

## The Patient Assistance Program Committee at the Jackson Free Clinic: Discussing the Need, Design, and Implementation

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### Abstract

Many populations face the barriers of high medication costs due to limited resources, especially those served by student-run free clinics (SRFCs). As part of the solution, patient assistance programs (PAPs) managed through pharmaceutical companies provide free medications to patients who are unable to afford them. Various PAP-related interventions have been proven to improve efficiency and patient care in SRFCs. The Jackson Free Clinic (JFC) serves some of the most vulnerable populations in Mississippi, which as a state has performed poorly nationally in a variety of healthcare metrics. Proximity to such a population and access to service from training health professionals provides a unique opportunity to create change by implementation of student-driven PAP services.

The newly established PAP committee undertakes the tasks necessary to enroll, track, and dispense individual patients' medications received through enrollment in an assistance program specific to the needed medication. The hope of the PAP committee is to reduce the responsibility of medical and pharmacy teams, increase enrollment likelihood, improve medication adherence, decrease patient wait time, and improve patient care. The development of the PAP committee has shown the value of implementing an organized PAP formulary, a consistent organizational structure, and an all-inclusive written hand-guide, which has created an improved training environment for committee members. Other results reported by regional SRFCs have suggested the clinical and cost benefits of implementing PAPs, particularly a committee. The novel method employed at JFC requires additional research and development toward the larger effort of improving patient care, which we plan to investigate with future endeavors.

**Keywords:** patient assistance program, student-run free clinic, student leadership, medication

### Introduction

Traditionally, the state of Mississippi has had difficulties with the overall health of its population. 53.2% of the state's population lives in rural areas and 41% lives below 200% of the federal poverty level.<sup>1,2</sup> The Jackson Free Clinic (JFC) serves some of the most vulnerable populations in Mississippi, which as a state has compared worse nationally in a variety of metrics for health status, including hypertension, obesity, and hyperlipidemia.<sup>3</sup> Additionally, many Mississippians report high out-of-pocket healthcare costs in comparison to their income, resulting in high rates of refusing or not seeking healthcare due to cost.<sup>2</sup> This data illustrates the overwhelming need for access to affordable health care – with special attention to pharmaceutical healthcare. Understanding the specific pharmaceutical needs of those being served by the JFC is imperative to effectively serve the state's most vulnerable and underserved populations.

In one case study on a student-run free clinic (SRFC), the served population reported prescription drug costs as the most frequently reported reason for failure to comply with a prescribed medication regimen.<sup>4</sup> Current literature discusses

the benefits of providing pharmaceutical care coverage as it minimizes out-of-pocket medication costs, yields increased medication adherence, and reduces secondary disease.<sup>5,6</sup> Patients who can readily access their prescribed medications will have better opportunities to manage their acute and chronic conditions, engage in preventative healthcare, and respond more readily to acute medical emergencies.

Patient assistance programs (PAPs), managed through pharmaceutical companies, provide free medications to qualifying patients who are unable to afford them. In a 2010 national survey, a large number of free clinics in the United States reported offering medications through patient assistance programs (77.3%).<sup>7</sup> Interventions such as written "guides for applying PAP", medication advisement by pharmacy students, and organizing PAP committees have proven to enhance efficiency and patient care in SRFCs.<sup>8-10</sup> For similar populations in the Southeast region such as New Orleans, Birmingham, and Nashville, SRFCs have successfully implemented PAP committees and improved patient care.<sup>8-11</sup> The success of nearby SRFCs, combined with the opportunity to serve Jackson's uninsured population, yields an ideal scenario to employ student-driven PAP committees.

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### Describing the Challenges

Implementing PAPs at the JFC was associated with two principal challenges: increasing utilization and improving efficiency. Prior to implementation of a PAP program, providers were often unable to prescribe their preferred medications, opting for the

most accessible medications instead. While a fraction of student clinicians were familiar with enrolling patients in PAPs, enrollment required a significant amount of time. To increase utilization of PAP during patient visits, improve clinic flow and efficiency, and expand the knowledge of common medications available, the JFC PAP Committee was developed. The primary goal of this report is to communicate how a PAP team can be created, the potential challenges, and caveats to conventional PAPs with hopes of encouraging other organizations to implement PAPs effectively.

### **Rationale for Development of a Committee**

It is important to discuss patients' sources of medications prior to the development of the JFC PAP committee. As the primary resource, the in-house pharmacy dispensed medications supplied primarily by the Direct Relief organization. In addition to the in-house pharmacy, outside free pharmacies, GoodRx, and the Walmart \$4 list were utilized to help provide patients with affordable medications. However, many medications were still not supplied by these resources. Given this challenge, pharmacy students searched for alternative ways to increase access to medications. Utilization of PAPs began with insulin and inhalers, but requests for more PAP medications continued to rise. As the demand for PAP applications increased, the JFC PAP committee assembled.

### **Organization and Practices of the JFC PAP Committee**

A Patient Assistance Program committee was designed and implemented at the JFC to ensure organizational efficiency, depicted by Figure 1. The attending pharmacist supervises all pharmaceutical operations. Under the direct supervision of the Academic Chief Executive Officer, the two PAP directors engage in decisions related to systems and oversee the PAP committee. The PAP committee at the JFC is a multi-disciplinary team composed of approximately 20 students who directly enroll patients into PAPs and manage medication ordering. Each of these students is enrolled at the University of Mississippi Medical Center in Jackson, Mississippi. For the purposes of this report, there was no study protocol generated or Informed Consent gathered from these students, as the hope of this work is to give insight into a process rather than to provide data on human subjects.

PAP committee members are expected to work at least two clinic days each semester. Two PAP committee members are present on any given clinic day at the JFC to promote efficiency in enrolling patients in PAPs and to ensure that existing JFC patients enrolled in PAPs have been notified of any medication deliveries to the JFC. The term of a PAP committee member lasts for one academic year, and the entire PAP committee meets at the beginning of each academic year for new member orientation and reminders to previously involved members. One of the key aspects of this yearly meeting is review of the "How to PAP" hand guide, which gives step-by-step guides on each aspect of the PAP enrollment and renewal process, serving

both as an introduction to PAP processes for new committee members and as a reference for all committee members undergoing PAP duties. Additionally, information concerning the current gaps in care for JFC patients and common comorbidities of the most prevalent conditions in the JFC patient population are reviewed during this meeting.

When a patient applies for a PAP medication for the first time, the PAP committee member that assists in their enrollment oversees each step of their application process and regularly contacts the patient with any updates concerning their PAP enrollment status and medication delivery. Additionally, the PAP directors relay information concerning approval, denial, and medication delivery to the committee member of each respective patient, ensuring that application modifications and renewals are completed in a timely manner. Maintaining active communication between the PAP directors, PAP committee members, and enrolled patients is crucial to the success and efficacy of the committee in patient care.

### **Creating the Formulary**

A total of 50 medications were included in the initial PAP formulary with a focus on insulins, inhalers, selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, and antipsychotics. Accessible by all student and physician volunteers during the enrollment process in clinic, this online formulary includes brand name, generic name, class, day supply, manufacturer/company, company fax, company phone number, and links to RxAssist.com.

### **Goal and Overview of the PAP Process**

To select student volunteers committed to the shared goals of JFC PAP Team, the Directors have implemented an application process modelled from other SRFCs.<sup>8-11</sup>

All selected members of the PAP committee are provided direct training prior to their first official shift. Training includes a walk-through and explanation of the "How to PAP" guide, followed by all new members simulating enrollment of a patient with existing PAP committee members acting as the patients. The hope of this training exercise is for new members to be comfortable with the process and logistics prior to interaction with a true JFC patient. A pair of students, one medical and one pharmacy, are scheduled for an 8-hour clinic shift during hours of operation. The primary role of the PAP member is to assist medical teams with completing PAP applications. RxAssist.com, known for its up-to-date collection of all PAP applications, is the primary source of our initial applications. The workflow for completing an individual PAP application is summarized in Figure 2.

### **Completing the PAP Application**

Once a medical team decides to initiate a PAP medication, the enrollment process begins with selecting the appropriate PAP application. Once the correct medication application is selected

on RxAssist.com, PAP committee members are responsible for explaining the process to patients and obtaining the required application information. This information includes but is not limited to basic demographic information, household size and income, insurance status, and current medications. After the patient signs the completed application, the provider section is completed and signed by the on-site attending or resident physician. Once signed, the completed application and prescription are faxed to the appropriate PAP foundation or manufacturer. As part of record-keeping, the completed application and any supporting documentation are scanned into the JFC electronic health record.

### **Continuity of Care with PAP Medications**

After the PAP application is faxed to the appropriate location, the application is stored in the patient assistance binder at the clinic for physical record-keeping (e.g., errors in faxing or small adjustments to the application). For online record-keeping, applications are added to a Microsoft Excel file which is securely stored on a University of Mississippi Medical Center SharePoint and is only accessible by PAP committee members. The online record-keeping includes status updates and the committee member responsible for each patient. For new PAP enrollments, the committee member who enrolls the patient assumes the primary responsibility for following up. Continuity of care includes transitioning this responsibility from PAP members graduating with the PAP committee to another PAP team member.

### **Distribution of Medications**

Prior to the final decision from the manufacturer, the submitted application requires approximately 1-2 weeks for processing. Application approvals and denials are forwarded from the PAP directors to the appropriate committee members. Once approved, medications are normally shipped directly to the patient's home. For medications requiring refrigeration, injection, or a stable home address, they can be shipped to the JFC for pick-up during normal business hours. One day prior to JFC's Saturday clinic, the PAP directors notify the committee members working the upcoming shift which medications have arrived for pickup. This notification allows the committee members to call patients in the morning to ensure they have time to pick up their medication. Patients who have not picked up medications are notified and reminded each Saturday.

### **Institutional PAPs**

Institutionalized Patient Assistance Programs (IPAPs) are federally funded initiatives aimed at providing eligible, uninsured patients with free/low-cost medications at federally qualified health centers, shared hospitals, and free clinics throughout the country. In contrast to conventional PAPs, IPAPs provide an on-site inventory of medications to the clinics that may be distributed directly to the patients without the need for individual patient applications.

JFC's PAP committee initiated contact with many pharmaceutical companies to further build their formulary and successfully enrolled in an IPAP with Pfizer Pharmaceuticals. The process included submitting an initiation application, performing an audit from a third-party company to ensure proper documentation and patient eligibility, and finally, a live interview with the Pfizer PAP coordinators to articulate the general process and workflow of JFC's PAP committee. The successful enrollment in Pfizer's IPAP has far-reaching implications for the clinic and its patient population. While the medications available from the Pfizer IPAP are not commonly utilized in regular care of patients at the JFC, we hope to further collaborate with IPAPs to continue expanding the JFC PAP formulary. Additions to the clinic's inventory of medications will lead to direct medication attainability and potential cost-avoidance for JFC's patient population. Nine medications available from the Pfizer IPAP are listed in Table 1.<sup>8-11</sup>

### **Barriers to Effective Implementation**

Implementing the PAP committee at JFC is associated with unique barriers, and noting these challenges may help other organizations in developing their PAP committees. The following section describes unique challenges: incomplete applications, lack of notifications, timing of refills, medications requiring specialty board-certification, proof of income for an underserved population.

During the approval process for the patient's PAP application, the application may be missing required information that was omitted upon original completion. It is common for the pharmaceutical company to notify the clinic via fax of any omissions or errors; however, occasionally a notification of deferral is not received at all. Failure to receive updates from the pharmaceutical companies leads to a delay in the delivery of medications to patients.

Many PAPs do not automatically ship refills to the patient. If a patient waits until their last pill or injection to call for a refill, the patient may not receive their medication at the appropriate time. To help reduce this issue, committee members document refills and expiration dates to anticipate the needs of patients and remind them of upcoming refills and re-enrollment periods.

Some PAP applications require specialists to complete the prescription and prescriber section of the application. For example, Dupixent's application requires a dermatologist to prescribe the medication. Given that most of our routine physicians are not board-certified dermatologists, these applications impose a significant barrier for SRFCs. Fortunately, the JFC hosts multiple specialty clinics including dermatology and gynecology where PAP members are present to help with enrollments.

In addition to the above barriers, some applications require proof of income such as a W2, pension statement, or Social

Security statement. Unfortunately, a significant portion of patients at the JFC are either homeless or unemployed and typically cannot provide any proof of income. The PAP committee created a verification form to submit alongside the application explaining the patient's financial situation, which includes the monthly income of the patient and anyone else in their household. This form has been successful as an alternative proof of income as it highlights the amount of aid and financial support the patient receives.

### Conclusion

Driven by the principal goal of communicating how the PAP team can be developed, caveats to conventional PAPs, and unique barriers, the authors hope to additionally encourage other organizations to implement PAPs effectively. Depicted by Figure 3, the authors suggest specific features for establishing and maintaining a successful PAP committee. For improving patient care at JFC, the development of the PAP committee has demonstrated the value of implementing an organized PAP formulary and a consistent organizational structure, which has created an improved training environment. Other results reported by regional SRFCs suggest the clinical and cost benefits of implementing PAPs, particularly a committee. The novel method employed at JFC requires additional research and development toward the larger effort of improving patient care, which we plan to investigate with future endeavors. In future works, the authors hope to investigate analyses on cost avoidance and how enrolling patients into PAPs may improve clinical outcomes of patients with previously uncontrolled medical conditions such as diabetes, hypercholesterolemia, and COPD.

**Type:** Clinical Experience, Idea Paper, Student Project

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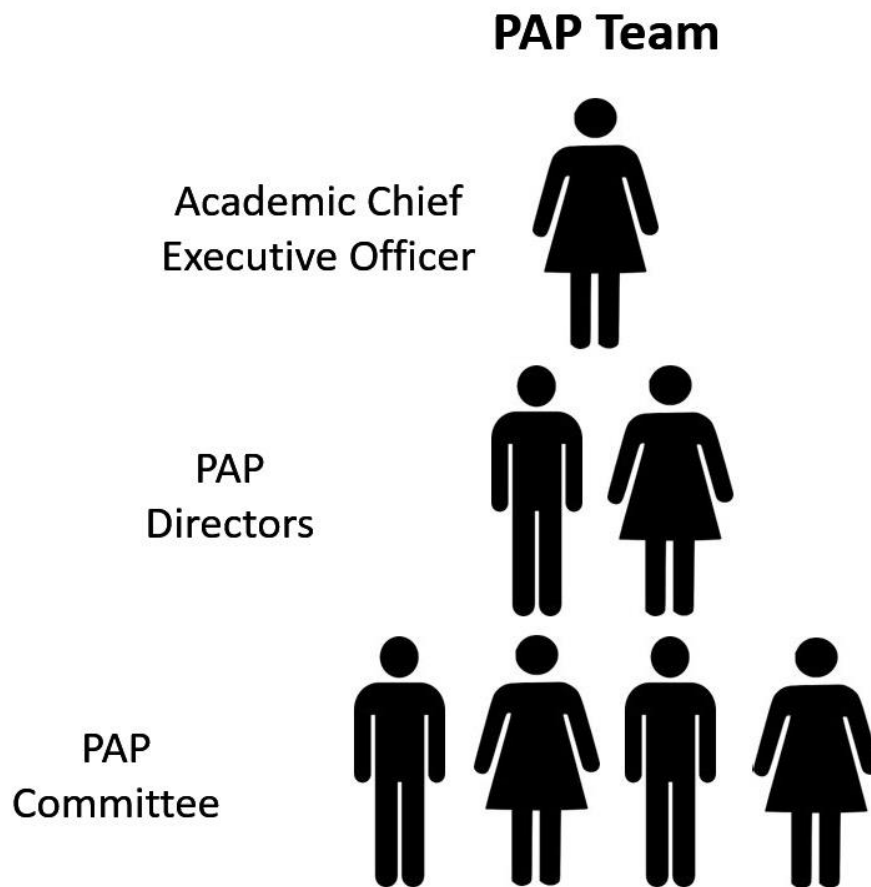
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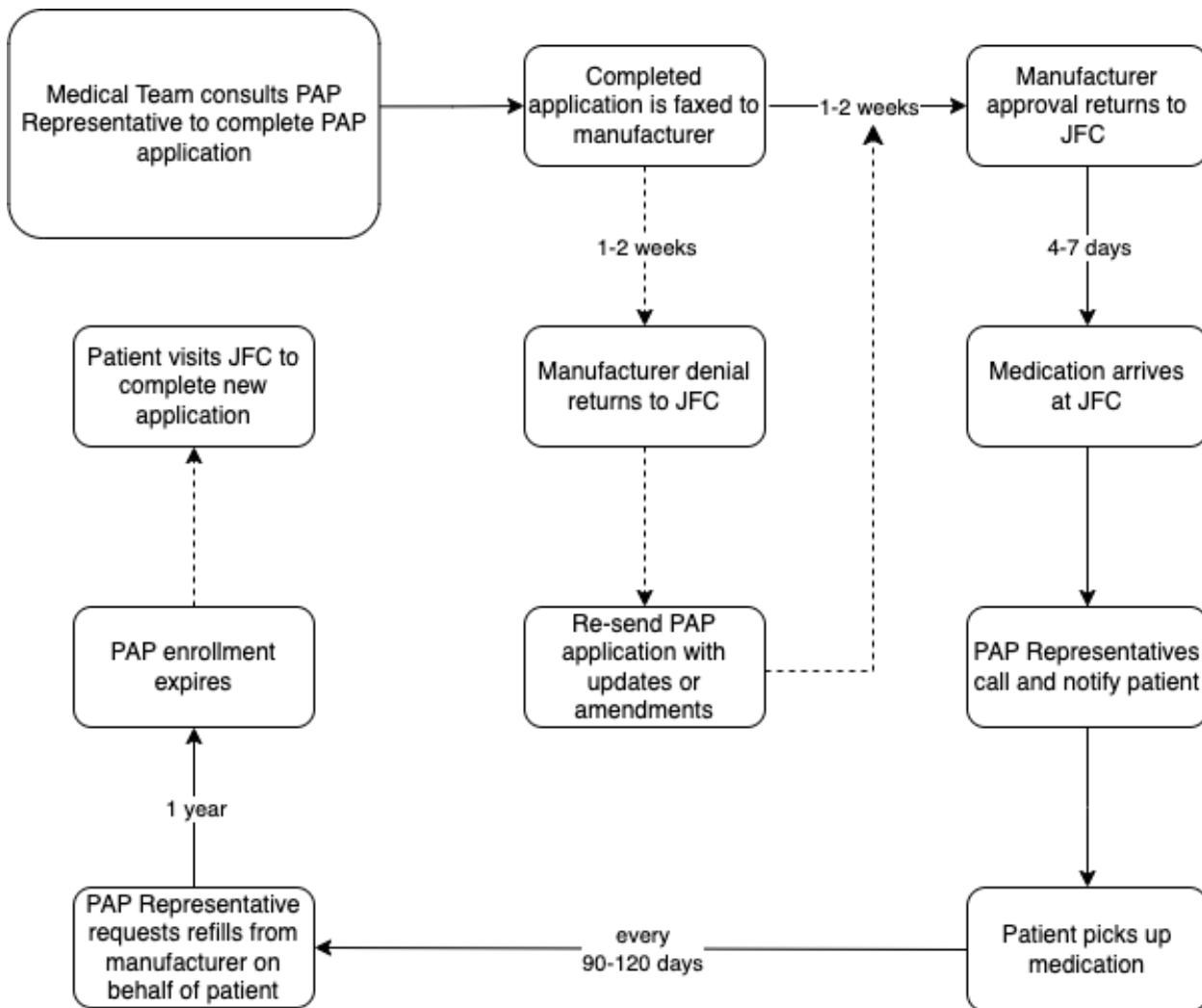
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**Fig. 1** JFC's PAP Committee hierarchy and chain of command begins with the Academic Chief Executive Officer, who manages the two PAP Committee Directors, who manage the entire PAP Committee



**Fig. 2:** JFC’s PAP workflow and timeline begins with a completed and submitted PAP application by the PAP representative after consultation with the patient’s medical team. After 1 to 2 weeks, a decision of approval or denial is communicated to the PAP committee. Denial leads to resubmission after appropriate edits with another 1- to 2-week processing period. After approval, medications arrive at the JFC after 4-7 days, and the patient is notified that their medication is ready for pickup. Every 90-120 days, the PAP representative requests refills from the manufacturer on behalf of the patient. One year after original approval, PAP enrollment expires, and the patient visits the JFC to complete a new application.

Conjugated estrogens/bazedoxifene (DUAVEE™) tablets	Rimegepant (NURTEC® ODT) oral disintegrating tablets
Conjugated estrogens (PREMARIN®, USP) tablets	Conjugated estrogens (PREMARIN®) Vaginal Cream
Conjugated estrogens plus medroxyprogesterone acetate (PREMPHASE®) tablets	Conjugated estrogens/medroxyprogesterone acetate (PREMPRO®) tablets
Diphtheria CRM197 Protein Pneumococcal 13-valent Conjugate Vaccine (PREVNAR 13®)	Dofetilide (TIKOSYN®) capsules
Zavegepant (Zavpret™) nasal spray	

**Table 1** Pfizer Institutional Patient Assistance Program Medication List. Pfizer reported 9 medications listed with generic and brand names in alphabetical order, namely Duavee, Nurtec, Premarin (tablets and vaginal cream), Premphase, Prempro, Prevnar 13, Tikosyn, and Zaypret



**Fig 3.** Pearls for a successful PAP Committee include clear hierarchy and roles, clear communication, adequate training, anticipating challenges, and knowledge of comorbid conditions and gaps in care