

# Heroin Addiction: A Novel Treatment Delivery System

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## **Executive Summary**

Heroin, an opioid drug with a high addictive potential, poses a serious public health and economic problem for the city of Baltimore. Baltimore, because it has the highest per capita heroin addiction rate in the United States, has earned the title of “heroin capital” of the country.

The high prevalence of heroin addiction in Baltimore presents a considerable societal and economic burden on the state of Maryland. Heroin addiction is associated with loss of productivity, higher healthcare expenditures, and increased costs associated with crime. Heroin addiction is a costly and dangerous condition afflicting the city of Baltimore and needs to be addressed more effectively.

Methadone maintenance treatment has been established in Baltimore for over three decades and has alleviated the burden of heroin addiction on the city considerably. However, some gaps in treatment exist and need to be addressed in an innovative way. The strict regulations that govern the methadone maintenance programs make it difficult for some patients to adhere to treatment.

Buprenorphine is a newer agent that has been on the radar since 2002. With the possibility of take-home medication and prescribing practices that are not limited to licensed methadone clinics, buprenorphine has the potential to revolutionize heroin addiction treatment.

The Baltimore Buprenorphine Initiative was launched as a way to facilitate the adoption of buprenorphine treatment in the city through the provision of necessary funds to train and reimburse physicians. However, even with the initiative in place, the uptake

of buprenorphine into office-based settings is not adequate to meet the demand of the heroin abusing population of Baltimore. Contributing factors to the lackluster response by physicians include stigmatization, logistical difficulties, lack of psychosocial treatment setup, and fear of diversion of the medication to the streets.

This paper details a novel buprenorphine delivery system, the Traveling Physician Program, that incorporates buprenorphine treatment into already established methadone clinics through the employment of a traveling physician. After specific training, the physician rotates through five different methadone clinics in Baltimore each week, providing buprenorphine treatment for the stable patients at those sites through weekly visits. The patients receive psychosocial support from the fixed clinic staff, maintain daily phone contact with a nurse, and attend group therapy sessions regularly. A pharmacy linked to the program fills the buprenorphine prescription for the patients in the program. A collaborative approach with open communication is maintained amongst the physician, clinic staff, pharmacist, and psychosocial support staff.

The Traveling Physician Program fits the harm reduction model and builds on the pre-existing organizational acceptance of maintenance therapy at methadone clinics. It leverages the psychosocial services and linkages to other social services that are already well established at the methadone clinic. These aspects of the Traveling Physician Program make it a feasible option for implementation and success at reaching a population in need. Widespread adoption of this model of buprenorphine treatment delivery in Baltimore has the potential to decrease the societal burden of heroin addiction and significantly improve the lives of the patients who suffer from the condition.

## **Introduction**

Heroin, an opioid drug that is synthesized from morphine, is a drug of abuse that is prevalent throughout the United States and internationally. After its rapid delivery to the brain, heroin binds to the opioid receptor, which is especially concentrated in the areas associated with pain and reward, and in the brainstem, which regulates many of the automatic processes essential for life.<sup>1</sup> Once heroin is injected, inhaled, or smoked, the abuser feels “a rush” of euphoria accompanied by a warm flushing of the skin.<sup>2</sup> After the initial rush, an alternately wakeful and drowsy state referred to as “the nod” occurs.<sup>3</sup> Regular use leads to a build-up of tolerance and chemical dependence and with chronic use, an individual reaches physical dependence.<sup>4</sup> The adaptation of the body to the presence of the drug is responsible for the drastic withdrawal symptoms that can occur when an individual abruptly ceases to use heroin. Withdrawal, which can begin as soon as a few hours after last use, is comprised of symptoms such as restlessness, muscle and bone pain, insomnia, vomiting and diarrhea, cold flashes with goose bumps, and kicking movements.<sup>5</sup> The discomfort of withdrawal presents a substantial hurdle on the path to recovery for many heroin users.

### ***A. Epidemiology of Heroin Addiction***

The rapid delivery of heroin to the brain contributes to its high addiction potential; it is estimated that 23% of individuals who use the drug become dependent on it.<sup>6</sup> As such, heroin addiction presents a considerable public health and economic problem for the United States. Heroin addiction has been on the rise over the past few years; the

number of individuals reporting heroin use in the United States in 2012 was 669,000, which extends the upward trend underway since 2007.<sup>7</sup> In addition, the number of individuals with a dependence on or abuse of the drug doubled from 214,000 in 2002 to 467,000 in 2012.<sup>8</sup> Interestingly, while the number of chronic users<sup>a</sup> has been decreasing since 2002, the number of individuals using heroin occasionally has increased.<sup>9</sup> This utilization shift may represent the emergence of a different population of heroin abusers, which could have implications for optimal treatment delivery.

While heroin addiction is pervasive across the United States, it is an especially pressing matter in the city of Baltimore. As the most commonly abused drug in the city, heroin accounted for 52% of the 229 intoxication-related deaths in Baltimore in 2009.<sup>10</sup> In addition to the considerable death toll, heroin addiction is a growing concern; the U.S. Drug Enforcement Agency reports that Baltimore has the highest per capita heroin addiction rate in the nation and the Baltimore Department of Health estimated that there were 60,000 heroin addicts in the city in 2009.<sup>11</sup> Due to its high prevalence and far-reaching implications, heroin addiction is an issue that Baltimore City must specifically focus on mitigating over the next decade.

A qualitative study was conducted by University of Maryland in 2006 to determine characteristics of the new wave of heroin addiction in Baltimore.<sup>12</sup> The demographic profile of the new generation is markedly different from the older generations. While heroin addiction was traditionally concentrated in urban areas, there has been a

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<sup>a</sup> According to the National Survey on Drug Use and Health, chronic use is defined as use at a frequency of greater than once a week, and occasional use is defined as use at a frequency of less than once a week.

considerable expansion of heroin abuse to the suburbs.<sup>13</sup> There has also been a shift in the racial background of heroin users, with the traditional majority comprised of African Americans abusers giving way to an increasing preponderance of Caucasians heroin abusers.<sup>14</sup> The socioeconomic background of the new generation is the middle, working-class, with initial exposure to drug abuse occurring through peers during school.<sup>15</sup> The family structure is generally intact, and older family members tend to be supportive of the struggling abuser as compared to the traditional heroin abuser with a broken family structure that was often laced with addiction itself.<sup>16</sup> These emerging trends are highly relevant to treatment considerations, as treatment delivery systems must meet the needs of this new generation of heroin addicts.

### ***B. Health Effects of Heroin Addiction***

Heroin addiction poses a significant threat to the health status of the user, with effects across a range of body systems and a plethora of organs. Injection drug use has been associated with an increased risk of pneumonia, tuberculosis, endocarditis, sexually transmitted illnesses, and viral hepatitis. In addition, injection with heroin elevates the risk of infection of the soft tissues, bones, joints, and the central nervous system.<sup>17</sup> It is also implicated in the HIV epidemic, with 3,900 cases of HIV transmission in the United States directly associated with the use of injection drugs in 2010.<sup>18</sup>

In addition to the dire effects on morbidity, heroin abuse can also result in death. The number of deaths from drug-induced causes has consistently increased since 1999<sup>19</sup>, and by 2010, heroin was the culprit of 3,036 deaths in the United States.<sup>20</sup> The deterioration of health associated with heroin abuse ranges from an increased

susceptibility to contracting communicable diseases to an elevated risk of mortality. The severity of these health effects makes heroin abuse a dangerous habit that truly diminishes the quality of life for addicts.

### ***C. Economic Impact of Heroin Addiction***

Beyond its damaging effects on the health status and quality of life of abusers, heroin addiction has widespread implications for society through its extensive economic impact. In 2000, heroin dependence was estimated to cost the United States \$21 billion, of which drug treatment expenses represented only 5.7% of the total cost.<sup>21</sup> The majority of the estimated cost to society is comprised of productivity loss (52.6%), crime (23.9%), and healthcare expenditures for the treatment of medical complications (23%), such as those delineated in the previous section.<sup>22</sup> It is estimated that a drug abuser incurs healthcare costs (excluding maintenance therapy) that annually exceed those of a non-drug abuser by \$1,000.<sup>23</sup>

Another major source of expense related to heroin abuse is the cost of incarceration. The yearly cost of incarceration for a drug offender is \$20,000 in Maryland, and according to the Department of Corrections, drug abuse represents the largest single category of offense among prisoners.<sup>24</sup> In June 2001, it was estimated that 24% of Maryland's inmate population was comprised of drug offenders, which made the state the third highest for percentage of state prison admissions related to drug offenses.<sup>25</sup> The cost of incarceration for these drug offenses is substantial, and there is evidence to suggest that the long-term impact on society goes beyond that, as these convicted

felons face difficulty reintegrating into society, thereby experiencing an increased likelihood of engaging in the very criminal activities that led to their initial incarceration.<sup>26</sup>

While no all-inclusive estimate exists for the economic burden of heroin abuse on the state of Maryland, it is important to note that Baltimore City received \$40,050,543 to fund for prevention and treatment from the Alcohol and Drug Abuse Administration in 2013, the largest allocation received by any of the counties in Maryland.<sup>27</sup> The amount of funding devoted to drug abuse services, combined with the economic burden of productivity loss, crime, and healthcare expenditures, makes heroin addiction a costly issue for Baltimore City.

#### ***D. Methadone Maintenance Treatment***

Heroin addiction, a complex issue, is a combination of a chemical brain disorder and the ensuing behavioral aspects of drug addiction. It should be noted that the treatment modalities that are discussed in this paper only address the use of heroin and do not treat the brain disorder.

The treatment option that currently dominates the field of heroin addiction treatment is methadone maintenance, which entails the administration of a daily dose of methadone to curb cravings for heroin. Methadone is a synthetic opiate that binds the opioid receptors to block the effects of heroin and prevent the development of withdrawal symptoms.<sup>28</sup> The cost estimate for one month of methadone maintenance treatment in a clinic setting ranges from \$117 to \$182 and the cost to patients is estimated to range from \$84-\$133.<sup>29</sup> The range in cost estimates can be partly explained by the variability in the level of supportive services offered at any given clinic.

While this cost may seem high, an analysis by the RAND Corporation found that each dollar spent on the treatment of drug addiction produces a societal savings of \$7.50 in decreased crime and increased productivity.<sup>30</sup> With this impressive return on investment, methadone treatment has proven to be a medically safe and cost-effective intervention for heroin addiction for over 30 years.<sup>31</sup>

An estimate of the number of heroin abusers on methadone maintenance therapy in Baltimore is difficult to obtain due to fragmented data and variability in retention rates. However, there are 20 methadone treatment clinics throughout Baltimore City.<sup>32</sup> Nevertheless, there are waiting lists for treatment. It is evident that there has been considerable uptake of methadone treatment in Baltimore City.

Despite its success, methadone maintenance may not be the optimal treatment for every heroin abuser. One limitation of the treatment is its delivery system. Stringent prescribing and dispensing regulations on the federal and state level aim to decrease the risk of diversion.<sup>33</sup> Diversion, the redistribution of prescribed drugs to the black market, is a consideration prevalent across the spectrum of substance abuse treatment. Though they exist for an important purpose, the strict regulations also limit the ease with which a new treatment clinic can be established, which, in turn, could adversely affect accessibility in areas where proximity of treatment options poses an issue. If an individual is hard-pressed financially, the transportation cost of traveling to the clinic to receive daily treatment could present a barrier, even more so if the clinic is not located in close proximity to the home.

The observed dose delivery approach that is characteristic of methadone maintenance treatment also presents limitations in terms of logistics. A certain level of staffing is required to meet this objective, and with that, the funding to pay them. These factors could contribute to the shortage of treatment clinic spots, which has resulted in waiting lists for treatment.<sup>34</sup> In addition, some heroin abusers may not be amenable to the daily administration of methadone under direct observation, as it may conflict with their work schedules or lifestyle choices.

As a full agonist, that is, a chemical that binds to a receptor and produces a biological response similar to the original agent, methadone produces the complete opioid effect, which could essentially be considered a replacement of the heroin addiction with a methadone one. Many heroin abusers have a negative impression of methadone for this reason<sup>35</sup>, making them hesitant to seek treatment for their addiction. These gaps in treatment leave room for improvement in addiction medicine.

## **Buprenorphine Treatment**

### ***A. Background***

A newer agent that has the potential to fill the gaps in methadone maintenance therapy is buprenorphine, a partial opioid agonist that has been clinically proven to reduce withdrawal symptoms and heroin cravings.<sup>36</sup> It is taken once every 2 days by placement under the tongue.<sup>37</sup> As a partial agonist, buprenorphine produces a less robust biological response than methadone, which is a full agonist. This can make buprenorphine advantageous over methadone due to the less severe physical dependence and withdrawal symptoms that result from the medication, largely due to

the partial nature of activation at the receptor.<sup>38</sup> In addition, buprenorphine therapy offers the possibility of treatment at home or in a private office setting, as it has less stringent medication administration regulations than methadone. Buprenorphine is available outside of the licensed methadone clinic system and can be prescribed according to the physician's discretion.<sup>39</sup> Research can inform the physician's decision of which agent to prescribe; characteristics that have been associated with successful buprenorphine treatment<sup>b</sup> include older age, concomitant diagnosis of major depressive disorder, initial opioid use via prescription pain medications, and no prior opioid dependence treatment.<sup>40</sup> In addition, the physician must consider whether the patient can be trusted with a supply of medications at home.

The Clinical Trials Network, which was established by the National Institute on Drug Abuse (NIDA) in 1999, demonstrated the effectiveness and safety of buprenorphine.<sup>41</sup> In 2002, it was approved for the treatment of opiate addiction in the United States<sup>42</sup> and in 2003, buprenorphine was added to the Medicaid formulary.<sup>43</sup> For the certification to prescribe it, physicians need to verify one of the following: their status as certified addiction specialists, their role as principal investigators in clinical trials with buprenorphine, or their participation in an eight-hour approved training session on the proper prescribing protocol.<sup>44</sup> The Drug Enforcement Administration maintains oversight on all physicians who have obtained the waiver and possesses the right to audit their prescribing records unannounced.<sup>45</sup>

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<sup>b</sup> The study examined patient characteristics that predict treatment outcome, with success defined as abstinence from heroin use during the twelfth week of the buprenorphine treatment and during at least two of the weeks from week nine to eleven.

Originally, the federal law capped the number of patients that physicians could treat with buprenorphine to 30 patients at a time<sup>46</sup> and patients could only be transitioned to take-home buprenorphine therapy after stabilization was maintained on methadone for nine months.<sup>47</sup> The regulations have loosened since then; physicians have the right to treat up to 100 patients simultaneously after a year of experience with the cap at 30 patients. In addition, the decision of when it is appropriate to transition a patient to take-home medication is now at the discretion of the physician.<sup>48</sup> The FDA approval and subsequent legal changes created fertile ground for buprenorphine to revolutionize the opiate addiction treatment methodology with its promise of office-based treatment and take-home medication.

### ***B. Buprenorphine in Baltimore***

At the advent of buprenorphine availability, its use was concentrated in patients of a higher socioeconomic status with good insurance coverage. In 2006, the Baltimore City Health Department and the Baltimore Substance Abuse Systems launched the Baltimore Buprenorphine Initiative (BBI). The BBI aimed to increase the availability of buprenorphine for treatment of the uninsured and indigent population through public grant funding. The Maryland Medicaid program covers buprenorphine and primary care physician visits through the Primary Adult Care program. For uninsured patients, state and city grants are used to fund buprenorphine treatment in outpatient programs.<sup>49</sup> In addition, the BBI covers the expenses of training and licensure for physicians who are interested in obtaining the waiver to prescribe buprenorphine.<sup>50</sup>

An estimate of the number of buprenorphine users in Baltimore does not exist, as its use is largely concentrated in office-based settings; no efforts to quantify the magnitude of buprenorphine use in Baltimore have been published. It is known, however, that the BBI's facilitation of buprenorphine adoption across Baltimore City was associated with a drop in the number of deaths due to heroin overdose in Baltimore City.<sup>51</sup> It is important to note that this association does not prove causation; there may have been other factors that contributed to the decrease in mortality due to heroin overdose. The positive correlation, however, does support the idea that increasing access to treatment is a successful way to reduce the mortality due to heroin overdose.

### ***C. Office-Based Buprenorphine Treatment***

In theory, the prospect of delivering buprenorphine treatment in an office setting is an attractive one. Patients who have achieved a level of stability would be afforded the privacy of a physician's office for their medication management rather than the often-stigmatized methadone clinic. In addition, the frequency of visits could decrease over time as the patient adheres to the treatment regimen, cultivating a relationship of mutual trust and respect with the physician.

However, up until now, the practice has not lived up to the expectation that the theory lays out. Several issues that arise with office-based buprenorphine treatment have stifled the widespread adoption of the practice throughout Baltimore City.<sup>c</sup>

#### **1. Stigma**

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<sup>c</sup> This section has greatly benefitted from an interview with Dr. Michael Fingerhood on January 7, 2014.

Stigmatization of the population of heroin abusers pervades society, and unfortunately this negative perception extends into the medical field. Some physicians have the impression that these patients will be drug seeking, demanding, manipulative, and irresponsible.<sup>52</sup> Others cite a concern for the effect of the presence of a heroin abuser in the waiting room on their other patients.<sup>53</sup> For these reasons, the practice of prescribing buprenorphine has not made significant strides outside of the community of addiction specialists, engendering a shortage of physicians available to administer buprenorphine treatment.<sup>54</sup>

## 2. Logistical Difficulty

In addition to the stigmatization, the logistics involved in setting up a practice that supports buprenorphine therapy present another obstacle. There are several components of buprenorphine treatment that may not be relevant to the treatment of other conditions; as such, many physicians would not be able to engage in providing buprenorphine therapy without making significant changes to their offices. For example, treatment with buprenorphine requires urine testing regularly in order to confirm abstinence from heroin and adherence to therapy. Certain physician specialties, such as psychiatry, may not have a lab setup in-house, making it logistically difficult for them to prescribe buprenorphine appropriately.<sup>55</sup> In addition, the induction phase of treatment requires multiple, frequent visits. In a traditional office setting, this may pose a scheduling issue if it is a busy practice or if many heroin abusers are being accepted as new patients within a short period of time.<sup>56</sup> These logistical considerations certainly do not make it impossible for any physician to incorporate buprenorphine treatment into the established practice, but they do increase the threshold of effort needed to do so.

### 3. Adjunctive Psychosocial Treatment

Beyond the simpler logistics of scheduling patients and conducting urine testing according to protocol, the psychosocial component of addiction treatment that is integral to achieving success may be difficult to implement in an office-based setting. There is significant evidence that supports the necessity of the psychosocial aspect of heroin addiction treatment; studies have found that adding psychosocial therapy to the medication treatment resulted in a greater reduction of heroin use as compared to medication treatment alone.<sup>57</sup>

Primary care physicians may lack the training and time to provide the behavioral interventions that are essential in the treatment of an addiction patient.<sup>58</sup> In one study, 50% of physicians prescribing buprenorphine reported that their addiction patients received a total of 1-3 hours of counseling each month and 24-28% reported between 4 and 6 hours of counseling.<sup>59</sup> The inadequate provision of psychosocial treatment services makes office-based administration of buprenorphine an incomplete approach to heroin addiction treatment.

### 4. Fear of diversion

Diversion, which has been previously defined as the redistribution of prescribed drugs to the black market, is an ingrained aspect of the addiction culture, especially for medications that produce favorable effects such as opiates. Physicians cite a fear of diversion as a barrier to adding buprenorphine treatment to their offered services.<sup>60</sup> Studies have been conducted to determine the extent of diversion of buprenorphine to the street market and to examine how it compares to the diversion of other abused

prescription drugs, such as oxycodone. The amount of diversion was noted to increase from 2005 to 2009, which is the period of time following the approval of the first generic version of the medication. Even with that increase, the extent of diversion of buprenorphine was found to be significantly less than the amount observed with methadone and oxycodone.<sup>61</sup>

In a survey of 602 heroin abusers who recently started treatment or were not in treatment at the time, 9% reported recent street-obtained buprenorphine use.<sup>62</sup> Notably, of that population, a majority of the heroin abusers (72%) were acquiring and utilizing the street-obtained buprenorphine to avoid the impending withdrawal symptoms; only a small percentage of heroin abusers (5%) reported using it to get the opiate high. Of those who were using the buprenorphine to avert withdrawal, half of the individuals were on a waiting list for methadone treatment at the time.

There are several important limitations of this study that must be taken into account when using the results to inform policy decisions. The population that was surveyed in this study was comprised of the participants of the AIDS Linked to the IntraVenous Experience study being conducted at the Johns Hopkins Bloomberg School of Public Health. As such, the population was predominantly urban, African American, and not actively injecting at the time of the survey. These distinguishing characteristics may affect the comparability of the findings to dissimilar populations. In addition, the extent of buprenorphine diversion estimated by this study is considerably lower than the estimate obtained from other studies, which may indicate that this study did not fully capture the magnitude of diversion in Baltimore.

Despite these limitations, the study does shed light on an important practice – the use of buprenorphine to eliminate withdrawal symptoms, particularly in a population that was awaiting treatment. There is a reasonable chance that if the individuals were placed in treatment, they may not have required the street-acquired buprenorphine. Additionally, this study is particularly important to consider despite its shortcomings because it is the only one that has been conducted in the city of Baltimore. The population that is surveyed in this study, while not readily generalized, would be highly representative of the target population of interventions launched in Baltimore City. Although diversion is an important concern, the benefits of treatment seem to outweigh the risk of diversion, and the diversion that does occur may be mitigated through increased access to physician-administered treatment.

## **Proposal of a Novel Buprenorphine Delivery System**

### ***A. Overview of the Traveling Physician Program***

In light of the shortage of physicians willing to provide buprenorphine treatment in an office-based setting, other options to widen the scope of practice must be considered. One feasible option would be to incorporate buprenorphine treatment at methadone clinics throughout Baltimore by employing a traveling physician. A physician who has obtained the waiver to prescribe buprenorphine would rotate through five different methadone clinics in Baltimore each week, serving as the buprenorphine physician for those sites. Ultimately, the hope would be an increase in the number of physicians who are interested in taking on this special task, enabling coverage of all methadone clinics in Baltimore.

The physician would meet with each of the buprenorphine-managed patients at their respective clinics on a weekly basis to monitor the success of their treatment. In addition to attendance at this weekly physician visit, the patients would be held accountable for attending group therapy sessions at the clinic twice a week and maintaining phone contact with a nurse as frequently as deemed necessary by the physician. In addition, an observed urine test would occur at the time of the physician visit on a weekly basis at first, then eventually on a monthly basis with the timing of the transition determined by the physician. Finally, the Traveling Physician Program would be linked to a local pharmacy that would be the only site at which a patient can fill the buprenorphine prescription. During the initial induction phase, the patient would visit the clinic more frequently as per protocol, and a clinic staff member would bear the responsibility of picking up the buprenorphine from the linked pharmacy for on-site administration. After the stabilization phase is reached, the patient is responsible for attaining the medication from the pharmacy himself.

A team-based, patient-centered treatment approach is crucial. Due to the absence of the buprenorphine-prescribing physician from the facility on four out of five weekdays, open communication between members of the treatment team is of vital importance. Meetings during which the discussion centers on the progress of the buprenorphine-managed patients must be conducted on a regular basis as timing permits; however, these meetings must be conducted at a minimum frequency of once a month at all clinics. In addition, records must include the various activities of the treatment program, such as daily nurse contact logs, weekly urine test results, attendance at the required group therapy sessions, and the logs of the linked pharmacy. The physician must

review and sign off on these records at each weekly visit to facilitate a comprehensive understanding of the status of the patient's recovery.

Contingent upon success of the initial implementation of the Traveling Physician Program, more physicians can be employed for each five-site rotation, allowing for more stable patients to be switched to buprenorphine treatment at each site. In addition, additional sites can be incorporated as physician interest in participating in the program increases. Finally, if the program expands to the point where the current clinic staff cannot handle the additional responsibility of daily contact with all of the buprenorphine patients, a nurse can be hired or reassigned to handle just the buprenorphine treatment activities while the rest of the clinic staff continues to work on the methadone maintenance arm of services.

Due to the novelty of the Traveling Physician Program, a large-scale implementation would greatly benefit from an initial pilot program. The pilot program should incorporate all components of the Traveling Physician Program. This would facilitate identification of issues in implementation, logistical considerations, and funding requirements.

### ***B. Adequate Training and Availability of Resources***

For the program to be implemented in a safe and effective manner, proper training and support is vital. In France, where all physicians can freely prescribe buprenorphine, there are reports of ineffective dosing and potentially dangerous medication combinations in the practices of physicians who did not receive any specific training on the proper administration of buprenorphine.<sup>63</sup> Increasing the number of physicians in Baltimore who obtain waivers to prescribe the medication would be a disservice to the

community without an accompanying training session to ensure that high quality care is being delivered. The currently mandated eight-hour buprenorphine training session has not been evaluated for its effectiveness. The pilot program could address this need for evaluation; a comparative study could be conducted with implementation of two training protocols for physicians, with half of the physicians attending the eight-hour training session and the other half receiving a more intensive training protocol to be designed by the Traveling Physician Program leadership. The physician's knowledge of proper buprenorphine use at the completion of training and retention of knowledge at several intervals after training completion can be compared across the two groups to determine whether a benefit exists with more intensive training.

In addition to training a physician to adopt a safe and effective prescribing practice, it would be prudent to have resources in place that could provide a newly trained physician with guidance in difficult cases. In a set of 99 interviews conducted at six different ambulatory clinics in the Bronx, NY, 72.1% of the physicians reported a willingness to engage in delivering buprenorphine therapy, provided that there was adequate training and support available.<sup>64</sup> All of the physicians at the clinics on interview days agreed to participate, and the majority of the interviewees were female, white, non-Hispanic, and residents. The majority of the physicians (82.8%) had encountered patients who were heroin users, but just 51.5% of them were comfortable addressing addiction treatment concerns. The specific training needs that the respondents reported were education and training specific to buprenorphine (83.8%), available consultation (19.2%), and on-site counselors or social workers (18.2%). These

findings highlight various methods that can be used to increase the competence and comfort level of the physicians delivering the buprenorphine maintenance treatment.

A national telephone consultation network may be a cost-efficient and effective way to provide ongoing support to local physicians delivering buprenorphine therapy. Careful consideration must be given to how the training and the ongoing support would be provided for the clinical teams involved in this program.

### ***C. Cost Considerations***

An important consideration for any undertaking is the overall cost of implementation, as well as the cost for each stakeholder. A major cost that many new programs face are startup costs associated with obtaining office space, furniture, staff, and equipment. With the traveling physician who visits established treatment centers, many of these costs are limited or even eliminated entirely. The majority of the cost for the Traveling Physician Program would be the cost for subsidizing the medication and new staff hires or increased pay for current staff that will take on additional responsibilities. Overhead costs would also be limited long-term; even with expansion, the program would still be capitalizing on existing resources and strategic partnerships that limit maintenance costs for the program itself.

In general, substance abuse treatment is funded through a combination of public and private means. In 2006, 64% of all substance abuse treatment funding was derived from public sources.<sup>65</sup> Funding for the Traveling Physician Program should be obtained from multiple public and private sources if possible, in order to limit the dependence on the ongoing support of one source.

The Substance Abuse Prevention and Treatment Block Grant program is a primary source of federal funding for substance abuse treatment programs.<sup>66</sup> The funds are distributed to Single State Agencies, which then allocate funding to programs within their states.<sup>67</sup> Each state has its own set of eligibility criteria for block grant funding, and comparing the eligibility criteria with the Traveling Physician Program's objectives would help determine whether the program qualifies for block grant funding. It is possible that the program's objectives cannot be altered in a way to meet the criteria without sacrificing the vision of the program, in which case a policy change for block grant funding allocation may be required.

Another source of federal funding for the program could be through agencies funded by the U.S. Departments of Labor, Housing and Urban Development, and Education. These funds may be restricted to non-medical use, but could be applied for expenses related to counseling and social work.<sup>68</sup>

An important, ongoing source of capital for the Traveling Physician Program is third party reimbursement. Both Medicare and Medicaid in the state of Maryland could cover buprenorphine maintenance therapy. There are several specific criteria for the qualification of substance abuse treatment for Medicare reimbursement; for example, the treatment must be deemed medically necessary and be provided in a Medicare-certified setting, whether it is an inpatient or outpatient treatment center.<sup>69</sup> For Medicare as well as several other health plans, reimbursement rates are higher for facility-based delivery of services as compared to office-based.<sup>70</sup> The proposed program benefits from this differential payment system, as the maintenance therapy is delivered at treatment centers rather than in a private office setting, resulting in higher

reimbursement rates. In addition, many times the copayment required of Medicare beneficiaries are lower for facility-based services as compared to office-based services.<sup>71</sup> These reimbursement practices make it an attractive option for physicians and clients alike.

In addition to Medicare, Medicaid is another public health insurance option that is a potential source of funding for the program. In the state of Maryland, Medicaid covers opioid maintenance treatment under its HealthChoice and Primary Adult Care programs once the provider submits a treatment plan and obtains approval.<sup>72</sup> Once approved, the provider is paid for 26 weeks under the self-referral option, after which medical necessity must be proved for continued eligibility.<sup>73</sup> Additional approvals occur at six-month intervals. For the Primary Adult Care program, the treatment delivery must occur at a community setting other than a hospital, which should be kept in mind as it could have implications for hospital-run treatment centers in Baltimore.

The combination of the low overhead costs for the Traveling Physician Program and third-party reimbursement for buprenorphine treatment makes it a financially feasible alternative to methadone maintenance treatment. With the advent of the Affordable Care Act, the third party reimbursement can be expected to play a more significant role in the future.

#### ***D. Rationale for the Program***

##### **1. Fits the Harm Reduction Model**

The Harm Reduction Model supports the utilization of interventions that are facilitative of positive health behaviors, as opposed to setting a coercive tone.

Interventions should be employed based on the needs of the population being served and barring any judgment of the health behavior being addressed.<sup>74</sup> By providing the buprenorphine therapy at the clinics that they are familiar and comfortable with, the Traveling Physician Program sets the practice of bringing the treatment to the population, rather than requiring the population to come to different treatment centers. In effect, making the community setting a high priority encourages patients to enter treatment.

## 2. Pre-existing Organizational Acceptance

Organizational acceptance of a new treatment practice heavily influences the success of adoption. Only through broad organizational acceptance of a new practice will the individuals employed by that organization feel comfortable embracing it.<sup>75</sup> By integrating the buprenorphine treatment into existing methadone clinics, it can be guaranteed that the organizations are familiar with, responsive to, and respectful of the needs of the treatment population. The methadone clinics have an organizational structure that is well adapted to providing maintenance therapy, and may find it easier to accommodate an additional modality of treatment than a site that is new to this type of treatment philosophy. The risk of organizational resistance is minimized when a new treatment practice is added to an existing, well-functioning treatment unit, making it easier for best practice to be adopted.

## 3. Provision of Psychosocial Services

A major drawback in extending maintenance therapy for addiction into the office-based setting is the lack of adequate psychosocial services in that sector. Adding the

resources necessary for provision of these services in a physician's office presents a considerable financial burden on the practice; this may lead to a physician foregoing these crucial services or providing them inadequately.<sup>76</sup> Integrating buprenorphine treatment into methadone clinics capitalizes on the psychosocial services that are already in place at the site. Initially, there would be no need to alter the way the psychosocial service providers of the methadone clinics operate. Over time, if the program expands, there may be a demand that is not being met efficiently by the structure of that unit in the methadone clinics. In that case, it could be useful to reassign existing or hire new psychosocial support staff to focus solely on the buprenorphine patient population.

#### 4. Linkage to Social Services

A sizeable proportion of the population served by methadone clinics present with a wide variety of adjunctive social issues that need to be addressed in addition to the addiction problem. While the methadone clinics may not directly fulfill every need of the patients, their status as a community-based treatment center facilitates their partnerships with local social service agencies.<sup>77</sup> The ability to tap into the resource network of the community may not be as attainable through the private office-based delivery of buprenorphine treatment. In addition, the very nature of a traveling physician encourages collaborative relationships across methadone clinics in Baltimore and the local social service agencies with which they independently collaborate.

#### 5. Supportive Evidence for Community-Based Initiatives

While comparisons of delivery of buprenorphine at mobile community sites versus fixed sites have not been undertaken, such literature does exist for the delivery of methadone maintenance. One such study in Baltimore found that more patients were retained in treatment over time in the mobile methadone treatment program compared to the fixed-site delivery of treatment.<sup>78</sup> This finding can be attributed to the decreased transportation cost and travel time for the patient when the site of treatment is conveniently located.

A program in the Bronx where buprenorphine treatment was initiated at a methadone clinic found that 60% of buprenorphine patients remained in treatment at six months, with 79% maintaining negative urine toxicology during the six-month observation period.<sup>79</sup> This high retention rate and substantial evidence of heroin abstinence lends support to the notion of delivering buprenorphine treatment at a setting that is familiar to the population being served. Perhaps even more interesting to note is that the patients who could not achieve stabilization on buprenorphine were smoothly transitioned back to a methadone maintenance treatment regimen. The co-location of these services makes it more feasible to seamlessly meet the sometimes-fickle needs of an addiction patient and protects against the patient slipping through the gaps in treatment modalities.

There are theoretical and practice-based sources of support for implementing a program in which buprenorphine treatment is delivered at the methadone clinics that patients are currently frequenting.

### ***E. Potential Barriers to Implementation***

Several obstacles complicate the implementation of the Traveling Physician Program. These include:

1. Willingness and ability of healthcare providers to participate

Integral to proper implementation is the willingness of a physician to embrace a career that entails traveling to various treatment centers in Baltimore, following up solely with patients maintained on buprenorphine. It can be expected that initially there may only be part-time sessions required at each clinic site, allowing for the physician to continue working at another medical practice. Over time, however, if the program scales up, the physician may have to devote a full-time career to this position. The private office and a roster of patients could be a difficult sacrifice for some established physicians. While the Traveling Physician Program greatly limits the number of physicians required for the delivery of buprenorphine maintenance on a larger scale in Baltimore, it is essential that the physicians that do engage are committed to the program and its objectives.

In addition, a physician who would be considered qualified for this position must be well-versed in addiction medicine, and be able to commit to the program for the duration of the pilot program. To avoid the issues observed in France with the poorly trained buprenorphine providers inappropriately prescribing the medication, it would be prudent to scrutinize the competence and past clinical experience of the traveling physician. While the mandated eight-hour buprenorphine training session supplements and refreshes the existing knowledge of the provider, a provider who brings a wealth of clinical acumen would best serve the program.

## 2. Political Climate

As with any major advancements in healthcare delivery, the political climate is important. Without the support of the political leadership of the city of Baltimore, as well as local health officials, it would be difficult to implement the Traveling Physician Program. In addition, a stakeholder analysis will be a key component in effectively planning and executing the program. With some foresight, the potential political resistance can be addressed early in implementation. The proper political support gives the Traveling Physician Program a better chance of success.

## 3. Cost to Patient

While the cost for implementation of the Traveling Physician Program is an important consideration, the financial burden that will be felt by the potential client must also be addressed. Under the Medicare Improvements for Patients and Providers Act of 2008, Medicare coverage was projected to reach 80% by 2014, but with the passage of the Affordable Care Act, parity benefits are guaranteed nationally. The increase in insurance coverage of mental health and substance abuse treatment secured by the parity benefits guarantee can be expected to allow more heroin abusers to afford treatment, as well as draw in more capital for the program.

In addition, the Maryland Medicaid Pharmacy Program includes coverage for buprenorphine, but limits it to 6 tablets/day for the 2mg formulation and 4 tablets/day for the 8mg formulation.<sup>80</sup> If a patient should require medication exceeding these limits, it is possible to obtain coverage, provided that the physician obtains prior authorization. The

inclusion of buprenorphine on the Medicaid formulary makes it a financially viable option for heroin abusers that have Medicaid coverage.

There are several options that could help make buprenorphine maintenance more affordable for patients, regardless of their insurance coverage. With the approval of a generic version on February 25, 2013, the potential cost to the patient dropped considerably.<sup>81</sup> In addition, pharmaceutical manufacturers produce copay cards that can be printed and used by an individual to receive a discount on their copayment when the medication is obtained at the pharmacy.<sup>82</sup> Similarly, prescription discount cards are available from certain third parties, such as AAA, pharmacy chains, and discount prescription websites.<sup>83</sup> With these measures supplemented by a full or partial subsidy through the Traveling Physician Program, buprenorphine could be an affordable alternative to methadone for heroin abusers.

#### 4. Willingness of methadone treatment clinics to participate

Provision of a new arm of services is a significant commitment for any organization as it inevitably involves financial and human capital redistribution. The methadone treatment clinics would certainly undergo changes in daily operation as a result of the Traveling Physician program, specifically in the realm of responsibilities of the ancillary staff. It would be at the discretion of each individual treatment center to determine whether one nurse will be assigned the responsibility of solely managing the patients on buprenorphine, or if the responsibility will be allocated among all nursing staff members. In addition, the mandatory group counseling that is a part of the buprenorphine program could potentially affect the logistics of counseling sessions. Finally, the observed urine

test at each weekly appointment can be costly in terms of a staff member's time and laboratory expenses. For the Traveling Physician Program to be implemented successfully, it would be invaluable to garner the support of treatment center staff and leadership.

## **Conclusion**

Buprenorphine represents a feasible alternative treatment for a subset of heroin abusers that do not benefit from methadone maintenance therapy. Through its at-home administration, buprenorphine has relative superiority over methadone for heroin abusers who avoid daily visits to methadone clinics due to the stigma associated with clinics or to schedule conflicts. In addition, as a partial agonist, buprenorphine is a favorable alternative for heroin abusers who are uncomfortable with the full agonist activity of methadone, which they perceive as a replacement of the heroin addiction with a methadone one. While it may not be the ideal option for all heroin abusers in Baltimore, buprenorphine meets the treatment needs for a subset of the population.

To address the issues of widespread access to buprenorphine treatment, a program in which certified buprenorphine providers rotate through several methadone clinics in the city of Baltimore should be implemented. The barriers discussed previously are part of the explanation for why community-based buprenorphine treatment has not been adopted to date. Some issues that may arise include a shortage of clinic staff dedicated to the buprenorphine-managed patients, the increased risk of diversion as buprenorphine availability increases, and the relative cost of buprenorphine. The potential shortage of clinic staff can be addressed as it surfaces through the

reassignment of responsibilities within the organizational structure or the hiring of new staff members if the budget permits. The increased risk of diversion may be unavoidable, but if averting withdrawal is the primary reason the street market exists, the expansion of availability of supervised treatment should curb the street demand for buprenorphine. As measures of accountability, there are weekly urine tests, daily phone contact with a nurse initially, and the higher frequency of visits until trust is established. The timely passage of the Affordable Care Act increases the feasibility of the Traveling Physician Program with its provisions that expand mental health and substance use disorder benefits and parity protections for 62 million Americans. The inclusion of mental health and substance use disorder services as an Essential Health Benefit for all new small group and individual private market plans, and the prohibition of medical underwriting will facilitate insurance reimbursement of addiction treatment<sup>84</sup>.

Buprenorphine has transformed the treatment of heroin addiction by offering patients a chance to regain control over their lives and maintain a 'normal' schedule. Through the greater sense of empowerment that the stable patients receive by being afforded the opportunity to take their medications at home, they may find the confidence to propel their lives forward in a positive direction. The potential economic and social effects of treating heroin addiction more effectively could change the landscape of Baltimore as we know it, making it a place where providing high quality patient-centered care is of utmost priority.

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