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PHARMACY AND THERAPEUTIC COMMITTEE AND ITS ORGANIZATION

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Abstract: It has been nearly 20 years since the Academy of Managed Care Pharmacy (AMCP) and other stakeholders adopted the Principles for a Sound Formulary System. Since that time, best practices for pharmacy and therapeutics (P&T) committees have matured throughout the health care system. On March 28, 2019, AMCP convened a group of thought leaders representing clinicians, academia, patient advocacy, payer organizations, and the pharmaceutical industry to consider P&T committee best practices in today's evolving health care system. Specifically, the group provided perspectives on (a) P&T committee composition and relevant stakeholders, (b) evaluation of emerging evidence for formulary decisions and recommendations around training of P&T committee members, and (c) characteristics and best practices of successful committees. Medication error is an important cause of patient morbidity and mortality, yet it can be a confusing and underappreciated concept. This article provides a review for practicing physicians that focuses on medication error (1) terminology and definitions, (2) incidence, (3) risk factors, (4) avoidance strategies, and (5) disclosure and legal consequences. A medication error is any error that occurs at any point in the medication use process. It has been estimated by the Institute of Medicine that medication errors cause 1 of 131 outpatient and 1 of 854 inpatient deaths. Medication factors (eg, similar sounding names, low therapeutic index), patient factors (eg, poor renal or hepatic function, impaired cognition, polypharmacy), and health care professional factors (eg, use of abbreviations in prescriptions and other communications, cognitive biases) can precipitate medication errors. Consequences faced by physicians after medication errors can include loss of patient trust, civil actions, criminal charges, and medical board discipline. Methods to prevent medication errors from occurring (eg, use of information technology, better drug labeling, and medication reconciliation) have been used with varying success. When an error is discovered, patients expect disclosure that is timely, given in person, and accompanied with an apology and communication of efforts to prevent future errors. Learning more about medication errors may enhance health care professionals' ability to provide safe care to their patients.

Index Terms - **FDA = Food and Drug Administration; IOM = Institute of Medicine, PTC = Pharmacy and Therapeutic Committee, MUE= medication-use evaluation, AMA = American Medical Association**

I. INTRODUCTION

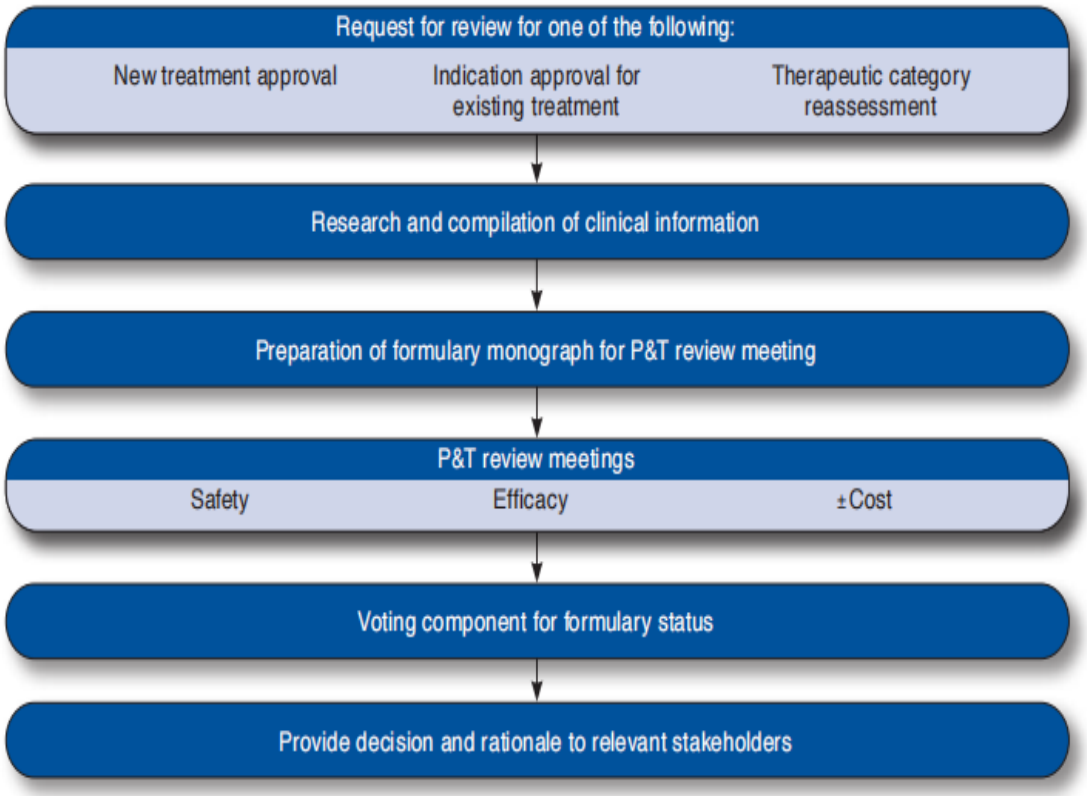
The pharmacy and therapeutics (PT) committee was introduced almost a century ago as a forum for discussing drug use in hospitals. Born out of the need to implement medication-management standards, the structure and function of the PT committee have evolved over time with clinical practice, payment reforms, and the delivery of health care services. Today, PT committee members are challenged with complex pharmaceutical agents for an ever-wider array of clinical indications—at unprecedented prices. an advisory committee that is responsible for developing, managing, updating, and administering a formulary system. Institutions may refer to this committee by a different name. New practitioners are often called on to contribute to the function of the pharmacy and therapeutics (PT) committee and its subcommittees by writing meeting minutes. Pharmacy residents typically take on this role as part of their residency responsibilities. A postgraduate year 2 (PGY2) drug information resident may support the PT committee in this way, and a postgraduate year 1 resident or a PGY2 resident in a specialized area of practice may support one of the PT subcommittees (e.g., a critical care, infectious diseases, or cardiology and thrombosis subcommittee) throughout the year. Other pharmacists in the department may also write minutes as part of their responsibilities in serving as a secretary of a subcommittee. Preparation and practice are key in developing this valuable skill. These guidelines outline important considerations and recommend processes for formulary system management within the context of a hospital or health system. Pharmacist responsibilities and roles in managing the formulary system in partnership with other healthcare professionals are embedded throughout. These guidelines also provide assistance to pharmacists in the organization and operation of the pharmacy and therapeutics (PT) committee or equivalent body, evaluation of medications for formularies and consideration of rational use of medications, and development and implementation of strategies to optimize medication use through the formulary system[1].

Pharmacy & Therapeutic committee

The PT committee is generally the medical staff committee responsible for managing the formulary system. The PT committee provides an evaluative, educational, and advisory service to the medical staff and organizational administration in all matters pertaining to the use of available medications. The PT committee should be responsible for overseeing policies and procedures related to all aspects of medication use within an institution. The PT committee's organization and authority should be outlined in the organization's medical staff bylaws, medical staff rules and regulations, and other organizational policies, as appropriate. The description of organization and authority becomes even more important as healthcare facilities merge into larger health systems. Typically, PT committee member appointments and voting rights are made based on guidance from the medical staff and other affected stake holders. Voting members may include facility medical staff, other prescribers, pharmacists, nurses, and administrators, and are a representative sample of the organization. If the scope of the PT committee includes a health system, site representation needs to be addressed to ensure equitable input and voting authority from each facility. Additional supporting PT committee members may include quality improvement managers, medication safety leaders, informaticists, other healthcare professionals and staff who participate in the medication-use process, and patient and family engagement advisors. The PT committee should have the following administrative components in place to maximize meeting effectiveness:

- Charter
- Role of the PT secretary and/or formulary manager
- Committee and subcommittee(s) responsibility and scope
- Process to track attendance
- Definition of quorum
- Process to allow (or disallow) delegation of vote
- Process to appeal committee decisions
- Defined term limits for members
- Process for identifying, disclosing, addressing, and reporting conflicts of interest (COIs)
- Policy and procedures
- Approach to voting, including roll call votes to ensure transparency
- Scope of committee responsibility (eg, specific site or entire system; inpatient or outpatient sites; drugs, devices, and biologics)
- Process for managing minutes, agendas, record keeping, and communication of decisions made

FIGURE 1 Example of a Typical P&T Process Overview[5-7]



P&T = pharmacy and therapeutics.

Other responsibilities of the PT committee include medication-use evaluation (MUE), adverse drug event monitoring and reporting, medication error prevention, medication safety, and development of clinical care plans and medication management initiatives (eg, delegation and practice protocols, restrictions, guidelines and clinical pathways). Information about these activities is available in ASHP guidelines on the topics[2-5]. Oversight of a formulary system and the capacity to make appropriate formulary decisions requires consideration of patient care factors and a thorough, unbiased review of the biomedical literature. Voting members should be required to provide COI statements to avoid actual or perceived interference with evidence-based decisions[6]. Some healthcare organizations exclude healthcare professionals with COIs from PT committee membership, whereas others allow participation in

committee discussions but prohibit voting on particular items. Practitioners requesting additions or changes to the formulary should also be required to disclose financial relationships with pharmaceutical companies, payers and insurance companies, and other potential COIs to the PT committee. Management of COI should be specified in organizational policies and procedures.

P&T Committees: Evaluation of Evidence and Training Recommendations

One of the first and most important steps in the formulary review process is the research and assessment of available literature to support the creation of an objective formulary monograph before the PT committee meeting. The types of information that may be used to support PT discussions include published randomized controlled trials (RCTs), meta-analyses, treatment guidelines, manufacturer dossiers, and internal organization datasets. Forum participants discussed findings from the SPEC Database,11 which helped provide background information on the type and frequency of information used by MCOs to make formulary decisions. This database was sourced from 17 payers, representing 130 million covered lives, and contains information on over 6,000 U.S. commercial health plan coverage policies for specialty drugs. A review of the SPEC Database found that RCTs and clinical guidelines were most commonly cited across payers as driving formulary decisions. However, many other types of studies, including economic evaluations and health technology assessments, were also noted to be relevant in making coverage decisions. Another takeaway was that the frequency of use for information types varied across.

Goals & Objectives

♦ Promote the appropriate use of high quality and cost-effective pharmaceuticals for HealthPartners members.
♦ Ensure compliance with appropriate standards and state and federal regulations.

FUNCTIONS OF PTC

Pharmacy and Therapeutics Committee is responsible for the following major functions:

♦ Maintain the Drug Formularies to promote safety, effectiveness, and affordability according to the Formulary Principles.
♦ Oversight consists of the Commercial Drug Formularies, the Medicare Formulary, and the State Programs Formulary (Minnesota Health Care Programs).
♦ Maintain pharmacy-related medical policies that promote the safety, effectiveness, and affordability of medications used in clinic settings.
♦ Maintain Formulary Principles that guide the management of the Drug Formularies.
♦ Review new drugs, drug classes, new clinical indications, therapeutic advantages, new chemical entities, and new safety information.
♦ Review the Drug Formularies and therapeutic classes at least annually.
♦ Review and update Pharmaceutical Management Policies and Procedures at least annually and as new pharmaceutical information becomes available. Policies are shared regularly with providers in a plan newsletter.
♦ Maintain a formulary that prevents selection bias or discrimination and facilitates appropriate access to affordable prescription drug choices. A non-discriminatory formulary design does not have cost or access barriers imposed by individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

Formulary and formulary system

A formulary is a continually updated list of available medications and related information, representing the clinical judgment, resulting from a review of the clinical evidence, of physicians, pharmacists, and other clinicians in the diagnosis, prophylaxis, or treatment of disease and promotion of health. A formulary includes, but is not limited to, a list of medications and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. A formulary system is the ongoing process through which a healthcare organization establishes policies regarding the use of drugs, therapies, and drug-related products, including medication delivery devices, and identifies those that are most medically appropriate, safe, and cost-effective to best serve the health interests of a given patient population. Formulary systems are used in many different settings, including hospitals, acute care facilities, home care settings, and long-term care facilities, as well as by payers such as Medicare, Medicaid, insurance companies, and managed care organizations. Many organizations[7].

Formulary Principles

The Health Partners Pharmacy and Therapeutics Committee develops and maintains its formulary based on these guiding principles. These principles reflect the 6 AIMS (safe, timely, effective, equitable, efficient, and patient centered). These principles are prioritized in descending order (i.e. effectiveness is weighted most heavily, followed by safety issues, and then by cost). Formulary decisions are made following a careful review of these often-competing principles.

1. Proven effectiveness documented in the medical literature. The primary consideration will be the degree to which a medication produces clinically desirable effects. Beneficial effects are assessed on the strength of scientific evidence including pre reviewed medical literature, pharmacoeconomic studies, and outcomes research, and standards of practice including treatment protocols and evidence-based practice guidelines such as Institute for Clinical Systems Improvement (ICSI). Randomized, controlled trials are weighted most heavily, followed by non-randomized trials, case reports, and medical opinion.
2. Maximizing safety and minimizing the potential for errors. The safety risk / benefit of a product will be compared with other treatments. We will minimize the potential for errors caused by product characteristics such as name, dosage form, and packaging that pose threats to patient safety or increase the potential for errors in the health care system.
3. Optimizing pharmacoeconomics. The overall value of a drug or therapy will be compared with existing treatments to assess pharmacy costs in relation to medical outcomes. We will
consider direct and indirect pharmacy and medical costs. We will take into consideration and give preference to those agents that optimize the use of financial and service resources over the largest potential population.
4. Emphasis on products essential to health.

5. Significant improvements in patient convenience, adherence, and satisfaction. We will review more favorably products that have significant improvements in patient convenience, adherence, and satisfaction. Examples include variables such as dosing convenience, variety of dosage forms, taste, ability to crush or divide doses, and storage requirements (refrigeration).
6. The formulary will support standard treatment algorithms.
7. Long term stability of formulary decisions. Changes to the formulary will be minimized for member care continuity.
8. The formulary will serve as a guideline for the vast majority of patients.
   a. Utilization management programs such as prior authorization, step-edits, MD-edits, quantity limits, and age limits will be applied to promote appropriate utilization.
   b. A "Formulary Exception" process will be readily available, easy to use, and timely.
   c. A "Transition of Care" policy will be available to assist members transitioning to HealthPartners.

Managing the formulary system

Health systems should develop, maintain, and implement a formulary management process. This evidence based process should not be based solely on economic factors. The formulary system should have aspects of financial stewardship incorporated and be standardized within integrated health systems when standardization leads to improved patient outcomes, safety, and cost-effectiveness. Decisions on the management of a formulary system should be founded on the evidence-based clinical, ethical, legal, social, logistical, philosophical, quality-of-life, safety, and economic factors that result in optimal patient care[8-10]. The process must include the active and direct involvement of physicians, pharmacists, and other appropriate healthcare professionals, as well representatives with expertise in finance, law, and informatics. Management of a formulary system is a significant component of a healthcare organization's ongoing medication-use policy development process. A comprehensive, well as maintained formulary is tailored to the organization's patient care needs, policy framework, and medication use systems while ensuring alignment with medication management standards of accrediting organizations.

Evolution of formularies

Formulary systems have evolved over time. Early formularies began as rudimentary drug lists developed by the military as early as the Revolutionary War and came into more widespread use during the 1950s[11]. Pharmacists, in conjunction with their organizations, developed policies to dispense generic equivalent drugs when a specific brand-name drug was prescribed. In the late 1950s, the ASHP minimum standard for pharmacies in hospitals called for the implementation of a formulary system. During the 1960s, the concept of a hospital formulary continued to grow. Hospitals developed policies that authorized pharmacists to make generic interchanges in an institutional formulary system based on prior consent from physicians[12]. ASHP and the American Hospital Association (AHA) issued joint statements on the legality of formularies[13], The American Medical Association (AMA) and the American Pharmaceutical (later Pharmacists) Association (APhA) subsequently joined with ASHP and AHA to revise the statements. In 1965, two significant events occurred:
(1) Medicare listed formularies as a reimbursement eligibility requirement[14]
(2) the Joint Commission on Accreditation of Hospitals (now known as the Joint Commission) included an active P&T committee in its accreditation requirements[15].
Even with these actions, formularies were typically no more than lists of drugs stocked by the pharmacy.
A well-managed formulary system ensures a close relationship among the organization's medication-use policies, the therapies offered by the organization, and the medications routinely stocked in the pharmacy. A formulary also identifies those medications that are most medically appropriate and cost-effective to best serve the health interests of the health system's patient population. The PT committee should review all medications used in the health system. These may include alternative remedies (herbals and supplements), nonprescription drugs, blood derivatives, contrast media, and other diagnostic and treatment agents. Institutional policies may need to be created for PT committee evaluation of agents not approved by the Food and Drug Administration (FDA) (eg, herbal supplements). The formulary system should review and approve all policies related to the medication-use process; all medication-use policies, regard less of their origination, should flow through the PT committee. The organization's medical staff leadership (ie, the body to which the PT committee reports) should complete the final policy approval. Policy review and revision should occur as new information becomes available and at regularly established intervals (eg, annually). The organization should have medication-use policies that address the following:

- How medications are requested for addition to or deletion from the formulary
- How medications are reviewed for addition to or deletion from the formulary, including who performs the reviews
- How and when drug class reviews are conducted
- The process for developing, implementing, and monitoring medication-use guidelines
- Methods and policies for ensuring the safe procurement, prescribing, distribution, administration, and monitoring of medications
- Methods for selection of suitable manufacturers for specific medications (ie, the pharmacy department is responsible for specifications for the quality, quantity, and source of supply of all medications, chemicals, biologicals, and pharmaceutical preparations used in the diagnosis and treatment of patients)
- The process for using nonformulary agents within the hospital and health system
- The process for managing radiopharmaceuticals
- The process for managing drug product shortages
- The process for developing an organization or health system–specific MUE plan
- Policies regarding specific medication-use processes (eg, procurement, prescribing, distribution, administration, monitoring, automation, and technology)
- The process for disseminating medication-use policies and how users will be educated regarding the process
- Process for accountability over medication delivery devices (eg, infusion pumps, dose error reduction software, intranasal atomizers)
- Consideration of medication access through prior authorization processes and patient assistance programs
- Implementation of PT committee decisions into the electronic health record (EHR)

A formal process to review medication use policies should be in place. This process may include the use of expert panels or subcommittees of the PT committee. Expert panels or subcommittees should serve in an advisory role to the PT committee, and their membership should include recognized experts in their areas of practice. The PT committee may also find subcommittees that address specific therapeutic areas to be beneficial (eg, pediatrics, antimicrobial, oncology therapy, cardiovascular, adverse drug reaction, pharmacogenomics, or biotechnology subcommittees). Panels and subcommittees are helpful in applying clinical study results to specific patient populations and developing recommended strategies for the safe and effective use of medications. Subcommittee and panel members can help educate groups of clinicians, who ultimately drive prescribing behaviors, about significant formulary changes. User groups, representing those primarily affected by the policy, may also be helpful. The PT committee should have formal interactions (ie, communication lines) with other committees whose functions may affect the medication-use process. These committees would include those responsible for developing tools to facilitate medication use (eg, forms or order set review committee, computerized provider order entry committee), those concerned with safety or performance improvement (eg, quality improvement or patient safety committees), those involved in developing patient care policies (eg, medical and nursing committees), those involved with investigational medications (eg, investigational review boards), and other committees whose actions may affect medication use (eg, nutrition, equipment and supply, and finance committees or patient and family engagement advisors). Recommendations from other committees, subcommittees of the PT committee, expert panels, and others should be submitted to the PT committee for review. PT committee decisions on recommendations should be communicated to the recommending group in a timely fashion. Finally, the role of pharmaceutical company representatives and medical science liaisons in a healthcare organization should be carefully considered. Organizational guidelines should define appropriate relationships and interactions with such individuals. At a minimum, these guidelines should address the provision of pharmaceutical samples, indirect or direct funding support, and educational programming regarding formulary and nonformulary medications. Applications for formulary additions should be initiated and completed independently by the requesting healthcare provider and not by an industry representative or vendor. Refer to ASHP's Guidelines on Pharmacists' Relationships with Industry for more information on appropriate interactions with industry[16].

Implementation of formulary decisions.

At both BSWH and CCHS, the system directors and pharmacy informaticists coordinate the creation of all the drug files in the EHR, streamlining the number of requests to build a drug record for the same medication. This helps with efficiency and standardization of dosing and administration, concentrations, risk evaluation and mitigation strategies management, and clinical decision support. No additional full-time equivalents were added by either health system to manage the system PT committee or system formulary. The implementation dates for formulary decisions are typically 8 and 6 weeks after the PT committee meeting for BWSH and CCHS, respectively. As stated previously, local hospitals can choose not to stock a medication, even if it is included in the system formulary, when it is not germane to the patient population they serve. The medication is listed as "formulary" but not stocked.

Principles for Pharmacy &Therapeutic Committees

Committee Composition and Meeting Logistics- The PT committee, composed of actively practicing physicians, pharmacists, and other health care professionals, is the mechanism for administering the formulary system, which includes developing and maintaining the formulary and establishing and implementing policies on the use of drug products. Best practices for the PT committee*:*

• Include a broad range of member expertise (e.g., specific clinical specialties, medication use processes, safety, and quality improvement) to provide unique perspectives
• Designate specific roles to be included in the PT committee (e.g., administration, HEOR, chair or department lead, nursing lead, and patient representation)
• Align on a clear working definition of value for the PT committee
• Maintain objectivity within the PT committee, holding each member accountable in the decision-making process
• Standardize and formalize PT committee processes
• Develop protocols around anonymous voting and confidentiality for the PT process
• Provide administrative time for data/monograph review before meetings and ample time during the PT meeting for review and discussion

Evidentiary Considerations

Formulary system decisions are based on scientific and economic considerations that achieve appropriate, safe, and cost-effective drug therapy.

Consider or include the following types of evidence in reviews:

• Randomized clinical trials, making sure to assess the study design and results objectively
• Real-world data, to provide additional context in coverage decision reassessments and formulary updates
• Cost-effectiveness research and modeling, to assess the value of a therapy
• Patient perspectives, to provide insight into the practical use of therapies and effect on quality of life outcomes
• Expert opinions and reports from external organizations are helpful for reevaluations, new indications, and instances where limited data are available

Training and Education

The formulary system should include educational programs for payers, practitioners, and patients concerning their roles and responsibilities. Consider building educational programs to support the competencies of new stakeholders. Provide training to all committee members and staff on the following:

• How to develop and present fair and relevant information in an accessible manner
• Methods, benefits, and limitations of various types of research approaches such as health technology assessments, cost-effectiveness research, and economic evaluations
• Clinical data interpretation skills

• Value and cost-benefit assessments P&T=pharmacy and therapeutics; HEOR=health economics and outcomes research.

Challenges of Pharmacy and Therapeutics Committee

Since approval by the FDA does not necessarily imply a therapeutic or safety advantage over existing therapy, an independent assessment of the safety and possible benefit of the drug (over existing drugs) must be performed. While new drugs are scrutinized with the intent of making decisions about formulary additions, this committee (or one of its collaborating committees or subcommittees, such as Medication Safety or Adverse Drug Effects) is also charged with reviewing emerging safety data, FDA mandated boxed warnings, and post-marketing surveillance toxicity data to determine when a drug should no longer be used (formulary deletions) or used in limited settings in the hospital (restricted use)[17]. Increasingly, the PT committee may be asked to investigate an adverse drug event or perform a root cause analysis following a medication error or serious adverse event. The goal of this process is to devise methods for improving the drug utilization processes in the hospital. Furthermore, implementation and monitoring of the Joint Commission's Core Measures and National Patient Safety Goals, such as glycemic control, anticoagulation therapy monitoring, and medication reconciliation has in many institutions been relegated to PT or one of its subcommittees[18]. The Pharmacy and Therapeutics committee may be involved in the drafting and review of policies and clinical guidelines created to improve the safety of other medications used within the hospital. High-risk drugs such as opioids and benzodiazepines have been associated with numerous in-hospital complications and many centers have developed guidelines for their use. These guidelines may be broadly applicable, or highly prescriptive and specify use based on, for example, dose, age, setting, or disease process. For example, the management of ethanol withdrawal in various settings in the hospital (e.g., emergency department (ED), medical or surgical floor, ICU) requires different parameters for monitoring and benzodiazepine dosing. A related challenge faced by PT committees is the use of medications outside of their approved indications. This so called "off label" prescribing is widely practiced and the data viewed by a PT committee upon considering a new drug for formulary addition generally lacks off label use information. In pediatric pharmacotherapy this is particularly important given the persistent lack of appropriate age-based data for the vast majority of medications that are administered to children[19]. Additionally, issues such as "use of own medications" or "use of alternative therapies" is increasingly common during inpatient hospitalizations, and the committee must work to develop appropriate policies to prevent errors in this process while addressing the liability concerns of hospital administration and legal departments[20]. Also, the attempt by FDA to improve the safety of certain medications through the use of Risk Evaluation and Mitigation Strategies (REMS) has expanded the regulatory role for the PT committee[21]. Although many of these apply to individual prescribers and patients in unique situations, certain REMS require the participation of the medical center invalidating credentials and practices. A recent development, now increasingly faced by PT committees, is how to respond to drug shortages. As raw product and production processes are limiting some drug manufacturing, sudden drug shortages occur causing a rapid search for reasonable and safe interim alternatives[22]. Given a broad sense of clinical pharmacology, medical toxicologists can participate in these discussions along with appropriate stakeholders, and guide the committee in choosing an appropriate replacement. Simultaneously, guidelines must be designed to ensure optimal utilization of the remaining stock. The recent shortage of succinyl choline caused internal strife within hospitals over limited supply, and required prompt action by the pharmacy and PT committee members to identify comparable alternatives for the various clinical settings in which it is utilized. The increasing number of "me too" drugs (within a prescribing class) approved by the FDA adds to the difficulty in choosing the safest, most effective, and least costly drug while allowing for some physician autonomy in prescribing[23]. Subtle changes in the relative effects of these new drugs may be touted as consequential, often (almost always) without the benefit of head-to-head comparisons with similar drugs. Fortunately, the current administration has committed to funding comparative effectiveness research that should provide more objective data for formulary choices[24].

Management of the Pharmacy &Therapeutic committee

It is imperative to have a coordinator who can centrally manage the formulary requests, drug reviews, and formulary decisions. This role is filled by the system director of clinical services at BSWH and the system director for formulary management at CCHS. In addition, pharmacy resources need to be dedicated to preparing formulary monographs, presenting formulary recommendations (including considerations for differences in patient populations and consultation services), conducting drug-use evaluations, and implementing decisions.

a) **Attendance**- It is important to record attendance at PT committee meetings for quorum and voting purposes as well as membership status. One strategy to help with attendance is altering meeting times to accommodate more physicians' schedules. Another strategy is replacing members who are regularly absent. At BSWH, all meetings are held virtually, and the physicians and pharmacists on the Dallas campus meet in person and call in to the virtual meeting as a group (this option is also available for other sites). At CCHS, there is the option to attend the meeting in person on the main campus or to call in to the meeting. Since there are large distances between sites, virtual meetings work well and allow the option not to travel. This results in higher engagement and more productive meetings.

b) **Timeline**- The time required to review a formulary request is often longer in a health system than in a single hospital. While an individual hospital's PT committee typically meets monthly, the BSWH and CCHS PT committees only meet 6 and 4 times per year, respectively. Consequently,the entire health-system review process can take 2 to 6 months. To set expectations appropriately, the requestor is notified of the timeline, meeting dates, and when to expect a final decision. For BSWH, an individual hospital's adaptation of a formulary decision can take weeks to months, depending on the MEC meeting schedule. At CCHS, all formulary implementation occurs on the same day throughout the system. Finally, at BSWH and CCHS, there is a process for an expedited review, invoked in special circumstances for certain medications (e.g., medications with breakthrough therapy designation, those for which formal studies have demonstrated significant improvement in patient outcomes).

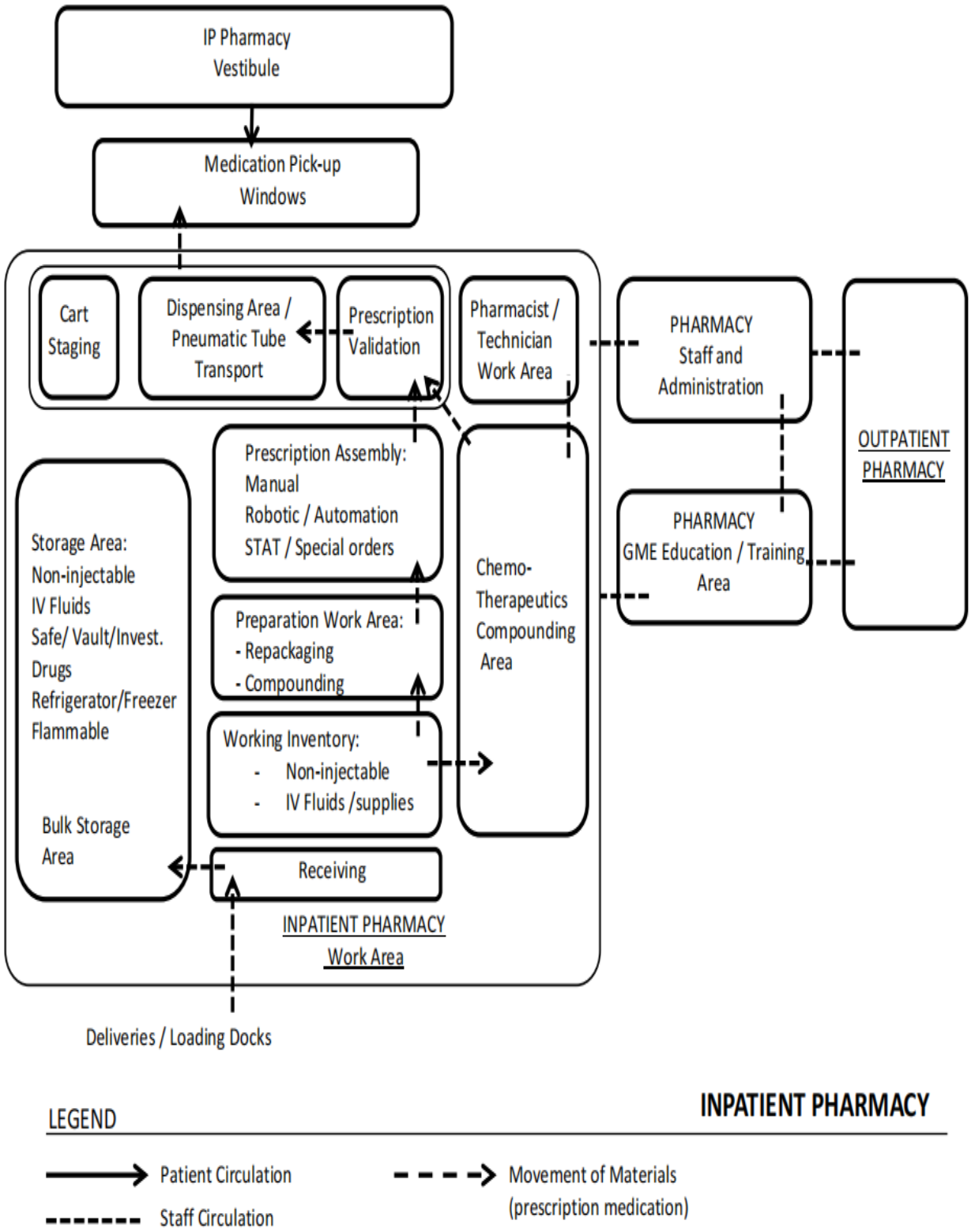
c) Appeals- It is key to have a process for handling requestors who disagree with decisions made by the system PT committee. The appeals process varies slightly between BSWH and CCHS. At BSWH, if a specific hospital does not agree with the system decision regarding a medication, then the request will be brought back to the system PT committee for further discussion. Based on evidence and additional information, the drug can either be added to formulary or removed from formulary once the final review is completed. At CCHS, an appeals process was created to allow the original requestor

or another prescriber an opportunity to provide (1) any additional evidence-based medicine not part of the original review and/or (2) any guideline or practice changes from the time the original request was reviewed. An appeals request can be rereviewed at the subsequent system PT committee meeting, with advocacy from the specialty panel chair, in light of the new information. The physician chair of the system PT committee works with the requestor on appeals and must be willing to uphold the final PT committee decision regardless of the outcome.

INPATIENT PHARMACY (IP)

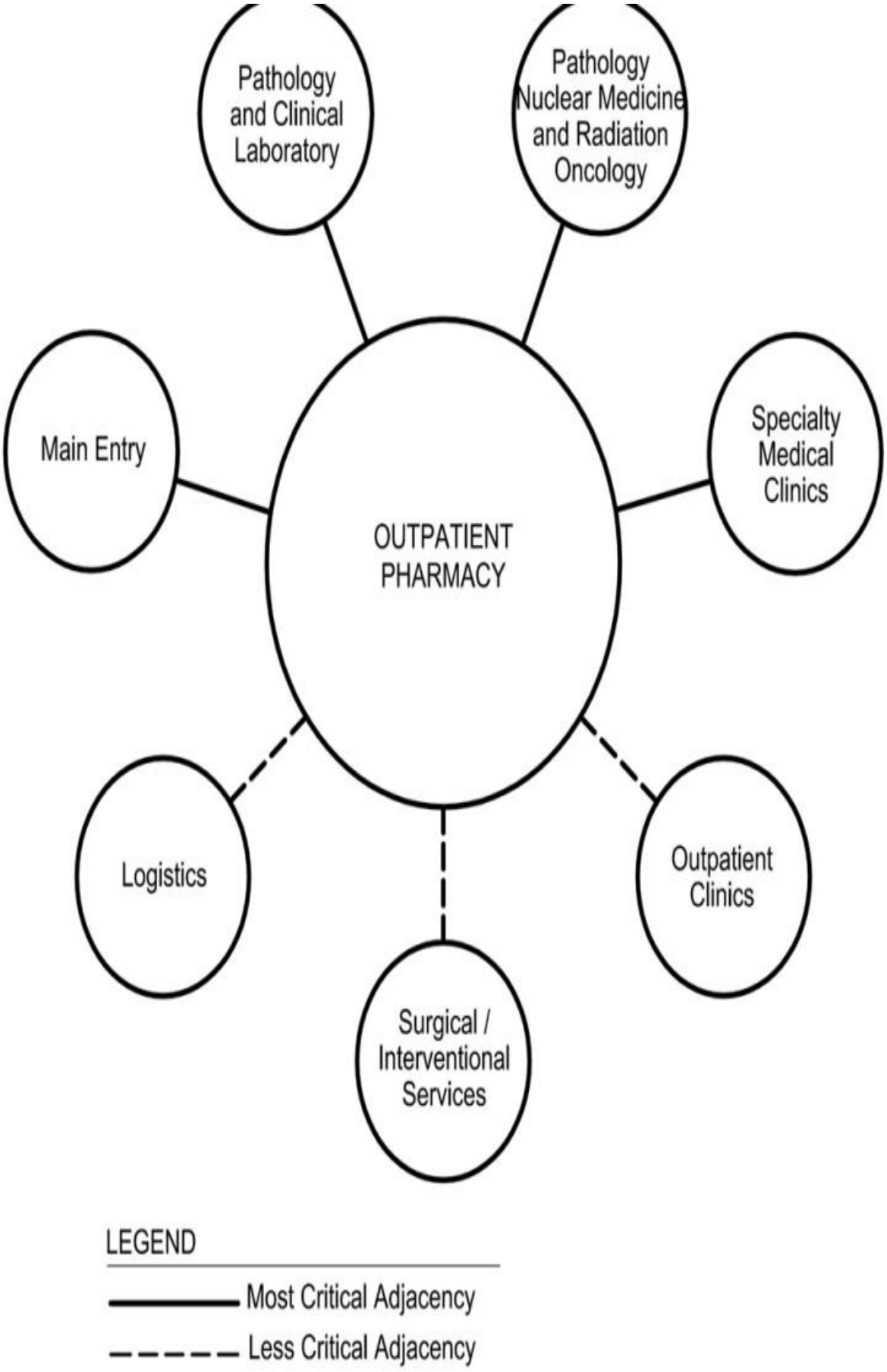
Inpatient Pharmacy provides services to a number of other services in a Military Treatment Facility (MTF) for patient care and support functions. The diagram below represents desirable relationships based on efficiency and functional considerations.

INPATIENT PHARMACY (IP) FUNCTIONAL DIAGRAM: The diagram below illustrates intradepartmental relationships among key areas / spaces. The diagram is necessarily generic. The planner shall use this as a basis for design only and shall consider project-specific requirements for each Military Treatment Facility.



OUTPATIENT PHARMACY (OP)

Outpatient Pharmacy provides services to a number of other services in a Military Treatment Facility (MTF) for patient care and support functions. The diagram below represents desirable relationships based on efficiency and functional considerations.



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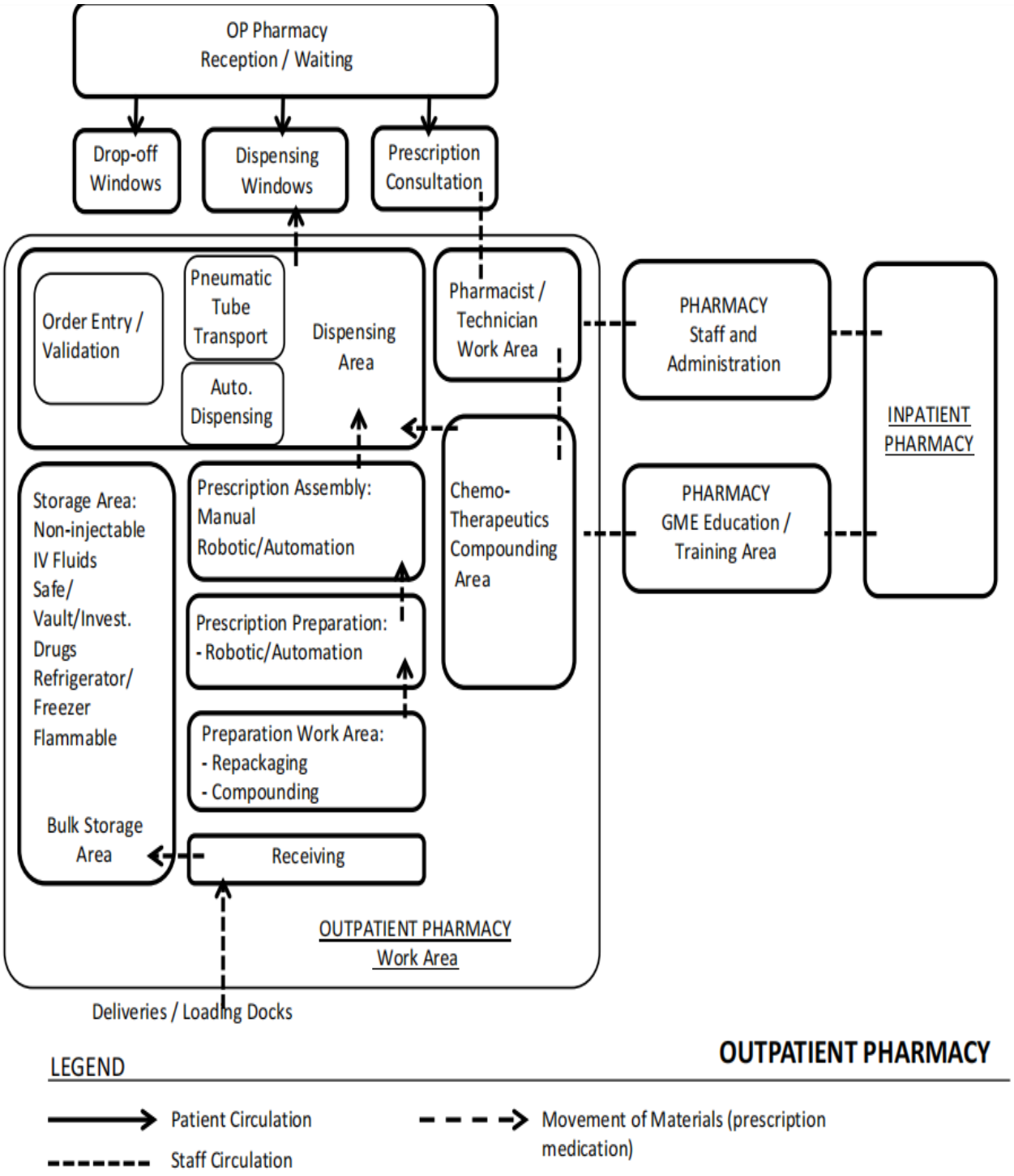
OUTPATIENT PHARMACY (OP) FUNCTIONAL DIAGRAM:

The diagram below illustrates intradepartmental relationships among key areas / spaces. The diagram is necessarily generic. The planner shall use this as a basis for design only and shall consider project-specific requirements for each Military Treatment Facility.



ORGANIZATION/COMPOSITION OF PTC

- The PTC is usually made up of health care professionals from the medical staff (with representatives of the major specialties), pharmacists, nursing personnel and representatives from various departments.
- Ideally, a well-known and respected physician will provide leadership for the committee (chairman), with a pharmacist as co-chair or executive secretary. These individuals should be appointed by the health care organization's administration.
- The PTC consists of:
  1. The medical superintendent- Chairman
  2. Chief of pharmacy services- Secretary
  3. One representative each from
    a) Dept. of internal medicine
    b) Dept. of surgery
    c) Dept. of clinical pharmacology
    d) Dept. of microbiology
    e) Dept. of nursing
    f) Dept. of nutrition

Operation of PTC

This committee should meet regularly at least six times in the year and also as and when necessary. The committee can invite its meetings persons within or outside the hospital who can contribute specialized or unique knowledge, skills and judgments. The agenda and the supplementary materials should be prepared by the Secretary and furnished to the committee members well in advance so that the members can study them properly before the meeting. A typical agenda may consists of the following categories in general: Minutes of the previous meeting. Review of the contents of the Hospital Formulary for purpose of bringing it up to date, and deleting of products not considered necessary for use. Information regarding new drugs which may have become commercially available. Review of side effects, adverse drug reactions, toxic effects and drug interactions since the last meeting. Review of drug safety in the hospital. Report of various subcommittees. Report of medical audit.

Role of PTC in "Emergency drug list"

The Time Factor is necessary for the Pharmacy and Therapeutics Committee of a hospital to get prepared boxes containing emergency drugs which should be always available readily for use at the bed-side. List of such drugs and other supplies should compiled by Committee, and it should find their place in "Emergency Kits" After the emergency boxes have been placed in the wards, it is very essential and compulsory that a system is developed whereby they are checked daily either by the hospital pharmacists or by nursing supervisor responsible for the ward

Examples of drugs for emergency box

Atropine sulphate 0.4 mg/ml
Digoxin 0.25 mg/ml
Heparin 10000 mg/ml
Mannitol inj 25%
Saline for inj
Water for inj 20 ml

Dig. Of emergency box.

Role of Pharmacist in PTC

Pharmacist are essential to the formulary management process. As the drug expert, the pharmacist can assure safe, efficacious and cost effective drug use through the formulary system.
Pharmacists guide the PTC activities to assure optimal medication management.
Establish committee meeting agenda.
Archive committee actions by keeping minutes of meeting.
Analyse scientific, clinical and economic information.
Follow up research when necessary
Communicate decisions.

Conclusion.

A health system can create and implement a multihospital system formulary and P&T committee to provide evidence-based medications for ideal healthcare. The formulary and P&T process should be multidisciplinary and include adequate representation from system hospitals. The aim of a system formulary and P&T committee is standardization; however, the system should allow flexibility for differences. Key points for a successful multihospital system formulary and P&T committee are patience, collaboration, resilience, and communication. When establishing a multihospital health-system formulary and PTC, the needs of individual hospitals are crucial. A designated member of the pharmacy department needs to centrally coordinate and manage formulary requests, medication reviews and monographs, meeting agendas and minutes, and a summary of decisions for implementation. It is imperative to create a timeline for formulary reviews to set expectations, as well as a process for formulary appeals. Collaboration across the various hospitals is critical for successful formulary standardization. When implementing a health-system PTC or standardizing a formulary system, it is important to be patient and give local sites time to make practice changes. Evidence based data and rationale must be provided to all sites to support formulary changes. Finally, there must be multidisciplinary collaboration. There are several options for formulary structures and PTC in a health system. Potential strengths and barriers should be evaluated before selecting a formulary management process.

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