

ORIGINAL ARTICLE

From A to Z: Medication Cost-Management Strategies for Disproportionate Share Hospitals

Andrea Henry, PharmD, MBA; Goldina Ikezuagu Erowele, PharmD; Uche Anadu Ndefo, PharmD, BCPS; Jackie Milton-Brown, PharmD; Enock Anassi, PharmD, MD; Wendy Green, PharmD, MPA; Adriana Alvidrez, PharmD, BCPS; Alphonsus U. Okpara, PharmD



Andrea Henry

Background: Harris County Hospital District, Houston, TX, is a publicly funded hospital system that provides care to residents of Harris County with a need-based payment system. The Harris County Hospital District pharmacy department, with a drug budget of more than \$75 million in fiscal year 2010, utilizes a closed formulary system that is managed by the Formulary Management and Pharmacoeconomics Service, along with the medical staff. This service is comprised of clinical pharmacists whose goal is to provide a comprehensive, safe, and cost-effective formulary.

Objective: To describe the unique formulary management process at a county hospital system and what makes this process cost-effective, which may benefit pharmacy departments in institutions serving an indigent patient population.

Summary: The Harris County Hospital District drug formulary is overseen by the Pharmacy & Therapeutics committee, which is supported by 5 therapeutic subcommittees, including antimicrobials, cardiovascular, general formulary, central nervous system, and oncology. The Pharmacy & Therapeutics Committee consists of a medical staff committee that is supported by clinical pharmacists, who serve as the facilitators of these 5 subcommittees. Their responsibilities include the provision of drug information for formulary decisions, providing parameters to govern the use of certain medications, communicating changes to the formulary, conducting class reviews and medication utilization evaluations, coordinating annual pharmaceutical bids, reviewing and writing medication use policies and procedures, facilitating the use of cost-effective medications, and monitoring the use of medications in the hospital system.

Conclusion: The processes incorporated by Harris County Hospital District in its formulary management are cost-effective and may be beneficial to other pharmacy departments, especially those institutions that serve an indigent patient population and are interested in cost-effective management strategies.

Stakeholder Perspective,
page 179

Am Health Drug Benefits.
2011;4(3):172-180.

Disclosures are at end of text

The Harris County Hospital District (HCHD) is an integrated public healthcare system for Harris County, TX, the nation's third most populous county.¹ More than 27% of Harris County residents are uninsured, and Texas state law requires counties to serve the indigent; therefore, most of these uninsured patients receive care at HCHD.² HCHD is comprised of 3 hospitals, 13 community health centers, 13 satellite homeless

shelter clinics, 8 school-based clinics, 4 mobile health clinics, and a free-standing dental center. The hospital district operates 975 licensed hospital beds and provides more than 1 million outpatient visits each year.

Each hospital and community health center has a dedicated pharmacy that provides comprehensive and cost-effective pharmaceutical care to residents of Harris County.³ With a pharmacy budget of more than \$75 mil-

Dr Henry is Manager; Dr Okpara is Director; Dr Erowele, Dr Anassi, Dr Green, and Dr Alvidrez are Clinical Pharmacist III, Formulary Management & Pharmacoeconomics Service; Dr Milton-Brown is Formulary Command Center Clinical Pharmacist; all at the Department of Pharmacy, Harris County Hospital District, Houston, TX; Dr Anadu Ndefo is Assistant Professor, Department of Pharmacy Practice, College of Pharmacy and Health Sciences, Texas Southern University, and Drug Information Specialist, Harris County Hospital District. The views expressed in this article reflect those of the authors and do not necessarily reflect the views of Harris County Hospital District.

lion in fiscal year 2010 (March 1, 2009, through February 28, 2010), the department served more than 40,000 inpatients and filled more than 2.6 million prescriptions throughout the year.

Ben Taub General Hospital (BTGH) is the district's largest hospital. It houses a Level I trauma center and serves as a teaching hospital for Baylor College of Medicine. Lyndon B. Johnson General Hospital is the area's second busiest emergency center (second to BTGH) and serves as the teaching hospital for the University of Texas Medical School at Houston. Quentin Mease is a 49-bed geriatric and physical rehabilitation facility that is staffed by faculty and residents of Baylor College of Medicine.

Formulary Decision Process

The medications on the formulary at HCHD are selected based on need, safety, and cost-effectiveness.⁴ The formulary is managed by a Pharmacy & Therapeutics (P&T) Committee that consists of physicians, pharmacists, dietitians, nurses, and administrators. The P&T Committee encompasses 5 therapeutic subcommittees, including general medicine, oncology, infectious disease, cardiovascular, and central nervous system, facilitated by the clinical pharmacy specialists on the Formulary Management and Pharmacoeconomics Service (FMPS). The latter consists of 1 formulary manager, 4 clinical pharmacy specialists, 1 formulary command center pharmacist, and 0.8 full-time equivalent of a drug information specialist.

The P&T Committee meets monthly for 10 months of the year, breaking in August and December. The subcommittees alternate monthly to manage the enormous workload on the committees. A clinical pharmacy specialist from FMPS serves as the facilitator for each subcommittee. The subcommittees consist of stakeholders in each specialty, including physicians and clinical pharmacists. The P&T Committee may decide to admit a drug to the formulary without restriction, not admit, delete, change restriction status, or deny a restriction change.

Addition of Medications to Drug Formulary

Physicians may request for a medication to be added to the formulary by completing a request for formulary addition form, which is readily available on the HCHD intranet. The requester is required to attach clinical trials, practice guidelines, estimated use, alternate comparable agents, or other pertinent information to support the request for the addition of the medication. The requester is also required to disclose any potential conflict of interest. The request is then sent to the appropriate chief of service (eg, the urology chief of service would have to review requests submitted by a urologist). If the

KEY POINTS

- Harris County Hospital District is located in the nation's third most populous county and is a publicly funded hospital system that provides care to low-income local residents using a need-based payment system.
- In 2010, the drug budget for the pharmacy department in this hospital system was more than \$75 million.
- The unique formulary management process at this hospital system is dependent on a complex yet effective formulary design that is overseen by various groups of clinical pharmacists whose goal is to provide comprehensive, safe, and cost-effective prescribed medications for its indigent patient population.
- This article outlines the elaborate and carefully designed pharmacy structure that enables this complex system to function in an efficient and effective way to ensure the safe and cost-effective drug utilization in this large disproportionate share hospital.
- The pharmacy system described in the article can serve as a model for pharmacy departments within similar care settings with disproportionate share hospitals or with a significant indigent patient population.

chief of service approves the request, it is then forwarded to the FMPS.

The facilitator for the appropriate subcommittee then completes a comprehensive drug monograph and forwards it to the subcommittee members for review. This drug monograph consists of efficacy data, safety data, estimated use, alternate agents, and cost analysis. The monograph also takes into account systemwide expenses, such as administration costs, nursing time, and other expenses that may be incurred as a result of adding or not adding the medication to the formulary. Cost considerations are always secondary to safety and efficacy. In addition to the drug monograph, a drug class review may be performed by an FMPS clinical pharmacy specialist. This review is utilized to inform the P&T Committee members about the choices available within a given therapeutic class.

The review of the addition request is then presented at a subcommittee meeting, where the requesting physician may appear to present reasons for the request. The subcommittee will review all materials presented and make a recommendation to the P&T Committee. The recommendations can range from "addition to the formulary," "addition with restrictions," "remain nonformulary," or "addition to the 'do not dispense' list."

The P&T Committee reviews the information pre-

sented by the subcommittee and makes a recommendation to the medical board, which consists of chiefs of staff, chiefs of individual services, and hospital administrators. The medical board reviews the information presented by the P&T Committee members and approves, denies, or modifies their recommendations.

Cost-savings associated with this process are calculated based on cost-avoidance of medications that are not added to the formulary and medications that are deleted from the formulary.

Upon the addition of a new medication to the formulary, a retrospective review that includes assessment of prescribing patterns, utilization, adverse effects, dosing errors, and cost-effectiveness must be conducted by the clinical pharmacy specialist facilitator at 3, 6, or 12 months after the addition of the drug. The FMPS continues to track, trend, and report information regarding cost, utilization, and adverse effects to the P&T Committee and to the medical board. The results of this review are used for additional educational campaigns, updates to the clinical decision-support system, and/or reevaluation of formulary status.

In 2009, 66 medications were reviewed by the P&T Committee, of which 21 were admitted to the formulary without restrictions, 9 were admitted with restrictions, 11 were not admitted, and 10 were removed from the formulary. Changes were made to restriction status on 14 drugs, and 1 restriction change was denied.

The effectiveness of the HCHD formulary system can be gauged when compared with drug utilization patterns nationwide. According to DrugTopics.com, atorvastatin (Lipitor), esomeprazole (Nexium), and clopidogrel (Plavix) were the top 3 branded medications dispensed in 2009.⁵ In that same timeframe at HCHD outpatient clinics, atorvastatin, which has restrictions, ranked 98; esomeprazole, which also has restrictions, ranked 104; and clopidogrel, which was restricted until 2007, ranked 27.

Nonformulary Process

The Joint Commission requires that hospitals have a process by which medications can be retrieved off formulary. Medications that are not added to the formulary after the process described above, or those that have not been reviewed, require the completion of a nonformulary form to be dispensed to a specific patient. Medications that are newly approved by the US Food and Drug Administration (FDA) can also be dispensed, pending completion of a nonformulary form.

The process begins when the pharmacist receives a request for a nonformulary medication for a patient, which usually comes from a physician and has been cosigned by the chief of service or the chief of the department. The nonformulary form includes the

patient's information; the drug requested with dose, frequency, and route; the anticipated duration of therapy; and detailed justification for the request. Nonformulary drugs are not stocked in the pharmacy; therefore, it may take up to 72 hours before therapy can be initiated.

The nonformulary request is then submitted to the pharmacy supervisor. Upon receipt of the request, the pharmacy supervisor reviews it and then recommends available formulary alternatives. In the event that formulary alternatives are not accepted, the supervisor is also permitted to approve nonformulary medications that have a low-cost impact and are within the scope of services in our institution.

HCHD does not offer therapy for infertility, transplants, sexual dysfunction, or cosmetic purposes, involving medications such as clomiphene (Clomid, Serophene) for ovulation, sildenafil (Viagra) for erectile dysfunction, or onabotulinumtoxinA (Botox) for wrinkles. Because HCHD does not provide transplant services, it does not offer transplant rejection medications on an outpatient basis as a part of its formulary; however, HCHD does continue transplant rejection medications when a transplant patient is admitted to the hospital.

If the supervisor cannot approve the nonformulary agent, it is referred to the clinical pharmacy specialist on call. The clinical pharmacy specialist on-call pager is held by the pharmacy resident, and a clinical pharmacy specialist is the pharmacy resident's backup. In the event that the clinical pharmacy specialist cannot approve the request, and the prescribing physician does not accept an alternative, the request is forwarded to the formulary command center (FCC) clinical physician on call, who is either the liaison to the chairperson of the P&T Committee or his/her designee. The approval or denial of the request is then relayed to the pharmacy and is documented in a shared pharmacy database. The approvals are indefinite, unless otherwise specified. Requests for medications that are outside of our scope of service are referred to case workers.

Formulary Restriction Programs

Formulary Command Center, Prior Authorization Program

In an effort to control costs and encourage cost-effective prescribing, HCHD implemented a prior authorization (PA) restriction program modeled after those used in the managed care environment. The program is designed to promote a tier structure to guide medication prescribing practices. Drugs are selected for this program because of high acquisition cost, safety concerns, or the potential for misuse or abuse. At the time of the program's inception in 1998, fewer than 10 agents were included, with a volume of 2700 calls annually.

The criteria established for each medication are developed by subcommittees using evidence-based medicine, and are approved by the P&T Committee and the medical board. Currently, 76 agents are under the program, which is managed by 1 clinical pharmacist. Approximately 13% of the drugs in the program are for cardiovascular conditions, 12% are central nervous system agents, and 7% are for diabetes. The remainder of the list is comprised of a wide range of therapeutic areas. The volume has increased to more than 10,000 calls annually, with the top requests for losartan (Cozaar), pioglitazone (Actos), and insulin glargine (Lantus).

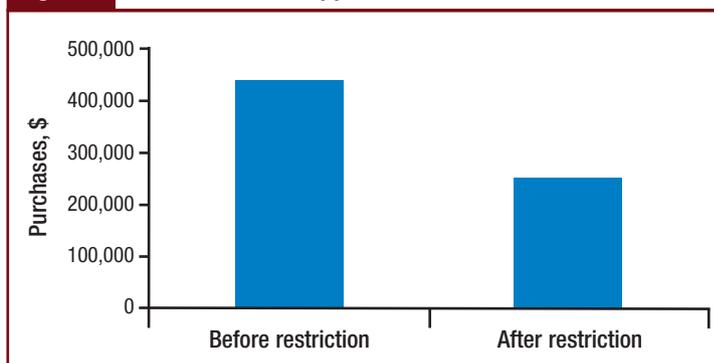
During normal business hours, the FCC clinical pharmacist answers a central phone line to approve or deny restricted medication requests according to preset criteria approved by the P&T Committee. If the criteria are not met, the pharmacist recommends an alternative formulary agent. If the alternative is not accepted by the prescribing physician, the caller is referred to the physician on call. A physician is on call 24 hours a day, 7 days a week, including holidays, to respond to denials and after-hours requests.

If an approval is granted, the FCC clinical pharmacist enters the approval in the notes or comments section of the patient's inpatient and/or outpatient profiles. Denials are documented in the FCC database. The pharmacist receiving approvals after hours, or on holidays or weekends, enters the approval in the same manner as the FCC pharmacist. Unless otherwise specified in the restriction criteria, approvals are valid indefinitely. The physician on call providing after-hours approvals sends the approval list to the FCC for record keeping.

Physician compliance with this program is measured by periodic medication use evaluations for agents that are identified as our top expenditures despite being a part of the restriction program. The medication use evaluations are also developed to strengthen the present criteria for certain agents and to evaluate the need for medications from the program. New agents added to the restriction program are also monitored through medication use evaluations. For example, physician compliance rate with the PA criteria for the leukotriene inhibitor and the tyrosine kinase inhibitor was 87% and 81%, respectively. Issues with compliance with prescribing guidelines can be identified and reported to our P&T Committee for further actions and/or recommendations.

Pharmacist compliance is reviewed quarterly by requesting a report from the information technology (IT) department on all new FCC prescriptions dispensed during that period, and verifying whether an approval is noted in the patient's profile. Pharmacy areas with low compliance can be identified, and corrective measures

Figure 1 Oral Nutritional Supplement Purchases



are implemented.

Medications that were previously on the formulary and later added to the FCC are reviewed after 6 months for changes in utilization, and a noticeable change in prescribing patterns is usually evident. For example, HCHD's purchases for oral nutritional supplements decreased significantly after their addition to our PA program, from \$440,000 to \$250,000 after only 6 months in the program (**Figure 1**). This information is used to calculate the cost-savings associated with the FCC. The cost-avoidance for agents added directly to the FCC, however, has been more difficult to ascertain, because the FCC serves as a deterrent to the prescribing of the restricted drugs.

Service Line Restrictions Program

Medications on the service line restrictions program are restricted according to a medical specialty or a particular quantity. Drugs are placed on this list to ensure proper use by the appropriate clinical specialist. These restrictions are upheld by the dispensing pharmacist.

When the pharmacist receives a medication order, the order is assessed for restrictions and is dispensed accordingly. If the prescription is not written by the appropriate service or physician, the pharmacist contacts the prescriber, who has the option of requesting an override from the FCC physician on call. Currently, 50 drugs are on this list; 12% of them are restricted to oncology, 8% are restricted to either rheumatology or hematology, and 6% each, to pediatrics, neonates, and renal services. These medications are reviewed before and after restriction to assess whether utilization, and therefore cost, has increased or decreased.

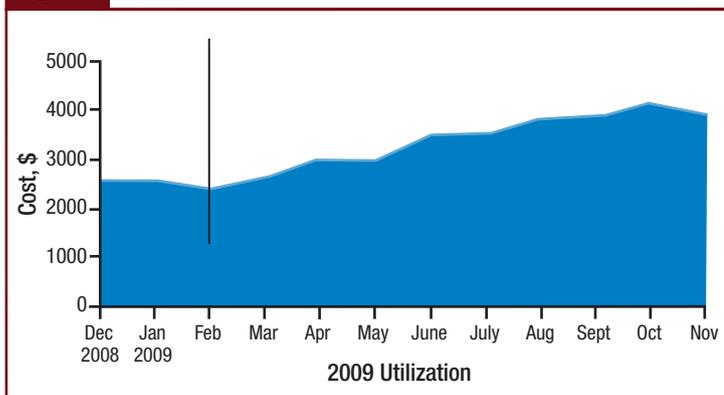
For example, hydrocodone tablets were on the service line restrictions program, requiring a signature from an attending physician for use. When the restriction was removed, the use of this medication doubled over time, indicating that the restriction had been working before the change (**Figure 2**).

Table 1 Selected Examples of Antimicrobial Approval Program

Restriction programs	Drug list
Infectious disease faculty approval required before dispensing	Ampicillin/sulbactam, piperacillin/tazobactam, ertapenem, doripenem, meropenem, daptomycin, linezolid, tigecycline, voriconazole, micafungin, abelcet, ambisome
Length of therapy for empiric use	Vancomycin, azithromycin, ciprofloxacin, moxifloxacin, levofloxacin
Infectious disease faculty approval required for high doses	Ceftriaxone and cefepime
Restricted to a service or an indication	Cefotaxime (pediatrics), azithromycin 600 mg (MAC prophylaxis)

MAC indicates *Mycobacterium avium* complex.

Figure 2 Hydrocodone/Acetaminophen Utilization in 2009



Therapeutic Substitutions/Interchanges Program

The Texas State Board of Pharmacy (TSBP) allows a pharmacy to interchange prescribed drugs as long as there is P&T Committee oversight and a formulary is established with a method for prescribers to override the interchange. The TSBP also requires that the pharmacist-in-charge or designee be a voting member of the committee.⁶ In the outpatient setting, physician approval is required for all therapeutic interchanges. The physician signs a waiver through the physician services orientation, authorizing pharmacy to interchange a list of medications according to the P&T Committee protocols. Signature cards are maintained in a database for pharmacy to access and verify authorizations. In the inpatient setting, the physician is notified by the pharmacist when a conversion has taken

place, and the conversion is noted in the patient’s profile and in the medical chart.

To accommodate this law, an automatic substitution waiver is signed by all physicians before substituting prescriptions written by them. Currently, 23 drugs are on the automatic substitution list. The list includes many classes, such as angiotensin II receptor blockers, calcium channel blocker and statin combinations, sulfonylureas, insulin analogs, and serotonin reuptake inhibitors. In 2009, 8 therapeutic interchanges and generic switches were authorized by the P&T Committee, with an approximate cost-avoidance of \$3.2 million.

The automatic substitution waiver includes all medications that have been approved by the P&T Committee for direct therapeutic conversions, which are listed according to their therapeutic class. The waiver includes TSBP mandates, as well as a note to inform the pharmacist that if the dose falls outside of any of the guidelines, the prescribing physician must be contacted for proper dosing conversion. The physician must sign and date the form, and the pharmacy maintains a file of these forms.

Antimicrobial Approval Program

Systematic approaches have been implemented in many institutions as a means of reducing inappropriate use of antibiotics and achieving optimal outcomes.⁷ The purpose of this program is to reduce cost, decrease resistance, and minimize adverse events.^{8,9} Selected antimicrobials require infectious disease faculty approval before dispensing, to decrease antimicrobial expenditures and improve susceptibilities without compromising patient outcomes or length of stay.^{10,11} The P&T Committee approves which antimicrobials should require infectious disease approval, by considering evidence-based data presented by the antimicrobial subcommittee. The subcommittee bases its decisions on medication cost, resistance, and/or adverse effects and reviews the list periodically to add or remove agents.

The program has evolved over time to include different layers of restriction, including restricting length of therapy for empiric use and restricting to a service or an indication (Table 1). The FMPS clinical pharmacist for the antimicrobial subcommittee is responsible for monitoring drugs on the antimicrobial restrictions list and evaluating use through medication use evaluations, monthly purchase variances, and prescribing pattern changes on monthly utilization reports.

Restriction Compliance Assessment Medication Utilization Evaluations

Medication utilization evaluations are continuously performed by the FMPS. The need for these evaluations

are generally identified by the addition of a new drug to the formulary, an increase in spending on a particular drug, inappropriate use, adverse effects, or a change in the formulary status of a drug. These needs are typically identified by the subcommittee assigned to the drug or by the facilitator or the clinical pharmacy specialist of the subcommittee.

To perform a medication utilization evaluation, an abstract containing the background, methods, and end points, along with a data collection form, are prepared by the clinical pharmacy specialist. These are then reviewed by the subcommittee, which can give input for revision. This information is then presented to the Medication Use Safety subcommittee, which can also provide input for revisions. Once the information has been presented to and approved by both subcommittees, the data collection begins from an IT report that lists patients who received the drug for a specific time period. The data are generally collected from inpatient paper charts and from electronic medical records for outpatient visits.

The data are then analyzed and summarized by the clinical pharmacy specialist, and the results are presented to the subcommittee. The subcommittee reviews the results of the medication utilization evaluation and makes recommendations, which can consist of changing the formulary status of a drug, adding an alert in computerized systems, education information for providers and/or pharmacists, or not making any changes at all. These recommendations are presented to the P&T Committee along with the results of the medication utilization evaluations.

For example, a recent medication utilization evaluation was completed for intravenous (IV) proton pump inhibitors (PPIs). Service line restriction criteria stated that patients must be admitted to the intensive care unit or to the emergency department with a gastrointestinal bleed to be prescribed IV PPIs. Such patients needed to receive a bolus dose followed by a maintenance infusion for less than 72 hours. The FMPS evaluated the adherence level to the medication utilization criteria and discovered that these criteria were met comprehensively only 8.7% of the time.¹²

Other Cost-Saving Processes

Brand and Generic Substitutions

Monitoring medication patent expirations can help to mitigate increasing drug costs by allowing the interchange of branded drugs to generic or nonproprietary formulations. Various online resources are dedicated to monitoring generic drug approvals, and the FDA publishes monthly reports on generic drug approvals.

Although generic drugs typically provide cost-effective alternatives, there is a caveat. As generics enter the

Table 2 Selected Cost-Saving Initiatives, Fiscal Year 2010

Therapeutic alternative conversions	Savings, \$
Alavert to loratadine	86,918
Alendronate-D to alendronate	103,694
All proton pump inhibitors to omeprazole	384,186
Factor VIII drugs (brand to brand)	11,912
Factor IX drugs (brand to brand)	32,698
Flutamide to bicalutamide	17,000
Fluticasone HFA to mometasone	93,787
Fluticasone/salmeterol to budesonide/formoterol	288,000
Zolmitriptan to rizatriptan	57,937
Zolmitriptan to sumatriptan	165,164
Protocols	
Erythropoiesis-stimulating agents	953,755
Factor VII	12,000
Immune globulin	165,000
Pharmaceutical bids	
Contrast media	226,000
Esomeprazole	1,810,157
Ezetimibe/simvastatin	332,682
Brand-to-generic conversions	
Arimidex to anastrozole	413,613
Casodex to bicalutamide	15,000
Temovate E to clobetasol	27,252
Depakote ER to divalproex ER	45,456
Proscar to finasteride	137,455
Camptosar to irinotecan	12,000
Lamictal to lamotrigine	194,180
CellCept to mycophenolate	196,852
Zofran to ondansetron	20,304
Rebetol to ribavirin	124,914
Generic-to-generic conversions	
Clindamycin	29,000
Enalapril	38,980
Lisinopril/hydrochlorothiazide	22,264
Education programs	
Neupogen/Neulasta	353,849
Total	6,372,009

NOTE: This list does not include any initiatives with a cost-savings of <\$10,000.
ER indicates extended release; HFA, hydrofluoroalkane.

Table 3 Key Factors to Consider in Pharmaceutical Bids

Brand-to-generic conversions
Cost of the drug
Dispensing data
Inpatient utilization
Market share analysis
Outpatient utilization
Patient assistance programs
Product availability
Purchase history

market, branded drugs may decrease in cost to compete for market share, making the branded product more cost-effective than the newly approved generic agent.

The clinical pharmacist assigned to the relevant subcommittee tracks the pricing of medications in that subcommittee and works with the inventory team to provide the most cost-effective option. Premier is the group purchasing organization that works to negotiate lower-cost contracts for pharmaceuticals for HCHD. Premier provides a program that monitors brand-to-generic switches and automatically switches products when the generic becomes available. Premier's program, however, only applies to our inpatient formulary and may not always identify the most cost-effective product; therefore, continuous monitoring is always appropriate.

On occasion, generic-to-generic conversions occur as a result of less-expensive generics becoming available from different manufacturers and price fluctuations between generics. These pricing opportunities are usually determined by using an inflation/deflation report provided by the wholesaler or by monitoring top-utilized generics on a monthly basis. This report shows the increased or decreased dollar amount and/or the increased or decreased percent for each drug from the previous month. **Table 2** shows examples of switches that occurred in fiscal year 2010.

Annual Outpatient Pharmaceutical Bid Review

The bid review is a comprehensive process that involves extensive data collection. The purpose is to solicit and receive the best possible price for branded medications based on previous utilization and purchase history. This process involves the FMPS' clinical pharmacy specialist preparing therapeutic classes review (ie, a bid list) and conducting a cost analysis for potential cost-savings opportunities with therapeutic alternatives or with therapeutic tiers. The bid list must be evaluated for discontinued products and brand-to-generic conversions.

The previous year's utilization must be gathered and presented to an HCHD purchasing agent for bid posting.

Once bids have been offered by pharmaceutical companies, the bid pricing list must be compiled with current 340B pricing (a federal outpatient drug discount program for disproportionate share hospitals), and Premier drug pricing (inpatient) and utilization for all our drugs (inpatient and outpatient). This information is evaluated by the subcommittees to determine if any changes need to be made based on pricing.

Recommendations are then forwarded to the P&T Committee for approval, and final approval is made by the medical board. The recommendations are compiled and communicated to the staff. The FMPS educates the staff via newsletters, in-service training, department meetings, and through other methods. The FMPS also works with the inventory team to ensure that adequate drug stock is available. When this process is completed, online formulary databases get updated. Key factors to consider when preparing a pharmaceutical bid list and process are listed in **Table 3**.

Budget Forecasting

Budget projections for the upcoming fiscal year can help to identify differences between current formulary alternatives and new drugs. It also helps in predicting the potential financial impact of new drugs on the pharmaceutical budget. We can expect to see a decrease in expenditures when branded medications become generic. In budget projecting, it is prudent to know which drugs have recently been FDA-approved or are pending approval for the upcoming fiscal year, new drug indications, utilization of the formulary alternative(s), anticipated cost of the new drug, and the potential for the new agent to fully or partially replace the formulary alternative(s).

The American Society of Health-System Pharmacists (ASHP) provides an annual update titled "Projecting Future Drug Expenditures" that is a useful reference for detailed information on budget projections (with the 2011 update recently published)¹³; Cardinal Health and Medco offer similar publications.

Cost-Effectiveness

According to an ASHP health policy alert issued on January 26, 2009, clinical pharmacists working in hospitals, ambulatory care clinics, physician offices, or community pharmacies provide a benefit-to-cost ratio of \$4.81:\$1.¹⁴ However, this information is not readily available for formulary management services. The FMPS at HCHD employs 6 full-time pharmacist equivalents whose primary responsibilities are outlined in this article.

Other responsibilities of these pharmacists include drug shortage management, education on new initia-

tives, variance reporting, lectures, precepting pharmacy students, and other scholarly activities. Based on the selected cost-savings presented in Table 2, comparing the wages and benefits (28.5% of wages) for the 6 full-time pharmacist equivalents results in a \$6.38:\$1 benefit-to-cost ratio.

Conclusion

Various avenues, including formulary decision processes, nonformulary processes, restriction programs, stewardship and streamlining programs, medication use evaluations, and pharmaceutical-pricing programs are used by HCHD to manage its drug formulary. These processes are cost-effective and may be beneficial for other pharmacy departments that serve indigent patient populations and are interested in cost-effectiveness strategies to control their drug costs. ■

Author Disclosure Statement

Drs Henry, Erowele, Anadu Ndefo, Milton-Brown, Anassi, Green, Alvidrez, and Okpara reported no conflicts of interest related to the contents of this article.

References

- Harris County Hospital District home page. March 29, 2011. www.hchdonline.com/about/news/2011/us-news-ranking.htm. Accessed June 17, 2010.
- Thompson JA, Lee V. The effect of health insurance disparities on the health care system. *AORN J*. 2007;86:745-756.
- Harris County Hospital District. Department of Pharmacy. www.hchdonline.com/health/pharmacy/main.htm. Accessed June 17, 2010.
- Harris County Hospital District. *Policy and Regulations Manual*. Revised March 2010. On file at HCHD.
- SDI/Verispan, VONA. 2009 top 200 branded drugs by total prescriptions. *Drug Topics*. 2010. <http://drugtopics.modernmedicine.com/drugtopics/data/articlestandard//drugtopics/252010/674969/article.pdf>. Accessed July 28, 2010.
- Texas State Board of Pharmacy. Pharmacy rules and laws. 2002-2004. Title 22; Part 15; Chapter 291; Subchapter D; Section 291.73 b2E. www.tsbp.state.tx.us/rules/. Accessed July 15, 2010.
- Bryan CS. Strategies to improve antibiotic use. *Infect Dis Clin North Am*. 1989;3:723-734.
- Raymond DP, Pelletier SJ, Sawyer RG. Antibiotic utilization strategies to limit antimicrobial resistance. *Semin Respir Crit Care Med*. 2002;23:497-501.
- White AC Jr, Atmar RL, Wilson J, et al. Effects of requiring prior authorization for selected antimicrobials: expenditures, susceptibilities, and clinical outcomes. *Clin Infect Dis*. 1997;25:230-239.
- Anassi EO, Ericsson C, Lal L, et al. Experience briefs: using a pharmaceutical restriction program to control antibiotic use. *Formulary*. 1995;30:711.
- Carling P, Fung T, Killion A, et al. Favorable impact of a multidisciplinary antibiotic management program conducted during 7 years. *Infect Control Hosp Epidemiol*. 2003;24:699-706.
- Ndefo UA, Erowele GI, Batubo DB. Retrospective analysis of esomeprazole use and adherence to established or approved prescribing guidelines in hospitalized patients. Poster presented at the American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting, December 6-10, 2009, Las Vegas, NV.
- Doloresco F, Fominaya C, Schumock GT, et al. Projecting future drug expenditures—2011. *Am J Health Syst Pharm*. 2011;68:e1-e12. www.ajhp.org/site/DrugExpenditures_2011.pdf. Accessed January 11, 2011.
- American Society of Health-System Pharmacists. Clinical pharmacists yield a median five-fold return on investment among 31 studies, review shows. *Health Policy Alerts*. January 26, 2009. www.ashp.org/policy-alert. Accessed January 11, 2011. www.ashp.org/DocLibrary/Advocacy/PolicyAlert/Pharmacist_ROI_Review.pdf.

STAKEHOLDER PERSPECTIVE

A Collaborative Approach to Drug Selection, Driven by Clinical Outcomes Excellence

PAYERS: The formulary selection process is treacherous, convoluted, and involved. Keeping the rational approach in the forefront takes exertion and integrity. All too often other standards—emotional, personal, financial, special interests, pharmaceutical marketing, and unconscious desire of power—take the place of excellence. In the formulary decision-making process, these must all be rejected. The final shared paradigm must be one of quality.

The model for drug decision-making for formulary purposes discussed in the present article by Dr Henry and colleagues is described by the System of Objectified Judgment Analysis (SOJA).¹ The goal is to provide a comprehensive, safe, and cost-effective approach to drug therapy. In the SOJA method, medication selection principles are specified for each therapeutic drug category, based on clinical efficacy, incidence and severity of adverse effects, dosage frequency,

drug interactions, acquisition cost, documentation, pharmacokinetics, and pharmaceutical aspects. Additional significance is given to the development of resistance for antimicrobial agents.

The use of the SOJA method means that drug selection decisions are based solely on rational criteria. The utilization of interactive software creates a transparent, realistic, and specific dashboard.

The example of the Harris County Hospital District discussed in this article illustrates this type of formulary management process, which makes use of process elements to cost-effectively benefit pharmacy departments in institutions and serve an indigent patient population.

When healthcare resources are limited, decisions will have far-reaching consequences with individual magnitudes greater than initially thought.² Decision makers may be unaware of the power exerted by these

Continued

STAKEHOLDER PERSPECTIVE *(Continued)*

multiple factors. Evidence-based medicine applies the use of balanced health outcomes information.

The SOJA method ensures that health outcomes information is given appropriate weight, based on decision-making processes in economics; such an approach is a valuable tool in discussions about drug selection for formularies.² The sequence of the decision matrix is efficacy, safety, tolerance, ease of use, applicability, and cost. Each medication is compared with the theoretical “perfect” agent within a therapeutic classification—to be administered once daily and have optimal clinical benefits and no side effects in 100% of patients. This is the benchmark of excellence.³

PATIENTS: Prescription drug spending in the United States increased at a rate of >10% annually and currently represents 11% of all healthcare expenditures. This imbalance will continue to trend worldwide.⁴

The Harris County Hospital District approach allows drug selection within a therapeutic category across a range of indications, confers clinical effective-

ness primacy over cost, and is suitable for the development of formularies that would stimulate cost-effective prescribing across primary or secondary care.⁴

In this collaborative approach, the team of physicians, nurses, pharmacists, and healthcare professionals are dedicated to the dissemination of evidence-based, noncommercial information to physicians and healthcare providers, with the goal of achieving better prescribing and patient outcomes—a unique form of excellence.

1. Janknegt R, Steenhoek A. The System of Objectified Judgment Analysis (SOJA). A tool in rational drug selection for formulary inclusion. *Drugs*. 1997;53: 550-562.

2. Janknegt R. Using health outcomes data to inform decision-making. *Pharmacoeconomics*. 2001;19(suppl 2):49-52.

3. van den Bemt BJ, van den Hoogen FH, Breedveld FC, et al. InforMatrix: treatment of rheumatoid arthritis using biologicals. *Expert Opin Pharmacother*. 2006;7: 1769-1789.

4. Alabbadi I, Crealey G, Scott M, et al. Impact of Modified System of Objectified Judgement Analysis (SOJA) methodology on prescribing costs of ACE inhibitors. *Clin Drug Investig*. 2006;26:485-494.

Diana Rangaves, PharmD, CEO
Clinical Consultant Services
Santa Rosa, CA