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CHAPTER 45

Hospital pharmacy management

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SUMMARY

Appropriate medicine use in the hospital setting is a multidisciplinary responsibility that includes—

- Selection and formulary management by a multidisciplinary committee
- Prescribing by the physician
- Procurement, storage, medication order review, and preparation and dispensing by the pharmacy department
- Medication administration by nurses or other health care professionals
- Monitoring the effect of medicines on the patient by all members of the health care team

The drug and therapeutics committee (DTC) is responsible for developing policies and procedures to promote rational medicine use. Its functions include—

- Management of the approved medicine list or hospital formulary
- Ongoing drug use review
- Adverse drug event reporting and implementation of safe medication practices

Members of the DTC should include representatives from the medical, pharmacy, and nursing staffs; hospital administrators; and the quality assurance coordinator. Subcommittees are often formed for in-depth analysis of particular issues.

The pharmacy department, under the direction of a qualified pharmacist, is responsible for the procurement, storage, and distribution of medications throughout the hospital. In larger hospitals, satellite pharmacies may bring the pharmacist closer to patient care areas, facilitating interactions between pharmacists and patients. In some settings the pharmacist is used as a resource for medicine information and specialized medication therapy management.

Medications may be distributed in bulk, in courses of therapy, or in unit doses. Unit-dose distribution is optimal for patient care but requires initial capital outlay for repackaging equipment and medication cabinets. Recent technological advances, such as computerized dispensing machines and bar coding, are now available to further promote safe medication practices.

Additional mechanisms for inpatient medicine management include—

- Patient medication profiles, maintained in the pharmacy department
- Medication administration records, maintained by nurses
- Periodic inspection of medicine storage areas
- Procedures for strict control of dangerous drugs and controlled substances
- Responsible disposal of pharmaceutical waste
- Procedures for after-hours pharmacy service

Small-scale pharmaceutical production often is not cost-effective and should be evaluated by the DTC.

The control of narcotics is of particular concern in the hospital setting and requires a systematic approach for the prevention and detection of abuse.

A hospital exists to provide diagnostic and curative services to patients. Pharmaceuticals are an integral part of patient care. Appropriate use of medicines in the hospital is a multidisciplinary responsibility shared by physicians, nurses, pharmacists, administrators, support personnel, and patients. A medical committee, sometimes called the drug and therapeutics committee, pharmacy and therapeutics committee, or the medicine and therapeutics committee, is responsible for approving policies and procedures and monitoring practices to promote safe and effective medicine use. The pharmacy department, under the direction of a qualified pharmacist, should be responsible for controlling the distribution of medicines and promoting their safe use. This task is challenging because medicines are prescribed by physicians, administered by nurses, and stored throughout the hospital.

This chapter covers hospital-specific pharmaceutical management issues, such as pharmacy department organization and alternative pharmaceutical distribution systems. Several functions of the DTC are discussed, with an emphasis on formulary management. Other important issues relevant to hospital pharmaceutical management are treated in Chapter 17 on treatment guidelines and formulary manuals, and Chapters 28 and 29 on investigating medicine use and on promoting rational prescribing, respectively. Chapter 35, “Pharmacovigilance,” discusses adverse drug reaction monitoring and medication error management.

45.1 Responsibilities of hospital staff

The hospital pharmacist should be an expert on medicines who advises on prescribing, administering, and monitoring, as well as a supply manager who ensures that medicines are available through procurement, storage, distribution, inventory control, and quality assurance. The balance between these two roles varies, depending on the individual's background and the work setting. A pharmacist may assume a prominent clinical role in settings where his or her knowledge of clinical pharmacology and capacity to provide expert advice have earned the acceptance of hospital medical and nursing staff.

The responsibility for establishing policies and procedures related to medication selection, procurement, distribution, and use often lies with the DTC. Because the medicine use process is multidisciplinary, the committee should include representation from all functional areas involved: medical staff, nursing, pharmacy, quality assurance, and hospital administration.

Purchasing and stock management

In some hospitals, a separate department manages all hospital purchasing (pharmaceuticals, medical supplies, equipment, and so forth); this department may be called medical stores or materiel management. In such cases, the chief pharmacist prepares an annual budget request for pharmaceutical purchases and places orders for medicines through the medical stores.

In other settings, the pharmacy department manages pharmaceutical purchasing directly. No single individual should have total control of pharmaceutical procurement. A designated committee should review and approve all purchases; either a special purchasing committee or the DTC (see below) may manage this function.

Procedures for procurement and inventory management should be written in a manual that has been approved by hospital administration and the appropriate committees; the procedures for purchasing should follow guidelines provided in Chapters 18 and 23. Stock management procedures are determined by the facility's size and whether a warehouse is attached to the hospital (see Chapters 44 and 46).

Medication use

The medication-use process can be divided into four components—

1. *Prescribing.* The physician has overall responsibility for the care of the patient, prescribing or ordering medications as part of the treatment plan. The mechanisms to ensure appropriate prescribing within the

hospital customarily fall within the purview of the medical staff committees, usually including the DTC. The DTC may establish protocols or procedures that allow pharmacists or nurses to prescribe within specific guidelines.

2. *Preparation and dispensing.* The pharmacy department, under the direction of a registered pharmacist, is responsible for preparing and dispensing medications. Policies and procedures for these functions should be approved by the DTC. The chief pharmacist reports to hospital administration.
3. *Medication administration.* Administering medications is generally the responsibility of the nursing staff. The chief nursing officer oversees all nursing functions. In some cases, physicians may administer medicines such as anesthetic agents. Other health care professionals may administer medicines within the scope of their practice (for example, midwives attending deliveries).
4. *Monitoring the effect of medications on the patient and ordering appropriate changes in therapy.* Monitoring activities are primarily the responsibility of the physician. However, observation and reporting are required from the person who administered the medication (usually the nurse) and from other members of the health care team involved in the patient's therapy. In some settings, a clinical pharmacist or pharmacologist monitors medication therapy in the hospital and consults on medication therapies that require special expertise to ensure safety and efficacy; for example, total parenteral nutrition, anticoagulation, or treatment with aminoglycoside antibiotics.

Government agencies and licensing boards regulate medications through laws and professional practice standards. The laws and regulations usually specify that the chief pharmacist be the person responsible for the control of medications within a hospital, including procurement, storage, and distribution throughout the facility.

Although the chief pharmacist is responsible for the pharmaceutical budget and the control of medications, he or she does not supervise those who prescribe or administer the medications. In addition, in some hospitals, purchasing, receiving, and storing of medications are handled by a medical stores department that is not under the supervision of the pharmacist.

These varying responsibilities illustrate the complexity of pharmaceutical procurement, storage, and use in the hospital. Efforts to improve the system should respect this complexity and include multidisciplinary representation and involvement. Coordination is required at the policy level through the DTC, at the management level (beginning with hospital administration), and through the different branches of the organizational tree.

45.2 Organization of hospital pharmacy services

In organizing hospital pharmacy services, both the way in which the staff is organized and the physical layout of the building must be considered.

Personnel

Hospital pharmacy personnel can be divided into three major categories—

1. *Management.* Management includes the chief pharmacist and sometimes deputy chief pharmacists, who are responsible for procurement, distribution, and control of all pharmaceuticals used within the institution and for management of personnel within the pharmacy department.
2. *Professional staff.* These professionals are qualified pharmacists who procure, distribute, and control medications and supervise support staff for these activities. In some facilities, pharmacists provide clinical consulting services and medicine information.
3. *Support staff.* The support staff category often includes a combination of trained pharmacy technicians, clerical personnel, and messengers.

The smallest hospitals may have only two or three pharmacy staff members, with the chief pharmacist as the only pharmacist. Larger teaching hospitals that provide extensive pharmaceutical distribution and clinical services may have more than 100 staff members.

The cornerstone for a well-functioning medication system is an up-to-date manual of policies and procedures. Staff members should be familiar with the manual and adhere to it.

Physical organization

The extent of the pharmacy's physical facility is determined by the size of the hospital and the services provided. A large pharmacy department might have the following sections within one physical space or in separate locations throughout the hospital—

- Administrative offices
- Bulk storage
- Narcotic or dangerous drug locker
- Manufacturing and repackaging
- Intravenous solution compounding
- Inpatient and outpatient dispensing
- Medicine information resource center
- After-hours pharmacy
- Emergency medicine storage

Inpatient dispensing is sometimes done from satellite pharmacies throughout the hospital. In larger hospitals, satellite pharmacies are beneficial because they enable a shorter turnaround time for individual medication orders, especially in distribution systems that dispense medications packaged for individual patients. Satellites also increase the pharmacist's presence in the patient care area, facilitating interactions with medical staff, nursing staff, and patients, and thus ultimately improving patient care.

With satellite pharmacies, there is reduced need for ward stocks. However, each satellite requires a certain minimum inventory level of pharmaceuticals. A system with multiple satellites most likely has a higher total inventory level than that of a central pharmacy system. The higher inventory and additional personnel costs needed to staff satellite pharmacies may be justified by reductions in pharmaceutical supply costs (because there is less wastage) and improvements in patient care. Whether or not multiple satellite pharmacies serve inpatients, separate pharmacies often serve inpatients and outpatients. Figure 45-1 illustrates how a hospital pharmacy with separate inpatient and outpatient departments is organized in one African country.

45.3 Hospital drug and therapeutics committee

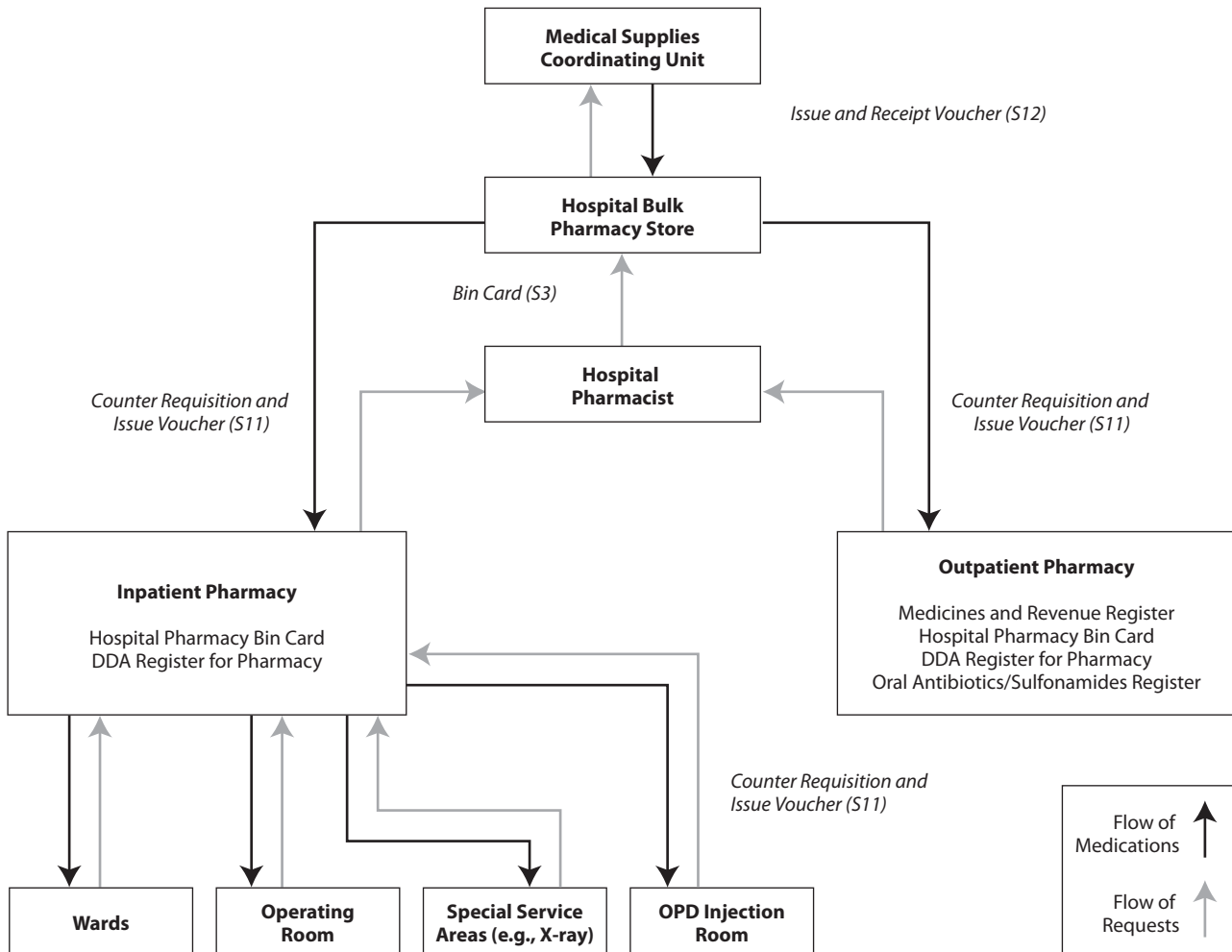
Most commonly, the committee designated to ensure the safe and effective use of medications in the hospital is the DTC. The American Society of Health-System Pharmacists' guidelines on DTCs state that "medication use is an inherently complex and dangerous process that requires constant evaluation. Organizations need to implement tools and processes necessary to meet the goals of using medications effectively and safely" (ASHP 2008).

Purpose and functions

The DTC promotes the rational use of medication through the development of relevant policies and procedures for medication selection, procurement, distribution, and use and through the education of patients and staff. Country Study 45-1 lists the functions of the DTC in an Afghan hospital.

In some hospitals, the DTC becomes overwhelmed with the difficulty of obtaining an adequate supply of medications. Members are caught up in routine decisions about which medicines to buy, how much, and from whom, rather than focusing on long-term planning, policies, and programs for improving the safe and cost-effective use of medications. As discussed, in most settings, daily purchasing decisions can be handled by the chief pharmacist, with supervision by the DTC or another committee responsible for procurement.

Figure 45-1 Multiple-department pharmacy system



Source: Ministry of Health, Government of Kenya, 1994.

DDA = Dangerous Drugs Act.

Note: Forms and registers for wards, operating room, special areas, and outpatient department (OPD) injection room are the same as for the central pharmacy system.

Membership

An effective DTC requires that members participate in meetings and assist with other committee activities. Membership should include representation from—

- Medical staff (including representation from each department)
- Pharmacy (the chief pharmacist often serves as the secretary)
- Nursing
- Hospital administration
- Quality assurance staff

The committee should have broad representation but be sufficiently small and manageable to conduct business effi-

ciently: a membership of eight to fifteen members often fulfills these criteria. The committee may occasionally invite a specialist to make a presentation or provide advice on a particular issue. For example, a cardiologist may attend a committee meeting to advise members regarding a formulary decision on a new cardiac medication. DTCs often have subcommittees to address particular issues, such as antibiotic use, drug use evaluations, or medication errors. Subcommittees can manage specific tasks without consuming a large portion of the DTC's meeting time.

Hospital formulary management

The hospital formulary is the cornerstone of medication management in the hospital, and it should be the principal concern of the DTC. The issues related to medication

Country Study 45-1**Functions of a hospital drug and therapeutics committee in Afghanistan**

Facility-based DTCs will be set up by the steering bodies of the individual health facilities in association with the National Pharmaceutical and Therapeutic Committee.

The DTCs' basic functions include—

- Establishing local policies and procedures on the use of medicines
- Ensuring that the national essential medicines list and local formularies are used appropriately in the facility
- Disseminating national standard treatment guidelines (STGs) and developing local STGs for common diseases and medical conditions
- Conducting medicine use evaluations in the facility
- Conducting facility-based pharmacovigilance activities
- Monitoring medicine use at the health facility

- Providing education to local health care providers on the appropriate use of medicines

The members will be appointed according to their positions and responsibilities within the health facility. The DTC member numbers will be defined based on the health facility level. In the majority of health facilities, the DTCs will include the following members—

- One representative from each specialized medical service of health facility (senior physician)
- One representative from the nursing department
- One representative from the pharmacy department
- One representative from the administration and finance department
- Other members appointed according to their personal expertise (specialists in pharmaceutical information or quality assurance)

Source: Ministry of Public Health, Government of Afghanistan, 2009.

selection for formularies are treated in detail in Chapter 17; the following list provides general guidelines for the hospital setting.

- Limit the formulary list to conserve resources—stocking all medicines on the national formulary is usually not necessary.
- Eliminate generic duplication—only one brand or label of each generic medicine should be routinely stocked.
- Minimize the number of strengths stocked for the same medication; multiples of lower strengths can be used for infrequently needed higher strengths.
- Select medications for the formulary based on diseases and conditions treated at the facility.
- Specify formulary medicines of choice for common therapeutic indications. Medicines of choice should be selected by comparing efficacy, safety, toxicity, pharmacokinetic properties, bioequivalence, and pharmaceutical and therapeutic equivalence. Cost-effectiveness and availability should be primary considerations, evaluating alternatives as described in Chapters 10 and 17. After medicines of choice are selected, they form the basis for standard treatment guidelines and for therapeutic substitution programs (see below).
- Include second-line alternatives to medicines of choice as needed, but minimize therapeutic duplication.

- Ensure that the hospital formulary corresponds with any national or regional standard treatment guidelines that have been formally approved by the health system.

In addition to the basic formulary process, many hospitals add two more features—therapeutic substitution and use restrictions for certain medications in the formulary.

Therapeutic substitution (sometimes called therapeutic interchange) is based on the hospital formulary. The DTC provides guidelines for substituting specific formulary medicines for specific nonformulary medicines (or a specific category of medications), usually for specific disease conditions. Whenever a prescription is written for a nonformulary medicine that is covered by the therapeutic substitution policy, the designated formulary product is automatically substituted by the pharmacy department (or nurse). Note that this substitution is not generic—the two products are chemically different.

The DTC should develop formal written policies specifying which medicines (or categories of medications) are suitable for automatic therapeutic substitution. These programs usually start with relatively noncontroversial medication categories, such as antacids and vitamins, and progress over time to other therapeutic groups, such as antibiotics and certain cardiac medications, as physicians become comfortable with therapeutic exchange. Two main arguments are used to

justify therapeutic substitution programs. One is that such programs ensure that only the most cost-effective products are routinely used, a policy that has obvious benefits in terms of controlling both actual purchase costs and inventory-holding costs (see Chapter 23). In settings where funds are limited, the more limited the list of medications that are routinely stocked, the more likely that all those medications will always be available. The other justification is that the DTC has presumably spent considerable effort selecting medications that offer the best therapeutic value for the conditions covered by therapeutic substitution. An ancillary benefit is that hospital staff will be more familiar with the proper methods for handling, reconstituting, and administering the formulary products.

Therapeutic substitution is often resisted by staff physicians, but almost 90 percent of hospitals in the United States (a stronghold of physician independence) have substitution policies in place (Pederson et al. 2008). Therapeutic substitution is often practiced informally and unintentionally in hospitals where stockouts are common—if the prescribed medicine is out of stock, another must be substituted. Physicians who practice in such settings are likely accustomed to the concept.

Normally, the therapeutic substitution policy allows escape clauses for specific patients. The physician can submit a special form that justifies the use of a specific nonformulary medicine for a specific patient (as discussed below).

Use restrictions are most often applied in larger hospitals where specialist physicians are on staff. Restrictions may apply to certain individual formulary medicines or to certain categories of medicines; the principle is that restricted medicines can be prescribed only by certain specialists or can be used only on certain wards. Such restrictions are generally applied to particularly expensive medications (such as anticlotting medications) or particularly toxic medications (such as cancer chemotherapy); however, some hospitals go further, requiring specialist consultation on many different categories of medications. Restrictions should be carefully considered; they decrease the use of medicines involved (which may or may not be desirable), increase the demand on specialists (and potentially the cost of services), and increase administrative burdens for nurses and pharmacists who must manage the process.

Methods to promote formulary adherence include the following—

- Review and take action on all nonformulary medicine use.
- Prohibit use or distribution of samples of nonformulary products.

- Establish procedures and approved product lists for therapeutic substitution.
- Provide easy access to the formulary list (copies at each medication ordering location and in pocket manuals).
- Involve medical staff in all impending formulary decisions.
- Advertise and promote formulary changes.

Requests to use nonformulary medicines should be monitored by the DTC. If many nonformulary medicine requests come from a particular physician, or if requests are frequent for a particular nonformulary medicine, the committee should take action. Actions may include adding the medicine to the formulary, educating physicians on the rationale for the nonformulary status of the medicine, or banning the medicine from use in the hospital. Country Study 45-2 is an example of a procedure for nonformulary medicine use in a hospital in the United States.

Drug use review

Drug use review (DUR) is a tool to identify such common problems as inappropriate product selection, incorrect dosing, avoidable adverse drug reactions, and errors in medication dispensing and administration. DUR may then be used to implement action plans for change. DUR is an ongoing, planned, systematic process for monitoring, evaluating, and improving medicine use and is an integral part of hospital efforts to ensure quality and cost-effectiveness. More appropriate and more effective use of medicines ultimately results in improved patient care and more efficient use of resources.

Chapter 28 provides an overview of the concepts and approaches for investigating medication use. Chapter 29 contains the specific methodologies for developing a hospital DUR program.

45.4 Inpatient medication management

In general, the issues presented in Chapter 30 for good dispensing practices are relevant to the hospital setting. Patient education and medication counseling are described in Chapter 33 and are also applicable in hospitals. The purchasing and inventory strategies described in Chapter 23 should be applied in the hospital setting.

Medication distribution systems

Medication distribution has long been the primary function of hospital pharmacy services.

Four basic types of medication distribution systems exist—

1. Bulk ward stock replenishment
2. Individual medication order system
3. Unit-dose system
4. Automated medication dispensing

Variations of each exist, and all four systems may be in use in the same facility, depending on the strategy developed. For example, a facility may use the bulk ward stock system for high-volume, low-cost medicines (aspirin, paracetamol, and antacids) that do not require a high level of control for preventing theft or medication errors. Individual medication order systems or unit doses can be used for medicines requiring a higher level of control (see Table 45-1). In addition, automated dispensing systems are now frequently used in developed countries and will become more common in the future.

Bulk ward stock

In a ward stock system, the pharmacy functions as a warehouse and dispenses bulk containers on requisition without reviewing individual patient medication orders for appropriateness. The main advantage is shorter turnaround time between prescribing and administering the medication. The

use of ward stock medications should be minimized, but it is appropriate and desirable for certain situations—

- In emergency departments and operating rooms, medications are usually required immediately after the physician prescribes them. Unless a pharmacy satellite is located in these emergency areas, dispensing medications according to individual patient orders is not possible. Unfortunately, medicines used in these situations are often expensive, and control is always a challenge for the pharmacy department.
- In life-threatening emergency situations, medications need to be kept in patient care areas as a time-saving measure.
- High-volume, low-cost medicines can be dispensed from ward stock if the patient safety risk is low.

Individual medication order system

The individual medication order system closely resembles dispensing to outpatients: a course of therapy is dispensed according to a written prescription for an individual patient. Compared with ward stock distribution, the advantages are that the pharmacist can review the appropriateness of ther-

Country Study 45-2

Procedure for the use of nonformulary medicines in a U.S. hospital

A limited formulary of medicines may not satisfy all individual or unique patient needs. A physician may request use of a nonformulary medicine on a one-time (one course of therapy), one-patient basis.

The physician requesting the nonformulary medicine or the pharmacist receiving the medicine order must fill out the nonformulary medicine request form. The pharmacist receiving the request must inform the physician of alternative medicines that may be used. The pharmacist must also indicate how long it will take before the medicine will be available. The physician and pharmacist should avoid obtaining the medicine by special delivery or borrowing from another hospital if possible.

Nonformulary medicines will be stocked in the nonformulary section of the pharmacy only during the individual patient's course of therapy. The pharmacy will track expenses related to nonformulary medicines and report to the drug and therapeutics committee.

Nonformulary Medicine Request Form (For One-Time/One-Patient Use)

Patient: _____ Room #: _____ Date: _____

Medicine name/strength/dosage form: _____

Current formulary alternatives (suggested by pharmacist): _____

Why is this agent preferable to the formulary alternatives suggested? _____

Was this medicine request prompted by a manufacturer's representative? yes no

Are you requesting permanent addition of the medicine to the medication formulary? yes no

If so, will you be present at the next pharmacy and therapeutics committee meeting to discuss the advantages of this medicine? yes no

If accepted, what formulary medicines do you recommend for deletion? _____

Prescribing doctor: _____

Signature: _____

Table 45-1 Comparison matrix for pharmaceutical distribution system

Factor	Bulk ward stock	Individual medication order	Unit dose	Automated dispensing
Material and supply costs	Low	Medium–low	High	Very high
Pharmacy labor costs	Low	Medium	High	High
Nursing labor costs	Medium–low	Low	Low	Low
Pilferage risk	High	Medium	Low	Very low
Medication error risk	High	Medium–low	Low	Low

apy, a patient-specific medication profile can be maintained, pharmacy charges to patients are facilitated, and closer control of inventory is possible. This system can limit the time intervals for dispensing: for example, an individual supply for three days of therapy is sent initially; if therapy is continued beyond three days, the empty container is returned to the pharmacy to be refilled.

Unit-dose medicine distribution

A preferred system from a patient care perspective is the unit-dose system, which has a lower possibility for error. Medications are dispensed in unit-dose packages (each dose is separately packaged) in separate bins or drawers for each patient. Commonly, a twenty-four-hour supply is provided. Medications returned to the pharmacy can be put back in stock without concern for identity or contamination. This system is efficient but requires a large initial capital outlay for the purchase of repackaging machines and medication cabinets with individual patient drawers. The cost per delivered dose is higher than with bulk packaging, but this increased expense may be offset by reduced wastage and easier detection of leakage. Hospitals in some countries have found innovative ways of adapting local technologies to construct their own fixtures and equipment.

Automated medication dispensing

Technology-based interventions have been investigated as a mechanism to improve medication distribution and reduce medication errors that lead to adverse drug reactions. The use of automated dispensing machines has become commonplace in many hospitals, but cost remains a big deterrent for implementation in resource-limited settings. The mechanism is founded on a computer interface between the hospital pharmacy computer terminals and the dispensing machines at the clinical ward. This system electronically controls and tracks the dispensing of unit doses for each patient based on individual medication profile. The dispensing machines allow medicines to be stored on the ward and to be more conveniently accessed by the clinical staff. (See chapter 11 in AHRQ 2001 for an overview.)

Patient medication profiles

Patient medication profiles are necessary if hospital pharmacists are to monitor inpatient medication therapy. Each profile contains data on the patient's current and recent pharmaceutical therapy, allergies, diagnosis, height, weight, age, and sex. Profiles work best in conjunction with unit-dose medicine distribution or automated dispensing systems but can be used with the individual medication order system.

A pharmacy profile allows the pharmacist to review all the medications that a patient is taking before dispensing the first dose and with each new medication order. Problems with pharmaceutical therapy, such as allergies, duplicate therapy, medicine-medicine interactions, medicine-disease interactions, inappropriate length of therapy, and inappropriate dosing, can be detected and avoided or corrected.

Computerized pharmacy systems display the patient's medication profile on the screen, and the pharmacist edits the screen with each new order. Medication interactions, dosage ranges, and other monitoring functions can be programmed into the computer. In developed countries, information technology advances now provide linkages to patient-specific information from laboratory and clinical monitoring.

Medication treatment record

Also known as the medication administration record (MAR), the medication treatment record helps the nurse schedule treatments for each patient and provides a permanent record of the medications administered. It also allows nurses to review the patient's pharmaceutical regimen and provides a way to compare quantities of medications dispensed from, and returned to, the pharmacy with quantities administered to the patient. Physicians review MARs to verify current therapy and as part of their routine rounds. The trend is toward computerizing MARs; in the United States, over two-thirds of hospital pharmacies surveyed in 2005 used computer-generated or electronic records (Pedersen et al. 2006). Country Study

45-3 describes the procedure for completing a medication treatment record used in Kenya.

Ward and department inspections

The pharmacy department should undertake periodic inspections of medication storage areas throughout the hospital to ensure appropriate levels of properly stored medications, to monitor expiration dates, and to remove unnecessary stock. Figure 45-2 is a sample ward inspection record. When problems are detected in inspections, pharmacy and nursing staff must develop methods to correct the situation.

Dangerous drugs and controlled substances

Controlled substances require greater attention in the hospital setting than other medications, just as they do outside the hospital. The various definitions and categories of controlled drugs all relate to abuse and addiction potential.

Procedures specific to the procurement, reception, storage, dispensing, and administration of controlled drugs should establish a readily retrievable trail of accountability for each individual drug unit. The records should document ordering, receiving, dispensing, administration, and wastage. Perpetual inventory records should be used at all storage sites, and controlled drug stocks should be counted and reconciled against the records daily, with unexplained losses reported to the pharmacy. Controlled substances stored throughout the hospital should be securely double locked within a well-constructed storage area, with the pharmacy department in control of the distribution and duplication of keys.

Methadone maintenance therapy (MMT) programs, which some countries are endorsing as a way to prevent the spread of HIV/AIDS, can significantly impact a hospital's ability to manage controlled drugs. In general terms, hospitals are already familiar with handling largely injectable narcotics, typically in 2 to 5 mL vials, along with other

Country Study 45-3 Kenya medication treatment record

Purpose

Each inpatient has a medication treatment sheet (see opposite) on which all medications prescribed are recorded by the consultant, medical officer, or clinical officer, and on which all medications administered are recorded by the nursing staff. In addition, individual prescriptions are required for Dangerous Drugs Act (DDA) drugs and specific other medicines designated by the hospital drug and therapeutics committee.

Procedure

- At the time of admission, a medication treatment sheet is completed by the clinician with the following information—
 - Patient's complete name (all names must be included to ensure proper identification)
 - Medication allergies
 - Inpatient number
 - Ward and bed number
 - Age and sex
- For easy access during hospitalization, the treatment sheet is kept at the foot or head of the patient's bed with the observation sheet. (Because of this accessibility, the diagnosis should not be written on the treatment sheet.)
- All medication orders must be written on the medication treatment sheet by an authorized prescriber (doctor or clinical officer). The order should include the date and time the order was written; the medication name, strength, dose, route of administration, frequency, and duration; a legible official name; and the signature of the prescriber.
- In addition, for DDA medicines and specific other medicines designated by the hospital drug and therapeutics committee, individual prescriptions are required; entries for DDA medicines must be in red ink.
- When a medication is administered to a patient, the nurse or clinician administering the medicine writes the date and time of administration and signs in the appropriate place on the medication treatment sheet.
- When an ordered medicine cannot be administered for any reason, the nurse writes in the patient's nursing notes the name of the medicine, the date, and time the medicine was to be administered, and the reason that the medicine could not be administered (patient not on ward, unavailability, any other reason).
- The nursing officer should regularly review medication treatment sheets to ensure that they are being used properly on all wards and that all required information is being recorded.

Ministry of Health
Medication Treatment Sheet

Patient _____ Allergies _____
 Inpatient Ward _____ Age _____
 Bed No. _____ Sex _____
 Name of Institution _____

Note: Use RED pen for DDA. Enter your own signature for every medicine given.

TO BE COMPLETED BY CLINICIAN		TO BE COMPLETED BY NURSING STAFF					
DATE	MEDICATIONS	TIME	DATES AND SIGNATURE				
		3 AM					
		9 AM					
		3 PM					
		9 PM					
		3 AM					
		9 AM					
		3 PM					
		9 PM					
		3 AM					
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STAT, PRN, AND PRE-OP MEDICATIONS

TO BE COMPLETED BY CLINICIAN		TO BE COMPLETED BY NURSING STAFF					
DATE	MEDICATIONS	DATES, TIMES, AND SIGNATURE					

Figure 45-2 Sample ward inspection record

Nursing ward: _____	Inspection date: _____
Check each item that complies with standards:	
<input type="checkbox"/>	Medication storage area orderly and clean
<input type="checkbox"/>	Internal use/injectable medications separated from disinfectants and toxic medications
<input type="checkbox"/>	Medications properly secured from theft
<input type="checkbox"/>	No unlabeled or mislabeled medicines present
<input type="checkbox"/>	No unauthorized floor stock
<input type="checkbox"/>	No excessive floor stock quantities
<input type="checkbox"/>	No expired products in stock
<input type="checkbox"/>	Medication refrigerator temperature maintained within limits (see temperature log)
<input type="checkbox"/>	Narcotics properly secured and records complete
<input type="checkbox"/>	Approved emergency medicines in stock
<input type="checkbox"/>	Concentration, date, and time mixed written on reconstituted injectables
<input type="checkbox"/>	Medication formulary list available
Pharmacist's comments on areas of nonadherence to standards:	

Action recommended:	

Pharmacist: _____	
Nurse in charge: _____	

small-volume preparations, but because of the dilute nature of the products used in methadone maintenance therapy for oral administration (typically 1 to 10 mg/mL) and daily treatment regimens (typically 70 mL per day), large physical volumes of products can be required. Even a small MMT program can dramatically increase the need for narcotic product secure storage space and handling of bulk products in facilities that are designed to handle much lower volumes (see Country Study 45-4). Methadone programs can also force the facilities' pharmacy service departments to take on unwanted small-scale production responsibilities.

After-hours pharmacy

Although the need for medications is continuous, many hospitals cannot justify staffing a pharmacy department twenty-four hours a day. If medications must be obtained while the pharmacy is closed, either an on-call pharmacist

can come in or a nursing supervisor can dispense medications. Medication dispensing by nonpharmacists should be limited, however, to preserve the system of checks and balances and to prevent medication errors. To minimize the risk of incorrect dispensing, the following measures can be taken—

- Establish procedures for after-hours pharmacy service.
- Require training or in-house certification of nurses before they undertake dispensing responsibility.
- Prohibit after-hours access to most of the pharmacy. A limited formulary of prepackaged and labeled medicines can be provided in a separate, locked night cabinet.
- Require completion of dispensing records by the nurse and subsequent review by the pharmacist.

45.5 Small-scale hospital pharmaceutical production

The several types of pharmaceutical production that exist have varying levels of complexity (see Chapter 7). The type of small-scale production of pharmaceuticals in a hospital pharmacy could include secondary production from existing raw materials that are usually imported and the packaging or repackaging of finished goods into smaller dispensing packs and course-of-therapy (COT) packages (tertiary production). Small-scale production can be further divided into nonsterile and sterile production or compounding. Most hospitals repackage medications in smaller unit-dose containers and may compound specialty items such as creams with special formulations; however, hospitals should evaluate the feasibility of producing any pharmaceutical products based on the availability of qualified staff, adequate facilities, sufficient equipment, and all the other necessary resources (see Country Study 45-5).

The following sections examine some of the management issues for each type of production, in order of increasing complexity.

Repackaging and course-of-therapy packaging

Repackaging and COT packaging are relatively simple forms of local pharmaceutical production. They require the ability to provide adequate packaging, labeling, and control of the final product.

Repackaging is usually considered when the product can be purchased in bulk quantities at a favorable price and then repackaged locally, where labor costs are lower, and when local-language labeling may be important. In addition to the cost savings, a more convenient package size can be made available to small health centers and individuals, as Table 45-2 illustrates.

Country Study 45-4 Scaling up methadone maintenance therapy in Vietnam

In an attempt to curtail the spread of HIV among injecting drug users in Vietnam, the government piloted the country's first community-based methadone program in seven clinics in Hai Phong, Ho Chi Minh City, and Ha Noi City in 2008. HIV prevalence is higher in injecting drug users (30 percent) than any other subpopulation in Vietnam. By 2010, about 1,800 clients had received free MMT along with basic health care services and HIV care and treatment, including antiretroviral therapy.

In planning for the program, the national Pharmacy and Therapeutics Committee chose a base of 10 mg/mL of methadone solution for the therapy. This decision made it necessary to transport large volumes of narcotics around the country—typically 2.5 liters per patient year—and to squeeze large, secure storage cabinets into already overcrowded hospital pharmacies. Then the pharmacies had to dilute the solution to 1 mg/mL to dispense to patients, a procedure which, because of the regulations on handling narcotics, is fairly onerous.

This system of providing methadone therapy product can be contrasted to the United Kingdom's methadone main-

tenance program, which distributes 1 g vials of methadone powder to dispensing sites, for a total of only 2.5 g vials per patient year. These 1 g powder vials fit more easily into existing narcotics storage cabinets, and a single vial is simply dissolved into commercially available 1 liter bottles of simple syrup at the dispensing site to produce the appropriate 1 mg/mL dose to dispense to patients.

As a result of positive pilot program results, the Ministry of Health in Vietnam plans to expand methadone maintenance therapy to cover 80,000 clients in thirty provinces. This will require moving 204,000 liters of narcotic product per year and assuring the capacity for its secure storage.

While many factors go into choosing the most appropriate preparations to use, physical storage and distribution sizes should not be neglected. The Pharmacy and Therapeutics Committee may need to reconsider its choice of methadone formulation in order to facilitate large-scale program expansion.

Sources: *Thanh Nien News* 2010; Family Health International 2010.

Many types of glass and plastic are used, with the choice often depending on what is being packaged. For instance, acids, solvents, and corrosive materials must be packaged in glass, with lids that can be firmly closed. Fortunately, the majority of simple liquids, solids, and tablets can be packaged in rigid plastic bottles or resealable polyethylene bags of various sizes and thicknesses, usually with a write-on panel for labeling or handwritten instructions to the patient.

Nonsterile production

Nonsterile production of topical ointments and oral or topical liquids is more difficult and complex than repackaging but less demanding than sterile production. If the facility plans to carry out only nonsterile production, resource requirements can be simplified. However, standard written instructions for batch preparation and packaging must be followed, and quality control must be closely monitored for each aspect of the process.

Every product requires a well-designed production control worksheet (also called a batch documentation sheet). It clearly specifies the production formula (the detailed recipe that the pharmacist must follow precisely) and the instructions for preparation. It includes spaces to verify

packaging, labeling, and other control procedures. Figure 45-3 shows a sample pharmacy production and control worksheet.

The chief pharmacist of the facility is usually responsible for developing the master production formulas and instructions, as well as for training production staff. The staff should always work from copies of the master production and control worksheet, with a unique control number pre-assigned by the pharmacist in charge. Any changes to that formula, such as scaling down quantities to make a smaller batch, should be made only by a qualified pharmacist.

A pharmacy preparation, no matter how simple, should never be made from memory. The working copy of the pharmacy production control worksheet should be readily available or posted in the production area for easy reference and initialing of each production step and control procedure.

Sterile production

Sterile production is the most demanding type, and it must be carried out in strict compliance with current good manufacturing practices (GMPs). Depending on need and capacity, sterile products that can be manufactured include eyedrops, small-volume injections, and large-volume injections (or parenteral products).

Country Study 45-5**Assessing the feasibility of small-scale pharmaceutical production in the Catholic Diocesan Hospital Pharmacies of Ghana**

The Diocesan Hospital Pharmacies (DHPs) were originally established in 1976 to provide pharmaceuticals and medical supplies to National Catholic Health Service facilities in Ghana. The DHP produced their own products such as infusions, injections, ointments, and drops to supply their clients more economically. Beginning in 1976, however, both the economy and the pharmaceutical market in Ghana expanded, and many competing pharmaceutical products became available from local and international sources. Furthermore, little additional funding was available to make capital improvements, which limited the DHPs' ability to accommodate increasing demands for improved quality assurance. In 2004, an assessment investigated the utility of the DHP to continue small-scale pharmaceutical production for thirty-three hospitals and sixty-six clinics in the context of the changing pharmaceutical market.

The assessment concluded that the DHPs—

- Should stop producing terminally sterilized products, for example, intravenous solutions, due to the high capital, personnel, and production costs, in addition to the associated risk to patients if the

requirements for sterile operations are not adequately met.

- Could continue to produce non-terminally sterile products, such as ophthalmic items, as long as they made several facility upgrades.
- Have a role in the compounding of non-sterile products, such as oral syrups, for their clients. The assessment recommended several production modifications to assure uniformity and efficiency.
- Should develop pharmacovigilance systems to identify and report adverse drug reactions and medicine product quality problems.

Overall, the assessment recommended that the DHPs focus their production on non-sterile products for which there was an increasing demand. Moreover, they should stop the production of other products that require more technical expertise and oversight due to quality and safety concerns. To ensure the supply of these sensitive products, the DHPs could consider developing a partnership with a local manufacturer or buy from international sources.

Source: RPM Plus 2004.

From a production process perspective, intravenous (IV) fluids are among the easiest products to make. The standard pharmacy production and control worksheet, including the sterility quality-control aspects, is used (see Figure 45-3). From a technical perspective, however, the production of IV fluids is very demanding on resources and personnel. Special (often quite expensive) equipment, facilities, techniques, and quality-control procedures need to be in place, along with the means to ensure continuous production with adequate reserves of ingredients and supplies, regular maintenance of equipment, and refresher training for production staff. The demands on supervisory personnel, who must ensure the high quality of the final product, are also much greater. Contaminated or incorrectly prepared IV fluids administered to very sick people can just as easily kill patients as help them.

Medications produced by the pharmacy must have adequate process and finished-product controls to ensure identity, strength, purity, and quality. A hospital pharmacy may have difficulty achieving the same cost efficiencies as a pharmaceutical manufacturer specializing in a particular product line. The DTC needs to evaluate the costs and benefits of producing such special preparations as compared to

purchasing commercial products. Chapter 7 includes more details on assessing the feasibility of small-scale pharmaceutical production.

45.6 Pharmaceutical disposal

Hospitals and other health care facilities generate all sorts of hazardous waste, from sharps to materials contaminated with bodily fluids to expired or damaged pharmaceuticals. Improper disposal of pharmaceuticals can result in contaminated water supplies, the resale of poor-quality medicines, and polluted air from improper incineration.

Often, hospitals can return products to the facility from where they were obtained. However, when that option is not available, a disposal plan should be in place and should be regularly monitored. Depending on the properties of the pharmaceutical waste, incineration, land disposal, and inertization (where the product is mixed with cement) can all be appropriate methods for disposal. Special care must be taken with certain classes of pharmaceuticals, such as narcotics, or toxic drugs, like anticancer medicines. Before a disposal technique is instituted, any government laws and

Table 45-2 Pharmaceutical repackaging

Product type	Name of product	Bulk package size	Repackaged size
Liquids	Denatured alcohol	20 L	500 mL
Solids	Talcum powder	50 kg	1 kg
Tablets	Aspirin 300 mg	1,000	100
	Aspirin 300 mg	1,000	12
	Co-trimoxazole 480 mg	1,000	10 (bid for 5 days)
	Mebendazole 100 mg	1,000	6 (bid for 3 days)

regulations relevant to health care waste management and environmental protection should be reviewed.

45.7 Controlling leakage and drug abuse

Chapter 43 discusses systematic approaches for detecting, analyzing, and preventing pharmaceutical losses caused by theft, bribery, and fraud. Those approaches are applicable to hospitals and other health facilities.

The control of narcotics is of particular concern in a hospital because it may be the only type of institution regularly stocking, dispensing, and administering them. Drug addiction among physicians, pharmacists, and nurses is quite common. To avoid drug abuse and prevent leakage—

- Be alert to changes in performance, injuries, and mood swings in workers.
- Ensure double-witness and double-signature procedures for wastage of narcotics.
- Limit access to narcotic storage areas.
- Check patient charts and medication administration records for patterns of consumption; be suspicious if patients receive noticeably more narcotics during a particular shift.
- Ask patients if they received the medications.
- Use locked boxes or wire cages to ensure security for medications moved from the pharmacy to the wards.
- Issue individual narcotic boxes to each anesthesiologist daily, and make sure that the box is returned to the pharmacy at the end of the day with a written record of quantities used for each patient.
- Count narcotic stocks daily and reconcile with inventory records.

The same procedures followed for narcotics are sometimes used for antibiotics and other medicines that are easily resold and commonly lost to theft, such as antiretrovirals to treat HIV/AIDS. ■

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★ = Key readings.

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ASSESSMENT GUIDE

Organization

- Which department and individuals are responsible for ordering medicines and managing inventory?
- What systems are used to manage inventory and procure pharmaceuticals?
- Apart from the central pharmacy, are there satellite pharmacies? If so, how many?
- How are medicines distributed to wards?
- Does a hospital formulary exist? If so, how many items are listed? When was it last updated?
- Is there an after-hours pharmacy? How is it managed?
- Does a pharmacy and therapeutics committee exist? If yes, how many meetings were held in the past year? What percentage of members attended? What issues were discussed?

Staffing

- How many pharmacy staff members—professional and support—are employed?
- What is the educational level of professional staff?
- What refresher training or continuing education have the professional pharmacy staff members received in the past two years?
- How do the professional pharmacy staff members spend their workdays—divided among clinical advice, preparation and dispensing, ward supervision, and administration?

Operation

- How many patients were admitted last year?
- What is the average number of prescriptions per day dispensed by pharmacies to inpatients? To outpatients?

- Among outpatients, what is the average dispensing communication time? What percentage of medicines dispensed are adequately labeled? What is the level of patient understanding?
- How often are ward storage areas inspected?
- Are the medication records accurately filled in?
- How many items are stocked in the central unit, satellite units, and ward stocks?
- How much does the hospital spend annually on pharmaceuticals?
- Does the hospital have procedures in place to dispose of expired or damaged pharmaceutical products?

Other pharmacy responsibilities

- Are preparations manufactured in the hospital? If so, how many? What quality-control measures exist?
- Is there a need for COT or special packaging for facility use? Are sufficient equipment, supplies, and personnel available for this type of production? Is it possible to ensure that packaging, labeling, and quality control are adequate?
- Are there any special regulations in effect that govern local manufacturing by a hospital pharmacy? Are these regulations being adequately enforced?
- Have drug use review activities occurred during the past year? If yes, who reviews the reports? What actions or improvements have occurred as a result of DUR?
- Is a system in place to track adverse drug reactions and medication errors? What actions or improvements have occurred as a result of this activity?

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