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Self-administered OPAT (S-OPAT) is a potential cost-effective equivalent option for uninsured patients requiring OPAT

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ABSTRACT A clinical decision report using:

Bhavan KP, Brown LS, Haley RW. Self-Administered Outpatient Antimicrobial Infusion by Uninsured Patients Discharged from a Safety-Net Hospital: A Propensity-Score-Balanced Retrospective Cohort Study. *PLoS Med.* 2015;12(12): e1001922. <https://doi.org/10.1371/journal.pmed.1001922>

for a patient with fungal peritonitis requiring OPAT.

Keywords: OPAT, medically uninsured, fungal peritonitis

Clinical-Social Context

Jason Gomez [pseudonym] is a 28-year-old Hispanic male and current smoker with a 1-year history of intermittent, cramping, non-radiating abdominal pain. Mr. Gomez presented from an outside hospital (OSH) with worsening abdominal pain, an abdominal computed tomography (CT) scan demonstrating free intraabdominal air with hydroperitoneum, peritoneal fluid cultures growing *Candida dubliniensis* and *Lactobacillus*, and started on ceftriaxone, metronidazole, and anidulafungin.

Upon admission, Mr. Gomez underwent an emergent exploratory laparotomy and a perforated pyloric channel ulcer was repaired. Again, peritoneal fluid cultures grew *Candida dubliniensis* and *Lactobacillus*. Following surgery, the standard 5-day treatment course of piperacillin-tazobactam and fluconazole was modified, utilizing anidulafungin instead of fluconazole due to patient's prolonged QTc interval and fluconazole's known QTc prolongation effects.^{1,2}

Following antimicrobial completion, Mr. Gomez experienced continued abdominal pain and leukocytosis. Upper GI series demonstrated no leak from the repaired ulcer, but CT scan demonstrated large intrabdominal fluid collections. CT-guided drains were placed to drain the fluid collections which grew *Candida dubliniensis*.

When the intraabdominal fluid collections had sufficiently decreased, Mr. Gomez was ready for discharge. However, a clinical question arose concerning Mr. Gomez's outpatient fungal peritonitis treatment. Concerned for QTc prolongation, Infectious Disease recommended a 4-week course of anidulafungin instead of fluconazole. However, anidulafungin is only available in an intravenous (IV) formulation. IV administration requires peripherally inserted catheter (PICC) placement, at home nursing support to administer and change the antimicrobial medication, weekly laboratory blood draws, etc., all resulting in significant cost.³

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Mr. Gomez was specifically concerned about the treatment cost as he had recently started a new job as a pipe worker and was currently uninsured. When discussing this plan with Mr. Gomez, he said, "I have no clue how I can pay for this with my new job and no insurance. I will have to decide between trying to pay for this medicine and my rent. I'll lose my place." Mr. Gomez was dismayed that the hospitalization had further set him back financially as he admittedly currently lived paycheck to paycheck and helped to financially support his brother. In addition, Mr. Gomez had stated that intermittent abdominal pain over the past year, caused him to miss repeated workdays, resulting in inability to maintain a steady job. Mr. Gomez also lacked a financial support system. While homecare administered antimicrobial therapy would get him out of the hospital and back to work sooner, the financial burden of this care was steep. To address Mr. Gomez's financial concerns, we investigated outpatient parenteral antibiotic therapy (OPAT) options that would adequately treat fungal peritonitis while being cost-effective.

Clinical Question

Which treatment options are available to provide cost-effective care for uninsured patients requiring OPAT?

Research Article

Bhavan KP, Brown LS, Haley RW. Self-Administered Outpatient Antimicrobial Infusion by Uninsured Patients Discharged from a Safety-Net Hospital: A Propensity-Score-Balanced Retrospective Cohort Study. *PLoS Med.* 2015;12(12): e1001922.
<https://doi.org/10.1371/journal.pmed.1001922>⁴

Description of Related Literature

PubMed was used to conduct a literature search. Initially, the search term used was: "outpatient intravenous medically uninsured." This initial search resulted in three articles. Due to the low number of results, each of these individual results were carefully examined to determine their applicable nature to the clinical question.

Owing to the lack of adequate results from the initial search, an additional PubMed search was conducted with the search term "outpatient intravenous insurance." This search term yielded 154 results. Of these 154 results, 150 articles were removed from consideration based on a cursory search of the articles' contents not being applicable. These articles were removed from consideration at this stage if they did not explicitly detail the use of at home infusions of antimicrobial agents. Articles that did not discuss the financial aspect of OPAT in relation to patients of lower SES or uninsured patients were also removed. Finally, medical subject headings (MeSH) terms were reviewed, and a Google Scholar search was conducted to reveal any overlooked studies. This revealed two additional overlooked articles.

In total, six results were more closely examined to determine their applicability to the clinical question.

A review article by Poretz 1991 introduced the scope of home intravenous antibiotic therapy, including the financial aspects of the clinical practice.⁵ Brown and Sands 1998 discussed the cost-effective nature of OPAT and innovation of infusion pumps, but failed to offer strategies to reduce the financial burden of OPAT itself.⁶ A retrospective cohort study by Yan et al. 2016, exploring the short-term clinical outcomes of 104 patients discharged on OPAT from a Canadian hospital lacking a formal self-administered OPAT (S-OPAT) program showed 43% of patients visited the emergency room and 26% of patients required readmission within 60 days for infection-related issues.⁷ While highlighting the clinical necessity of a formal S-OPAT program, this study failed to explore the financial impact of OPAT programs for uninsured patients and was limited by the study design and sample size.

Three studies detailed strategies to lower the financial burden of OPAT in uninsured patients. In Bhavan et al. 2015, uninsured patients were educated in S-OPAT in order to decrease the financial burden of antimicrobial outpatient therapy.⁴ In Butcher 2017, uninsured patients requiring long-term administration of antimicrobials were treated at an outpatient clinic specifically devised to relieve the financial burden of IV antibiotics on the uninsured.⁸ While Butcher 2017 offered a solution (subsidized outpatient clinic for the uninsured requiring OPAT) to the clinical question, it failed to present concrete data detailing the success of the program or compare it to a control group. Hamad et al. 2020 detailed a hospital-sponsored S-OPAT pilot program for 17 uninsured patients and



evaluated hospital days saved and estimated patient income created by shorter hospital stays.⁹ While Hamad et al. 2020 presented data supporting the success of this pilot program—533 hospital days saved, \$900,000 estimated patient income saved—it was limited by small sample size and lack of control group.⁹

There is a dearth of published studies to address this specific question of cost-effective equivalent alternatives to the healthcare professional administered OPAT (H-OPAT). Provided this, ultimately Bhavan et al. 2015, a retrospective cohort study, was the most relevant to the clinical question as it proposed a novel cost-effective strategy.⁴ This article offered a cost-effective alternative to OPAT for uninsured patients—the self-administration of OPAT—and compared the effectiveness of S-OPAT to the standard H-OPAT, that is OPAT that is administered by a healthcare professional.⁴

The Grade of Recommendation using the SORT criteria for self-administration of OPAT is Grade B, based on limited quality patient-oriented evidence.¹⁰

Critical Appraisal

Bhavan et al. 2015 assesses the clinical efficacy of S-OPAT compared to traditional H-OPAT.⁷ The study design was a retrospective cohort study with the level of evidence using the SORT criteria being Level 2: limited-quality patient-oriented evidence.¹⁰

The S-OPAT program involved training uninsured patients in the self-administration of IV antimicrobial agents and included testing patient's ability to self-administer prior to discharge to ensure competency.⁴ This retrospective cohort study had a total of 1168 patients, which consisted of Parkland Hospital patients requiring OPAT between 2009-2013: 944 patients in the S-OPAT group and 224 patients in the H-OPAT group.⁴ All data was collected from electronic medical record chart review. To evaluate the efficacy of S-OPAT compared to H-OPAT, the study looked at both 30-day readmission rate (primary outcome) and 1-year mortality rate (secondary outcome) in both groups.⁴ Between the two groups, controlling for confounding and selection bias, the S-OPAT patients had a 47% lower 30-day readmission rate: the adjusted hazard ratio was 0.53 and a p-value of 0.003.⁴ Adjusting for confounding and selection bias, 1-year mortality rates between S-OPAT and H-OPAT were not significantly different: the adjusted hazard ratio was 0.86 and a p-value of 0.73.⁴ From this data, the study concluded that S-OPAT is an effective and financially advantageous clinical strategy for uninsured patients requiring long term IV antimicrobial therapy.

The study has several weaknesses, the main one being study design. This study is a retrospective cohort study and not a randomized controlled clinical trial.⁴ The determining factor for group placement was health insurance enrollment, which allows for considerable selection bias and confounding because the patient populations will differ substantially in various socioeconomic characteristics.⁴ Because the S-OPAT patients were placed in the treatment group because they lacked insurance, this group had a larger quantity of disadvantaged patients, referred to by Bhaven et al. as “the working poor,” who generally have the most financial difficulty in obtaining health insurance, but do not qualify for government programs such as Medicare/Medicaid.⁴ This is demonstrated in this study by S-OPAT and H-OPAT patient groups having statistically significant differences in baseline characteristics including: age, race/ethnicity, language, home location, and BMI.⁴ The researchers attempted to correct the inherent selection bias in nonrandom group placement by developing propensity scores to model membership in either OPAT group.⁴ This attempted to approximate a randomized study, but residual selection bias could remain that is not factored into the propensity score calculation process.

A randomized controlled clinical trial would decrease the selection bias and confounding associated with this observational retrospective study design and be able to more appropriately answer if S-OPAT provides equivalent care to H-OPAT.

Importantly, S-OPAT required the development of education materials, pamphlets, competency testing through an established standardized protocol.⁴ Due to the amount of preparation and infrastructure required to initiate and enact self-administration of OPAT, this therapeutic maneuver is not currently feasible at our hospital.

Clinical Application

Concerning OPAT, Mr. Gomez's primary concern was cost due to his financial situation. Thus, S-OPAT, a cost-effective alternative to H-OPAT, was investigated as a feasible alternative. While the study by Bhavan et al. 2015 demonstrated that S-OPAT was both a clinically- and cost-effective alternative to traditional H-OPAT, the patients

in the study benefited from large-scale infrastructure changes and educational programs at the participating hospital.

While the financial benefits of S-OPAT did address the financial concern, Mr. Gomez was also worried about undertaking the responsibility of self-administering his antimicrobials. Mr. Gomez admitted that he had not graduated high school and that “science was not his best subject.” Thus, he did not feel comfortable undertaking this responsibility without a healthcare professional, especially with our hospital currently lacking S-OPAT education. Because of the lack of a proper educational program, the treatment team questioned the external validity of clinical conclusions of Bhavan et al. 2015 to Mr. Gomez’s clinical situation. Without proper education, S-OPAT could result in complications that would require further hospitalization and result in worse financial burden than the cost of H-OPAT.

A multidisciplinary meeting with the treatment team, Infectious Disease, and Mr. Gomez was held in which financial and clinical aspects of H-OPAT and S-OPAT were discussed. Through shared decision making, the potential harms to Mr. Gomez, of enacting S-OPAT without the proper educational program and infrastructure outweighed the initial financial benefits. Thus, Mr. Gomez was ultimately discharged on 4 weeks of H-OPAT IV anidulafungin, at a substantial out of pocket cost for which Mr. Gomez stated he would attempt to pay with a personal loan. Upon follow-up four weeks post-discharge, Mr. Gomez was doing well clinically and working extra hours to pay off his medical debt.

New Knowledge Related to Clinical Decision Science

In the process of making clinical decisions, physicians often overlook the financial cost and the patient’s comfort level with the proposed treatment. These aspects were important for Mr. Gomez, an uninsured man without a high school education requiring OPAT. Bhavan et al. 2015 demonstrated evidence that S-OPAT by uninsured patients is a cost-effective and acceptable clinical strategy. However, our hospital lacked the educational program and infrastructure described in the study. Thus, Mr. Gomez did not feel that he was prepared to handle S-OPAT.

Patient comfort with proposed treatment is essential for maintaining the physician-patient therapeutic alliance. Mr. Gomez’s hesitancy for S-OPAT was one of the most important aspects to consider in the shared decision-making process. While S-OPAT may have saved Mr. Gomez money, his discomfort with the treatment had the potential to lead to further complications including rehospitalization, potentially adding to his health and financial burdens. If the treatment decision had been made solely based on finances, Mr. Gomez’s hesitancy with this approach would have been overlooked. Thus, when different social aspects of a patient’s life conflict with each other, it is most important to consider the patient’s comfort level with the proposed clinical decision.

Moreover, a treatment plan should be devised collaboratively, considering not only clinical outcomes, but also the financial burden and the patient’s comfort with the proposed treatment. While H-OPAT was not the most affordable choice for Mr. Gomez, it was the treatment choice that he was most comfortable pursuing when accounting for his medical knowledge base. If the patient had felt more comfortable with S-OPAT by having a support system that included medical professionals, or if our hospital had a formal S-OPAT educational program, then this could have resulted in the decision to pursue more cost-effective S-OPAT. By ensuring that multiple aspects of the treatment decision are considered and analyzed— with focus paid to the patient’s comfort level—the chosen treatment has a greater chance of meaningful success and benefit for the patient.

Conflict Of Interest Statement

The author declares no conflicts of interest.

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