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Integrated outpatient treatment of opioid use disorder and injection-related infections: A description of a new care model

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ABSTRACT

Persons with opioid use disorder (OUD) hospitalized with severe, injection-related infections (SIRI) are frequently hospitalized for the duration of IV antibiotic treatment due to concerns regarding their eligibility for outpatient parenteral antimicrobial therapy (OPAT), which is the standard of care for prolonged IV antibiotic courses for patients without drug use. As part of a pilot study, a novel, integrated care model was developed where patients with OUD and SIRI receive addiction consultation and buprenorphine induction while hospitalized, followed by ongoing management in an outpatient clinic that combines office-based opioid treatment with buprenorphine pharmacotherapy and counseling services with OPAT. Through three illustrative case vignettes the outpatient model is described along with challenges, lessons learned and future directions.

1. Introduction

Hospitalizations for severe, injection-related infections (SIRI), like endocarditis and osteomyelitis, have increased dramatically during the opioid epidemic (Ronan and Herzig, 2016; Fleischauer et al., 2017). These severe infections typically require prolonged courses of IV antibiotic therapy. Persons with SIRI are frequently hospitalized for the duration of IV antibiotic treatment (often 6 weeks or longer) largely due to concerns of ongoing IDU, misuse of the requisite IV catheter, and inadequate outpatient follow up (Fanucchi et al., 2016). In contrast, outpatient parenteral antimicrobial therapy (OPAT) via a peripherally-inserted central catheter (PICC) is the standard of care for continuing IV medications for patients without drug use and is commonly used in treatment of IE and other infections requiring prolonged IV antibiotics (Norris et al., 2018). In addition to being cost-effective (Mitchell et al., 2017), OPAT is generally associated with improved patient satisfaction, as patients may return to their life outside the hospital and return to meaningful roles and responsibilities that provide a sense of purpose (e.g., time and responsibilities with family). There is a decreased risk of hospital-acquired infections as well (Norris et al., 2018). In OPAT, patients are taught to self-administer IV antibiotic doses according to a prescribed schedule at home though a PICC line. Persons with IDU have been excluded from OPAT studies, leaving little evidence to support outpatient transitional care in this population (Norris et al., 2018; Suzuki et al., 2018).

Until very recently, hospitalization for SIRI rarely included pharmacotherapy with buprenorphine or methadone to address the underlying OUD (Fanucchi et al., 2018; Jicha et al., 2018; Rosenthal et al., 2015; Fanucchi and Lofwall, 2016), despite clear evidence that these medications decrease illicit opioid use, mortality and are cost-effective (Volkow et al., 2014; Liebschutz et al., 2014). Several hospitals have developed addiction consultation services to address this immediate need and initiate medication for OUD in the inpatient setting (Wakeman et al., 2017; Trowbridge et al., 2017; Englander et al., 2017). These clinical programs are an essential step to mitigate the potential harms of hospitalization for SIRI, which include untreated active addiction, opioid withdrawal and loss of physiologic opioid tolerance, which increase the risk of overdose, as well as in-hospital illicit drug use (Fanucchi et al., 2018). Because OUD is a chronic, relapsing disease, arranging linkage and follow up care from the hospital is critical (Wakeman et al., 2017; Trowbridge et al., 2017), but there are challenges and barriers to doing so, particularly for persons with severe medical complications of OUD (Wakeman and Rich, 2017).

Identifying residential substance use disorder (SUD) treatment facilities able to provide continuation of OUD pharmacotherapy and supervise OPAT is a logical path to both decrease cost and potentially improve clinical care. In a prospective, observational study of 42 patients hospitalized with SIRI in Lexington, KY, only 8 (19.0%) accepted discharge to residential treatment to complete IV antibiotics, 27 (64.3%) were discharged home after a prolonged hospital stay, and 5

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(11.9%) left against medical advice before IV antibiotic treatment completed (Fanucchi et al., 2018). Patient-reported reasons for declining discharge to residential treatment included distance from home, program restrictions (e.g. phone and visitor policy), and previous negative experiences with residential treatment (Fanucchi et al., 2018). These results are consistent with a retrospective study done in Portland, OR where only 15.5% of potentially eligible patients with SIRI accepted discharge to a residential SUD treatment facility (Englander et al., 2018). While discharge to a residential facility may be an option for some patients with SUD to complete IV antibiotics, low patient acceptance indicates that other innovative outpatient models must be developed.

As part of a pilot study (ClinicalTrials.gov, NCT03048643) conducted at the University of Kentucky (UK) medical center between March 1, 2017 and October 2, 2018, we developed a novel, integrated care model where patients hospitalized with OUD and SIRI received addiction consultation, counseling and buprenorphine induction while hospitalized, followed by ongoing management in an outpatient clinic that combines office-based opioid treatment with buprenorphine pharmacotherapy and counseling services with OPAT. Participants had infections requiring ≥2 weeks of IV antibiotic therapy (e.g. endocarditis), were accepting of buprenorphine treatment, and medically stable for home discharge. The following sections will describe this novel care model with three illustrative cases (two successful and one more challenging) and then discuss the implications of it along with unmet clinical research needs. Detailed inclusion criteria, as well as results of the pilot study will be presented elsewhere. Identifying case details have been removed or changed to protect patient confidentiality. The study was approved by the UK Institutional Review Board.

2. Description of the integrated care model

2.1. Inpatient buprenorphine initiation and discharge transition planning

Once screening and informed consent procedures were completed, hospitalized adults with OUD and SIRI were enrolled. All participants received a comprehensive SUD assessment by a DATA-2000 waivered physician, protocol-based induction onto sublingual buprenorphine/naloxone (BUP) (Substance Abuse and Mental Health Services Administration, 2018), and weekly individual counseling by a licensed therapist while hospitalized. During the hospitalization, patients received education on safe injection practices, risks of PICC line misuse, recognition and prevention of overdose prevention, and use of naloxone. Additionally, the PICC line was placed, and OPAT was arranged following clinical guidelines (during the study (Norris et al., 2018), and now updated (Tice et al., 2004)) including inpatient consultation by an infectious disease physician with details of antibiotic recommendations and laboratory testing, involvement of an OPAT nurse, a case manager, a clear communication plan, and scheduled follow-up with infectious disease. In addition, insurance approval for OPAT was obtained, home antibiotic delivery was arranged with a home infusion company, and weekly PICC line dressing changes were scheduled in the infectious disease clinic. Participants received education on PICC line care and home antibiotic administration from the home infusion company. Home health agencies frequently complete PICC line dressing changes and lab draws for OPAT patients, but were unwilling to accept patients with SUDs at the time of this study. Therefore, dressing changes and lab draws were completed at outpatient appointments. Homeless individuals were not eligible for OPAT.

Prior to discharge, insurance prior authorization for BUP was also obtained if needed, follow-up appointment information was provided, a prescription for both BUP (quantity sufficient until the scheduled follow-up appointment) and a naloxone rescue kit were provided.

2.2. Post-discharge outpatient integrated model – B-OPAT

After the tasks above were completed and the primary medical team determined that the patient was medically stable, participants were discharged home. The first scheduled follow-up appointment for BUP treatment was within 4-days of discharge. Participants were then followed for 12 weeks. For the first 4 weeks, participants came to outpatient clinic appointments with an addiction medicine psychiatrist three times per week, then twice per week for weeks 5–8, and once per week for weeks 9–12. After each appointment, participants received a short BUP prescription to last until the next outpatient appointment. Treatment also included a skin exam of the arms (site of IDU for all patients) to screen for new IDU, urine drug testing, and required participation in weekly counseling sessions with a licensed clinical social worker who was also a certified drug and alcohol counselor. If physician or counseling visits were missed, patients understood they may not be able to decrease their visit frequency.

While the PICC line was still in place, a check of the PICC line and dressing along with an assessment of self-reported compliance with antibiotic doses occurred at each outpatient visit. The PICC line dressing was changed weekly at the infectious diseases clinic, which is close to the clinic where BUP treatment was provided, and each participant had at least one follow up appointment with an infectious disease physician during the outpatient phase of the study.

Research assessments for the pilot study occurred upon enrollment in the hospital, weekly for 12 weeks after discharge, and then monthly for 3 follow-up months, with a $50 payment for completing each session. Participants could receive a $250 bonus at the end of the 6 month outpatient period for completing all research assessments. None of the payments were contingent upon urine toxicology results or clinic appointment attendance. A summary of clinical activities and patient responsibilities during the hospitalization, discharge transition, and outpatient integrated treatment is presented in the Table 1.

2.2.1. Case 1

CC is an unemployed, college-educated adult who presented to the hospital with several days of fever, chills and shortness of breath in the context of twice daily IV heroin use for the last 2.5 years and smoking 1 pack/day of cigarettes for the last 9 years. CC was found to have methicillin-sensitive *Staphylococcus aureus* tricuspid valve endocarditis complicated by septic pulmonary emboli and septic arthritis, as well as hepatitis C infection. CC was started on IV antibiotics and opioid withdrawal symptoms were initially managed with clonidine, methocarbamol, loperamide, ibuprofen, and gabapentin. Within the first week of the hospitalization, CC was seen by the addiction medicine internist who gathered further history (see below), diagnosed current severe OUD by DSM-5 criteria and began buprenorphine. The patient was eager for medication treatment motivated by wanting to be well for a child and family. CC stabilized quickly to BUP 16 mg daily. A licensed counselor saw CC weekly, initially diagnosing substance-induced depressive disorder. After approximately two weeks inpatient, a PICC line was placed and CC was discharged to complete another 5 weeks of IV nafcillin. CC was offered treatment for hepatitis C but did not begin it during the follow up period.

CC reported initial use of alcohol, cigarettes and marijuana in the early teen years followed by cocaine, benzodiazepines and prescription opioid use recreationally in high school. Snorting of pain pills began in college with first use of heroin in the early 20s when pain pills became more difficult to find. The longest period of illicit opioid abstinence was for 6 months while on 120 mg of methadone daily through a licensed opioid treatment program, but this ended when CC was briefly incarcerated and then relapsed immediately afterwards. CC also went to an out-of-state residential treatment program and relapsed immediately upon returning home.

As an outpatient, the patient was adherent to physician, counseling, infectious disease, and dressing change appointments and maintained

Table 1
Clinical activities and patient responsibilities during hospitalization, transition to outpatient, and while outpatient.

Inpatient management of OUD and SIRI	Discharge transition planning	Outpatient integrated treatment of OUD and OPAT	
Clinical activities specific to OUD treatment			Patient responsibilities in OUD treatment
• Addiction medicine consultation • BUP induction • Overdose education • Naloxone training • Safe injection education • Assessment of housing stability	• Insurance approval BUP • Prescription for BUP • Prescription for naloxone • Referral to syringe exchange • Appointment scheduled	• Addiction medicine provider appointments • Counseling appointments • Monitor BUP treatment	• Attend BUP appointments 1–3× weekly • Attend counseling appointments weekly • Take BUP daily • Work on personal and treatment goals
Clinical activities specific to SIRI treatment and OPAT			Patient responsibilities in OPAT
• Primary medical team evaluation, management, and stabilization • ID consultation • Determination of antibiotic course	• PICC placed • Insurance approval OPAT • Patient PICC line education • Antibiotics and PICC line supplies delivered to home • PICC line dressing changes and lab draws scheduled • ID appointment scheduled	• Weekly dressing changes • Review of labs • ID appointment • PICC removed • Treatment of comorbid medical conditions if applicable (e.g. HCV)	• Administer antibiotics • Take care of PICC and dressing • Attend appointments • Weekly PICC dressing changes

abstinence from all illicit drugs based on urine toxicology testing and self-report. CC focused on removing drug contacts, improving relationships with a daughter and other family members, and getting back to sports activities. CC slowly became more active and took on more care-giving roles at home, which brought enjoyment and a self-reported sense of purpose. The depressive symptoms resolved. CC remained stable on 16 mg of BUP daily, received nicotine replacement therapy for smoking cessation, and was tapered off gabapentin. At the end of the study, CC was transferred to an office-based opioid treatment program that was closer to home and remained abstinent at 3-month follow-up, while on BUP 16 mg daily.

2.2.2. Case 2

BB is a part-time employed adult who presented to the hospital with several days of pleuritic chest pain and shortness of breath in the context of injecting heroin 4–10 times daily for past 1.5 years, illicit oral use of gabapentin (~2400 mg daily) to self-treat back pain and "nerves [anxiety]" for the past 5 years, occasional intranasal alprazolam use for past 5 years and smoking 1 pack/day of cigarettes for over 30 years. BB was found to have methicillin-resistant *Staphylococcus aureus* tricuspid valve endocarditis complicated by septic pulmonary emboli and osteomyelitis, as well as chronic hepatitis B and spontaneously resolved hepatitis C. Initial urine drug screen was notable for morphine and norfentanyl, as well as clonazepam and cocaine metabolites. BB told the clinical team early in the hospitalization about experiencing opioid withdrawal, and symptoms were initially managed with ondansetron, melatonin, and oxycodone 5 mg every 4 h. The consulting addiction medicine physician diagnosed current severe opioid use disorder and mild benzodiazepine use disorder by DSM 5 criteria and began BUP. Prior to BUP induction, BB used heroin intranasally while hospitalized due to withdrawal and cravings. BB wanted OUD treatment, noting motivators of wanting to be able to have a car and money and to be present for family including grandchildren. BB noted previously struggling to attain abstinence due to withdrawal and being around other actively addicted persons, and stabilized quickly to BUP 16 mg daily. A PICC was placed approximately two weeks into the hospitalization, and BB was discharged to complete another 4 weeks of IV vancomycin. The hepatitis B did not meet criteria for treatment (low viral load, no cirrhosis), and primary care follow up was recommended.

Further history was significant for first-degree relatives with opioid use disorder and likely alcohol use disorder. The patient reported struggling in high school, but receiving a GED and having gainful employment in construction. BB had several drug-related arrests and prison time. Cigarette, binge alcohol use, and daily marijuana use started in pre-adolescence, with marijuana use stopping after approximately 10 years because of feelings of paranoia. BB used hallucinogens weekly for a couple of years as a teenager, followed by intranasal cocaine in the late 20's. BB recognized their opioid addiction while in the mid-20's and tried to self-treat unsuccessfully with illicit buprenorphine and methadone many times over the previous years.

Soon after discharge, BB's teeth were removed due to severe dental caries, and the procedure was tolerated well without use of opioid analgesics. About 2 weeks post-discharge, the antibiotics failed to be delivered over a long holiday weekend due to a delivery company error. BB notified the medical team who tried but was unable to get the antibiotics delivered, resulting in a brief hospitalization to continue antibiotics. BB then returned to outpatient care where antibiotics were completed without further problems, and BUP 16 mg daily continued. BB began working odd-jobs, which they took pride in and enjoyed. In counseling, BB reported ongoing problems with anxiety dating back to young adulthood. The addiction medicine psychiatrist diagnosed current Generalized Anxiety Disorder, prescribed escitalopram 10 mg daily along with cognitive behavioral therapy and mindful breathing exercises. BB reported marked improvement. Throughout the 12-week period there was no illicit opioid or other drug use by self-report and urine drug screens; however, during 3-month follow-up, although engaged in another opioid use disorder treatment program, BB reported intermittent heroin use and tested positive on urine screens for opiates and other illicit drugs. It was unclear if GAD treatment continued.

2.2.3. Case 3

DD is an unemployed adult with previous osteomyelitis of the spine due to injection drug use who re-presented to the hospital with shortness of breath after leaving several days prior against medical advice while being treated for methicillin-resistant *Staphylococcus aureus* tricuspid valve endocarditis complicated by septic pulmonary emboli. DD had been injecting heroin multiple times daily, and methamphetamine daily or several times per week. Initial urine drug screen was notable for morphine, fentanyl, methamphetamine, and cannabinoids. DD was initially seen by psychiatry on the day of re-admission, diagnosed with OUD, stimulant use disorder, and possible benzodiazepine use disorder. They were started on BUP 8 mg and given clonidine, methocarbamol, and lorazepam for withdrawal symptoms. Approximately 1 week into the hospitalization, a urine test was positive for methamphetamine and BUP, and the inpatient team was concerned about inpatient behaviors (e.g. leaving the floor frequently, illicit drug use while hospitalized, refusing to wear a hospital gown). The patient noted ongoing cravings and the BUP dose was increased to 16 mg with an agreement to limit trips off of the floor, and to be present for scheduled antibiotic doses. A

PICC line was placed approximately 2 weeks into the hospitalization. Nearly 3 weeks into the hospital stay, a visitor was found injecting in DD's bathroom. DD was very upset by this event, and later notified the primary team that this person had been a significant other, who later died of overdose outside of the hospital. DD was very distressed, and felt responsible for the death. Shortly thereafter, DD was discharged to complete another 3 weeks of vancomycin.

Further history is notable for having a psychiatric hospitalization as a child for aggressive behaviors, being expelled from high school for drug use, multiple drug-related arrests, having spent > 2 years in prison, and being currently on probation. Though having told the inpatient team prior to discharge that they were going to live with a family member, this plan fell through and DD became homeless. On arriving to the first outpatient clinic appointment, DD had missed one day of IV antibiotics, and had used heroin and methamphetamine. Due to being homeless, DD was re-admitted to the hospital and completed IV antibiotic therapy there.

3. Discussion

The first two cases illustrate that a comprehensive outpatient model that incorporates OUD treatment with BUP and counseling with OPAT is feasible for some persons hospitalized with OUD and SIRI requiring prolonged IV antibiotics. The third case presents some of the specific challenges that arise, such as unstable housing. Notably, while persons with OUD are often assumed to be poor candidates for OPAT due to concerns about compliance, we assert that patients with OUD who are engaged in treatment can participate in and take responsibility for complex aspects of their own medical care. The common practice of keeping patients with SIRI in the hospital to complete prolonged courses of IV antibiotics is not only very costly, but often difficult for patients to tolerate. Once they are no longer critically ill, the prolonged absence from home, combined with boredom in the hospital, limited addiction treatment, and sometimes negative interactions with hospital staff who may have misconceptions about substance use disorder, can lead to unintended consequences, such as discharge against medical advice and in-hospital drug use, and may interfere with positive outcomes. Furthermore, there was no catheter misuse detected during this pilot study. Alternatives to prolonged hospitalization include discharge to: 1) residential treatment facilities, but this is limited by low patient acceptance, 2) nursing facilities, but many do not accept people with IDU (Wakeman and Rich, 2017), 3) medical respite facilities for homeless individuals (Beieler et al., 2016), which are not widely available, and 4) innovative outpatient models that incorporate OPAT with evidence-based treatment of OUD such as the one described herein. It seems likely that external pressures from treatment and patient advocacy groups, policy makers and/or payors will likely be needed to expand access to non-acute hospital treatment options.

There were specific challenges to establishing this model that are relevant to future implementation or research efforts. Because there were no existing outpatient models integrating OPAT and OUD treatment, very frequent outpatient visits were built into the model to allow close supervision given the potential safety concerns. Thrice weekly visit frequency is intensive for the patient, provider, and clinic staffing, potentially financially burdensome for the patient given transportation and visit copayments, and probably not needed for many patients although notably less time consuming than intensive outpatient treatment. Furthermore, study incentives may have augmented appointment attendance, though research assessments were separated from clinical care. For future studies and/or programmatic implementation, we anticipate that provider visits could be once weekly, with more frequent contacts for individual and group counseling based on the patient response to treatment. We also recommend consideration of telehealth options to facilitate contact with patients when transportation is a barrier to attending appointments. Furthermore, because home health agencies were unwilling to accept persons with IDU, PICC line dressing changes had to be arranged at the ID clinic, which is far less convenient than having dressing changes and laboratory blood samples drawn at home. Such stigma-related burdens increase the number of tasks and the amount of responsibility required of persons with SUD receiving OPAT relative to those without SUD. Thus, until these barriers are removed, we recommend co-location of infectious disease, PICC line care, and addiction treatment into one setting.

In addition, some individuals, while not homeless, had significant challenges to participating in outpatient treatment, including needing to care for children or other relatives, having family members in active addiction, having ongoing stimulant use disorders, having intermittent access to a functioning cell phone, lack of transportation, legal complications, and lapses in insurance coverage. The third case describes in particular how acute loss and trauma (e.g. overdose death of a loved one), as well as complicated legal, psychosocial, and psychiatric comorbidities may challenge outpatient treatment. These issues are common in OUD treatment generally, but are particularly salient when the individual is recovering from a significant medical event, also has a PICC line in place and is completing IV antibiotics. We recommend that case management with wrap around services including transportation and telephone assistance be a key element of outpatient programs for persons with OUD and SIRI. The development of additional models, such as integration of OPAT with intensive outpatient treatment or within licensed opioid treatment programs, may be other innovative options to transition persons with OUD and SIRI out of the hospital, facilitate ongoing treatment of OUD, and meet the treatment needs of individuals with higher addiction severity and/or psychosocial complexity.

4. Conclusions

The opioid epidemic has brought complex challenges to healthcare systems that require innovative approaches to improve outcomes, reduce cost, and address stigma. For persons with OUD hospitalized with SIRI, prolonged, costly hospitalizations are certainly not patient-centered and may negatively impact outcomes, and there are no data suggesting that extended inpatient stays are the best approach for all patients with OUD. Comprehensive outpatient care models that integrate pharmacotherapy and counseling for OUD along with OPAT may be a safe and feasible alternative to prolonged hospitalizations. Further research is required to define care models and settings that effectively transition persons with OUD and complex medical conditions out of the hospital, improve retention in outpatient treatment, and reduce further OUD-related morbidity and mortality.

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Declaration of Competing Interest

The authors do not have relevant conflicts of interest to disclose.

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