Reducing HIV Stigma to Increase HIV Testing Among Adolescents and Young Adults in Kazakhstan Using a Crowdsourcing Approach

Study Protocol

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STUDY TEAM

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1. Summary

Given rising rates of HIV incidence among adolescents and young adults (AYA) in Kazakhstan and high levels of HIV stigma and low HIV testing uptake, this proposal will use crowdsourcing to develop a digital intervention to reduce HIV stigma and promote HIV self-testing among AYA in Kazakhstan. This study aims to use a community-based participatory approach that engages local AYA and youth organizations to develop a crowdsourced digital HIV stigma reduction and self-testing intervention to reduce HIV stigma and increase HIV testing among AYA in Kazakhstan and to pilot test this crowdsourced HIV stigma reduction and self-testing intervention in a preliminary efficacy trial to assess feasibility and acceptability and obtain preliminary estimates of its effects on decreasing HIV stigma (primary outcome) and increasing HIV testing (secondary outcome) among AYA (n=168) in Kazakhstan who received the intervention compared to individuals who did not.

2. Introduction

2.1 Background

Globally adolescents and young adults (AYA) are at increased risk for HIV acquisition. Eastern Europe and Central Asia is the only global region with a projected increase in AYA living with HIV from 2010 to 2050. Incident HIV infections among AYA in the region are projected to increase at alarming rates, with the population of 15-24 year olds living with HIV projected to increase by 28% by 2030. In Kazakhstan, AYA bear one of the largest burdens of HIV infection. Over 23% of all HIV infections in Kazakhstan are estimated to be among AYA.[2] Increases in AYA HIV incidence are largely driven by risky sexual behaviors, such as unprotected sex and use of substances before or during sex. Despite growing rates of HIV infection among AYA in Kazakhstan, AYA have some of the lowest HIV testing rates in the country compared to other risk groups. In 2015, only 22% of girls aged 15-24 were tested for HIV in the past year and only 15% of boys were tested for HIV.[18]

HIV-related stigma is a major deterrent to HIV related protective behaviors, including HIV testing. HIV stigma is multidimensional and has adverse consequences for the prevention and management of HIV/AIDS. In Kazakhstan, we have found that HIV stigma inhibits AYA from getting tested for HIV, learning their serostatus and accessing care.[4,19] Stigma impedes HIV testing in two main ways: 1) it reduces AYA's desire to be tested through AYA's anticipated, perceived, and/or vicarious stigma; and 2) it interferes with HIV testing because the location is stigmatizing. HIV tests are traditionally administered at designated city AIDS Centers, which are inconveniently located for many and where it is clear what types of services individuals are receiving. AYA often avoid HIV testing because individuals who attend AIDS Centers are generally perceived as engaging in HIV risk behaviors, such as pre-marital/extra-marital sex and substance use, and because it raises the suspicion of being HIV positive. Rapid HIV tests conducted at home or in the community could help overcome some of this stigma. However, although rapid HIV tests are available in Kazakhstan, they are not widely used and AYA are not generally aware of their availability. Furthermore, due to stigma, many AYA are afraid to be tested out of fear they will test positive for HIV and face discrimination from family, friends, healthcare providers, and others in the community.

Crowdsourcing and social media are powerful tools that can engage the local community to reduce HIV stigma and promote HIV testing and other protective behaviors. Conventional approaches to designing and implementing HIV testing or stigma reduction interventions often do not sufficiently involve target communities and thus have frequently resulted in low community/key population engagement.[7] By contrast, crowdsourcing takes a "bottom up" approach to designing HIV stigma reduction and HIV testing interventions. It has high involvement from local communities/key populations in designing and disseminating public health messages and intervention strategies. Where conventional approaches rely on public health expert opinions, this strategy builds on community "crowd input". Crowdsourcing thus increases community engagement from a broad range of non-experts with lived

experiences, including individuals in affected populations, experience-rich community leaders, and creative individuals. This approach fosters innovation and greater inclusion of perspectives from diverse community members, compared to conventional approaches such as disseminating public health messages and materials issued by National Ministries of Health. Crowdsourcing may be particularly useful for developing HIV stigma reduction interventions because local populations are often more aware of the types of content and messaging that are appropriate and effective in their cultural context than researchers or public health experts.

HIV self-testing can also reduce stigma and increase access to HIV testing, especially for AYA in low and middle income countries. Providing AYA with access to HIV rapid self-test kits allows AYA to access HIV testing outside of the AIDS Center and in a private location. This allows them to avoid known testing settings, thus addressing the fear of involuntary disclosure of perceived HIV serostatus or related risks, such as sexual behaviors or substance use. Offering a crowdsourced digital intervention with HIV self-testing kits also allows AYA to avoid the complications of accessing HIV testing during the COVID-19 pandemic. HIV self-testing among AYA has been shown to be effective in increasing HIV testing uptake in other countries, including LMICs,[20–25] but many AYA in Kazakhstan are unaware of the availability of HIV self-testing and it is not widely used, which is one gap the proposed crowdsourcing intervention aims to address. Individuals testing positive for HIV through a rapid test will have the support of research staff to help link them to confirmatory testing and overcome initial barriers to initiate HIV care. Once proven feasible and sustainably implemented outside of the research study through local community-based and youth organizations who work with people living with HIV, this model can help link newly positive HIV individuals to care and thus improve the HIV care cascade.

This work will result in an integrated digital crowdsourced stigma reduction and self-testing intervention to reduce HIV stigma and improve HIV testing uptake among the key population of AYA in Kazakhstan.

2.2 Specific Aims and Hypotheses

Specific Aim 1: To develop a crowdsourced digital HIV stigma reduction and self-testing intervention targeting AYA in Kazakhstan. Using a community-based participatory approach that engages local AYA and youth organizations, we will launch a national crowdsourcing contest in which AYA will design multimedia content to reduce HIV stigma in order to promote HIV testing among peers.

Specific Aim 2: To pilot test this crowdsourced HIV stigma reduction and self-testing intervention in a preliminary efficacy trial. We will assess the intervention's feasibility and acceptability and obtain preliminary estimates of its effects on decreasing HIV stigma (primary outcome) and increasing HIV testing (secondary outcome) among AYA in Kazakhstan who received the intervention compared to individuals who did not. Participants (n=200) will be randomized 1:1 to 1) receive the winning multimedia crowdsourced HIV stigma reduction content and a link for HIV self-testing, or 2) receive standard Kazakhstan Ministry of Health HIV informational materials and a link for HIV self-testing.

2.3. Innovation

1) This project uses crowdsourcing to reduce HIV-related stigma to increase HIV self-testing. This is a novel approach in Kazakhstan which, instead of primarily relying on Ministry of Health messaging and testing facilities at AIDS Centers, will engage communities to help develop culturally tailored content that appeals to the AYA population most vulnerable in this setting's HIV epidemic.

2) Crowdsourcing is a novel strategy particularly suited for and specifically targeted at engaging AYA. As crowdsourcing is enabled by the Internet and social media, AYA are an ideal group to apply this intervention to because they have high rates of Internet and social media usage and are tech savvy.

3) This project fosters innovation in that it moves testing away from current post-Soviet test settings at AIDS Centers and towards community-based settings, thus

removing testing barriers and addressing HIV stigma.

3. Study Design

3.1 Study Overview and Study Setting

We will develop a digital crowdsourced intervention package and compare the intervention to traditional Ministry of Health AIDS messaging in a pilot randomized controlled trial in Almaty, Kazakhstan. The crowdsourcing contest will be conducted nationally. The pilot RCT will be conducted in Almaty, Kazakhstan. Eligible AYA will be randomized to either intervention arm (participants will be shown a collection of winning videos, images, and concepts from the crowdsourced contest) or control arm (standard AIDS Center messaging) in a 1:1 ratio. Materials will be able to be viewed digitally.

3.2 Aim 1- Develop a crowdsourced intervention package

In phase 1, we will develop a crowdsourced stigma reduction and self-testing intervention package that includes videos, images, and concepts that aim to reduce HIV stigma to increase HIV self-testing. We will post an open call for a crowdsourcing contest to solicit multi-media entries aimed at reducing HIV stigma to increase HIV testing. AYA across all of Kazakhstan between the ages of 13-29 will be eligible to submit entries to the crowdsourcing contest. Entries will be solicited through an announcement promoted via websites and social media accounts operated by local youth organizations. We expect that we will obtain at least 50 contest entries.

3.2.1 Crowdsourcing Contest Procedures

In phase 1, we will first implement an open contest and evaluate contest entries using standardized criteria to develop the intervention package. A call for entries will be first announced on multiple platforms accompanied by in-person informational events to promote the contest. We expect that we will receive at least 50 contest entries. We will accept individual and group entries. Contestants may submit any type of the following

multi-media materials to the contest: images/photos, video, audio, text, comics. Contestants will be informed that if they choose to include identifiable images of individuals in their submissions, they must fill out a photo/video permission form for each individual and obtain permission to use that person's image. Entries will be submitted via Columbia University Global Health Research Center of Central Asia's (GHRCCA's) web portal. Each entry will first be screened by two research staff to ensure eligibility criteria are met (e.g., submission is not too long, image is not blurry, content is not stigmatizing). Entries will then be judged blind by an expert panel on several criteria, such as innovation and potential impact to reduce HIV stigma related to HIV testing. The expert judging panel will consist of experts from youth organizations, AIDS Centers, and international organizations, as well as researchers. If we receive more than 100 submissions, we will also establish a crowd panel to blindly judge submissions and identify the top 100 submissions, which will then be judged blind by the expert panel. Each submission will be reviewed by three expert judges. Each judge will rank each submission on a scale of 1-10 and the ranking scores will be averaged. Entries will be judged in two age categories: 13-19 and 20-29. We will provide participation certificates for all eligible entries. Prizes will be awarded to the top ten finalists in each age category, and larger prizes will be awarded to the top three entries in each category. Examples of smaller prizes include portable phone charging banks, gift cards, pens, etc., and examples of larger prizes include an Ipad, game system, etc. All individuals who submitted an entry will receive a certificate and a small appreciation prize (e.g., a pen). Top-ranked submissions will be used as materials for the stigma-reduction intervention.

3.3 Aim 2- Pilot Randomized Controlled Trial

3.3.1 Survey Pre-Testing preparation phase

Research has identified the costs of discrepancies between intended and actual meaning of survey items. When items are thought to mean something from the researcher's perspective and mean something quite different from the participant's

perspective, inaccuracies in conclusions and mischaracterization occur. Cognitive interviewing is a method that systematically collects information in specific domains influencing item interpretation, including readability, applicability, relevancy, and cross-cultural equivalence, as well as processes participants go through to end up with a final answer, such as “editing” response choices and managing self-presentation. Prior to the start of the RCT, we will conduct cognitive interviewing for the translated BL, 1mo, and 3mo survey measure (in both Russian and Kazakh) to evaluate the agreement between the intended meaning of items and the actual interpretation of these by adolescents and young adults in Kazakhstan.

3.3.2 Survey Pre-Testing Study recruitment

Prior to launch of the RCT, we will conduct cognitive interviewing with 20 AYA (10 Russian-speaking, 10 Kazakh-speaking) to gain a better understanding of how AYA in Kazakhstan interpret the survey items and help ensure that AYA interpretation matches the meaning intended by the research team.

Eligible participants for the survey pre-testing phase will be AYA between the ages of 16-24, speak Russian and/or Kazakh, and reside in Kazakhstan. Participants will be recruited through local youth organizations. Staff at youth organizations will be informed about the study and asked to share information about the study to eligible AYA and their parents who access services or attend events at their organization. Potentially interested AYA will be given the contact information of research staff so that they can contact staff directly to participate. They can also give permission to have their contact information shared with research staff, who can then reach out to complete informed consent and confirmatory eligibility screening procedures. For adolescents under 18 participating in the survey pre-testing, we will also obtain parental permission. Research staff will video call AYA (and parents when applicable) to receive AYA consent and parental permission to participate in the study. Informed assent/consent forms will be emailed to both parents and AYA before the initial meeting where informed assent/consent will be conducted and eligibility confirmed. Because

procedures are being conducted remotely, instead of obtaining written consent, an RA will sign the assent/consent forms indicating that the AYA has provided assent/consent and the parent has provided parental permission.

3.3.3 Survey Pre-Testing Procedures

After completing the informed consent process, eligible AYA will complete an interview with a research staff member via Columbia University's Zoom platform. Interviews will be recorded to ensure that no important information is missed. No identifying information will be recorded. Participants will read survey questions aloud and verbalize their thought process involved in answering the question. The interviewer will model the process at the beginning of the interview for demonstration purposes. Participants read each question (including instructions or definitions) and answer option while talking through what they are thinking to themselves to come up with their answer choice. For questions that are confusing or where participants may have a different interpretation than the research team, the interviewer will ask probing questions (e.g., 'What do you think this question is asking? How do you feel about it? How would you recommend this question or answers be changed?) to better identify specific problems and reframe the questions to be more culturally and contextually relevant. Clarifications and modifications to the survey questions will be made based on participant feedback.

Interviews will last approximately 60-90 minutes and participants will receive approximately $15 USD compensation as a phone card or gift card. Only authorized research staff will have access to the data. Interviews will be transcribed and uploaded to Columbia University's secure Box system. Interviews will be deleted following completion of data analysis. Participants in the survey pre-testing phase will not be eligible to participate in the RCT phase.

3.3.4 RCT Study recruitment

In phase 2, we will pilot test the crowdsourced intervention among AYA in Almaty,

Kazakhstan. We plan to recruit 168 AYA and randomize them 1:1 to the intervention and control arms. Eligible participants will be AYA between the ages of 16-24, report previous sex with another individual in the past year, not be living with HIV or have unknown HIV status, and reside in Almaty, Kazakhstan. Participants will be recruited through announcements promoted via websites and social media accounts, including those operated by local youth organizations. Announcements will be posted in both Russian and Kazakh languages. The announcements will include a link connecting AYA to an online screening survey. The link will remain active until 168 eligible AYA have enrolled. Eligible AYA will be invited to join the online cohort and complete informed consent online. For adolescents under 18, we are requesting a waiver of parental permission because the study is minimal risk and under Kazakh law adolescents 16 and older are allowed to obtain an HIV test without parental permission. Once enrolled, AYA will be electronically randomized to a study arm to complete a baseline survey and receive intervention or control content.

We will conduct a pilot RCT comparing the crowdsourced stigma reduction and self-testing intervention to standard AIDS Center messaging and test the feasibility and acceptability of the intervention. AYA will be recruited via flyers and from local youth organizations in Kazakhstan. We aim to recruit 168 AYA and randomize 1:1 to the intervention and control arms. Eligibile AYA will 1) be between 16-24 years old, 2) have had sex in the past year, 3) not be living with HIV or have unknown HIV status, 4) reside in Almaty, Kazakhstan, 5) speak Russian or Kazakh, and 6) own a smartphone. To establish linkage for follow-up surveys, unique ID and access codes will be issued to each participant. Participants' phone numbers, email addresses, and social media account IDs will be collected as contact information for follow-up.

3.3.5 Recruitment Procedure

AYA will be recruited through flyers, email, and social media accounts operated by youth organizations in Kazakhstan. Interested participants will complete an online eligibility screening survey. If eligible, participants will progress to the informed

consent screen, where they will read information about the study and be asked to provide informed consent. Contact information for study staff will be provided in case participants have any questions about the study. Because the study is minimal risk and Kazakh law allows adolescents ages 16 and older to order HIV-test kits without parental permission, we are requesting a waiver of parental permission to participate in the pilot RCT. Once individuals provide informed consent, they will complete a baseline survey and be randomized 1:1 to receive the digital intervention content or the standard AIDS Center content. In both arms, after the content is presented, there will be a link provided to order an HIV self-test kit from Columbia University's Global Health Research Center of Central Asia's (GHRCCA's) website, where AYA will input the address they would like to receive the test at into the order form. (This address may be a secure public mail box (similar to Amazon locker) and does not need to be their home address.)

Participants will be asked for their email addresses and/or phone numbers as contact information for follow-up surveys. Participants in the intervention arm will be sent intervention content once a week for one month via Qualtrics link. All participants will be sent follow-up surveys through Qualtrics at the one month and three month periods after baseline completion. Participants who do not complete the follow-up survey within a week will be sent an email and/or text message reminding them to complete the survey. All individuals who enroll in the study will receive ~$10 USD for each assessment as a phone card or gift card. Those who complete all surveys will be given an opportunity to win a small prize through a raffle.

Participants ordering an HIV test will receive a message via WhatsApp using standardized methods to submit a photo of their HIV test result. Participants can submit photos of HIV self-test results to confirm HIV test uptake at any time after enrollment.

Any persons with newly identified HIV infection will be referred for treatment at the Almaty AIDS Center in accordance with standard clinical procedures.

3.3.6 Baseline Questionnaire

After enrollment, participants will complete a brief self-administered online baseline questionnaire. Study staff will be available to assist in the event of confusion about specific questions. The questionnaire will contain items including sociodemographics, HIV testing history, HIV stigma, HIV knowledge, sexual history, sexual orientation, substance use, social media use, and sources of information. Contact information will be obtained for the participants, including phone number, email address, and social media IDs. The survey will take about 30-60 minutes to complete.

3.3.7 Intervention Content

After completing the online baseline survey, participants will be randomized to receive the digital crowdsourced intervention or standard of care (AIDS Center materials). Participants will view the materials online (via Qualtrics) and will then be directed to a page with a link where they can order HIV self-test kits. Participants will be sent one link a week for one month to view intervention or standard of care materials.

3.3.8 Follow-up surveys

One month and three months after completing the baseline survey, participants will be sent follow-up surveys containing the same items that were in the baseline survey. Each survey will take approximately 30-60 minutes to complete.

3.3.9 HIV Testing and Linkage to Care

After viewing intervention content or standard of care content, participants will be directed to a page with a link where they can order HIV self-test kits via GHRCCA's secure web portal. Participants may order a test kit at any point between baseline and the 3-month follow-up. Test kits will be sent in a plain box that does not reveal what is inside. Participants receiving a test kit will be sent a follow-up message via WhatsApp using standardized methods that have been used in other studies to electronically submit their test results. Participants who test positive for HIV will be

contacted by research staff to facilitate referral to HIV confirmatory testing and care at the city AIDS Center.

3.3.10 Qualitative Interviews

At the end of the study, we will conduct qualitative interviews with AYA (n=20), staff of youth partner organizations (n=5), AIDS Center staff (n=5), and web portal technicians (n=2). This will enable us to identify multi-level factors and processes that enhance or diminish intervention implementation, as well as organizational capacity. We will also identify facilitators and barriers for sustaining intervention components over time. All interviews will be audio-recorded and transcribed.

3.3.11 Data analyses

1) Primary Outcomes: The impact of the intervention will be evaluated based on the change in stigma score for each study group (follow-up stigma score minus baseline stigma score). Change in HIV stigma from baseline to follow-up periods will be calculated and compared between the intervention and control arms using multi-level linear mixed models.

2) Secondary Outcomes: We will use logistic regression to compare HIV testing uptake (i.e., ordered HIV self-test from website) during the 3-month period between individuals in the intervention arm vs. the control arm. We will also use logistic regression to compare differences in self-reported HIV test uptake and linkage to HIV care (for those with a positive HIV rapid test result).

We will also assess feasibility and acceptability of the intervention.

4 Ethical Considerations

4.1 Risk Analysis

4.1.1 Risk to the participants

The primary risks to participants are psychological discomfort from answering sensitive questions and loss of confidentiality. To address these issues, participants will be informed that they can skip any question they do not feel comfortable answering. Participants contact information will also be stored in a secure, password-protected database that is only accessible by authorized research staff. In addition, boxes containing HIV self-test kits will be plain boxes that do not indicate the contents of the box. Participants may choose to have the boxes mailed to a secure public mailbox where they can pick-up the test instead of having it mailed to their home address.

4.1.2 Benefits of the study

Participants will have access to order HIV self-tests, which they may not have previously been aware of. Participants may also experience lower levels of stigma due to their participation in the study. For individuals who test HIV positive, they will have the benefit of research staff to help link them to follow-up care. Through their participation, participants may also contribute to the development of an HIV stigma reduction and self-testing intervention that can be distributed more broadly in Kazakhstan to help the larger population of AYA.

4.1.3 Alternatives to Participation

Participants may choose not to participate in the study or drop out of the study at any time and request to have their data removed from the study database.

4.1.4 Compensation

Participants will be compensated for their time and effort based on compensation rates used in similar studies. Participants will receive approximately $10 USD for completion of each of the surveys and for the interviews. In addition, participants completing all follow-up surveys will be entered in a raffle to win small prizes.

4.2 Confidentiality

To minimize risk, we will employ staff members who have been trained in human subjects protections and HIV pre- and post-test counseling. Study staff have had many years of experience conducting HIV research. The study consent form will inform participants of confidentiality procedures. Participants will be told that they may decline to answer questions or may withdraw from the study at any time.

For the baseline and follow-up assessments, all data will be directly entered online into Columbia University School of Social Work's Qualtrics system. Surveys will be tested to ensure accuracy, completeness, and internal consistency. Upon completion of the study, a dataset that contains only non-identifiable data will be downloaded for analysis in statistical software programs. During collection of the data, all data will be transmitted securely using SSL (TLS) 128-bit encryption across the internet. SSL provides users with the assurance of access to a valid site and prevents data interception or tampering with information. Data will be located on a secured server at Columbia University. Access to the data will be password protected.

We will use standardized methods for HIV testing photo verification that have been used in other studies. WhatsApp has secure end-to-end encryption using a Signal protocol. This ensures that only authorized research staff will be able to see the photo and any chat messages between participants and research staff. End-to-end encryption prevents third parties and WhatsApp from having access to messages or calls. Even if encryption keys from a user's device are ever physically compromised, they cannot be used to decrypt previously transmitted messages. In addition, the

photos submitted will not be labeled with any identifying information. They will simply be a photo of a test result.

No presentation or publication of the study results will refer to participants individually. Results will be reported in aggregate form. Exceptions to confidentiality for participants are those required by law and include reports of child or elder abuse and the threat of suicide or homicide. Although we are not asking questions about child or elder abuse and do not expect any such instances to be reported, participants will be informed of these exceptions in the informed consent process.

4.3 Data and Safety Monitoring Procedures

The study processes will be monitored on a weekly basis. The study team will review all the collected data, check the study procedures, and discuss study problems and reported adverse events (if any) weekly. In addition, the recruitment and randomization procedures for both arms will be double-checked.

4.4 Compliance

Drs. Alissa Davis and Gaukhar Mergenova will lead the implementation of the study and overall study coordination. Drs. Davis and Mergenova will be responsible for overseeing all study procedures and for research and fiscal administration. The research team will communicate weekly to discuss the design, data analysis, subject safety, and any administrative issues. All research results will be shared with Co-PIs, key personnel, and consultants. The Co-PIs will work together to discuss any challenges in the research project.

4.5 Participant Withdrawal

Participants will be informed that they may withdraw from the study at any time without any consequences.

4.6 Institutional review board

The protocol for the proposed research will be reviewed and monitored by the Columbia University IRB (FWA00003831) and the Al-Farabi Kazakh National University IRB (FWA00031261).

4.7 Informed consent

All participants in this study will provide informed consent prior to participation in any research procedures. Participants will be well informed about the purpose of this study, potential risks of the study, and the research procedures conducted during the study. Participants will complete informed consent online through Columbia University School of Social Work's Qualtrics platform. For adolescents under 18, we are requesting a waiver of parental permission because the study is minimal risk and adolescents 16 and older are allowed to obtain an HIV test without parental permission in Kazakhstan.

5 Future Use

5.1 Contact for future research studies

During the informed consent process, participants will be asked if they would like to be contacted for future research studies. Participants who give permission to be contacted will have their contact information retained and may be contacted by the research team if they conduct future research studies among this population.

5.2 Contact for future research studies

Participant research data will be retained for future data analysis by the research team. Per NIH guidelines on data sharing, the research team will share data with any other Columbia University researcher who has obtained IRB approval to access the data and has proposed a specific research question for data analysis. The research team will also share data with any outside researcher who has obtained IRB approval to access the data, has a signed Data Use Agreement between Columbia University and their

home institution, and has proposed a specific research question for data analysis.