Michigan Model for Health: Learning to Enhance and Adapt for Prevention (MI-LEAP)

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RESEARCH STRATEGY

SIGNIFICANCE

Implementation of evidence-based programs and youth substance use. Quality implementation of evidence-based programs (EBPs) for youth in community settings is critical for reducing the burden of alcohol, tobacco, and other drug (ATOD) use and its consequences. Adolescence marks a time of life with high rates of ATOD use.[25] *Healthy People 2020* identifies ATOD use a leading health indicator associated with morbidity and mortality among youth.[26] Universal, school-based prevention EBPs reach large broad-based populations of adolescents and are essential to reducing ATOD use.[2] One such prevention program is the Michigan Model for Health (MMH). MMH, the official health curriculum for the State of Michigan, is a theoretically-based, comprehensive skills-focused program with a core unit on ATOD use.[27,28] In an RCT of MMH, researchers found that high school youth receiving MMH were less likely to report ATOD use than youth in the control condition.[29] In real-world conditions, quality implementation of EBPs is ***essential*** to program effectiveness; yet, youth rarely receive programs as intended. For example, 76% of 9th grade public school students received the MMH unit on ATOD use but 58% of educators did not meet state-designated fidelity requirements.[28] Our survey of Genesee County high school teachers also suggests limited adherence to the curriculum: 36% use less than half and only 27% report using three-quarters or more of the curriculum content.[30] The current paradigm for intervention development focuses disproportionately on program efficacy (e.g., internal validity) and less on how interventions function in real-world contexts (e.g., external validity).[8] This paradigm contributes to the widely acknowledged research-to-practice gap and limits societal benefits from significant intervention research investments.[9,10] Implementation science addresses this gap. Research to date, however, does not incorporate extensively theoretically-based implementation science frameworks to study factors associated with EBP implementation in schools.[2] Approaches to enhancing the effective implementation of EBPs in schools is also understudied, as most research has focused on clinical interventions.[31] The cost of implementation fundamentally influences program delivery in schools, who often have carefully allocated resources.[2,13] Economic evaluation can inform decisions about implementing interventions efficiently and effectively but is underutilized. Consequently, theoretically-guided research investigating factors influencing implementation, implementation strategies to enhance program delivery, and economic evaluation of these strategies is critical to bridging the research-to-practice gap but has not been widely applied in school-based ATOD prevention interventions.[2]

Theoretical framework for investigating factors associated with EBP implementation in schools. The Consolidated Framework for Implementation Research (CFIR) provides a useful guide for the examination of factors associated with EBP implementation. Figure 1 depicts this comprehensive framework which includes domains across socioecological levels (e.g., intervention, context, provider characteristics) that can aid in understanding EBP delivery in a given setting.[11] Researchers have found, for example, that intervention characteristics (e.g., program packaging) were associated with fidelity in a school-based ATOD prevention program.[32] Researchers also suggest that features of the context, are associated with fidelity, but this has focused on clinical settings.[33,34] Provider characteristics, such knowledge about the EBPs, may also influence fidelity. Researchers found that providers with negative perceptions of an EBP were less likely to deliver it with fidelity.[32] This framework has been widely applied in clinical settings but has rarely been applied to implementation in schools. Research examining factors across multiple domains is essential to effectively design strategies to improve implementation.[23] Applying well-developed implementation science frameworks is a promising approach to understanding ATOD prevention EBPs.

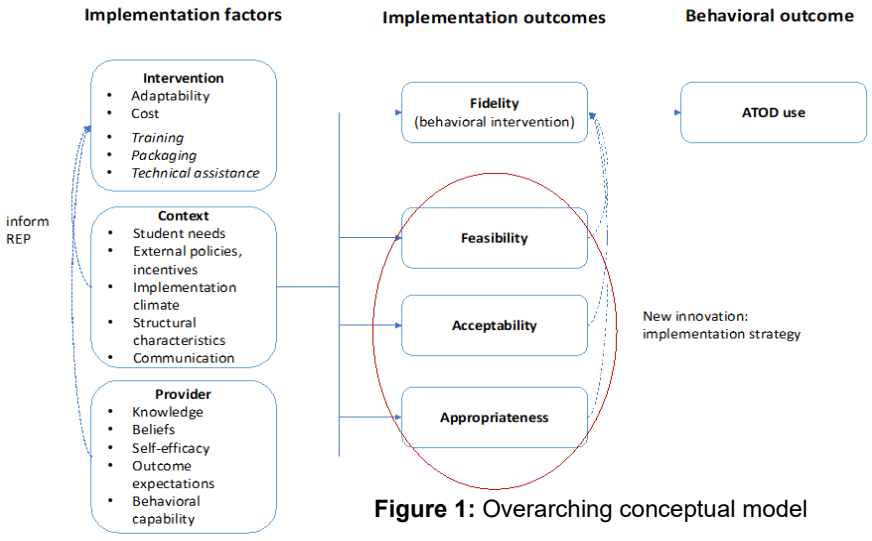

Figure 1: Overarching conceptual model

Evidence-based implementation strategies. Evidence-based implementation strategies help facilitate the translation of research to practice through mitigating barriers to quality implementation of effective interventions.[14] Implementation strategies are needed to realize the public health benefits of EBPs.[35] Replicating Effective Programs (REP) is an implementation strategy focused on maximizing flexibility and fidelity in EBP delivery.[23] Unlike other implementation strategies (e.g., evidence-based quality improvement, NIATx),[36,37] REP was developed for community-based settings to implement EBPs and has been used with prevention-focused interventions. REP, based on the CDC's research-to-practice framework,[38] is guided by Social Learning[39] and Diffusion of Innovations Theories.[40] Standard REP includes three primary components—program packaging, provider training, and facilitation (Table 3). Standard REP is a low intensity, *minimal cost* intervention that has improved uptake of brief HIV-focused interventions.[41] Researchers have also developed enhanced REP for more complex clinical behavioral interventions, which includes added customization for program packaging and training, and active engagement of internal and external facilitator.[42] Information about organizational context, providers and the intervention are essential to customizing REP for optimal program-organization fit. Researchers have found enhanced program fidelity among clinical sites using enhanced versus standard REP.[43] REP and enhanced REP, however, have not been tested in school settings and very little research has been done to investigate the effects of either REP on implementation and behavioral outcomes in *school* settings. Although improved outcomes with enhanced REP are promising, the added costs can be substantial.[43] Thus, economic evaluation is vital to assess the costs and benefits of different strategies.

Table 3: Replicating Effective Programs (REP) Components (*adapted from Kilbourne et al, 2015)*

	Standard REP	Enhanced REP
Package	Intervention manual development	Intervention manuals customized to sites using data from organization needs assessment on population and setting resources
Training	Standard training	Customized training based on input from package step above
Facilitation	As needed technical assistance; Monitor intervention uptake via observation, qualitative and quantitative data	**External facilitation components**: Works with IF and providers to review potential barriers and set goals; Technical assistance: EF gives specific implementation guidance and facilitates information sharing and long-term plans for sustainability **Internal facilitation components**: Regular meetings with EF, providers to set goals, align intervention with organization, advocate for implementation to leadership

Economic evaluation of implementation. The goal of implementation research is to determine the best strategies to improve EBP delivery in community settings. Most economic evaluation in implementation, however, has focused on the costs of interventions and ***not*** the costs of implementation strategies required to deploy and sustain interventions in community settings.[13] Understanding the resources needed to achieve desired behavioral outcomes (e.g., reduced ATOD use) is essential to implementing EBPs.[44] Because economic factors related to implementation influence the program delivery,[12,13,15] economic evaluation can inform implementation strategies.[45,46] Systematic examination of outcomes related to implementation strategies, and the costs of achieving them, is essential for integrating EBPs in real-world settings.[13] Organizations benefit from evidence that supports (or refutes) investment in specific implementation strategies as an efficient use of resources and can help prioritize implementation efforts. The Cost of Implementing New Strategies (COINS) provides a useful framework for evaluating implementation costs.[44] COINS aids in identifying a range of costs across multiple phases of implementation (e.g., pre-implementation, implementation, and sustainability) and is congruent with REP phases (see Table 7).[23,44] Many types of economic evaluation exist, but one well suited to implementation science is cost-effectiveness. Cost-effectiveness assesses whether incremental benefits of one strategy versus another are sufficient to justify additional costs and has been used to support selective EBPs for youth in clinical settings[47,38] Cost-effectiveness data can help inform decisions about resource allocation for program selection and implementation.[45] Economic analysis of implementation strategies, however, is understudied.

Significance of the Expected Research Contribution

I expect to make the following unique and significant contributions to the field of implementation science. First, through identifying barriers and facilitators to implementation, I will contribute to the application of implementation science theory across non-clinical settings (e.g., school) with a focus on prevention. Second, my theoretically guided research will inform implementation strategy customization for school-based ATOD prevention EBP, with attention to the complexity of an educational context and competing demands of schools' primary goals and objectives (e.g., student learning & retention). My research will help expand the application of evidence-based implementation strategies (e.g., REP) in non-clinical settings to enhance EBP delivery in schools to prevent youth ATOD use. Finally, I will contribute to advancing economic evaluation of

implementation through identifying the cost-efficient strategies to enhance program delivery. This is especially important in schools that reach a broad range of youth, where resources are often limited. The economic evaluation will aid in identifying feasible, sustainable implementation strategies to enhance quality EBP implementation.

Consideration of sex as a biological variable

I will consider sex as a biological variable in terms of participant outcomes for substance use. Researchers have found differences in substance use between adolescent males and females, with males having generally higher rates of ATOD use.[25] Researchers have also found that adolescents may respond differently to clinical and school-based ATOD treatment and prevention programs.[29,49] Consequently, it is vital to account for these potential differences when investigating the implementation of youth ATOD prevention programs.

INNOVATION

The proposed research has several innovations: **1) Application of implementation science frameworks in non-clinical community (i.e., school) settings.** Although implementation research in non-clinical settings is growing, most research has focused on psychotherapy treatment. Also, the application of well-developed clinically-focused implementation science theories and frameworks for universal prevention in schools is limited. The proposed research applies implementation science theories to universal ATOD prevention in schools. **2) Testing implementation strategies with a scaled-up intervention**. Researchers generally follow a linear paradigm of intervention development from efficacy trials to dissemination. Bridging the research-to-practice gap will require a shift to include implementation research with EBPs in various stages of development. Researchers have not systematically applied implementation science frameworks to school-based ATOD prevention programs even though some programs *have already been adopted and widely disseminated*. **3) Economic evaluation of implementation and implementation strategies**: Researchers to date have focused primarily on quantifying intervention costs; less has focused on implementation strategy costs.[12,13] Yet, implementation strategies range from less cost-intensive (e.g., standard REP) to more cost-intensive (e.g., plan-do-study-act cycles).[50,51] This research is innovative because it will focus on economic evaluation of implementation strategies in schools, an underdeveloped area of implementation science.

APPROACH

The Aims are reorganized based on the response to the summary statement, December 2018.

AIM 1: Conduct secondary data analysis comparing the effectiveness and cost-effectiveness of two implementation strategies.

Mid-year progress Aim 1a: I am currently working on options to address missing data for Aim 1a.

In **Aim 1a**, I will compare using Replicating Effective Programs (REP) and Enhanced REP to deliver the Life Goals Collaborative Care: LGCC intervention on program fidelity and participant alcohol, tobacco, and other drug (ATOD) use. LGCC is an EBP developed for psychiatric disorders, which also addresses substance use.[60] Similar to MMH, LGCC emphasizes skill building for behavior change to reduce negative outcomes.[61] LGCC has undergone customization guided by feedback on factors related to implementation in initial clinical trials and additional adaptations to include two conditions of enhanced REP. I will compare these conditions on fidelity and ATOD use. This will provide critical experience investigating implementation strategies to prepare me for applying REP in a novel setting- schools (Aim 3). In **Aim 1b**, Guided by the Costs of Implementing New Strategies (COINS) framework, I will estimate the costs and cost-effectiveness of REP and Enhanced REP on LGCC intervention fidelity and participant ATOD use. **Sample.** Eighty community clinics received standard REP at the start of the study. After 6 months, the non-responsive sites (n=60) were randomized to receive enhanced REP with both external facilitation: EF and internal facilitation: IF (n=30, 600 participants) or EF only (n=30, 600 participants) to facilitate LGCC implementation. **Procedures.** The study incorporated a sequential, multiple assignment, randomized trial design that included implementation and effectiveness components.[43] Data were collected at 6 and 12 months following randomization.

Mid-year progress Aim 1b: I have a manuscript for the ADEPT cost-effectiveness analysis under review.

Aim 1a. Measures. ATOD use. Using items from the National Institute on Drug Abuse's Modified Alcohol, Smoking and Substance Involvement Screening Test[63] and the Alcohol Use Disorders Identification Test[64] we assessed past month marijuana, illegal drug, and tobacco use and binge drinking. We will create a summed

composite scale using these items. Implementation outcome. Our implementation outcome will be adherence, a dimension of fidelity based on Proctor et al.,[12] defined as the extent to which the program occurred as intended (see Table 4).[32] Researchers debate the best approach to measuring fidelity dimensions, but we adopted an approach that was minimally invasive and suitable to a real-world context.[42] We measured adherence by creating a total score of the number of group sessions and care management contacts using a combination of provider logs and confirmatory data from patient surveys.[42] **Data Analysis.** We will compare fidelity (i.e., adherence) by REP condition (EF and IF vs. EF only). We will also use growth curve modeling to investigate individual change over time in ATOD use and between-individual change due to group membership (e.g., EF and IF vs. EF only), accounting for nesting effects. We will control for baseline and demographic characteristics and will examine potential differences in ATOD use by sex. Standard longitudinal methods such as growth curve modeling can be used to investigate the main effect aims in factorial experimental designs.[65] These analyses will provide an opportunity to work with data from an ongoing implementation study with ATOD outcomes. **Expected outcome:** We expect that patients receiving LGCC in clinics with enhanced REP using EF and IF will report less ATOD use than those in clinics with enhanced REP and EF only.

Aim 1b: Measures. Implementation costs: Implementation costs will be guided by the COINS approach (see Table 7). Implementation costs include indirect costs such as time spent training and supervising, training compensation (e.g., pay during non-work hours), time costs of assisting with intervention delivery, and nonlabor costs such as costs of the curriculum (manual and materials), training time, technical assistance, facilitator time, and travel costs.[13,72] **Data analytic approach.** We will estimate the costs of each REP condition using data in Table 7, with the base case analysis being the enhanced REP+EF (external facilitation) only. The primary outcome will be change in reported ATOD use during the intervention period. We will use net costs (net increase in costs from the enhanced REP condition with external: EF and internal: IF facilitation compared to EF only) and net effectiveness (net decrease in substance use from the enhanced REP condition with EF and IF compared to EF only) to calculate the incremental cost-effectiveness ratio for behavioral and implementation outcomes: $\frac{Cost_{E-REP:IF+EF} - Cost_{E-REP:EF}}{Outcome_{E-REP:IF+EF} - Outcome_{E-REP:EF}}$. We will conduct uncertainty analyses to evaluate variability in results from potential bias in parameter estimates (e.g., duration of consultations for facilitation) and use these results to construct confidence intervals around cost and cost-effectiveness estimates as a measure of uncertainty around results.[73] We will also conduct sensitivity analyses to characterize how extensive an implementation strategy must be to justify a change in approach from a behavioral (e.g., ATOD use) and economic perspective. We will vary certain assumptions to meet a range of possible scenarios (e.g., extent of facilitation).[45] These analyses will be essential in informing economic evaluation for the pilot study. **Expected outcome**: We expect patients in the enhanced REP with IF and EF will report a greater reduction in ATOD use relative to dollar spent compared to those in REP with IF.

Mid-Year Progress Aim 2: Since the end of Year 1, I have had two papers related to this research published, one in Prevention Science, and one in the Journal of School Health. I have also submitted a qualitative study related to the project that is currently under review.

AIM 2: Evaluate factors associated with the fidelity of a school-based ATOD prevention program (the Michigan Model for Health: MMH) to tailor an implementation strategy.

The objective of Aim 2 is to investigate factors associated with implementation guided by CFIR to better understand implementation in school settings (Figure 1). This will inform Replicating Effective Programs (REP) design for MMH delivery. This research is expected to provide information regarding barriers and facilitators to MMH implementation and foundational knowledge to effectively design implementation strategies. **Overview**. I will use data from an ongoing study (Health Education Experts Study) of high school health teachers and administration to assess factors related to the implementation of an EBP.[30] This includes quantitative and qualitative data addressing factors across multiple domains guided by CFIR. **Sample and setting.** Participants are Michigan high school health class teachers, high school administrators, and other key personnel in MMH implementation (e.g., Regional Health Coordinators). We currently have survey (n=20) and interview (n=4) data from participants in Genesee County collected in collaboration with the GISD Regional Health Coordinator. We will recruit additional participants in collaboration with MI DHHS through their network of Regional Health Coordinators. MI DHHS has successfully recruited health teachers and administrators in previous health curricula studies and they are deeply committed to supporting MMH delivery.[28] We expect to recruit 200 more teachers for the survey based on response rates from previous MI DHHS surveys. With this

sample size (n=220), we would have 80% power to detect a 50% change in odds of our outcome (e.g., fidelity). We are also recruiting 10-15 more teachers for interviews. **Procedures.** We will use a mixed methods approach to develop a comprehensive understanding of ATOD prevention programs in schools. Mixed methods combine statistical results with in-depth personal experiences and aids in prioritizing implementation challenges and developing solutions.[55] The survey is administered online through the U-M Qualtrics survey system. Participants received $10 remuneration for completing the survey. Health teachers willing to participate in the interviews will be contacted by project staff via email and postal mail. Those agreeing to participate will be consented using an online consent form and interviewed either in-person or virtually (e.g., Skype). These interviews will be audio recorded for in-depth analysis. **Measures.** See Table 5 for a summary of quantitative measures.[56] We developed measures for domains listed based on the Consolidated Framework for Implementation Research (CFIR),[57,] and Replicating Effective Programs (REP) [23] unless otherwise indicated. CFIR is a comprehensive framework that aids in identifying the most relevant, context-specific factors related to implementation.[33] Factors included in this study are informed by previous school-based research and input from community partners at GISD and MI DHHS; this includes constructs related to the intervention (e.g., packaging/manual), context (e.g., implementation climate) and providers (e.g., knowledge and beliefs).[32] The implementation outcome is dose delivered: a fidelity dimension.[12] We assess dose delivered by asking about the proportion of the MMH curriculum teachers reported delivering to students, from 0: none to 4: 75% or more. The measure is consistent with dose delivered in a previous study of MMH.[28] The semi-structured interviews focus on the intervention, context, and provider characteristics, including barriers and facilitators to MMH delivery. **Data Analysis:** Quantitative data analysis: We will use multinomial logistic regression models to estimate the probability of an outcome relative to a baseline category for a given set of predictors.[58] We will account for nesting by school as needed; our community partners indicate, however, that many high schools in Michigan are staffed by one certified health teacher. Guided by Hosmer and Lemeshow's approach,[59] we will choose variables for inclusion based on statistical and substantive contributions to the overall model.[59] In the interest of parsimony and reducing model over fitting, we will use both theoretical considerations and the Wald test to eliminate variables that do not contribute to the model. Qualitative Data analysis: We will analyze the structured interviews using N-vivo. First, we will mark separate segments responses that represent distinct constructs. Next, we will review data chunks to establish agreement and then assign chunks into meaningful categories guided by CFIR. Next, we will combine categorized data chunks. Finally, we will review data to identify common themes. Results from qualitative data analysis will inform model building and provide context for interpreting and applying quantitative results. **Expected outcomes:** We expect to identify specific factors across CFIR domains that influence dose delivered.[33] For example, we may find that teachers report MMH is not fully meeting students' needs around substance use and that this is associated with less dose delivered. These results will be critical to informing REP for the pilot study (Aim 3).

Table 5: Study implementation measures

Domain/construct	*Framework*
Intervention	
Adaptability	*CFIR*[11]
Packaging	*CFIR*[11]*; REP*[23]
Training	*REP*[23]
Technical assistance	*CFIR*[11]*; REP*[23]
Context	
Student needs	*CFIR*[11]
External policies	*CFIR*[11]
Networks and communication	*CFIR*[11]
Structural characteristics	*CFIR*[11]
Implementation climate	*CFIR*[11]
Provider characteristics	
Knowledge	*CFIR*[11]*, IMB*[39]
Beliefs	*CFIR*[11]*, IMB*[39]
Self-efficacy	*CFIR*[11]*, SCT*[39]
Outcome expectations	*CFIR*[11]*, SCT*[39]
Behavioral capability	*CFIR*[11]*, SCT*[39]
Implementation Outcomes	
Appropriateness (fit) (Aims 2-3)	*IOF*[12,53,54]
Acceptability (Aims 2-3)	*IOF*[12,53,54]
Feasibility (Aims 2-3)	*IOF*[12,53,54]
Fidelity: adherence (Aims 2-3)	*IOF*[12,42]
Fidelity: dose delivered (Aim 1)	*IOF*[12,28]

CFIR: consolidated framework for implementation research, REP: replicating effective programs, ICS: implementation climate survey, IMB: information-motivation-behavioral skills model, SCT: social cognitive theory, IOF: implementation outcomes framework

Mid-Year Progress for Aim 3: We have completed meetings with an advisory committee and developed a plan for tailoring the MMH curriculum. Related to this, the research team created a website for the tailored curriculum to be amenable to online instruction partly in response to COVID-19. We are designing a tailored training to complement the curriculum. I am working with Amy Kilbourne to design an Implementation Facilitation training for health coordinators. We have also begun designing an implementation guide for deploying Enhanced REP for MMH. This process of designing Enhanced REP has been slowed due to the COVID-19 pandemic. The adapted curriculum, teacher and facilitation training, and pilot study are planned for early 2021, consistent with the original proposed timeline, dependent on schools and the pandemic status.

Aim 3: MMH REP pilot: building on the skills developed in Aim 1 and Training Goals 1–3, I will conduct a prospective implementation pilot of the MMH in the GISD. REP is well suited for implementing MMH because it includes a curriculum manual and teacher training processes. The overall purpose of this pilot is to assess the appropriateness, feasibility, and acceptability of using REP for MMH, a universal ATOD prevention program.[62] I will create a customized package for delivering MMH using standard and enhanced REP. Informed by data from Aim 1, I will investigate the effectiveness of standard and enhanced REP on implementation and behavioral outcomes. **Sample and setting.** We will study high schools from Genesee County, MI. Like other communities facing declining populations and economic challenges, the county has had higher unemployment levels compared to state and national averages for over a decade,[66] and youth report higher rates of ATOD use compared to state averages (Table 6). This pilot study will include 8 schools from the Genesee Intermediate School District (**GISD**), as informed by other implementation pilot studies[62] and study resource limitations. GISD includes 21 school districts and 25 public high schools. In collaboration with GISD partners, we will identify high schools using MMH that fail to meet MI DHHS standards for implementation (75% or less of the curriculum) to contact regarding participation. We will select schools using data from our MMH implementation study that have comparable student demographics (e.g., % free/reduced lunch). **Procedures.** We will recruit schools in collaboration with GISD leadership. Identified schools will be randomized to either standard REP or enhanced REP (see Table 3). The standard REP condition will receive a customized MMH manual (adapted from the current manual) based on results from Aim 2 to meet the needs of the context and providers; this may include creating on online manual. Standard REP will also include customized training based on Aim 2 (e.g., adapting content to new substances or substance forms, updated teacher resources) and brief, as needed technical assistance. Enhanced REP will also include internal and external facilitators with specific expertise in health education and implementation with weekly teacher contact to provide specific guidance for overcoming MMH delivery barriers. Enhanced REP will also include additional training and packaging customization (e.g., supplemental ATOD resources). The study team will meet with teachers and parents at participating schools to share study information. Teachers will complete a survey on MMH implementation and using Enhanced REP to deliver MMH post-intervention. We will also conduct qualitative interviews of teachers in participating schools to obtain in-depth information about using MMH delivery with REP. Students receiving the MMH at participating schools will be eligible for student-level surveys. Students will be recruited in participating schools in conjunction with GISD partners. Following parental consent and participant assent, students will complete a self-administered questionnaire through a secure, online survey about ATOD and related behaviors. As MMH is integrated as part of the school curriculum, students will complete the initial survey during their 9th or 10th grade health class prior to MMH delivery and 3 months post-delivery. Students who do not consent will receive an alternate activity. I expect 300 students to participate based on a 60% response rate.[67] Students will receive $10 for the surveys.

Table 6: Demographics and youth substance use

	Michigan	Genesee County	Flint
Median household income	$49,087	$41,879	$24,679
Per capita income	$26,143	$22,536	$14,527
% living in poverty - children >18yo	23.7	32.1	62.4
% racial/ethnic minority	20	25	40
Adolescent substance use % (past 30 days)[a]			
Marijuana	19.3	25.6	n/a

Alcohol (any)	25.9	27.5	n/a
Alcohol (binge)	12.5	16.1	n/a
Cigarettes	10	10.4	n/a
Prescription drug misuse	15.8	6.9	n/a

[a]among 11th graders: Michigan Youth Risk Behavior Survey 2015

Aim 3a Measures. Fidelity: adherence (MMH): Adherence, the extent to which an EBP is delivered as intended, will be assessed by teacher self-report. The measure includes specific procedures used (e.g., active learning) and engagement in specific MMH activities (e.g., four corners discussion) as detailed in the curriculum.[12,68] We will create teacher checklists of MMH lesson components and create a composite adherence score based on the checklist. Acceptability, appropriateness, and feasibility (REP): We will use Weiner et al.'s[53,56] measures to assess acceptability, appropriateness, and feasibility. Each construct has 4 items (e.g., REP is appealing, REP seems suitable), from 1: Strongly disagree to 5: Strongly agree. ATOD and associated outcomes (behavioral outcomes): We will use items from CDC's Youth Risk Behavior Survey,[69] that includes measures for substance use including tobacco, marijuana, alcohol, and other drugs, and associated consequences (e.g., injury, DUI). We will also assess MMH-specific constructs using an adapted survey of MMH from O'Neill et al.; this includes drug refusal skills (e.g., identifying proper responses to peers when offered drugs) and self-management skills (e.g., identifying appropriate ways to express anger or frustration).[27] Implementation factors and outcomes (qualitative data): We will use the CFIR interview guide[57] to guide qualitative investigation of using REP to deliver MMH; this will focus on factors identified in Table 5, and adapted based on results from Aim 1. In addition, we will ask for in-depth feedback on acceptability, feasibility, and appropriateness from teachers regarding the delivery of MMH using REP. The questions are guided by the constructs listed in Table 4. **Data analytic approach.** Implementation outcomes: We will assess adherence using the composite adherence score. We will evaluate appropriateness, acceptability and feasibility using data from the teacher survey and interviews. Qualitative data will be analyzed as described in Aim 1 and we will triangulate the findings using descriptive data from the Weiner et al. measures.[53] Behavioral intervention effectiveness: Given the sample size associated with this pilot study, we will focus on estimating intervention effects, variance of the treatment effect, and directions of associations with outcomes of interest as opposed to statistical significance.[70] We will use generalized linear models to investigate the effects of implementation condition on ATOD use and related consequences at 3 months post-intervention, controlling for demographics and baseline functioning, and accounting for clustering by school. We will test the overall main effect of implementation condition on outcomes and investigate mean values of outcomes (e.g., substance use) by condition.[71] We will also investigate ATOD use by sex to determine if the intervention condition had differential effects. Finally, we will use variance estimates of outcomes to inform sample size calculation for a larger, multi-site effectiveness study that will be the focus of a future R01 proposal. **Expected outcome:** We expect that enhanced REP will increase adherence to the MMH curriculum compared to standard REP and teachers will report REP is feasible, acceptable, and appropriate to guide MMH delivery. We also expect that students in schools with enhanced REP will report less ATOD use than those with standard REP.

Aim 3b: Procedures. Guided by Costs of Implementing New Strategies (COINS), we will monitor the activities listed in Table 7 to estimate implementation strategy costs. The study team will track time for labor costs-most of the resource/costs. This will include tracking time in study team activities as well as time logs for community partners to track REP activities. The study team will also track and compile all non-labor costs. **Measures.** Costs: Implementation cost measures are guided by COINS and include indirect and non-labor costs.[72] We will measure implementation costs using available cost data from the school district, summary data from previous empirical studies on implementation costs, and routinely available cost data using market prices.[45]

Table 7: Intervention costs informed by Costs of Implementing New Strategies (COINS)

Phases	*Description*	*Activities*	*Resource/cost type*
Pre-implementation	*Identify barriers*	*Stakeholder meetings*	*RF, PM/ labor costs*
		Survey	*Secondary data, PM, RF/labor costs*
		Interviews	*Secondary data, PM, RF/labor costs*
	Draft package	*Identify adaptations*	*RF, CP/ labor costs*
		Identify core elements	*RF, CP/ labor costs*
		Program adaptations: online	*P/ labor costs*
			domain costs/nonlabor
		Program adaptations: manual	*PM, RA/ labor costs*
	Pilot test package	*refinement*	*RF, RA, PM/ labor costs*
	Orientation	*identify schools*	*RF, PM, CP/ labor costs*
		Logistics of delivery	*RF, PM/ labor costs*
		Refine training	*RF, CP/ labor costs*

		Identify EF IF	*CP/ labor costs*
	Training	*Staff training: intervention*	*RF, CP/ labor costs* *travel costs, RF/nonlabor* *training compensation/nonlabor* *space/nonlabor*
Implementation			*hosting/nonlabor*
		Disseminate package	*PM/labor costs*
	Technical assistance	*Internal facilitation*	*CP/ labor costs*
		External facilitation	*PM/labor costs*
	Evaluation	*Interviews*	*RF, RA/labor costs* *remuneration/nonlabor*
		Survey	*RF, RA/labor costs* *remuneration/nonlabor*
	Refinement	*Analyze data*	*Secondary data, PM, RF/labor costs*
		training, package refinement	*PM, RF, CP/labor costs*
	Organizational		
Sustainability	*changes*	*Recommendations for REP*	*PM, RF, CP/labor costs*
		Reproduce package	*CP/ labor costs*
		Continue to refine	*CP, RF/labor costs*

PM: project manager; RA: research assistant; RF: research faculty, CP: community partner, P: programmer
Table adapted from Saldana et al[44]

Data Analytic Approach. I will report summary statistics for implementation costs including mean costs with 95% confidence intervals. All costs will be adjusted to current year US dollars. I will estimate costs of REP and E-REP using the cost data, with the comparator strategy being REP. The outcome will be change in reported ATOD use. I will use net costs (net increase in costs from E- REP compared to REP) and net effectiveness (net decrease in ATOD use for E-REP versus REP) to calculate the incremental cost-effectiveness ratio for student outcomes: $\frac{Cost_{E-REP} - Cost_{REP}}{Outcome_{ATOD\ use\ E-REP} - Outcome_{ATOD\ use\ REP}}$. I will conduct a one-way sensitivity analysis on all input parameters to provide estimates of the costs and incremental cost-effectiveness to decision-makers. The analysis will include 2- and 3-way sensitivity analyses on the parameters most sensitive in influencing the cost-effectiveness ratio.[6] **Expected outcome**: I expect that students in the enhanced REP condition will report greater reduction in ATOD use relative to dollar spent on the implementation strategy compared to those in standard REP.

Missing data. We will conduct tests of selective attrition as needed to explore if those lost to follow up and with missing data on outcomes differ from those retained. In addition, we will use approaches such as multiple imputation and full-information maximum likelihood as needed to address missing values on model predictors to avoid biases due to complete case analysis.[74] Full-information maximum likelihood and multiple imputation are both preferred over deletion approaches or nonstochastic imputation methods (e.g., mean imputation).[74,75]

Potential Problems and Alternative Strategies: Enrollent biases: Schools, teachers, and administrators that support the MMH standardized curriculum may be more likely to enroll in the study, which may create enrollment bias; I will work with school district partners guided by my mentorship team and training in community-engaged research to reduce risk of enrollment bias. Through effective research-community collaborations, we facilitate enrollment of schools best suited to the study. Self-report biases: Participants, students, and staff may be influenced by social desirability biases. To minimize this, study staff and participants will be clearly informed of confidentiality and anonymity procedures, sensitive questions will be asked via a self-administered survey, and interviews will take place in private areas where others cannot overhear. School/district confidentiality: We will work with our partners at the GISD and local school districts to address potential concerns to school/district level confidentiality. All formal reports will only include aggregated information and be reviewed by district partners prior to dissemination.