	97	8	59	0
Provided sex for gifts in lifetime	31	6	29	2
Drinks alcohol	82	58	79	85
Had sex under the influence of alcohol	59	25	48	15
Unprotected sex with alcohol use	31	15	24	13
Age first had sex (mean years)	17.1	16.6	16.3	18.7
Sexual orientation:				
Straight	99	1	100	98
Gay	0	60	0	0
Bisexual	0	35	0	2
Other/Don't know	1	4	0	0
Gender of lifetime sexual partners				
Men only	97	60	100	0
Women only	0	0	0	100
Both men and women	3	40	0	0
Ever had sex with a transgender person	7	10	11	0
Number of sex partners in last 30 days (mean)	6.4	1.8	5.4	0.7
Unprotected sex in the last 30 days	76	32	45	59

*Caution in interpretation is needed with small sample sizes, especially for TGW.

Preventive Behaviors

HSS provides measures of the reach, access, and uptake of HIV elimination programs. Notable findings include:

- Knowing where to get an HIV test was reported by 89% of MSM and 82% of HRW, with lower levels reported by TGW (79%) and TGM (64%).
- Ever tested for HIV was high among TGW (90%) and HRW (84%)...

- Within the whole sample, testing in the last year…
- Most obtained their last HIV test results, ranging from 60% of TGM to 96% of HRW.
- No one reported receiving and HIV-positive result on their prior test.

Table: Preventive behaviors and access to prevention programs for key populations, Bhutan, 2021.

Variable	**HRW % (N=119)**	**MSM % (N=133)**	**TGW % (N=29*)**	**TGM % (N=66)**
Know where to get an HIV test	82	89	79	64
Ever tested	84	57	90	45
Tested last year	41	36	69	21
Got result	96	92	88	60
Result HIV-positive	0	0	0	0
Ever attended HIV educational event	59	43	83	58
Attend an HIV education event in last year	29	6	59	32
Ever talked with an outreach worker about HIV	53	29	76	69
Talked with outreach worker in last year	32	7	56	41
Ever tested for STI	63	43	86	23
Tested for STI in last year	35	18	58	16

*Caution in interpretation is needed with small sample sizes, especially for TGW.

Stigma and Discrimination

Table: Preventive behaviors and access to prevention programs for key populations, Bhutan, 2021.

Variable	HRW % (N=119)	MSM % (N=133)	TGW % (N=29*)	TGM % (N=66)
Open to family about key population status:				
All	13	11	55	68
Some	18	31	28	26
No one	69	58	17	6
Experienced stigma from friends due to key population status	63	32	48	53
Experienced stigma from strangers due to key population stats	57	33	79	86
Experienced discrimination when accessing health services	17	12	24	30

*Caution in interpretation is needed with small sample sizes, especially for TGW.

CONCLUSIONS, LIMITATIONS, RECOMMENDATIONS

Conclusions

The first round of the HSS in Bhutan met its **General Objective** (below) of establishing a methodological approach to HSS for HRW, MSM, TGW, and TGM. The study found the methods feasible in terms of recruitment of the target population, willingness to participate, and quality of data including HIV testing and interviews on sensitive topics. For the first time in Bhutan, HIV rapid testing was offered in the field by lay counselors with 97% acceptance to test. This first round of HSS can serve as the basis for repeated rounds to track trends in key HIV indicators over time.

General Objective:

1. To establish an HIV Sentinel Surveillance system for key populations in Bhutan.

Due to challenges imposed by the COVID-19 epidemic, other HSS activities were curtailed and therefore other **Specific Objectives** (below) met with tempered success. Due to the COVID-19 epidemic, recruitment could not be done in the important border area Group 2 districts (i.e., Phuentsholing/Chukkha and Gelephu). Moreover, recruitment could not be done in Samdrup Jongkhar, also an important border district in Group 3. Additionally, the compressed timeframe due to COVID-19 resulted in sample sizes not being met for some key populations in some districts.

Nonetheless, data were obtained to meet the specific objective of HIV detection in community-recruited samples of key populations. **These HSS data provide some evidence that the prevalence of HIV remains below a critical level of 4% for all key populations in Bhutan.**

Data collected also provided indicators of HIV risk and preventive behaviors and measures of stigma and discrimination among key populations in Bhutan. Indicator data worth highlighting include:

- Many key population members had multiple sex partners and unprotected sex in the 30 days preceding the interview. Despite COVID-19 restrictions on mobility and gatherings, risk for HIV/STI continued.
- Access and use of HIV/STI prevention programs were low in the year 2020. Fewer than half of HRW, MSM, and TGM attending an educational event, talking to an outreach worker, or testing for HIV or STIs in 2020. Somewhat more than half of TGW engaged in these prevention activities.
- Experiences of stigma and discrimination were common among key populations in Bhutan, particularly among transgender people.

Specific Objectives:

1. To determine HIV prevalence and track trends in HIV prevalence over time among MSM, TGW, TGM, and HRW in Bhutan.

2. To measure and track indicators of HIV risk and preventive behaviors among MSM, TGW, TGM, and HRW.
3. To assess the reach, uptake, and trends in HIV care and prevention programs for MSM, TGW, TGM, and HRW.

Limitations

While the General Objective of developing and launching HSS and the Specific Objectives of gathering of indicator data on the HIV epidemic were broadly met, there are several limitations to bear in mind, particularly with interpretation of this 2021 round of data collection. Key limitations include:

- **HSS 2021 data may not be typical or representative of key populations due to the COVID-19 pandemic.** Unfortunately, the COVID-19 epidemic had severe impact on the ability to conduct HSS. Venues where HRW and other key populations congregate (e.g., dryangs, karaoke clubs, bars, street areas) were closed for much of the last year and more. Shutdowns occurred for the country and for specific districts particularly along the border. Overall mobility was low, and interactions likely more limited. It is not certain whether this limitation will result in over-estimation of risk behavior (e.g., sex work increasing due to fewer employment opportunities) or under-estimation (e.g., fewer sex partners with venue and border closures or attempts to minimize COVID-19 risk by avoiding contact with others). COVID-19 may also be a cause for less access to and use of prevention services. Finally, data from this round of HSS may affect interpretation of trends in subsequent rounds of HSS.
- **Potential participation bias.** It is possible that some persons will avoid participation in public health research and surveillance activities due to suspicion of authorities and concerns over privacy and confidentiality. This potential bias may be more severe among key populations experiencing marginalization in society and with the offering of HIV testing. The later potential bias may mean that persons who know they are living with HIV

would avoid participating in the study. A possible consequence may be under-estimation of HIV prevalence and reported risk behaviors. The peer-driven recruitment design may mitigate this potential bias by being recruited by a trusted member of the community. On the other hand, closely connected social networks may also be a deterrent.

- **Small sample sizes.** As discussed above, the context of Bhutan is that the target populations are small in relative and absolute numbers. Recruitment of large sample sizes of key populations for conventional statistical analysis is difficult, impractical, to infeasible for some populations or areas. Small sample sizes leave imprecision in estimates and uncertainties in interpretation. Results presented here must be interpreted cautiously. We hold that the design of the HSS is a pragmatic approach to the challenge of small sample sizes. The lessons learned from this first 2021 round of HSS can be built upon for larger sample sizes in the future and analysis of trends over multiple rounds.

Recommendations

- **Restart HSS in Group 2 districts (Phuentsholing, Gelephu) and Samdrug Jongkhar (Group 3) as soon as the COVID-19 pandemic permits.** A large data gap in HIV prevalence and risk persists due to the closure of the key border areas of Bhutan during the implementation of HSS in 2021. It is recommended to re-launch HSS as soon as feasible in terms of the COVID-19 epidemic and resources to gather data from Phuentsholing, Gelephu, and Samdrup Jongkhar. These data would complete the targeted sample sizes for all key populations and Groups.
- **Conduct the second round of HSS in 2023.** Plan on implementing HSS for 2023 as the next biennial round of data collection. Surveillance is the ongoing collection of data relevant to the control of diseases and therefore is not a one-off exercise. As noted above, COVID-19 year not typical and will need to be carefully considered when interpreting changes in indicators between rounds.
- **Increase the sample size for future HSS rounds.** While the current low prevalence of HIV among MSM and detection of 0 infections among other key populations is encouraging,

there are uncertainties as discussed above. Raising the sample size, such as recruiting the largest number given the time and resources or to 50 per key population per Group area, will lend more certainty to the evidence for low HIV prevalence and be more sensitive to small increases in transmission and risk in future HSS rounds.

- **Dissemination of findings to community groups.** With an eye to caution on interpretation of small numbers and confidentiality, findings of this first round of HSS needs to be shared with public health officials, non-governmental organizations, and community members. Sharing if information will strengthen interpretation of the data, identify underlying causes of findings, and appropriate responses to help Bhutan achieve HIV elimination goals by 2030.

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Appendices: Study Protocol and Questionnaire

REBH Sl. No1. STUDY TITLE

HIV Sentinel Surveillance among Key Populations in Bhutan

Study protocol

(Version 2: 3/29/2021)

Implementing Agency

National AIDS Control Programme (NACP), Thimphu, Bhutan

Funding Agency:

Global Fund and Royal Government of Bhutan

REBH Sl. No_2. NAMES AND INSTITUTIONAL AFFILIATIONS OF THE PRINCIPAL INVESTIGATOR AND OTHER INVESTIGATORS

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Roles of the Investigators

Principal Investigator	**Co-Investigators**
• To guide the overall proposal development and implementation of the research activities • To mobilize fund and logistics of research • To recruit local staff and participants	• To assist the PI in all matters pertaining to the research • To participate and contribute in the proposal development and implementation of the research

• To obtain permission including ethical approvals • To assist technical advisors in providing local information and data related to subject matter • To assist ITA in the proposal development, implementation and analysis and report writing • To ensure smooth conduct of research • To draft report and data dissemination tools in collaboration with ITA • To guide in submission of the final report to MoH, Global Fund, and REBH	• To assist local staff to learn how to conduct research and data analysis • To support PI and other advisors in terms of information gathering, obtaining approvals and other activities related to the study
International Technical Advisor • To guide, train, and develop the proposal in collaboration with NTA, PI, assistant PI and other key stake holders • To train project staff on data collection, data entry, and data analysis • To train NTA, PI, designated assistants to the PI and staff • To guide and help write reports and data dissemination tools in collaboration with PI and NTA	

REBH Sl.No3. PROJECT SUMMARY

This protocol details the principles and procedures for an HIV Sentinel Surveillance system to track infection and related risk and preventive behaviors among high risk women (HRW, i.e., women in environments where commercial sex work and initiation of casual sex occurs, including dryangs, karaoke clubs, etc.), men who have sex with men (MSM), transgender women (TGW), and transgender men (TGM) in Bhutan. HIV Sentinel Surveillance will be conducted every two years using community-recruited samples. The sampling method will be a peer-directed recruitment (PDR) approach developed for the recent Population Size Estimation exercise successfully implemented in Bhutan in 2019/2020. PDR will enlist key population (KP) peers to refer other eligible peers to recruit at total of 133 HRW, 139 MSM, 30 TGW, and 90 TGM. The selected sentinel sites include 9 dzongkhag (Thimphu, Paro, Punakha, Wangdue, Chhukha, Sarpang, Bumthang, Mongar, and Samdrup Jonghkar).

The sample size is based on a Lot Quality Assurance (LQA) approach whereby zero HIV-positive results in any “lot” or group of 30 participants determines HIV prevalence is below 4%. Any HIV-positive result in a lot indicates a threshold has been passed whereby HIV prevalence may be greater than 5%. Finding any HIV-positive in the lot triggers further investigation, including increased sample size for that KP, enhanced partner notification, mobilizing community support for information and testing, and HIV counseling and testing within hotspot areas.

Participants who are willing and able to provide verbal informed consent will be interviewed by outreach worker/peer staff on risk and preventive behaviors, followed by HIV counseling and testing at the location of their choice. Counseling and an observed rapid oral HIV self test (HIVST) will be done by trained, certified peers outreach workers. Persons testing reactive or indeterminate on the initial field screen will be brought to the HISC for confirmatory testing following national testing protocols. Participants who are confirmed positive will be referred by the HISC health worker to HIV care and treatment.

The proposed HIV Sentinel Surveillance for KP is envisioned to be one part of a comprehensive surveillance system that also includes case-based reporting data, detailed profiles of all newly diagnosed cases, partner notification, updated KP population size estimates, programmatic data from services for KP, and epidemic modeling. Taken together, these data on HIV-related indicators will help track changes in behaviors over time, gauge successes and shortfalls in epidemic control, set targets for prevention programs, and identify points for interventions to end the HIV epidemic in Bhutan.

REBH SI. No 4. BACKGROUND AND RATIONALE

The HIV Epidemic in Bhutan and the Need for HIV Sentinel Surveillance among Key Populations

Historically, Bhutan has experienced a low-level HIV epidemic [1]. Compared to other counties in the region, Bhutan's HIV epidemic started later, with the first case diagnosed in 1993, and progressed more slowly. Sporadic cases appeared between 1993 and 2000. From 2000 to 2013, the number of new HIV diagnoses rose from 9 to 51. Since 2013, there has been a plateau in the number of new HIV diagnoses, fluctuating between 49 and 58 annually. To June 2019 there were a cumulated 663 HIV diagnoses, 505 of whom are known to be alive, and 450 of whom are on antiretroviral treatment provided by the Ministry of Health. UNAIDS models place the number of people living with HIV in Bhutan at 1,265. The national response to HIV is geared to end the epidemic by 2030. Targets to achieve this vision include increasing the proportion of persons living with HIV who are diagnosed to >90%, the proportion of those diagnosed on antiretroviral treatment at 100%, and the proportion with sustained viral suppression at >90%.

Bhutan may stand in contrast to other countries in South and South East Asia in its pattern of HIV epidemiologic progression. Typically, key populations (KP) at elevated risk acquire infection early in an epidemic, when the conditions for rapid spread were already present (e.g., high sexual partner turn-over, multiple concurrent partnerships, low condom use). These KP include men who have sex with men (MSM), transgender women (TGW), and high risk women (HRW) who work or frequent venues and hotspots were commercial sex and casual partnering are initiated. Transgender men (TGM) are also a sexual/gender minority group for whom there are few studies assessing their risk for HIV. HIV incidence rises fast in these populations, often accelerating after a threshold of 5% prevalence is surpassed. HIV transmission to the sexual partners of key populations becomes substantial, raising the overall prevalence of HIV for the nation. At this point, the epidemic has moved from low-level to concentrated.

Several factors are cause for concern that conditions are present for greater spread of HIV among key populations in Bhutan. First, with a passive surveillance system, under-reporting of HIV cases is possible. Second, UNAIDS projections and low CD4 counts among persons newly diagnosed with HIV indicate that many infections go undiagnosed for long periods of time. Therefore, the number of people living with HIV may be under-estimated and the potential for onward transmission from persons who are untreated may be high. Third, MSM, TGW, TGM, and HRW status has not been systematically recorded in surveillance or program data. A disproportionate burden of infection in these populations may be unrecognized. Fourth, indicators of risk suggest high potential for increased sexual transmission of HIV. These include rising incidence of sexually transmitted infections (STIs), low condom use in all types of partnerships, high levels of multiple sex partners, and the apparent emergence of commercial and transactional sex [1-5]. Finally, there is increasing concern that the prevention needs of KP have been inadequately addressed in Bhutan [3,6,7].

Whether Bhutan will follow a progression from a low level to concentrated epidemic, similar to other countries in the region, or start on a trajectory towards eliminating HIV by 2030 may hinge upon reaching KP with effective programs. The Ministry of Health of Bhutan has embarked on a nationwide HIV prevention and awareness program with targeted interventions for MSM, TGW, TGM, and HRW. Unfortunately, there is a scarcity of data on these populations in Bhutan – particularly the current prevalence of HIV, risk behaviors that lead to HIV acquisition and transmission, and access to and uptake of prevention programs including HIV testing. To guide the national effort to end the epidemic, an efficient approach to HIV Sentinel Surveillance for KP is needed that is adapted to Bhutan's specific epidemic, demographic, and cultural context.

A recent population size estimation exercise conducted among MSM, TGW, TGM, and HRW in Bhutan [8] lays the groundwork for an HIV Sentinel Surveillance system. The exercise applied multiple methods to arrive at robust population size estimates, mapped the venues where KP can be reached, and gauged their levels of risk and preventive behaviors through face-to-face interviews. The study successfully recruited 948 KP (including 517 HRW, 273 MSM, 34 TGW

women, and 124 TGM) using a hybrid venue- / peer-referral sampling approach. Synthesis of the several population size estimates and extrapolation arrived at an estimated 1,726 MSM, 1,221 HRW, 76 TGW, and 302 TGM. Interview data found high levels of risk behaviors (e.g., sex for money, multiple partnering, early sexual debut, sex with alcohol) coupled with low levels of preventive behaviors (e.g., condom use, HIV testing, receiving prevention outreach) and wide experiences of discrimination and stigmatization of KP. The exercise had the added benefit of building capacity for outreach worker/peer teams to conduct the methods needed for a community-based HIV Sentinel Surveillance system.

Unfortunately, HIV testing was not done in the population size estimation leaving the data gap of HIV prevalence among KP in Bhutan. Community member input at the formative phase cautioned against adding HIV testing as threatening the primary aims of population size estimation, venue mapping, and frank disclosure of risk behaviors. The requirements of written informed consent and health professional delivery of counseling and testing were considered barriers to participation. Stigma, discrimination, and fear of learning one's HIV serostatus were also cited as reasons not to include HIV testing in the mapping and size estimation exercise.

At present, Bhutan's MOH is preparing for trained, certified peer outreach workers to conduct counseling and initial rapid HIV testing using rapid supervised HIV Self Test kits (oral swap) in the field with the option of blood-based finger prick rapid test kits. This new policy can partially address barriers to testing among KP. With any initial positive or indeterminate results in the field, the peer counselors can bring the participant to the local HISC or other health facility for confirmatory testing, further counseling, and linkage to care if confirmed positive. The new process provides a potentially acceptable means to integrate community-based HIV prevalence measures into Sentinel Surveillance. With the inclusion of HIV prevalence among KP, a critical data gap in understanding the epidemic in Bhutan will be filled.

The current protocol describes the principles and procedures of an HIV Sentinel Surveillance system that will measure HIV prevalence and related risk and preventive behaviors among MSM,

HRW, TGW, and TGM in Bhutan. The approach will build on the capacities and lessons learned during the Population Size Estimation exercise with the addition of HIV testing. The sampling method will use the peer-driven recruitment (PDR) approach successfully deployed for the size estimation. Following verbal informed consent, peer outreach workers will conduct a detailed interview on risk and preventive behaviors followed by counseling and an observed rapid oral HIVST. These certified peer counselors will escort any participant with a reactive or indeterminate result to the nearby HISC or approved testing site for confirmatory testing and linkage to care and social services. The proposed HIV Sentinel Surveillance sites include 9 dzongkhag (Thimphu, Paro, Punakha, Wangdue, Chhukha, Sarpang, Bumthang, Mongar, and Samdrup Jonghkar). A required sample size of 133 HRW, 139 MSM, 30 TGW, and 90 TGM is gauged to have sufficient power to determine that HIV prevalence is below 4% using a Lot Quality Assurance approach [9]. Any HIV-positive result in a lot indicates a threshold has been passed whereby HIV prevalence may be greater than 5%. Finding any HIV-positive in the lot triggers further investigation, including increased sample size for that KP, enhanced partner notification, mobilizing community support for information and testing, and testing within hotspot areas. HIV Sentinel Surveillance is proposed to be implemented on biennial basis.

The proposed HIV Sentinel Surveillance for KP is envisioned as only one part of a comprehensive surveillance system that also includes case-based reporting data, detailed profiles of all newly diagnosed cases, partner notification, updated KP population size estimates, programmatic data from clinics and prevention services for KP, and epidemic modeling. Taken together, these data will help track changes in the epidemic and its determinants over time, gauge successes and shortfalls in epidemic control, set targets for prevention programs, and identify points for HIV interventions to end the epidemic in Bhutan.

REBH SI.No5. OBJECTIVES

General objective:

2. To establish an HIV Sentinel Surveillance system for key populations in Bhutan.

Specific objectives:

4. To determine HIV prevalence and track trends in HIV prevalence over time among MSM, TGW, TGM, and HRW in Bhutan.
5. To measure and track indicators of HIV risk and preventive behaviors among MSM, TGW, TGM, and HRW.
6. To assess the reach, uptake, and trends in HIV care and prevention programs for MSM, TGW, TGM, and HRW.

REBH SI.No. 6. STUDY DESIGN

Conceptual Framework and Characteristics of HIV Sentinel Surveillance

UNAIDS defines surveillance is the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice [10]. No single source of information can provide a complete picture of the HIV epidemic; several complementary data collection systems are needed. These data systems include the reporting of diagnosed HIV infections, reporting of sexually transmitted infection (STI) diagnoses, clinic data on patients receiving anti-retroviral treatment (ART) and other HIV-related program data. Sentinel surveillance is one component of a comprehensive public health surveillance system for HIV. Sentinel surveillance entails the short-term and periodic tracking of HIV prevalence among populations at highest risk for infection, such as key populations (KP), to serve as an early warning system for emerging trends in the epidemic [10].

Sentinel surveillance has several pragmatic characteristics. First, the methods are consistent over person, place, and time. Truly representative surveys of KP at high risk for HIV are difficult and costly. Sentinel surveillance therefore relies on approaches that may not be representative of the

whole population, but are simple and consistently implemented to enable interpretation of relative differences in HIV prevalence between groups and locations and changes in the epidemic over time. Second, sentinel surveillance targets populations at highest risk for HIV to obtain early warning signals. Sentinel surveillance seeks to identify HIV among populations where infection may first appear, for example sampling at hotspots, within sexual networks, or among clients of STI clinics, drug treatment centers, jails, or services with high proportions of key populations among their clientele. Third, sentinel surveillance is designed to be resource efficient in order to be sustainable over time. Sentinel surveillance may therefore be based in facilities that already collect blood that can be used for HIV testing (e.g., antenatal clinics, STI clinics, NGOs providing outreach and mobile HIV testing). Trade-offs in efficiencies with facility-based sentinel surveillance, however, entail potential biases in who does or does not access services and limited amounts of behavioral data.

Alternative approaches to sentinel surveillance entail recruitment of community-based samples (i.e., reaching persons not accessing services) outside of facilities. State-of-the-art community-based sampling methods include respondent-driven sampling or RDS (by peer referral) and time-location sampling or TLS (by intercepting at venues) [11]. However, RDS and TLS have high cost, practical limitations, and theoretical assumptions that are difficult to meet. These include having numerous venues where KP congregate, for TLS, and for RDS a large enough target population size, highly connected social networks, accurate assessment of personal network sizes, and random recruitment from one's network. Adaptations, modifications, and hybrid designs of RDS and TLS that relax assumptions have also been used for HIV Sentinel Surveillance, including targeted interventions, snowball sampling, stratified snowball sampling, and starfish sampling [12]. If systematically implemented, diversified using multiple sources, and consistent over time and place, the practical advantages of these adapted sampling methods may outweigh the potential loss of rigor of conventional RDS and TLS.

Unique Challenges to HIV Sentinel Surveillance for Key Populations in Bhutan

Several factors unique to Bhutan make conventional RDS and TLS or facility-based approaches for HIV Sentinel Surveillance challenging. First is Bhutan's small and sparse population. The recent population size estimation exercise projects 1,726 MSM, 1,221 HRW, 76 TGW, and 302 TGM. Second, HIV prevalence among KP in Bhutan is likely low. Sample sizes for precise estimates of HIV prevalence typical for HIV Sentinel Surveillance are not viable. For example, a survey found only 0.83% HIV prevalence among women in entertainment sites [13] and no cases detected in a survey of 30 MSM [3]. To estimate HIV prevalence at 1% even with a wide 50% relative margin of error, a sample size of 865 is required. Third, facilities serving many KP do not ask or record KP status, making a facility-based HIV Sentinel Surveillance system not possible unless these practices change. Fourth, access to KP is difficult. Not all HRW work from venues and not all women working at entertainment venues are HRW. Moreover, MSM do not congregate at physical venues as in other countries worldwide. Further, the population size estimation exercise found social network sizes of KP were small and diffused throughout Bhutan. These factors indicate that HIV Sentinel Surveillance based on TLS, or and RDS is not theoretically appropriate or practically feasible. Therefore, a pragmatic approach to HIV Sentinel Surveillance is needed for contexts such as Bhutan's where HIV prevalence is low, KP are highly hidden and diffuse, and facilities and services do not record KP status. Our proposed protocol seeks to balance these factors through a "Lot Quality Assurance" statistical approach using a hybrid venue-/peer-referral sampling method.

HIV Sentinel Surveillance Using a "Lot Quality Assurance" Approach

The lot quality assurance (LQA) approach is based on assuring a high degree of confidence that signal events are not missed, such as product defects in manufacturing, when it is not feasible to obtain large sample sizes. LQA has also been adapted for Malaria surveillance [9]. In epidemiological terms, the LQA approach chooses high statistical power to reduce the risk of a type II error. That is, the sample size is geared to avoid falsely concluding there is no or low HIV infection in a population when in fact prevalence is higher. LQA also sets a "threshold" for case detection that when exceeded, further investigation is conducted. Thus, the LQA approach

provides a sentinel signal for initiating responses for further data collection and prevention interventions.

The present protocol sets a threshold of a single HIV-positive case detected in any grouping of 30 participants by KP type. If this threshold is breached, a two-pronged response is launched. First, additional data are gathered at the site where the case was detected using rapid assessment methods and adaptive sampling. Second, an outbreak investigation type response is initiated. For example, if one HIV-positive HRW is detected, then the sample size is increased by re-visiting venues and recruiting more HRW in that area. Qualitative data is also gathered to assess the risk environment and identify potential reasons for increased HIV prevalence. The single case detection would also trigger a prevention response for HRW in the area, such as partner notification, outreach education, mobilization of peers, mobile testing at HRW hotspots, STI screening, and referral to treatment.

The calculations for the LQA sample size are presented below. The total sample size for all nine study sites will be 133 HRW, 139 MSM, 30 TGW, and 90 TGM.

Peer-Driven Recruitment (PDR) Sampling Design

We propose to use the sampling method developed for the recent Population Size Estimation exercise [8]. A formative assessment was first done to map the venues where KP congregate and to also establish the willingness of peers to refer friends and acquaintances from their social networks. A locally adapted, hybrid approach was developed for sampling, called “peer-driven recruitment” (PDR).

The PDR method entails peer outreach workers contacting their networks to make introductions to the study. After the participation of their contacts, participants are asked to refer other eligible KP to the outreach worker or bring the outreach worker to venues where their peers can be found. Additional recruitment is done by visiting venues to enroll eligible participants with further

snowballing at the venues or by later referral. A further mechanism of recruitment used peer outreach workers intercepting individuals on LGBT-oriented online sites including geo-locating dating apps and inviting them to participate. The resultant PDR surveys obtain diverse samples of KP members who are not directly affiliated with hotspots, as required by TLS. The PDR approach is also not dependent upon large social networks for long-chains of peer referrals self-presenting at a fixed study site as required by RDS. The hybrid PDR approach is similar to other sampling methods employed for HIV Sentinel Surveillance such as targeted interventions, stratified snowball sampling, and starfish sampling [12].

Procedures

- **Study field teams:** Study field teams will consist of three peer outreach workers, one HISC health worker, and a team lead. The peer outreach workers will conduct recruitment, eligibility screening, interviews, and pre- and post- test counseling. The HISC health worker will supervise the peer outreach workers and be available to conduct HIV counseling and testing if preferred by the participant. The team lead oversees all study operations, including oversight of data quality. Three field teams will be constituted to match peers with the target populations: one team for HRW, one team for MSM, and one team for TGW and TGM.
- **Initial contact:** Once a peer outreach worker has approached or is referred to a prospective participant, an initial explanation of the study will be provided. Outreach contact and referrals may be made in person, by phone, or by online contact through a social media app. If the person is willing to participate, the peer will identify a place and time that the participant is comfortable to meet in private. The peer will explain that the team will be working in pairs, a peer outreach worker and health care worker.
- **Eligibility and informed consent:** The peer outreach worker will conduct eligibility screening and informed consent, and answer any questions the KP participant may have.
- **Interview:** If eligible and providing informed consent, the peer will administer the standardized HIV risk questionnaire (see appendix). To ensure autonomy, participants

may terminate the interview at any time. Due to COVID-19, there will be two options to complete the risk questionnaire.

1. The first option will be to meet in person at a place of the participant's choice.
2. The second option will be to complete the risk question online using a media app of the participant's choice.

- **HIV counseling and testing:** All HIV testing will be done after completing the questionnaire. Peer outreach workers will be provided with training on HIV counseling and testing using an approved oral, rapid HIV test. Upon successful completion of training, they will be provided a Certificate of Authorization by the BMHC. Participants may choose one of three options for HIV testing:
    1. Participants who completed the risk questionnaire with the peer outreach worker in person will be offered HIV testing immediately following the interview. Observed, assisted, rapid, oral self-testing for HIV in the presence of the peer outreach worker and HISC worker will be done. The peer outreach worker will provide pre-test counseling, guide the participant through the self-test procedures, read the result of the test, conduct post-test counseling, and referrals. A negative result will be disclosed by the peer outreach worker along with health education messages on HIV prevention. A reactive (positive) or indeterminate result will be referred to the HISC worker (see below). Throughout the process, the HISC worker will be available to supervise, provide assistance as needed, and if the test is HIV positive, to bring the participant to the HISC for HIV confirmatory testing.
    2. Participants who completed the risk questionnaire online will be asked to make an appointment with the peer outreach worker at a time and location of their choice to conduct HIV testing. The participant will be informed that an HISC worker will be on hand to provide supervision and assist with referrals as needed. At the designated appointment, HIV counseling and testing will be conducted as described per option 1 above.

3. Participants who do not wish to do HIV counseling and testing with the peer outreach worker will be offered the opportunity to test with the HISC worker. This may occur when the participant may recognize or know the peer outreach worker as part of their social circle. The option to test with the HISC worker can be done as part of options 1 and 2 above, or a separate appointment will be made for the participant to visit the HISC.

- In agreement with the principle of autonomy, the participant may decline to be tested for HIV at any point during the study procedures.
- **Confirmatory testing and linkage to care:** A reactive or indeterminate result will be referred to the HISC health care worker. The health care worker will explain the meaning of the preliminary result and the need for confirmatory testing. The peer outreach worker and health care worker will together escort the participant to the local HISC or agree upon a time and means to re-connect for follow-up. The HISC worker will provide linkage to care and ART for participants confirmed positive for HIV.
- **Reimbursement and further peer referrals:** Upon completion of the interview and testing, the participant will be given reimbursement incentives in consideration of their time, use of airtime, and transport needed for their participation and referral of peers. For their own participation, participants will be given Nu 500 in cell phone airtime. Participants will also be asked to refer potentially eligible acquaintances to the study. To make referrals and introductions of peers, participants will need to make calls, go online, meet with acquaintances in person, or meet with peer outreach workers together. To reimburse their airtime, online, or transportation, Nu 200 in airtime will be given for each recruit. Referrals can be done in person (e.g., making introductions at venues) or through providing their friends with study contact information.
- **Response to HIV-positive cases.** In addition to direct linkage of HIV positive cases to the HISC for confirmatory testing and care, the detection of a new HIV-positive case will trigger several measures. First, the targeted sample size for the KP in the particular area will be expanded beyond the minimum of 30. This will entail continuing peer referrals and venue-based recruitment. Second, partner notification efforts will engage the index case

to find sexual partners to be offered counseling and testing. Third, mobile testing can be implemented in the hotspots and areas of the index case, including both HIV and STI testing. Fourth, the study team (peer and health care worker) will work with local community stakeholders (e.g., venue owners, NGOs) to disseminate health education information on HIV testing and prevention. This may entail, for example, mobilization events at venues or local HISC or information through online sites, such as Rainbow Bhutan. Fifth, qualitative rapid assessment through in-depth interviews with KP members and other stakeholders and participant observation will be done to identify the patterns and sources of infection and propose additional response measures.

Biennial Frequency

To maintain the LQA HIV sentinel surveillance system as feasible, we propose alternating years to be used for the different target populations. For example, even years (i.e., 2020, 2022, 2024) would conduct sentinel surveillance among sexual and gender minorities (i.e., MSM and TG); odd years would conduct sentinel surveillance among HRW. Alternatively, all KP could be done on the same year, with HIV Sentinel Surveillance conducted every two years.

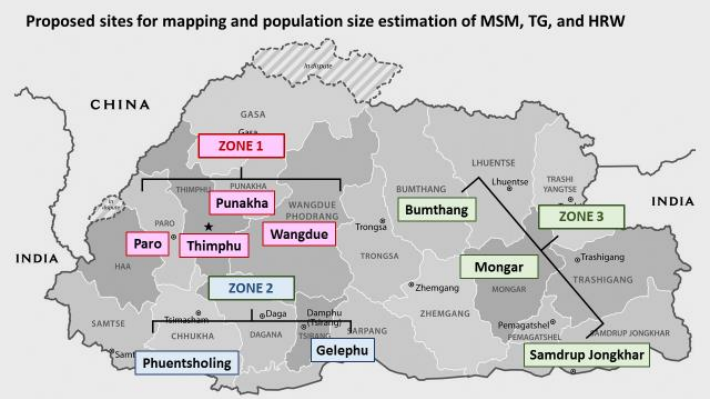
Analysis and Interpretation

The LQA approach has the primary function of establishing an early warning system that HIV prevalence may have exceeded 5% in a particular KP. In the low HIV prevalence setting of Bhutan, a precise estimate of HIV prevalence would require an infeasibly large sample size. Similarly, changes in prevalence between waves is not feasible. Rather, analysis will focus on describing the conditions when the one case detection threshold is breached.

Although HIV prevalence is expected to be low, related risk and preventive behaviors can be measured with sufficient precision. The sample size calculation presented below provides the

margin of error expected for key risk and preventive behaviors based on the results of the population size estimation exercise.

REBH SI.No7. STUDY SETTING



Justification for Study Sites Selected. HIV Sentinel Surveillance will be implemented in 9 dzongkhag study sites. For logistical purposes, these 9 study sites are organized into 3 groups or zones (see map). The 9 study sites are Thimphu, Paro, Wangdue, Punakha, Phuentsholing (Chhukka), Gelephu, Bumthang, Mongar, Samdrup Jongkhar. The sites were selected considering several criteria: 1) participation in the Population Size Estimation exercise that demonstrated the feasibility of reaching the sample size, 2) the sites cover ~80% of the urban population of Bhutan, 3) HISC and partnering NGOs provide services to key populations and persons living with HIV in these locations; and 4) the sites cover a substantial part of the geographic and cultural diversity of the country, including the capital and largest city, the major border, and eastern, central, and western regions.

REBH SI.No8. STUDY PARTICIPANTS / ELIGIBILITY CRITERIA

Four key populations are included in the HIV Sentinel Surveillance proposal: high risk women (HRW), men who have sex with men (MSM), transgender women (TGW), and transgender men (TGM). These populations bear a disproportionate burden of HIV infection in many parts of the world, including South and Southeast Asia. The recent Population Size Estimation exercise also demonstrated high risk behaviors among these KP in Bhutan, such as multiple partners, inconsistent condom use, and low levels of testing for HIV.

Definitions of these key populations vary greatly, taking into account multiple factors such as identity vs. behavior, recent vs. lifetime timeframe, rapidly changing communities and cultures, and comparability with definitions used by prior studies, programs, and public health surveillance. Recognizing definitions of these populations are complex and contextual, we adopt a public health response perspective. The target populations are those at risk for HIV due to their current behaviour. The target populations are also those who can be contacted through peers, outreach to venues, or through social media. We acknowledge this definition may not include persons with distant past behaviours, persons whose situations may be temporary (e.g., worksites, barracks), persons who may not recognize or express their gender identity or sexual orientation, and persons who are not connected to other members of the key populations.

The following operationalize the eligibility criteria for HIV Sentinel Surveillance:

- **High risk women (HRW):** Bhutanese or non-Bhutanese women age 18 years and above who work or visit hotspot environments where high risk sexual behaviors are frequently initiated (e.g., commercial sex work, transactional sex, multiple and concurrent partnering, high partner turn-over, and sexual networking within and between KP).
- **Men who have sex with men (MSM):** Bhutanese or non-Bhutanese males age 18 and above, who report anal or oral sex with another male in the past 12 months, regardless of their sexual orientation.
- **Transgender women (TGW) and men (TGM):** Bhutanese or non-Bhutanese persons age 18 and above who were assigned male sex at birth and now self-identify as “transgender” or “woman” or a gender other than male. TGW may or may not have undergone gender transition procedures (e.g., sex reassignment surgery, breast augmentation, facial implants), take hormones, or dress in women’s clothes or present as female all the time. TGM follow a parallel definition, reversing the gender in the above definition for TGW.

REBH SI.No9. SAMPLE SIZE

The total sample size is 133 HRW, 139 MSM, 30 TGW, and 90 TGM. The table below describes how these samples are distributed across the 9 study site dzongkhag in the three operational groups. TGW may be recruited from any dzongkhag.

Table: Targeted sample sizes for 9 study site districts (by grouping) for HIV Sentinel Surveillance in Bhutan.

Group	HRW sample size	MSM sample size	TGW sample size	TGM sample size
Group 1: Thimphu, Paro, Punakha, Wangdue	73	54	--	30
Group 2: Phuentsholing, Gelephu	30	55	--	30
Group 3: Bumthang, Gelephu, Monggar, Samdrup Jongkhar	30	30	--	30
Total	**133**	**139**	**30***	**90**

*Sample may be recruited from any grouping.

The above sample sizes are based on having sufficient statistical power to achieve the objectives of HIV Sentinel Surveillance in Bhutan, meeting several considerations:

- HIV prevalence is unknown among these key populations in Bhutan, but likely rare at present. Of 663 HIV cases reported to date, only a few have been recorded as MSM, TGW or HRW. Moreover, few persons recorded as MSM, TGW, or female entertainment employee have been identified as HIV-positive in the HISC testing system. A conventional sample size to measure a low prevalence would be infeasible. For example, one published survey of HRW recruited at venues found HIV prevalence to be 0.83%. At this prevalence, a sample size of 471 HRW would be needed to ensure that the lower bound of the 95% confidence interval is above 0. That is, the sample size would be exceedingly difficult to recruit and would still not provide a usable estimate of HIV prevalence.

- A method to address this challenge is to use a Lot Quality Assurance (LQA) approach that sets a threshold for detection as a sentinel signal to investigate further. For LQA, minimum sample size of 30 is needed to have >90% power (beta 0.90) to determine that HIV prevalence remains below 4% (in the event of no HIV-positive participants) or a substantial chance (alpha 0.05, or 1 in 20) that HIV prevalence may exceed 5% in the event that the threshold of 1 infection detected is breached.
- The one HIV infection detection threshold for an enhanced response is set for each 30 samples. If an infection is detected within any grouping of 30, the response protocol is triggered to conduct further investigation. Further investigation includes increasing the sample size at that site, conducting enhanced partner notification, mobilizing community support for information and testing, and/or testing around hotspot areas.
- The total sample is apportioned to be "population per size" based on the 2019/2020 Population Size Estimation exercise. The smallest estimated population size is set to 30 (for the LQA minimum) while the remaining sample is proportionately distributed to the other groupings based on relative estimated population sizes. In this manner, the total sample is approximately representative of the key populations in the whole target area and does not require sampling weights for analysis.
- The target sample sizes are feasible to achieve based on the recruitment achieved by the peer-directed sampling (PDS) method used during the Population Size Estimation exercise. For HRW, the PDS method recruited 94 HRW in group 1 dzongkhag, 72 in group 2 dzongkhag, and 29 in group 3 dzongkhag. For MSM, the PDS approach recruited 98 MSM in group 1, 108 MSM in group 2, and 67 MSM in group 3. A total of 34 TGW were recruited by PDS over all dzongkhag; 124 TGM were recruited approximately balanced across the dzongkhag groupings.
- The pooled sample sizes provide sufficient statistical power (beta >80%) to measure key indicators of risk and preventive behaviors with acceptable precision (i.e., margin of error, see table below). For HRW and MSM, this level of precision is sufficient to detect meaningful improvements or deteriorations in indicators over successive rounds of HIV sentinel surveillance, achieving or failing to meet set targets (e.g., HIV testing), or

significant differences between groups. Point estimates in the table are from the Population Size Estimation exercise.

- Sample size estimates take into consideration a finite population correction factor based on the Population Size Estimation exercise. The net effect is a greater precision is achieved for small sample sizes given the small total key population sizes. The table below shows high precision for a wide range of HIV indicators.

Table: Precision achieved for a range of HIV-related risk and preventive behavioral indicators, finite population correction for estimated total population sizes, HIV Sentinel surveillance, Bhutan.

Indicator or measure	**HRW sample size 133, population size 353**	**MSM sample size 139, population size 1,415**	**TGW sample size 30, population size 62**	**TGM sample size 90, population size 234**
Tested for HIV in last year	24% ±5.7	41% ±5.1	59% ±12.8	22% ±5.1
Tested for STI in last year	13% ±4.5	23% ±6.7	50% ±13.0	4% ±3.8
100% condom use, last 30 days, paying partners	86% ±4.7	64% ±7.6	53% ±12.9	Na
100% condom use, last 30 days, casual partners	65% ±6.4	43% ±7.8	27% ±11.5	Na
Outreach worker contact, last year	18% ±5.2	7% ±4.0	56% ±12.9	53% ±7.0
Multiple partners in last 30 days (>1)	88% ±3.4	70% ±7.2	80% ±10.4	28% ±6.9

REBH Sl.No10-16. RECRUITMENT, DATA COLLECTION, VARIABLES, DATA SOURCES/MEASUREMENT, DATA MANAGEMENT, ANALYSIS

Recruitment

The study will use peer-driven recruitment (PDR) to enroll the sample size. PDR entails peer outreach workers contacting their networks to make introductions to the study. After their participation, they are asked to refer other eligible KP to the outreach worker or bring the outreach worker to venues where their peers can be found. Additional recruitment is done by visiting venues to enroll eligible participants with further snowballing at the venues or by later referral. A further mechanism of recruitment used peer outreach workers intercepting individuals on LGBT-oriented online sites including geo-locating data apps and inviting them to participate. The resultant PDR surveys obtain diverse samples of KP members who are not directly affiliated with hotspots nor did it depend upon long-chains of peer referrals self-presenting at a fixed study site. The hybrid PDR approach is similar to other sampling methods employed for HIV Sentinel Surveillance such as targeted interventions, stratified snowball sampling, and starfish sampling [12].

Data Collection, Variables, Data Sources/Measurement, Data Management

Data collection will be through face-to-face interviews and through the results of the HIV testing.

Variables to be collected are those included in the questionnaire used for the population size estimation exercise, presented in the appendix. The source of the questionnaire instrument is from a study of HIV risk among dryang women in Bhutan [13]. Questions were adapted for the MSM, TGW, and TGM populations through a focus group discussion with community stakeholders. The adapted questionnaire was pilot tested by peers for reliability and comprehension. The final questionnaire was field tested during the Population Size Estimation in

Bhutan in 2019-2020 that included all four target populations (HRW, MSM, TGW, and TGM). Domains include demographic characteristics, use of alcohol, sexual orientation, sexual risk behaviors, contact with HIV prevention programs, STI history, experiences of stigma and discrimination, HIV testing history, results of last HIV test, and engagement in HIV care. The results of the oral fluid rapid HIV test will be recorded on the final page. To preserve confidentiality, verbal informed consent is sought.

Data are initially entered on the paper questionnaires by the peer interviewer/counselor. Data will be reviewed by the project coordinator on a daily basis for the initial week at each field site and then weekly thereafter. Reviews will take place with the interviewers to resolve errors, omissions, discrepancies, and to standardize interview methods for all peers. Upon completion of the study, data will be double entered into an Excel database by the project coordinator and one health care worker. The separately entered data will be compared with reconciliation of discrepant entries. Initial analysis will examine the data for completeness, out of range responses, and other inconsistencies. The databases will be stored on password protected computers with access limited to the project coordinator, health care worker, and principal investigators. In some cases, the questionnaire may be completed online but appointment made of HIV testing in person.

Analysis and Dissemination

Analysis will be primarily descriptive. As discussed above, HIV prevalence is expected to be low and therefore a precise, population-based estimate is not feasible. The primary analysis is therefore based on the LQA approach to conclude whether there is evidence that HIV prevalence remains below 4% for each KP. If the 1 case threshold is breached, the primary analysis will be descriptive of the conditions surrounding that case, further data collected, and response measures taken. For other key indicators, such as risk and preventive behaviors, point estimates and 95% confidence intervals will be presented, with stratification by KP. Further analysis will be

possible on the correlates of key indicators, for example, characterizing the KP who have never tested for HIV or never had contact with HIV prevention programs.

To ensure the highest transparency, buy-in, and ultimate use of the HIV Sentinel Surveillance Data, we envision multiple avenues to disseminate findings of this study:

5. **Forums with partnering institutions, NGO, and other government of Bhutan agencies.** We propose the rapid dissemination of preliminary results in meetings with select representatives of the different agencies who have a stake in the findings of this study. Their input at an early stage will help identify biases and challenges not previously considered with potential modifications to conclusions and recommendations. Their early input will also foster transparency, ownership, and ultimate buy-in on findings.
6. **Forums reaching KP community members and their representatives.** With agreement from the above stakeholders, early dissemination of findings will be done through public forums with KP community members and their representatives. These may include in-face public meetings inviting key persons, or online by posted results on websites reaching the KP (e.g., Rainbow Bhutan) using PowerPoint presentations. These forums can elicit public commentary that can be included in the final comprehensive report.
7. **Comprehensive report.** Data from each wave of HIV Sentinel Surveillance will be included in a comprehensive report of all findings. The report will incorporate relevant background, methods, results, interpretations, limitations, conclusions, and recommendations.
8. **Factsheets, posters, and abstracts.** Once the comprehensive report is accepted, further dissemination can occur through written materials, such as factsheets for distribution by the HISC and peer outreach workers, posters to hang in HISC, DiC, and NGO offices, and abstracts submitted to present in national, regional, and international conferences.
9. **Publications in the scientific literature.** We envision that this study's findings will contribute to the scientific literature by sharing methodological adaptions, lessons learned, and conclusions with researchers and public health officials facing similar challenges. Under the leadership of the PI, the team will decide upon topics for publication, authorship, and timelines for submission. The *Bhutan Health Journal* is likely

to be an important vehicle for reaching the local and regional audience. Other international journals will be considered.

REBH Sl.No17. RESEARCH ETHICS

Ethical review. This protocol will be reviewed and monitored by the Research Ethics Board of Health (REBH) of Bhutan. Verbal informed consent will be obtained from all participants. Verbal consent instead of written consent is requested to ensure that no identifiers are linked to the study data and thereby protecting confidentiality and privacy.

Adhering to Ethical Principles of Research. The following steps shall ensure that the ethical principles of research are upheld: respect of persons, beneficence, and justice.

1. **Respect of persons** is the recognition that participants are free to make their own decision whether to participant in this study or not, or to withdraw from the study at any time. The informed consent process will disclose the nature of the study, the possible harms, the potential benefits, how privacy will be maintained, and the use of the data so that each person can decide for him or herself (see Informed Consent section below). Individuals will be empowered to make free decisions and be given all the information needed to make informed decisions.
2. **Beneficence** is to take all measures to avoid causing harm to participants. For our study, this includes steps taken to preserve the privacy and confidentiality of participants being members of KP populations, their HIV status, and responses to sensitive question (see Confidentiality section below).
3. **Justice** is the fair and equal distribution of benefits and risks of participation in the research study. The data collected for this study will provide information on the HIV epidemic concerning KP in Bhutan. The risks of the study, primarily loss of privacy, are born by the KP participants (HRW, MSM, TGW, and TGM). In turn, the information gathered by the study will help benefit these study populations. These benefits include advocating for community-based prevention and care programs for HRW,

MSM, TGW, and TGM; to identifying barriers and facilitators for KP to use health services; to targeting outreach efforts for KP, and helping to ensure stigma-free services for KP.

Potential Harms and Means to Mitigate Them. A potential severe risk to participants that may occur in several parts of this study is the unwanted and inadvertent disclosure of their HIV status, KP status (HRW, MSM, TGW, TGM), or engagement in stigmatized sexual behaviors to persons outside the study team. As in most of the world, members of these communities face potential stigma, discrimination, and violence if their sexual orientation or behaviors are found out. Repercussions can include loss of job, rejection by family and friends, different treatment with services, loss of financial support, injury, and severe pervasive stress. Compounding the situation, Bhutan is a small country and the study sites are located in small towns (relative to Asia). Peer outreach workers may be acquainted with participants. If the participant knows or is acquainted with the peer outreach work, another interviewer can be assigned. Multiple measures to protect privacy and confidentiality are detailed below.

Another potential harm is the stress of learning one's HIV status. To mitigate this possible harm, participants will be referred to the HIV care programs that provide psychological counseling and social support. A related potential harm that may occur is the psychological stress resulting from discussing personal behavior with study staff. The interviews on sexual risk behavior, for example, may trigger recollection of interpersonal violence and other traumatic events. To mitigate this potential harm, study staff are certified counselors with professional training and experience. A refresher training will be done prior to field activities, including training on sensitivity to gender and sexual minorities. Additionally, participants can be referred to the MOH psycho-social welfare services.

Finally, acute health and social welfare needs may arise in the course of field activities and data collection. For example, the sexual abuse of minors and indicators of trafficking must be reported

to social service authorities. Other acute health issues include high concern for HIV or STI infection will result in referrals or escort to the nearest health facilities.

Potential Benefits to Participants and Society. Participants can directly benefit from learning their HIV status to obtain treatment and to reduce their risk of onward transmission of HIV. Participants who are HIV negative will be informed of means to prevent and treat infections, and be referred or guided to the HISC as appropriate. To reimburse participants for their time, airtime, and transport, they will be offered small non-monetary tokens of appreciation, such as cell phone airtime. Other benefits of the study accrue to the communities and society at large. The proposed study will generate data to strengthen the national HIV response on several levels. The risk behavior data provide a better understanding of the drivers of HIV transmission in Bhutan and points for future prevention interventions. The survey data also provide a baseline for the reach and coverage of programs for KP as part of monitoring and evaluation.

REBH SI.No18. PROTOCOL AMENDMENTS

Any considered important protocol modifications will be submitted to the REBH for review and approval prior to implementation.

REBH SI.No19. INFORMED CONSENT

Verbal informed consent will be obtained for this study for the interview to complete the questionnaire and for HIV counseling and testing. Verbal consent is sought instead of written consent to ensure the privacy and confidentiality of participants by having no identifying information appearing on any forms or databases. Consent will be obtained by the study field staff by reviewing the consent form with the participant. The staff will review the purpose of the study, the procedures, the potential harms, potential benefits (including incentives), who is the PI and investigators, and who to contact if they have complaints. Sufficient time will be given to

answer participant questions. Participants will also be given options to find the final report of the study (e.g., via Rainbow Bhutan office or website, MoH address, PI contact information). Participants may choose to keep a copy of the consent sheet.

REBH SI.No20. CONFIDENTIALITY

We will take several measures to reduce the risk of inadvertent disclosure of sensitive information about participants:

- Questionnaires and electronic databases will not include any personally identifying information. Informed consent will be verbal only.
- Any temporarily or accidentally obtained contact information (e.g., phone numbers called, email contact, IP addresses, rendez-vous to meet participants) will be destroyed after their use. Only persons who have a need to know will view such information.
- Data collection will be done by health professionals working with trained peer outreach workers. These staff have undergone training on research ethics and professional conduct concerning privacy of information.
- Given the small size of the communities, participants can opt to be interviewed and counseled by a professional HISC health worker rather than a peer outreach worker.
- We will implement a refresher training on research ethics and privacy to the study staff in preparation for field work.
- Interviewers will ensure privacy when interviewing key informants and survey respondents in the field.
- An oath of confidentiality before collecting or accessing to any study-related information, will be required of personnel to sign agreeing to protect the security and confidentiality of participants interviewed or persons seen in the field.
- Computer based files will only be made available to personnel involved in the study through the use of access privileges and passwords.

- Records will be kept in a secured location and only accessible to personnel involved in the study.
- Staff will receive ethical training prior to data collection, including protections for special populations and maintaining confidentiality.
- Dissemination materials will not include information that may identify or appear to identify individuals (e.g., no data with less than 5 participant will be shown).
- Any breach of confidentiality will be reported to the REBH along with measures to ensure such occurrences do not happen in the future.

REBH SI.No21. DECLARATION OF INTERESTS

All investigators listed in this protocol declare they have no conflicts of interests, financial or other competing interests, for the overall study and each study site.

REBH SI.No22. ACCESS TO DATA

Access to primary data will be only on a need to know basis to ensure integrity and quality. These include the principal investigators, project coordinator, and primary data analyst. Please see section REBH SI.No 20: CONFIDENTIALITY above.

REBH SI.No23. ANCILLARY AND POST-TRIAL CARE

Not applicable

REBH SI.No24. SPONSOR / FUNDING

This study is funded by Global Fund for HIV/AIDS Program and the Ministry of Health of Bhutan.

REBH SI.No 25. TRIAL REGISTRATION

Not applicable

REBH SI.No26. APPENDICES

Appendix A. Consent Form

Appendix B. Questionnaire

Appendix C. Training Agenda

Appendix D. Budget

Appendix E. APPLICATION FORM for INITIAL REVIEW

REBH SI.No27. FACILITIES

The study will be conducted with HISC, Lhaksam, Rainbow Bhutan under the supervision of the National HIV/AIDS & STIs Control Program of the Ministry of Health Bhutan. All necessary supports (e.g., computers, offices, etc.) are in place.

REBH SI.No28. STUDY TIMELINE

S/No	Activities in 2021	April	May	June	July	Aug	Sept
1	Protocol revision and REBH approval						
2	Training and pilot testing						
3	Collection of data						
4	Data Entry and analysis						
5	Final Report						
7	Dissemination of study findings						

REBH SI.No29. REFERENCES

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Appendix A

Consent form

Name of Principal Investigator:
Mr Lekey Khandu
Program Manager,
HIV/AIDS program of Department of Public Health,
Ministry of Health

PART I: Information Sheet

Introduction

Good Morning, I am ……., working for the Ministry of Health. We are conducting a study on HIV prevalence and risk behaviors of men who have sex with men, transgender persons, and high risk women in Bhutan. This study is very important for Bhutan to develop strategies for public health approaches to combating HIV.

We will not write any name or any information that will reveal your identity. We will maintain the confidentiality of the information gathered. All information gathered will be reported as aggregate data.

If you don't agree to participate or want to withdraw any time during the interview, you are most welcome to withdraw from answering any questions or decide not to participate any time. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or the Principal Investigator, Mr Lekey Khandu, Program Manager for HIV/AIDS, DoPH, Ministry of Health, Telephone Number 17425548, email lkhandu@health.gov.bt

Purpose

Key population are communities that bear a high incidence and burden of HIV worldwide, yet data on the prevalence of HIV and the behaviours that place them at risk are scant in Bhutan. The present protocol addresses four key populations: men who have sex with men (MSM), transgender women (TGW), transgender men (TGM), and high risk women (HRW). Therefore, this study aims to establish national and selected geographic area HIV prevalence estimates, including sexual risk behaviour, for MSM, TGW, TGM, and HRW in Bhutan, which will used for developing public health strategies by the Ministry of Health.

Type of Research Intervention

This is a bio-behavioral survey where we will be asking you some question regarding your life styles and also collect oral samples for testing for HIV. Therefore, just now, you are invited to participate as you are referred by a peer outreach worker or previous respondent whom we have interviewed. You are being referred to participate because we believe that you can provide us substantial information about MSM/TGW/TGM/HRW. We will ask some question about your sexual risk behavior that puts you at risk for HIV and STI infections. The interview will take about 30-45 minutes. We expect to actively participate but if you feel the questions are sensitive and you do not wish to participate, you choose to not answer them, and you can also leave the discussion without citing any reasons.

Voluntary Participation

Your decision to participate in this study is entirely voluntary. It is your choice whether to participate or not. Even if you choose not to participate, all the services you receive from MoH and other clinics will continue and nothing will change. You may also choose to change your mind

later and stop participating, even if you have agreed earlier, and health services that you and/or your family receive will continue.

INFORMED CONSENT

You will be asked to provide a verbal consent once you have read this information and agree to participate in this study. Verbal consent is sought instead of written consent to ensure your privacy and confidentiality and there are no identifiers.

REBH SI.No20. CONFIDENTIALITY

To ensure your confidentiality, we will take several measures to reduce the risk of inadvertent disclosure of sensitive information about participants:

- Questionnaires and electronic databases will not include any personally identifying information.
- Any temporarily or accidentally obtained contact information (e.g., phone numbers called, email contact, IP addresses, rendez-vous to meet participants) will be destroyed after their use. Only persons who have a need to know will view such information.
- Data collection will be done by health professionals working with trained peer outreach workers. These staff have undergone training on research ethics and professional conduct concerning privacy of information.
- Given the small size of the communities, participants can opt to be interviewed and counseled by a professional HISC health worker rather than a peer outreach worker.
- The interviewers were trained on research ethics and privacy to the study staff in preparation for field work.
- Interviewers will ensure privacy when interviewing key informants and survey respondents in the field.
- The interviewers sign an oath of confidentiality retained by the MoH.

- Computer based files will only be made available to personnel involved in the study through the use of access privileges and passwords.
- Records will be kept in a secured location and only accessible to personnel involved in the study.
- Staff received ethical training prior to data collection on protections for vulnerable populations.
- Dissemination materials will not include information that may identify or appear to identify individuals (e.g., no data with less than 5 participant will be shown).
- Any breach of confidentiality will be reported to the REBH along with measures to ensure such occurrences do not happen in the future.

Risks & Benefits

There is no physical risk in participating in this survey for getting tested for HIV by oral test as there is no invasive procedure involved for this study. Instead it will help you know your HIV status for timely care, support and treatment for qualitative life and also help to prevent the transmission of HIV from the source. In regard to the information that we asked you, including your test result, we will maintain confidential. We will not write or ask any information that you don't want us to write or that will lead to your identification. If you know or are acquainted with the peer outreach worker who is interviewing you, we can provide you a different interviewer.

There is the stress of learning that you are HIV positive if your test is positive. If you test positive, you can receive HIV care that includes psychological counseling and social support. You may also feel stress in discussing personal behavior with the study staff. Study staff are certified counselors with professional training and experience and can refer you to further professional support services.

Apart from learning your HIV status, there is no direct benefit of the study to you but the study will let the Ministry of Health know how many people with different sexual orientation are there in Bhutan and their risk behaviour. The information will be used to develop strategies and priorities to reduce sexuality related diseases.

Right to Refuse or Withdraw

You can withdraw/refuse to participate and also withdraw from participation any time without citing any reasons. You can also refrain from answering any questions if you feel it is sensitive or you do not want to reveal. Your refusal to participate will not affect the services that you receive from the Ministry of Health or Hospitals and the Government. You may stop from participating in the research at any time that you wish without either you or your family losing any of your rights as a patient and citizen of Bhutan.

Sharing of the results

The knowledge that we get from this study will be generated as report and submitted to Global Fund that is funding the study and the Ministry of Health. The information will also be shared among the key population community, organizations, and may also be published. In the final report there will not be any information leading to identification of organizations or you.

Who to Contact

This proposal has been reviewed and approved by the Research Ethics Board for Health. If you need further information about the study you may wish to contact following persons:

1. Mr Lekey Khandu, Program Manager for National HIV/AIDS, DoPH, Ministry of Health, Telephone Number 17425548, email lkhando@health.gov.bt

2. Mr Kinley Dorjee, Assistant Research Officer, Telephone Number 17450682; Email mail: kdorjee@health.gov.bt, REBH, MOH.

PART II: Certificate of Consent: Statement by the researcher/person taking consent

I have accurately read out the information sheet to the participants and also handed over the information sheet containing all the details of the study to the participants. To the best of my ability, I made sure that the person understood the research objectives, possible benefits and risk of the research, voluntary participation, and confidentiality of the information. I assured that all information shall remain confidential.

I ensure that the participant voluntarily participated in the study and I have conducted this data collection with utmost integrity and ethical standards. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant were answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the verbal consent has been given freely and voluntarily.

A copy of information sheet and informed consent form has been provided to the participant.

Participant Study Code :_____ Date:____/____/____

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____ (day/month/year)

Sentinel Surveillance Questionnaire

Kuzuzangpola, I am... currently doing a research activity for the Ministry of Health. The main objective of the research is to find out the prevalence of HIV and related risk behaviors of high risk women (HRW), men who have sex with men (MSM), transgender women (TGW), and transgender men (TGM), so that the MoH can develop programmatic interventions. If you permit, it may take around 15-30 minutes. It is completely voluntary, information you provided will be strictly confidential. I will ensure that your identity will not be revealed to anyone and information gathered from here will not be used for any other purposed other than for this research purpose.

Do you have any questions?

Will you be willing to participate?

Yes (proceed to verbal consent) **No (stop interview)**

Thank you for your time.

These questions will be asked to HRW, MSM, TGW, TGM who are above 18 years old and who provided verbal consent

Study ID No: _____District: _____

Interviewer Name: _____Interview location: _____

Date:_____Time:_____

Eligibility verified (Please circle): 1. Yes 2. No

Consent obtained (Please circle): 1. Yes 2. No

This questionnaire is for (circle answer): 1) HRW 2) MSM 3) TGW 4) TGM

A: Demographics: I will ask few questions on your demographics.

Please Circle the appropriate answer and write wherever applicable			
Q. N.	**Questions and Filters**	**Coding Categories**	**Skip to**
1	Which part of Bhutan you are from?	1. District_____ 2. Village/Municipality_____ 3. Non-Bhutanse (Specify country) _____	
2	Where do you live now?	1. District_____ 2. Name of town_____	
3	How old are you?	1. Age in completed Years…….. 2. Don't know	

Please Circle the appropriate answer and write wherever applicable			
Q. N.	**Questions and Filters**	**Coding Categories**	**Skip to**
		3. Can't say	
4	What is your education level?	1. No Education 2. Primary (Grade PP-6) 3. Middle Sec School (Grade 7-10) 4. Higher secondary school (Grade 11-12) 5. University 6. Others (Specify) ……	
5	May I know your marital status?	1. Married 2. Living together, not officially married 3. Single never married 4. Divorced 5. Widowed 6. Others (Specify)……	
6	May I know your occupation?	1. Civil servants 2. Housewife 3. Religious body 4. Unemployed 5. Students/trainees 6. Farmers 7. Entertainment/bar workers 8. Migrants worker 9. Driver (taxi/trucker/govt/corporate) 10. Corporate employee 11. Others (specify):_____	

Please Circle the appropriate answer and write wherever applicable			
Q. N.	**Questions and Filters**	**Coding Categories**	**Skip to**
7	What was your sex assigned to you at birth?	1. Male 2. Female 3. Intersex 4. Don't know 5. Other, specify: _____ 6. No response	
8	What is your current gender identity?	1. Male 2. Female 3. Transwoman 4. Transman 5. Don't know 6. Other, specify:_____ 7. No response	

BEHAVIOR (Now let me ask you some questions regarding your lifestyle)

Q. N.	Questions and Filters	Coding Categories	Skip to
9	Do you drink alcohol (Whiskey/Beer/Wine/local)?	1. Yes 2. No 3. No response	If No go to 10
10	Did you have sex under the influence alcohol?	1. Yes 2. No 3. Don't know 4. No response If yes, was this: a. Vaginal sex b. Anal sex c. Both	No/Don't know go to 10
11	Did you use condom during the last sexual intercourse you had under the influence of alcohol?	1. Yes 2. No 3. Can't remember 4. Don't know 5. No response	
12	May I know your sexual identity? How do you identify? (If asked explain)	1. Straight, heterosexual 2. Gay 3. Bisexual 4. Lesbian 5. Other identity (Queer, questioning, non-binary, etc), enter: _____ 6. Don't know 7. No response	
13	At what age did you have your first sex?	1. Age (in years) for first vaginal sex …… (insert "don't know if can't recall)	Never skip to 18

Q. N.	Questions and Filters	Coding Categories	Skip to
		2. Age (in years) for first anal sex …… (insert "don't know if can't recall) 3. Never had vaginal sex so far 4. Never had anal sex so far 5. No response	
14	In your lifetime, what gender have been your sexual partners?	1. Men only 2. Women only 3. Both women and men. 4. No response	
15	May I know your sexual orientation? (i.e., Who are you attracted to)	1. I prefer sex with men only 2. I prefer sex with women only 3. I like sex with both women and men 4. No response	
16	Have you ever had sex with a transgender person?	1. Yes 2. No 3. Don't know 4. No response If yes, were they: d. Transwoman e. Transman f. Both	
17	In the last 30 days, how many sexual partners did you have sex with (include both vaginal and anal). Circle and write numbers for each	1. Total number of all partners……. 2. Spouse…… 3. Regular partners…….. 4. Casual partners……. 5. Paying partners (cash exchanged)……	

Q. N.	Questions and Filters	Coding Categories	Skip to
		6. Transactional partners (other goods, help, services exchanged):……. 7. No response	
18	Did you always use condom with your sexual partners each time you had sex with them in the last 30 days? (multiple answers possible, include both vaginal and anal sex)	1. Spouse: a. Always b. Sometimes c. Never d. Don't recall e. No response 2. Regular partners: a. Always b. Sometimes c. Never d. Don't recall e. No response 3. Casual partners: a. Always b. Sometimes c. Never d. Don't recall e. No response 4. Paying partners: a. Always b. Sometimes c. Never d. Don't recall e. No response	

Q. N.	Questions and Filters	Coding Categories	Skip to
		5. Transactional partners: a. Always b. Sometimes c. Never d. Don't recall e. No response	
19	In your lifetime, have you provided sex for…? (multiple answers possible)	1. Cash a. Yes If Yes, when was the last time Date /Month: ……. b. No 2. Gifts a. Yes If Yes, when was the last time Date /Month: ……. b. No 3. Other (Specify)…….. 4. No response	

HIV TESTING AND PREVENTION PROGRAMS: Now I will be asking about HIV testing and support services

Q. N.	Questions and Filters	Coding Categories	Skip to
20	Do you know of a place where people can go to get tested for HIV?	1. Yes 2. No	If No go to 20

Q. N.	Questions and Filters	Coding Categories	Skip to
21	Where is that place?	1. Referral Hospital 2. District Hospital 3. Basic Health Unit (BHU) 4. HISC 5. Private Hospital 6. Other (Specify)_____	
22	Have you been ever tested to see if you have HIV?	1. Yes 2. No 3. No response a. If Yes where did you get your most recent test done:_____	
23	When was the last time you were tested?	1. Less than 12 months ago 2. Between 12 – 23 months ago 3. 2 or more years ago 4. Don't recall 5. No response	
24	Did you get the result of the test?	1. Yes 2. No 3. Don't Know 4. No response	
25	What was the result?	1. Negative 2. Positive 3. Indeterminate 4. Don't know 5. No response, declined	

Q. N.	Questions and Filters	Coding Categories	Skip to
26	If HIV-positive: Are you currently seeing a health care provider for your HIV infection?	1. Yes 2. No 3. Don't know 4. No response, decline to say	
27	If HIV-positive: Are you currently receiving anti-retroviral treatment for your HIV infection?	1. Yes 2. No 3. Don't know 4. No response, decline to say	
28	Have you ever attended any HIV educational events?	1. Yes (specify):_____ 2. No 3. Don't know 4. No response If yes, was this in 2019? a. Yes b. No	
29	Has an outreach worker ever talked to you about HIV prevention?	1. Yes 2. No 3. Don't know 4. No response If yes, was this in 2019? c. Yes d. No	

Q. N.	Questions and Filters	Coding Categories	Skip to
30	Have you ever got tested for sexually transmitted infections (STI)?	1. Yes 2. No 3. Don't know 4. No response If yes, was this in 2019? a. Yes b. No	
31	Have you ever had following symptoms? (Multiple answer possible)	1. Genital ulcers a) If yes, was this in 2019? Circle Yes / No / DK / No response 2. Discharge from genitals a) If yes, was this in 2019? Circle Yes / No /DK / No response	
32	Are you open with your [according to KP: gender presentation, sexual orientation, status as HRW] to your family?	1. Yes, to all or most family members 2. Only to one or a few 3. No one 4. No response	
33	Have you experienced stigma because of your [according to KP: gender presentation, sexual orientation, status as HRW] from your friends?	1. Often 2. Sometimes 3. Never 4. Don't Know 5. No response	

Q. N.	Questions and Filters	Coding Categories	Skip to
34	Have you experienced stigma because of your [according to KP: gender presentation, sexual orientation, status as HRW] from the strangers?	6. Often 7. Sometimes 8. Never 9. Don't Know 10. No response	
35	Because of your [according to KP: gender presentation, sexual orientation, status as HRW], did you experience discrimination when accessing health services?	1. Often 2. Sometimes 3. Never 4. Don't Know 5. No response	

Do you have any questions for us?

Rapid test result (circle):

1. Reactive
2. Non-reactive
3. Indeterminate
4. Not done – declined
5. Not done – other reason: _____

<u>THANK YOU FOR YOUR TIME</u>

Appendix C

Training Agenda: HIV Sentinel Surveillance

Attendees: Investigators, HISC, Team Leads, Interviewers/Outreach Workers

Date	Activities	Responsibility
Day 1	HIV counseling and testing basics for certification	?
Day 2	HIV counseling and testing, role play, assessment	?
Day 3	Debrief of the population size exercise, lessons learned	Lekey Khandu
	Updates of KP mapping, HIV risk data, surveillance data	
	Methods for conducting HIV sentinel surveillance	Willi McFarland
	Review of protocol	
Day 4	Sensitization to KP populations, HIV risk, ethical issues	Lekey Khandu
	Review of informed consent, role play	
	Review and revision of questionnaire, role play	Willi McFarland
	Field and pilot testing	
Day 5	Debrief on field test, discussion of revisions	Lekey Khandu & Willi McFarland
	Questions and Answers	
	Agreed upon timeline, next steps	
	Adjourn	

Appendix D: Estimated Budget needed for HIV Sentinel Surveillance

S/No	Activities (time)	Participants	Costs	Budget (NU)
1	Training of the field investigators on the study protocol for two days.	14 ORWs and 6 HISC Counselors.	Venue Refreshments Per diem Supplies	11825.00
2	Data Collection peer referral	12 months (4 quarter) for 14 ORWs and 6 Counselors.	Venue Per diem Refreshments Supplies Incentives for CM Transport	10000.00
3	Data Entry and analysis	6 counselors and NACP staff	Venue Per diem Refreshments Supplies Data entry cost	5000.00
5	Communication cost for further peer referral	Respondent MSM, HRW, TGM (302)	(Nu 500 in cell phone air time. Participants will also be asked to refer potentially eligible acquaintances to the study, with an incentive of Nu 200 for each recruit)	3500.00

6	Analysis, report writing and dissemination			5000.00
			Total (USD)	**USD 34480.00**

Appendix E

ANNEX 3

Form AF/03-008/05

APPLICATION FORM for INITIAL REVIEW

Instructions: This form has 30 items. Follow the item specific instructions and fills all applicable items from 2 through 30. (To mark "✓" the given options double clicks on the first half of the box "☐")

1	Protocol Number (*Protocol Number will be assigned by REBH Secretariat*):
2	Protocol Title: **HIV Sentinel Surveillance among Key Populations in Bhutan**
3	Protocol Version Number: 02
4	PARTICULARS OF THE PRINCIPAL INVESTIGATOR (PI) Name: Lekey Khandu Address: National HIV, AIDS and STIs Control Program, Dept. of Public Health, Ministry of Health. Contact Number: 17425548…….. E-mail: lkhandu@health.gov.bt
5	Proponent of the study: …Mr Lekey Khandu……..
6	STUDY TYPE: (Mark "✓ "whichever apply to the study. Tick all that apply)

	☐ Survey ☐ Retrospective ☐ Prospective Social ✔ Behavioural research ☐ Community based ☐ Individual based ✔ Screening ☐ Observational ☐ Epidemiology ☐ Intervention study ☐ Medical ☐ Research on stored biological samples ☐ Clinical Trial: ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Genetic Study ☐ Others……
7	CHARACTERISTICS of PARTICIPANTS: Age Range (Specify): Impaired: ☐ None ☐ Physically ☐ Cognitively ☐ Mentally Limitation: ☐ illiteracy ☐ Prisoners ☐ Hospitalized ☐ Nursing home ☐ Pregnancy ☐ Poor/uninsured ☐ Employees of study site ☐ Students or staff of the PI ☐ Military personnel ✔ Others vulnerable to coercion, specify (Men having sex with men, Transgender and high-risk women)
8	REQUESTED EXCLUSION OF PARTICIPANTS: ☐ None ☐ Male ☐ Female ✔ Children ☐ Other (specify): .18 years above of above-mentioned groups....
9	SPECIAL RESOURCE REQUIREMENTS (Tick all that apply, ONLY if applicable): ☐ Intensive Care ☐ Isolation unit ☐ Surgery ☐ Psychiatric institution ☐ Paediatric Intensive Care ☐ Transfusion ☐ CAT scan ☐ EKG scam ☐ Gene therapy ☐ Controlled substances (Narcotics / Psychotropic) ☐ Prosthetics ☐ Gynaecological services ☐ Others (specify)…… ☐ Organ transplantation, specify……

1	IONIZING RADIATION USE (X-rays, radioisotopes, etc): ✔ None or Not Applicable (NA) ☐ Medically indicated only ☐ All
1	INVESTIGATIONAL NEW DRUG (IND) / DEVICE (IDE): ✔ None ☐ IND ☐ IDE DRA No.:…….. DRA No:…… Name: …….. Name: …… Sponsor: …….. Sponsor: …….. Holder: …… Holder: ……..
1	PROCEDURE USE: ☐ Invasive ✔ Non-invasive
1	MULTI-SITE COLLABORATION: ☐ YES, ✔ NO
1	FINANCIAL DISCLOSURE: ✔ YES ☐ NO If NO why not? .....

15. CO-INVESTIGATOR(S)				
Name and Institution	BMHC No.	Role in the study	Does s/he meet or will meet authorship criteria* (Yes/ No)	Contact Number
1. Karma Lhazeen, Dept of Public Health (DoPH), Ministry of Health.		Protocol review, and report writing, analysis, report writing.	**Yes**	**+975-17614849**
2. Tashi Tobgay, Institute of		Protocol review, and report writing,	**Yes**	**+975-17606984**

Health Partners, Thimphu.		analysis, report writing.		
3. Rixin Jamtsho, CDD, DoPH, Ministry of Health		Data collection, analysis and interpretation of the result and critical review of the report.	**Yes**	**+975-77229882**
4. Doley Tshering, NACP, DoPH, Ministry of Health.		Data collection, analysis and interpretation of the result and critical review of the report.	**Yes**	**+975-17645977**
5. Willi McFarland, Center for Public Health Research, San Francisco Department of Public Health and University of California San Francisco, USA.		Support in protocol drafting, training of field investigators, analysis and report writing.	**Yes**	

***** The ICMJE recommends that authorship be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND

4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

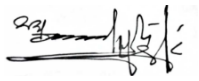
16	Has the Principal Investigator (PI) ever been involved in or convicted of a crime, disciplined by a public or private medical organization, or by a licensing authority? ✔ No ☐ Yes, explain ……..
17	Does the PI, the study colleagues or their families have any financial relationship with the sponsor other than payment for the conduct of the study? ✔ No ☐ Yes, If Yes describe the relationship …….
18	Does the PI, the study colleagues or their families have any other personal considerations that may compromise, or have the appearance of compromising a researcher's professional judgment in conducting or reporting research? ✔ No ☐ Yes, If Yes describe it …….
19	For this study, how many of the following will the PI supervise? Sub-investigators: Study sites include HISC heath workers operating in nine districts ☐ NA
20	How many (in total) of the following does the PI currently supervise? Ongoing studies…… Sub-investigators …… ✔ NA
21	Type of facility at the research site: ✔ Health facility ☐ University ✔ Community ✔ Others, specify: Identified hot spots
22	Clinical Monitor Name, if applicable: **Not applicable** Contact Number: ……..E-mail: ……..

23	**For genetic study only,** indicate whether it involves any form of gene transfer ☐ Yes ✔ No If YES has the study been reviewed by: ○ NA ○ None ○Bio-safety○ Recombinant DNA Advisory boards
24	**For study that involves sending of biological samples outside the country;** is there a Material Transfer Agreement? ☐ Yes ✔ No ☐ NA
25	How long will the research data be stored by the PI? … years after closing the study.

26		IS THERE A **REQUEST FOR INFORMED CONSENT WAIVER**? ☐ Yes (**GOTO 26.2**) ✔ No (But Waiver for written consent)
		26.1. Does the informed consent include the following? (Check 26.1.1 through 26.1.2)
	26.1.1.	**Information sheet**: ✔ Yes ☐ No
	26.1.2	26.1.2.1. For participants ≥ 18 years: ☐ NA (If NA **GOTO 26.1.2.2**) 26.1.2.1.1. Informed Consent: ✔ Yes ☐ No
		26.1.2.2. For participants 12 -18 years: ✔ NA (If NA **GOTO 26.1.2.3**) 26.1.2.2.1. Informed Consent from the parent(s) or legal guardian: ☐ Yes ☐ No 26.1.2.2.2. Informed Assent from the participant: ☐ Yes ☐ No
		26.1.2.3. For participants 7 to <12 years: ✔ NA (If NA **GOTO 26.1.2.4**) 26.1.2.3.1. Informed Consent from the parent(s) or legal guardian: ☐ Yes ☐ No 26.1.2.3.2. Verbal Informed Assent from the participant: ☐ Yes ☐ No
		26.1.2.4. For participants <7 years: ✔ NA (If NA **GOTO 26.1.2.5**)

		26.1.2.4.1. Informed Consent from the parent(s) or legal guardian: ☐ Yes ☐ No
		26.1.2.5. For participants who are incompetent to give informed consent: ✔ NA (**GOTO 26.1.2.6**) 26.1.2.5.1. Informed Consent from the parent(s) or legal guardian: ☐ Yes ☐ No 26.1.2.5.2. Informed Assent from the participant: ☐ Yes ☐ No
		26.1.2.6. If participants are illiterate: ☐ NA (If NA **GOTO 26.1.2.7**) (Only verbal consent) 26.1.2.6.1. Provision for thumb impression: ☐ Yes ☐ No 26.1.2.6.2. Provision for witness: ☐ Yes ☐ No
		26.1.2.7. Is there a statement by the researcher or person taking consent declaring that the informed consent is appropriately administered: ✔ Yes ☐ No
	26.1.3	Dzongkha version of 26.1.3.1. information sheet: ✔ Yes ☐ No 26.1.3.2. informed consent form: ✔ Yes ☐ No (statement by the researcher)
	26.2. If there is a request for informed consent waiver, provide justifications: We will request only verbal consent due to the following reasons; 1. Key target population are sensitive in nature and any identifiers if included has potential to bridge the confidently of their gender. 2. If we ask for any identifiers including written consent and signature, it would compromise on recruitment of the respondents. 3. There is possible legal implication for both the researchers and participants if any identifiers are disclosed.	

27	What precautions will be used to maintain the confidentiality of identifiable health information? ✔ Records will be kept in a secured location and only accessible to personnel involved in the study. ✔ Computer based files will only be made available to personnel involved in the study through the use of access privileges and passwords. ✔ Before accessing to any study-related information, personnel have to sign statements agreeing to protect the security and confidentiality of identifiable health information. ✔ Whenever feasible, identifiers will be removed from study-related information. ✔ Other, specify…(Waiver of the written informed consent is sought).
28	What kind of means will be used to recruit subjects for the study? ✔ Personal contact ✔ Referrals ✔ from database other than the PI's list ☐ Advertising (All recruitment materials must be approved by REBH before use.) ✔ Other, specify…Social media, venue intercept (COVID-19 permitting)
29	Has the research study been disapproved or terminated by any other Research Board? ✔ No ☐ Yes, explain……..
30	**SIGNATURES:** Date: 29/3/21



Principal Investigator

Date:……

Protocol Chairperson (if applicable)

COMPLETION:

Date:……

Member-Secretary, REBH