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A Community Prevention Model to Prevent Children from Inhaling and Ingesting Harmful Legal Products

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1. Background

1.1 Overview

Over the past decade, increased attention has focused on the abuse of harmful legal products (HLPs) by children to get high (Alcoholism and Drug Abuse Weekly, 2007; 2008; 2010; Child Health Alert, 2008; Kluger, 2010; Marsolek, White, & Litovitz, 2010; McCabe, Teter, & Boyd, 2006; Perron & Howard, 2009; Wu, Ringwalt, Mannelli, & Patkar, 2008). HLPs are legal products that can be inhaled or ingested and are readily available to children and adolescents and can be found in the home, garage, office, school, or local stores and shops (Alliance for Consumer Education, 2010; Ballard, 1998; Campbell, 1994).

Given the ubiquity, low cost, and ease of use of HLPs, it is difficult to prevent their abuse by children. Moreover, few programs focusing on HLPs have been developed or evaluated, and few models are available to guide prevention efforts dealing with this substance abuse problem (Brouette & Anton, 2001; Delva, Spencer, & Lin, 2000; Twombly & Holtz, 2008). This article helps to reduce this knowledge void by presenting a general community prevention model (CPM) for reducing the use of HLPs to get high among pre- and early-adolescent children with special application to rural communities.

This CPM is being implemented in a randomized-controlled trial (RCT) in rural Alaska that is funded by the National Institutes of Health. This RCT is designed as a two-cohort community study given the annual research cost restrictions of implementing the CPM in all intervention communities simultaneously. Each cohort consists of four pairs of matched and

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randomly assigned communities to either intervention or control conditions (Gruenewald, 2009). The intervention communities implemented the CPM over a 21-month period with the first three months focusing on community mobilization, the community readiness assessment, and establishing the coalition base. The remaining 18 months are devoted to continued implementation of the community mobilization and the environmental strategies activities.

1.2 Use of Harmful Legal Products by Children

Most inhalable HLPs are volatile substances, often solvents (AADAC, 2004). Examples of inhalants include paint thinners, gasoline, and model airplane glue. Other types of inhalants include aerosols, nitrites (“poppers”), and anesthetics (AADAC, 2004; CSAT, 2003; Wu, Pilowsky, & Schlenger, 2004; Wu, Schlenger, & Ringwalt, 2005). Ingestible HLPs include over-the-counter medications such as cough syrup, antihistamines, and cold medications, prescription drugs like Oxycontin, and common household products like cooking extracts, disinfectants, mouthwash, and other products high in ethanol (Banerji & Anderson, 2001; Fleming, McElroy, & Hughes, 2004; Mazor, DesLauriers, & Mycyk, 2005; Pates, McBride, Li, & Ramadan, 2002; Steinman, 2006; Wu et al., 2009). Studies indicate that the use of legal products to get high, especially inhalants, are often the first category of substances to be abused by adolescents and thus may constitute an introductory drug (Anderson & Loomis, 2003; Authors, 2007; Wu & Howard, 2007).

Since these products are legal for children to purchase (unlike alcohol and tobacco, which are age-restricted) and are readily available in everyday environments, it is difficult to keep them out of the hands of youth who might want to use them to get high. Many HLPs are inexpensive and packaged in such a way that they can be easily concealed; relatively small amounts are capable of producing euphoric effects (Lorenc, 2003). The resulting “high” occurs rapidly and attenuates relatively quickly (Blum, 1984; Kurtzman, Otsuka, & Wahl, 2001).

The use of legal products to get high is a serious problem among children in the U.S. The 2009 Monitoring the Future survey (MTF) found that 14.9% of eighth-graders, 12.3% of tenth-graders, and 9.5% of twelfth-graders had used inhalants to get high at least once in their lifetime (Johnston, O'Malley, Bachman, & Schulenberg, 2010). Further, the 2009 MTF results show that the lifetime prevalence rate for inhalant use among eighth-graders exceeded the prevalence rate for marijuana, making inhalants the third most commonly used substance for this population, behind only alcohol and cigarettes. Among fifth- and sixth-graders in 14 rural Alaskan communities, a 2007 survey found the lifetime prevalence of using HLPs to get high to be 19% (Authors, 2009). Prescription drugs had the highest lifetime prevalence rate (11%) of four types of HLPs surveyed, followed by over-the-counter-drugs (8%), inhalants (7%), and household products (6%). A second survey in 2010 in eight rural Alaskan communities found that prescription drugs continued to have the highest lifetime prevalence rate (10%), followed by inhalants (9%), over-the-counter medications (10%), and household products (6%) (ICHS & PIRE, 2010).

What follows is a conceptual overview of the CPM model including working and operational definitions of the outcomes of the study. We also describe the CPM in detail and provide lessons learned from the first 21 months of implementation of the model.

2. Conceptual Overview of the Community Prevention Model

2.1 Conceptual Framework and Rationale

Figure 1 presents the underlying theoretical assumptions of the community prevention model (CPM) to reduce use of harmful legal products (HLPs) to get high among children.

The model shows the causal relationship between the CPM intervention and proximal, intermediate, and distal outcomes.

The community mobilization and environmental strategies model components are intended to impact a set of proximal outcomes targeting increased (a) concerns associated with HLPs use among children, (b) responsibility for dealing with this problem, and (c) engagement in HLPs prevention activities that are associated with community coalitions, households, schools, and retail outlets. Baker, Kupersmidt, Voegler-Lee, Arnold, and Willoughby (2010) found in a randomized-controlled trial that lack of teacher concerns about a classroom-based prevention intervention predicted less participation in implementing the intervention. Camacho, Williams, Vogtsberger, and Simpson (1995) found that individual concern about susceptibility to AIDS predicted lower HIV/AIDS risk behavior six months after an AIDS intervention. Perceived responsibility for drug therapy outcomes has been found to act as a mediator of the effects of an intervention that focuses on clarity of standards, personal control, and professional duty, plus a set of outcomes that concern identifying, resolving, and preventing drug therapy problems (Planas et al., 2005). Engagement in environmental prevention activities has found to be important for increasing community readiness and reducing the availability substances in a number of empirical studies (e.g., Holder et al., 2000; Treno, Gruenewald, Lee, & Remer, 2007; Wagenaar et al., 1999; Authors, 2008; Authors 2009c).

The increase in concerns, responsibility, and engagement of coalition members, parents, school personnel, and retailers are expected to positively impact community readiness to implement the environmental strategies as well as implementation of the strategies. As former research suggests, we expect the increase in community readiness to prevent HLPs use among children to directly impact success in the implementation of the environmental strategies in the CPM (Authors, 2008; Feinberg, Greenberg, & Osgood, 2004; Slater et al., 2005; Stith et al., 2006; Wandersman & Florin, 2003). The model further posits that environmental strategies will reduce availability of HLPs in the community, which will reduce children's use of HLPs to get high. Availability of substances has been found to play an important role in substance use (Chen, Grube, & Gruenewald, 2010; Dent, Grube, & Biglan, 2005; DiFranza, Savageau, & Fletcher, 2009; Jason, Pokorny, & Adams, 2008; Paschall, Grube, & Kypri, 2009; Tutt, Bauer, & DiFranza, 2009), including their use of legal products to get high (Authors, 2008a; Authors, 2009d).

2.2 Outcomes Defined

The conceptual view of the CPM model includes three levels of outcomes that we hypothesize are sequentially and causally connected: proximal outcomes, intermediate outcomes, and distal outcomes. Proximal outcomes include levels of community concern and felt responsibility about availability of and about use of HLPS by children, and engagement in activities to reduce or prevent HLPS use by youths. These proximal outcomes are measured at the community and coalition membership level, and also at the level of the principal targets of the environmental strategies (parents, school staff, and retailers). Taken together, concern, responsibility, and engagement provide the foundation for successful implementation and sustainability of environmental strategies to reduce availability and use of HLPS.

Proximal Outcomes—Community concern is defined as the participating coalition membership's assessment of the community's level of concerns about harmful legal products being available and accessible to children in the community in general and homes, schools, and retail outlets specifically. Community responsibility pertains to the extent to which the participating coalition membership believes the community including coalition members,

parents and other caregivers, school personnel, retailers, and media personnel have responsibility to assist in the prevention of the abuse of such products. The definition of community engagement focuses on the extent to which the coalition participants of the community mobilization strategy are involved in mobilization activities. Further, engagement that pertains to the environmental strategies refers to implementation of activities within the household, school, and retail environments.

Operational definitions of the proximal outcomes for concern, perceived responsibility, and engagement, are measured differently for particular CPM components. For the assessment of community mobilization strategy effects, a post intervention self-administered survey is administered to coalition members in the intervention communities. The measures of the proximal outcomes for parents and other caregivers are included in a post-intervention telephone interview in the intervention condition. School personnel are responding to items that measure the proximal outcomes in an internet survey in the intervention communities. Retailers are providing data on these outcomes via an in-person interview of retail managers or owners.

We define household (i.e., parent/caregiver) concern as the extent to which HLPs are available in the home or the home of others in general. Further, definitions of perceived responsibility and actual engagement of parents and other caregivers include the extent of perceived responsibility or engagement relating to (1) inventorying, locking up, replacing, monitoring products that can be abused, (2) communicating with their children, setting rules and consequences, and (3) advocating the reduction of access to HLPs in the community in general and in homes, schools, and retail outlets.

School personnel concern is defined as the level of concern about students having access to HLPs in school and from other students while in school and about students using legal products to get high. School personnel are also being queried about their perceived responsibility and actual engagement in inventorying, monitoring, and restricting access to HLPs in schools, setting school policies, and advocating such actions be taken in school.

Retailer concern pertains to children in their community purchasing or shoplifting HLPs to get high in their business or other businesses in the community. The definitions of perceived responsibility and engagement relating to HLPs include taking action to display HLP project signs, identify high-risk products, develop written store policies, train employees to implement policies, and post warning labels or signs.

Intermediate Outcomes—Community readiness is defined as the extent to which a community is ready to implement a community prevention model that targets children's HLPs use to get high. Our definition of community readiness from the Community Readiness Model (Oetting, Jumper-Thurman, Plested, & Edwards, 2001) has six dimensions: (a) existing prevention efforts, (b) community knowledge of these efforts, (c) community leadership, (d) community climate, (e) knowledge about the problem, and (f) prevention resources. Taking these six dimensions into consideration, a readiness index is constructed consisting of nine levels: (1) tolerance or no awareness, (2) denial, (3) vague awareness, (4) preplanning, (5) preparation, (6) initiation, (7) institutionalization or stabilization, (8) confirmation/expansion, and (9) professionalization (Authors, 2008; Plested, Edwards & Jumper-Thurman, 2005).

Community readiness is measured using data collected by the research team via a community readiness tool developed by the Tri Ethic Center at Colorado State University to assess and diagnose a community's propensity to take prevention related action (Oetting et al., 2001; Plested et al., 2005). Eight or nine community key informants are asked semi-

structured questions that provide information about what is occurring in the community and what local perceptions are in relation to a specific problem. These informants are identified by community workers in health promotion as the most knowledgeable individuals regarding substance abuse prevention work in their community. The eventual result is the overall level of community readiness index. Each level of readiness requires different interventions in order to move the community to the next level until, eventually, initiation and maintenance of programs and policies can be achieved.

The availability of HLPs in the community is defined for three environments: households, schools, and retail outlets. Household availability pertains to the extent to which parents and other caregivers of children restrict access to HLPs by not buying, locking up, and/or substituting for legal products that might be used to get high. Availability of HLPs in schools pertains to the extent to which HLPs are available in schools or access is restricted to authorized personnel. Availability in retail outlets pertains to the extent to which retailers restrict access by controlling HLPs displays, substituting products for HLPs, and denying sales of HLPs to children.

Measures of availability vary with environmental strategy (ES). For the household ES, we are collecting data from parents of fifth through seventh grade students prior to the intervention and two years later in both the intervention and control communities. Availability in schools is being assessed via an inventory of HLPs in participating schools. A research team member partners with the school staff who are responsible for various areas including classrooms, kitchens, art classrooms, janitorial storage, and shops. We are using purchase attempts as our measure of retail availability. Children attempt to purchase targeted products before and after the CPM has been implemented, and purchase success is recorded.

Distal Outcome—The use of HLPs to get high, which is a distal outcome, is defined as the extent to which children use inhalants, prescription drugs, over-the-counter drugs, and household products to get high. In this study we measure use during their lifetime and the past 30 days. Pre and early adolescent use of HLPs is measured in a group administered school survey of children in the fifth to seventh grades prior to implementing the CPM and two years later after completion of the intervention.

3. Description of the Community Prevention Model (CPM) to Reduce Use of Harmful Legal Products

3.1 Background

From 2004 to 2008, the National Institute on Drug Abuse (NIDA) funded a pre-post intervention only feasibility study that showed the study team could successfully implement and evaluate a three-component CPM model consisting of community mobilization, environmental strategies focusing on households, schools, and retail outlets, and a school curriculum (Think Smart) in rural Alaska (Authors, 2007a). We found increases in community readiness (Authors, 2008), decreases in parents' perceived and actual availability in the home (Authors, In review), decreases in successful purchase attempts by children (Authors, 2009), and decreases in use of HLPs to get high among children in the fifth to seventh grades in communities that implemented the CPM (Authors, 2009c).

Although the three-component model was successfully implemented and produced positive effects, it was too complex to be sustained or diffused to other communities in Alaska. Subsequently, the study team has been awarded two other NIDA grants to test separately the school-based Think Smart curriculum (2005-2009) and a two-component CPM consisting of community mobilization and environmental strategies that target households, schools, and

retail outlets (2009-2014). The Think Smart curriculum has been found to produce positive effects in a randomized-controlled trial (Authors, 2009). This article focuses on a two-component community prevention model (CPM). We present the conceptual framework, the component activities, and the outputs that are expected to prevent the use of HLPs to get high among children in the model currently being implemented as the RCT. We do not have implementation results this early in the study. Rather, the focus of this article is on describing the model and the conceptual basis for the interventions.

3.2.1 Community Mobilization Strategy in Action—Effective community mobilization is considered essential to implementing a successful set of environmental strategies. Although there are a number of community mobilization models, we selected the Communities Mobilizing for Change on Alcohol model (Wagenaar et al., 1999) that demonstrates that effective community mobilization can support prevention actions to reduce alcohol problems and help engage community members. While there were several promising prevention planning models that included community mobilization—e.g., Communities that CARE (Hawkins, Catalano, & Catalano, 1992) and Getting to Outcomes (Wandersman, Imm, Chinman, & Kaftarian, 2000), this strategy was the only evidenced-based, community mobilization model available at the beginning of the study [2004]; and, based on prior experience in working with an Alaskan community coalition, the team felt it was a good fit for Alaska communities. The community mobilization process for the current study, which spans 21 months, is outlined below. The seven activities of this strategy include:

- assessing the community and providing results for planning
- building a base focusing on community coalitions
- expanding the base
- developing a plan of action
- implementing the plan of action
- seeking feedback and disseminating results, and
- maintaining or sustaining the effort.

Activity 1: Initially, Activity 1 focuses on assessing how ready a community is to address HLPs use. The activity includes a formal evaluation of community readiness and local prevention capacity using a community readiness tool developed by the Tri Ethnic center at Colorado State University (Oetting et al., 2001; Plested et al., 2005). This tool assesses and diagnoses a community's propensity to take prevention-related action. The community readiness data collected from the key informants are analyzed by the research team for each community, a community report is produced, and the results and next steps are integrated into coalition training.

Activity 2: Activity 2 emphasizes organizing new, or identifying existing, coalitions or partnerships that are or can be focused on the targeted problem and support the prevention activities. Coalitions or partnerships consisting of key leaders, agencies, and organizations provide a substantial base to mobilize an entire community to address a health or social problem (Lewis et al., 1996; MacLean et al., 2003). Initially, the Alaska-based intermediary prevention partner identifies and contracts with a local agency to serve as the fiscal agent for the HLPs prevention project in each community, and to house a part-time community prevention organizer—one-half time for small communities and three-quarter time for larger communities. The community prevention organizer provides coalition staff support to coordinate and implement prevention activities (Pluye, Potvin, & Denis, 2004). The Alaska

intermediary agency partner and the community prevention organizer help enlist support for the implementation of the community mobilization strategy through a HLPs prevention steering committee or workgroup consisting of two to six members of the participating coalitions. Coalition capacity-building through training and technical assistance is also essential to strengthening or expanding the base of coalitions (Florin, Mitchell, & Stevenson, 1993; Mitchell, Florin, & Stevenson, 2002). We introduce the CPM project to the coalition and follow-up with a Prevention 101 training or a Prevention 102 training depending on a needs assessment. These trainings are conducted in the early stages of the project.

Activity 3: Activity 3 focuses on expanding the community base supporting the interventions. After initially identifying coalitions and key individuals, efforts are made to expand the membership to include relevant community members, often people from outside typical prevention networks. The CPO and the coalition members assume responsibility for this activity. A framework of 13 community subsystems provides guidance on important community representatives that include: (1) policymakers; (2) mental health/substance abuse prevention and treatment agencies; (3) schools; (4) elders; (5) families; (6) social service agencies; (7) retailers and merchants; (8) healthcare agencies; (9) media; (10) law enforcement; (11) tribal leaders; (12) faith organizations; and (13) courts. In small communities especially, individuals may assume roles in multiple sectors.

Activities 4-5: Activities 4 and 5 involve developing and implementing a community action plan that targets the problem. A community prevention action plan should provide concrete steps and strategies to implement the environmental strategies and further the community mobilization strategy. In this study, a community action plan template is drafted by the Alaska intermediary partner in collaboration with the community prevention organizer and the coalition HLPs prevention work group. A baseline community readiness score provided to the coalition workgroup informs the community where they stand on the nine-point readiness scale relating to the implementation of environmental strategies to prevent HLPs use among their children. The community mobilization and environmental strategies are individually and collectively addressed by setting milestones and identifying persons responsible for each task in the action plan. Importantly, the action plan provides concrete steps and strategies to implement the CPM including media advocacy. A finalized draft of the action plan is sent to the overall coalition for review and feedback. Coalition members and other interested community members are recruited for the tasks that are specified in the action plan. The external training and technical assistance providers, community prevention organizer, and coalition HLPs prevention work group are charged with monitoring the implementation and reporting to the coalition at regular intervals.

Media advocacy is an essential aspect of this action plan and is intended to motivate community leaders, parents, administrators, and teachers at local schools, and retail merchants to become involved with community prevention interventions (Holder & Treno, 1997). Media advocacy refers to the strategic use of news media and other local forms of public communication to advance a social or public policy initiative. Unlike persuasive media campaigns, which use media to change beliefs, attitudes, or behavior directly, media advocacy works with local news outlets (radio, television, newspapers, and magazines) and other information sources to increase local media attention to a specific public health problem and possible solutions. In small or rural communities, media advocacy may out of necessity use informal media channels such as church bulletins, flyers, and postings on bulletin boards in locations where community members congregate. Talk radio programming was used in most communities throughout the intervention period, as were scanner channels on local television that showed messages about local events. Local newspapers received press releases for the different intervention components as well as a general announcement of the funding and local partnership working to address the issue. A

portable display was developed to be used when communities gathered to engage them further in the project.

Activity 6: Activity 6 involves disseminating research results to the community during and after the CPM has been implemented, which is essential to support mobilization (Authors, 2003). Moreover, an essential element of a sustainability plan is to share evaluation results with key community leaders and prevention champions (Authors, 2004). Baseline results on community readiness and capacity building disseminated to coalitions or partnership members, which is disseminated early in the study, can guide training and technical assistance provided to the coalitions, alliances, and CPOs. Further, baseline survey results on children's use of HLPs can stimulate local interest and, later on, evaluation impact results provide information on success (or failure) and guide decisions about whether the intervention components are worth sustaining. At the end of the study, both general and community-specific results are planned to be disseminated to key participating groups in each intervention community.

Activity 7: Finally, Activity 7 consists of a sustainability strategy is implemented that highlights how to strengthen community infrastructure—interagency structures, formal linkages, resources, data quality, champions, and prevention expertise—to continue addressing children's use of harmful legal products after the study has been completed. Authors (2010) present a strategy for sustainable coalition capacity development that targets these elements of a community prevention system. This strategy was adapted from a sustainability support system originally developed through a CSAP-funded SPF-SIG project in Tennessee (Authors 2009a; 2009b). Evaluation results presented in Authors (2010) show that some types of coalition infrastructure (e.g., inadequate structure or a lack of a champion network) could be strengthened through this coalition capacity building strategy while other types of infrastructure (e.g., formal linkages among community agencies) could not. The assumption is that if key infrastructure of a prevention system can be strengthened to support continuation of prevention innovations, then these innovations can be integrated into routine community activities (Author, 2004). Sustainability training on the step-by-step implementation for each intervention community is part of the study's plan.

3.2.2 Environmental Strategies—Environmental strategies (ES) for this study focus on reducing access to HLPs and substituting alternative products for HLPs in the community, thereby affecting their availability to children to get high. The implementation period is 18 months. This prevention approach differs from traditional individualistic approaches in several ways: (1) ES focus on changing community systems rather than individual behavior, (2) ES use the local news media to target community leaders or organizations rather than attempting to change individual behavior through media messages, (3) ES view the community as a resource to mobilize for system change rather than the target group of information, and (4) ES seek either to reduce supply or associated risk rather than to reduce demand (Gruenewald, Holder, & Treno, 2003). Birckmayer, Holder, Yacoubian, and Friend (2004) suggest that many of the environmental factors that contribute to alcohol and tobacco use, such as availability and price, also affect drug use including use of legal products to get high. Authors (2008a), in a statewide study in Kentucky, found that the community-level perceived availability of drugs had a strong association with inhalant prevalence. The proposed CPM model targets availability of HLPs in households, schools, and retail outlets.

Household ES: This environmental strategy targets access to harmful legal products within the home (Brook et al., 2001; Authors, In review; Swahn, Hammig, & Ikeda, 2002) or the context of the household as a “safe” environment in which to use these products. Prior research has shown that parental monitoring is an important protective factor against

substance use (Beyers, Toumbourou, Catalano, Arthur, & Hawkins, 2004; Steinberg, Fletcher, & Darling, 1994). In addition, Ford (2009) found that adolescents who report strong bonds to parents are less likely to report non-medical use of prescription drugs; Ford theorized that part of the reason for this relationship may be that adolescents who are strongly bonded to parents are more likely to have their behavior monitored.

In the current study, the household ES is designed to encourage parents and guardians to be concerned about the potential for a HLPs problem in their household and to assume responsibility for reducing HLPs access in the household. The household ES encourages parents to take specific actions including (a) inventorying HLPs in the household, (b) securing them in locked cabinets, (c) substituting HLPs with less harmful products, (d) communicating and enforcing rules regarding HLPs use to their children, and (e) monitoring HLPs. In addition, the household ES is designed to encourage parents and guardians to participate in HLPs prevention activities in the wider community and to be advocates for getting friends and neighbors to restrict access to HLPs or substitute products in place of HLPs in their households. Advocating for others to restrict access in their own homes can create a supportive environment for parents to become more active and engaged in protecting their children. Four important activities associated with the household ES are:

- Disseminating a parent and caregiver handbook.
- Conducting Family Night 1 events to educate parents and caregivers about the HLPs problem concerning children and solutions to the problem.
- Conducting Family Night 2 events to prepare parents and caregivers for advocacy.
- Providing technical assistance to parents and caregivers after each family event.

Initially in Activity 1, parents and caregivers of children in the fifth to seventh grades are introduced to the HLPs prevention project through a mailed parent and caregiver handbook, which summarizes the materials used in Family Night 1. Specifically, the handbook includes steps parents and caregivers can take in the household to reduce availability and restrict access to HLPs, as well as resources such as a home inventory of HLPs, and exercises the parents can complete, such as writing down their own thoughts and feelings about the use of HLPs to get high. The handbook also includes a section for the parent or caregiver to write down questions that they would like to discuss or learn more about during the Family Night events. Contact information is provided by the school system with consent from the parents, or the schools disseminate the materials directly. Once the handbooks have been sent to the parents/caregivers, the CPOs contact them by phone to ask whether they have received the handbook and whether they have read it and completed some of the exercises. They also try to recruit them for participation in Family Night 1.

Activity 2 entails implementation of a one and one-half hour Family Night 1 event. An additional Family Night 1 is convened if a sufficient number of parents/caregivers have not been recruited for the first event. Often, the media events to publicize the event fail to elicit enough interest, making a second event necessary. We found that the initial Family Night 1, even in the event of a small turnout, helps recruit additional parents for a follow-up Family Night 1.

Activity 3, which is a Family Night 2, is also a one and one-half hour event that is implemented about six months later and includes a recap of the material from Family Night 1, but it also provides content specifically related to advocacy by parents. It is recognized that new family members may participate in Family Night 2 without having participated in Family Night 1.

Following Family Nights 1 and 2 events, Activity 4, (i.e., technical assistance) is implemented. This activity consists of two telephone consultations with the Family Night 1 participants prior to Family Night 2 and two additional follow-up telephone consultations are provided after Family Night 2 over the remainder of the 18-month ES implementation.

School ES: This environmental strategy parallels and supports household environmental strategy and is designed to promote practical actions to restrict availability of legal but potentially abusable products at school. Baseline student survey data from four Alaska communities showed that between 48% and 91% of students responded that it would be “sort of easy” or “very easy” to obtain four different types of HLPs in the school setting in order to get high if they wanted to do so (Authors, 2007).

Some potentially abusable products can be found in typical classrooms, while others are often available in specialized classes (e.g., shop or vocational classes, art classes, and others) as well as in cafeterias, storage closets, or janitorial supply areas. Many potentially harmful legal products are available at schools, ranging from vanilla extract to Lysol to dusting sprays. The Commonwealth of Massachusetts Department of Public Health (2006) notes that schools should (among other things) review purchases of school supplies, substitute safer products where possible, institute policies that ban materials that may be inhaled, and provide information to faculty and other staff through in-service trainings and printed material about the dangers of inhalants. Strict school policies and other changes in the school environment to prevent inhalant abuse (as well as, presumably, abuse of other harmful yet legal products) are consistent with a trend recently noted by Weiss (2005). The five key activities of the school ES are:

- Inventorying HLPs in schools.
- Conducting school-wide in-service training in each participating school.
- Conducting a web-based needs assessment survey to assess technical assistance needs and address unresolved questions.
- Providing technical assistance based on needs assessment.
- Repeating needs assessment seven months after the in-service training.

The School ES revolves around five activities that school personnel are asked to implement. Initially in Activity 1, the research team in partnership with school personnel conducts an inventory of critical areas of the school environment where products might be accessible to children in the fifth, sixth, and seventh grades including administrative offices, general classrooms, art classrooms, vocational education shop classrooms, kitchens, cafeterias, and janitorial areas. For general classrooms, we are drawing a 50% systematic sample of classrooms to reduce time and cost of the inventory. The inventory form is used to capture information about specific products known to be in schools, level of security and monitoring of these products, and written policies and procedures about students' accessibility to these products.

Following the inventory, a school-wide in-service training (Activity 2) for faculty and staff is convened in each participating school. This in-service training provides an overview of the problem of HLPs abuse and emphasizes the importance of schools as a partner within a larger multi-component environmental strategy in the broader community. Training participants review actions that schools might take to reduce the potential for abuse of HLPs, and all participating school staff receive materials that can be reviewed after the in-service training is complete. Because of turnover in school staff, the in-service training is repeated at the start of each academic year, providing a booster review for staff who return and an introduction for new staff.

Three months after the initial training, a semi-structured web-based needs assessment survey (Activity 3) is administered with all participants to assess technical assistance needs and barriers and address unresolved questions. Project staff review participant responses to this semi-structured survey and use this information to provide technical assistance as needed.

Activity 4 consisting of technical assistance is also provided to school personnel in need via telephone. This assistance focuses on the identified needs in the web-based survey. This semi-structured technical assistance (Activity 5) is repeated seven months after the in-service training followed by additional technical assistance.

Retail Environmental Strategy (ES): The retail ES is being used to raise the level of concern and responsibility for children using HLPs to get high. Further, we have tailored this environmental strategy to encourage retailers to take actions to prevent the purchase or theft of legal products to get high, including inventorying high-risk products in retail outlets, developing written store policies regarding sales of HLPs, posting warning labels or signs, and controlling display of HLPs. Authors (2010) implemented an earlier version of current retail focused ES in four Alaska communities of a feasibility study that showed significant associations among retailers who took these actions and reduced sales of HLPs to children. Further, we expect parents/guardians, school personnel, and community citizens to join in on encouraging retailers to participate in the CPM. There are three activities included in this strategy.

- Conducting a formal visit with the manager or owner of each retail outlet by project staff.
- Conducting technical assistance with each retailer.
- Engaging community leaders, parents and caregivers, and school staff in visiting retailer outlets.

Activity 1 of the retail environmental strategy begins with a formal visit with the manager or owner of each retail outlet by project staff. During this visit, the community prevention organizer provides an introduction to the project and gives retail staff an in-depth packet of information. The project staff person also reviews the suggested retail actions. The goal of this visit is to obtain a signed commitment letter from each retailer indicating that he or she supports reducing access to HLPs in their community and will take actions to do so. In addition, we review the suggested retail actions with each retailer and seek to obtain a commitment from each one of them to take one or more of the actions.

Activity 2 entails implementation of technical assistance with each retailer. This technical assistance is provided either via telephone or in person (depending on retailer preferences), and it is designed to gather information about actions taken, along with barriers and challenges encountered. Additional one-on-one technical assistance is provided to assist retailers in resolving challenges and implementing the suggested actions. Because the retail environment is a very dynamic and busy one, the retail environmental strategy assumes that not all retailers will be willing or able to participate.

Activity 3 is to engage community leaders, teachers, and parents in making additional visits to retailers with project staff. These visits are not punitive in nature but rather are designed to motivate retailers who are reluctant to participate in the project, are struggling with the project interventions, or who are hesitant to take the suggested actions.

4. Community Participation Mechanisms

Alaska, like many rural areas, has had disappointing experiences with researchers in the past (Norton & Manson, 1996). In an effort to overcome the resulting skepticism and to conduct an efficacy trial with rigorous methods, we work to honor the contribution that local communities can make to research and to assure a study that is culturally sensitive (Kreuter, Lukwago, Bucholtz, Clark, & Sanders-Thompson, 2003). While traditional efficacy research privileges researchers control in order to maintain ideal experimental conditions, our approach emphasizes community participation and collaboration in order (1) to honor and respect the participating communities and their perspectives and (2) to increase the likelihood of the success and sustainability of an intervention model that relies heavily on community involvement. This research plan builds upon other researchers' experiences in developing hybrid efficacy-effectiveness trials that reduce the problems often encountered when translating science-based prevention from experimental to real-world conditions (Carroll & Rounsaville, 2003; Lee et al., 2008; Authors, 2008b). This study subscribes to the beliefs that participatory research is both a process and a goal (Greenwood, Whyte, & Harkavy, 1993), that community-based research falls on a participatory continuum, and that there are benefits to be gained from moving toward increased community participation. Specifically, we implemented an adaptation of the mechanisms of the Tribal Participatory Research model (Fisher & Ball, 2002) as guiding principles for the study: (1) establishing community oversight, (2) using indigenous facilitators and local research staff; (3) providing training and enforcement via technical assistance (TA) to key community participants; and (4) using culturally specific intervention and assessment methods.

Community oversight is provided by a local coalition (planning team or alliance) that gives direction to and advocates for the study. As described earlier, a coalition steering committee or work consisting of two to six persons is formed in each experimental community to lead the implementation of the community mobilization strategy.

Indigenous intervention facilitators (i.e., CPOs) and research staff are hired from the community and involve layers of intermediaries. The first level consists of a Community Prevention Organizer (CPO), who interacts most directly with the community in implementing the CPM. He or she is responsible for organizing and implementing the CPM in his/her community, including the community mobilization and environmental strategies with assistance of staff from the statewide prevention partner and the research team. Our experience with the Alaska feasibility study demonstrated that hiring a part-time CPO in each community, with the full-time equivalent (FTE) dependent on the size of the community, was essential to the success of mobilizing the community and implementing environmental strategies. The second intermediary level is a local agency that receives funding from the CPM project to provide the CPO with office space and support services. We require a memorandum of agreement (MOA) in each community that sets forth this contractual arrangement. The assumption is that community control of the CPM's key community resource will enhance community participation. The third intermediary level consists of a statewide prevention partner, who interacts as an intermediary between the community and the research team. As a result of lessons learned in the feasibility study, we shifted direct supervisory responsibility to the statewide prevention partner via contract to be responsible for supervising the CPO, providing coalition training, capacity-building, and technical assistance to the CPOs and coalitions. Local data coordinators also are hired in experimental and control communities to collect much of the data, which further reinforces community partnership. These community research staff members are supervised by the Alaska-based research team. Initially, we found in the feasibility study that the research team's presence in the intervention communities was essential to continuing community support for the research component of the project.

Training and TA is being provided by the statewide prevention partner to CPOs and coalitions that relate to the implementation of the CPM. Initially, CPOs and a community champion engage in a two-day training in Anchorage, which is the research team in-state base of operations. Additional on-site training and TA is provided on a regular basis by the statewide prevention partner to coalitions including the project steering communities. Training of the local data coordinators as a group is provided by the Alaska-based research team in Anchorage and follow-up consultation is provided as needed.

Culturally sensitivity materials and implementation and research protocols to the rhythm of the communities are also important community participation mechanisms. All materials are adapted and developed for the specific community of focus. Additionally, all intervention and research activities are reviewed by several influential community members who serve as a local Community Advisory Board (CAB) for the project. The CAB is not considered part of the CPM, but rather as an overarching group to monitor the progress and report back to the research team their observations regarding implementation of both the CPM and the research components. Negotiated flexibility is afforded in the implementation of both the CPM and the research to ensure that local customs and perspectives are taken into account. Careful documentation of this flexibility is maintained through the CAB reviews, as well as in the process data collection. It is assumed that these mechanisms can provide a significant and structured way to integrate participatory principles into a community-focused, randomized-controlled trial.

5. Lessons Learned in Implementing the CPM Study in the Cohort 1 Communities

Implementing and evaluating multiple prevention strategies that focus on the entire community, along with a high degree of cross-community diversity, have presented challenges that do not exist for other prevention approaches (Lachance, 2006). In general, we designed and implemented a 21-month CPM implementation plan that laid out an implementation and monitoring schedule for two cohorts of communities. There are a number of lessons learned after implementation in the Cohort 1 study communities that are noted below.

5.1 Lessons Learned from Implementing the CPM

5.1.1 Planning implementation of the CPM—One lesson learned is to spend more time at the beginning of the study, prior to implementation, developing a detailed implementation plan, finalizing all intervention materials, and integrating the CPM into communities. We developed a CPM implementation plan for our four Cohort 1 communities with a detailed work plan by task that identified the person responsible for each task along with a timeline, but the final details of each intervention and research task of the plan were not presented at the beginning of study. For example, the community mobilization component activities concerning coalition capacity-building, which is the base for the mobilization strategy, was the least developed activity prior to implementation; therefore, this activity was the least implemented. We made the mistake of not pushing for coalition capacity-building training early in the community mobilization process. Further, we did not adequately plan for sustaining the environmental strategies, which is also a key activity of the community mobilization strategy. Plans are being made to correct this problem as we implement the CPM in the remaining four Cohort 2 communities of the study.

5.1.2 Incorporating flexibility into a planned intervention—A related lesson learned is that while the development of a detailed implementation plan is important, it is necessary to recognize that incorporating an adaptive implementation strategy is essential

for a successful implementation as circumstances change in particular communities. For example, when household ES events became difficult to schedule in several communities because the fishing season had begun (making participant availability difficult), a decision was made to postpone this event to early fall after fishing season had ended in all communities, thereby maintaining the uniformity of implementation across all intervention communities. There is a great challenge in implementing community prevention models as a planned intervention design in diverse communities. While fidelity is key to achieving the desired outcomes, flexibility is key for community buy-in, the practicality of implementation, and ensuring sustainability (Backer, 2001; Castro, Barrera, & Martinez, 2004).

5.1.3 Adequate intervention dosage—It is difficult to achieve sufficient dosage and reach for the CPM events in a short timeframe or with only a single planned event. Low turnout and limited participation in project events is a reality. A further lesson, however, is that low turnout at project events (e.g., Family Night) can be overcome by providing multiple opportunities for participation and the use of local participants as recruiters. Participant satisfaction and the subsequent word-of-mouth recruitment from groups like parents and school staff has been the single best way to increase participation in subsequent events.

5.1.4 Intervention material to communities—Community expertise in producing materials for project activities may be lacking. Communities need materials that are produced for them, but are locally oriented and responsive to their local community context. We maximized the use of the statewide prevention partner's expertise by producing specific products, such as press release templates for the CPOs that can be easily customized for their respective community. This provides communities with quality materials and reduces stress of local project participants in producing these products.

5.1.5 Media advocacy—It is very difficult to get community participants to develop and implement a customized media plan, which is considered an essential part of the CPM. Communities operate on their own schedules, and we found every effort to dictate timing on media events to be a considerable challenge. Taking into consideration the rhythm of the community is essential. The lesson learned is to increase the amount of Community Prevention Organizer training associated with developing and implementing a media plan and to get the organizers to begin implementation of this plan in the early stages of the CPM implementation. Moreover, we have learned that it is important to be flexible and to highlight the use of nontraditional channels of rural community communication such as community bulletin boards and word-of-mouth.

5.1.6 Retail outlet engagement—We have found it essential to reinforce early adopters among retailers in each community and apply pressure to resistant retailers. Early adopters should be recruited to serve as champions of the RES. It is a significant challenge to engage retailers in the CPM, given their workload and business management priorities. It is difficult to get a majority of retailers in any given community to implement the recommended actions of the CPM. Some community-minded retailers are early adopters, but others are resistant to change.

5.1.7 CPM sustainability—Another lesson learned is to begin working with communities early in the implementation period to increase the potential for sustainability. For the Cohort 1 communities, we failed to adequately address sustaining the CPM, although we do not know yet the extent to which those communities are planning to sustain interventions. We did develop a sustainability strategy described earlier; however, we did not implement this

sustainability strategy in the Cohort 1 communities because of timing issues in the development and implementation of the strategy. Importantly, for the Cohort 2 communities that implement the CPM, we plan to implement this sustainability strategy early in the process.

5.2 Lessons Relating to Implementing the RCT Study

5.2.1 Finalizing research instruments—An important research related lesson learned is to spend more time finalizing the conceptual framework and research instruments earlier in the study. We realized prior to implementation that there were missing proximal outcomes (i.e., community concerns about the HLPs problem and perceived responsibility in preventing this problem) that needed to be added to the framework. The measurement and instrumentation relating to these proximal outcomes was not well documented in the literature so it took longer than expected to complete these tasks, which caused some delay in collecting all of the required baseline data for the RCT.

5.2.2 Recruitment of communities to participate in the study—The lesson noted in recruiting the study communities is that sufficient time must be allowed to respond to the rhythm of the community in entering into agreements that require participation of multiple community actors, including coalitions, schools, and key health agencies. It is important to note that multiple face-to-face meetings are needed in all communities in order to solidify commitment to the project. Further, we had to randomly assign communities to the intervention and controls, and, due to implementation expense, divide the 16 communities into two cohorts that would allow for two implementations two years apart. To reduce concern for the random cohort assignment, we offered control community participants coalition training and TA after the post study data were collected. Communities accepted the “flip of the coin” for determining condition assignment. The team also kept in contact with key leaders of the Cohort 2 communities prior to them implementing the CPM. Importantly, all eight Cohort 1 communities that initially agreed to participation in the study regardless of cohort assignment continued to participate in the study.

5.2.3 Research team presence—It is critical to maintain a frequent and meaningful presence in the participating communities. Local expertise in the CPM is difficult to achieve in a short time period, and community members look to the project team to help them shape the CPM in their communities. A local presence is critical to the implementation of the CPM, and having sufficient resources to provide this presence is important. Sufficient resources need to be devoted to maintaining a research presence and developing local expertise to sustain the model. We added to the model a Community Advisory Board (CAB) for each intervention community that consisted of three prominent community leaders who would monitor the implementation of the intervention and research. We are following up with the CABs three times during the study via a combination of telephone and on-site meetings to obtain feedback on the model implementation.

5.2.4 Randomized-controlled trial in rural communities—We have learned that there are a sufficient number of rural communities in Alaska willing to participate in a randomized-controlled trial and contamination between intervention and control communities is not problematic given the state's limited road system; that sufficient community involvement can be obtained with incentives and a rigorous recruitment protocol; that innovative research questions can be posited as is the case of children's use of legal products to get high in rural Alaskan communities; and that external validity is not necessarily weakened in that if the CPM can be implemented in rural Alaska, it can be implemented in any rural community in the United States. We also have learned that the cost of research in rural Alaska is significantly higher than rural communities elsewhere in the

U.S., and that time for implementation of a CPM prohibits a follow-up assessment after completing the model.

The randomized-controlled trial (RCT) has long been the gold standard for clinical research, representing the best way to determine efficacy and effectiveness of intervention and prevention programs (West et al., 2008). However, the RCT implemented in community settings offers a number of challenges that must be overcome. These include but are not limited to population availability, contamination, time for follow-up, external validity, cost, ethics and informed consent, and the inhibition of innovative research questions (Sanson-Fisher, Bonevski, Green, & D'Este, 2007).

6. Conclusions

In conclusion, implementation of a community-focused, randomized-controlled trial is challenging and requires substantial collaboration with communities. Although rigorous intervention research is not as flexible as is called for in participatory research, experience in implementing this study over a 21-month period in the study's Cohort 1 communities has shown that a balance between rigorous research and community-driven research can be met. To date, we have been able to collect valid and reliable baseline data, we have put forth efforts to honor the contributions that communities make, and to be present in the communities when possible in order to answer questions and provide information. Importantly, we report results back to the communities in an easily digestible format. In essence, the research team has formed a partnership with its participating communities that should allow for continued collaboration in conducting high-quality research in rural Alaska. Empirical results on the implementation process and CPM effects will be forthcoming after full implementation of the model in 2014.

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Biographies

Knowlton Johnson, Ph.D., is currently a Senior Scientist for the Pacific Institute for Research and Evaluation, Inc (PIRE)- Louisville Center. He had been conducting intervention research for 40 years while at the University of Maryland, University of Alaska, Anchorage, University of Louisville, and PIRE. Over the past 12 years his research and development activities have focused on prevention of inhalants and other harmful legal products use among youth and treatment of homeless chronic alcoholics in Alaska; prevention and treatment of alcohol and other drug use/abuse in Afghanistan, Brazil, El Salvador, Peru, and Thailand; HIV/AIDS prevention and care in Thailand and Liberia; and system/organization capacity-building and sustainability of prevention systems and innovations.

Kristen A. Ogilvie, Ph.D., is currently an Associate Research Scientist in the Alaska Office of the Pacific Institute for Research and Evaluation. Trained as an anthropologist, Dr. Ogilvie's research interests include exploring how anthropological approaches can be merged with traditional prevention science to improve the effects of preventive interventions, enhance the process of scientific inquiry, and ensure meaningful collaboration with communities involved in research. As the research manager of PIRE's Alaska Office, she has managed three U.S. National Institutes of Health-funded studies all based in Alaska, working with over 20 communities throughout the state.

David Collins, Ph.D., has worked in the field of substance abuse prevention since 1994. He has worked on numerous evaluations of substance abuse prevention projects, including the state of Ohio's Prevention State Incentive Grant (SIG), the Kentucky State Incentive Grant (1997-2002), and more recently, a Drug Testing Demonstration Grant in Nelson County, Kentucky from the federal Department of Education.

Matthew Courser, Ph.D., was trained as a survey methodologist and has worked with PIRE since 2003. He specializes in the evaluation of prevention and treatment programs and also currently evaluates a number of educational professional development programs.

Lisa Dirks, M.ADM., has worked with the Pacific Institute for Research and Evaluation (PIRE) Alaska Office since 2007. While at PIRE she has supported prevention research on harmful legal products, substance abuse among lower wage workers and program evaluation of a chronic homeless inebriate program in Alaska. Prior to working with PIRE, she worked on a variety of public health research projects with American Indian/Alaska Native populations. She is interested in collaborative community-based research.

Diane Ogilvie, MAED., has worked over 20 years in education, substance abuse prevention and treatment, and related areas. A vocal advocate for strong communities and families, Ms. Ogilvie has also developed multiple treatment curricula including Lessons from Our Elders, an Alaska Native values-based curriculum for those who are working toward wellness and sobriety in the correction and treatment settings in Alaska. In the past five years, under her direction, Akeela staff has worked with over 60 communities and 35 agencies in the areas of alcohol, tobacco and other drug (ATOD) prevention and treatment efforts.

David L. Driscoll, Ph.D., is the Director of the Institute for Health Studies and an associate professor in the College of Health and Social Welfare. His research combines epidemiological and anthropological methods to link population-level health data and sociocultural context in order to assess and create effective public health programs. He has more than 10 years of experience working for a host of federal agencies and research foundations and associations.

Joel W. Grube, Ph.D. is Senior Research Scientist and Director of the Prevention Research Center, Pacific Institute for Research and Evaluation, in Berkeley, California. His research focuses on social-psychological and environmental factors influencing drinking, smoking, drug use, and other problem behaviors among adolescents and young adults.

Figure 1. A Conceptual View of the Community Prevention Model to Reduce Children's Use of Harmful Legal Products

¹Concerns about HLP Use. ²Responsibility in HLP Prevention. ³Engagement in HLP Prevention.