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## Development and Implementation of Charitable Pharmacy Services within a Federally-Qualified Health Center (FQHC)

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When established, the Northeast Tennessee Dispensary of Hope was strategically located near a nurse-run clinic that provided care to indigent and homeless patients (operated by East Tennessee State University's College of Nursing). Providers at the Johnson City Downtown Clinic were involved in the care of over half of the patients served by the Northeast Tennessee Dispensary of Hope. In 2012, that clinic established a new location as a result of Health Resources and Services Administration (HRSA) grant funding. The new facility was built with additional space to accommodate more patients as well as auxiliary services, including dental hygiene, physical therapy, an ambulatory care pharmacist specializing in psychiatric care, dietetics and nutrition counseling, audiology, radiology, and designated space for a dispensing pharmacy. When the opportunity presented itself for the pharmacy to move into this nurse-managed Community Health Center and Federally Qualified Health Center (FQHC), there were numerous opportunities that could collectively lead to better patient care. The College of Nursing and the Bill Gatton College of Pharmacy at ETSU partnered together to move operations of the pharmacy into the new Johnson City Community Health Center (JCCHC).

The ETSU Charitable Pharmacy opened its doors in August 2014, taking over operations from the previous Northeast Tennessee Dispensary of Hope location. The pharmacy is open to serve patients four days a week, Monday through Thursday, during the hours of 9:00 AM to 1:00 PM. Medication inventory consists of a restricted formulary based off of prescribing patterns, medication access, and cost. The pharmacy does not maintain a Drug Enforcement Agency (DEA) license, so no controlled substances are dispensed. The pharmacy typically serves approximately 25 patients each day and dispenses an average of 80 prescriptions daily. Operations are run by a pharmacist, technician, and typically a student pharmacist. Two college of pharmacy faculty contribute to staffing efforts, as well as two Community Pharmacy Practice Research Fellows.

During the transition phase, the pharmacist serving as team-leader worked closely with the Board of Pharmacy within the State of Tennessee to ensure that services were established in accordance with Tennessee law. Some states, like Tennessee, offer charitable pharmacy licenses; however, that designation may or may not apply based on anticipated pharmacy operations. Working with a local Board of Pharmacy inspector prior to opening is critical. Identifying an appropriate dispensing system is also a key factor. For this pharmacy, a system was needed that offered dual electronic inventory management, like QS/1<sup>®</sup>. Additionally, some companies, such as QS/1<sup>®</sup> and RxKey<sup>®</sup>, offer discounts to

charitable organizations who contract to use their pharmacy systems.

Patients are referred to the pharmacy by their healthcare provider. The goal of the pharmacy is to serve as a bridge solution to mitigate lack of medication access while patients establish access through assistance programs or during times of economic hardship. To be eligible for services, patients must have a household income at or below 200% of the Federal Poverty Level (FPL) and must lack prescription drug insurance. Patients must provide documentation to show proof of income to determine eligibility and position on the sliding fee scale, utilizing the same process as the FQHC. Administrative assistants of the clinic maintain income documentation of pharmacy patients as well to avoid duplication. Various documentation sources are accepted as proof of income, and the type of documentation provided dictates the frequency for having to renew eligibility. Depending on the source where the medication was obtained, the sliding fee scale may or may not apply. Cost of medication is a fraction of the comparable cost at other community pharmacies, and is only assessed for inventory purchased directly from a standard wholesaler (as opposed to one of the charitable sources discussed later on). The cost to the patient is typically \$1 per prescription for medications that the pharmacy must purchase. Over two-thirds of all prescriptions dispensed are given out at no cost to the patient. A sliding fee scale was established to enhance the number of patients the pharmacy can serve while providing an affordable way for underserved patients to access medication. Since opening, the ETSU Charitable pharmacy has seen an increase in prescription volumes as reported from the old location, along with a substantial increase in patient referrals, most notably from JCCHC clinic providers.

In addition to dispensing medications, ETSU Charitable Pharmacy also offers clinical services that are specialized due to its unique location within the FQHC. Patients who receive medications through Patient Assistance Programs offered by drug companies receive counseling and drug information from a pharmacist or student pharmacist onsite. Patients are also offered individualized, one-on-one health coaching and disease state management appointments. Pharmacists work with student pharmacists to identify high-risk patients with diabetes or complex medication regimens and recruit the patient to come in to the pharmacy for a visit. Patients are typically identified during the drug utilization review (DUR) process based off pharmacist assessment, but patients may also be identified by their nurse practitioner and have occasionally self-identified a need for this service as well. In a private counseling room at the pharmacy, pharmacists work with patients to identify opportunities to maximize drug

therapy and improve overall health outcomes. Additionally, patients who are current smokers or who have expressed interest in smoking cessation are targeted for educational sessions to help them successfully quit while identifying potential therapeutic options to assist them. This information is collected as part of the pharmacy intake paperwork, when patients are asked to report several health status factors, including smoking history, as part of their social history. During the DUR process, pharmacists are encouraged to review social history to identify opportunities for intervention along with looking for cessation medications. Patients are also recruited if behaviors and signs of tobacco use are observed while the patient is in the pharmacy.

Serving a sizable percentage of Spanish-speaking patients, the pharmacy had to identify a method of translation for these patients, as no staff member is fluent in Spanish. By partnering with a FQHC, we were able to utilize existing interpreters who work at the clinic when interacting with and providing counseling for these patients. Many telephonic and video interpreting services are available, such as LanguageLine Solutions® for clinics or pharmacies who may not have interpreters on staff or may have needs for many different languages.



Figure 2: Timeline for establishment of charitable pharmacy services in Washington County, TN.

### Multifaceted Approach to Establishing Services

#### Gaining Access to Medications

As previously mentioned, ETSU Charitable Pharmacy was developed in replacement of the Northeast Tennessee Dispensary of Hope. While under operation by a local health system, the pharmacy budget was \$3,000/month including medication and supply ordering, not including personnel or overhead costs. As a charitable service to the community, the budget was fairly loose without significant oversight. Funding came directly from the health system, as well small and occasional local and regional grants for charitable entities, such as the Diabetes Impact project. ETSU Charitable Pharmacy was given a budget of \$2,500 each

month for purchasing medications, which presented a significant challenge in providing for patient medication needs. Other personnel and operational costs were maintained as low as possible, through judicious spending and staffing. Overhead costs (lighting, training) were included in the clinic's operating budget. Additional funding for pharmacy technician staffing was provided by a HRSA grant. Initial financial support came from funding provided by MSHA and ongoing financial support was maintained through the ETSU College of Nursing. In order to help offset a fraction of the overall costs, a sliding fee scale was instituted for qualifying patients receiving any medication purchased from the pharmacy's wholesaler.

To supplement the limited medication budget, the ETSU Charitable Pharmacy contracted with the Dispensary of Hope (DOH) to gain access to charitably supplied medications. This is a fully-licensed, charitable, medication distributor that supplies medications donated from manufacturers and providers to charitable pharmacies and clinics serving the poor and underserved. For a yearly enrollment of \$7,500, the pharmacy was able to significantly increase medication classes stocked, including critical drug classes such as antipsychotics, and inhaled corticosteroids, which the pharmacy would otherwise be unable to afford. Within the first nine months of being open, the pharmacy was able to stock approximately \$739,849.65 worth of medication to dispense to patients. DOH also provided access to diabetic testing supplies including lancets, lancing devices, meters, and testing strips for very affordable prices.<sup>4</sup>

In addition to DOH medications and supplies, pharmacists coordinated the availability of sample medications from drug manufacturers by requesting monthly allotments for providers at the JCCHC. Our primary focus was on diabetic needs including basal and bolus insulin as well as insulin syringes, due to patient demographics and cost barriers to purchasing. Pharmacists assisted primary care providers in accessing medications via Patient Assistance Programs directly from drug manufacturers. For generic medications unable to be acquired from the DOH, the pharmacy coordinated a contract with Morris & Dickson Co., L.L.C. (a full line wholesale pharmaceutical distributor) for purchasing needs. Being a state-owned institution meant eligibility for the MMCAPS program (Minnesota Multistate Contracting Alliance for Pharmacy), a purchasing organization for government facilities that provide healthcare services. This allows for a reduction in wholesale cost, which was an especially crucial resource for generic medications not accessible from other previously mentioned sources that were determined to be on the pharmacy's formulary.<sup>5</sup> While DOH staff work diligently to maintain access and locate new

sources regularly, there is not always the guarantee of a medication being available from the DOH, thus the need for an alternative inventory source (wholesaler) as well when out of stock.

Community partnerships are also an opportunity for medication access. Several providers in the community have allowed ETSU Charitable Pharmacy to request samples on their behalf, or have donated samples for use by the pharmacy. Further, MSHA frequently donates medications when there are formulary changes at the hospital. Other charitable organizations have developed relationships with long-term care facilities for additional medication access opportunities, although our pharmacy has yet to navigate such a relationship. In general the ETSU Charitable Pharmacy's product mix varies, but is approximately 65% from the Dispensary of Hope, 25% from drug samples and donations, and 10% purchased from a traditional wholesaler.

One of the most unique features of the pharmacy is the development of a formulary and a Pharmacy & Therapeutics (P&T) committee within the community pharmacy practice to guide inventory decisions, purchasing, and prescribing habits. This initiative was led by two pharmacy faculty members practicing at the pharmacy, with engagement of several health care disciplines, including medicine, nursing, nurse practitioners, and mental health providers, as discussed later. The committee worked to strike a balance between providing the most cost-effective medications while also providing evidence-based care.

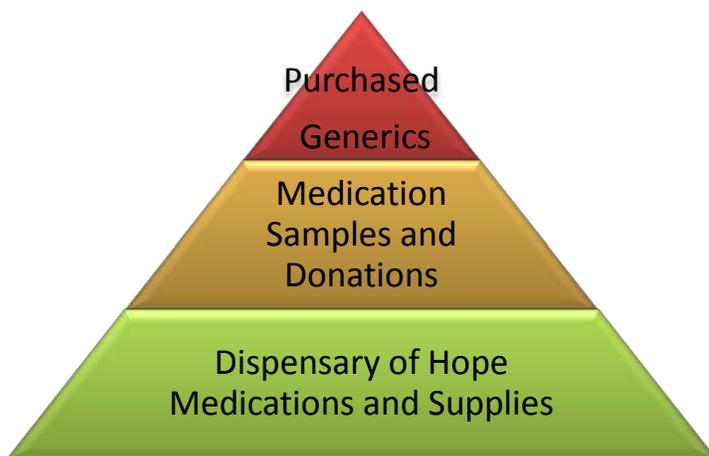


Figure 3: Inventory sources utilized by the ETSU Charitable Pharmacy.

#### Gaining Provider Buy-In

In order to reinforce the continuum of care for patients served by ETSU Charitable pharmacy, it was critical to engage the nurse providers within the clinic in the medication use process. The interdisciplinary clinic had an established ambulatory care pharmacist present approximately 4 days a week, along with student pharmacists completing Advanced Pharmacy Practice Experiences (APPEs). However, because of the ratio of pharmacists to nurse practitioners being approximately 1:6 on any given day, there was still immense opportunity to provide more comprehensive clinical pharmacy services.

Early on, it was identified that a critical tool for success and enhanced patient care was the development of a P&T Committee within JCCHC. The P&T Committee served several purposes. First, it helped the pharmacy develop and maintain a working formulary, which would in turn allow for enhanced management of resources and easier clinical decision-making for nurse practitioners when prescribing for ETSU Charitable Pharmacy patients. Additionally, the P&T Committee served as a means to help educate nurse providers on evidence-based medicine recommendations and enhance prescribing at the clinic on a more global level. A pharmacist at ETSU Charitable Pharmacy chairs the P&T Committee. Initially the committee met monthly and was comprised of the two pharmacy faculty members, a representative nurse practitioner, and the center's clinical manager, along with the occasional guest and student pharmacist. After roughly six months of operation, P&T meetings were moved to once per quarter and occurred during the clinic's bimonthly Peer Review education sessions. Membership expanded to include all nurse practitioners at the clinic and all clinical pharmacists. While not a true committee at that point because of full participation, it was beneficial to have various subspecialties represented to discuss their unique needs. Based on experience, it has appeared that compliance with the formulary changes have been enhanced since this change was made.

In addition to the P&T discussions held quarterly, faculty representatives from ETSU Charitable Pharmacy contributed educational presentations during bimonthly Peer Review sessions on requested medication-related topics. These presentations were coordinated with the nurse practitioner responsible for Peer Review on topics requested by nurse practitioners, as well as areas that were identified as having frequent opportunities for improvement in prescribing patterns. The focus of these presentations were a brief guideline review with a heavy focus on patient case presentations, allowing for discussion of clinical pearls, active learning, and discussion of prescribing when patient factors (i.e. access, medication cost) prevent first-line therapy.

Attempts were also made to engage clinical practitioners on a more routine basis as well. Monthly newsletters were distributed, focusing on drug information, evidence-based guidelines and recommendations, operational and inventory updates, and other clinical pearls. In addition, any urgent messages were communicated to all nursing staff at daily morning meetings as needed by the center's clinical manager. During the start-up, communications were dispatched routinely via weekly pharmacy notes due to an evolving workflow and new integration into the clinic practice model. After several months of operations, frequency of weekly pharmacy notes decreased. Currently notes are utilized primarily to notify prescribers of new medications or medications that are out of stock.

In the future, a major opportunity exists through the development of clinical collaborative practice agreements to enhance medication management by pharmacists at ETSU Charitable Pharmacy in conjunction with nurse practitioners in the clinic. In 2014, the state of Tennessee passed collaborative practice legislation; however, at this time the Board of Pharmacy has yet to establish rules for the implementation of this legislation by pharmacists. Once more streamlined processes are in place and better efficiency can be reached, the natural next step will be to explore more collaborative agreements for enhanced disease state management and increased patient care due to evolving medication access.

#### *Gaining Patient Buy-In*

Despite increased access to medications and a more convenient location to the clinic that serves the majority of the patients served at ETSU Charitable Pharmacy, there have still been barriers in patient adherence. Other charitable pharmacies have discussed challenges in adherence. Less than 50% of patients with chronic diseases take their essential medications as directed, due to cost-related and non-cost barriers involved in medication adherence.<sup>6</sup> As the pharmacy continues to grow and serve more patients, it is important to further identify non-cost barriers to help address and assist patients in understanding solutions to further improve adherence. Establishing a charitable pharmacy within an FQHC did allow for improved coordination of care. At the previous location, the pharmacy primarily served patients being discharged from local healthcare facilities, but this new partnership and location has allowed for patients to establish care with a Primary Care Provider, and made facilitating medication changes based on current availability much easier. Providing necessary patient education and counseling has been one of the biggest challenges that pharmacy staff and

student pharmacists have encountered. Due to our structure and limited staff, patients often have long waiting times (frequently 30 minutes up to one hour), which seems to decrease their interest in extensive medication counseling and offers for disease state management education. However, counseling is offered and provided routinely for both new and refilled prescriptions for all patients. Engagement of student pharmacists in the counseling process has served to be a great learning experience and information provided to patients is tailored to individual patient needs and circumstances and is intended to maximize medication use and health outcomes.

Patient follow-up and consistency continues to be a challenge. While the patient population served lacks insurance and can often not afford any additional out-of-pocket costs, there are still additional barriers and factors involved in their adherence.<sup>7,8</sup> Previous work has shown that patients who experience homelessness also commonly experience frequent transitions of care and change in providers in the health care system, as well as transitions throughout social and legal services. With these factors, these patients are highly susceptible to medication errors, gaps in medication use, and inconsistent access.<sup>7,9</sup> All of these factors have been evidenced in our patient population.

Recognizing some of these challenges, our pharmacists and student pharmacists made a concerted effort to extend the offer for disease state management education at the point of service versus scheduling patients at a later time. Our pharmacy provides an office for in-depth counseling on medications, glucometers, and disease state education and comprehensive medication reviews. To enhance our services, pharmacists coordinated educational materials for smoking cessation through our local health department and diabetes education materials through NovoMedLink™. Student pharmacists also provided follow-up calls to assist patient success and increase accountability for fragile conditions such as smoking cessation and diabetes care. Despite these efforts, we have not fully resolved our adherence and care issues. Pharmacy and clinic staff are working to identify ways to take the care to locations where homeless and indigent patients reside in the community, in hopes of increasing access.

Resource	Description	Website
Dispensary	Charitable	<a href="http://www.dispensaryofhope.org">www.dispensaryofhope.org</a>

of Hope	medication distributor	
GoodRx	Prescription discount program	<a href="http://www.goodrx.com">www.goodrx.com</a>
Needy Meds	Patient assistance program directory	<a href="http://www.needymeds.org">www.needymeds.org</a>
Partnership for Prescription Assistance	Patient assistance program directory	<a href="http://www.pparx.org">www.pparx.org</a>
Rx Assist	Patient assistance program directory	<a href="http://www.rxassist.org">www.rxassist.org</a>

*Table 1: Select medication access resources available to assist charitable pharmacies and patients.*

### Challenges

As outlined above, there have been challenges that have emerged since the implementation of ETSU Charitable Pharmacy at its new location. Because the pharmacy is run as a partnership between various players, maintaining open communication, clear expectations, and working towards a common goal is critical. When conflict arises, usually the root cause has been communication-related. The financial stability of any charitable organization can be difficult, so it was critical that various avenues for funding were explored. Those avenues included community donors, fundraising, grant funding, and installment of a sliding fee scale for qualifying patients receiving qualifying medications. Significant efforts are made to minimize costs such as medication-related, staff-related, overhead, etc. while maintaining a high level of care for patients served. Such efforts include identification of grant funding, critical thinking to utilize no-cost medications while trying to practice guideline and evidence-based care, and securing pharmacy intern, pharmacy technician, and pharmacist volunteers whenever possible. Despite this, financial stability of the pharmacy continues to be a challenge.

In moving the pharmacy to the JCCHC, some patients struggled with transportation to the pharmacy, especially homeless patients, as the previous location was central to the homeless population within downtown Johnson City. Various strategies were explored (i.e. transportation vouchers, delivery to homeless clinics and housing) to improve access for these patients, however because of their transient nature, patient follow-up, monitoring, and pick-up of medications

remain a challenge. Additionally, because of financial and time constraints, the pharmacy's hours and days of operation are limited. This has been problematic for some patients and has hindered access for some.

Paid employees, faculty members, post-graduate fellows, and students staff the pharmacy. Student availability waxes and wanes throughout the year, which can be problematic due to their critical role in pharmacy operations and clinical services. College of Pharmacy faculty have had to reduce their staffing hours because of inflexibility between the practice site's hours and various faculty requirements that interrupt staffing time. A major lesson learned was that faculty experienced immense difficulty successfully managing Pharmacist-in-Charge (PIC) duties, even with the pharmacy operating at reduced hours.

Lastly, relationships must be cultivated and developed with time. Collaboration between healthcare team members is often a result of working together and developing a mutual appreciation for each team members' strengths. Pharmacy staff needed to continually work to gain the trust and acceptance of clinic staff and providers and to show worth as a member of the healthcare team within the clinic, whether through more pharmacist-led education or through help in identifying and resolving medication-related problems for clinic patients. In general, feedback from clinic providers to pharmacy staff and administrators regarding pharmacy operations and interventions has been very positive.

### Future Plans

Recognizing the ability to continue to streamline the continuum of care, increase patient medication access, and enhance services offered to patients, clinical pharmacists at this site are actively engaging with nurse practitioners at the JCCHC on methods to improve care. One of the next steps is the development of a collaborative pharmacy practice agreement under Tennessee law with nurse practitioners at the clinic to include initiation, adjustment, cessation, and transition to another pharmacotherapy agent within the same class per protocol. Within the JCCHC and ETSU Charitable Pharmacy, student pharmacists under the supervision of pharmacy faculty have begun to develop clinical education programs. We have identified the need to improve patient access to education and counseling for smoking cessation, diabetes management, and anticoagulation monitoring. Due to the high demand and volume of the FQHC, patients' education about their disease states is often minimal, and patients' lower health literacy enhances their need to understand their disease state, have educational interventions for adverse health behaviors, and

have pharmacists work to identify and correct adherence barriers.

### Conclusion

Development of a charitable pharmacy within a FQHC allowed for enhanced medication access and availability of clinical education programs for an indigent patient population. This innovative partnership between the College of Nursing and College of Pharmacy increased medication access to a vulnerable patient population and allowed for investigation of innovative community pharmacy models, including development of a Pharmacy & Therapeutics committee, opportunities for collaborative practice, and pharmacist-provided prescribing education. Additionally, expanding on the multidisciplinary network of providers within the clinic has allowed for increased partnerships, education, and enhanced application of evidence-based practices. This has not only had an impact on satisfaction amongst providers on the healthcare team but ideally has resulted in enhanced medication access, better care, and continuity for patients served.

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