Distribution of Safe Smoking Kits in the City of Philadelphia: A Harm Reduction Approach

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Abstract

Beyond the inherent risks of smoking crack cocaine, the use of improvised crack pipes predisposes users to cuts and burns on their lips and damage to their lungs. As a result, they are more likely to contract Human Immunodeficiency Virus (HIV) and Hepatitis C (HCV) [39], [52], [2], [24]. In accordance with the harm reduction approach, distribution of safe smoking kits mitigates the risk of disease transmission in this population [24]. These kits would include heat resistant pipes, rubber mouthpieces, alcohol wipes, and vaseline and be covered as part of the \$30 million subset of the American Rescue Plan allocated for harm reduction programs. Despite the potential to produce significant cost savings in the form of foregone cost of HIV/HCV treatment, the Commonwealth of Pennsylvania bars the use of federal funding to support such programs [55]. This program is financially viable and ethically justified by the principle of double effect.

BACKGROUND

Infectious Disease

HIV infections are increasing disproportionately in minority communities. "African Americans represented 12% of the US population, but accounted for 42% (15,340) of HIV diagnosis in 2019. Hispanics/Latinos represented 19% of the US population, but accounted for 29% (10,502) of HIV diagnoses in 2019" [9].

Infection rates for acute Hepatitis C more than doubled since 2013, which is a 124% increase. Persons aged 20-39 had the highest incidence of acute Hepatitis C. "During 2020, 41 states reported a total of 107,300 newly identified chronic HCV cases, corresponding to 40.7 chronic HCV cases per 100,000. Hepatitis C-associated deaths during 2020 increased 4% (3.45 deaths per 100,000 people), compared to 2019 (3.33 deaths per 100,000 people). The death rates were higher among American Indian/Alaska Native persons and non-Hispanic Black persons (3.2 times and 1.8 times, respectively) than among non-Hispanic White persons [7]. Getting tested for HCV is also of paramount importance because treatments can cure most people in 8 to 12 weeks.

Harm Reduction in Philadelphia

Prevention Point is a nonprofit public health organization in Philadelphia that provides harm reduction services. At this site, people who use drugs are able to receive clean needles and, when available, crack pipes to curb the spread of diseases such as HIV and Hepatitis C. They are also able to receive vaccinations, wound care, and access mental health services to combat the psychological aspect of substance use disorder [47]. Prevention Point was able to operate in spite of the Maintaining Drug Involved Premises Statute due to Executive Order (4-92). Executive order (4-92), issued by Mayor Ed Rendell in Philadelphia, 1992. It states " 'Whereas, HIV/AIDS presents a significant risk to the health of the citizens of Philadelphia... Whereas, sterile syringe exchange programs are proven by clinical studies to be effective in reducing spread of HIV... authorize the Commissioner of Public Health to issue orders necessary for the institution of a city-wide sterile syringe exchange program' "[62].

INTRODUCTION

Since 2015 the rate of cocaine consumption in the United States has been rising [58]. Specifically in Philadelphia, cocaine "remains a pervasive drug threat" that will continue to increase with surges in foreign cocaine production [15]. Cocaine is often mixed with baking soda and boiled to yield a crystalline solid known as crack cocaine, which is then administered via injection or inhalation [21]. There is risk of overdose with use of crack but compared to injection, smoking has a smaller risk of overdose [40]. However, smoking crack exposes users to blood-borne illnesses such as HIV [11] and HCV [19], [24], when sharing smoking materials. Such risks pose a threat to public health and warrant intervention.

Despite the efforts of current community engagement and law enforcement's new crackdown on "open-air drug markets", through Drug Market Intervention(DMI) [56], crack use and its related health complications have continued to rise [58]. The DMI strategy involves investigating and targeting areas of open selling of illicit materials using an increased police force [16]. Philadelphia's police budget has increased by over 140 million dollars from 2006 to 2020, yet the use of crack has also continued to rise [50]. It is evident that increased policing is ineffective, so action must be taken from the domain of harm reduction.

The harm reduction theory aims to implement measures that ensure people who use drugs can do so in the safest way possible. The goal is not to immediately rehabilitate, but to provide materials such as safe smoking kits to decrease the spread of disease and keep the individual alive long enough to seek help for their substance use. This approach acknowledges the harms of using crack while recognizing that stigmatization and lack of support for individuals who use crack only makes the epidemic worse. Such harm reduction programs can receive funds from the America Rescue Plan [14].

The American Rescue Plan is the response by the Biden Administration to the economic crisis brought on by COVID-19. There is a \$30 million subset of funds allocated specifically to combat the overdose epidemic. The objective of these funds is to support development of harm reduction programs, increase overdose prevention education, and decrease stigma surrounding people who use drugs [22], [49]. We propose that these funds should be used to distribute safe smoking kits.

Distribution of safe smoking kits is critical for mitigating risks inherent to use of shared and homemade crack pipes. By utilizing a safe smoking kit, the individual decreases their likelihood of transmitting and contracting HIV and HCV [28]. The safe smoking kit would supply the user with a long-stemmed glass or pyrex pipe, rubber mouth piece, wooden push sticks, pipe screens, alcohol wipes, vaseline, and a brush to clean the pipe [23].

In addition to examining the benefits of the kit itself, it is also imperative to consider the medical, political, financial, and ethical aspects of crack use and disease prevention.

MEDICAL

Biology of Crack Use

Crack use causes three major effects, inhibition of dopamine reuptake, inhibition of serotonin release and inhibition of norepinephrine reuptake, all of which contribute to increased disease susceptibility [57]. Dopamine is an excitatory neurotransmitter that is linked to impulse control, libido, and plays a key role in the brain's reward pathway. In inhibiting the reuptake of dopamine, the level of dopamine in neuronal synapses is increased. This leads to constant dopaminergic receptor stimulation and increased activity of the brain's reward pathways [43]. High levels of dopamine result in euphoria that contributes to crack's high potential for abuse. In addition, sustained elevated levels of dopamine can lead to poor impulse control and poor decision making [59].

While elevated levels of dopamine alone can be detrimental, these effects are compounded by crack's inhibition of serotonin release. Serotonin is responsible for inhibitory actions within the brain and plays a role in wound healing [39]. Serotonin is released from platelets upon injury; it stops blood flow and initiates tissue repair. In burn injuries, there are elevated levels of serotonin within the epithelium that enhance repair cell proliferation, specifically fibroblast proliferation, facilitating wound healing. Conversely if serotonin levels are lowered, like they are in people who use crack, wound healing can be dysregulated and lead to poorer outcomes for thermal injuries. This leaves individuals who smoke crack particularly susceptible to decreased healing in cuts and burns sustained to their lips with the use of homemade crack pipes [52].

Finally, crack leads to increased levels of norepinephrine by inhibiting its reuptake. Norepinephrine is a hormone associated with the "fight or flight" response, vasoconstriction, and regulation of the sleep cycle [6]. Norepinephrine is derived from dopamine. Therefore, increased dopamine seen in crack use further contributes to elevated norepinephrine [6]. Elevated levels of norepinephrine have been linked to hypertension and decreased quality and length of sleep [38]. Both elevated blood pressure and poor sleep have negative contributions to

development of disease.

Increased Risk of Injury and Exposure to Communicable Diseases

The intrinsic risks of crack use are well established including development of depression, high blood pressure, malnutrition, psychosis, and even death [30]. People who use crack also increase their risk of injury and likelihood of contracting HIV and HCV. The spread of these diseases is not caused directly by crack itself but rather by the repurposing of items into pipes and the sharing of those pipes [24].

Metal pipes can cause severe burns to users who are already predisposed to impaired wound healing [24]. The use of short stemmed pipes, regardless of the material, leads to copious inhalation of hot smoke, inducing respiratory irritation and susceptibility to respiratory illnesses [24]. In addition, the filter placed in the pipe has the potential to cause harm if metal particles are dislodged and inhaled. Once inhaled, these particles damage the respiratory tract, further contributing to the increased risk of respiratory illness [24].

HIV is one of the most prevalent diseases associated with crack usage and is acquired through contact with infected bodily fluids [2]. It is stored in the body's immune cells where it proliferates and destroys CD4+ cells, making individuals more vulnerable to infection as disease progresses. People who use crack are susceptible to contracting HIV through two major behavioral practices: engaging in unprotected sex and sharing of crack pipes [8], [10], [45]. Smoking crack can lead to burns and cuts on a person's lips resulting in blood being distributed in and on inhalation instruments [44]. When shared, these instruments can serve as a means of spreading HIV [24].

HCV is another blood borne virus commonly spread through crack use. There are numerous studies in Canada that show elevated rates of HCV among people who smoke crack cocaine. Prevalence rates of HCV among individuals who smoke crack cocaine in Canada range from 37% in Ottawa to 43% in Vancouver to 29% in Toronto. These rates are substantially higher than among the general Canadian population [48]. While most people who contract HCV are asymptomatic, symptoms can range from general malaise to cirrhosis and liver cancer [61]. HCV is spread through the sharing of needles and unprotected sex, but also through sharing smoking materials via the same mechanism as HIV [61]. Therefore, sharing crack pipes leaves people who smoke crack more at risk than the general population to contract HCV [33].

Reduced Harm Using Safe Smoking Kits

Crack pipes tend to be constructed of improvised materials including metal soda cans, plastics, and thin glass pipes all of which release toxic fumes, cause burns, and can break easily [23]. The safe smoking kits would diminish the disease risk associated with use of homemade pipes. Kits would include the following: long-stemmed glass or Pyrex pipes, rubber mouthpieces, plastic tubing, pipe screens, wooden push sticks, alcohol wipes, lip balm/Vaseline, and a brush to clean the pipes.

The heat resistant glass/Pyrex pipe can withstand very high temperatures, preventing explosion, which could injure the user [20]. A rubber mouth piece that can be removed from the pipe and cleaned would reduce contact with bodily fluids by providing a barrier if the pipe is shared. Plastic tubing distances the mouth from the glass pipe and would diminish the chances of getting cuts and burns [24]. A metal pipe screen l fits snugly inside the pipe and would be replaced after each use to decrease the respiratory hazard presented by repeated heating of brillo or steel wool [53]. The screens do release toxic chemicals when heated to high temperatures but this is an accepted risk, as they are needed to prevent debris from entering the body. A wooden push stick would be used to position the screen inside the pipe without damaging the glass [24]. Alcohol wipes would sanitize the pipe before and after use. Vaseline would help heal the cuts on the face and lips [27]. A small brush would function to clean the pipe and prevent buildup of dirt and other smoke byproducts [24].

HARM REDUCTION THEORY: IMPLEMENTATION OF SAFE SMOKING KITS

Political Challenges

Implementation of the harm reduction theory using safe smoking kits has been successfully carried out in other countries. Namely, sites in Vancouver, Canada have led to decreased disease burden through widespread distribution of safe smoking kits at health service points. Longitudinal studies have demonstrated that people who obtain smoking materials solely through health service points are 18% less likely to suffer from health problems related to crack use [46]. While this program has found success in Vancouver, there are three significant hurdles that have to be overcome before it can find widespread implementation in the United States: the "Crack House Statute," social stigma, and access to federal funding [42].

The "Crack House Statute," is officially named the Maintaining Drug Involved Premises Statute and was built into the Anti-Drug Abuse Act of 1968. This statute makes it illegal to own, lease, or operate any place with the intent to use, distribute or manufacture illicit drugs. It calls into question whether those organizations and/or volunteers who distribute safe smoking kits will be held accountable for providing drug paraphernalia to users, regardless of the intent because of the inclusion of the crack pipe [33].

Prevention Point was offered amnesty from the Maintaining Drug Involved Premises Statute by Executive Order (4-92). The Safe Smoking Kit offers similar relief from the burden of HIV and HCV. Due to its function and goal being similar to that of the sterile syringe exchanges, the safe smoking kits should be given similar protections under Executive Order (4-92).

The stigmatization of drug use has made any discussion pertaining to this topic controversial. Crack in particular has been used as a racist dog whistle to refer to minorities [54]. This stigma and racist connotation make it difficult to find locations where safe smoking kits can be distributed. Community members become fearful that these programs will make their neighborhoods unsafe by increasing crime and homelessness rates. Even among those that support harm reduction programs in theory, there is persistence of a "not in my backyard" mentality where people will want to support those in need as long as it does not affect them and their community [32].

In the Commonwealth of Pennsylvania, harm reduction programs such as syringe exchange sites (e.g. Prevention Point) are barred from obtaining funds from or applying for grants allocated by the Federal Government for the purpose of fighting addiction and drug related deaths [22], [55], [51]. This includes application for grants to fund safe smoking kits, since they are considered drug paraphernalia.

Financial Challenges and Solutions

We assert that preventing harm reduction agencies from obtaining federal grant money to implement distribution of safe smoking kits ends up costing the state a significant amount of money when people who smoke crack seek treatment for diseases incurred from use of unsafe smoking equipment. Therefore, it is in the best interest of the state to allow for federal grant applications from harm reduction organizations such as Prevention Point.

In Vancouver, sites that have similar operating models to Prevention Point are distributing safe smoking kits. The kits distributed contain the materials as proposed above and cost \$.46 USD per kit [4]. Evidence shows that distribution of safe smoking kits led to a 1.27% decrease in HCV cases at this site [25]. Furthermore, the site demonstrated that distribution of safe smoking kits was cost effective, saving an annual \$1.2 million CAD (\$1.06 million USD)[1] [29].

Determining the cost effectiveness of the Vancouver site involved collection of pipe-sharing behaviors, HCV and HIV positivity rates, and the number of daily smoking events. These data were not available for the Philadelphia population of people who smoke crack. However, a cost benefit analysis was constructed by combining trends observed from Vancouver and data available for the Philadelphia population.

Methods and Variables

This analysis was conducted by examining the HCV cases prevented at the Vancouver safe smoking facility (SSF). This population had an estimated 4,330 people who use crack and in this population implementation of the SSF prevented 55 cases of HCV [29].

Response rate – Our response rate is the percentage decrease in HCV cases, calculated as a percentage of total HCV cases. This value is calculated by dividing the prevented cases (55) by total cases (4,330) to arrive at a value of 1.27%. The Vancouver SSF did not specifically examine HIV cases prevented but since the mechanism of HIV transmission is similar to HCV, the same response rate of 1.27% was used.

Number of Philadelphia residents at risk - In Philadelphia, the number of people who use crack was estimated using data from the 2018 National HIV Behavioral Surveillance Survey. This study interviewed 620 people who inject drugs in the Philadelphia area and 56% of those people also use crack [12]. Therefore, our analysis has an estimated number of people who use crack in Philadelphia of 347. Since Philadelphia does not have the same data on drug use patterns that was available for the Vancouver population the analysis was conducted using a range of response rates, all lower than that observed in Vancouver. The lowest response rate analyzed was 0.0001%, 0.003 cases prevented, followed by a response rate of 0.0101%. The response rate was increased by 0.01% up to the highest response rate analyzed of 0.1101%. Each response rate was multiplied by the number of people who use crack in Philadelphia to determine the number of HCV and HIV cases prevented.

Cost Savings- For each response rate, the forgone cost of treating HCV and HIV was calculated by multiplying the number of prevented cases by the cost of treatment. Since HIV treatment is continuous from the point of diagnosis throughout an individual's lifetime, this cost of treatment represents the discounted cost. The cost of the safe smoking kits was calculated by multiplying the cost of one kit by the number of people who use crack. This value was then subtracted from the forgone treatment cost to give the potential cost savings for each response rate. A quantity of 10 safe smoking kits per person was used based on Prevention Point's current model of distributing 10 packs of sterile syringes to their clients.

Analysis and Results

Table 1 shows the results of a cost-benefit analysis in Vancouver for HCV. It is presented below.

Table 1

HCV Cost Analysis in Vancouver

A	В	с	D	E	F	G
Response Rate	Population of People who use crack [29]	Cost of Kit [4]	Cost to Treat HCV [3]	Total Cost of Kits	Number of prevented HCV people who use crack	Foregone Cost of HCV treatment
1.27%	4,330	\$0.46	\$17,965	\$1,992	55	\$987,913

Column A represents the response rate, calculated by dividing column F, the number of HCV positive individuals by column B, the population of people who use crack. The total cost of the kits, column E was calculated by multiplying column B by the cost of a single kit, column C. Foregone cost of HCV treatment, column G was calculated by multiplying the cost of treatment in column D by column F.

Table 2 shows the results of a cost benefit analysis in Philadelphia for HCV. It is presented below.

Table 2

HCV Cost Benefit Analysis in Philadelphia

A	В	с	D	E	F	G	н
Range of Response Rates	Philadelphi a Population of Crack Users [12]	Cost of 10 Kits	Cost to Treat HCV [3]	Total Cost of Kits	Number of Prevented HCV Positive Crack users	Foregone Cost of HCV Treatment (lifetime)	Cost Savings for HCV
0.0001%	347	\$4.60	\$17,965	\$1,597	0.0003	\$6	\$(1,591)
0.0101%	347	\$4.60	\$17,965	\$1,597	0.0351	\$630	\$(967)
0.0201%	347	\$4.60	\$17,965	\$1,597	0.0698	\$1,254	\$(343)
0.0301%	347	\$4.60	\$17,965	\$1,597	0.1045	\$1,887	\$280
0.0401%	347	\$4.60	\$17,965	\$1,597	0.1392	\$2,501	\$904
0.0501%	347	\$4.60	\$17,965	\$1,597	0.1739	\$3,125	\$1,528
0.0601%	347	\$4.60	\$17,965	\$1,597	0.2087	\$3,749	\$2,152
0.0701%	347	\$4.60	\$17,965	\$1,597	0.2434	\$4,372	\$2,775
0.0801%	347	\$4.60	\$17,965	\$1,597	0.2781	\$4,996	\$3,399
0.0901%	347	\$4.60	\$17,965	\$1,597	0.3128	\$5,620	\$4,023
0.1001%	347	\$4.60	\$17,965	\$1,597	0.3475	\$6,224	\$4,647
0.1101%	347	\$4.60	\$17,965	\$1,597	0.3823	\$6,867	\$5,270

Column A demonstrates the range of response rates. Column E, the total cost of the kits, was calculated by multiplying the population of people who use crack in column B by the cost of 10 safe smoking kits in column C. The number of prevented HCV positive users, column F was calculated for each response rate by multiplying column A by column B. The result in column F was multiplied by column E to obtain the foregone cost of HCV treatment in column G. Finally, column E was subtracted from column G to get the total cost savings in column H.

Table 3 shows the results of a cost benefit analysis in Vancouver for HIV. It is presented below

Table 3

HIV Cost Analysis in Vancouver

А	В	с	D	E	F	G
Response Rate	Population of People who use crack [29]	Cost of Kit [4]	Cost to Treat HIV [5]	Total Cost of Kits	Number of prevented HIV people who use crack	Foregone Cost of HIV treatment (lifetime)
1.27%	4,330	\$0.46	\$420,000	\$1,992	55	\$23,096,220

Column A represents the response rate, calculated by dividing column F, the number of HIV positive individuals by column B, the population of people who use crack. The total cost of the kits, column E was calculated by multiplying column B by the cost of a single kit, column C. Foregone cost of HIV treatment, column G was calculated by multiplying the cost of treatment in column D by column F. Table 4 shows the results of a cost benefit analysis in Philadelphia for HIV. It is presented below.

Table 4

HIV Cost Benefit Analysis in Philadelphia

A	В	с	D	E	F	G	н
Range of Response Rates	Philadelphi a Population of Crack Users [12]	Cost of 10 Kits	Cost to Treat HIV [5]	Total Cost of Kits	Number of Prevented HIV Positive Crack users	Foregone Cost of HIV Treatment (lifetime)	Cost Savings for HIV
0.0001%	347	\$4.60	\$420,000	\$1,597	0.0003	\$146	\$(1,451)
0.0101%	347	\$4.60	\$420,000	\$1,597	0.0351	\$14,728	\$13,131
0.0201%	347	\$4.60	\$420,000	\$1,597	0.0698	\$29,311	\$27,714
0.0301%	347	\$4.60	\$420,000	\$1,597	0.1045	\$43,893	\$42,296
0.0401%	347	\$4.60	\$420,000	\$1,597	0.1392	\$58,475	\$56,878
0.0501%	347	\$4.60	\$420,000	\$1,597	0.1739	\$73,058	\$71,461
0.0601%	347	\$4.60	\$420,000	\$1,597	0.2087	\$87,640	\$86,043
0.0701%	347	\$4.60	\$420,000	\$1,597	0.2434	\$102,223	\$100,626
0.0801%	347	\$4.60	\$420,000	\$1,597	0.2781	\$116,805	\$115,208
0.0901%	347	\$4.60	\$420,000	\$1,597	0.3128	\$131,387	\$129,790
0.1001%	347	\$4.60	\$420,000	\$1,597	0.3475	\$145,970	\$144,373
0.1101%	347	\$4.60	\$420,000	\$1,597	0.3823	\$160,552	\$158,955

Column A demonstrates the range of response rates. Column E, the total cost of the kits, was calculated by multiplying the population of people who use crack in column B by the cost of 10 safe smoking kits in column C. The number of prevented HIV positive users, column F was calculated for each response rate by multiplying column A by column B. The result in column F was multiplied by column E to obtain the foregone cost of HIV treatment in column G. Finally, column E was subtracted from column G to get the total cost savings in column H.

Distribution of safe smoking kits is cost effective for prevention of HCV beginning at a response rate of 0.0301% and cost effective for prevention of HIV beginning at a response rate of 0.0101%. Based on the response rate of 1.27% in Vancouver, it is likely that the actual response rate in Philadelphia is much higher. Given this, we determined that distribution of safe smoking kits at an existing safe syringe site like Prevention Point will be cost effective and should be implemented utilizing funds from the federal Harm Reduction Programs grant.

Our analysis shows that the implementation of a SSF site in Philadelphia will improve the efficiency of government spending, since a significant portion of affected people in Philadelphia are receiving care under Medicaid. In this population of 620 people who inject drugs (PWID) in Philadelphia, PA, evidence shows that 90% of individuals had health insurance (n=558). Of those 558 individuals, 89% were insured by medicaid (n=496) [12]. The healthcare of the majority of these individuals is already being funded by government programs. Therefore, utilizing government funds to sponsor a safe smoking kit program would lead to fewer Medicaid dollars being used to treat HIV and HCV in this population.

ETHICAL CONSIDERATIONS

Harm Reduction Theory

Advocacy for distribution of safe smoking kits is driven by the kit's potential to be used as a harm reduction technique. Harm reduction is an approach focused on minimizing the negative sequelae that go hand-in-hand with the use of drugs [41]. Harm reduction techniques have a medical and ethical impact on both the individual and society as a whole. These techniques accept individuals as they are, while also tailoring a person's treatment to fit their needs [36]. There are specific principles that are quintessential to an understanding of harm reduction, as listed by the Harm Reduction Coalition. The following principles, adapted to various bloodborne diseases like HIV and HCV, are the foundation of the Harm Reduction Theory:

- Accepts, for better and or worse, that licit and illicit drug use and risky sexual behavior are part of our world and chooses to work to minimize its harmful effects rather than simply ignore or condemn them.
- Understands drug use and risky sexual behavior as a complex, multi-faceted phenomenon that encompasses a continuum of behaviors from severe abuse to total abstinence, and acknowledges that some ways of using drugs and engaging in sexual relations are clearly safer than others.
- Establishes quality of individual and community life and well-being-not necessarily cessation of all drug use and sexual behavior-as the criteria for successful interventions and policies.
- Calls for the non-judgmental, non-coercive provision of services and resources to people who use drugs and engage in risky sexual behavior and the communities in which they live in order to assist them in reducing attendant harm.
- Ensures that people who use drugs and those with a history of drug use and those individuals who are HIV positive routinely have a real voice in the creation of programs and policies designed to serve them.
- Affirms people who use drugs and those who engage in risky sexual behavior themselves as the primary agents of reducing the harms of their drug use and sexual behavior, and seeks to empower these individuals to share information and support each other in strategies which meet their actual conditions of use and behavior.
- Recognizes that the realities of poverty, class, racism, social isolation, past trauma, sex-based

discrimination and other social inequalities affect both people's vulnerability to and capacity for effectively dealing with drug-related harm and risky sexual behavior.

• Does not attempt to minimize or ignore the real and tragic harm and danger associated with licit and illicit drug use and risky sexual behavior [41].

The safe smoking kit has the potential to reduce HIV and HCV infections so it can be used as a harm reduction agent and in and of itself save lives. If we as a society value human life as sacred, we must find a way to preserve it. Distribution of safe smoking kits presents a viable means of curbing the rise in HIV and HCV diagnoses, especially among minorities in the United States. This can be accomplished as part of a comprehensive harm reduction action program directed by trained health care professionals.

Critics of both the harm reduction approach and the use of safe smoking kits as a harm reduction agent argue that these initiatives are a waste of taxpayer's money. First, many argue that the use of a harm reduction technique like safe smoking kits only encourages people to continue their destructive action. In the case of safe smoking kits, critics believe its use will only lead to a higher HIV and HCV infection rates because it will give some a false sense of protection. Similarly, detractors argue these approaches lead people away from seeking testing and treatment since they now have a safety net of sorts for their risky behaviors. Some also believe that we would be wasting valuable money on producing these kits, when that money could be spent on prevention programs that are more ethical and socially acceptable.

Proponents of the harm reduction theory point to the various successes of this approach. The Needle and Syringe Exchange programs have decreased the HIV infection rate among IV drug users in the United States. The Opioid Substitution Therapy (PST) or Opioid Replacement Therapy (ORT) replaces illegal opioids, such as heroin, with a longer acting but less euphoric opioid such as methadone or buprenorphine under medical supervision. Supervised Injection Sites provide sterile injection equipment, information about drugs and basic health care, treatment referrals and access to health care professionals. All three of these examples show the efficacy of the harm reduction theory. According to Navanethem Pillay, U.N High Commissioner for Human Rights, "Too often, drug users suffer discrimination, are forced to accept treatment, are marginalized, and often harmed by approaches which overemphasize criminalization and punishment while underemphasizing harm reduction and respect for human rights.

This is despite the longstanding evidence that a harm reduction approach is the most effective way of protecting rights, limiting personal suffering, and reducing the incidence of HIV" [17]. What we learned in the past can have a profound impact on the present and future and ultimately, save lives. Finally, to address these criticisms and to strengthen the arguments for this harm reduction approach, it must be determined whether or not broader access to safe smoking kits would promote more good than harm, not only for the minority population but also for their associates and communities at large.

Ethical Analysis

Society, in general, has always recognized that in our complex world there are times when we are faced with situations that have two consequences--one good and the other evil. The time-honored ethical principle that has been applied in these situations is called the principle of double effect. As the name itself implies, human action has two distinct effects. One effect is intended and good; the other is unintended and harmful. As an ethical principle, it was never intended to be an inflexible rule or a mathematical formula, but rather it is to be used as an efficient guide to prudent judgment in solving difficult moral dilemmas [35]. This principle focuses on the agent in terms of intentions and accountability, not just contingent consequences. The principle of double effect specifies four conditions, which must be fulfilled for an action with both a good and a harmful effect to be ethically justified:

1) The action, considered by itself and independently of its effects, must not be morally harmful. The object of the action must be good or indifferent.

2) The harmful effect must not be the means of producing the good effect.

3) The harmful effect is sincerely not intended, but merely tolerated.

4) There must be a proportionate reason for performing the action, in spite of the harmful consequence [31].

In the case of safe smoking kits, the good effect is that the kits have the potential to decrease HIV and HCV infections and ultimately to save lives. The harmful effect is that some believe that it may send a wrong message that risky behavior is condoned and even encouraged. This could lead to scandal. To determine if the distribution of safe smoking kits is ethical, this issue will be examined in light of the four conditions of the principle of double effect.

The first condition allows for the distribution of the safe smoking kits because the object of the action, in and of itself, is good. The moral object is the precise good that is freely willed in this action. The moral object of this action is to decrease rates of HIV and HCV which can potentially save lives by providing an effective and alternative plan to help prevent these infections. The immediate goal is not to endorse or encourage risky sexual behavior or substance use. Rather, the first goal is to offer an effective prevention tool for drug addicted and sexually active people who meet the criteria for the program. The second goal is to protect individuals' health, in particular minority individuals, by decreasing HIV and HCV infections and deaths.

The second condition permits making safe smoking kits available by health care professionals at community-based organizations and clinics because the good effect of offering an effective alternative prevention tool that can save lives is not produced by means of the harmful effect. The two effects are completely independent. Making safe smoking kits available at approved community-based organizations and clinics coordinated by qualified health care professionals has no intention of encouraging risky sexual behavior and drug use. In fact, the opposite is true. To argue that public health officials are encouraging or condoning risky sexual behavior or drug use is illogical. This is "like suggesting that airbags and seatbelts encourage unsafe driving" [26].

The third condition is met because the direct intention of making safe smoking kits available is to protect and preserve human life and to encourage HIV and HCV prevention, education, social support, professional counseling, testing and medical care. We know "when people who have open sores share pipes, the glass can serve as a vector for certain bloodborne diseases such as HCV and HIV" [13]. The direct intention of this program is to preserve the lives of the most vulnerable people, especially those who are minorities. Through education and other prevention techniques, the potential of spreading HIV and HCV decreases, thereby decreasing the potential for death. The foreseen but unintended consequence of safe smoking kit distribution may be the belief that it is condoning and even encouraging risky sexual behavior and drug use. One might also argue that it could give a "false" sense of security to those who engage in risky sexual behavior and drug use. Nevertheless, there is no scientific evidence that proves this will encourage or even increase HIV and HCV infections. In fact, research shows that the opposite is true.

Finally, the argument for the ethical justification of making safe smoking kits available by the principle of double effect focuses on the fourth condition of whether there is a proportionately grave reason for allowing the unintended possibility of scandal and the possibility of increased risky sexual behavior and drug use. Proportionate reason is the linchpin that holds this complex moral principle together.

Proportionate reason refers to a specific value and its relation to all elements in the action [60]. The specific value in allowing for safe smoking kits is to preserve human life by decreasing HIV and HCV infections and encouraging responsible sexual behavior to vulnerable members of society. The harm, which may come about by trying to achieve this value, is the foreseen but unintended possibility that some may view it as condoning and even encouraging risky sexual behavior and drug use. The ethical question is whether the value of preserving human life outweighs the harm of the foreseen, but unintended, possibility of scandal and increased risky sexual behavior and drug use? To determine if a proper relationship exists between the specific value and the other elements of the act, ethicist Richard McCormick, S.J. proposes three criteria for the establishment of proportionate reason:

1) The means used will not cause more harm than necessary to achieve the value.

2) No less harmful way exists to protect the value.

3) The means used to achieve the value will not undermine it [37].[1]

The application of McCormick's criteria to making safe smoking kits available nationwide as an alternative HIV and HCV prevention tool supports the argument that there is a proportionate reason for allowing this program. First, according to public health officials, the use of safe smoking kits, as part of a comprehensive HIV/HCV prevention program, can decrease HIV and HCV infection rates, decrease the use of medical resources and potentially save lives. Studies show that sharing of needles and crack pipes does increase the risk of HIV and HCV. It has been shown that smoking crack with the use of metal and glass pipes, which produces wounds in and around the mouth, makes people more vulnerable to HIV transmission during activities such as oral sex or sharing crack pipes [25]. If making safe smoking kits readily available for at-risk people, as part of a comprehensive program, saves lives and does not increase HIV and HCV infections or condone risky

sexual or drug behavior, then this program does not cause more harm than necessary. To verify these facts, the program should be initiated on a wide-scale basis in order to collect more data. Larger clinical trials in major cities in the United States, especially cities with large minority populations, would offer valuable data regarding this issue.

Second, at present, there does not appear to be an alternative that is as effective as safe smoking kits for at-risk individuals. It is true that other means of prevention exist in regards to HIV, such as abstinence but according to health care authorities, abstinence is not realistic for many at-risk individuals. In the United States 1 out of 8 HIV infected people out of the 1.2 million infected are unaware they are infected and continue to infect others. Many of these infected are participating in risky sexual behavior. For crack addicted individuals, critics say that drug rehabilitation centers are a viable option. This may be true, but anyone involved in drug addiction knows that rehabilitation is not possible unless the drug addicted person is open and ready to accept rehabilitation. If safe smoking kits are effective in decreasing new HIV and HCV infections, then this program needs to be expanded to every major city in the United States.

The critical aspect that cannot be overlooked in making safe smoking kits readily available at various supervised sites for at-risk individuals is the element of human contact. This human contact allows health care workers to form personal relationships with at-risk individuals and thus provide the opportunity to offer them appropriate health care, personal counseling, testing and referrals to treatment centers. Various studies have confirmed that intravenous drug users reduce risk-laden behaviors when pertinent information and services, such as counseling, are made available, and especially when they are offered by peers who are members of the drug-using subcultures [1]. Making safe smoking kits available to at-risk individuals by trained health care professionals not only has the potential to save human lives but also to foster human dignity and respect.

Third, safe smoking kits do not undermine the value of human life. One can argue convincingly that the intention of making safe smoking kits available is to save human lives. From current data in Canada this approach appears to be quite effective. It seems clear that there is a proportionate reason to allow safe smoking kits to be made available in the United States using taxpayer money. Safe smoking kits contribute to the well-being of at-risk individuals and society as a whole because this tool has the potential to decrease the HIV and HCV infection rates and ultimately, save medical resources and human lives. It also offers these vulnerable individuals the opportunity to realize that they are valued as persons and that, with the appropriate assistance, HIV and HCV infections can be avoided. Therefore, it is ethically justified under the principle of double effect to allow for safe smoking kits to be made available to at-risk individuals at approved community-based organizations that are coordinated by health care professionals. Ethically, the greater good of those individuals at-risk and the common good of society are advanced by financially supporting the use of safe smoking kits in major cities in the United States.

CONCLUSION

Study Limitations

The following limitations were encountered when completing the financial analysis: the Vancouver study only looked at decreased HCV cases. However, it has been established that the mechanism of transmission of HCV and HIV are similar. We follow this evidence by using the same response rate. Second, the estimated number of people who use crack in Philadelphia was determined from data collected for a smaller survey and therefore may not be representative of the entire population of people who use crack in Philadelphia. Finally, primary research of people who use crack in Philadelphia is required to determine how many safe smoking kits are required to curb pipe sharing.

Recommendations

Our research provides strong evidence that safe smoking kits should be distributed at locations that already participate in a needle exchange program. In doing so, the only added cost to the establishment will be the cost of the crack pipes themselves. This is also highly feasible, because trained healthcare staff at these locations have established trust with the community of people who use drugs. These locations would also encourage safe disposal of used pipes through provision of personal sharps containers and multiple, convenient locations for proper disposal of used equipment. At such organizations, there would be a comprehensive education program for those who are receiving smoking supplies. This would include educating individuals about safer smoking equipment and practices, safe disposal of used equipment, the risk of sharing smoking supplies, transmission of HIV and HCV, and issues surrounding responsible sexual behavior. Education would include materials that could be accessed both in person at the site and also online via a webpage and social media. Since many

of the potential harms associated with smoking crack are due to risky sexual behavior, the safe smoking kits would also include condoms and lubricant. Finally, distribution of safe smoking kits at established and trusted locations will provide the opportunity to collect more data from specific cohorts in the Philadelphia area to provide a more comprehensive cost benefit analysis, conduct large scale clinical trials, and enable organizations to tailor future harm reduction efforts to the specific needs of their community.

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