

Youth-to-youth empowerment study to support health equity for urban American Indian/Alaska Native and Black adolescents in Denver Metro, Colorado, USA: a mixed methods, youth-centred aetiological study protocol

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ABSTRACT

Introduction Promoting positive substance use and sexual health outcomes for urban American Indian and Alaska Native (AIAN) and Black youth requires multilevel approaches that address the underlying structural conditions that promote behavioural health inequities. However, researchers rarely employ this complex approach. Developing and operationalising a strengths-based conceptual framework grounded in the socioecological model is a critical first step to inform multilevel interventions to reduce these inequities.

Methods and analysis Guided by the socioecological model, a youth-centred mixed methods approach will be employed to develop and evaluate a comprehensive multilevel conceptual framework of risks and protective factors associated with substance misuse and adverse sexual health behaviours among AIAN and Black youth of Denver Metro, Colorado. We will use multilevel structural equation modelling, with secondary and geographical data. The secondary data include the Healthy Kids Colorado Survey data (n=631 AIAN, n=5350 Black and n=30 557 non-Hispanic white), the Colorado Department of Education School View data (n=33 schools) and the American Community Survey data (n=73 neighbourhoods). We will also engage approximately 30 youth through scenario-based interviewing to capture perspectives on the constructs that are not captured in the secondary data. The quantitative and qualitative data will be integrated to elucidate a conceptual framework that will be used to develop and optimise a multilevel intervention to reduce adverse substance use and sexual health outcomes in AIAN and Black youth in Denver Metro, Colorado.

Ethics and dissemination The results of the study will be shared at conferences, meetings and in published articles. Study findings will also be presented to the local community through presentations, social media, newsletters, flyers and brochures. The names of all

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Prevention of substance misuse and sexual risk-taking among youth of colour requires multilevel interventions that modify the social and structural conditions that potentiate risk; however, most interventions focus on the individual or interpersonal levels of the socioecological model.

WHAT THIS STUDY ADDS

⇒ This study presents a youth-centred approach to develop and conceptualise a multilevel framework.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The framework will develop a multilevel intervention to promote positive behavioural health outcomes for adolescents of colour in Denver, Colorado.

participants, schools and neighbourhoods will be kept private. This study was approved by the Colorado Multiple Institutional Research Board (protocol number 21-4038).

INTRODUCTION

Over the developmental span of adolescence, relationships that become more emotionally and sexually intimate and occasional experimentation with substances are considered normative exploratory behaviours.^{1 2} For urban American Indian and Alaska Native (AIAN) and Black adolescents in the USA, however, such exploration is more likely to result in adverse social, economic and legal outcomes^{3–5}; untreated substance misuse and

use disorders in adulthood^{6–8}; and disparities in sexual and reproductive health outcomes when compared with non-Hispanic white (NHW) adolescents.^{9 10} Moreover, disparities emerge and persist through mutually reinforcing social and structural systems of disadvantage that encompass all socioecological levels—individual, interpersonal, community, institutional and societal.^{11 12} Urban AIAN and Black adolescents are more likely to be situated in a web of adverse social and structural contexts than their NHW peers.^{13 14} The inability of efforts to date to yield sustained improvements in substance use and sexual health disparities among urban AIAN and Black adolescents stems from failure to account for this complexity.^{15 16}

Public health interventions that move beyond the individual and interpersonal levels have been recommended for years, as multilevel approaches that combine social, physical and environmental aspects are likely to have cumulative and enduring effects on health.^{15 17–20} Most examples of this complex approach, however, have focused on physical activity, nutrition and cancer.^{21–23} Multilevel approaches to promote positive substance use and sexual health outcomes are more accurately individual-level interventions. For example, in an extensive search of the literature, we identified four multilevel interventions that promote positive adolescent substance use and sexual health outcomes. The individual-level outcomes included knowledge and attitudes towards substance use and adverse sexual behaviours and testing for HIV/AIDS. At the second level, interventions addressed guardian–child and clinician–child communication skills, and social awareness of adverse behaviour outcomes using billboards in the community.^{17 24–26} While these interventions included multiple levels, they did not consider the structural contexts associated with behavioural health inequities. This is likely because researchers who focus on multiple levels of intervention often ground their work theoretically in individual health behaviour theory, such as the theory of planned behaviour, combined with the socioecological model.^{15 27} While they often provide extensive detail on the health behaviour theory employed, constructs of the socioecological model are rarely clearly defined or translated into the intervention.²⁸ Additionally, resilience is commonly absent from multilevel theoretical approaches.

Recent research has found that resilience is dependent on the quality of the social and physical contexts that surround adolescents as much as and likely far more than personality traits or cognitions.^{29 30} Further, communities of colour are characterised by strong cultural traditions and deep family connections that likely foster resilience.^{31–33} The potential of these inherent strengths to inform a conceptual framework to ground the design and evaluation of interventions has been largely overlooked in previous health equity research, overshadowed by focus on risk.³⁴ To address the underlying determinants of adverse behavioural health outcomes experienced by AIAN and Black adolescents, multilevel interventions that

include the modification of social and structural contexts and that leverage the resilient capacity of communities of colour are essential.²⁷

This paper describes our study to address these profound gaps in research. We discuss our mixed methods approach that engages urban AIAN and Black adolescents who reside in Denver Metro, Colorado to inform the development of a multilevel conceptual framework of factors most relevant to substance use and sexual health outcomes. Our study takes a health equity and strengths-based approach by centring the voices, perspectives and lived expertise of youth of colour throughout to examine the structures that cause behavioural health inequities and identify solutions to address them.³⁵ This conceptual framework will be used to inform multilevel interventions that focus on social and structural contexts and their synergistic relationships with individual-level and interpersonal-level factors that potentiate resilience to risk behaviours.

Theoretical framework

The socioecological model is a useful heuristic for examining multilevel social and structural determinants of substance misuse and adverse sexual health outcomes and for guiding the development of multilevel interventions to reduce behavioural health inequities.^{15 27} This model considers the complex interplay among individual, interpersonal, community and societal factors. In this context, it allows us to understand the range of factors that promote resilience to substance misuse and adverse sexual health outcomes among urban AIAN and Black adolescents.

Rationale for population of focus

Urban AIAN and Black adolescents have distinct histories and cultures, and many share commonalities in historical and contemporary experiences and patterns of exposure to social and structural disadvantages.^{36 37} Failure to rectify these insidious and pervasive social and structural barriers experienced by urban AIAN and Black youth hinders efforts to reduce substance misuse and adverse sexual health outcomes, and more broadly limits opportunities for healthy development among urban AIAN and Black adolescents.^{38 39}

School environments are foundational contexts during adolescence,^{40 41} and urban AIAN and Black adolescents are more likely to experience punitive and exclusionary discipline practices in school when compared with their NHW peers.⁴² These practices disrupt the potential for supportive environments that mitigate adverse adolescent health behaviours.⁴³ Exclusion from social and structural contexts that provide adequate resources, empathy and support places many urban AIAN and Black adolescents at significant disadvantage for substance misuse and adverse sexual health outcomes.^{44 45}

Urban AIAN and Black adolescents are more likely to experience legal consequences when engaging in occasional experimentation with substances compared with

their NHW peers due to hypersurveillance and over-policing in neighbourhoods in which urban AIAN and Black adolescents are more likely to reside.⁴⁶ For urban AIAN and Black youth, substance use has historically been viewed as a crime or deviant behaviour—a legacy of the War on Drugs.⁴⁷ In contrast, for NHW adolescents, substance use has often been seen as a reflection of unmet social needs and poor mental health. Urban AIAN and Black youth are disproportionately represented in the juvenile justice system due in part to disproportionate punitive law enforcement of their substance use.^{47–49}

We acknowledge that these racial groups do not reflect all youth of colour in Denver Metro, Colorado. However, due to the smaller sample sizes of AIAN and Black youth, health behaviour research and evaluation tend to focus on Latine and NHW youth. Our study seeks to address this gap. The focus on these two race groups will include multiracial and multicultural perspectives. Moreover, this limited focus will also allow for deeper examination of intersecting social identities (eg, gender identity and expression, sexual orientation) and ethnic and cultural diversity within each race group. Findings can be used to illuminate future efforts that focus on all youth of colour.

METHODS

Study aims

This study proposes to accomplish the following aims: (1) engage urban AIAN and Black high school youth in Denver Metro, Colorado to elucidate a conceptual framework of risk and resilience to substance misuse and adverse sexual health outcomes; (2) evaluate the multi-level determinants of risk and resilience to substance misuse and adverse sexual health outcomes among urban Black and AIAN high school youth (ages 14–18) in Denver Metro, Colorado identified in aim 1; and (3) identify the most critical levels on which to intervene to inform multilevel interventions that prevent harmful substance use and adverse sexual health behaviours.

Patient and public involvement in current research

The principal investigator (PI) distributed flyers to high schools and youth-serving organisations in Denver Metro, Colorado, seeking youth who were in 10th or 11th grade and who had an interest in social justice and health equity research for youth of colour. The flyers that were created did not specify race/ethnicity. Per the request of our community advisory board (CAB), a picture of the PI, who identifies as a Black woman, was included. The CAB felt that including a picture would show the youth who they will be working with, which will allow them to better determine if the PI could be trusted. We were interested in 10th and 11th graders because we preferred students who could commit to 2–3 years on our project. In addition, developmentally, ninth graders may be too young to engage in the research process. Six high school youth of colour contacted the PI and were interviewed. The interview consisted of questions about their volunteer

experience, their interest in social justice and health equity, work availability and their interest in the project. All high school students had experience volunteering with organisations that focus on improving education, social and health outcomes for communities of colour. They were also very interested in advocating for justice and equity for their peers of colour. Based on their experience and interest, all six high school students who were interviewed were hired.

We took a youth-engaged approach to gain a deeper and more accurate understanding of the complex social and structural contexts experienced by urban AIAN and Black youth that challenge opportunities for healthy development. Our youth-centred approach will honour and leverage culturally specific AIAN and Black philosophical traditions of healing, resilience and resistance. This approach is essential to the development of a culturally responsive and developmentally relevant multilevel intervention to reduce substance misuse and sexual health disparities. The youth researchers will be involved in all phases of our research.

Study design

This study will be accomplished in six phases (figure 1).

Phase I: team building

Phase I occurred in the fall of 2022 and consisted of recruitment of youth researchers, trust building, and foundational training on research, social epidemiology, protection of human subjects and research ethics. During this phase, we began the practice of journaling, reflection and debriefing, which we will continue in all phases of the research. We also created a resource list for students out of concern that the research could retraumatise the youth researchers. Notably, youth researchers have expressed that the ability to talk about and take action through research to reduce the discriminatory practices and oppressive systems they navigate daily is exhilarating and cathartic.

Phase II: youth as researchers

In the fall of 2023, youth researchers were trained in adolescent development, public health theory, decolonised research and school and family-based intervention. The youth researchers also began the development of a multilevel conceptual framework. Guided by the socioecology model and using the nominal group technique, the youth researchers identified risk and protective factors associated with substance use and sexual health outcomes at each level of the socioecological model.³⁵

Phase III: quantitative

Phase III will begin in the fall of 2024, and we will use secondary data from three publicly available data sets, namely Healthy Kids Colorado Survey (HKCS), Colorado Education Statistics Data (CESD) and American Community Survey (ACS). The youth research will select items from each survey that measure the factors they included in their conceptual framework.

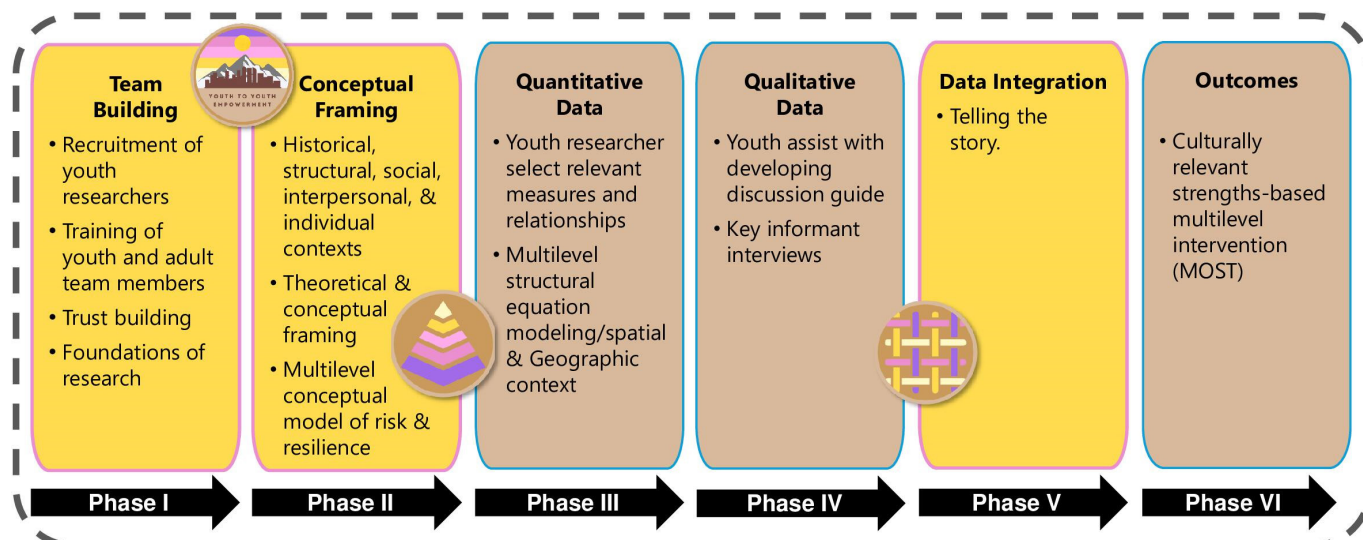


Figure 1 Youth-engaged sequential mixed methods approach.

Youth researchers will then create path models illustrating how the identified factors may be associated. We will use the path models to specify our statistical model of the moderated and mediated relationships of structural disadvantage across levels of the socioecological model by applying multilevel structural equation modelling (MSEM).³⁶ MSEM will allow us to examine the multilayered and interrelated associations among factors. This approach handles hierarchical data where individuals are nested in a cluster (eg, students within schools), which in turn are nested in a higher-level cluster (eg, schools within neighbourhoods). MSEM consists of two components: the measurement model and the structural model. As it relates to measurement models, variables that cannot be measured directly and are considered latent (observed) variables on the latent construct. For example, the latent construct of school resources may be measured by manifest variables of school funding, teacher–student ratios and teacher training/education. The structural model component of MSEM represents hypotheses informed by our youth-developed path models of direct and indirect relationships among constructs.

While we have yet to create our path models, we describe potential hypothesised associations among interpersonal-level, school-level and neighbourhood-level effects examined in this study.

- Hypothesis 1.1: At level 1, we hypothesise that parent/guardian and teacher support, minimal parent/guardian monitoring and racial/ethnic identity will be positively associated with adolescent substance misuse and adverse sexual health behaviours among AIAN and Black adolescents.
- Hypothesis 1.2: At level 2, limited school resources, lower scores on student assessments as an indicator of school effectiveness in preparing students for academic success (academic), inappropriate school disciplinary practices (school progress) and

segregated schools will increase substance misuse and adverse sexual health behaviours.

- Hypothesis 1.3: At level 3, concentrated poverty, low neighbourhood educational attainment, residential segregation and neighbourhood blight will be positively associated with adolescent substance misuse and adverse sexual health behaviours.
- Hypothesis 1.4: These neighbourhood-level factors will have an indirect effect on adverse sexual health behaviours through school-level factors.

Quantitative data overview

The HKCS is in alignment with the Youth Risk Behavior Surveillance System, a national surveillance system in the USA that monitors health-related behaviours that contribute to leading causes of death and disability among youth and adults. The HKCS is a sample of high school-aged youth in Colorado; the survey is administered in randomly selected schools and schools that opt in every 2 years. This survey captures data on alcohol and other drug use, adverse sexual health behaviours and other health and well-being measures. For this study, we will use data from Denver and Aurora public high schools. The sample includes 33 high schools and 30 557 NHW, 5350 Black and 631 AIAN youth in grades 9–12. School identification numbers link these data with the CESD to obtain school-level characteristics.

For school-level constructs, the 2023 CESD will be used. These data are collected by the Colorado Department of Education and include yearly education statistics (eg, dropout rates, teacher turnover rates and financial resources allocated to support schools) about each school in the state of Colorado. The collection of these data is mandated by the Colorado State Assembly. We will use data for the 33 schools included in the HKCS sample.

For the neighbourhood level, we will use the 2023 ACS data. The ACS is a federal government-funded annual survey that collects geographic and individual level

information about the USA. This survey gathers 1-year estimates of social and economic factors of neighbourhoods at the Census block and tract levels throughout the USA. It includes data such as concentrated poverty and neighbourhood educational attainment. We will obtain data of the 73 neighbourhoods that fall within each of the 33 school boundaries of our CESD and HKCS samples.

Measures overview

Youth researchers will receive an overview of the purpose of the surveys, how the surveys are created and secondary data analysis. We will then collectively review the HKCS, CESD and ACS surveys and, as discussed with the youth researchers, will identify which items best reflect the constructs identified in our conceptual framework. However, based on informal discussions with youth researchers, we believe the measures listed in the following sections will be particularly relevant.

Outcome measures

Adverse sexual risk behaviour measures are included in the HKCS data. The measures used will include sexual debut before the age of 13, four or more sexual partners in a lifetime, as well as condom use and drinking alcohol or using other drugs before the last sexual experience in the past 30 days. Substance use will be measured by current use (past 30 days) of cigarettes, vaping, alcohol, marijuana and opioids.

Interpersonal-level factors

HKCS data include measures of the following constructs: parental support (eg, can talk to guardian about problems, have fun with guardian), teacher support (eg, teacher praises, encourages) and parental monitoring (eg, guardian knows where they are and who they are with).

School context measures

CESD school measures are resources (eg, per pupil funding), progress (eg, dropout rates), academics (eg, academic achievement scores) and school racial demographics/segregation.

Neighbourhood measures

ACS data will be spatially referenced and include measures of neighbourhood poverty, neighbourhood educational attainment, residential segregation and neighbourhood blight (measured by economic investment, disinvestment and vacant buildings).

We acknowledge that our measures are deficit-focused; however, available secondary quantitative data that focus on resilience and strengths among youth in Denver Metro, Colorado are scant. These measures are based on risk theory, and surveys have been designed to identify and detect risk behaviours and factors.

Phase IV: qualitative

Phase IV will take place in late 2024 through early 2025. Using scenario-based interviewing (SBI), youth researchers will elicit feedback on the conceptual framework that they created for up to 30 high school youth of colour. To note, while our focus is on urban AIAN and Black youth, we will not turn away youth who are interested in participating in our study.

Phase V: finalising the story

Phase V will begin in the spring and summer of 2025. During this phase, we will integrate the data from the quantitative and qualitative findings of phase III and phase IV.

Phase VI: outcomes

Based on the findings of our mixed methods study, we will then be well positioned to begin phase VI. During this phase, we will develop a multilevel intervention guided by the findings of the previous phases in 2026.

ANALYTIC APPROACH

Phase III: quantitative

Descriptive analysis of the sample will be conducted using SPSS V.27.⁵⁰ MSEM models will be analysed using Mplus V.8.⁵¹ We will estimate a series of Structural Equation Models (SEM) and Multilevel Structural Equation Models (MSEM) to examine the direct, indirect and interactive effects of individual and interpersonal, school and neighbourhood-level constructs on substance misuse and sexual risk-taking of urban AIAN and Black high school youth. Youth researchers will assist with specifying the hypothesised relationships among variables. The analytic modelling process will consist of (1) confirmatory factor analysis to assess the factorial and structural validity of each construct (measurement model); and (2) path analysis assessing the direct, indirect and interrelated relationships among constructs (structural model). The models will control age, gender and grade level; however, we may explore other intersecting identities. We will use a stepwise approach beginning with examining interpersonal-level and individual-level factors on substance misuse and adverse sexual health behaviours (level 1), followed by estimating the level 2 model and concluding with level 3. The base model for level 3 to estimate substance misuse (SU) is: $SU_{tsi} = \beta_{0,ts} + \beta_1 X_{tsi} + \epsilon_{tsi}$, where SU_{tsi} represents the substance misuse score for the i th child in the sth school within neighbourhood t ; $\beta_{0,ts}$ is the intercept specific for the sth school within neighbourhood t ; $\beta_{1,ts}$ is the regression slope in the sth school within neighbourhood t ; and X_{tsi} are individual-level covariates. ϵ_{tsi} represents the residual errors at the individual, school and neighbourhood levels. We will extend the base model to (1) quantify neighbourhood differences in average substance misuse and adverse sexual health behaviours for each race group; (2) examine the effects of neighbourhood characteristics (eg, racial and economic segregation) on outcomes; and (3) examine

the direct, mediating and moderating effects of school-level characteristics on substance misuse and sexual health outcomes and on explaining between-level variation among outcomes of interest. A similar approach will be applied to estimate sexual risk-taking as the outcome. Models will be estimated using a maximum likelihood estimator with robust SEs to account for potential non-normality. Model fit will be assessed using root mean square error of approximation, comparative fit index and standardised root mean square residual. Given the georeferenced nature of the data, we will use the global Moran's *I* statistic as a diagnostic tool to assess potential spatial autocorrelation among the model residuals. If significant autocorrelation exists, we will further extend the models to include spatial autocorrelation in the data, akin to spatial SEM, which can be estimated using Bayesian estimation techniques. Youth researchers will assist with interpreting the findings of the analyses.

Power analyses

We conducted power analysis for multilevel SEM that considered both the sample size at the level of the individual as well as the higher levels (ie, schools and neighbourhoods) using Monte Carlo simulation analyses in Mplus V.8.⁵¹ Power calculations were conducted separately for NHW (*n*=30 557), AIAN (*n*=631) and Black (*n*=5350) high school youth in grades 9–12 each, assuming 33 schools and 73 neighbourhoods. We set alpha at 0.05 and calculated the power to detect effect associations for all paths illustrated in figure 2, controlling for gender and simultaneously adjusting for predictors at multiple levels. The estimated power for detecting these effect sizes of 0.20 across all models was 87% or greater.

Phase IV: qualitative

Attempting to elicit deep and rich data from adolescents through qualitative interviews can be challenging,

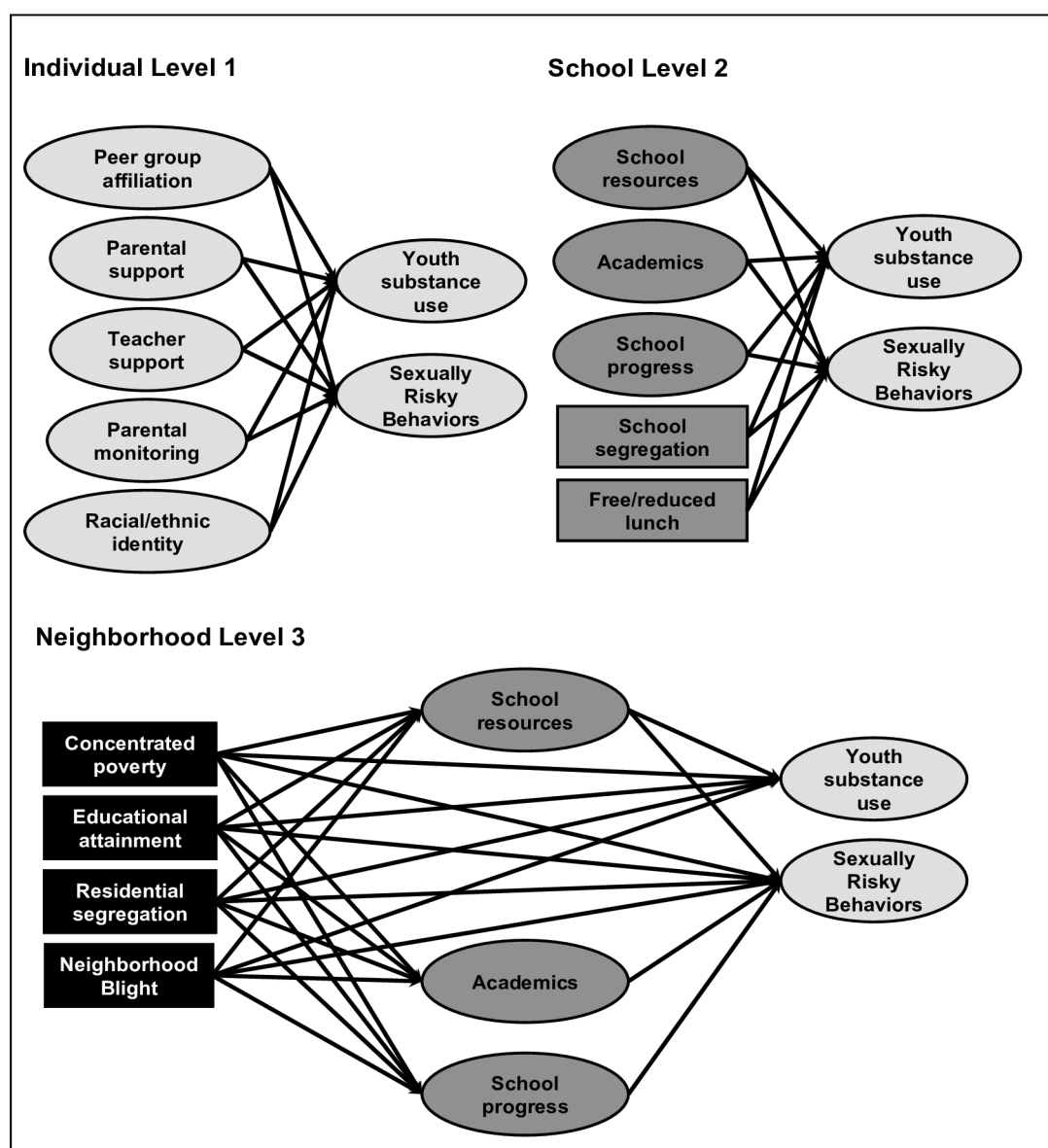


Figure 2 Path diagram of the hypothesised relationship of the constructs of interest.

particularly when gathering information on sensitive or personal topics. SBIs have been shown to overcome this challenge.⁵² SBI is particularly useful to our study because we are interested in adolescent substance misuse, sexual risk-taking and sensitive topics that adolescents may not feel comfortable discussing with an interviewer.

Sampling and recruitment

We will partner with high schools to provide in-school spaces for safe and secure data collection. We will sample youth from high schools considered to have exceptional, average and poor school climates, with climate scores based on school resources, school progress and academics. We will partner with high school principals and teachers who will distribute flyers describing our study and our need for students to participate in SBIs. We will sample youth of each school climate until saturation is achieved, that is, until no new information is discovered in the data analysis. All minors must return a signed parent permission form and provide assent prior to enrolment into the study; students 18 years or older must return a signed consent form before enrolment.

Data collection

SBIs will be conducted to interpret, explain and elaborate on the results obtained in phase III. We will also elicit narratives of protective factors that exist within communities of colour that promote positive behavioural health outcomes. The perspectives of youth researchers and the findings from phase III of the study will be used to develop a series of scenarios and associated open-ended questions; our youth researchers will be involved with developing these scenarios and associated questions. We will introduce students to a series of scenarios that include summaries of how various students experience their social relationships and neighbourhood and school environments and how these experiences mitigate substance misuse and adverse sexual health behaviours. We will include questions about how these scenarios relate to what peers have experienced. Interviews will be audio-recorded and transcribed. Youth will receive \$25 for participation. Youth participants will be interviewed by the PI and the project coordinator, who are both adults in the study and have experience with qualitative research methods.

Data analysis

Audio recordings will be transcribed, reviewed for accuracy and analysed using ATLAS.ti. We will conduct thematic analysis within and across AIAN and Black racial groups, comparing themes and categories to identify commonalities and differences as they relate to (1) explanations of relationships among socioecological levels with substance misuse and sexual risk-taking; (2) associated risk and resilience factors in each level; and (3) the most critical levels on which to intervene. We will develop code names, definitions and inclusion/exclusion criteria.

Each transcript will be coded independently. Inter-coder agreement will be assessed by 80% agreement.

Phase V: data integration

Data will be connected through sampling, recruiting youth from the schools sampled in the HKCS data for SBIs. We will identify common and essential components to generate into a single comprehensive framework. Findings will inform the development, implementation and measurement of a multilevel approach to reduce substance misuse and promote positive sexual health behaviours among high school youth who share school and neighbourhood environments.

ETHICS AND DISSEMINATION

The study will not involve any medical tests or procedures; therefore, there are no anticipated physical risks. As with any research study, there is a risk of accidental breach of privacy. We have taken steps to minimise this risk, such as ensuring rigorous data security protections. Because this project involves primarily secondary analyses of data collected as part of ongoing state-level surveillance systems, no additional risks to participants are expected.

The study also involves the exploration of risk factors for sensitive outcomes (ie, substance use and sexual risk-taking), and this could cause emotional discomfort. In comparison to what youth are exposed to on social media and/or in music, interview questions to be included in this study are developmentally appropriate and unlikely to pose more risk than encountered by adolescents in their daily activity.

Interview questions will be developed by our youth researchers and our CAB. Questions could nonetheless make some participants uncomfortable or bring up unpleasant memories. We do not know how common this risk is due to a lack of data on this topic. However, based on the expertise of the CAB, final interview questions will likely not lead to adverse experiences among participants. We do not anticipate significant issues to arise within this study. However, a resource list with mental and behavioural health support and services will be offered to interviewees. Our team has created safety and reporting procedures that include participant and research team safety, mandatory reporting required by law, guidance for referring participants to needed services, and stress management and racial healing strategies for the research team.

A 'certificate of confidentiality' has been issued by the National Institute on Drug Abuse of the National Institutes of Health, which further protects participants by prohibiting the disclosure of information to anyone not involved in the research. Participants will complete an assent form that provides an overview of these protections. This study's protocol and procedures have been reviewed and approved by the Colorado Multiple Institutional Review Board (protocol number 21-4038).

The results of the study will be shared by the team, including the youth researchers, at national academic conferences and meetings and published in peer-reviewed journals to support public health and prevention science scholars in their advocacy towards a focus on social and structural interventions to create contexts where, by default, youth of colour can make healthy decisions. Findings will also be presented to the local community through presentations in locations such as local school board and city council meetings, community health fairs and parent nights in local schools. We also plan to disseminate findings through social media, newsletters, reports, flyers and brochures that can be used to inform the development of policy and practice that promote healthy development for young people of colour. The names of all participants, schools and neighbourhoods will be kept private when presenting findings in both academic and community settings.

Contributors NT leads the conception and design, data acquisition, analysis and interpretation of data, funding acquisition, investigation, methodology, writing—original draft preparation, supervision, writing, review and editing. AHa, YMD, AHi, OS and AW co-lead the investigation, data acquisition, analysis and interpretation of data, writing, reviewing and editing. DTD, BS, RSM, NRW and CK co-lead the conception, methodology, analysis and data interpretation, writing, reviewing and editing. NT accepts full responsibility for the finished work and/or the conduct of the study, had access to the data and controlled the decision to publish as the guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Ethics approval This study was approved by the Colorado Multiple Institutional Research Board (COMIRB; protocol number 21-4038).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available.

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