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TOBACCO SMOKING AMONG PEOPLE LIVING WITH HIV IN UGANDA

ABSTRACT

Background: With effective HIV treatment, people living with HIV (PLWH) can have a near-normal life expectancy. However, many PLWH smoke with the smoking prevalence among PLWH being much higher than in the general population. PLWH who smoke are twice as likely to die prematurely as non-smoking PLWH even when receiving effective HIV treatment. Unfortunately, smoking cessation interventions that are effective in general population smokers are not effective in helping PLWH who smoke to quit. There is a pressing need to understand PLWH's smoking behaviour including its determinants and, on this basis, develop smoking cessation interventions that are tailored to their needs.

Objectives: The main objective is to investigate the smoking behaviour and factors associated with current smoking status among PLWH who are in HIV care so as to inform the design of innovative and effective PLWH focused smoking cessation interventions that are implementable and scalable in Uganda.

Methods: The study will comprise: 1) a cross-sectional survey among PLWH (regardless of current smoking status); 2) qualitative interviews with PLWH who smoke or have recently quit smoking (within the past year); and 3) qualitative interviews with HIV-care programme health care workers and policy makers.
Conclusions: The data gathered from this study will be useful for designing tailored and potentially effective smoking cessation interventions for PLWH that are implementable and scalable in Uganda and other LMICs.

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ACRONYMS and ABBREVIATIONS

ART	Antiretroviral therapy
COM-B	Capability, Opportunity, Motivation- Behaviour
DHS	Demographic and Health Surveys
HIV+	HIV positive
HR	Hazard ratio
ID	Identification
LMIC	Low- and middle- income country
MakSPH	Makerere School of Public Health
ODK	Open data kit
PI	Principal investigator
PLWH	People living with HIV

1.0 CHAPTER ONE: Introduction and background

With antiretroviral therapy (ART), people living with HIV (PLWH) are expected to have a near normal life expectancy.[1] However, smoking is now one of the key causes of excess morbidity and mortality in this population:[2,3] Nearly a quarter of deaths among PLWH on ART are attributable to smoking.[4] HIV-positive (HIV+) individuals, on average, lose 12.3 life-years if they smoke: more than twice the number of years lost to HIV infection alone.[5] Smoking shortens life expectancy among PLWH even when on ART, as observed in a US study among 924 HIV+ women (hazard ratio (HR) 1.5 [95%CI: 1.1-2.2]),[2] and another among 17,995 HIV+ individuals from Europe and North America (mortality rate ratio 1.9 [95%CI: 1.6–2.4]).[3] PLWH who smoke are more susceptible to tobacco-related illnesses such as cardiovascular disease and cancer when compared to smoking HIV-negative individuals.[6-8] Moreover, among PLWH, smoking increases the risk of progressing to AIDS (HR 1.4 [95% CI: 1.1-1.7]),[2] developing tuberculosis (TB),[9-12] and non-adherence to ART.[13,14]

2.0 CHAPTER TWO: Literature review

A secondary analysis of Demographic and Health Surveys (DHS) data from 24 Sub-Saharan African countries reported that the prevalence of any tobacco use (i.e. tobacco smoking and/or smokeless tobacco use) was higher in HIV+ men than HIV-negative men (Risk Ratios (RR) 1.42 [95%CI: 1.26-1.60]), and also higher in HIV+ women than HIV-negative women (RR 1.34 [95%CI: 1.04-1.72]).[15] The prevalence of tobacco use was 26.0% (95%CI: 22.7%-29.4%) among HIV+ men and 2.8% (95%CI: 1.6%-4.3%) among HIV+ women.[15] When only considering current smoking, the prevalence was also higher in HIV+ men than HIV-negative men (RR 1.47 [95%CI: 1.29-1.66]), and also higher in HIV+ women than HIV-negative women (RR 1.87 [95%CI: 1.29-2.72]).[15] The prevalence of smoking was 24.2% (95%CI: 20.9%-27.6%) among HIV+ men and 1% (95%CI: 0.6%-1.4%) among HIV+ women.[15] Murphy et al, also reported similar results from data from 25 Sub-Saharan African countries: the odds of being a current smoker was 1.12 (95% CI: 1.04-1.25; p<0.01) for HIV+ compared to HIV- individuals.[16] For Uganda specifically, the general population smoking prevalence of 7.4% (14.6% for men and 2.6% for women),[17] is much lower than that among PLWH of 10% (20% for men and 6% for women).[18]

Systematic reviews[19-21] have found that even intensive smoking cessation interventions whose efficacy is well established for the general population such as combining pharmacotherapy (e.g. nicotine replacement therapy and varenicline) and behavioural support,[22-24] are only effective in achieving short-term (<6 months), but not long-term abstinence among PLWH. Some of the cited reasons are that the interventions are not grounded in the realities of living with HIV and the HIV care context.[19-21] Moreover none of these studies were conducted in Sub-Saharan Africa where the burden of HIV is greatest and exacerbated by high prevalence of smoking among PLWH.[15]

A few high-income country studies have characterized smoking among PLWH,[25-27] and highlighted the following factors as contributing to the high smoking prevalence among PLWH: a sense of fatalism; use of tobacco to cope with physical

comorbidities and HIV-related symptoms such as neuropathic pain; and stigma and mental health comorbidities such as anxiety, stress and depression, all of which are higher in this population.[25,26] Co-consumption of tobacco with alcohol, cannabis and injected drugs, as well as low employment and low educational attainment can make it hard for PLWH to quit smoking.[27] In particular, co-consumption of tobacco with alcohol is an important consideration in this population because the HIV virus, alcohol and smoking are potentially synergistic on biochemical processes leading to cancers, liver cirrhosis and cardiovascular disease.[28,29] In addition, besides the strong positive association between smoking and alcohol use,[30,31] these two behaviours are both associated with low medication adherence.[13,14,32] Thus, if there is an association between smoking and hazardous drinking among PLWH, then an intervention addressing alcohol consumption in addition to smoking might be warranted. Unfortunately for LMICs, little attention has been paid towards smoking behaviour and the influencing factors among PLWH, with only a few, mainly descriptive studies; with those exploring influencing factors mainly focusing on smoking, readiness and intentions to quit smoking, and including small samples (150–320 PLWH).[33-37] Thus, similar work is required in LMICs- smoking behaviour and its determinants vary across nations and cultures.[38]

3.0 CHAPTER THREE: Problem statement, justification and conceptual framework

3.1 Problem statement

The prevalence of smoking among PLWH is higher than the general population in Sub-Saharan Africa including Uganda. However, there is a dearth of information on the factors associated with current smoking among Ugandan and Sub- Saharan African PLWH. This presents a missed opportunity for designing appropriate smoking cessation interventions among PLWH in Uganda and other LMICs.

High income country studies have demonstrated clear consequences of excess smoking related mortality (mortality rate ratio 1.9 [95%CI: 1.6–2.4][3]) among PLWH. Currently available smoking cessation interventions do not result in long-term quitting among PLWH including those in HIV care.

PLWH who are in HIV care are expected to have comprehensive risk reduction interventions to minimize increased risk of co-morbidity and mortality. However, in-order to design effective smoking cessation interventions, there is a need to understand the smoking behaviour, factors (including knowledge, attitudes and perceptions) that are associated with current smoking status and potential and actual barriers to smoking cessation in this population. In addition, there is need to understand the nature of, and barriers and facilitators to integrating smoking cessation into HIV care. Specifically, understanding health worker knowledge, practice, attitudes and perceptions, and health systems readiness, responsiveness and challenges to integration is important. This information is currently lacking particularly for LMICs, including Uganda. This study will therefore focus on PLWH who are attending HIV care in highly active ART accredited health facilities in Uganda to investigate their smoking behaviour, the key factors associated with current smoking status, and facilitators and barriers to smoking cessation. From a qualitative point of view, in-depth interviews will be conducted with current and

previous smokers to document the barriers to and facilitators of smoking cessation among PLWH in HIV care. The study will also solicit health worker knowledge, attitudes and perceptions towards, and perceptions on the barriers and facilitators to, integration of smoking cessation services into HIV care programmes. Key informant interviews will also be conducted with policy makers to explore opportunities and threats to the design and implementation of appropriate smoking cessation interventions for PLWH. Study findings will help to inform the design of innovative and potentially effective smoking cessation interventions that can lead to long-term quitting and improving HIV outcomes among PLWH in Uganda and other LMICs.

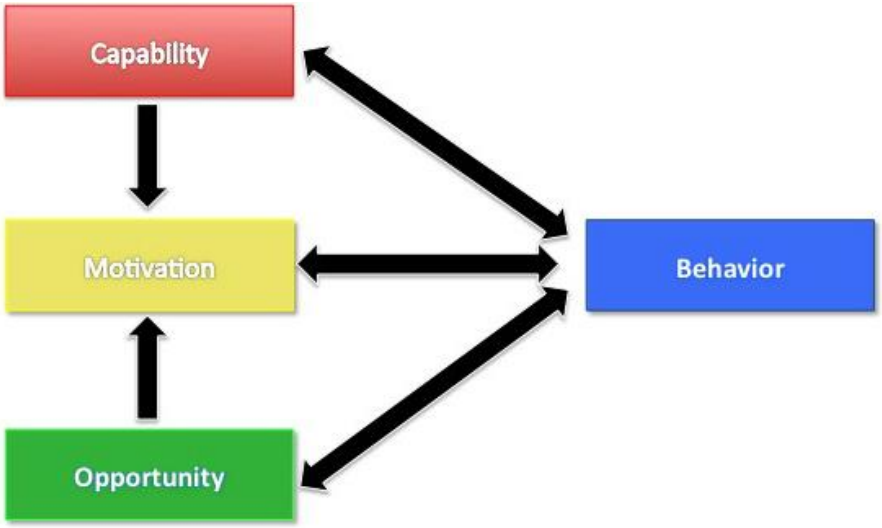
3.2 Justification for the study

The proposed study addresses the twin problems of smoking and HIV infection in sub-Saharan Africa. The role of smoking on morbidity and mortality among PLWH in LMICs has largely been ignored. The study will improve scientific knowledge by providing important, LMIC specific data on which smoking cessation intervention development can be based including smoking patterns and social and behavioural factors that influence smoking behaviours (including quitting) among PLWH. The development of targeted smoking cessation interventions for this key core group in Uganda using the data that will be gathered in this study could potentially contribute to improved immune response and virologic response, reduction in occurrence, and improved management of comorbid health conditions (e.g. AIDS related and non-AIDS related cancers and TB); and ultimately reduce in morbidity and mortality among PLWH.

3.3 Conceptual framework

The study is informed by the COM-B model/ framework which denotes a 'behaviour system' in which capability (C), opportunity (O), and motivation (M) interact to generate behaviour (B) that in turn influences these components (Figure 1).[39] The individual's psychological and physical capability to engage in the activity concerned, influence behaviour.[39] For successful long-term quitting, individuals need the necessary knowledge and skills, and to believe that change is practical, achievable and sustainable. Automatic brain mechanisms and processes that energize and direct behaviour, also influence behaviour.[39] For example, an inaccurate perception of short life expectancy reported among PLWH, including those on ART, affects their perceived susceptibility to the harms of smoking,[40,41] and could influence their smoking behaviour and motivation to quit.[41] Compared to general population smokers, more effort might be needed to make PLWH who smoke believe that stopping smoking will improve their HIV outcomes, general health, wellbeing and life expectancy. The beliefs that PLWH hold about HIV infection and its treatment, as well as smoking are crucial to understanding what would motivate them to quit. Other physical or social opportunities that make smoking possible or prompt it,[39] may play a bigger part; e.g. ability to smoke anywhere, or having many close acquaintances who smoke.

Figure 1: COM-B model[39]



The COM-B model is useful to make a 'behavioural diagnosis' for PLWH who smoke. In addition the COM-B can also be used with healthcare professionals to understand what is needed to get them to deliver smoking cessation interventions to their patients. Thus, the data generated will inform the tailored smoking cessation intervention **content** and **delivery**, and will be used to design a tailored intervention blue print that will be ready for feasibility testing.

4.0 CHAPTER FOUR: Objectives

4.1 Overall objective

The main objective is to investigate the smoking behaviour and factors associated with current smoking status among PLWH who are in HIV care so as to inform the design of innovative and effective PLWH focused smoking cessation interventions that are implementable and scalable in Uganda.

4.2 Specific objectives

The study will address the following specific objectives:

1. To identify the factors associated with current smoking status among PLWH
2. To assess the smoking patterns and behaviours among PLWH who smoke
3. To explore facilitators and barriers of quitting smoking among current and previous PLWH smokers
4. To determine the willingness of PLWH in HIV care who smoke to engage in subsequent smoking related intervention studies
5. To assess health workers' current knowledge, practice and perceptions on smoking and integration of smoking cessation interventions into HIV care programmes including the potential barriers and facilitators.
6. To assess the opportunities and threats towards integrating smoking cessation interventions within HIV programmes from the policy makers' perspective.

5.0 CHAPTER FIVE: Methodology

5.1 Study sites

We will purposively select two districts, based on high smoking prevalence, from each of geographical regions of Uganda: Central, East, North and West. In each of these districts, we will choose one or two high volume HIV clinics (maximum 16 clinics in total) using available information on ART accredited health facilities in Uganda. Study participants will be recruited from these 16 clinics

5.2 Study population

The study will be conducted among PLWH aged 18 and older; and able to complete the survey/ in-depth interview in local languages or in English. Exclusions include HIV+ individuals who are unable (e.g. too ill) to provide consent.

Key informant interviews will be conducted with health workers involved in HIV health service design, planning, management and delivery and policy makers who are involved in the tobacco control and HIV policies in Uganda.

5.3 Study design

The study will comprise three study components: 1) a cross-sectional survey among PLWH (regardless of current smoking status); 2) qualitative interviews with PLWH who smoke or have recently quit smoking (within the past year); and 3) qualitative interviews with HIV-care programme health workers and policy makers.

A cross-sectional survey among PLWH (objectives 1, 2 and 4)

For this study component we will recruit PLWH regardless of current smoking status from participating HIV clinics. It will take about 60 minutes for each participant to complete the survey.

Sampling and sample size

We aim to recruit as large a sample as possible within the resources available over the study period, and estimate we will be able to enrol approximately 750 participants in total within a 9 month recruitment period. This will allow us enough power to be able to make comparisons between current smokers (approx. 375) and those who do not currently smoke (approx. 375).

As an indicative example of potential power to address factors associated with smoking within this population, we provide a sample size estimate for investigating the association between alcohol use and current smoking status. Assuming the prevalence of alcohol use among HIV+ individuals who do not smoke as 26%,[42] and that the prevalence of alcohol use is 1.5 times higher in smoking HIV+ individuals in HIV care, a type-I error rate of 5%, a power of 80% to detect this risk ratio, the expected minimum sample size is 204 per group (i.e. 204 current smokers, and 204 individuals who do not currently smoke , totalling 408 in total). If the non-response rate is 10%, then the sample-size will be (204/0.9) 227 per group. We assume a design-effect of 1.6 to account for multistage sampling including at facilities within a district and correlation of respondents within selected facilities. This will result in an

adjusted sample size of 227*1.6= 364 per group (i.e. 364 current smokers, and 364 individuals who do not currently smoke giving a total of 728)

To enrol the targeted total of 750 participants (approx. 84 each month over 9 months) from 16 health facility, we will aim to recruit about 47 participants from each facility. This will be achievable with one research assistant at each health facility recruiting approximately 5/6 participants from their assigned health facility each month.

With a prevalence of smoking of 10% among HIV+ clients in care; we shall need to screen a total of approximately 3750 HIV+ individuals in care in order to obtain 375 smokers.

Participant recruitment
Clinic staff from the 16 participating clinics will inform potential participants (age ≥ 18 years with HIV infection) about our study and refer those that are interested to research staff who will determine eligibility. All individuals referred by the clinic staff will be screened for study eligibility by research staff. Those who are potentially eligible will be given written study information. In the case of literacy problems, the research staff will also provide the information verbally: in such a case, a participant could have a clinic staff member or their relative or friend acting as a witness to the process if they wish. Research staff will also introduce the study to clinic attendees by making short (~5 minutes) announcements during clinic hours to encourage clinic attendees to ask their clinicians about the study if they wish to be referred for participation. We will also put study posters and leaflets within participating clinics.

Survey data
We will collect demographic data (including sex, age, education, employment and socio-economic status indicators) and data on ART status, smoking behaviour (current smoking status, duration of smoking, forms of tobacco smoked, quantity and frequency of use), reasons for smoking and quit intentions, motivations and behaviours. We will also collect data, using pre-existing tools, on participant's psychosocial and clinical variables that have been identified in literature as potentially contributing to the high smoking prevalence and difficulties in quitting among PLWH:[25-27] anxiety, stress and depression;[43,44] nicotine dependence;[45-47] alcohol use;[48] use of other substances;[48] physical and social environment (Table 1).[49-51] We will also collect data on quality of life.[52-54] The survey will also include brief questions to assess the willingness of PLWH who smoke in HIV care to engage in subsequent smoking related intervention studies.

Table 1: A summary of variables explored in the quantitative survey

Variables	Measures/ Source of questions
Socio-demographic and ART status	
Socio-demographic: • Date of birth, sex, education and marital status	Ugandan DHS
ART status • Current ART status and length of time receiving ART	N/A
Tobacco use related variables	
Tobacco smoking: • Current smoking status, product type, frequency, and age on initiation	Global Adult Tobacco Survey
Nicotine dependence (smoked tobacco)	Fagerstrom Test for Nicotine Dependence[55] Mood and Physical Symptoms Scale[45]
Reasons for smoking	Attitudes Towards Smoking Scale (ATS-18)[56] Risk perception
Quit intentions, motivation and behaviours	Questions from Fava et al[57] (application of the stages of change model); and Global Adult Tobacco Survey
Capacity to stop	Self-efficacy questionnaire Multidimentional Scale of Perceived Social Support
Physical and social environment	Maron et al;[58] Global Adult Tobacco Survey
Smokeless tobacco use: • Current smokeless tobacco use status, product type, frequency, and age on initiation	Global Adult Tobacco Survey
Other health related variables	
Alcohol use	AUDIT-C
Use of other substances (Cannabis)	ASSIST-Lite[59]
Health Related Quality of Life	EQ-5D-3L[53,54]
Stress	Perceived Stress Scale[43]
Depression	Patient Health Questionnaire-9[60]
Intervention variables	
Willingness to participate in smoking related intervention studies	N/A

Data collection

Data collection questionnaires will be developed on SMART phones using Open Data Kit (ODK). The survey will be interviewer-administered face-to-face by trained research assistants using mobile smart phones. A questionnaire will be developed, translated to the appropriate non-English languages, piloted among ~10 participants

and any required adjustments made before being used for the survey. Specific programming will be used to minimise missing data on questionnaires. Appropriate skip patterns in the tools will be ensured so as to improve accuracy, flow and efficiency of completing the questionnaire. The research assistants will be trained to check for missing data and inconsistencies at the end of each survey, and before the participant leaves whenever possible (participants will be allowed to leave soon after finishing the survey if they cannot, or do not want to, wait for data checks). An authorized data manager at Makerere University School of Public Health (MakSPH) will conduct data quality checks every 2-4 weeks and give feedback to the Ugandan principal investigator (PI) who will be overseeing the data collection activities. This feedback will be relayed to the research assistants as appropriate with booster training sessions provided if necessary.

We will also use hard copies of the questionnaire in cases where the SMART phones cannot be used, for example due to malfunction. Data collected this way will be entered into the ODK system as soon as this is possible and the paper copy of the questionnaire (source document) stored securely under lock and key at MaKSPH.

Research assistants will be trained on the protocol and data collection tools, as well as ethics in research especially among patients attending HIV care.

Statistical analysis
Exploratory data analysis will be conducted on all variables including the current smoking status of the study participants. Descriptive statistics will be generated providing proportions or percentages for categorical data, and mean (standard deviation) and median (Iinterquartile range) for the continuous variables. Data will also be presented using graphs that will include box plots, scatter plots for the continuous data. Bar and pie charts showing the distribution of categorical data will also be generated.

For the factors associated with smoking, the regression models will include known key determinant such as use of alcohol, awareness of the dangers of smoking, in addition to participant's social-demographics characteristics (age, sex, education) and other potential confounders in the adjusted statistical regression models. Statistical significance will be determined at 5% type-I, and 95% CI for all respective regression coefficients will be obtained. All the analysis will use STATA version 15. The analysis will account for design effect as is the case in sample size determination. We will check for missing data and if missingness is high and differential, we shall construct propensity scores to use as weights in the regression models.

Qualitative interviews with PLWH who smoke or have recently quit (Objectives 3)
Qualitative face-to-face in-depth interviews will be conducted with PLWH who are smokers or recent quitters (quit within the past year) to explore facilitators and

barriers of quitting smoking. It is anticipated that each interview will take approximately 60 minutes.

Sampling and sample size

Twenty four interviews will be conducted with participants who will be purposively recruited from four clinics located in contrasting geographical areas: Mulago National Referral Hospital, Kampala, and clinics in Arua (North West), Masindi/Hoima (tobacco-growing areas) and Moroto (North East: an area of high HIV prevalence and high smoking). We will aim for six interviews to be conducted at each clinics. We will extend the sample if important issues emerge which require further investigation.

Participant recruitment

Participant recruitment will be carried out as follows: in four selected HIV clinics taken from the larger number included in the survey, survey respondents who are current smokers or recent quitters will be asked, by the researcher at the end of the survey, if they would be willing to take part in the qualitative study. This will happen at each of the four clinics until the 6 interviews for the clinic are complete, after which research assistants will stop mentioning the qualitative study to survey participants. As for the survey, clinic staff will inform potential participants (age ≥ 18 years with HIV infection) about the study and refer those that are interested to research staff who will determine eligibility. Research staff will also will introduce the study to clinic attendees by making short (~5 minutes) announcements during clinic hours to encourage clinic attendees to ask their clinicians about the study if they wish to be referred for participation. We will also put study posters and leaflets within participating clinics. Those who are interested in study participation will be provided with a participant information sheet for, and if they wish give written informed consent to participate in, this part of the study. In the case of literacy problems, the research staff will also provide the information verbally: in such a case, a participant could have a clinic staff member or their relative or friend acting as a witness to the process if they wish. Recruitment will continue until the required number of interviews has taken place (n=24). Three women and three men will be recruited from each of the participating clinics. We will aim to recruit between four and eight recent quitters, the rest will be current smokers. The interviews will be conducted by trained research assistants.

Interview data

The topics covered in the interviews will include the following:

*Social context 1 (risk factors for smoking):*Contextual information related to common risk factors for continued smoking e.g. social isolation, normative smoking, living with smokers, cultivating tobacco. Other relevant information will include location and mobility (rural or urban, long-established or recently moved to area), employment status and occupation, family circumstances and caring responsibilities.

Social context 2 (smoking): Respondents will be asked about their parents' or carers' tobacco history if known (for intergenerational trajectories of use), individual smoking history including effects of HIV diagnosis and being on ART

(initiate/increase/decrease/quit[61]), daily and other context of smoking, use by significant others (particularly cohabiting), type of tobacco used and on what occasions (manufactured, self-rolled, illicit, chewing, snuff), typical expenditure, brands used, location of purchases, awareness of tobacco advertising.

Health status, expectations and co-morbidities: Current health status (HIV, ART, TB) and future expectations, other co-morbidities including mental health (depression, anxiety), alcohol, cannabis or other drug use, understanding of effects of tobacco on current and future health.

Interest in tobacco cessation: Experience of quit attempts, understanding and views on barriers and facilitators to cessation, experience of, knowledge of and interest in cessation support, wish list and logistics for cessation support (e.g. location and frequency of support, availability of counselling, medication etc.)

Data collection
Topic guides in English or the local language(s) will be piloted in ~3-5 interviews, adapted appropriately and used for interviews to ensure consistency. All interviews will be audio-recorded on encrypted recorders, transcribed verbatim, anonymised and translated into English.

Data analysis
Category-centred analysis through thematic coding using NVivo software will be combined with narrative analysis of individual cases[62] respecting research participants as subjects with both histories and intentions.[63] Researchers from the University of York and MakSPH will assign thematic codes to the data, discuss emerging themes in the light of relevant theory, relate individual life story narratives to meta-narratives in the shape of local and regional histories[64] and compare primary data with the literature on similar issues in different settings to produce analytical insights with potential generalisability.[65]

Qualitative interviews with HIV programme health workers and policy makers (objective 5 and 6)
Qualitative interviews will be conducted with health workers and policy makers to gather information on potential barriers and facilitators for integration of smoking cessation in HIV programmes. Each interview will take approximately 60 minutes.

Sampling and sample size
The study targets health workers in HIV clinics drawn from the four geographical regions of Uganda. The health workers will be selected from the health facilities sampled for the survey (Table 2). The selection process will endeavour to get representation from a range of levels of care including: national referral hospital, regional referral hospital, district hospital, health centre levels IV and III. This will allow for the study to benefit from a wide range of views on integration. In each of the health facilities, two health workers will be selected one at leadership level and the other from the HIV clinic. In addition, the tobacco control focal person and HIV programme manager at the Ministry of Health will be interviewed.

Recruitment

Research staff will approach health workers through their clinic managers after explaining the purpose of the study. Those who are interested in study participation will be provided with a participant information sheet for, and if they wish give written informed consent to participate in, this part of the study. The tobacco control focal person and HIV programme manager at the Ministry of Health will be directly approached by the researchers. The interviews will be conducted by a senior researcher.

Table 2: Sampling strategy for health worker and policy maker interviews

Grouping	Type of interviewee(s)	Number of in-depth interveiws
National Referral Hospital	Health workers	2
Regional Referral Hospitals	Health workers	2
General Hospitals	Health workers	2
Health IV	Health workers	2
KCCA Health facilities-Kampala	Health workers	2
Health Centre III	Health workers	2
Tobacco control focal person	Policy maker	1
HIV programme manager	Policy maker	1
Total		14

Interview data

During in-depth interviews with health care workers we will explore perceptions, knowledge, attitudes and practices with regards to smoking among PLWH, and smoking cessation integration in HIV care in Uganda. This will include exploring knowledge and perceptions on risk factors associated with smoking among people living with HIV, and on the benefits of smoking cessation for this population. We will explore health workers' perception on their role in smoking cessation, and the current knowledge and skills for this role, training and support needs to be able offer tobacco cessation to the HIV clients.

For in-depth interviews with policy makers we will explore the opportunities and threats towards integrating smoking cessation interventions within HIV programmes from a policy making perspective.

The study will also gather data on how HIV treatment and care services are currently structured and delivered, and identify key contextual barriers/facilitators to implement smoking cessation interventions within HIV health services. As part of this, we will explore if there are already existing practices or material that support the provision of

smoking cessation interventions (e.g. asking about and recording of smoking status and how that data is used, smoking/ healthy living counselling).

Data collection
Topic guides in English or the local language(s) will be used for interviews to ensure consistency. All interviews will be audio-recorded on encrypted recorders, transcribed verbatim, anonymised and translated into English.

Data analysis
Qualitative data will be transcribed and analysed using the thematic analysis approach designed to ensure exploration of both inductive and deductive themes.[29] Analysis will be done using NVIVO version 11.

5.4 Training of research assistants

Twenty quantitative survey research assistants will be recruited from a pool of researchers in the MakSPH database. The identified researchers will undergo a two-day training aimed at standardizing the understanding of the survey and ensuring quality of the data. Day one of the training will orient the researchers on survey objectives, methods, and process of data collection including a review of the data collection tools and consent form. On the second day, the researchers will do a pilot with identified HIV+ individuals at one of the HIV clinics in the nearby district.

Four research assistants will be recruited from the same pool to carry out the qualitative interviews in the appropriate local language (Luganda in Kampala, Lugbara in Arua, Orunyoro in Masindi/Hoima, and Ng'akarimojong in Moroto). Interviewers will undertake training which will include the content and objectives of the qualitative study, the context of the research, privacy and confidentiality guidelines and qualitative interviewing techniques including the importance of a dialogic approach[66] and establishing rapport.

All research assistants will also receive training in supporting interviewees if they become distressed, including options such as taking a break from the interview, seeking support from clinic counsellors, resuming the interview at a later date or terminating the research encounter. Training will also be provided on how researchers should deal with any disclosure by interviewees that they are at personal risk e.g. from domestic violence.

The training will be facilitated by the research team in Uganda with support from the University of York research team.

5.5 Data management

Quantitative survey data
Data collected from all consenting participants will be electronically sent from the SMART phones to the aggregate cloud server. Authorized data manager at the MakSPH data management centre will then download these data, and conduct merging, and data cleaning. The data manager at the central office will be responsible for providing feedback, especially on data quality including missingness

or inconsistencies, to the data collectors through the field study coordinators so as to enhance data quality. No double data entry will be required for data that is electronically captured: double entry will only be done for data collected on hard copy questionnaires. Data will be downloaded from ODK stored on a server with password protection, and files with data will be stripped of personal identifier such as names to so as to further ensure improved data confidentiality.

Qualitative interview data
Data will be managed using Nvivo. Data will be downloaded onto a secure password protected computer at MakSPH.

Data access and transfer
Access to identifiable private information will be limited to research staff involved in the study, and representatives from regulatory authorities, for example, if the research is audited. All research forms (questionnaires) and transcripts will only carry the unique ID, no names will be used. All documentation having names of study participants (such as attendance registers, locator forms and informed consent forms) will be locked away in file cabinets at MakSPH and will only be accessible to research staff. Computer files linking names with IDs will be password protected and only accessible by the same people.

Encrypted data transfer to the University of York will be done via a secure Drop-off services available through the University of York. Access to all study data, including survey data, audio-recordings and transcripts will be restricted to only authorised study personal by using secure password protected computers and encrypted data transfer.

5.6 Ethical considerations

Ethical review and approval process
We will ensure that all procedures conform to Ugandan and United Kingdom ethical standards. Ethics and other relevant regulatory approvals will be sought from the MakSPH Institutional Review Board and other relevant institutions in Uganda and the Health Sciences Research Governance Committee at the University of York. Approvals will be sought for the study protocol and procedures including all informed consent procedures; and for study materials including questionnaires, topic guides, participant information sheets and informed consent forms to be used in this research project.

Informed consent
Informed and written consent will be obtained, separately for each of the three study components, by trained research assistants in all cases after participants have been provided with study information, in English, or one of the local languages according to their preference, including: a brief description of the purpose of the study; estimated time to complete the survey or in-depth interview; audio recording; risks and benefits of participation; how confidentiality will be ensured; compensation; a statement indicating that participation is voluntary; and contact information for the country lead/principal investigator in Uganda and the MakSPH Institutional Review

Board Chairperson. Research assistants will go through the respective information sheet with potential participants if required, before the participants are enrolled in the study. Potential participants will be given an opportunity to ask questions they may need addressed before making a decision. As per Ugandan standards, a 'thumbprint' signature will be allowed for illiterate individuals who are eligible and would like to participate in the study.

Confidentiality

The project will be conducted by appropriately qualified and experienced staff who are trained on the importance of keeping confidentiality. Study procedures will be held in private rooms. To ensure participant confidentiality, each participant will be assigned a unique study ID number and no identifying information will be stored with the study data. Any information linking participants ID to their identifying information will be stored securely, separated from the study data. All study data will be stored on a secure server that can only be accessed by project staff with password protection. Any paper copies (e.g. consent forms) will be stored in locked cabinets in locked offices at the MakSPH. All data collected will be kept confidential in line with the Data Protection Act (Uganda and UK) – access to participants' personal detail will be restricted to research staff only. Monitors and auditors may also need to access the data. At the end of the study, data will be securely archived at MakSPH or the University of York as appropriate, for a minimum of 10 years.

Potential risks and benefits

The primary beneficiaries of this study are HIV patients in LMICs. The findings of the research will guide the development of smoking cessation interventions with a potential to improve the health and wellbeing of this specific population. If the interventions are developed and show promise, they will be further evaluated in a definitive trial; and if effective and cost-effective they would be given to the wider population of HIV positive individuals who smoke.

The risks associated with the research are minimal. For PLWH, there is potential stigma in attending HIV treatment and care clinics. However, the project is recruiting participants who are already attending these clinics and there is no additional risk with regards to HIV related stigma. There is also potential stigma associated with being a smoker. For the survey, we will be recruiting current, ex- and never smokers and any stigma related to smoking status will be masked. Our procedures for questionnaire completion involve interviewer-administration which means researchers collecting the data will know the participants' smoking status. Our qualitative interviews will be recruiting smokers and ex-smokers which could reveal participants' smoking status if not already disclosed. At recruitment we will explain this risk. Participant information sheets will also highlight this risk to participants for them to make an informed choice with regards to participation in the quantitative survey and qualitative interviews. Our past experience has shown that most men feel comfortable with disclosing their smoking status; we are aware however that this might not be the case for women. All our study procedures will be conducted by experienced and appropriately qualified researchers who are trained on privacy and confidentiality.

In order to explore the role of social stressors as potential barriers to smoking cessation, the qualitative interviews will explore a range of personal issues relating to participants' family status, health status and expectations (see list of topics in interview data section, above). Research participants may allude to distressing events such as bereavements or domestic violence;[67] researchers will receive training in supporting interviewees; a break may be taken in the interview, help may be sought from clinic staff (e.g. counsellors) or the interview can be resumed at a later date or cancelled altogether.

The study does not include any clinical tests and therefore the chances on incidental findings is minimal. However, it is possible that during in-depth interviews incidental findings may emerge through self-report. In such cases, the participant will be referred to the clinicians whose care they are under; their clinician will be informed with patient's consent.

The study does not involve any invasive/potentially harmful procedures and is therefore considered low risk for participants. We do not anticipate any adverse events associated with participation in this study. If any information disclosed by participants warrants alerting other organizations, we will liaise with clinic staff and follow the procedures that are normally followed at the clinic where the interview is being conducted.

Participant Burden and Compensation

We will minimise participant burden; the explicit wishes of the participant will be respected including the right to withdraw at any time; the interest of the participant will prevail over those of science and society; provision will be made for indemnity; the study will also not interfere with any treatment, the participants are already receiving; no financial incentive will be offered to the participants except reimbursement for their transport to the clinics. Participants will also be offered a snack during completion of study procedures.

5.7 Research team and roles

University of York, UK

Dr Mdege, an Associate Professor in Global Public Health will serve as PI on the project. She has 16 years research experience in LMICs including Bangladesh, South Africa and Zimbabwe on interventions for HIV treatment and prevention and smoking cessation. ***Prof Siddiqi***, a Professor in Global Public Health, is an internationally recognized expert on lung health, tobacco use and smoking cessation, particularly for TB patients in LMICs. He will contribute to the survey design. ***Dr Ratschen*** is a Senior Lecturer and an applied health researcher focusing on the development and evaluation of complex tobacco smoking interventions for individuals with mental health problems, as well as other vulnerable populations such as the homeless and prisoners. She will contribute to the survey design. ***Dr Thirlway*** is a Research Fellow and qualitative researcher who focuses on smoking cessation, health, class and culture. She will lead the qualitative study with PLWH and contribute to the qualitative study with health workers and policy makers. ***Dr Msosa***,

a Postdoctoral Research Associate, specialises in the political and governance context of health in LMICs including Malawi and Uganda. He will contribute to the qualitative studies.

MakSPH, Uganda

Ms Namusisi, has extensive experience conducting tobacco control research in Africa including both quantitative and qualitative studies will be the country lead investigator in Uganda. She will oversee study implementation including ethics and other approvals, training, data collection, management and analysis in Uganda, and will lead the qualitative study with health workers and policy makers. ***Dr Matovu*** is a behavioural scientist with extensive experience in social and behaviour change communication, mixed methods and intervention design, particularly on intervention logic model design and effective behaviour change techniques Uganda. He will contribute to the qualitative studies. ***Dr Makumbi***, Associate Professor and Biostatistician, will co-lead the cross-sectional survey and serve as the biostatistician responsible for survey data analysis.

5.8 Work plan

	2019												2020	
Activities	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**1**	**2**
Protocol writing	■	■												
Ethics approval			■	■	■	■								
Cross sectional survey						■	■	■	■	■	■	■	■	■
Qualitative interviews with PLWH who smoke							■	■	■	■	■	■		
Qualitative interviews with health care workers and policy makers							■	■	■	■	■	■		
Data analysis and report-writing											■	■	■	■
Dissemination workshop														■

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