Letter to the Editor

Formulary Stewardship As a Novel Training Method for Postgraduate Pharmacy Practice Residents

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TO THE EDITOR:

PATIENT CASE

Pharmacy resident receives a page at 0200.

“Hi, how are you? I am the pharmacy resident covering the infectious diseases formulary stewardship pager returning a page, how can I help you?”

“Hello, I am a medical resident covering the medicine floor, I have a patient who is 73 years old presenting with an isolated elevated temperature of 101.1°F. He had a recent admission for extended spectrum beta lactamase (ESBL) *Klebsiella pneumoniae* bacteremia treated with 14 days of ertapenem. Blood cultures are currently pending. I would like to request ertapenem for my patient for broad spectrum coverage.”

“Thank you for the information, do you mind if I take fifteen minutes to look at the patient’s medical record and give you a call back?”

The pharmacy resident reviewed the patient’s current labs, past medical history, and the notes from the patient’s previous admission. The pharmacy resident noted that in addition to bacteremia, the patient was treated for a gout flare during the last admission. After 15 minutes, the pharmacy resident calls the medical resident. The team informed the pharmacist that the patient was very comfortable with no complaints and was feeling “quite well except for his gout flare.” Besides the isolated temperature, the patient remained afebrile during admission and his white blood cell count was within normal limits. With this

new information, the pharmacy resident recommended holding off on antibiotics until cultures returned and suggested that the isolated fever was most likely due to the gout flare if the patient wasn’t exhibiting any other symptoms. In addition, the pharmacy resident emphasized that if patient was truly bacteremic, there would be a risk that it would be ertapenem-resistant *Klebsiella pneumoniae*, and more aggressive antibiotics may be necessary. The pharmacist encouraged the physician to call back at any point during the night if the patient’s condition worsened and antibiotics would be automatically approved until susceptibilities returned. Blood cultures returned negative, and the patient was ultimately treated for a gout flare. The pharmacy resident avoided the unnecessary use of broad-spectrum antibiotics, which ultimately resulted in cost savings, improved antibiotic stewardship, and physician education.

OPERATIONAL ASPECT OF THE DRUG FORMULARY SYSTEM

A Drug Formulary System is an ongoing process whereby a health care organization, through its physicians, pharmacists, and other health care professionals, establishes policies on the use of drug products and therapies and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population.¹ Formulary stewardship to encourage the use of formulary medications and limit non-formulary medications can improve patient safety.

Technology that supports patient safety is enhanced by formulary stewardship. At our institution, all

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formulary medications are built in our electronic health record (EHR) system, with appropriate decision support. In addition, formulary medications have been built to go through our sterile products technology, which assists in automating the process of routing, preparing, inspecting, tracking, and reporting on intravenous and oral liquid doses. Finally, all of these medications are barcoded and stocked in automated dispensing machines. Formulary stewardship deters the use of non-formulary items and ultimately decreases medication errors and increases safety by utilizing medications that are already built into our technology systems.

Although there are many benefits of a restricted formulary, all patient needs may not be met and hospitals are required to have a mechanism to obtain non-formulary medications. The formulary system should include a well-defined process for the physician or other prescriber to use a non-formulary drug when medically indicated.¹

The formulary system should:

- Enable individual patient needs to be met with non-formulary drug products when it is demonstrated to be clinically justified by the physician or other prescriber.

- Institute an efficient process for the timely procurement of non-formulary drug products and impose minimal administrative burdens.
- Provide access to a formal appeal process if a request for a non-formulary drug is denied.
- Include policies that state that practitioners should not be penalized for prescribing non-formulary drug products that are medically necessary.

HISTORY OF THE FORMULARY STEWARDSHIP PROGRAM

In 1992, computerized physician order entry (CPOE) was implemented at Yale-New Haven Hospital. Prescribers had the ability to order non-formulary medications through a free-text ordering pathway with only an on-screen alert to deter use. Non-formulary medication use was at high volumes causing a significant impact on the hospital budget. In 2001, in attempts to address this issue, 2 physician chief of staff representatives, the pharmacist clinical coordinator, and associate director developed the concept of formulary stewardship. The process they developed is outlined in Figure 1.

Figure 1. Flow diagram showing the formulary stewardship method.

With implementation of formulary stewardship, prescribers would no longer be able to order non-formulary medications via the CPOE system. Instead, non-formulary medications and restricted drugs, including restricted antibiotics, would be limited to pharmacist order entry only and would need approval through formulary stewardship. Prescribers wishing to use any non-formulary/restricted drug would make a request to the chief of staff representative via the “formulary pager.” Subsequently, a discussion along with a clinical evaluation would be conducted. After reviewing the case, the chief of staff representative holding the formulary pager decided whether the non-formulary drug or an equivalent formulary drug would be utilized. The chief of staff representative and drug information specialist held the pager 24 hours a day, 7 days a week, including holidays.

The pager was originally held by a rotation between 2 physician chief of staff representatives. After the process became more established, pharmacy

clinical specialists and pharmacy residents rotated with holding the pager and serving as chief of staff representative equivalents. Chief of staff representatives transitioned to providing clinical and administrative support to the pharmacists holding the pager when the pharmacist’s recommendation was met with resistance or when the clinical situation required physician interpretation. Requests are documented in a formulary pager database that has grown to include 42,000 requests over the past 15 years at our 1,500-bed academic medical center.

Non-formulary trend analysis is performed to help identify medication use evaluation targets and streamline the formulary for potential formulary additions, deletions, or restrictions. Non-formulary medications at our institution are not routinely stocked, which makes communication with the purchasing department vital. Restricted medications are routinely stocked, but their use is restricted to certain indications (Figures 2 and 3).

Figure 2. Bar graph showing the top 15 non-formulary medication requests from October 2014 to September 2015.

Figure 3. Non-formulary drug utilization trends.

FORMULARY STEWARDSHIP AS PART OF RESIDENCY TRAINING

Formulary stewardship has become a multifaceted educational tool that allows for layered learning among both pharmacists and physicians. Key players in the program include resident coverage, the drug information pharmacy specialist, and the physician chief of staff representatives. This is a unique learning experience for pharmacy residents that allows them to gain skills such as critical thinking, time management, operations management, formulary management, antibiotic stewardship, and communication.

Currently, our institution employs 14 PGY1 and 10 PGY2 residents who all have the responsibility of holding the pager throughout the year.

TRAINING AND RESOURCES

Before residents begin evaluating non-formulary drug requests, they are provided training and resources. During their 4-week orientation period, residents are exposed to real-time cases with more experienced preceptors and past residents. Together, the preceptors and new residents troubleshoot medication requests. In addition, a formulary preceptor is assigned to the PGY1 resident during the year to serve as a resource and mentor. Early in the year, the residents meet with their preceptor the day after carrying the pager. As the year progresses and the resident is successfully achieving the learning experience goals, those meetings become monthly or even as needed depending on the type of requests the resident

receives. Residents are trained to utilize several tools such as a communication script and key trigger words to maximize effective communication with prescribers. The communication script provides residents with standardized statements that can be used when talking to prescribers and making recommendations. To help convey concerns of potentially using less safe or less efficacious non-formulary drugs, residents also use “CUS” words, including “concerned,” “understand,” and “safe,” when recommending alternative therapies. After the initial training period is over, the formulary backup coverage is removed, but the residents still meet with their formulary preceptor to review recent non-formulary requests.

A formulary request review session or “huddle” is held every Monday for 1 hour for all residents and available pharmacy staff to discuss recent non-formulary drug requests. During this huddle, residents who held the formulary pager over the weekend present their recent non-formulary drug request cases to a physician specialist and drug information pharmacist. The cases are used as an educational tool to generate discussion on current literature, appropriateness of use, and opinions for alternative recommendations.

Resources to assist with non-formulary evaluations include guidelines outlining approval criteria on non-formulary and restricted drugs. These guidelines include restriction criteria determined by the Pharmacy & Therapeutics Committee. Previously documented non-formulary requests can be searched in the formulary database to provide information

on how similar requests were handled. A repository of journal articles, including clinical trials, national guidelines, and other supporting literature is available on a network drive to assist with primary literature research.

MEETING AMERICAN SOCIETY OF HEALTH SYSTEM PHARMACISTS PGY1 ACCREDITATION STANDARDS

This novel training method has been carefully developed to assist in achieving the American Society of Health-System Pharmacists (ASHP)

accreditation standards for a PGY1 residency program (Table 1). Following are specific examples that residents experience related to the learning objectives and activities.

R1.1.3 & R1.1.4 Collect, analyze, and assess information on which to base safe and effective medication therapy. Every request needs to be evaluated through health data that are collected verbally from the requester and through the hospital's EHR. The resident provides appropriate evidence-based recommendations for formulary stewardship.

Table 1. Summary table of American Society of Health-System Pharmacists postgraduate year 1 educational goals and objectives for the formulary stewardship learning experience

Goal	Objectives	Activity
Competency area: R1 Patient Care		
R1.1 In collaboration with the health care team, provide safe and effective patient care to a diverse range of patients, including those with multiple co-morbidities, high-risk medication regimens, and multiple medications following a consistent patient care process.	R1.1.3 (Analyzing) Collect information on which to base safe and effective medication therapy.	Use an efficient and effective method for collecting pertinent medical information to assess the appropriateness of the request. This includes clarification of information (such as allergic reactions) as needed.
	R1.1.4 (Analyzing) Analyze and assess information on which to base safe and effective medication therapy.	Provide safe and effective evidence-based recommendations for the formulary stewardship request based on an assessment of the patient current status.
	R1.1.7 (Applying) Document direct patient care activities appropriately in the medical record or where appropriate.	Provide timely, clear, and concise communication of pertinent information in the medical record (including communication to the next pharmacist and to pharmacy purchasing) and documentation in the formulary database.
	R1.1.8 (Applying) Demonstrate responsibility to patients.	Demonstrate ownership of the process by prioritizing and following through on requests and escalating to Chief of Staff leadership when appropriate.
R1.3 Prepare, dispense, and manage medications to support safe and effective drug therapy for patients.	R1.3.2 (Applying) Manage aspects of the medication-use process related to formulary management.	Ensure stewardship requests for medications are managed in compliance with Pharmacy & Therapeutics/Formulary Integration Committee policies and in a manner that ensures patient safety.
Competency area: R2 Advancing Practice and Improving Patient Care		
R2.2 Demonstrate ability to evaluate and investigate practice, review data, and assimilate scientific evidence to improve patient care and/or the medication-use system.	R2.2.1 (Analyzing) Identify changes needed to improve patient care and/or the medication-use system.	Recommend evidence-based updates and make changes to the formulary guidelines as needed.

(continued)

Table 1. Summary table of American Society of Health-System Pharmacists postgraduate year 1 educational goals and objectives for the formulary stewardship learning experience (CONT.)

Competency area: R3 Leadership and Management		
R3.1 Demonstrate leadership skills.	R3.1.1 (Applying) Demonstrate personal, interpersonal, and teamwork skills critical for effective leadership.	Demonstrate understanding of perspectives of various health care professionals and utilize effective negotiation skills when responding to formulary stewardship requests.
	R3.1.2 (Applying) Apply a process of ongoing self-evaluation and personal performance improvement.	At meetings with formulary preceptor, engage in the self-evaluation process in order to summarize strengths and areas for improvement as related to your participation in the formulary stewardship process and demonstrate continual professional growth based on feedback.

A resident may receive 3 different pages overnight for complex and controversial daptomycin, fosfomycin, and levalbuterol hydrochloride requests. The resident needs to find a way to quickly analyze and prioritize the requests in order to deliver timely responses and optimize patient care. The resident chooses to evaluate the daptomycin request first. As the resident quickly evaluates the patient's chart, he or she notes that the patient appears to be in septic shock with a probable methicillin-resistant *Staphylococcus aureus* (MRSA) infection. The prescriber strongly insists on daptomycin due to the patient's "vancomycin allergy." Upon further investigation in the chart, the pharmacy resident realizes the "vancomycin allergy" is infusion-related and that the patient tolerated a past vancomycin administration when provided with premedication and a slowed infusion rate. Improper allergy documentation results in sub-optimal antimicrobial use leading to increase of *Clostridium difficile* rates, increased resistant organisms, and increased hospital costs. Therefore, using communication skills, the resident firmly recommends vancomycin and explains the reasoning of using the formulary alternative instead of daptomycin. For the fosfomycin request, the resident evaluates and makes a firm decision to hold therapy for 48 hours as the patient last received a dose the previous day. The pharmacy resident educates the physician that fosfomycin treats for 48 to 72 hours based on the patient's renal function and that it is not a daily dosed medication. The physician appreciates this education. Finally, evaluation of the levalbuterol hydrochloride request reveals that the prescriber was worried about

tachycardia resulting from albuterol use. The resident explains to the prescriber utilizing primary literature that the clinical difference in heart rate between the 2 agents is clinically insignificant and it is safe to use albuterol.

R1.1.7 Document direct patient care activities appropriately in the medical record or where appropriate. Resident communication is documented in the medical record and verbally communicated with the medical team. The resident provides pertinent information in the medical record (including communication to the next pharmacist and to pharmacy purchasing) with regard to follow-up. When a pharmacist evaluates and decides to approve or deny an order, a formulary note must be posted to the patient's chart explaining the reason for use or denial with an alternative recommendation. Feedback on the resident's efficiency and quality of notes is provided by the formulary preceptor. In addition, the resident provides written documentation of the request in the hospital's formulary database.

R1.1.8 Demonstrate responsibility to patients. The resident demonstrates ownership of the process by following through on requests and escalating to physician chief of staff representatives. Appropriate evidence-based recommendations are provided for formulary stewardship. The resident makes decisions to improve all aspects of patient care. For example, some non-formulary medications like fosfomycin can help facilitate the discharge process for the patient.

R1.3.2 Manage aspects of the medication-use process related to formulary management. The resident ensures that non-formulary medications are

managed in compliance with Pharmacy & Therapeutics Committee policies and in a manner that ensures patient safety. Appropriate evidence-based recommendations are provided for the formulary stewardship. Part of the formulary process is to ensure that the pharmacy carries the non-formulary medication before approving a request; this requires communication with the operations and purchasing department. High-cost items such as ledipasvir/sofosbuvir (*Harvoni*) may need to be dispensed securely to ensure appropriate barriers are in place to prevent inventory loss or diversion.

R2.2.1 Identify changes needed to improve patient care and/or the medication-use system.

The resident has the opportunity to recommend updates to the formulary guidelines or even potential changes to the formulary. As an example, intravenous acetaminophen was restricted to approval via the formulary pager for treatment of pain in adult surgical patients who were not able to take oral therapy and nonsteroidal anti-inflammatory drugs (NSAIDs). Through discussions with their formulary preceptors, several residents suggested that the restriction criteria for intravenous acetaminophen be re-evaluated, as there was a high volume of requests that were not approved. This prompted a non-formulary trend analysis along with a formal re-evaluation of its formulary status at the Pharmacy & Therapeutics Committee meeting. Subsequently, intravenous acetaminophen was removed from formulary for adult patients.

R3.1.1 Demonstrate personal, interpersonal, and teamwork skills critical for effective leadership. The resident demonstrates ownership of the process by following through on requests and escalating to physician chief of staff representatives when appropriate. The resident is the gatekeeper of the non-formulary medications and needs the skills to make difficult and timely decisions in the best interest of the patient. These decisions require firmness and authority, because not everyone will be pleased with the decision (Table 1).

BENEFITS OF FORMULARY STEWARDSHIP TO RESIDENTS

This unique and innovative learning experience for pharmacy residents allows them to gain skills in critical thinking, time management, operations management, formulary management, antibiotic stewardship, application of evidence-based medicine, and communication. This is one of the most powerful

learning experiences for the residents, as each request evaluated allows them to simultaneously utilize and refine many skills. We have seen that the goals for this longitudinal learning experience are achievable by as early as 6 months. Residents typically begin the year receiving plenty of feedback from formal preceptors on formulary requests, but it noticeably declines as the resident gains more experience fielding different types of requests. Residents have positively commented on how well the formulary stewardship has impacted their professional development, for example: "Through formulary stewardship, I gained a Rolodex worth of unique experiences which helped tremendously when answering questions during interviews." Another resident stated, "Through this experience, I have been able to evaluate patients with diverse and rare disease states that I otherwise would not have seen just through my rotations. Additionally, it has strengthened my ability to communicate with providers and open dialogue to discuss the options for optimal patient care."

In addition, residents learn the concept of antimicrobial stewardship through formulary stewardship and its effect on the institution's microbial resistance rates. For example, our institution does not utilize carbapenems as empiric therapy because of resistance rates. Our institution can also continue to utilize fosfomycin due to antimicrobial stewardship.

OBSTACLES TO IMPLEMENTATION

With any successful initiative, there are always obstacles to its implementation and success. Some considerations to evaluate prior to implementation include the institution's ability to staff the formulary stewardship process as a 24/7 service, allow training time for residents, educate new medical staff regarding the formulary stewardship process, and develop an escalation process to prevent delays in therapy.

Ability to Adequately Staff

If an institution hopes to implement formulary stewardship, they first need to evaluate the size and commitment of their staff. At Yale-New Haven Hospital, a 1,500-bed hospital, the Drug Information Center is staffed by the drug information pharmacy specialist as well as 1 or 2 pharmacy residents. These pharmacy residents field requests Monday through Friday from 8:00 a.m. to 4:00 p.m. The residents are able to utilize other pharmacy staff during the day as backup. Once a resident is working on 2 requests, the next request is fielded to either the drug information

specialist or the appropriate PGY2 pharmacy resident who specializes in that area. From 4:00 p.m. to 8:00 a.m. the following morning, a resident is assigned to cover formulary stewardship. The resident is not required to be on site and is able to field pages anywhere that there is a reliable wireless connection. For an institution to successfully implement formulary stewardship, the pharmacy department must be large enough to facilitate 24 hours a day, 365 days per year coverage. In addition, during the time that pharmacy residents are attending orientation and/or waiting to be licensed, nonresident staff will be required to cover the formulary stewardship responsibilities.

Training of New Pharmacy Residents

Institutions that hope to implement formulary stewardship should provide residents with resources regarding Pharmaceutics & Therapeutics Committee decisions in order to allow them to assess requests, resources regarding the escalation process, and contact information for chief of staff representatives. These tools were provided to Yale-New Haven Hospital pharmacy residents during orientation. Residents are provided resources such as the formulary database, which includes all documented formulary requests as well as the decisions and the medical record numbers of the patients. Residents are also provided with formulary stewardship guidelines, which establish approval criteria.

Timely Review of Requests

If an institution hopes to implement formulary stewardship, they should consider initially dividing the requests by specialty, and then combine the requests once the pharmacy residents feel strong enough clinically to field a higher volume of requests. The ability to think critically and efficiently about a complex case is not a skill that is immediately acquired by any new practitioner. Early in the year, residents are encouraged to utilize their backup and PGY2 co-residents as

a double-check in order to perform an efficient review of requests. The pagers are initially split at the beginning of the year into pediatrics requests, infectious disease requests, and all other requests with one resident holding each pager. This allows for a lower volume of pages at the beginning of the year while residents are developing their formulary stewardship skills. Later in the year as the residents become more comfortable, they are able to hold multiple pagers at once.

CONCLUSION

Formulary stewardship is a novel training method that has allowed the pharmacy residents of Yale-New Haven Hospital to meet multiple ASHP accreditation standards. It has helped them grow into practitioners who exhibit critical thinking skills, excellent time management, and consider all aspects of a medication, clinical and operational. In addition to benefits to residents, it provides cost savings, increased antibiotic stewardship, and increased safety to the institution. Yale-New Haven Hospital has utilized formulary stewardship since 2001 and will continue to do so for years to come.

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