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Use of an electronic pillbox to increase number of methadone take-home doses during the COVID-19 pandemic

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ABSTRACT

This study describes use of the commercially available Medminder electronic pillbox at a community substance use disorder treatment program to safely increase the number of methadone take-home doses administered during the COVID-19 pandemic. The pillbox contains 28 cells that lock independently and can be opened only during preprogrammed time windows. This study provided patients (n = 42) deemed vulnerable to take-home mismanagement or more severe symptoms from COVID-19 infection the pillbox and observed them for 11 weeks. A telephone support line was staffed daily to manage technical issues. Overall, patients received about 14 more take-home doses per month after receiving the pillbox. Most medication was dispensed within scheduled windows. The study observed few incidents of suspected tampering, though five patients had their pillbox rescinded to allow more intensive on-site clinical monitoring. The study supports use of an electronic pillbox with a telephone support line to help vulnerable patients to better observe stay-at-home guidelines during the COVID-19 pandemic. The pillbox may offer public health and clinical benefits that extend beyond the pandemic by increasing program treatment capacity and patient satisfaction.

1. Introduction

The coronavirus (COVID-19) pandemic presents considerable challenges to the treatment of people with opioid use disorder (Volkow, 2020). Federal regulations require that patients receiving methadone maintenance, the most prevalent and effective treatment for opioid use disorder (Gowing et al., 2011), attend licensed treatment programs on a daily or often near daily basis to receive their medication, which is ordinarily dispensed in liquid form (*Title 42, part 8. Medication assisted treatment for opioid use disorder*, n.d.). In the context of the current pandemic, routine travel to and from these programs, together with regular contact with clinical staff and other patients, enhances patients' risk of acquiring and transmitting COVID-19 (Centers for Disease Control and Prevention, 2020).

Recognizing these risks to individual and public health, the Substance Abuse and Mental Health Services Administration (SAMHSA), which oversees methadone regulations, issued temporary new guidelines that permit patients to receive an increased number of methadone doses away from the program to self-administer in the privacy of their homes (SAMHSA, 2020). These new guidelines expand the number of patients who are now permitted to receive multiple take homes, allowing clinically unstable patients to receive up to 2 weeks, and stable patients to receive up to a month of methadone take-home doses. The SAMHSA made these changes abruptly in response to the pandemic and clinics struggled to develop strategies to easily and effectively monitor patients' take-home doses. Receipt of multiple take-home doses, especially by those using illicit drugs or alcohol, enhances risks for misuse, diversion, and overdose (Hedegaard et al., 2018; Jones et al., 2016).

In response to these concerns, our community-based substance use disorder treatment program (Addiction Treatment Services) in Baltimore, Maryland (MD), adopted the use of a commercially available and HIPAA-compliant Medminder (version "Jon") electronic pillbox to help both the program and the patients better manage take-home medication (Dunn et al., in press). The pillbox contains 28 cells that are locked independently via remote access and open only during preprogrammed time windows. The pillbox transmits text and email messages to designated staff to monitor patient use of the take-home doses. To use the pillbox, patients are transitioned from liquid to tablet methadone.

The current study describes the clinical feasibility and acceptability of using the electronic pillbox with 42 patients in the Addiction Treatment Services (ATS) who staff determined to be vulnerable to mismanagement of take-home doses or at high medical risk of

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developing severe complications if infected with COVID-19. The following retrospective chart review describes the operational structure of how the ATS integrated the pillbox as an open-label routine care resource and the outcomes that the ATS achieved. The demographic and clinical characteristics of patients are presented, along with the roles of program staff in educating patients, monitoring pillbox use, and operating a patient telephone support line. Outcomes presented in this report include pre-pillbox versus post-pillbox changes in number of delivered take-homes, percent of take-home doses dispensed within and outside of scheduled windows, evidence of suspected tampering, use of the telephone support line, and mechanical issues associated with use of this technology.

2. Method

2.1. Participants

The study evaluated 42 patients treated at the ATS program in Baltimore, MD, a community-based center offering agonist and nonagonist treatment to people with opioid and other substance use disorders. ATS maintains a census of about 300 people, most with opioid use disorder who are treated with methadone. The ATS initially offered the Medminder electronic pillbox to 47 patients. Five patients refused, citing disfavor with tablets (n = 3), disinterest (n = 1), and lack of reliable access to electricity to maintain charge in the box (n = 1). We include in this report patients who received a pillbox from 4/8/20 to 7/6/20. The Johns Hopkins University School of Medicine Institutional Review Board approved the study, after receiving approval from the research restart committee that the School of Medicine ran, which was instituted during the pandemic.

2.2. Medminder pillbox

The commercially available and HIPAA-compliant Medminder "Jon" version electronic pillbox (medminder.com) has the dimensions of 14″ × 11″ × 2″, weighs approximately 5.5 pounds when empty, and contains 28 cells (using a 7 × 4 grid) that lock independently and open during preprogrammed time windows, though assigned staff can reprogram individual cells to open outside of programmed times when clinically indicated. We have evaluated preliminary feasibility of this pillbox in a previous Phase II randomized controlled feasibility trial (Dunn et al., in press). The Johns Hopkins Bayview Medical Center agreed to cover the cost of the monthly pillbox lease of $40.00 for each pillbox.

The Medminder pillbox communicates to a secure cloud-based server via an autonomous cellular signal that does not rely on patient cellular access. Assigned staff members have access to each individual Medminder box via the server to set or modify available dosing periods and review alerts. Each cell contains a medication cup that patients can remove from the pillbox when the dose is scheduled to be taken, and they can return it once the medication is removed from the cup. Cells provide a visual prompt to take the medication when it unlocks and a beeping sound ensues if patients do not remove the medication cup after 30 min. The research staff programmed the pillbox to send assigned staff either a text or email message in response to routine and any irregular opening of the cells, which includes failure to remove or return medication cup within the allotted time or suspected tampering with other compartments or the lid of the pillbox. Tampering alerts include: "unscheduled refill happened" or "empty medication cup removed"; in these cases, either the pillbox lid or an individual cell may have been breached. The pillbox cannot determine if medication removed from the box was actually ingested. The pillbox generates a considerable amount of data on its use that is stored on the MedMinder HIPAA-compliant server. Patients were registered to the pillbox with a unique study number so that no patient identifiers are included on the server. The current study evaluated each patient across the following variables: 1) number of take-homes received; 2) pillbox recording of removal and return of medication cups, within and outside of scheduled window openings; 3) incidents of suspected tampering with medication compartments; 4) incidents of pillbox-related errors.

2.3. Procedure

We began to use the Medminder pillbox about one month after SAMSHA issued new guidelines increasing the number of methadone take-home doses that patients could receive during the pandemic (3/16/2020). The research team discussed decisions regarding which patients might benefit most from receiving take-home doses via the pillbox at weekly medical rounds, which medical and mental health staff attended via telehealth ("Zoom™") technology. The team gave priority to patients clinically determined to be at high risk for mismanaging take homes dispensed in the conventional method (due to current drug use or unsafe living conditions), or had serious health problems that might increase risk of severe complications if infected with COVID-19. Overall, we classified these patients into three non–mutually exclusive groups. The first consisted of patients who were currently using illicit substances, identified through a recent history of drug-positive urinalysis samples, self-report drug use, and/or appearing intoxicated at the program. The second group included patients who we believed to be currently abstinent, but who had a recent documented history of take-home mismanagement or were living with a person(s) who was using illicit substances. The final group comprised patients who were abstinent and stable in recovery, but suffered high-risk health problems (e.g., COPD) or cognitive impairment, documented in their medical chart. While suspected current drug use always resulted in assignment to group 1, the study could not avoid some overlap in criteria across groups (e.g., some patients in group 1 had a documented history of take-home management or acute medical problems; some patients in groups 2 and 3 may have engaged in undetected substance use). Nevertheless, the study assigned patients to only one of the three groups. The number of take homes initially allotted to each of these patients varied almost exclusively based on current drug use status. Patients currently using drugs initially received no more than 6 take-homes. The study provided patients who were more recently abstinent (approximately 6 months prior to the pandemic) with 13 take homes, while those with longer periods of abstinence could receive 27 take homes.

Assigned program staff contacted via telephone patients identified as candidates for the pillbox. Staff informed patients that using the pillbox requires taking methadone in a tablet form, and that their usual dose might need to be adjusted slightly to accommodate tablet dosing (only 10 mg tablets). For example, patients receiving a dose of 85 mg of methadone had to decrease to 80 mg or increase to 90 mg; patient preference was accepted in the absence of any medical contraindications for their choice. Staff provided instructions for pillbox use to patients agreeable to using the pillbox under these conditions. After verifying that the patient had reliable electricity (to keep the box charged), the staff person explained that the pillbox must be placed in the "ON" position, indicated by a readily apparent green light on the device. The patient and program staff worked together to establish a 3-hour daily window to access take-home medication. Staff then informed patients that only one cell would be unlocked during that predetermined time, that the plastic medication cup must be removed and promptly returned following ingestion, and that the flashing light and beeping features are meant to prompt proper and timely attention to the device and could be "turned off" if the patient requested it. Patients received a telephone support line contact number, which two program staff manned from 7:30 am to 8:00 pm (including weekends), to address pillbox malfunction or to open a compartment outside of the scheduled window. Patients also received a Fact Sheet summarizing use of the pillbox. Finally, staff counseled patients on proper storage of the pillbox, which included keeping it in a safe location and out of the reach of children. While the pillbox used in the study did not have video capabilities to better document ingestion of dispensed doses, the technology is nonetheless a

remarkable improvement on less secure routine take-home dispensing practices that also provide no video confirmation of dose ingestion.

Nursing staff, who followed an electronic calendar to track take-home schedules and ensure proper dispensing, filled the pillboxes. At each refill visit, patients received sanitary wipes to clean the pillbox and asked to place it in designated office space. Nursing staff pre-filled medication cups prior to the patient's arrival to the program. After transferring the refilled medication cups into the pillbox, nursing staff reviewed proper use and storage guidelines with the patient, and provided the patient a prescription card to verify that the methadone was prescribed to remain compliant with legal requirements for dispensing. On higher volume days, the program staffed two nurses to minimize delays and ensure that patients could be in and out of the program quickly. Nurses tracked and destroyed any unused medication, dissolving pills in water and pouring the liquid down the drain, documenting this information and presenting it at medical rounds.

Prescribers and other treatment team members reviewed all cases weekly. At these reviews, the team made decisions to retain or modify the number of dispensed take homes, or to discontinue use of the pillbox if more intensive schedules of onsite clinical assessment and monitoring was warranted (e.g., patients presenting at the clinic under the obvious influence of drugs or alcohol, appearing disheveled and disorganized, repeatedly failing to keep scheduled telehealth or telephonic counseling sessions, and those suspected of pillbox mismanagement). Due to initial social distancing concerns during the study period, the study did not collect urine samples. Following weekly treatment rounds, counselors were tasked with communicating decisions to patients about any changes in take-home schedules; patients could speak to the prescriber directly when requested.

2.4. Data analysis

This retrospective chart review describes data from medical charts that the study collected prior to the onset of COVID-19 and following transition to the Medminder pillbox, as well as the Medminder website, and telephone support line and nursing medication records. For presentation of the data, we grouped patients into one of three categories based on the primary rationale supporting the switch to pillbox use: 1) currently using illicit drugs or alcohol (Current Use; n = 18); 2) vulnerable to take-home mismanagement, either through a program history of mismanagement or living with a person who is misusing illicit substances or alcohol (Mismanagement; n = 15); 3) acute medical problems or cognitive difficulties that impair tracking take-homes (Med/Cog; n = 9). Due to the small sample size and overlap across these clinical subgroups, the study did not conduct analyses comparing outcomes across subgroups.

3. Results

3.1. Baseline characteristics

Table 1 shows demographics, insurance coverage, time in treatment, methadone dose, and substance use characteristics of patients. These characteristics are similar to what we have reported in other studies conducted at our treatment program (e.g., Kidorf et al., 2019), with the exception of mean age, which is somewhat higher in the current study. The study observed patients for an average of 11 weeks.

3.2. Changes in monthly methadone take-home doses dispensed

Table 2 shows the average number of take homes per month dispensed to patients in each of the three subgroups, before and after the study assigned them to the pillbox. On average, patients had been provided 11 take homes/month prior to the pillbox, and 25.6 after pillbox assignment, representing a mean increase of about 14–15 more take homes per month. The increase varied within patient's subgroup, with Current Use patients receiving larger monthly increases (19 more take homes per month) than Mismanagement or Med/Cog patients (about 12 and 8 more take homes per month, respectively), though they were required to attend the clinic more frequently in response to their current use (i.e., weekly or bimonthly versus monthly medication reporting schedules).

Table 1
Demographics and treatment characteristics.

Variable	Overall (n = 42)	Current use[a] (n = 18)	Med/Cog[a] (n = 15)	Mismanagement[a] (n = 9)
	M (SD) or %	M (SD) or %	M (SD) or %	M (SD) or %
Demographics				
Age	53.2 (15.2)	47.0 (13.5)	57.0 (16.8)	59.1 (11.9)
Gender				
Male	61.9%	61.1%	53.3%	77.8%
Female	38.1%	38.9%	46.7%	22.2%
Race				
White	57.1%	55.6%	60.0%	55.6%
Non-White	42.9%	44.4%	40.0%	44.4%
Insurance coverage				
Uninsured	35.7%	27.8%	40.0%	44.4%
Medicaid	54.8%	61.1%	60.0%	33.3%
Commercial	9.5%	11.1%	0.0%	22.2%
Treatment status				
Time on program (months)	103.9 (111.2)	51.9 (72.5)	112.5 (119.4)	193.3 (109.6)
Methadone dose	78.0 (28.4)	81.3 (19.7)	70.1 (29.7)	84.4 (39.8)
Positive urinalysis results[b]				
Opiates	0.17 (0.32)	0.38 (0.40)	0.01 (0.05)	0.00 (0.00)
Cocaine	0.15 (0.34)	0.34 (0.45)	0.00 (0.00)	0.00 (0.00)
Benzodiazepines	0.08 (0.24)	0.18 (0.33)	0.00 (0.00)	0.06 (0.17)

[a] Primary risk category for receiving liquid methadone take-homes per usual programmatic guidelines. Current Use: patients misusing illicit drugs or alcohol; Med/Cog: patients with acute medical problems or cognitive difficulties; Mismanagement: patients with a program history of take-home mismanagement, or living with a person with active misuse of substances.
[b] Results from urine samples collected during 90-days prior to starting the study, M (SD) proportion of positive results per patient.

3.3. Dispensing of take homes

As Table 2 shows, the study scheduled a total of 70.2 take homes for the total sample and the study dispensed almost all take homes (69.7, 99.3%) within the scheduled window of time; patients missed only a few take homes (0.6, <1%). Mismanagement patients had no missed doses. Take-home doses that were not dispensed were confirmed through nursing pillbox counts on refill dates.

3.4. Suspected tampering with pillbox compartments

The study identified suspected tampering incidents based on text or email alerts that included: "unscheduled refill happened" or "empty medication cup removed". The overall mean number of suspected tampering incidents per patient was small (2.5), with patients assigned to the Med/Cog category having more incidents (see Table 2). Overall, the study suspected 12 patients of tampering with the pillbox and half of those were in the Med/Cog category. Support line staff and counseling reviewed these incidents with patients. Repeated text messaging that suggested tampering resulted in losing pillbox privileges.

Table 2
Methadone take homes dispensed.

Study outcomes	Overall (n = 42)	Current use[a] (n = 18)	Med/ Cog[a] (n = 15)	Mismanagement[a] (n = 9)
	M (SD)	M (SD)	M (SD)	M (SD)
Time in study				
Weeks	11.1 (1.7)	11.4 (1.7)	11.0 (1.8)	10.6 (1.5)
Range (weeks)	6.0–12.7	6.0–12.7	6.6–12.6	7.9–11.9
Take homes/month before pillbox	11.0 (8.3)	5.6 (6.0)	14.3 (7.1)	16.4 (8.1)
Take homes/month after pillbox	25.6 (1.2)	24.9 (1.1)	26.3 (1.0)	25.9 (1.2)
Scheduled take homes (per patient)	70.2 (15.7)	65.4 (17.2)	75.8 (8.4)	70.6 (20.2)
Take homes dispensed	69.7 (15.7)	65.0 (17.4)	74.7 (8.4)	70.6 (20.2)
Within scheduled window	68.7 (16.1)	63.8 (17.2)	74.1 (8.4)	69.4 (21.7)
Outside scheduled window	1.0 (1.7)	1.2 (1.8)	0.7 (1.3)	1.1 (2.3)
Take-homes not dispensed	0.6 (1.5)	0.4 (1.2)	1.1 (2.0)	0.0 (0.0)
Suspected tampering with pillbox (incidents per patient)	2.5 (5.6)	0.9 (2.4)	4.6 (8.1)	1.9 (4.7)
Calls to telephone support line (per patient)	2.3 (2.3)	2.3 (2.3)	1.3 (1.7)	3.7 (2.7)

[a] Primary risk category for receiving methadone take-homes. Current Use: patients misusing illicit drugs or alcohol; Med/Cog: patients with acute medical problems or cognitive difficulties; Mismanagement: patients with a documented recent history of take-home mismanagement, or living with a person with active misuse of substances.

3.5. Pillbox rescinded

The study removed five patients from the pillbox during the study period due to repeated pillbox text messages suggesting tampering. Four of them were Current Use patients, and one was a Mismanagement patient. One of the Current Use patients also expressed dissatisfaction with tablets. Each patient returned to standard liquid dosing and take-home dispensing, with more intensive onsite evaluation and monitoring. Despite these incidents, no patients reported overdose during the study period.

3.6. Calls to telephone support line

On average, each patient called the support line about 2 times during the study; Mismanagement patients called more often (see Table 2). Overall, Current Use patients (n = 15) represented about half of the 31 patients who called the support line. Patients most often called to report a pillbox malfunction, though some needed staff to open a compartment outside of the daily window or to set a new daily window for taking methadone due to change in work schedule or other reasons.

3.7. Pillbox mechanical issues

About a fifth (19.9%) of pillbox openings were not recorded correctly, which we attributed to issues with the box connecting to a cellular signal. In almost all cases, a medication cup was recorded as having been taken out of the cell but not returned, or vice versa. On rare occasions, the wrong cell opened, which the study addressed in all known instances through the telephone support line.

4. Discussion

Introduced as an alternative to *standard* methadone take-home dispensing practices during the COVID-19 pandemic, the Medminder electronic pillbox provided novel in-home electronic medication monitoring of methadone take-home doses. This change enabled providers to more securely dispense more take-home doses of methadone to patients than would have ordinarily occurred based on routine clinical practices prior to SAMHSA's relaxed take-home guidelines. By receiving multiple and consecutive take-home doses, patients who had ongoing alcohol or substance use, medical, and/or cognitive vulnerabilities could better observe stay-at-home orders and reduce their potential exposure to COVID-19 (Centers for Disease Control and Prevention, 2020). These patients may not have previously qualified for take-home dosing or to receive large quantities of take-home doses according to pre-COVID-19 regulations. The many safety features of the pillbox, together with a monitoring system and responsive telephone support line, facilitated good communication and reduced the possibility of mismanagement of take-home medication. That most patients offered the device agreed to use it demonstrates good acceptability across a range of clinical profiles commonly observed in opioid treatment program settings.

The rapid transition to the use of the pillbox demonstrates good feasibility; the treatment program was able to readily integrate it within routine practices with minimal adverse impact to patients. For example, few patients evidenced difficulty in managing take homes or utilizing the pillbox, and no patients reported overdoses. Only a handful of patients, generally those with current substance use, demonstrated sufficient clinical instability or suspicion of tampering to remove the pillbox and increase the intensity of clinical attention. Because the study did not routinely collect urine samples during this phase of operations in the treatment program, we were not able to evaluate the impact of extending take-home doses on objective rates of drug use.

This study may have implications beyond the management of methadone during a pandemic. There is a long and well-documented need to expand treatment access and satisfaction for people with opioid use disorder, with the rate of persons needing treatment significantly outpacing the number of treatment spaces that are available and occupied (Jones et al., 2015; Topmiller et al., 2018). Addressing this treatment need has become even more pressing following the introduction of fentanyl into the heroin supply for which the overdose protective qualities of methadone maintenance treatment are more critically needed (Gryczynski et al., 2019; Ochalek et al., 2019). Data from the current study suggest that use of an electronic pillbox may provide a viable way to enhance access to methadone treatment.

Another implication of these data beyond COVID-19 is that the pillbox has strong potential to increase satisfaction and quality of life for patients receiving treatment by reducing travel time to and from the program and its associated costs, especially if extended to those living in rural settings far from OTP facilities (Joudry et al., 2019). People who are satisfied with methadone treatment remain in treatment longer and achieve better outcomes (Kelly et al., 2010). More widespread use of the pillbox to deliver take homes aligns closely with recent calls from research (e.g., Joudry et al., 2020; Kleinman, 2020) to reduce treatment's travel burden by adopting new strategies to deliver methadone, such as through community pharmacy dispensing. Many other countries have already adopted such practices (Calcaterra et al., 2019) and two small pilot studies in North Carolina and Baltimore are evaluating this practice in the United States (Brooner et al., 2020). Maintaining the ability to dispense a larger number of take-home doses in a post-COVID-19 environment using a secure electronic pillbox to provide in-home monitoring of take-home doses is both a laudable and now an achievable goal.

The primary limitation of this pilot report is its small sample size, which reduces confidence in inferences made from these findings. Our sample was limited to the number of pillboxes that were secured based on our financial agreement with Johns Hopkins Bayview Medical

Center, with an understanding that positive results might merit continued investment. This study provided a welcome opportunity to weigh the preliminary advantages of pillbox delivery to patients against the program burden and financial costs associated with purchasing these devices (about $1.00/day). Another limitation is the clinical division of study patients for data analysis. Future work might identify additional and possibly better ways to categorize patients and identify subgroups who are more vulnerable to experiencing problems using the pillbox.

An additional limitation is the electronic pillbox itself, which currently monitors removal and return of medication cups but not actual methadone ingestion. The company that provided the pillboxes to us at a reduced cost has informed us that they are developing a newer platform with video capabilities and will have it available for commercial use within several months. The current pillbox, without video features, could also be paired with other technology (e.g., video directly observed therapy technologies) to extend the assessment of adherence to medication ingestion. Nevertheless, these findings provide preliminary support for the acceptability and feasibility of using the pillbox to help vulnerable patients reduce risk of COVID-19 exposure and take-home mismanagement. At the very least, this alternative approach to the delivery of methadone take-home doses warrants more rigorous evaluations to provide a strong scientific foundation for expanding its use in community-based treatment settings.

Conclusions that can be drawn from this report are also limited due to the study's use of a retrospective chart review and relatively short follow-up period, with patients recruited from one substance use disorder treatment program in Baltimore City. Prospective analyses that sensitively measure substance use, methadone diversion, treatment satisfaction, and even co-resident feedback are needed to augment these observational data and provide more information on the acceptability, feasibility, and effectiveness of the approach used in this study. We hope that the procedures and data articulated in the current report will inform future studies.

CRediT authorship contribution statement

All of the participating authors were meaningfully involved in the study and each of them made substantive contributions to the report. All authors approved of the final submission.

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