



An observational study on the use of long acting buprenorphine (Sublocade) and a Tamper resistant PICC for Outpatient IV antibiotic administration in Patients with serious infections and Opioid Use Disorder; The STOP OUD project

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ABSTRACT

What is STOP OUD?: The STOP OUD project is an observational study on the use of long-acting buprenorphine (Sublocade) and a Tamper resistant PICC clamp for Outpatient IV antibiotic administration in Patients with serious infections and Opioid Use Disorder (STOP OUD).

Background: The US opioid crisis is driving up serious infections related to intravenous drug use. These infections require prolonged courses of antibiotics, often resulting in lengthy hospital stays. Extended hospitalizations for monitored parenteral antibiotics for patients with opioid use disorder are challenging for patients, reduce bed capacity, and are associated with significant cost. This observational study reviews the administration of intravenous (IV) antibiotics in a monitored outpatient setting using long-acting injectable buprenorphine (Sublocade, Indivior Inc., North Chesterfield, VA) and a tamper resistant clamp in patients with opioid use disorder.

Methods: Long-acting buprenorphine and a tamper resistant clamp were used to treat patients with serious infections and opioid use disorder as outpatients.

Results: Hospital days avoided were 30-days per STOP OUD project participant. Eleven of thirteen STOP OUD project participants completed their antibiotic courses as prescribed, there was no evidence of peripherally inserted central catheter (PICC) tampering, and they rated their care as a mean of 4.9/5 (SD 0.4). Institutional savings per STOP OUD patient was \$33,000. Outpatient infusion costs were \$9,300 for a net savings of \$23,700 per STOP OUD project participant. Infections resolved in all participants.

Conclusions: The STOP OUD project reduced hospital length of stay for patients with opioid use disorder and serious infections, and had a favorable financial impact.

Introduction

More than 2 million people in the United States are estimated to have opioid use disorder (OUD), often resulting from prescription opioids for pain. Pennsylvania has been severely affected by the crisis and has the third-highest rate of drug overdose deaths in the US (Hedegaard et al., 2018). Individuals with substance use disorder (SUD) often inject drugs, which can lead to serious infections. Caring for patients with

OUD and serious infections is complex. Infections like endocarditis and osteomyelitis require 4 – 6-week courses of antibiotics resulting in extended hospital stays (Schranz et al., A, 2020). Patients with OUD and serious infection often experience poor clinical outcomes (Bearnot et al., Bearnot et al., 2019).

In patients without a history of SUD, outpatient antibiotic therapy (OPAT) through a peripherally inserted central catheter (PICC) is routinely offered. OPAT is safe, cost effective, and improves patient sat-

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isfaction, allowing patients to return home sooner (Fanucchi et al., Fanucchi et al., 2020, Buehrle et al., 2017). Patients with intravenous drug use (IVDU) are not offered OPAT due to concerns regarding misuse of their intravenous access for nonprescription drug administration (Fanucchi et al., Fanucchi et al., 2019). A retrospective cohort study in a single tertiary care center revealed that access to oral antibiotic therapy in patients with OUD with invasive infections is beneficial if IV antibiotic therapy cannot be completed; however, further research is warranted before implementing this observation into clinical practice (Marks et al., 2020).

Medications such as buprenorphine or methadone are effective in treating patients with OUD (Bell et al., Bell and Strang, 2020, Coffa et al., Coffa and Snyder, 2019, McElrath et al., K. 2018). Buprenorphine diminishes dependency on opioids, increases safety in cases of overdose, and lowers the potential for opioid misuse (Substance Abuse and Mental Health Services Administration, 2021). A study including 20 participants with infections who received combined OPAT and medications for opioid use disorder (MOUD) showed a significant reduction in hospital length of stay (Fanucchi et al., Fanucchi et al., 2020). A retrospective study revealed decreased mortality in patients receiving MOUD post hospitalization for IVDU associated endocarditis in the month MOUD was used (Kimmel et al., 2020). Several small pilot studies looked at the prospect of OPAT in patients with OUD admitted with severe injection-related infections but are limited either by sample size or retrospective study design (Fanucchi et al., Fanucchi et al., 2020).

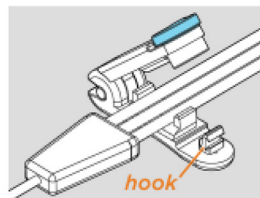
Our project adds to the existing literature by using long-acting injectable buprenorphine (Sublocade) to ensure MOUD compliance. Patients with OUD start by using full agonist opioids such as oxycodone or heroin. When they present to the hospital, they are generally experiencing withdrawal symptoms. Buprenorphine is administered sublingually to alleviate the symptoms of withdrawal. After seven days of sublingual buprenorphine and if they are tolerating the medication well, the patient can be offered long-acting injectable buprenorphine. One 300 mg shot provides thirty days of protection from withdrawal and opioid overdose. This extended duration of action ensures compliance with MOUD therapy during OPAT.

We also used a tamper resistant PICC clamp (Neuma Innovations, Burlingame CA, 2018, Fig. 1). Placing PICC lines in individuals with OUD raises the concern that opioids will be injected into the PICC line, leading to infection or overdose. We use a lockable plastic clamp which can be placed on the PICC line to deter tampering. It is a single use product which is broken when removed and a new one is applied following the infusion. PICC line tampering is immediately recognized if the clamp is broken or missing.

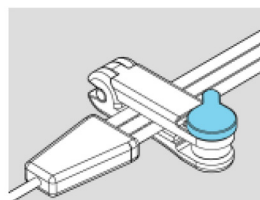
This project reports on the feasibility of administering OPAT to patients with severe infections and OUD using long-acting buprenorphine and a tamper resistant clamp.

Methods

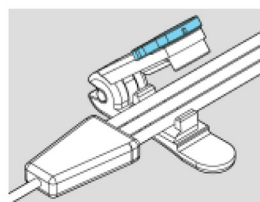
This was a multicenter observational report. Patients with a history of SUD/OUD use as defined by DSM-5 criteria admitted to the hospital with serious infections requiring prolonged (> 10 days) parenteral antibiotic therapy were considered for the study. Education was delivered across service lines and hospitals regarding the STOP OUD program. Referrals were made by hospitalists, infectious disease specialists, and case managers. Participants were given the option of continued inpatient care or outpatient STOP OUD care. The participants had to be willing to have a PICC line placed, sign a controlled substance agreement, have a stable living arrangement, and be able and willing to travel to the outpatient infusion center daily. Participants needed to have weekly lab work and to have expressed a desire to stop using recreational drugs. Insurance which covered treatment, testing, and follow-up was required and participants could not be incarcerated.



STEP 1
Place the lines into the walled cradle.
Note the *hook* that will snap together with the *blue knob* and hold the clamp closed.



STEP 2
Pinch the clamp and it will lock shut.
Now the lines are protected.



STEP 3
Turn the *blue knob* to open the clamp.
This action breaks off the *hook* and the clamp cannot be used again. The hook debris is captured in the knob for quick and clean disposal.

Fig. 1. The Neuma Clamp. Neuma innovations LLC. 2018. The Neuma PICC and central line protection clamp introduction and frequently asked questions. www.neumainnovations.com. Accessed 11/19/2021.

The STOP OUD process was followed (Fig. 2)

Study population

Twenty-two patients were referred to the STOP OUD team between May of 2020 and November of 2021 (Fig. 3). Of the thirteen who were included (Table 1), two failed to complete their courses of IV antibiotics. Once noncompliance was noted, they were contacted and readmission was offered and declined in both cases. The PICC lines were removed by

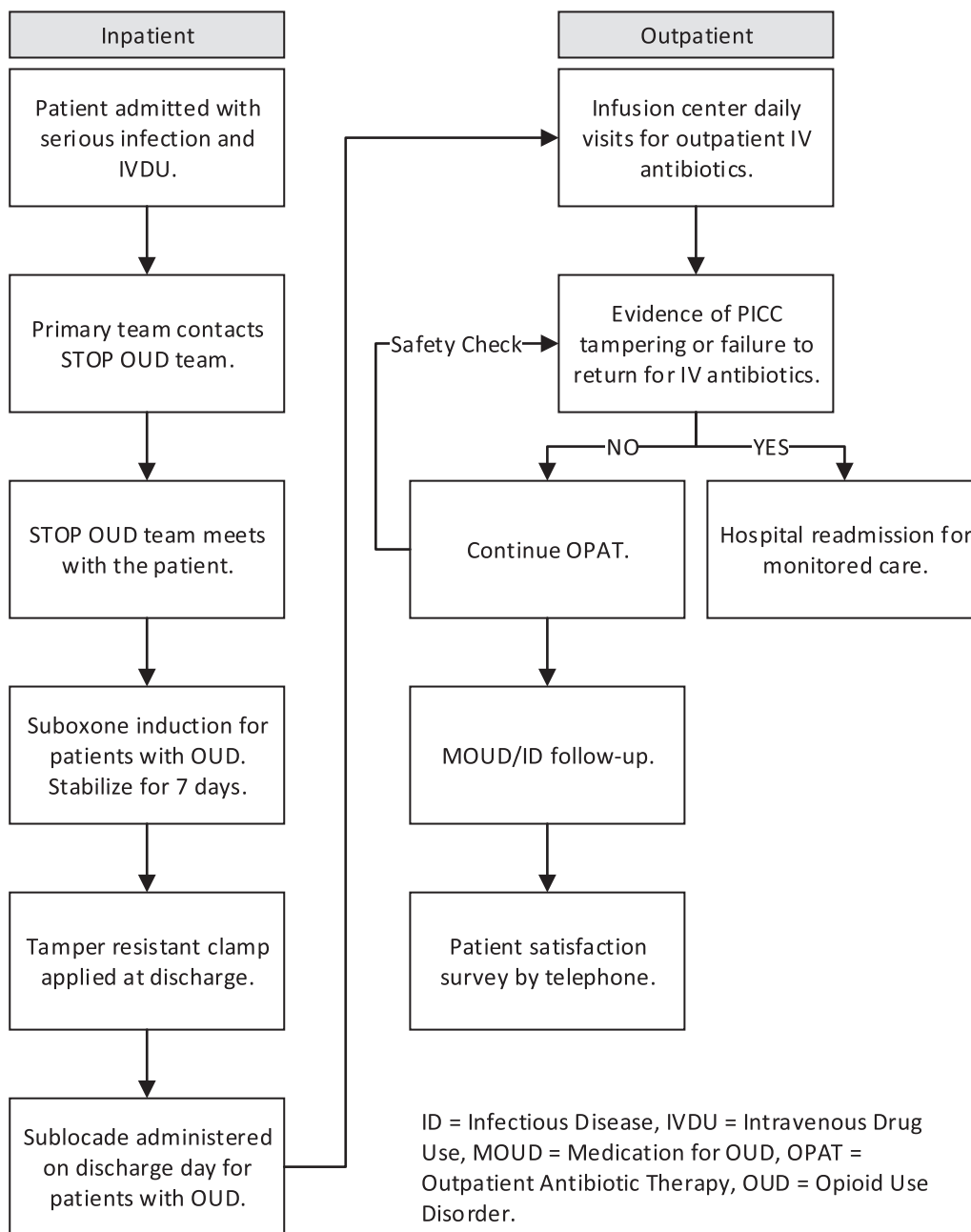


Fig. 2. STOP OUD Process.

home care nurses. Five were readmitted due to medical complications in their care. The first was a PICC-associated DVT which was found on the last day of IV antibiotic therapy. The participant with worsening valvular heart disease was readmitted after completion of OPAT. The participant with fever was readmitted after completion of OPAT. The participant with pneumonia was readmitted for four days during the course of IV antibiotic therapy. The participant with a UTI was admitted for ten days during IV antibiotic therapy.

Patients were excluded if they were unable to meet inclusion criteria (Table 2). All participants were offered drug and alcohol support services. None of the patients were lost to follow-up.

Intervention adherence

Eleven of thirteen participants completed OPAT. The STOP OUD project was designed to detect non-compliance. Participants traveled

to the infusion center for daily IV antibiotic doses. In two cases, participant noncompliance was promptly detected and reported. There were no cases of PICC line tampering.

Statistical methods

Descriptive statistics were used to summarize the characteristics of the patients. Categorical variables were reported as number and percent, and numerical variables were reported as mean and range. Hospital days avoided were calculated by subtracting the participants' hospital length of stay from the total duration of antibiotic administration. This projection was based on the number of days required to complete the course of IV antibiotics according to the Infectious Disease Society of America guidelines.

The cost per day was provided by the hospital finance department. The cost per day multiplied by hospital days avoided produces the sav-

Table 1
STOP OUD included subject characteristics.

Pt #	Age	Gender	Race	Hosp LOS	Hosp days avoided	Organism	Antibiotic	Infection	Substance use history	PICC related adverse events	Course completed?	Infection resolved?	Readmission
1	26	M	Caucasian	8	34	MSSA	Ceftriaxone	Bacteremia, spinal abscess, diskitis	Amphetamine	None	Y	Y	None
2	57	M	Black	14	27	MSSA	Daptomycin	Bacteremia, septic arthritis	Heroin	Arm DVT	Y	Y	Treatment for DVT
3	36	F	Caucasian	7	51	MSSA	Ceftriaxone	Bacteremia, diskitis, spinal osteomyelitis	Heroin	None	Y	Y	None
4	43	M	Puerto Rican	12	37	MSSA	Ceftriaxone	Bacteremia, pneumonia	Heroin	None	Y	Y	None
5	60	M	Caucasian	18	28	MSSA	Ceftriaxone	Bacteremia, prosthetic joint infection	Heroin	None	Y	Y	Fever
6	26	M	Caucasian	6	21	MSSA	Ceftriaxone	Osteomyelitis	Heroin	None	N	Y	None
7	26	F	Caucasian	38	22	MSSA	Ceftarolin, daptomycin, doxycycline	Bacteremia, infective endocarditis	Heroin	None	Y	Y	Worsening valvular heart disease
8	34	M	Caucasian	9	28	Strep viridans	Ceftriaxone	Hand abscess, tenosynovitis	IV cocaine	None	Y	Y	Pneumonia
9	45	F	Caucasian	5	45	MRSA, MRCNS	Daptomycin	Hand infection	Heroin	None	Y	Y	UTI
10	34	F	Caucasian	5	9	None	Ceftriaxone	Hand tenosynovitis	Heroin	None	Y	Y	None
11	29	M	Caucasian	16	31	MRSA	Daptomycin	Infective endocarditis	Heroin	None	Y	Y	None
12	35	M	Caucasian	5	37	Beta strep	Ceftriaxone	Prosthetic hip infection	Heroin	None	N	Y	None
13	26	F	Hispanic	8	21	MRSA	Daptomycin	Infective endocarditis, epidural abscess	Heroin	None	Y	Y	None
				Ave.	30								

MSSA = methicillin sensitive Staphylococcus aureus, MRSA = methicillin resistant Staphylococcus aureus, MRCNS = methicillin resistant coagulase negative Staphylococcus, M = male, F = female, UTI = urinary tract infection, DVT = deep venous thrombosis, PICC = peripherally inserted central catheter, IV = intravenous.

Table 2
STOP OUD excluded subject characteristics.

Pt #	Reason excluded	Organism	Infection	Substance use history	Language	Gender	Race	SO	GI
1	Homeless, left against medical advice	MRSA	Bacteremia	Heroin	English	Male	Black	NA	NA
2	Out of state insurance not covering OPAT	MRSA	Bacteremia, lower extremity cellulitis	Heroin	English	Female	Caucasian	Straight	Cisgender
3	Left against medical advice	MRSA	Bacteremia, empyema	Heroin	English	Male	Caucasian	NA	NA
4	Missed OPAT, readmitted	MRSA	Bacteremia	Heroin	English	Female	Caucasian	Lesbian	Cisgender
5	Left against medical advice	Staph <i>epi</i> and propioni-bacterium	Osteomyelitis shoulder	Heroin	English	Male	Caucasian	NA	NA
6	Left against medical advice	Polymicrobial	Osteomyelitis	Heroin	English	Male	Black	NA	NA
7	Left against medical advice	MSSA	Endocarditis	Heroin	English	Female	Caucasian	NA	NA
8	Left against medical advice	MSSA	Endocarditis	Heroin	English	Female	Caucasian	Straight	Cisgender
9	Left against medical advice	Strep mitis	Endocarditis	Heroin	English	Male	None	Straight	Cisgender

MRSA = methicillin resistant Staphylococcus aureus, MSSA = methicillin sensitive Staphylococcus aureus, OPAT = outpatient antibiotic therapy.

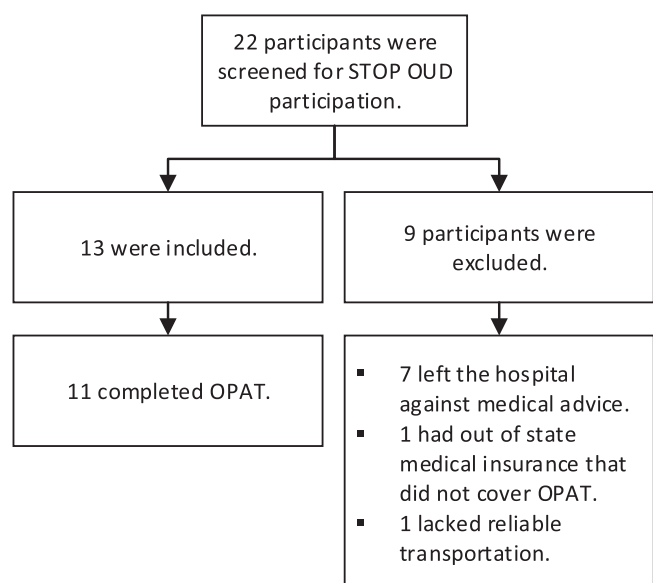


Fig. 3. STOP OUD Participants.

ings per STOP OUD project participant. The national average hospital length of stay in 2016 was approximately 4.5 days with an average revenue per admission of \$11,700 (Freeman et al., Freeman et al., 2018). Estimated additional revenue per STOP OUD project participant is hospital days avoided divided by average length of stay multiplied by the average revenue per admission. The total estimated financial variance per STOP OUD project participant is the savings per patient plus the additional revenue. Outpatient costs were provided by the hospital finance department. Outpatient costs included those related to the infusion center pharmacy receipts (not charges). The monetary impact per STOP OUD project participant was projected based on system financial data. A 5-point Likert scale was used for the patient satisfaction survey (Fig. 4).

All analysis was done in Microsoft Excel

Ethical considerations

Participants were informed of the project design. The project director coordinated with the providers involved in the participant’s care. Participation in the STOP OUD project was not limited by race, sex, sexual orientation, or gender identity. Participant safety and compliance was monitored throughout therapy during daily infusion center visits.

Date of call: _____ Patient name: _____

HELLO! My name is _____ and I am calling to see how things are going (or have gone) with your IV antibiotic treatment. Can I take a few minutes to ask you some questions? Your answers to these questions will be used to help us understand the care you received. Your answers are strictly confidential.

1. Did you receive all of your antibiotic doses?
 - Yes
 - No
2. If no, how many did you miss?
1, 2, 3, 4, 5, 6, more _____
 - 1.1. What were the dates of those missed doses?
Dates: _____
 - 1.2. If you missed doses, why did you miss those doses? Lack of transportation? Cost? I didn't want to go? I didn't think it was necessary? Other? _____

Note: If the patient has missed doses this should be reported to their Infectious Disease specialist and may be an indication for readmission.

3. What are the biggest hurdles you had to overcome to receive the antibiotic doses?
Transportation, cost, inconvenience, work schedule?
4. Did you have to miss work to receive antibiotic doses?
 - Yes
 - No
 - 4.1. Did your employer give you time off to receive your antibiotics doses?
 - Yes
 - No
5. Did your insurance cover this treatment?
 - Yes
 - No
6. If not, what alternative payment arrangement or insurance coverage was arranged?
7. Are you glad you made the decision to receive your antibiotics at home instead of staying in the hospital?
 - Yes
 - No

For each of the following questions please answer using the numbers 1 – 5 where 1 is not at all and 5 is very much.

8. I am likely to follow up for ongoing Suboxone (MOUD) therapy: 1, 2, 3, 4, 5
9. How would you rate your hospital care? 1, 2, 3, 4, 5

Any other comments?

Thank you for your time and thank you for your participation in this quality improvement project. The results of this project will be used to do improve the care we give to people like you.

Fig. 4.

The project was observational in design and was exempted by the Institutional Review Board of UPMC, Central Pennsylvania Region.

Results

Mean hospital days avoided by the STOP OUD project were thirty. Each hospital day costs the health system approximately \$1,100, leading to institutional savings of \$33,000 per participant. Assuming an average length of stay of 4.5 days, 6.6 additional admissions could be accommodated in the vacated bed. Assuming average hospital revenue per admission of \$11,700 (Liang et al., 2020), an estimated \$78,371 per participant could be generated, with an estimated favorable variance of \$111,371 per STOP OUD project participant. Participants rated their care highly at a mean of 4.9/5 (SD 0.4).

Outpatient costs ranged from \$170 - \$200 per day for the infusion center and \$100 - \$150 per day for pharmacy, drug, and misc. costs. The total cost per patient per day for outpatient infusions was \$270 - \$350, or approx. \$9,300 for a 30-day course of care.

Inpatient savings (approx. \$1,100/day) less outpatient costs (approx. \$310/day) yields net savings of \$790 per patient per day, or \$23,700 per 30-day course of care.

Discussion

An increasing number of patients with OUD are hospitalized with severe, injection-related infections amidst the opioid epidemic (Kim et al., 2020). Prolonged hospitalizations increase health costs, consume healthcare resources, and are burdensome for patients. Our hospital system's standard of care prior to implementation of the STOP OUD

project was for individuals with OUD/SUD and serious infections to remain in the hospital for monitored care through the completion of their antibiotic course. The average length of stay for this group in 2019 was 41.6 days. Inpatient monitored care has its proponents (Tice et al., 2004, Rapoport et al., 2017). Outpatient parenteral antibiotic therapy has been found to be more cost-effective than inpatient treatment (Beieler, 2016). Following initiation of long-acting injectable buprenorphine, participants enrolled in the STOP OUD project were discharged after approximately 2 weeks, or approximately 4 weeks sooner than was previously observed for a similar patient population.

Several pilot studies have been published which have described outpatient IV antibiotic use in patients with OUD. A recent review has similarly shown successful completion of outpatient IV antibiotic therapy in patients with OUD. No deaths were reported using this approach (Suzuki et al., Suzuki et al., 2018). Our study adds to this research through the successful use of long-acting injectable buprenorphine, a tamper resistant clamp, and monitored outpatient antibiotic infusions.

Keeping this patient population in the hospital can be a challenge. While against medical advice (AMA) discharges comprise 2% of US discharges (Alfandre et al., 2017), 32% of patients in our study group left the hospital prematurely. This occurred despite the availability of buprenorphine. The use of MOUD, a tamper resistant clamp, and a shortened hospital length of stay all work together to support this vulnerable patient population to complete their inpatient stay and safely return home to complete treatment.

Heroin was the most common type of injection drug encountered in our project. Other injectable drugs such as cocaine and methamphetamine were used. These individuals were not treated with buprenorphine. Since there is no medication which protects patients from injectable cocaine or methamphetamine, these patients may be at higher risk of drug relapse following hospital discharge. While the two patients in our study successfully completed OPAT, further study is warranted to verify the safety of this approach.

Administering IV antibiotics in an infusion center has advantages as well as limitations. The advantage is the safety and compliance check. If the participant fails to present for a dose or if the clamp is missing, it is known immediately. The disadvantages with this approach are that antibiotics can only be given once daily and participants must have transportation to the infusion center.

Building a STOP OUD program requires multidisciplinary collaboration. Addiction medicine, infectious disease, IV therapy, infusion services, pharmacy, nursing, case management, and inpatient providers all play a role. We started STOP OUD programs at each of our system hospitals. The key elements of our STOP OUD program include inpatient buprenorphine induction, long-acting injectable buprenorphine administration, a supply of tamper resistant clamps, 7-day per week availability of outpatient infusion services, MOUD and infectious disease follow up, and a path to readmission for noncompliance or safety concerns. The wholesale price of long-acting buprenorphine 300 mg injections is \$1,394/dose (Lexicomp, 2021), a cost which is offset by savings seen through a reduced hospital length of stay.

Limitations

Given the small sample size in this study, generalizability to a larger population is limited. The patients needed to be motivated to seek substance use treatment. Despite the offer of buprenorphine, several screened patients declined. Urine toxicology testing was not a part of this project. While these results are promising, the safety of this approach needs to be confirmed with further study.

Outpatient MOUD follow up is important for patients with OUD. Some of our participants received either methadone or buprenorphine outside of our program. We elected to support our patients' previously established support systems rather than compel them into our MOUD treatment program. The downside of this is that we did not control their outpatient MOUD follow up. We were able to follow our patients closely

while they were receiving their antibiotics. However, once they completed antibiotic treatment, long-term follow up was limited.

Selection bias was not controlled in the study due to the observational study design.

Conclusion

This project adds to available knowledge that outpatient IV antibiotics can be given safely to patients with severe infection and OUD/SUD. Long-acting injectable buprenorphine and tamper resistant PICC clamps can add to the safety of treating OUD/SUD patients with severe infections outside the hospital. This project appeals to patients and health systems alike by satisfying the triple aim of improved patient experience, improved population health, and reduced cost (Berwick et al., 2008).

Declaration of Competing Interest

The authors report no declarations of interest.

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Main point

This observational study reports on the use of long acting buprenorphine and a tamper resistant clamp in the outpatient treatment of serious infections in patients who inject drugs.

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