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Global Substance Abuse Trends: Connecting the Science and the Policy

Included in this edition of The Journal of Global Drug Policy and Practice are the results of a study entitled, "Characteristics and Evidences of Effectiveness of a Locally Developed Prevention Framework: The Community Prevention Education Continuum." This paper provides a detailed analysis of an on-going Canadian program called Community Prevention Education Continuum (CPEC) that utilizes multiple, concurrent, evidence-based approaches in youth substance abuse prevention and which follows best-practice processes in community action. Starting out as a partnership between the Royal Canadian Mounted Police regional addictions service providers, CPEC evolved into a robust initiative that focuses on extraordinary community partnerships and mobilization. The results of the study showed a significant and long-lasting reduction in youth substance use.



We are also pleased to offer a reprint from Pain Medicine News entitled "Marijuana Usage in Chronic Pain Patients: Driving and Work Guidelines for Clinicians." This paper focuses on the use of marijuana in patients with chronic pain. Bypassing a philosophical bias as to whether marijuana is good or bad, it evaluates safety and risk versus the benefit of the drug.

Our commentary, "Determining Medicine through Science: Clinical Approach to Cannabidiol Studies Results in Positive Outcomes for Patients," provides an overview on the current issues in the U.S. surrounding the study and use of cannabidiol (CBD), the non-psychoactive compound found in Cannabis sativa L. that has shown promise in treating severe forms of childhood epilepsy. It explores the differences between the non-regulated and untested version of this compound grown in Colorado by the Stanley Brothers called "Charlotte's Web" versus the GW Pharmaceutical version called Epidiolex(TM) which has just received orphan drug status from the Food and Drug Administration and is available in certain clinical settings.



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Marijuana Usage In Chronic Pain Patients: Driving and Work Guidelines for Clinicians

Gerald M. Aronoff, MD, DABPM, *Past President American Academy of Pain Medicine Carolina Pain Associates, PA, Charlotte, North Carolina*

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For those of us involved in clinical medicine and who are in the position of rendering opinions regarding the use of marijuana in patients with chronic pain (or other medicinal uses), ours is a daunting task. We need to recognize that the issue must bypass our philosophical bias as to whether marijuana is good or bad, and focus our attention on efficacy, safety, and risk versus benefit. We also need to acknowledge an ethical dilemma as well as a legal one.

Our goal as health care providers should be to improve our patients' health and well-being, to replace maladaptive self-defeating behaviors with more adaptive coping skills, and to educate patients about behaviors or activities that could put them or others at risk for adverse outcomes. Even if marijuana were 100% legal, I would still have qualms about its use in patients with chronic pain. For reasons described in detail in this review, I believe that the use of marijuana in patients with chronic pain receiving opioid analgesics or other controlled substances puts them at significant increased risk for adverse outcomes. This is especially true in settings that require their complete attention, alertness, and mental acuity, as is always true while driving and frequently true at the workplace. The use of marijuana by patients in these situations also may put the prescriber and his or her medical practice at increased risk for adverse outcomes.

Legalizing or medicalizing marijuana does remove the specter of diversion that surrounds obtaining an illegal substance, but not nearly enough to justify its widespread use by pain patients, in my opinion.

Overview of Marijuana and Its Potential Effects

Clinical research with marijuana demonstrates efficacy with intractable nausea, anorexia, and vomiting in cancer chemotherapy, HIV/AIDS, cachexia, and other debilitating medical disorders.

There also are multiple studies documenting efficacy with intractable pain disorders.¹⁻³

However, studies do acknowledge that there is a difference between medicinal marijuana in the form of dronabinol (Marinol, AbbVie) at a therapeutic dose and the tetrahydrocannabinol (THC) found in smoked marijuana. Marinol is a fixed dosage and has a known purity level, whereas smoked marijuana is extremely variable in terms of THC potency and the purity of the substance being smoked.⁴

Physician bias regarding the safety of marijuana may come from personal experience with patients, the media, scientific studies, or anecdotal reports. Regardless, there is a large body of data demonstrating that marijuana may cause significant mental status changes. These include altered perception, hallucinations, delusions, euphoria, and dysphoria.⁴ The individual smoking marijuana also is at risk for long-term effects, among which is possible substance abuse.

Clinicians who have worked with patients with a history of substance abuse recognize the high incidence of initial marijuana experimentation with peers followed by a desire to get a better “high.” Some users thus transition to more potent illicit substances, such as opiates, cocaine, and heroin. My clinical practice includes such a high-risk population of current or former substance

abusers. Reviewing their early drug abuse history does indeed reveal childhood/adolescent experimentation, with marijuana acting as a gateway drug that led to either only more regular marijuana abuse or, more commonly, the use of more potent substances.

Since the November 2012 elections, in which Colorado and Washington legalized recreational marijuana, I revisited this issue with many of the patients in my high-risk population. The majority agreed that legalizing recreational marijuana for individuals over the age of 18 can be expected to result in major psychosocial problems, and significant added risks in the workplace and other activities of daily living (eg, riding bicycles), as well as an increase in driving accidents. Their comments reinforce my conviction that many children, adolescents, and young adults will be exposed to recreational marijuana more readily than would have been the case when there were established legal sanctions against its use. In an observational study, Pesce et al noted that up to 19% of the chronic pain patient population used cannabinoids; this study showed roughly a 4-fold incidence in the use of cocaine and methamphetamine among marijuana users in this population.⁵

The pharmacokinetics of cannabinoids show that the effects are perceptible within seconds and fully apparent within minutes. There is a very poor relationship between plasma or urine concentrations and the degree of cannabinoid-induced intoxication.⁶ The pharmacodynamics of cannabinoids indicate that the substances exert their effect by interacting with specific endogenous cannabinoid receptors. Cannabinoids are extremely lipid-soluble, and it has been noted that THC increases the release of dopamine from the nucleus accumbens and prefrontal

cortex,⁷ “producing an effect common to many drugs of misuse (including heroin, cocaine, amphetamine, and nicotine), [which] may be the basis of its reinforcing properties and recreational use. It is reversed by naloxone, suggesting an opioid link.”

A review of the pharmacology and effects of cannabis indicates that the amount of THC contained in current marijuana cigarettes often is many times greater than that seen in the 1960s and 1970s.⁶ This finding is important because the effects of THC are dose-related, and Ashton notes that most of the research on cannabis was performed in the 1970s using doses of 5 to 25 mg THC.⁶ This is consistent with other articles suggesting that in prior research studies, participants may have been given marijuana cigarettes with between 1.5% and 4% THC, whereas marijuana on the street today may have THC levels of between 10% and 30% or more. The data translate into estimates that impairment levels today are significantly higher than those previously found. This has led some to conclude that “legalizing marijuana for any reason will adversely impact public safety. More people would die and be injured on the highways, and the cost to insurance companies and the general population would soar.”⁸

Marijuana and Driving

Several other studies have noted that marijuana has played a significant role in motor vehicle accidents across the United States, with as many as 33% of drivers tested at the scene of the accident being positive for marijuana, and another 12% testing positive for marijuana and cocaine.^{9,10}

An article on the California Compassionate Use Act (CUA) discusses the inherent dangers to public safety resulting from drugged driving. It notes, “the CUA does not supersede legislation prohibiting persons from engaging in conduct that endangers others. California law prohibits driving under the influence of alcohol and drugs, and as a matter of law a person authorized to use alcohol or a drug does not normally constitute a defense to a violation.”¹¹

In reviewing the multiple psychological effects of cannabis in humans as they relate to driving ability, the following can be noted:

Effects on mood, which in recreational users is more euphoric with a high that comes on within minutes of smoking, may last for 2 hours or more, depending on dose.¹² Dysphoric reactions also can occur, often are dose-related, and are more common in naive and psychologically vulnerable users.⁶

Effects on perception include distortion of spatial perception and impairment in time perception. Hallucinations may occur with high doses.⁶

Cannabis may impair both cognition and psychomotor performance.⁶ The effects are dose-related but can be demonstrated after relatively small doses (5-10 mg THC in a joint). This has been confirmed in multiple neurocognitive and psychomotor tests. Furthermore, the effects are additive with those of other central nervous system (CNS) depressants.

“Numerous studies have shown that cannabis impairs road-driving performance and have linked cannabis use with increased incidents of road traffic accidents ... a large proportion of such drivers have not taken alcohol or have concentrations below the legal limit.”¹³ Furthermore,

“there is sufficient consistency and coherence from experimental studies and studies of cannabinoid levels among accident victims... to conclude that there is an increased risk of motor vehicle accidents among persons who drive when intoxicated with cannabis. ... The risk is magnified when cannabis is combined with intoxicating doses of alcohol.”¹⁴

In a population-based, case-control study, Laumon et al ¹⁵ reviewed cannabis intoxication and fatal road crashes in France between October 2001 and September 2003. The study cases were 6,766 drivers considered at fault in their crash. The results indicated “at least 2.5% of fatal crashes were estimated as being attributable to cannabis, compared with 28.6% for alcohol.” The researchers also noted the following:

Marijuana use increases the risk for a motor vehicle accident. “However, in France its share in fatal crashes is significantly lower than that associated with positive blood alcohol concentration.”

A causal link can be found between cannabis and motor vehicle crashes. Furthermore, “the risk of responsibility” for fatal traffic crashes driving after smoking marijuana is significantly dose-related.

It was already known that cannabis consumption, even at low doses, hampers certain faculties necessary for driving a vehicle.

The study estimates the share of fatal crashes attributable to cannabis and alcohol, thus allowing for comparison of the respective road safety issues, which the authors believe to be comparable.

The National Highway Traffic Safety Administration (NHTSA) evaluated the effects of alcohol and marijuana in 16 recreational marijuana users in a 4-way crossover-designed study. Although the effects of low doses of marijuana and alcohol were minimal, moderate doses of marijuana and alcohol combined severely impeded driving performance in city traffic situations.³

According to the NHTSA, short-term effects seen with marijuana usage that can affect driving ability include memory and learning problems, distorted perception, difficulty in thinking and problem solving, and loss of coordination. “Heavy users may have increased difficulty sustaining attention, shifting attention to meet the demands of changes in the environment, and then registering, processing, and using information.”¹⁶

The NHTSA further noted that data from road traffic arrests and fatalities indicate that marijuana is just behind alcohol as the most commonly detected psychoactive substance among driving populations. Impairment with marijuana can impair driving performance, “as measured by performance on driving simulator tasks and open and closed driving courses,” for as long as 3 hours. Effects of marijuana use on driving include “decreased car handling performance, increased reaction times, impaired time and distance estimation, inability to maintain headway, lateral travel, subjective sleepiness, [poor] motor and coordination, and impaired sustained vigilance.”¹⁶ The NHTSA noted that some drivers may have periods of driving while under the

influence of marijuana, “by overcompensating for self-perceived impairment,” but added that these episodes tend to be brief. It further noted, however, that the greater the demands that are placed on a driver’s abilities, “the [greater] the likely impairment.” Marijuana use may have particular detrimental effects on monotonous and prolonged driving, with “decision times to evaluate situations and determine appropriate responses” being increased.³

The NHTSA concludes that “low doses of THC moderately impaired cognitive and psychomotor tasks associated with driving, while severe driving impairment is observed with high doses, chronic use, and in combination with low doses of alcohol. The more difficult and unpredictable the task, the more likely marijuana will impair performance.”¹⁶ Of note, a 2009 article on driver safety procedure published by the California Department of Motor Vehicles stressed that physician-approved medical marijuana should be handled in the same manner as any other prescription medication that may affect safe driving.¹⁷

As of April 2013, 18 states and Washington, DC, sanction medical use of marijuana for debilitating medical conditions; legislation is pending in 10 others. In discussing the impact of marijuana as it relates to employment law in New Jersey, attorney Christine Bonavita reviewed the New Jersey Medical Marijuana Law and noted that “employees are not permitted legally to use marijuana on work premises and that the act also prohibits a person legally using marijuana from operating, navigating, or being in physical control of a vehicle, aircraft, railroad train, stationary heavy equipment, or vessel while under the influence of marijuana.” It was noted that the act did not define what it meant to be “under the influence.” Specific state drugged driving

laws are overviewed in the Figure.

Author Policy/Test of Reaction Time

Several years ago, I adopted a policy in my clinical practice that I consider to be both prudent and within the intent of the federal law that prohibits use of marijuana and considers it to be an illegal substance. Additionally, it is clear from the multiple sources noted here that even low doses of THC may, in susceptible individuals, cause mental status changes, perceptual distortions, and impaired judgment. At moderate to high doses, these problems are frequent. Therefore, it is wise to get urine or oral drug screens at the initial office visit and then randomly thereafter, with a frequency dependent on stratified risk factors for substance misuse, abuse, addiction, and diversion. In the event that the drug screen is positive for marijuana or any other illicit/illegal substance, no prescription will be written for any controlled substance. If the patient is receiving an opioid analgesic for pain, the prescription will not be written. The patient will be counseled and may return for treatment that may or may not include use of opioid analgesics. Before a prescription for opioids is written, the patient must have a normal drug screen and give reassurance that he or she will no longer use any illicit substances. If there is another positive urine drug screen, the patient will be tapered from all controlled substances and a substance abuse protocol will be implemented.

This treatment approach is recommended to all clinicians writing prescriptions for controlled substances for their pain patients. From a risk-management perspective, it is foolhardy to continue writing opioids for patients known to be using/abusing marijuana or other substances

deemed to be illegal. In the event that the patient in question has a work accident or motor vehicle accident in which there is an injury or death, the clinician writing the prescription for the controlled substances with full knowledge that the patient was abusing an illicit drug capable of causing mental status changes, judgment, and perceptual problems would be in a position that is difficult to defend. The physician could potentially be held liable, since he or she provided the drug that may be linked to the tragic accident/fatality. A patient under the influence of marijuana who causes a fatality and is deemed to be an impaired driver could be charged with vehicular homicide. The question that remains to be addressed is whether the health care provider who is aware that the patient was a regular user of marijuana and still provided controlled substances—including opiates for chronic pain—would be considered to be involved as an accomplice. A current legal review noted that administration of medications under such circumstances is soon to be questioned by the Supreme Court, as current policies and common case law support third-party liability to protect the public from potential harm.¹⁸ When discussing this with my patients, I advise them that I am unwilling to risk my medical license or my freedom because of their wish to be involved in the use of recreational drugs.

I have become increasingly concerned about the potential for driving accidents and work injuries in patients who are receiving CNS-active medications without appropriate monitoring. For nearly a decade I have implemented guidelines to improve driving and work safety, recognizing that an impaired patient can increase injury risk to himself or herself, as well as to innocent pedestrians, other drivers, or to co-workers. Based on the literature cited above and my clinical experience, I recommend that clinicians prescribing psychoactive medication or treating patients

who are receiving psychoactive medication from other prescribers carefully monitor mental status at each office visit. This includes monitoring mental acuity, attention span, concentration, cognitive function, thinking, mood, and affect.

Additionally, I use what many of my colleagues have been calling the Aronoff Driving Test but that more properly, I feel, should be called the Aronoff Test of Reaction Time. I have been using the following protocol since 1999. With a patient not anticipating the event, the physician or other health care provider throws a soft rubber or “Nerf” ball (nothing harder, eg, a golf ball, as this could be viewed as an assault) at the patient. The patient’s reaction is observed. A normal response is for the patient to react appropriately and catch the ball (or reach for the ball to avoid being struck). I believe that a sedated patient (or a patient with impaired reaction time from other causes) with decreased mental acuity or impaired reflexes will generally not be able to catch or deflect the ball, and thus will be struck by the ball.

Although this test has not been subjected to scientific validity measures, I have been using it for more than 12 years in more than 5,000 patient encounters. I believe that this test, combined with a detailed mental status examination, gives a good estimate of whether a patient has adequate reaction time to function in a number of situations, including driving and work, and therefore is recommended as a clinically useful tool in an office setting.

Summary

It is essential that health care providers write prescriptions for opiates or other CNS depressants

for patients in a very responsible manner with the recognition that patients often use multiple other prescription medications or over-the-counter substances. We need to be aware of all these and take them into account when we consider safety for return to work or driving. It is our ethical responsibility to protect our patients and the public at large. Allowing our patients or recreational users to use marijuana before working or driving increases the risks for adverse outcomes on many levels.

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Characteristics and Evidences of Effectiveness of a Locally Developed Prevention Framework: The Community Prevention Education Continuum

Colin Mangham, Drug Prevention Network of Canada

Background

Substance abuse remains one of the most significant problems in modern society, costing billions of dollars in health, social, legal, and economic costs but also taking a human toll on individuals and families. They are a leading cause of accidental death and injury, especially in traffic crashes (1). Because of their inexperience, among other factors, youth are especially vulnerable to such accidents. Substance abuse is linked to poor school performance, truancy, school dropout, and to a host of other problems experienced by young people (2). While the use of alcohol and cannabis appear to have declined in the past number of years, use remains high. Among British Columbia (BC) youth in 2008, for example, 63% of students who reported using alcohol in the past month also reported that they had engaged in binge drinking at least once in that period. About 16% of BC high school students reported using cannabis on a daily or almost daily basis (3).

Over the years, many efforts have been made to try to prevent substance abuse before it starts by reducing the early onset of substance use itself, and by seeking to reduce or alter harmful patterns of substance use among those already using. By far, the most commonly used approach

in addressing youthful substance use has been universal school-based prevention programs geared at reducing onset of use. Too often in Canada, these programs have been spottily implemented or left to do the job of prevention by themselves. This spottiness has not been deliberate. It simply reflects the reality that provincial curricula do not contain the funding, space, time, and resources needed to fully implement single large and lengthy programs requiring large amounts of class time and school commitment. Programs often do not run from K to 12 and therefore leave educational gaps where students are not exposed to the issues some years, but are in other years. Adequate teacher training specific to substance use education remains an issue as well. Indeed, the ability and expectation of single programs to do it all alone are being increasingly questioned (4) (5) (6) (7).

We have long known that community-*wide* efforts are required to generate the power needed to achieve changes in things as deeply entrenched as substance use attitudes and practices. The case of tobacco provides an excellent example. No one tobacco education or reduction program by itself achieved reductions in smoking. Rather, the combination of many kinds of efforts, occurring consistently over time, certainly contributed to what is a significant shift in the normative climate surrounding tobacco use. Through this shift, we now enjoy large reductions in smoking (8). Had we stopped our efforts because this program or that program did not reduce smoking onset immediately, we would have made a mistake.

We also know that such an approach is innately preferable because it gives ownership of both the issues and the problems where it belongs – among and across the whole community.

Without such ownership, no effort will be implemented for long. Reviews of best practices and evidence-based practices in prevention have always suggested a more comprehensive approach works best, one that includes ongoing education across age spans, parental involvement, varied approaches, high levels of youth involvement, local ownership and involvement to sustain efforts over time, and different approaches to meet the needs of specific youth rather than a one size fits all approach (9) (10). What we often have lacked is a good example of community wide prevention to study, one that has remained in operation over a sufficient amount of time to fairly assess its impacts. This paper is about such an example - the Community Prevention Education Continuum (CPEC), a name given a continuum of component activities led by community partners in an area of British Columbia, Canada.

CPEC evolved from a relationship forged in around 2000 between the Royal Canadian Mounted Police (RCMP) and regional addictions service provider. It now includes many community partners and exemplifies locally conceived and developed efforts couched within a vehicular strategy of community mobilization. CPEC contains many locally driven initiatives across a broad spectrum of ages of youth and involves an array of local and provincial organizations and individuals working together. By all local accounts, paraphrasing the perceptions of the two founding institutions and their community partners, *“Something very positive has happened in this area because of CPEC.”*

Such a relatively long lasting and robust initiative, that includes many of the elements of evidence-based practices in prevention and appears to follow best-practice processes in

community action, is worthy of study. This paper reports a retrospective analysis of CPEC that addresses the following questions:

1. From participants' perceptions, just what is CPEC, and what differences, if any, can these participants observe in important intermediate outcomes of such an effort (inter-agency relationships, youth involvement, awareness of importance of community support for healthy youth development, community "tone")?
2. What changes, if any, can be observed in youth substance use patterns in the communities involved?

This study has several limitations. First, much of the information is self-report from community members involved in CPEC. Second, it is retrospective, or after the fact. Where differences are found, the possibility always exists that any differences found could have been influenced by factors other than CPEC. For example, youth substance has declined across Canada over the past decade. So we are measuring any change against change that is already happening. And finally, it is limited in the number of interviews to key community leaders responsible for various elements of CPEC. Any other reporting is second hand. However, even given these limitations, a story unfolds about CPEC, and often, the perceptions of those people involved forms the best source we can find. Within the structure and aims of participatory research from which this study draws for its approach, such perceptions are valid and important in understanding fully, or as fully as possible, the dynamics of what is going on in a community. Indeed it is largely these dynamics in which we are interested when we examine community prevention processes. Because the perceptions of people involved with CPEC are naturally positive, it may seem to

make the study seem biased, but this is simply an exploratory look at CPEC and an attempt to explain what it is and how it works.

Method

We used three techniques to conduct the retrospective analysis, within the scope allowed by funding.¹ First, key informants were selected from among community members involved in some way with CPEC. Face to face interviews were conducted with these individuals following semi-structured and open formats. The individuals discussed their perceptions of any differences they felt emerging in their communities over the term of CPEC and especially since 2005 when CPEC had become well established. In particular, we sought to tap perceptions of inter-agency relationships, youth involvement, awareness of importance of community support for healthy youth development, and community “tone.” Second, we examined archival data – print and radio coverage and Public Service Announcement (PSA) pieces, police reporting of *Arrive Alive* (11) data, and *Preventing Alcohol and Risk Trauma in Youth* (P.A.R.T.Y.) (12) program reports for 2004 to 2007. Finally, we drew data from the addictions service provider’s Alcohol and Drug Use survey conducted in 2005, 2007, and 2009. From this we were able to examine trends in onset of alcohol and cannabis use. We chose these two substances because they are the two major substances of choice for adolescents not only in the region but across Canada. This survey included all grade 8 to 12 students attending school on the day of the surveys, with a completed/usable survey rate of 80% or higher in all cases.

¹ Funding for this project was provided by the RCMP ‘E’ Division Drug Awareness

Findings

Interviews

This section addresses the first research question:

From participants' perceptions, just what is CPEC, and what differences, if any, can these participants observe in important intermediate outcomes of such an effort (inter-agency relationships, youth involvement, awareness of importance of community support for healthy youth development, community "tone")?

The interviews revealed numerous things about the way CPEC developed, how it is organized, and also perceptions of the impacts of coming together and doing what is now collectively called CPEC.

CPEC began as a direct result of the efforts of two individuals, A Drug and Organized Crime Awareness (DOCAS) Officer in the Royal Canadian Mounted Police, and a counselling staffer at a regional addictions service provider. In all of the interviews it was made clear that these two individuals were the key agents of bringing the community together around youth substance abuse issues and youth assets building. The relationship formed between these two individuals with differing philosophical backgrounds and their subsequent work together, are seen as key to CPEC's growth and implementation, in the view of all others involved. Secondly, the relationships these two individuals formed with other people and organizations were felt by all who were interviewed to be of key importance to the perceived success of CPEC. Their

respective organizations in turn (RCMP and EKSS), remain central players in CPEC. However, it became evident in the interviews that no one person or organization presents him or itself as in charge of CPEC or in any way more important than any other. The egalitarianism among all players is very tangible.

Interviews were conducted with key informants in each of the following organizations:

- RCMP
- Addictions Services
- Community Mental Health Services
- Radio Station
- Regional Newspaper
- Hospital Forensics Department and Emergency Room
- City Governments
- Chambers of Commerce
- Partners in Safety
- School Districts
- A Realty Owner and Staff who provided human, financial, and logistical support
- The *Preventing Alcohol and Risk Trauma in Youth* (P.A.R.T.Y.) Student Council in area high schools – about 30 youth leaders total

Interviews were conducted with at least one person from each of these groups deemed by CPEC participants to be most able to provide information.

The manner in which these groups have come together centres around a common concern expressed by many of the persons interviewed - that in every sense, healthy youth development was a good investment. All of the adults interviewed expressed the feeling that CPEC has had a positive influence – people are more aware of youth issues, there exists an increased sense of love and caring for “our youth,” youth themselves are substantially more involved, and that the whole community knows at least something about the what’s and why’s of CPEC . They particularly expressed a conviction that their organizations are working together, that they know each other better, and that they are united in a common cause.

According to all of the persons interviewed, CPEC came about *organically* in response to a need and has grown from the bottom up. This evolution is attributed by those interviewed to be largely the result of relationships being built that led to cross-organizational cooperation. It became clear in the interviews that the participating individuals and their organizations share mutual respect, mutual goals, and mutual a joint commitment to local youth development.

The goal leading to the genesis of CPEC was to provide a stable platform from which further and ongoing community prevention initiatives could build. This platform was provided by the Drug Abuse Resistance Education (D.A.R.E.) program, which was already in the schools, supported by RCMP D.A.R.E. and Drug Awareness officers, with good school and parent cooperation. Likewise, the regional addictions service provider was providing outreach programs in the community. The RCMP and the regional addictions services provider were finding that there still were simply too many gaps and that alone they could not do it all. The two organizations

combined efforts, sought community partners, leading to what is CPEC today. Following is a list of the major elements in the CPEC continuum:

Table 1. CPEC Elements, Populations, and Partner Responsibilities

CPEC Element	Population Reached	Key Responsibility
Print and radio public service messages (PSA's)	Population at-Large	P.A.R.T.Y Student Council newspaper staff
Articles in a regional newspaper	Population at-large	P.A.R.T.Y. Student Council
Early family support and education	Young children and families	The addictions service provider: health authority
D.A.R.E. cards	Kindergarten to grade 2	RCMP
Peer education ; RETRO BILL© (Retro Bill is a character who teaches about personal safety)	Grade 3	PARTY Student Council; RCMP; the addictions service provider
<i>Be Safe Fair</i>	Grade 4	RCMP; the addictions service provider; Physiotherapists/ sports trainers
S.T.A.R.S. Grade 7's lead groups of grade 4's under guidance of Addictions staff	Grade 4-7	the addictions service provider
D.A.R.E	Grade 5	RCMP
Peer education; RCMP/professional hockey team	Grade 6	RCMP; the addictions service provider; P.A.R.T.Y. Student Council
Peer education	Grade 7	P.A.R.T.Y. Student Council

Outdoor education “whole counselling experience”	Grade 7	The addictions service providers; health authority; outdoor educators
IMAGES Youth create and display art under guidance of counselors	Grades 7-10	RCMP; the addictions service provider, mental health services
THE GREAT CANNABIS DEBATE Grade 8 students research and debate whether cannabis laws should be changed	Grade 8	RCMP; Secondary School Students
Outdoor education/whole counselling experience	Grade 8	the addictions service provider
THE BIRTHDAY PARTY Part of the P.A.R.T.Y. program; students learn interactively about risks of drinking and driving	Grade 9	RCMP Traffic Safety and Integrated Road Safety Units
P.A.R.T.Y. Program	Grade 10	RCMP; the addictions service provider; hospital; health authority; search and rescue; community mental Health association; fire services
D.A.R.E. Letter to Self	Grade 11	RCMP

Arrive Alive; SMART Grad SMART Grad is the dry grad celebration	Grade 12	RCMP; P.A.R.T.Y. Student Council; the addictions service provider
D.A.R.E. SCHOLARSHIP Based on essays written about the influence of D.A.R.E., students are awarded scholarships	Grade 12	RCMP; P.A.R.T.Y. Student Council

CPEC, then, is simply a framework for community organizations, institutions and individuals to develop partnerships in building healthy youth. The exact components of the continuum depend on local preferences and needs. The important factor, to CPEC partners, is to provide a continuum of coordinated activities, services and opportunities for building strengths and protective factors in children and youth.

The continuum of activities continues to multiply, continually generating spinoff activities and initiatives. CPEC contains activities and programs at every grade level. From responses in the interviews, this comprehensiveness is one attribute of CPEC that helped initiate the interest of the organizations now involved. It is obvious as well from the interviews that the entire enterprise is youth centred and is engendered by a love for the community's young people, not from "having" to do something. The excitement and enthusiasm toward youth assets building and CPEC components was pervasive in most of the interviews and certainly seems to permeate everyone involved.

The variety of activities in CPEC (See Table 1) reflects a broad local involvement. In particular, the P.A.R.T.Y. Student Council has become highly successful in generating year-round Public Service Announcements (PSA'S). Over 340 such spots are broadcast each year, often centred on key events such as Halloween, Christmas, New Year's, spring break, graduation, and summer holidays. These spots are student created and voiced. They combine safety and substance abuse messages and are well recognized in the community. To the outside observer they appear in fact to have become a local institution. Development of the PSA's begins in regular P.A.R.T.Y. Student Council meetings. Adult advisors report remarkably little need to edit or tone down content. The Council members seem to have a good sense of what will work and what is "out of the box," as one person noted. The PSA broadcasts by a regional radio station are paid for by sponsoring companies. CPEC participants say that in this way, "everybody wins." The idea of WIN-WIN-WIN permeates all of CPEC. An unwritten rule exists that "if there is a loser in the room, it is no good for anyone." For the print PSA's, typically posters, local volunteers play the parts depicted. The budget for the posters remains very low but the examples reviewed for this paper are clear, attractive, and convey clear messages. These are placed all about the participating communities. P.A.R.T.Y. Student Council also places print pieces, posters, and notices at least monthly into a regional advertiser newspaper that goes out to most homes in the region.

The P.A.R.T.Y. Program (*Prevent Alcohol and Risk Trauma Among Youth*) was developed at Sunnyhills and Women's Hospitals in Ontario (12). In the case of CPEC, The P.A.R.T.Y. Student Council guides the development of the P.A.R.T.Y. day for grade 10's. This includes a number of interactive activities including visiting the hospital morgue to learn about brain injury

in particular, and numerous other activities centred on alcohol, other drugs and safety.

Evaluations in Ontario and on Vancouver Island suggest the program reduces risk of death or injury in alcohol-related accidents, as well as other risky driving behaviours such as use of cell phones while driving (13). The P.A.R.T.Y. Student Council has taken on a comprehensive youth leadership role in the region, including helping with the locally developed peer education components. In these locally conceived activities, older students go into younger classes to discuss and answer questions about substance abuse and personal safety. The P.A.R.T.Y. program is the only part of the continuum requiring a special staff coordinator. A few years ago, it faced possible termination due to lack of funding. But a local Realtor and his company have taken on the core funding of the P.A.R.T.Y. program, including fund raising and providing office facilities for the P.A.R.T.Y. Program Coordinator.

The outdoor education/whole counselling experiences are organized together by the addictions service provider, community mental health services, and local/regional organizations involved in outdoor education. They provide an interactive day program where the addictions service provider youth counsellors take youth through challenging self-discovery activities and “whole counselling.” Discussions about things like substance use are non-judgmental and meet youth where they are. Teachers also go along on these outings. Local volunteers/restaurants provide cooking and meals.

The D.A.R.E. program provides part of the platform for CPEC . In addition to the regular grade 5 classroom program and parent involvement, locally created or adapted activities are employed

in CPEC such as the D.A.R.E. Scholarship; D.A.R.E. Cards for young students; “Retro Bill,” (the National Safety Buddies Host); and the “Letter to Self,” where grade 11 students open, read, and respond to letters they wrote to themselves when they were back in grade 5.

In addition to putting “boots on the ground” in support of community based youth development, the investment in D.A.R.E. also puts RCMP Officers in close contact with children at an age when they need adult mentors and examples. In the case of CPEC, many former D.A.R.E. students participate in either P.A.R.T.Y. Student Council or in other ways. The individual and institutional relationships the RCMP members enjoy with local youth are aided substantially by those relationships first developed in D.A.R.E. Another benefit of CPEC described by the RCMP is that it provides a structure for concrete community drug awareness responsibilities to be shared internally across detachments. In addition to the regular involvement of Drug Awareness and D.A.R.E. Officers, General Investigation, Traffic, and Integrated Road Safety divisions all bear responsibility for specific drug awareness activities such as the P.A.R.T.Y. day or in speaking with youth and adults in other settings.

In the IMAGES component, students create and share art that reflects their feelings and aspirations. The addictions service provider counsellors work with the youth in doing so. The display of this art further recognizes local youth.

Local communities, Columbia Basin Trust Grants, corporate support, and small provincial incentive grants, all provide money where needed. However, the total CPEC “budget” is not large. Outside the P.A.R.T.Y Coordinator, there are no extra salaries to pay, and those interviewed indicated that there is never a large amount of money needed, nor is there extra work beyond what they are already supposed to be doing as a part of their professional responsibilities.

As do others involved with CPEC, the school administrators and counsellors interviewed all noted a change in the community in recent years since CPEC began. All persons interviewed mentioned that formerly, the communities were known for rowdiness, public alcohol consumption, partying and so forth. All acknowledged that positive changes in community atmosphere have taken place, including such things as increased awareness, increased adult involvement with youth, more expressed caution and concern about youth substance abuse, and increased sense of being like a team, working together toward a common goal – healthy youth.

The interviews illuminated a number of characteristics that may help explain the success the communities have experienced in the formation, growth and evolution of CPEC. These are listed below and discussed more fully in the next section.

1. **CPEC is process rather than program driven.** People do not think of CPEC as a collection of programs, but as a way of working together to provide a continuum of educational and support initiatives for local youth, particularly in building strengths and protective factors in youth. They are committed to that process and to its aim of helping

children and youth in their community make healthy choices. No one has a program that he or she or they are trying to push at the expense of the process.

2. **CPEC provides a platform for individual programs and organizations that enhances their power by working together with others in the community.**
3. **CPEC is for the most part low budget.**
4. **Individual people and their relationships are the foundation.**
5. **CPEC has a shared aim everyone agrees on.**
6. **CPEC is largely youth led.**
7. **CPEC is conceived and driven locally.**
8. **Nothing goes forward without being “win - win - win.”**
9. **No hierarchy or separate turf issues appear to exist.**
10. **CPEC capitalizes on the gifts of many people and organizations in the community.**

These attributes, clearly visible from talking with and observing people involved with CPEC, have helped in the longevity, vitality, and comprehensiveness of CPEC. Moreover, they are consistent with best practice standards in prevention identified by the Canadian Centre on Substance Abuse (9).

Substance Use Trend Data

This section addresses the second research question:

What changes, if any, can be observed in youth substance use patterns
in the communities involved?

Several indicators of substance abuse and related problems were found. First, the addictions service provider tracks prevalence patterns in grades 7-12 through a biannual survey. The 2005, 2007 and 2009 data are available; 2002/3 was a pilot year for the instrument. Data are available by community. Six of the eight key communities for which data are kept were deemed by the organizations leading CPEC to have participated fully. Two of the communities either did not participate in CPEC over the 2005-2009 time frame of the survey, or their participation was spottier than the others as reported by the two organizations leading CPEC. For the purposes of this paper these two communities are used for comparison purposes. All of the communities have similar socio-economic and demographic profiles.

Baseline use in all communities roughly matched the 2003 – 2008 grade 8-12 provincial averages in lifetime use for alcohol (44%) and cannabis (37%). The provincial average decrease in alcohol use for grade 8 to 12 was 4% (3) (14)

Due to confidentiality concerns, no community is identified. Pooled grade 8 to 12 data are used in this study, since usage rates are too low among grade 7 students to be useful in comparing trends. The response rate in all cases was more than 80% of mainstream students in the community, and administration was to all students in school on the day the survey was administered. Response rates, gender and grade proportions are comparable across all communities. Prevalence data from 2005 to 2009 are provided in Figures 1 and 2. Figures 3 and 4 show the changes that occurred from 2005 to 2009 in the percentages in reported lifetime use of both alcohol and cannabis. Percentages of students reporting lifetime use have declined significantly (z test for difference in two proportions, .01 level of significance) in all communities except Comparison Community 2, where the decrease in alcohol use is minimal and cannabis use actually increased slightly. For alcohol, the decreases in CPEC Communities 2 – 6 are significantly sharper in CPEC communities than in the two comparison communities. In three of the CPEC communities, lifetime alcohol use is down over 10 percentage points. In the comparison communities, lifetime use has declined about 3% or less since 2005.

For cannabis, the difference in decrease of use between CPEC and non-CPEC communities is more pronounced. Use declined 10 percentage points or more since 2005 in all of the CPEC communities, while decreases were minimal in Comparison Community 1 (about 1 percentage

point) and actually increased a little over 3% in Comparison Community 2. The differences in change in percentage are significant between each of the CPEC Communities and the Comparison Communities. (z test for two proportions, .01 level).

Figure 1. Trends in Reported Lifetime Alcohol Use 2005 - 2009, Grade 8-12

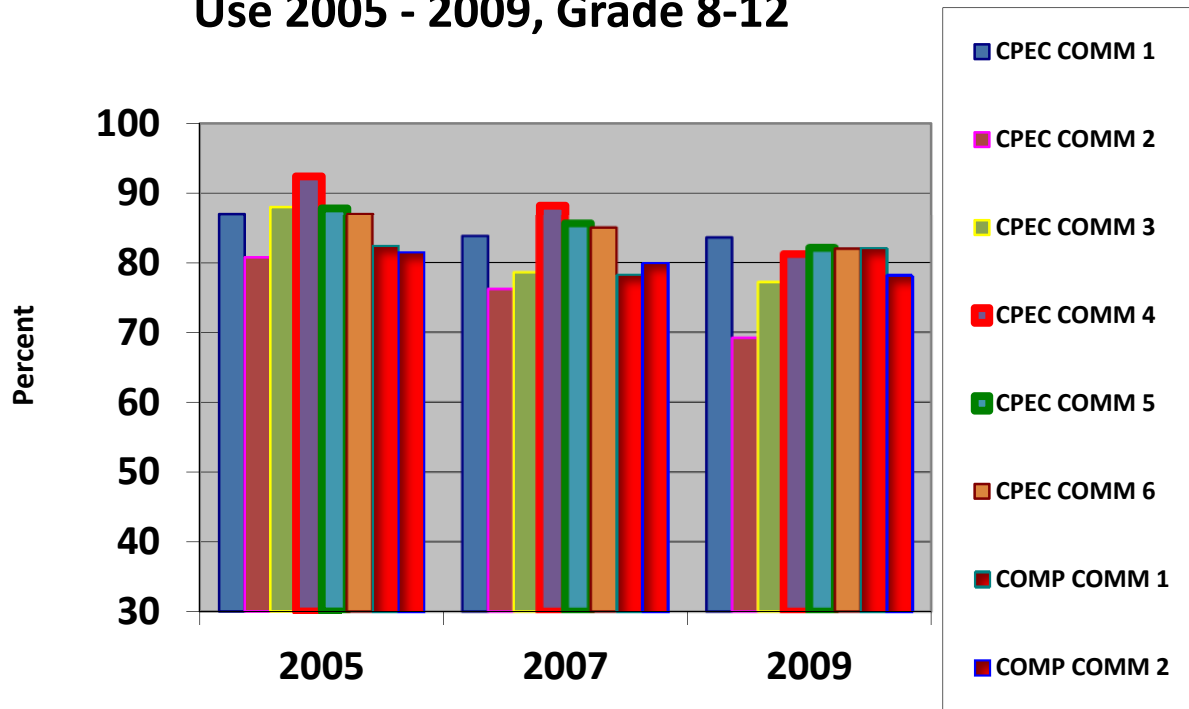


Figure 2. Trends in Reported Lifetime Marijuana Use 2005 - 2009, Grade 8-12

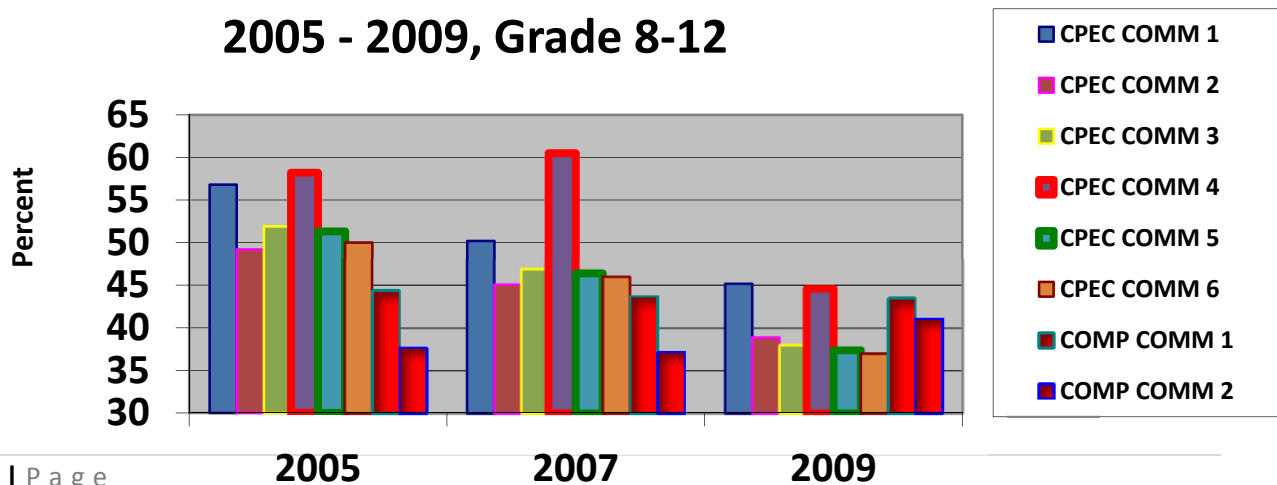


Figure 3. Change in Percentage, Lifetime Alcohol Use from 2005 to 2009, Grade 8-12

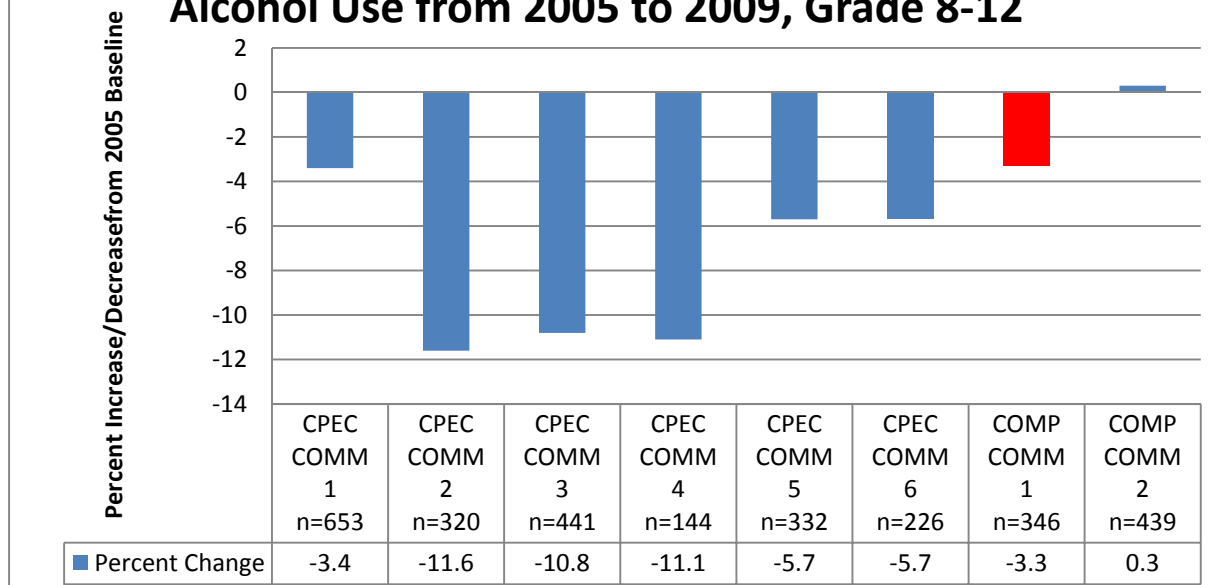
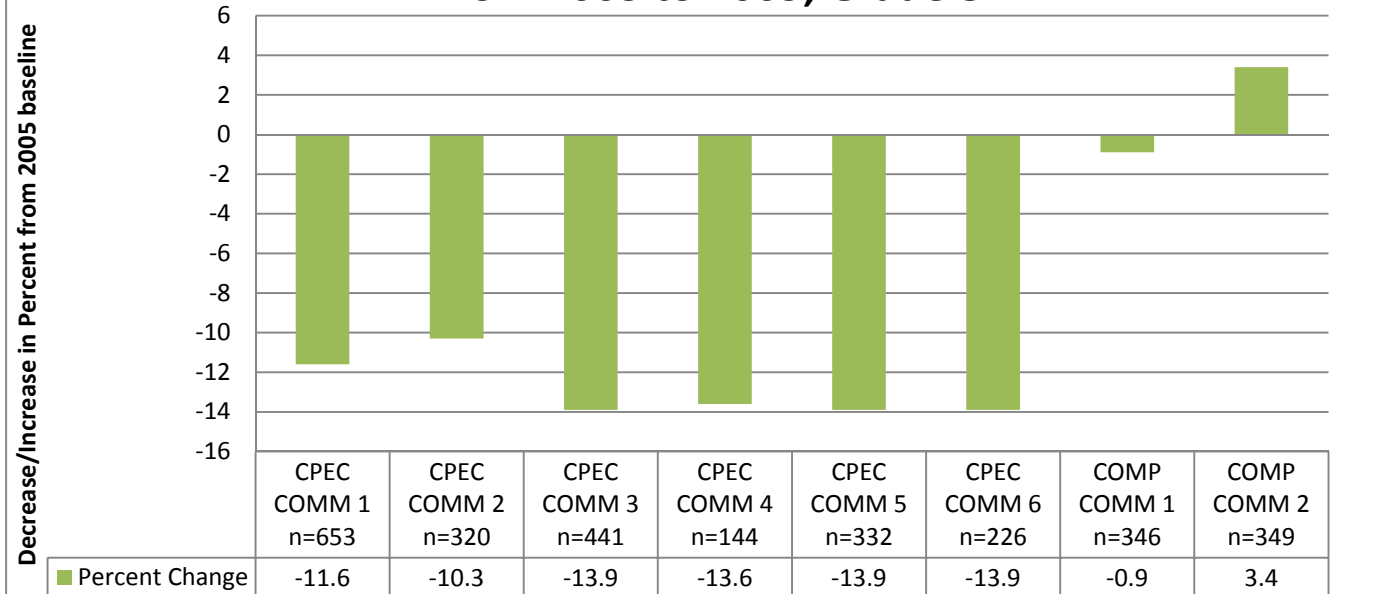
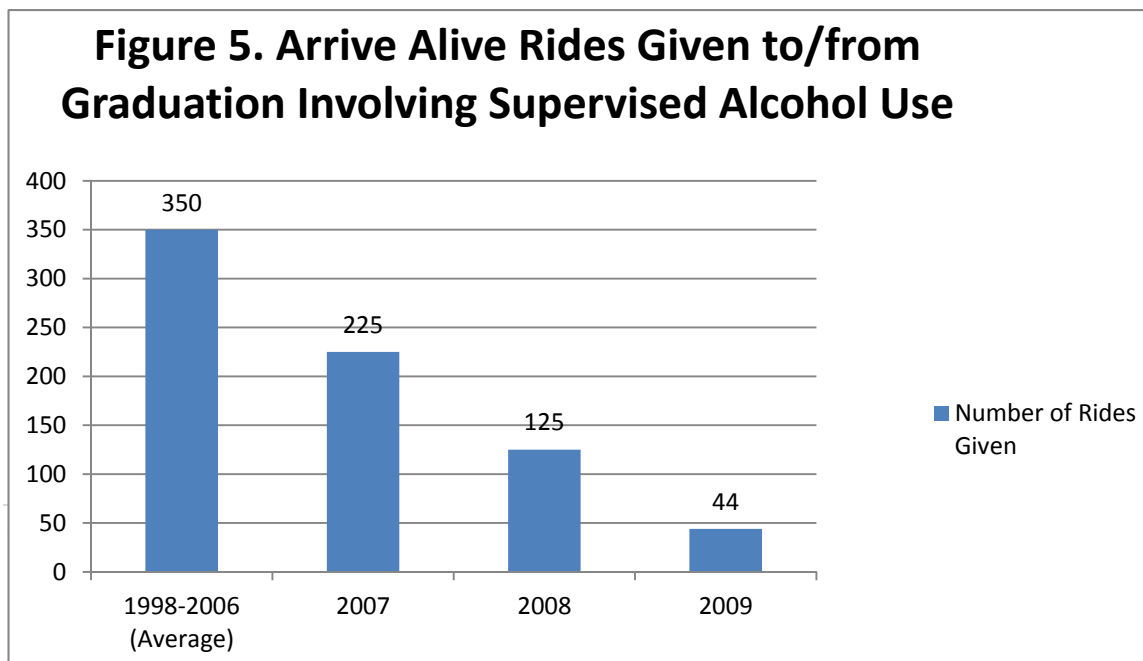


Figure 4. Change in Percentage, Lifetime Marijuana Use from 2005 to 2009, Grade 8-12



High school usage rates have declined across the province during recent years - down 3% for alcohol and 7% for cannabis from 2002 to 2008 in the Provincial Adolescent Health Survey which uses congruent sampling and methodology (3) (14) This somewhat complicates discriminating locally produced change from the overall provincial downward trend in use, although the trend downward in the CPEC communities is sharper than the provincial trend. The differences in decrease *between* the CPEC and non-CPEC communities are more meaningful, and suggest that something else is happening beyond the general provincial decrease, and it is arguable that CPEC has played a role in the sharper than average decreases.

Changes in attitudes and practices related to alcohol use are suggested also by ArriveAlive data. ArriveAlive focuses on providing rides to and from drinking events. In the case of one CPEC community, rides have been provided yearly to and from a grade 12 graduation party involving alcohol use. The RCMP, which monitors these events, reported a dramatic decrease since 2006, from over 300 in 2006 to less than 50 rides given in 2009 (see Figure 5). Police reported a correspondingly large increase in participation in the alternate Dry Grad (no alcohol) and in quieter home celebrations with less reported intoxication.



Conclusions

This study has a number of limitations and delimitations. CPEC has been implemented during a broader provincial decline in adolescent substance use. Retrospective trend data are used that estimate only changes in prevalence in the communities. Lifetime use is only one prevalence indicator and focuses on onset of use rather than on specific use patterns. Substance use is only one indicator that could be used as a measure of effectiveness of CPEC. For example we were unable to directly measure changes if any in protective factors in youth, being limited to the perceptions of people involved and to a gross review of the CPEC continuum of prevention elements.

Summing up the interviews and other data presented in this paper, however, a number of positive signs emerge regarding CPEC. First, CPEC provides an unquestionable real-world example of successful community mobilization, if success is measured by such things as durability, broad community involvement, strong youth involvement, strong acceptance by stakeholders, and elements reaching all ages of school-age children and youth. In this regard, there is much to learn from CPEC about how such a comprehensive, community-wide effort grows from the ground up. A number of key themes have been identified in this paper that would be useful for consideration by other communities. Clearly, CPEC has had a strong perceived impact on the communities. All of those interviewed feel their communities and their youth are better for having CPEC.

Second, even with trend data only, it is evident that the CPEC communities as a whole have enjoyed significantly greater net reductions in prevalence of alcohol and cannabis use than

communities without it. This needs to be explored further and verified with closer analysis, but provides a potential indicator of impact on local norm climates regarding adolescent substance use. Substance use in the CPEC communities in 2005 was higher than in the two comparison communities. Now it is roughly equal. This too is a positive indicator.

Although attributing causation of changes in prevalence in a retrospective study like this one is difficult, the findings fit certain epidemiological principles of causation using the Bradford Hill criteria (15). These are:

1. A *temporal relationship* exists (The intervention precedes the change). The drops in lifetime use correspond with the implementation of CPEC, and where CPEC was missing, change was smaller or non-existent.
2. Cause and effect are *plausible* (it is reasonable to assume a cause and effect relationship between the intervention and the change). CPEC contains many evidence-based best practices and has been implemented over time, not lasting just a short duration. We would expect some causal relationship to exist.
3. The *strength* of the differences. Most of the CPEC communities have declines in use much larger than the non-CPEC communities.
4. The findings are *consistent* with recent research evidence that a strength-building, community-wide approach with many elements similar to CPEC can produce significant impacts on substance use among youth (16)

5. The findings show *specificity*: That is, there are no other significant explanations for the differences in change as all the communities share common demographics, media access, etc.

While more research is needed to ascertain CPEC's impacts on substance use, people involved with CPEC feel that it is having positive effects on attitudes and norms in their communities and has caused the communities to take long term ownership of the job of helping their youth to develop in healthy ways. Taken together, the positive indicators of changes in substance use and the felt contributions of CPEC in the communities beg consideration that CPEC is producing tangible impacts on normative climate and subsequent behaviours.

The themes identified earlier that emerged from the interviews show some of the possible reasons for CPEC's staying power and growth, producing a successful implementation at a time when many prevention initiatives have difficulty enduring:

1. **CPEC is process rather than program driven.** People do not think of CPEC as a collection of programs, but as a way of working together to provide a continuum of educational and support initiatives for local youth, particularly in building strengths and protective factors in youth. They are committed to that process and to its aim of helping children and youth in their community make healthy choices. No one has a program that he or she or they are trying to push at the expense of the process.

2. **CPEC provides a platform for individual programs and organizations that enhances their power by working together with others in the community.** A prime example of this is found in the D.A.R.E. program. Within CPEC, D.A.R.E. is not stand-alone, but is implemented as one element in a continuum, meshing with other components to create a whole. Programs like D.A.R.E. have been criticized for not producing impacts on substance use. CPEC demonstrates a way for school-based programs to contribute to a whole rather than to be expected to do the job by themselves, which no program in Canada has done. For the RCMP, CPEC appears to be an effective way to get the most “mileage” out of its resources by building relationships and partnering with others in the community.
3. **CPEC is for the most part low budget.** One of the largest barriers to sustaining community based prevention efforts is lack of money. Programs start, then falter as initial funding levels change or disappear. In the case of CPEC, energy is not spent on trying to raise money all the time, but on the actual carrying out of the continuum.
4. **Individual people and their relationships are the foundation.** - Clearly, strong relationships have been forged during the process of CPEC’s birth and growth. Relationships between individuals based on mutual respect and mutual desired outcomes run throughout the organizations. More than this, the individual personalities of the two prime movers within the RCMP and the addictions service provider have, in the words of the Mayor of one of the communities, “figured out local culture and how to work with it.” CPEC, in form and function, is an extension of the people and organizations involved.

- 5. CPEC has a shared aim everyone agrees on.** Most people interviewed do NOT see CPEC as being principally about substance abuse, but about healthy youth development. This aim has broad support. Organizations that may have differences in philosophy or practice regarding specific issues, such as substance abuse, find common ground in working to develop healthy youth. This unity provides an example to the addictions field, where debate and disagreement over the philosophy and aims of harm reduction specifically have caused splintering and disagreements (17). Within CPEC harm reduction is not a political or philosophical issue. It is just part of a continuum of efforts to help youth. Harm reduction and incidence reduction fit together within CPEC because both are considered important. In the words of one of the key CPEC partners, “our intentions meet at a certain point and that point is “healthier youth and healthier community.”
- 6. CPEC is largely youth led.** Youth are central to the working of CPEC. They are remarkably involved and accepted into adult workplaces as they perform their responsibilities. They bear significant, not marginal, responsibility in CPEC and to all accounts they are doing it well. The P.A.R.T.Y. Student Council, with regional representation, leads this involvement. In interviews with members of this Council, it became clear that the adults involved in CPEC really do step back and that the ideas and energy behind many of the elements of the continuum and all of the social marketing (PSA) work comes directly through the youth.
- 7. CPEC is conceived and driven locally.** Many CPEC elements were borne from simply sitting down together and discussing what is needed. Where programs are used such as D.A.R.E., the program is taken beyond the classroom in locally conceived extensions

such as the “letter to self” for grade 11 students. Through the interviews it became plain that the people working with CPEC understand their communities and the needs of local youth and families. This is a key element of effective prevention identified in the CICAD Hemispherical Guidelines for School-Based Prevention (18). One gets the feeling that CPEC is quite organic, taking shape as needed and not existing as a rigid structure implemented from afar or flowing top down through a hierarchy. It is an outgrowth of local people reaching out to meet local needs. This local control and involvement from the outset, is key in that it addresses many key barriers to community mobilization such as lack of buy in and ownership (19). It is interesting to note that none of the people interviewed is following a text on community mobilization, but that community mobilization has formed naturally as need to be vehicle for CPEC.

8. **Nothing goes forward without being “win - win - win.”** None of the persons interviewed showed feelings of being stressed or burdened by CPEC responsibilities. None expressed concern that they or their organization was carrying too much financial burden. This is attributable to the commitment that anything done be “win-win-win.” If it is not, other directions are taken. This spreading of responsibility and avoidance of placing too much or too little on any one person or group, also addresses a significant barrier to successful community mobilization, which is that efforts falter when people are either overwhelmed or on the other hand not engaged.
9. **No hierarchy or separate turf issues appear to exist.** No one person interviewed expressed the least sense that they were more or less important than anyone else. Many of the people interviewed clearly feel they play important roles in CPEC, but no one

interviewed expressed the least sense of answering to anyone but to their internal organizational structures. It was evident CPEC involves a roundtable approach.

10. CPEC capitalizes on the gifts of many people and organizations in the community.

Kretzmann and McKnight, in *Building Communities from the Inside Out: A Path Toward Finding and Mobilizing a Community's Assets*, talk about community mapping and particularly the importance of identifying the many “gifts” within a community. (20)

These are the many varied talents or resources that different people and organizations and institutions possess that can contribute to an overall effort to improve the community. As CPEC has developed, just such gifts have been sought and obtained. The gifts of youth, seniors, artists, journalists, police, researchers, parents, chefs, photographers, broadcasters, sports professionals, outdoor educators, counsellors, teachers, physicians, health professionals, and business people are some examples of the many talents and resources that have been brought together by CPEC.

A number of recommendations for further research arise from this study. First, more study is needed of CPEC and its potential impacts. For example, prospective tracking studies that track key proxy and direct variables will provide a much clearer picture of the communities.

Replication of CPEC in another regional cluster would also help further illuminate the dynamics of CPEC type community action. Additional dimensions of substance use need to be measured to determine differences if any over the CPEC implementation period. It would be informative as well to compare implementation between the CPEC framework and more formal community-wide programs, examining differences if any in implementation, fit, components, buy-in, duration, and cost-benefits. Policy makers would benefit from examining how CPEC has built

partnerships finding common ground between abstinence and harm reduction based initiatives.

Finally, CPEC offers an example of successful long-term implementation. The dynamics of this implementation should be studied.

The organic manner in which CPEC came about, grew, and has gained broad acceptance and participation, provides a remarkable example of local action and initiative that should be considered by any community. It is unlikely this emergence and growth would have happened without the specific people involved. The RCMP and regional addictions service provider developed a strong working relationship that has endured and that remains the backbone of CPEC. The specific training, job description, and the presence, availability, and enthusiasm of the Drug and Organized Crime Awareness Officer enabled this development. The CPEC model offers to the RCMP a way of getting the most out of its DOCAS program and of involving the whole detachment in youth development efforts. As other communities choose to use the CPEC template, they will forge the continuum uniquely based on local resources, temperament, and conditions.

Addendum: Where to From Here?

This study examined CPEC from 2005 to 2009, the scope allowed by funding. In the interim, a project has been initiated in a major urban community in British Columbia to replicate the CPEC template using the elements of success identified in this study. Local partnerships are being forged and a tracking mechanism is being approved. This project will look more deeply at the qualitative processes and impacts in the community.

Certain external changes have happened over the past five years, however, and we are considering further adaptations to meet these challenges. One challenge is politically-based opposition to the direct involvement of law enforcement officers in the classroom. While there is evidence that in fact police are viewed as highly credible by students (21) police and their community partners must deal with opponents who continue to assert that police-led programs, such as D.A.R.E., “do not work.” These criticisms are based on the belief that school-based programs acting alone must be able to reduce drug use onset. This is an unrealistic expectation for any single program operating year to year in the real world, not just D.A.R.E. However, the organizations participating in CPEC thus far appear to recognize that it requires initiatives on the scope of CPEC and beyond and considerable time to influence the normative climate regarding substance use. The challenge to change thinking away from the idea of a single program “magic bullet” remains significant.

A second obvious challenge lies in the political referenda that have resulted in the outright legalization of cannabis in some jurisdictions in the United States and in the continued spread of

availability of “medical marijuana.” These realities and the often uninformed dialogue they produce in the media and pop culture almost certainly will continue to erode public perception of risks of cannabis use. For example, in British Columbia, Canada, where CPEC was studied, there is frequent coverage of the legalization of marijuana in Washington State, together with a seeming preoccupation with licencing and aesthetic issues rather than the harms of the substance, especially but not limited to adolescents (22) (23) (24). Such messages run counter to efforts to reduce the onset and use of cannabis.

As we look forward to implementing and testing the generic CPEC approach of whole-community involvement with the goal of helping to shift social norms regarding substance use in healthy directions, we may also look to the potential of moving beyond a specific focus on young people. For example, alcohol abuse among adults continues to produce massive social, economic, health and emotional costs. And alcohol produces effects across all age groups. A CPEC type approach embracing the whole community in collective awareness and action on alcohol abuse certainly offers another application of the model.

CPEC and other long term approaches directed at underlying normative climates offer a different way forward than obsession with investing in singular packaged programs. They embrace the very basic principles of community action. They are organic, taking their form from the contexts specific to the communities where they are engendered. They support the idea that prevention in individual lives, in families, and in communities, is a process more than an epiphany.

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Determining Medicine through Science: Clinical Approach to Cannabidiol Studies Can Result in Positive Outcomes for Patients

The Honorable Carlton E. Turner, Ph.D., D.Sc.

There is a growing movement in the United States to legalize an extract of the *Cannabis sativa* L. plant known as “Charlotte’s Web” (CW) for medicinal purposes. Legislation for this purpose has been introduced in several states. Parents, with children suffering from severe forms of epilepsy, are applying intense political pressure. The parents believe that CW will help their children and should be legalized. Since CW comes from a fiber type *Cannabis* plant and is not *smoked*, some legislators believe passage of a bill to legalize CW would not be legalizing “medical marijuana.” However, a United Nations working group, at the University of Mississippi, determined that the genus and species of all types of *Cannabis* is simple *Cannabis sativa* L.; thus, legalizing CW is simply legalizing pot. In reality, by passing a bill to legalize CW, the legislators are making sick children guinea pigs for commercial pot growers.

The current extract known as “Charlotte’s Web” is produced only in Colorado in a non-certified and unregulated production environment. This extract is produced by Joel Stanley and his brothers, who own a large marijuana growing operation in that state. They are reported to have 52 acres, 16,000 sq. ft. of greenhouses and at least 4 “medical marijuana dispensaries.” They started a non-profit foundation called “The Realm of Caring” to promote and provide marijuana therapy to patients. It appears that their goal is to sell marijuana for profit without regard to international treaties, federal laws or the U.S. Food and Drug Administration (FDA) drug approval process.

Cannabidiol (CBD), a non-psychoactive compound from the *Cannabis* plant, has shown promise in reducing the number of seizures in some children with severe forms of epilepsy. The Stanley brothers produce CW that contains not only CBD, but also tetrahydrocannabinol (THC), which is the mind-altering component of marijuana. No government certified lab has analyzed samples of CW. So the statements from Stanley that CW contains ratios between 15 and 50 to 1 of CBD to THC are not proven. Because the plant is used as grown, each batch of CW will have its unique ratio of CBD to THC.

Any state legislature authorizing a medicine created from an untested substance is a dangerous move. Science has shown that marijuana can cause permanent brain damage and other health problems. There may be other dangers that are not yet known. For elected officials to knowingly bypass the FDA and the very safeguards that keep the public safe is ludicrous. Charlotte's Web has never been clinically tested and there is no data that documents the side effects or problems that may be encountered through its interaction with other drugs.

To make CW legal in states where legislation is pending, *Cannabis sativa* L. would have to be grown in those states. Thus, those state legislatures would be, in effect, "legalizing marijuana as medicine." In order to make CW, the crude drug marijuana would have to be produced from *Cannabis* rich in CBD, extracted with a chemical solvent, concentrated, and then mixed with some vegetable oil. That process yields a crude drug that can be given orally but does not meet federal manufacturing requirements for human drugs. Additionally, it will take several months to obtain seeds, legally or illegally, and grow *Cannabis* plants in those states for the production of CW.

Crude *Cannabis* plant material (marijuana) is unstable and will not have a consistent batch to batch composition. Also, of concern about “Charlotte’s Web”, there are possible contaminants from pesticides and herbicides. The chemical solvents used to make CW are critical. Clinically, who will determine the appropriate therapeutic ratio of CBD to THC, the mind altering substance in pot that can induce seizures? Who will be available to assist patients with bad reactions to this crude drug?

There is a solution for parents desperate to help their sick children. Rather than pushing for unregulated, untested and unsafe strains of crude marijuana extracts, grown and produced under unknown conditions that will put children more in harm’s way, state legislators can establish and fund treatment programs that protect sick children and provide the best clinical care available.

CBD now has orphan drug (pharmaceutical agent developed specifically to treat a rare medical condition) status with the FDA and is called Epidiolex™. It is a natural and pure drug that has a known potency and is controlled by regulatory agencies and administered in clinical settings providing maximum medical support. Epidiolex™ can be provided through investigational new drug (IND) research at no cost to participating patients. Additionally, onsite medical specialists support the medical needs of all patients.

Epidiolex™ is produced by GW Pharmaceuticals (GW) founded in 1998 and listed on both the NASDAQ Global Market (GWPH) and AIM, a market of the London Stock Exchange. GW is licensed by the United Kingdom Home Office to work with a range of controlled drugs for medical research purposes. The group's lead program is the development of a product portfolio of cannabinoid prescription medicines to meet patient needs in a wide range of therapeutic indications. One, Sativex® oral spray, is on the market in 11 countries for spasticity due to multiple sclerosis and

in development for cancer pain and neuropathic pain of various origins and Epidiolex™ for childhood epilepsy.

GW has assembled a large in-house team with extensive experience in developing cannabinoids, medicines containing controlled substances, as well as plant-based prescription pharmaceutical products. They maintain in-house control over all aspects of the cannabinoid product development process including botanical research, extraction technology, formulation into drug delivery technologies, clinical trials and regulatory affairs. GW follows current good manufacturing practices (cGMP) for pharmaceutical products for clinical trials and commercial purposes.

GW has filed a Drug Master File (DMF) as required by FDA that provides data from pre-clinical animal studies to rule out birth defects including a detailed composition of matter of their drug (each dose will be same as previous or future doses), how the drug is manufactured in order to be used in humans, stability of the drug, metabolism profile and other data. The compilation of a DMF costs millions. *Epidiolex™, unlike CW, contains only trace amounts of THC.*

Rather than having innocent children used as guinea pigs by commercial marijuana producers, states facing this type of legislation can demonstrate their true compassion for sick children by funding clinical treatment programs at recognized medical facilities. A **truly compassionate approach** would be to make the experimental CBD-based drug Epidiolex™ or pure CBD available to patients through clinical treatment trials under a compassionate IND (expanded access IND's) protocol. The treatment of sick children in a comprehensive clinical environment is the proper approach. It is ethical to allow our existing scientific process to guide us in determining safe and effective

medicines. This is a medical/health issue and should not be treated as an unethical, irrational and political/legislative approach that treats our sick children as medical guinea pigs.

About The Author

The Honorable Carlton E. Turner, Ph.D., D.Sc. was a full research professor at the University of Mississippi (UM), School of Pharmacy and Director of its Research Institute of Pharmaceutical Sciences (RIPS). While at UM, he was the Director of the Marijuana/Cocaine project funded by the National Institute on Drug Abuse. One of his post-doctoral students currently is the director of the UM Marijuana Project.

Dr. Turner has authored over 100 peer reviewed research papers ranging from analytical data to chapters in psychiatric text books. He was an author of “Marihuana: An Annotated Bibliography” Volume I and II and annual addendums. He has served as a consultant to the United Nations (UN), Canadian and American Senates, various state legislatures and foreign governments.

He served on President Reagan’s White House staff as Special and Deputy Assistant to the President and Director of The Drug Abuse Policy Office. He held cabinet rank and assisted Mrs. Reagan with her “Just Say No” campaign. He developed the concept of The First Lady to First Lady Drug prevention/awareness campaign and chaired The First Lady to First Lady Conferences at the UN and the White House.

In 1981, Dr. Turner was given the responsibility to develop a program to rid the U.S. Military of illicit drug users. The modern drug testing program used today is based on the testing program he implemented in the military.

He has been the president/CEO of clinical laboratories and biotech companies (public and private) and has developed and overseen drug development programs for pure drugs, biologic drugs and vaccines. He knows the FDA procedure for drugs and neutraceuticals from the Investigative New Drug Application (INDs) through Phase I safety, Phase II efficacy, Phase III dosage and subsequent drug approval through the New Drug Application (NDA) process.