



Research paper

## Design and outcome measures for the AB InBev Global Smart Drinking Goals evaluation



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## ABSTRACT

We describe the rationale for and design of an independent evaluation of the Global Smart Drinking Goals (GSDG) program. The primary purpose of this program, supported by the AB InBev Foundation, is to reduce harms associated with alcohol use by 10%. Our evaluation focuses on the effects of prevention strategies sponsored by the Foundation that are being implemented in six city pilots located in as many countries. These strategies are designed to reduce heavy episodic drinking, underage drinking, drink driving, and alcohol-related violence. Each city pilot has been matched with a comparison city in which the GSDG program will not be implemented. In this quasi-experimental community trial, we will assess each city pilot's progress toward reaching its harm reduction goals, relative to its comparison city, by means of annual adult and youth surveys. We will then supplement these analyses with the use of pertinent local archival data, where available. We discuss several challenges related to this evaluation and its quasi-experimental design. These include operating in a fluid and unpredictable environment in regard to the implementation, adaptation, and (on occasion) abandonment of the prevention strategies selected by each city pilot. We also discuss issues concerning our decision to accept funding from the alcohol industry and the measures we have taken to ensure the independence of our evaluation.

### 1. Introduction

Alcohol use constitutes a significant public health concern worldwide. It has been associated with a wide range of adverse outcomes, including dependence and other mental and behavioral problems, liver cirrhosis, cancers, cardiovascular disease, car crashes and fatalities, and intentional and unintentional injuries [1]. Globally, alcohol use has been identified as the seventh leading risk factor for death and disability adjusted life years (DALYS<sup>1</sup>), accounting for about 4% of deaths among females and 12% of deaths among males aged 15–49 years [2].

In response to this ongoing public health problem, AB InBev (ABI), the world's largest brewer, has committed to supporting United Nations (UN) Sustainable Development Goal 3.2, and the parallel World Health Organization goal, to reduce the harmful use of alcohol by at least 10% through the implementation of evidence-based programs, practices, and policies [3].

That said, there has been an extensive debate in the research literature as to whether *any* use of alcohol can and should be considered harmful. Most recently, Connor's [4] summary of available

epidemiological evidence concluded that the association between alcohol use and cancer is strong, and that the current belief that low levels of use are protective against cardiovascular disease is no longer tenable. Other investigators are also responding skeptically to claims of the protective nature of moderate drinking [e.g., 5]. The preponderance of evidence now suggests that any apparent positive effects on cardiac health are offset by adverse effects on cancer, cirrhosis, and injury [6–8].

#### 1.1. Global Smart Drinking Goals

The evaluation described in this article focuses on strategies and activities intended to address ABI's Phase 1 Global Smart Drinking Goal (GSDG) of reducing alcohol-related harms by 10% in six city pilots. ABI has committed to support multiyear community trials in Leuven, Belgium; Brasilia, Brazil; Jiangshan, China; Zacatecas, Mexico; Columbus, Ohio, USA; and Alexandra Township, Johannesburg, South Africa. To guide, support, and facilitate the work in the city pilots and to bring scientific rigor to the work of achieving other GSDG-related efforts, it created the AB InBev Foundation [9] and made a commitment to provide it with \$150 million over ten years. Among the responsibilities of

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**Abbreviations used in this article**

ABI	AB InBev
BAC	Blood Alcohol Concentration
DALYS	Death and Disability Adjusted Life Years
GBD	Global Burden of Disease
GSDG	Global Smart Drinking Goal
MADD	Mothers Against Drinking and Driving
NIH	National Institutes of Health
NAB	No-Alcohol Beer
PIRE	Pacific Institute for Research and Evaluation
SBI	Screening and Brief Intervention
UN	United Nations
WHO	World Health Organization
YHL	Years of Healthy Life

the Foundation are to: (a) provide support to enhance the functioning of a steering committee (steerco) in each city pilot that was created by ABI for this purpose; (b) provide technical assistance to guide the steerco in selecting and implementing prevention strategies that are likely to make a substantive contribution to reducing harmful drinking; (c) reviewing each steerco's annual program plans; (d) fund those intervention strategies in each steerco's plan that are expected to contribute to meaningful reductions in harmful drinking; and (e) support an independent monitoring and evaluation effort. Note that steerco's are free to implement, with local support, other intervention strategies not funded by the Foundation.

ABI's goal is to achieve a 10% reduction in alcohol-related harm in each city pilot by the year 2020. However, target dates have been postponed for several steerco's that either organized slowly or substantially modified or replaced their original interventions because Foundation-funded technical assistance led them to realize that their nascent interventions were unlikely to yield the population-level effects desired. Once the project is complete, the six-city pilot study is intended to serve as a model for the worldwide dissemination and implementation of effective programs, policies, and practices to reduce alcohol-related harms.

To conduct an independent evaluation of the effects of the six-city pilot program on harmful drinking, the Foundation contracted with HBSA, a supporting organization of the Pacific Institute for Research and Evaluation (PIRE). In this paper we describe the six-city pilot program and our evaluation plan.

### 1.2. Prior community prevention trials

Over the past two decades, several community trials in the United States and elsewhere have tested efforts to prevent unhealthy drinking or harms related to drinking. Unlike the Foundation's trial, the great majority of prior trials have focused on high-income countries. Although community trials sometimes have been defined as focusing on primary prevention [10], we saw no reason not to include secondary prevention as well: in this case, reduction of risky drinking and alcohol-related harms. Prior alcohol-related community trials that comprise a mix of both primary and secondary prevention strategies include the "Saving Lives Program" [11], "Communities Mobilizing for Change on Alcohol" [12], the "Community Trials" project [13], "Operation Safe Crossing" [14], the "Sacramento Neighborhood Alcohol Prevention Project" [15], the "Stockholm Prevents Alcohol and Drug Problems" program [16,17], the "Safer California Universities Project" [18], the "Alcohol Action in Rural Communities Project" [19], and the "Oregon Reducing Access to Alcohol Project" [20]; for a review, see Stockings and colleagues [21]. Collectively, these studies address reductions in harms in a variety of contexts by using a range of intervention strategies—for example, media

advocacy, education, policy enforcement (including sales to minors and drink driving), responsible beverage service, and other strategies to prevent over-consumption. Many of these trials depended in part on the success of local community organization and mobilization, often through coalitions organized or co-opted for that purpose. Typically, selections of appropriate and often multiple strategies have followed an examination of local data to identify the nature and extent of alcohol-related harms in the community, the populations affected, and the physical and social contexts in which these harms occurred. Most were evaluated using designs that involved comparing matched intervention and comparison communities. The review by Stockings et al. [21] indicates that multi-component community interventions have generally achieved only modest effects on harmful alcohol use and related consequences, indicating the need for further research to improve the implementation of population-level evidence-based interventions and the identification of promising prevention strategies. Moreover, almost all multi-component community trials to date have been conducted in high-income countries.

## 2. Interventions

### 2.1. Overview

Our evaluation focuses on the aggregated effects of multi-component interventions on *per capita* alcohol use and related harms in the Foundation's six city pilots, relative to six matched comparison cities. Intervention components include screening and brief interventions by health providers and other evidence-based interventions (e.g., enforcement of drink-driving and underage drinking laws), as well as interventions that currently lack evidence of effectiveness (e.g., that seek to prevent alcohol-related sexual assault) but that local steering committees have deemed sufficiently promising to warrant implementation.

In each city pilot, ABI originally signed a memorandum of understanding with local and, in some cases, regional and national governments pledging to work jointly toward the achievement of the company's GSDGs and its global commitment to supporting the UN's and WHO's goals to reduce harmful drinking by 10%. At the outset of the project, the activities of the city pilots were selected, guided, and implemented by their respective steerco's. The composition of these coalitions varies but always includes representatives of the city's local or regional government and the local ABI company affiliate (i.e., a brewer or distributor), which may provide independent funding to implement steerco-sponsored strategies. Many steerco's also include public health, health services, and law enforcement leaders, as well as local academics.

City pilots have also varied considerably as to when they initiated prevention policies and practices. In Brazil, China, and Mexico, programming began before either the evaluation team or technical assistance providers were in place. Brazil, for example, contracted with a quasi-public corporation to design and implement an evidence-based program focusing on road safety and screening and brief intervention (SBI) [22], then secured funding both from ABI and from senior government officials who were represented on the steerco. In Mexico, to prevent alcohol sales to underage youth, the government and ABI embraced a joint legislative and enforcement agenda that included reducing the operating hours of bars and adopting a mystery shopper program and supportive training of package store operators. In Mexico and China, government officials and academics on the steerco's also secured ABI funding to implement or expand a variety of homegrown programs that lacked an evidence base related to reducing harmful alcohol use at the population level.

Concerned that the interventions implemented often lacked evidence of effectiveness as well as the reach and penetration needed to achieve the targeted reduction in harms, ABI ceded control of most steerco funding and guidance to the Foundation, which is staffed by public health professionals. The Foundation then contracted with HBSA and several technical assistance providers. Chief among these was Ohio State

University, which, in conjunction with the University of Southern California and San Diego University, developed a webinar-driven toolkit of evidence-based practice. The toolkit describes effective population-level interventions that are expected to have the broadest reach (and thus impact), as well as effective individual-level interventions.

The Foundation recently implemented a set of procedures to increase the likelihood that the steerco's will achieve the 10% GSDG target. To select the suite of programs and policies that the steerco's will implement, each one now participates in a planning workshop in collaboration with Foundation personnel. The process includes the use of data to identify the population(s) to be targeted, the development of program logic models, and close consultation with the Foundation's technical assistance providers to ensure that the interventions are either evidence-based or, in regard to harms that lack a strong evidence base, constitute promising practices. Some steerco's also have developed or expanded funding for local interventions advocated by government or academic partners, often drawing in supplemental funding from the government or the ABI region.

In conjunction with ABI's Business Intelligence unit (an internal consulting arm of ABI), the HBSA evaluation team has also developed a set of tools to help inform the decisions that ABI, the Foundation, and the steerco's make concerning the selection of various prevention-related programs and policies. These tools provide systematic and comparable information on the evidence base, likely impact, uncertainties, and complexity of interventions that the steerco's are considering, and facilitate interpreting that information within the context of the likely cost of the intervention. To further inform each steerco's decision-making, HBSA provides its baseline survey and administrative data on drinking levels and patterns, alcohol expectancies, and alcohol-related harms among youth and adults. The baseline data also assesses adults' attitudes toward strengthening alcohol control policies, such as increasing the minimum legal drinking age or the enforcement of underage drinking and drink-driving laws.

In addition, the Foundation has developed screening criteria to guide its own decision-making as to whether to fund the particular interventions that the steerco's propose. Assessment criteria embedded in this tool include: the strength of the intervention's existing evidence base; its appropriateness given the local social, political, and cultural context; community readiness and availability of existing resources required for implementation; whether the group targeted is well-defined and what proportion of it is likely to be reached by the intervention; and (of greatest importance) the likelihood that the intervention, if successfully implemented, would contribute at least 2% to the 10% harm reduction goal.

## 2.2. Key interventions implemented or funded and in advanced planning

This section describes the key interventions that the city pilots are implementing or planning, and reflects program status as of July 2019. Environmental interventions targeting *on-premises establishments* are underway or in early implementation stages in two cities, and others are exploring this approach. The local ABI affiliate on the steerco worked with the regional government of Zacatecas state to pass and publicize earlier closing hours for bars. Interventions designed for *off-premise establishments* include earlier closing hours and "mystery shopper" programs in the twin cities of Zacatecas/Guadalupe in which underage youth attempt to purchase alcohol from convenience stores and, depending on the outcomes of the attempts, the stores' owners are rewarded or penalized. In the twin cities, the local ABI affiliate owns more than 50 franchise-operated convenience stores that exclusively stock the beer it distributes. The affiliate there has replaced operators of stores that repeatedly sold to minors. The Alexandra steerco has discovered disused bylaws banning underage sales and is launching a compliance campaign.

*Traffic and road safety interventions* include a public statement by ABI that it will not oppose worldwide efforts to lower the legal driver blood

alcohol limit from 0.08 g/dL to 0.05 g/dL [23]. In addition, the steerco in Columbus is collaborating with Mothers Against Drinking and Driving (MADD) to increase ignition interlock use, which is MADD's top legislative priority for the state. The steerco's in Zacatecas, Alexandra, and Columbus are all working to increase drink-driving enforcement, often through roadside breath testing and expedited offender processing programs. In addition, the steerco's in Brasilia and Alexandra are identifying crash hot spots and making them safer. The Columbus steerco has also promoted designated driver programs.

*Media campaigns* can either stand alone or support other interventions. As an integral part of their global GSDG initiative, ABI and ABIF have launched campaigns in several city pilots to raise public awareness of the nature and extent of problems related to alcohol consumption and to inform the public, and encourage public acceptance, of the prevention strategies that participating cities are promoting. These media campaigns, which employ a variety of strategies, are a component of ABIF's global effort to change social norms about drinking in order to reduce harmful drinking. For example, the campaign associated with the mystery shopper program in Zacatecas includes stickers on cooler doors announcing that store clerks will not sell alcohol to minors and prominently displays posters about the dangers of underage drinking.

*Screening and brief intervention (SBI) and other individual interventions.* Prior to ABI's establishment of the Foundation, the Company contracted for support of the adoption of SBI in the city pilots in Jiangshan and Brasilia. The SBI intervention used has a strong evidence base. It involves screening in primary health care contexts using the AUDIT-C, which comprises a brief set of questions that assesses an individual's risk of harmful drinking practices, followed by motivational interviewing for those who screen positive [22]. This model has been implemented or is in advanced planning, with local variations, in all city pilots except Columbus. Columbus is instead administering an electronic version of SBI to students at four local universities and seeking to require that freshmen access the associated web-based application. Both Brasilia and Zacatecas are basing school-based programs on *Intervención Breve*, which is based on *Entrevista Motivacional* [24].

Although *family-based interventions* have tended to yield positive effects for the families exposed to the program [25], their reach is modest. The Zacatecas steerco is conducting a pilot of *Communities that Care* [26], which has been adapted as "Empresas que se Cuidan" (Companies that Care) to focus on families in several work settings. The Brasilia steerco is piloting use of the *Strengthening Families Program* [27,28].

Unproven efforts include *school-based interventions* in Zacatecas, which initially included brief, locally developed school curricula, pamphlets, high-tech media, plays, and the deployment of school psychologists. These have recently been phased out or are now supported by local ABI affiliates, all of which are free to implement any strategies that they believe will serve their communities. The Foundation has advised the steerco's, however, that it will strongly focus its financial support on initiatives that have a demonstrated evidence base.

*Violence prevention interventions.* Because baseline data showed that alcohol-related violence constitutes a much larger component of aggregated alcohol-related harms than either underage drinking or impaired driving, several steerco's have sought to focus resources on violence prevention. Alexandra plans to adapt a labor-intensive coaching-based intimate partner and sexual violence intervention that has proven effective in Africa and focuses in part on alcohol, probably SASA! [29], which evaluations have demonstrated to have a community-wide effect. SASA!, which means 'now' in Kiswahili, is an acronym for the intervention's steps: Start, Awareness, Support, and Action. Brasilia is developing an environmentally oriented program focused on targeted enforcement and related supply-side interventions to reduce consumption in violence hotspots. Because of the scarcity of evidence-based interventions focused on alcohol-related violence, ABIF has funded violence prevention experts to develop an intervention that the Jiangshan steerco can pilot.

### 3. Evaluation design

#### 3.1. Comparison sites

The evaluation comprises a set of six quasi-experimental community trials. Prior to HBSA's involvement in the evaluation, ABI had selected all but one of the intervention cities, and two of the comparison cities had been selected by the Gallup organization, which has collected survey data in many of the sites. We retained two of the comparison cities that Gallup had selected, Aguascalientes, Mexico (for the aggregated Zacatecas/Guadalupe city pilot) and Lanxi, China (for the Jiangshan city pilot). We replaced comparison sites that primarily used a different language than the treatment site (Belgium), were simply an untargeted neighborhood within the intervention city (Brasilia), or were governed by markedly different state alcohol laws (Columbus). Based on comparable population size, ethnicity, socio-economic status, the presence of such key characteristics as a major university, and steering agreement about their similarity, we picked as comparisons sites Hasselt, Belgium (for the Leuven city pilot); Planaltinas, Brazil (for the aggregated Ceilândia, Taguatinga, and Plano Piloto city pilot); Cincinnati, Ohio (for Columbus, Ohio); and Tembisa, South Africa (for Alexandra Township).

#### 3.2. Key outcomes

In all participating communities—both the intervention (pilot) and comparison cities—the evaluation's two *primary outcomes* are (1) *per capita* alcohol consumption and (2) aggregated level of harms related to drinking. We are assessing the first because it is the indicator that the WHO, the UN, and GBD use to assess population-level efforts to reduce harmful use of alcohol. We are assessing aggregated level of harms related to drinking in terms of years of healthy life (YHL) saved [30], which equates to the disability-adjusted life years (DALYs) prevented. In Section 3.5 we specify how we will calculate YHL saved.

The *secondary outcomes* that we will measure, and which when considered in aggregate constitute our YHL saved, include underage drinking prevalence, alcohol related crashes, physical violence, sexual violence, property crime, and mortality. Table 1 displays our measures of constructs related to both adult alcohol use and alcohol-related harms, which are consistent across surveys administered in the city pilots. We also will assess other survey-based secondary measures including: the number of drinks adults consume beyond an initial drink per drinking occasion (i.e., their first drink is uncounted, paralleling [31]; the frequency and quantity of heavy episodic drinking; drink driving and riding with a drinking driver; alcohol-attributable injuries; and subsequently regretted alcohol-involved sex.

One of ABI's other GSDG goals is to increase the consumption of no- and low-alcohol beer (NABLAB, less than 0.5% alcohol content) by increasing to 20%, by 2025, the proportion of the company's sales of NABLAB relative to its total beer sales [32]. A recent technological change to NAB products has ensured that they are truly alcohol-free and thus may be legal to sell to minors in some countries. Our evaluation will monitor the prevalence of the consumption of NAB in those city pilots where it is available, by examining the change in grams of pure alcohol consumed prior to and following the beverage's introduction, after accounting for the market share of the product and for alcohol content changes elsewhere in ABI's product portfolio. Finally, we will also monitor whether NAB is either being advertised or sold to (and consumed by) minors, in which case it may serve either as a gateway to youth drinking or as a potentially illegal mechanism to develop youth awareness of and loyalty to an ABI brand.

#### 3.3. Data sources and collection

*Surveys.* We will primarily rely on annual surveys to assess progress towards the Foundation's GSDGs. We will analyze trends over time of key outcomes in each city pilot compared to its matched comparison

**Table 1**

Adult measures of alcohol use and alcohol-related harms.

Alcohol Use
Have you ever had a whole alcoholic drink - more than a sip or a taste, such as beer, wine or distilled spirits? (1 = Yes, 2 = No)
During the LAST 12 MONTHS, did you have a whole drink (more than a sip or a taste) of any kind of alcoholic beverage such as beer, wine, champagne, distilled spirits, like vodka, tequila, whiskey ... ? (1 = Yes, 2 = No)
During the LAST 12 MONTHS, how often did you have a drink with alcohol in it, such as beer with alcohol, wine, liquor or spirits? Was it at least once a week, at least once a month, less than once a month, or never? (1 = At least once a week, 2 = At least once a month, 3 = Less than once a month, 4 = Never)
Considering just the past 30 days, have you had a whole alcoholic drink (more than a sip or a taste) with alcohol in it, such as commercial or homemade beer, wine, liquor or spirits?
In the LAST 30 DAYS, did you drink:
• Beer or homemade beer
• Any type of wine or champagne?
• Flavored alcoholic beverages sold in cans or bottles, such as..?
• Distilled spirits, such as..?
• Homemade alcohol - that is, alcohol NOT made in a factory, such as ... ?
In the last 30 DAYS, on how many DAYS did you drink:
• beer or homemade beer?
• any type of wine or champagne?
• flavored alcoholic beverages sold in cans or bottles, such as ... ?
• distilled spirits, such as ... ?
• homemade alcohol - that is, alcohol NOT made in a factory, such as ... ?
Please think about a typical day when you drank ... .. in the last 30 days. How many drinks of that alcohol type did you usually have on a day when you drank it?
• beer or homemade beer
• any type of wine or champagne
• flavored alcoholic beverages sold in cans or bottles
• distilled spirits
• homemade alcohol
What was the greatest number of whole drinks of an alcoholic beverage you had on any ONE day in the last 30 days? A whole drink is a small bottle (longneck) or can of beer, a glass of wine, a shot of liquor, or a whole mixed drink.
On how many of the last 30 days did you have at least X whole drinks of an alcoholic beverage in a 2-h period? Write the actual number of days:
On how many of the last 30 days did you have at least 6 whole drinks of an alcohol drink in one day?
Now changing to think only of the LAST 7 DAYS, on how many of the LAST 7 days did you have a whole alcoholic drink (more than a sip or taste)?
<b>Alcohol-related Problems</b>
During the past 12 months, how often did you do each of the following? Rode in a car or other motor vehicle with a driver who you thought had too much alcohol to drink
Please think about the times you drank alcohol in the past 12 months. How many times, if any, did each of the following things happen to you WHILE YOU WERE DRINKING in the past 12 months?
• You drove a car or other motor vehicle, like a motorcycle or scooter, after having too much to drink
• You hit, punched, slapped or drew a weapon on someone while you were drinking in the past 12 months
• Someone hit, punched, slapped or drew a weapon on you
• You had an injury that required medical attention
• Someone sexually fondled or grabbed you without invitation.
• You sexually fondled or grabbed someone without invitation
• You had unintended sex that you later regretted
• You had sex with someone that didn't want it
• You damaged someone's property.
• You took something that didn't belong to you
• You were robbed
• You were arrested or had other legal problems while you were drinking in the past 12 months
• You tried to commit suicide

Response options: 1 = 0/None, 2 = 1–2 times, 3 = 3–5 times, 4 = More than 5 times.

site.

Before we became involved in the evaluation, ABI health policy staff collaborated with the Comisión Nacional contra las Adicciones (CONADIC) in Mexico to design a survey of adults and youth that was fielded in Zacatecas in late 2015. Subsequently, in the other city pilots ABI contracted with the Gallup organization to develop, pilot, and administer adult and youth surveys to assess a variety of outcomes

including alcohol consumption and impaired driving. The original surveys, which will serve as baseline data for our analyses, were fielded in late 2016 and included approximately 1500 adults in each city pilot and a comparison site, except for South Africa, where an intervention city (Alexandra) has only recently been identified.

Starting in 2018, we began fielding repeated annual cross-sectional surveys in Belgium, Brazil, China, and South Africa, both to household-based adult and school-based adolescent samples. In Columbus, we instead are only fielding a mail survey of adults because the school system there never surveys its students. In Mexico, the federal government dictated use of the 2015 survey instrument in 2018. Starting in 2019, we expect to field a survey that is a hybrid drawn from that instrument and our own.

Initial power calculations suggested that 1500 completed adult household surveys for each intervention and comparison city, assuming a *priori* an intra-class correlation (ICC) of 0.010, would be sufficient to detect a 9% or greater reduction in harmful drinking with a power of 80%. We revisited our sample size calculations using the baseline surveys' intra-class correlations for alcohol consumption and related harms (ICCs = 0.00-0.035). That allowed us to reduce annual sample sizes in Brazil, China, and the U.S. We used a similar approach to calculate the number of completed school-based student surveys we would need to attain 80% power to detect a 9% or greater reduction in drinking harms. These analyses indicated that we would need 1500 surveys per city pair.

Our surveys use a set of common core measures. Both the adult and youth surveys cover the following key domains: the consumption of different types of alcohol and non-alcoholic beer, binge episodic drinking, drinking reasons and contexts, protective behavioral strategies, driving after drinking and other alcohol-related harms, attitudes towards alcohol use and alcohol-related policy, prescriptive and descriptive norms concerning alcohol use, alcohol use disorder, and respondents' demographic characteristics. Table 2 displays examples of

both the activities that the city pilots are planning to implement in 2019 and the constructs that we will use to measure their effects.

**Local and international archival data.** We are supplementing the annual survey data collected, where feasible, with longitudinal local archival data (e.g., police-reported crime or crashes, hospital-treated injuries, and mystery shopper programs) of sufficient quality. We also are using Global Burden of Disease data, notably on murders, life-years lost per murder, and the estimated burden of disease associated with various levels of alcohol consumption. We will use the archival data to assess likely intervention effects on alcohol-related harms.

**Supplemental data.** We also will collect additional data in response to local opportunities to evaluate promising interventions that address specific outcomes. For example, in Zacatecas and its comparison city, we are administering a variety of data collection activities to evaluate a 2018 Zacatecas law mandating earlier closing hours for the sale of alcohol at on- and off-premise establishments. These include pedestrian intercept and roadside surveys to estimate blood alcohol levels; interviews with local bar owners, servers, bar security staff, police, and emergency medical technicians (EMTs) to gauge their response to changes in these laws and regulations; and late-night checks of both on- and off-premises establishments to determine compliance with the new laws. We are also using underage purchase data to evaluate a mystery shopper intervention implemented by Grupo Modelo that provides feedback and imposes sanctions on off-premises Modelorama outlets that sell beer to minors. In some cases (as in the Belgian city pilot), steerco have contracted with local universities to evaluate youth interventions that lack a strong evidence-base.

### 3.4. Process data

We are conducting regular interviews with key stakeholders, including members of each steerco. We matched a process evaluator to

**Table 2**  
Examples of city pilot strategies, by pertinent survey constructs.

Constructs measured	Alcohol use			Alcohol concerns		Alcohol sources	Alcohol policy	Alcohol-related harms			
	Under-age drinking	Heavy episodic drinking	Quantity frequency (excluding no-alcohol beer)	Drinking reasons & expectancies	Talked with health care provider about alcohol use	AUDIT & CAGE	Sources of alcohol	Alcohol policy enforcement	Physical violence	Sexual violence	Drink driving
Evidence-based strategies implemented											
Road and traffic safety; e.g., ignition interlock mandates, driver BAC testing, safety improvements at crash hot-spots		X					X	X			X
Earlier closing hours for on- and off-premise establishments		X	X			X		X	X	X	X
Screening and brief intervention (SBI & E-SBI)		X	X		X	X			X	X	X
Responsible beverage service to terminate service to "drunk" patrons	X	X	X			X			X	X	X
Mystery shopping to prevent sales to minors	X	X	X				X	X	X	X	
School-based or family-centered youth drinking intervention	X	X	X	X			X		X	X	
Prevent alcohol-related interpersonal violence		X	X						X	X	

each site who monitors the prevention interventions implemented there and identifies other events and activities in both the pilot and comparison cities that might independently affect the evaluation's outcomes. The monitoring effort includes not only the strategies themselves, but whom they have targeted, when they were implemented, and for how long. We are also soliciting information concerning ongoing adaptations of the interventions. To this end we are interviewing the chair of each steering committee. We are also interviewing key informants in both the intervention and comparison cities to secure information concerning other activities that might independently affect rates of alcohol use and related harms. In addition, we are performing an environmental scan of local and regional policies and practices that may facilitate or constrain harms related to alcohol use, including closing hours for on- and off-premises establishments, server and convenience store clerk training in responsible alcohol service and sales, and law enforcement activities associated with the prevention of harms. Finally, we are monitoring the content and reach of media that publicize the interventions, changes to existing alcohol-related laws, and events (such as car crashes) that are attributed to alcohol consumption.

**Human subjects concerns.** All HBSA-sponsored data collection procedures are approved by HBSA's Institutional Review Board (IRB). In-country approvals related to the collection of survey data have also been obtained as appropriate. Gallup's IRB has approved all procedures related to data that the company collected for ABI and HBSA.

### 3.5. Analysis plan

Our evaluation focuses on each city pilot's progress toward its goal of a 10% reduction in harmful use of alcohol, within the performance period specified, as measured in years of healthy life (YHL) saved. Specifically, we will estimate the YHL saved as a function of alcohol consumption and the number of alcohol-related incidents occurring for each type of harm in each city pilot relative to its comparison city. As [Table 3](#) specifies, we assigned preliminary YHL values, primarily drawn from the Global Burden of Disease results tool or the literature, to a variety of alcohol-related harmful events such as excess consumption, crashes, and assaults. The largest YHL gain comes from preventing a death and the smallest from preventing a property crime. For each intervention, we will compute the percentage of harm from drinking (measured in YHLs lost) that it addresses and the percentage reduction it achieves. That computation will account for reach, i.e., the portion of those at risk who are exposed to the intervention. Miller and Ringwalt (working paper, 2019) estimate the baseline YHL loss per year and per harmful event by city.

Consider two examples. First, suppose SBI in primary care reached 10% of the drinking population. An estimated 80% of those screening positive typically would receive the recommended brief intervention [22,33]. Assume the brief intervention reduced consumption among excessive drinkers by 12%, as one meta-analysis suggests [34,35], with a proportional reduction in harmful alcohol use. Then the SBI program would result in a 0.96% reduction in harmful alcohol use ( $10\% * 80\% * 12\%$ ). Second, suppose Zacatecas launched intensive random breath testing of drivers, achieving the 15% reduction in drink-driving crashes historically associated with that intervention [36]. Computed from the 0.668 YHL loss per crash from [Table 3](#), drink-driving accounts for an estimated 8.9% of YHL loss from harmful alcohol use in Zacatecas [37]. So, the checkpoint program would be expected to produce a 1,34% reduction in harmful alcohol use ( $15\% * 8.9\%$ ).

**Primary outcome analyses.** Our analysis strategy is designed to assess the overall or joint effects on our two primary outcomes of all the prevention strategies implemented within the city pilots. To that end, for each city pair, we will conduct multi-level analyses of changes over time in alcohol consumption and in YHLs lost to harmful alcohol use. While we primarily will analyze data for individual city pairs, we also will experiment with cross-site analyses that account for clustering of individuals within communities, treating our nested communities as

**Table 3**

Preliminary estimates of years of healthy life (YHLs) associated with various harm-related incidents in the U.S., with country-specific estimates identified.

Type of harm-related incident	YHLs per US incident <sup>a</sup>	Source
One crash death (country-specific)	47.7	Global Burden of Disease results tool
One murder (county-specific)	53.1	Global Burden of Disease results tool
One alcohol use disorder (country-specific)	0.102	Global Burden of Disease results tool
One drink driving nonfatal injury	0.853	Zaloshnja et al. [53]
One drink driving crash (country-specific)	0.668	Zaloshnja et al. [53]
One drink driving crash without injury (country-specific)	0.034	Zaloshnja et al. [53]
One drink driving trip (country-specific)	0.00085	Zaloshnja et al. [53]
One unintentional non-crash injury (country-specific)	0.128	Corso et al. [55]; Global Burden of Disease results tool
One fetal alcohol syndrome birth (country-specific)	0.302	Miller & Hendrie [52]; Global Burden of Disease results tool
One medically identified suicidal act (country-specific)	3.67	Global Burden of Disease results tool
One violent interpersonal crime	0.255	Miller et al. [56,57]
One physical assault	0.110	Miller et al. [56,57]
One robbery	0.123	Miller et al. [56,57]
One attempted or completed rape	0.548	Miller et al. [56,57]
One unwanted sexual touching	0.055	One-tenth of rape
One theft	0.018	Miller et al. [56]
One case of vandalism	0.0055	Miller et al. [54,55]
Consumption of 1000 drinks by continuing binge drinkers (country-specific)	0.057	Computed from total YHLs lost
One year of underage drinking (country-specific)	0.080	Miller et al. [57]
Consumption of 1000 drinks by continuing underage drinkers (country-specific)	0.057	Miller et al. [57]

<sup>a</sup> Undiscounted per Global Burden of Disease conventions.

random effects and intervention condition (intervention or comparison) and time (e.g., survey wave) as fixed effects [38]. The analyses will contrast trends over time in each city pilot with its respective comparison site to examine differences in these trends at the local level, adjusting for any baseline differences and city demographic characteristics.

**Secondary outcome analyses.** Similar analyses will be applied to the survey-based and archival secondary outcome measures. As needed, supplemental focused studies will evaluate the effects of unique steering committee-initiated interventions on the specific outcomes they target (e.g., drivers' blood alcohol concentration (BAC) levels, sales of alcohol to minors, changes in social norms concerning the acceptability of alcohol use) and whether those changes are associated with gains in YHL. These analyses are intended to yield insight into whether the interventions might plausibly have caused the YHL gains observed.

## 4. Discussion

The community trial described here is one more in a long list of such trials that have focused on communities and used community-based processes to support, plan, and effect change. A distinguishing and controversial feature of the ABI GSDG program is the involvement of the alcohol industry in funding both the interventions in the city pilots and, through the foundation it established, the evaluations of their effects. Health researchers and advocates have expressed valid concerns about conducting research with funding from the tobacco, alcohol, gambling, pharmaceutical, and food industries [39–45]. These concerns include an apparent or real conflict of interest that can introduce biases into

research methodologies, findings, and interpretations that may help to advance the business interests of corporate funders as well as the financial interests of researchers.

HBSA is well aware of these and related concerns. In response, we have taken several steps to insure independence and transparency. First, we negotiated a contractual agreement with the AB InBev Foundation that gives us full independence in designing and conducting our study and in publishing its results in peer-reviewed journals without interference (although we do provide an opportunity to comment on a penultimate draft). Our contract also states explicitly that neither HBSA nor any individual investigators can be mentioned in any public communications by ABI to advance its business interests. In addition, to reduce the appearance that we might report favorable findings to maintain our relationship with our client, we secured a four-year contract, as opposed to a succession of single-year contracts with annual options to renew based on our performance and interim findings.

Second, to further insure transparency, we registered the GSDG evaluation with the National Institutes of Health (NIH; [ClinicalTrials.gov](https://clinicaltrials.gov) ID: NCT03262259). Third, we stipulated that, subject to approval by appropriate data owners and Institutional Review Boards, study data will be made available to other researchers through a data warehouse we have established for that purpose. This warehouse will allow colleagues to access the datasets we use in our evaluation and attempt to replicate or refute our findings or pursue other research topics. Where data sharing is not possible, upon request, we will run supplemental analyses and provide results.

Our ability to develop a compelling and focused evaluation design is necessarily limited by the developmental and fluid nature of the set of prevention strategies we are assessing, many of which have no evidentiary base, nor can they be described as theory-driven. A challenge has been to anticipate, as best we can, their wide variety and to include constructs in our cross-site surveys to measure their effects. Even then, the implementation of any given strategy is very likely to evolve over time and may be terminated if it is unlikely to achieve its desired effects. It is also entirely possible that some evidence-based strategies selected by the steerco are not being implemented with the fidelity required to achieve the effects recorded by prior evaluations, or fail to be sustained with the resources and oversight required.

Our task is even more complicated because at the inception of the GSDG initiative, and prior to the creation of the Foundation, the city pilots were given wide latitude as to the types of programs they selected (or developed themselves) and then implemented. Most of the steerco lacked a grounding in prevention science and were unaware that many strategies they planned to implement lacked evidence of effectiveness. The mid-course corrections spearheaded by the Foundation as a condition of its funding thus led to some wholesale substitutions of one program for another. Further, the Foundation has delayed the performance dates by which some city pilots are expected to meet their 10% reduction goals to allow them to strengthen their steerco and develop and implement effective strategies. Thus, our targets are constantly in motion. As [Table 2](#) demonstrates, the fit between the some of the strategies we have presented as examples and the constructs that we have included in our surveys is less than ideal. We do, however, have confidence in our measures of alcohol use and related harms and believe we can measure changes in the primary and secondary outcomes of interest.

The confidence with which we can attribute positive findings from our evaluation to the discrete interventions fielded by the city pilots is limited by the quasi-experimental design of our evaluation. A randomized design, of course, that comprised many more participating city pilots would have been preferable to the matched communities and would have obviated concerns about the largely covert effects of selection bias. In the context of community trials, however, randomization sometimes is infeasible [46–48]. The presence of our comparison sites does provide the opportunity to compare trends over time in the prevalence of our evaluation's key outcomes, and thus begin to address questions concerning the added benefits of the city pilots' interventions.

As in many other community trials [49], the implementation periods of many strategies administered by the steerco are relatively brief. While the Foundation has extended the performance deadlines of some of the city pilots, the effects of the interventions they are sponsoring may not manifest measurable population-level results. The brevity of the evaluation period (particularly for those steerco whose Foundation-sponsored activities will conclude in 2020 unless extended) suggests the need for steerco to focus on interventions with a strong evidence base that have immediate effects, like changes in policies concerning alcohol sales at on- or off-premise establishments or in drivers' permissible blood alcohol levels. However, as a non-profit organization the Foundation is constrained from funding any lobbying efforts. To the extent that the steerco fail to reach their targeted harm reductions, it may be due to structural forces well beyond their control, including local political considerations and unrealistic expectations concerning the amount of change they can achieve in harm reduction in a limited amount of time.

Another potential limitation of our study design concerns the proper role of the community in the evaluation of the effects of community trials. Left to their own devices the steerco in the study's city pilots sometimes selected and implemented prevention programs of limited value, and the Safe Ride program mentioned earlier yielded iatrogenic effects. Efforts by the Foundation to develop a rational planning process met with resistance in some cases. The HBSA evaluation has similarly met with some resistance as we have presented information pertinent to the selection of prevention strategies most likely to achieve the 10% harm reduction goal. Some of this information has been, for the city pilots, counter-intuitive, and some have bristled at efforts to impose on them evidence concerning potential interventions that has accrued from studies in the United States and Europe.

Along a continuum from high community involvement in the evaluation, sometimes characterized as community-based participatory research, to a more traditional investigator-driven approach, our research design may be characterized as relatively hierarchical. With some misgivings, we adopted this approach because of the nature of task the Foundation assigned us: to measure the extent to which each city pilot achieved a 10% reduction in harmful alcohol use. To ensure the independence of our evaluation, we deliberately will exclude city pilot staff from authorship of our main effects (although not ancillary and descriptive) papers, which certainly will not alleviate any local suspicions of our roles and intentions as evaluators. We have done so with some regret, since we recognize that under ideal circumstances the relationship between evaluation staff and community members should be one of collegiality, which includes sharing findings in process and inviting participation in the interpretation and discussion of these findings.

Despite these limitations, we are optimistic that with our combination of population-based and focused evaluation approaches, we will be able to detect intervention effects, if they occur, even if some sites may fall short of their 10% harm reduction goal. This study represents a unique opportunity to evaluate a set of interventions designed to reduce harmful alcohol use and related consequences. Many of these interventions are evidence-based but have yet to be administered in developing countries. The initiative is also serving as an incubator for promising programs—like those targeting physical and sexual violence—that lack such a base but are worthy of evaluation as pilot studies and, if successful, replication. The evaluation will also yield important information concerning the intentions of the alcohol industry—and particularly ABI, the world's largest brewer of the alcohol type that causes the most harm in the United States [50,51]—in funding both the implementation and evaluation of programs that seek to reduce the harms associated with consumption.

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