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Introduction

The specialty of hospital pharmacy has been defined as follows:[1]

> . . . the department or service in a hospital which is under the direction of a professionally competent, legally qualified pharmacist, and from which all medications are supplied to the nursing units and other services, where special prescriptions are filled for patients in the hospital, where prescriptions are filled for ambulatory patients and out-patients, where pharmaceuticals are manufactured in bulk, where narcotic and other prescribed drugs are dispensed, where biologicals are stored and dispensed, where injectable preparations should be prepared and sterilized, and where professional supplies are often stocked and dispensed.

Although the above definition may have been applicable at the time that it was written, the modern practice of hospital pharmacy involves much more. The computerization of the pharmacy department makes it possible for the staff to participate in patient education programs, poison control center activities, preparation of patient drug use profiles, parenteral nutrition program participation, cooperating in the teaching and research programs of the hospital, communicating new product information to nursing service and other hospital personnel and dispensing radiopharmaceuticals.

With such a broad definition of purpose, one might wonder about the origin of this branch of the profession of pharmacy. According to Urdang,[2] the hospital pharmacist was the first recognized representative of the pharmaceutical profession. He states that hospital pharmacists were employed in the hospitals which were a part of many early monasteries. Many of the descriptions of these old hospitals include a description of the "apothecary shop" and its garden for the cultivation of medicinal herbs.

From this ancient period, hospital pharmacy passes into the early American era, 1752 to be exact, when Pennsylvania Hospital, the first in North America was opened, with Jonathan Roberts as its hospital pharmacist. Since this historic date, two hundred and twenty-nine years have passed, and a number of outstanding persons associated with the hospital pharmacy have received professional recognition and the accolade of pharmaceutical historians.

The greatest strides in the profession were made in the early 1940s.

It was during this period that the American Society of Hospital Pharmacists was formed, August 21, 1942. Besides the formation of a distinct professional society, the other major contributing factors were the publishing of the Society's official organ, the *American Journal of Hospital Pharmacy*, the formation of affiliated chapters at the state level, the acceptance of the Society as a member of the United States Pharmacopoeial Convention, the establishment of minimum standards for pharmacies in hospitals, the institution of internships and training programs in connection with accredited colleges of pharmacy, and the institutes and continuing education programs which the Society has cosponsored with its affiliates and other hospital organizations. These are only a few of the many advances made by this hitherto unheard-of body of pharmacists. It is no wonder that those who have watched this remarkable progress during the past 3 decades foresee an even brighter and more successful future.

Today, the prognosticators of the past can take pride in their prediction of the progress to be made in the practice of hospital pharmacy. Clearly, the definition cited in the opening paragraph of this chapter is deficient in that it does not encompass the newer areas of institutional pharmacy practice. Of necessity, it must include the responsibility for unit dose, hyperalimentation, intravenous additive, and educational and clinical pharmacy programs. In certain locales, it could even involve participation in scientific and administrative research endeavors. By the same token, such activities as bulk manufacturing and dispensing of professional supplies should properly be de-emphasized.

In 1982 there were 6983 hospitals registered by the American Hospital Association. Community hospitals numbered approximately 5800 and large hospitals (those with 400 or more beds) numbered 605. Hospitals in 1982 handled 36,379,000 admissions, performed 19,539,639 surgical operations, delivered 3,514,457 babies and treated 248,124,000 ambulatory patients. The average daily census was 762,000 patients and the average length of stay was 7.6 days. Community hospital expenditures totaled $104.9 billion in 1982. Payroll represented 48.3% of community hospital expenditures for more than $8.8 billion.

Average inpatient revenue per inpatient day was $392.11 in U.S. community hospitals in 1982. Revenue per inpatient day showd a strong correlation to hospital size. As community hospitals increased in size, so did the inpatient revenue, ranging from $270.66 per day for hospitals with fewer than 25 beds to $451.79 per day for those with 500 beds or more. Total revenue for outpatient care in community hospitals was $16.7 billion in 1982.

Many modern hospital administrators, after surveying this tremendous purchase and use of drugs, have suddenly realized that only trained pharmaceutical personnel are capable of storing, handling, pricing, and dispensing these products. As a result, many hospitals have

retained the services of a pharmacist either on a full-time or part-time basis.

The presence of adequate pharmaceutical personnel in many hospitals has benefited both patient and staff members, for hospital manufacture of various pharmaceutical products as well as parenteral solutions has reduced the cost of medication. In addition, it enables the members of the staff to prescribe mixtures which require compounding skill. Also, hospital pharmacists have become involved in the preparation of hyperalimentation products, dialysis fluids, intravenous additive programs, unit dose packaging and unit dose dispensing. Without the knowledge possessed by a trained pharmacist, these preparations could not be properly or safely prepared in the hospital.

Whereas in the past, pharmacists acted as pharmacologic advisor to the physician concerning the pharmacology, toxicology, and posology of the new classes of drugs, today this clinical role has expanded to the point where it is a specialty unto itself. These clinical pharmacists are involved in the preparation of patient drug profiles, recording patient drug history, advising physicians of possible drug-drug interactions and drug effects on clinical laboratory test results.

Because of their special training, hospital pharmacists are now serving on the faculties of many of the hospital schools of nursing, teaching courses in pharmaceutical mathematics and pharmacology. This particular duty helps immeasurably to strengthen the professional bond between these two allied health professions.

In addition, the hospital pharmacists of today's hospitals serve on such vital committees as the Pharmacy and Therapeutics Committee, the Safety Committee, Committee on Standardization, the Antibiotics Committee, the Committee on Environmental Sepsis, the Policy Committee of the Administrative Staff, Research Committee, Planning Committee, Loss Control Risk Management Committee and the Ambulatory Care Committee.

These paragraphs have briefly summed up the past and present of hospital pharmacy. Consideration must now be given to its future.

The American Hospital Association has registered 6,983 hospitals. Of these, about 1,000 hospitals are more than 200-bed capacity, whereas the remainder of them have 100 or fewer beds. It is in the hospitals of no more than 100 beds that the greatest challenge for providing adequate pharmaceutical services exists. Statistics show that less than 70% of all hospitals possess a pharmacy.

With these figures in mind, it would seem that the profession of hospital pharmacy must now satisfy a newly recognized need, that of placing a hospital pharmacist in every hospital throughout the country. This is necessary since the hospital pharmacist, in his new role, is a vital link in the chain of health professions dedicated to the care of hospitalized patients.

Another advantage to the hospital resulting from the specialized training of the hospital pharmacist manifests itself in the smaller hospital. In these institutions, the individual serving as a hospital pharmacist may also serve as an assistant to the administrator, purchasing agent, supervisor of the central sterile supply room and in some instances as a laboratory technician. By combining his duties, a hospital pharmacist is within the financial reach of every hospital, irrespective of size.

Archambault,[4] in a study on the manpower needs of hospital pharmacists, arrived at the conclusion that there is an annual need for more than 400 hospital pharmacists.

Competition for the services of qualified hospital and clinical pharmacists by hospitals is best evidenced by a perusal of some of the listings in hospital journals. It will be noted that many positions are available and range from staff pharmacist to Chief Pharmacist. Salaries range from $30,000 to $60,000 or more depending upon the size and location of the hospital. Some of the inducements offered include 4 weeks' vacation with pay, liberal sick leave, meals free while on duty, 100% hospital paid health policy for the pharmacist and his/her family, hospitalization, pension plan, and 9 to 11 paid holidays. The work week ranged from a low of 35 hours to a high of 44 hours with the majority of institutions adhering to the standard 40 hours.

Dr. Charles Letourneau,[5] a consultant in a hospital administration and Editorial Director of the Journal, *Hospital Management*, wrote—

"... the function of the hospital pharmacist is vital not only to the professional care of the patient but to the management of the hospital as well. The management function of the hospital pharmacist is a relatively recent concept which is rapidly achieving recognition in the hospital field. Hospital administration is the coordination of men, money and materials to provide facilities to assist a physician to treat his patient. The pharmacist participates in hospital administration in addition to his professional obligations."

Should the profession meet the challenge of the future, the opportunities and resources of institutional pharmacy practice would be greatly increased. With this increase, it is inevitable that new young blood with administrative and clinical qualifications must be attracted to the profession in sufficient quantity to make this a profession with a notable past, a noble and invigorating present, and a brilliant future.

The following ASHP *Statement of Goals for Institutional Pharmacy* was developed by the ASHP Council on Professional Affairs, approved by the ASHP Board of Directors on March 20, 1980 and by the ASHP House of Delegates on April 21, 1980.

ASHP STATEMENT OF GOALS FOR INSTITUTIONAL PHARMACY

Just as any organization must have long-range goals toward which its daily activities are directed, so must a profession, its members, and their representative societies. This document, intended to be a basic statement of purpose for the American Society of Hospital Pharmacists and its membership, has been prepared with this in mind.

The American Society of Hospital Pharmacists, in its Constitution and Bylaws, sets forth the following objectives:

1. To provide the benefits of a qualified hospital pharmacist to patients and health care institutions, to the allied health professions, and to the profession of pharmacy.
2. To assist in providing an adequate supply of such qualified hospital pharmacists.
3. To assure a high quality of professional practice through the establishment and maintenance of standards of professional ethics, education, and attainments and through the promotion of economic welfare.
4. To promote research in hospital pharmacy practices and in the pharmaceutical sciences in general.
5. To disseminate pharmaceutical knowledge by providing for interchange of information among hospital pharmacists and with members of allied specialties and professions.

More broadly, the Society's primary purpose is the advancement of rational, patient-oriented drug therapy in hospitals and other organized health care settings.[a]

To the preceding can be added the following objectives:

1. To expand and strengthen institutional pharmacists' abilities to: (a) effectively manage an organized pharmaceutical service; (b) develop and provide clinical services[b]; (c) conduct and participate in clinical and pharmaceutical research; (d) conduct and participate in educational programs for health practitioners, students, and the public.
2. To increase the knowledge and understanding of contemporary institutional pharmacy practice by the public, government, pharmaceutical industry, and other health care professionals.
3. To promote compensation and benefits commensurate with pharmacists' responsibilities and contributions to patient care.
4. To help provide an adequate supply of qualified supportive personnel for institutional pharmacy services.
5. To help ensure that health care reimbursement and payment systems do not inhibit the implementation of innovative pharmaceutical services or adversely reflect on institutional pharmacy practice.

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[a]Directions for the American Society of Hospital Pharmacists in organized health care delivery. *Am J Hosp Pharm.* 1975; 32:702–3.

[b]ASHP statement on clinical functions in institutional pharmacy practice. *Am J Hosp Pharm.* 1978; 35:813.

6. To assist in the development and advancement of the pharmacy profession.

The foregoing serves as a collective statement of goals of the Society and its constituency. Transforming these goals into realities will require the dedicated efforts of all institutional pharmacists, both as individuals and as members of the Society.

Minimum Standards

The original *Minimum Standard for Pharmacies in Hospitals* was developed and adopted by the American College of Surgeons in 1935. A revised version was adopted by the American Society of Hospital Pharmacists in 1950 and such was approved by the American Pharmaceutical Association. Later, a *"Guide to Application"* for each of the six sections of the *Minimum Standard* was appended as supplementary material. This *"Guide to Application"* was developed by the American Society of Hospital Pharmacists without approval from other organizations. Thus, there is an important differentiation which must be recognized between the two documents—the former is an official document, whereas the latter is supplementary information.

Because the new practitioner and the student may not have available to them the journals carrying the *ASHP Guidelines Minimum Standard for Pharmacies in Institutions,* they are hereinafter reproduced in detail.[7]

ASHP GUIDELINES: MINIMUM STANDARD FOR PHARMACIES IN INSTITUTIONS[a]

Am J Hosp Pharm. 1985; 42:372–5

Pharmaceutical services[b] in institutions have numerous components, the most prominent being (1) the procurement, distribution, and control of all pharmaceuticals used within the facility, (2) the evaluation and dissemination of comprehensive information about drugs and their use to the institution's staff and patients, and (3) the monitoring, evaluation, and assurance of the quality of drug use. These functions are carried out in cooperation with other institutional departments and programs.

[a]Approved by the ASPH Board of Directors, November 14–15, 1984. Revised by the ASHP Council on Clinical Affairs. Supersedes the previous version, which was approved on August 1, 1977.

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[b]The terms "pharmaceutical services" and "pharmacy" as used in this document are synonymous. The term "pharmacist" is used in the collective sense, referring to the pharmacy staff.

The primary function of this document is to serve as a guide for the development and provision of pharmaceutical services in institutions. It will also be useful in evaluating the scope and quality of these services. It does not, however, provide detailed instructions for operating a pharmacy—other Society publications serve this function.

Standard I: Administration

The pharmaceutical service shall[a] be directed by a professionally competent, legally qualified pharmacist. He or she must be on the same level within the institution's administrative structure as directors of other clinical services. The director of pharmaceutical services[b] is responsible for (1) setting the long- and short-range goals of the pharmacy based on developments and trends in health care and institutional pharmacy practice and the specific needs of the institution, (2) developing a plan and schedule for achieving these goals, (3) supervising the implementation of the plan and the day-to-day activities associated with it, and (4) determining if the goals and schedule are being met and instituting corrective actions where necessary.

The director of pharmaceutical services, in carrying out these tasks, shall employ an adequate number of completent and qualified personnel.

- The director of pharmaceutical services must be thoroughly knowledgeable about hospital pharmacy practice and management. He or she should have completed a pharmacy residency program accredited by the American Society of Hospital Pharmacists.
- Sufficient supportive personnel (technical, clerical, secretarial) shall be available in order to minimize the use of pharmacists in nonjudgmental tasks. Appropriate supervisory controls[c] for supportive personnel must be maintained.
- The director of pharmaceutical services shall assure that work schedules, procedures, and assignments use pharmacy personnel and resources in the most efficient manner possible.
- All personnel must possess the education and training needed for their responsibilities. Competence of all staff must be maintained through relevant continuing-education programs and activities.
- Personnel must be selected and assigned solely on the basis of job-related qualifications and performance. The employment and discharge of pharmacy personnel shall be the responsibility of the director of pharmaceutical services. There should be an established procedure, based on

[a]The terms "shall" and "must" are used to indicate a mandatory statement. The term "should" reflects the commonly accepted or recommended method; it permits the use of equally effective alternatives.

[b]The title "director of pharmaceutical services" or a similar title is preferred over "chief pharmacist" or "consultant pharmacist."

[c]Any system of control which assures the quality of the outcome of the work performed by supportive personnel is deemed to be "appropriate."

predetermined objectives, for orienting new personnel to the pharmacy and their respective positions. Procedures for the routine evaluation of pharmacy personnel performance shall be established.

- Lines of authority and areas of responsibility within the pharmacy shall be clearly defined. Written position descriptions for all categories of pharmacy personnel must be prepared and revised as necessary.
- An operations manual governing all pharmacy functions should be prepared. It should be continually revised to reflect changes in procedures, organization, etc. All pharmacy personnel should be familiar with the contents of the manual.
- Policies and procedures for managing drug expenditures should be established. They should include such methods as controlled formularies, competitive bid and group purchasing, drug-use review programs, and cost-effective clinical services.
- The director of pharmaceutical services should prepare periodic reports to the institution's administration containing qualitative and quantitative information on the pharmacy's activities for the period plus the current position of the pharmacy with respect to its long- and short-range plans. These reports require that a system for routinely monitoring pharmacy workload and expenses be established. The system should provide for the determination and analysis of the amounts and costs of drugs and services furnished to specific patients and/or patient categories.
- There shall be an ongoing, systematic program for assuring the quality of pharmaceutical services. This program should be integrated with the institution's organized quality assurance program.
- Hospitals provide services to patients 24 hours a day. Pharmaceutical services are an integral part of the total care provided by the hospital, and the services of a pharmacist should, therefore, be available at all times. Where around-the-clock operation of the pharmacy is not feasible, a pharmacist must be available on an "on-call" basis. The use of night cabinets and drug dispensing by nonpharmacists should be minimized and eliminated wherever possible.
- Some small facilities may not require, or be able to obtain, the services of a full-time pharmacist. However, it should be noted that the concepts, principles, and recommendations contained in this standard apply to *all* hospitals, regardless of size or type. Thus, the part-time director of pharmaceutical services has the same basic obligations and responsibilities as his or her full-time counterpart in the larger institution.
- The relevant standards and guidelines of the American Society of Hospital Pharmacists and the Joint Commission on Accreditation of Hospitals must be adhered to regardless of the particular financial and organizational arrangements by which pharmaceutical services are provided to the facility and its patients.

Standard II: Facilities

There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy.

- The pharmacy shall be located in an area (or areas) that facilitate(s) the provision of services to patients. It must be integrated with the facility's communication and transportation systems.

- Space and equipment, in an amount and type to provide secure, environmentally controlled storage of drugs, shall be available.
- There shall be designated space and equipment suitable for the preparation of sterile products and other drug compounding and packaging operations.
- The pharmacy should have a private area for pharmacist-patient consultations. The director of pharmaceutical services should also have a private office or area.
- Current drug information resources must be available. These should include appropriate pharmacy and medical journals and texts and drug literature search and retrieval resources.

Standard III: Drug Distribution and Control

The pharmacy shall be responsible for the procurement, distribution, and control of *all* drugs used within the institution. This responsibility extends to drugs and related services provided to ambulatory patients. Policies and procedures governing these functions shall be developed by the pharmacist with input from other involved hospital staff (e.g., nurses) and committees (pharmacy and therapeutics committee, patient-care committee, etc.). In doing so, it is essential that the pharmacist routinely be present in all patient-care areas, establish rapport with the personnel, and become familiar with and contribute to medical and nursing procedures relating to drugs.

- The pharmacist shall maintain an up-to-date formulary of drug products approved for use in the institution. While the items to be included in the formulary are selected by the pharmacy and therapeutics committee (or its equivalent), it is the pharmacist's responsibility to establish specifications for these drug products and to select their source of supply. In doing so, it is advisable that written specifications for multisource items be prepared and used in the acquisition process.
- Policies and procedures controlling the use of investigational drugs (if used in the institution) shall be developed and followed. The pharmacy shall be responsible for storing, packaging, labeling, distributing, and maintaining inventory records of investigational drugs. It should also be responsible (in cooperation with the principal investigator) for providing information about these drugs.
- There shall be a procedure for providing drugs and pharmaceutical services in the event of a disaster.
- Written policies governing the activities of medical sales representatives within the hospital shall be prepared and approved by the pharmacy and therapeutics committee. Sales representatives should receive a copy of these policies and their activities should be controlled. The use of drug samples within the institution should be eliminated to the extent possible. However, if the use of drug samples is permitted, they must be controlled and distributed only through the pharmacy.
- The pharmacist must review the physician's original order, or a direct copy thereof, prior to dispensing any drug (except for emergency use). There shall be no transcribing of medication orders by nursing or clerical staffs (except for their own records). Hospitalwide and pharmacy stand-

alone computer systems must be secure against unauthorized entry. All systems must provide for review and verification of the physician's original order before the drug is dispensed.

- A medication profile for all inpatients and all (or selected) outpatients shall be maintained and used.
- The pharmacist must institute the control procedures needed to ensure that patients receive the correct drugs at the proper times. In accomplishing this, it is necessary that all drugs used in the institution (including i.v. fluids) be distributed by the pharmacy. All drugs must be packaged, labeled, and distributed in a manner that meets applicable professional standards and legal requirements. An accountability system for controlled substances that meets all applicable governmental requirements must be maintained.
- In the interest of patient safety, all drugs dispensed by the pharmacist for administration to patients should be in single unit packages and, to the extent possible, in ready-to-administer form. The need for nurses to manipulate drugs (i.e., withdraw doses from multidose containers, label containers, etc.) prior to their administration should be minimized; thus, the unit dose system of preparing and distributing drugs should be used.
- Pharmacy personel shall prepare all sterile products (e.g., chemotherapy injections, continuous and intermittent i.v. preparations, irrigation solutions), except in emergencies.
- The pharmacist, in cooperation with hospital staff, must establish policies and procedures for handling drugs that are putative occupational hazards. The procedures should maintain the integrity of the drug and protect hospital personnel.
- Floor stocks of drugs must be kept as small as possible and limited to drugs for emergency use and routinely used "safe" items, such as mouthwash and antiseptic solutions. All drug storage areas within the hospital must be routinely inspected to ensure that no outdated or unusable items are present, that all stock items are properly labeled and stored, etc.[a]
- There shall be a system for removing from use any drugs subjected to a product recall.
- When feasible, the pharmacist should prepare those drug formulations, strenths, dosage forms, and packages that are not available commercially but which are useful in the care of patients. Adequate quality assurance procedures shall be developed for these operations.
- A written stop-order policy or other system shall be established to ensure that drug orders are not inappropriately continued.
- Policies and procedures shall be established for the identification and use of medications brought into the institution by patients.

Standard IV: Drug Information

The pharmacy is responsible for providing the institution's staff and patients with accurate, comprehensive information about drugs and their use and shall serve as its center for drug information.

- The pharmacist (in cooperation with the organization's librarian, if any)

[a]Examples of nursing unit inspection forms are available upon request from the American Society of Hospital Pharmacists.

is responsible for maintaining up-to-date drug information resources (both in the pharmacy and at patient-care areas) and using them effectively. The pharmacist, in addition to supplying specific drug information, must be able to furnish objective evaluations of the drug literature and to provide informed opinion on drug-related matters.

- The pharmacist must keep the institution's staff well informed about the drugs used in the institution and their various dosage forms and packagings. This is accomplished through newsletters, seminars, displays, etc., developed by the pharmacy. No drug shall be administerd unless the medical and nursing personnel have received adequate information about, and are familiar with, its therapeutic use, adverse effects, and dosage.
- The pharmacist must help ensure that all patients are given adequate information about the drugs they receive. This is particularly important for ambulatory, home care, and discharge patients. These patient education activities shall be coordinated with the nursing and medical staffs and patient education department (if any).

Standard V: Assuring Rational Drug Therapy

An important aspect of pharmaceutical services is that of maximizing rational drug use. In this regard, the pharmacist, in concert with the medical staff, must develop policies and procedures for assuring the quality of drug therapy.

- Sufficient patient information must be collected, maintained, and reviewed by the pharmacist to ensure meaningful and effective participation in patient care. This requires that a medication profile be maintained for all inpatients and for those ambulatory patients routinely receiving care at the hospital. A pharmacist-conducted medication history from patients may be useful in this regard.
- All physicians' medication orders (except in emergency situations) must be reviewed for appropriateness by the pharmacist prior to the dispensing of the first dose. Any questions regarding the order must be resolved with the prescriber at this time and a written notation of these discussions made in the chart or copy of the physician's order. The nursing staff must be informed of any changes made in the order.
- The pharmacist, in cooperation with the pharmacy and therapeutics committee, shall develop a mechanism for the reporting and review (by the committee or other appropriate medical staff group) of adverse drug reactions.
- Appropriate clinical information about patients must be available and accessible to the pharmacist for use in his or her daily practice activities.
- The pharmacist must review each patient's drug regimen on a concurrent basis and directly communicate any suggested changes to the prescriber.
- A formalized drug-use program, developed and conducted jointly with the medical staff, shall be initiated and integrated with the overall hospital patient-care evaluation program. This program should include, but not be limited to, the use of antibiotics and other anti-infective agents.
- The pharmacist must actively participate in developing and maintaining the hospital formulary. This is particularly important in small hospitals lacking the services of various medical specialists.

- The pharmacist shall be a member of the pharmacy and therapeutics infection control, patient-care, use review, and other committees where input concerning the use of drugs is required.

Standard VI: Research

The pharmacist should conduct, participate in, and support medical and pharmaceutical research appropriate to the goals, objectives, and resources of the pharmacy and the institution.

- The pharmacist should maintain adequate information on all investigational drug studies and similar research projects involving drugs in which the facility's patients are participants.
- The pharmacist should be represented on the institution's Institutional Review Board.
- The pharmacist shall ensure that policies and procedures for the safe and proper use of investigational drugs are established and followed.

Supplemental References

The American Society of Hospital Pharmacists (4630 Montgomery Avenue, Bethesda, MD 20814) has numerous publications which elaborate on many of the concepts embodied in this Standard. They are described in the Society's publications catalog, available upon request.

ABILITIES REQUIRED OF HOSPITAL PHARMACISTS

The American Society of Hospital Pharmacists and the American Association of Colleges of Pharmacy, recognizing the specialty of hospital pharmacy and the fact that qualified practitioners must be specially educated, have developed and approved *ASHP Guidelines on the Competencies Required in Institutional Pharmacy Practice.*

For the convenience of the practitioner and student, the *Statement* is hereinafter reproduced.[8]

ASHP GUIDELINES ON THE COMPETENCIES REQUIRED IN INSTITUTIONAL PHARMACY PRACTICE*

Preface

The practice of pharmacy in health care institutions continues to undergo evolutionary and even radical changes. It has changed to a personal health service charged with assuring pharmaceutic and therapeutic appropriateness of all its functions in the care of patients. Professional, societal, governmental and economic factors will continue to force further changes and the pharmacist practicing in an institution must be ready not only to adapt to these changes but to take the lead in introducing them. In all cases, the basis for the institutional pharmacist's contribution to health care is a thorough knowledge of drugs and their actions. To bring this expertise to bear in the most effective manner, the institutional pharmacist must interact and cooperate closely with all other health professionals practicing in the institution and he must assist the patient and the patient's family to cope with the problems of illness.

It is recognized that a large and diverse body of expertise is required in the operation of a pharmacy department. No one pharmacist may possess or have opportunity to demonstrate this breadth of expertise. For a variety of reasons, some institutions offer greater opportunity than others for the pharmacist to use his unique skills. All institutional pharmacists should, however, develop minimal competencies in each area and be capable of becoming expert in any one or several of them. This requires more than casual acquaintance with a broad area of knowledge and emphasizes the need for a sound professional education grounded on a firm base of physical, biological and social sciences.

This statement addresses itself to the various competencies which must be demonstrated collectively by the professional staff of an institutional pharmacy department. The statement recognizes not only the need for but the responsibility of a department to make pharmaceutical services available to both inpatients and ambulatory patients as well as to promote the rational use of drugs by health professionals and the public. The department must participate in all programs and functions of the institution where pharmaceutical expertise is needed. The professional staff of the pharmacy department must have the ability to carry out collectively the following service functions.

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*Approved by the American Society of Hospital Pharmacists, April 1975, and by the American Association of Colleges of Pharmacy, July 1975.

This document supersedes the Statement on the Abilities Required of Hospital Pharmacists, March 1972.

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I. Effective Administration and Management of a Pharmacy Department in an Institution

The successful delivery of any pharmacy service offered will be based on expert management and administrative procedures. The director of pharmacy services or personnel specializing in departmental administration must be familiar with the health care system in general and the specific function of the institution in particular so that the pharmacy's goals can be achieved in cooperation with all other departments in the institution and with other programs that insure continuity of care for the patient.

Broad areas of administrative and management responsibilities include planning and integrating professional services, budgeting, inventory control, cost review, cost effectiveness, audit, maintenance of records and preparation of reports. As a basis for this responsibility, pharmacy personnel must be thoroughly familiar with the organization of a hospital, with staff and line relationships and with appropriate lines of communication.

Pharmacy activities must be coordinated with medical, nursing and other services and with the administrative elements of the hospital. Pharmacy administrative personnel must be able to prepare suitable written communications to the hospital staff concerning pertinent pharmacy matters.

The director of pharmacy services, or his designee, is responsible for the justification and accountability of all pharmaceutical services in terms of patient care and the expenditure of funds. He must be able to analyze and interpret prescribing trends and the economic impact of new drug developments, which for budgeting purposes are translated to his forecast of future drug expenditures. He must maintain an adequate system of stock and inventory control. He must have the ability to control operational costs without compromising services.

The director of pharmacy services is responsible for records on all pharmacy operations which may be legally or administratively required. The data collected should be translated into periodic or special reports. These may include, but usually are not limited to, data on prescriptions dispensed, controlled drugs dispensed, drug purchases, inspections and improvements in operations. The use of automated data processing systems may allow more effective and efficient handling of pharmacy records and data. A basic knowledge and understanding of the applications of such systems to pharmacy operations is important to the department.

II. Assimilation and Provision of Comprehensive Information on Drugs and Their Actions

Fundamental to the pharmacist's contribution to health care is his knowledge of drugs and their actions. The pharmacy department is the

primary source of information concerning drugs. The pharmacy must maintain the appropriate information sources and develop mechanisms for evaluating information and transmitting it to the institution's professional staff and to patients.

The pharmacist must have the ability to use his basic science knowledge and his knowledge of the effects of drugs on biological systems in assessing such determinants of drug action as absorption, distribution, metabolism and excretion of a drug; drug interactions with other drugs, foods or diagnostic agents; effects of a disease state on the drug's action; and miscellaneous patient and drug variables. Thus, the pharmacist practicing in an institution must be knowledgeable in chemistry, pharmacology, toxicology, pathophysiology, pharmaceutics, therapeutics, and patient care techniques, and he should have some background in the social sciences.

III. Development and Conduct of a Product Formulation and Packaging Program

Frequently, the institutional pharmacist must respond to the need for special dosage forms and formulations not available commercially. Not infrequently, this also involves a knowledge of appropriate packaging. An adequate understanding of the principles involved in the formulation and preparation of pharmaceutical dosage forms is needed. This involves the concepts of biopharmaceutics, bioavailability, pharmacokinetics, pharmaceutics, stability, physicochemical, kinetics, microbiology, quality assurance and techniques of medication administration. In some instances, as in the case of intravenous admixtures and total parenteral nutrition, the pharmacist must also be familiar with patient variables such as electrolyte and fluid balance, and such factors as personal hygiene, environmental control and equipment performance. Similar concepts hold true in radiopharmacy. Furthermore, the pharmacist must be able to evaluate the economic factors involved, including the cost of labor, raw materials, space, equipment depreciation and other items of fixed overhead.

IV. Conduct of and Participation in Research

The institutional pharmacist must be prepared to participate in clinical research originated by the medical staff and to conduct pharmaceutical research or initiate research himself. In doing so, he may act as the principal or coprincipal investigator or he may use the resources of the department to support a particular research study. The pharmacist must be able to establish a data base, either for the drugs being used or the patients participating in the study. Equally important, he must have the ability to collect appropriate data, interpret them, apply the

conclusions drawn from the data and transmit the results in an adequate manner.

An educational background with appropriate orientation and training in research methodology, including criteria for and structure of a research report, is mandatory.

V. Development and Conduct of Patient-oriented Services

Pharmacy, as practiced in health care institutions, is developing a wide spectrum of clinical services which have become part of overall pharmaceutical service but may not be directly associated with drug distribution. Fundamental to these clinical services is the pharmacist's knowledge of drugs, diseases and patient and drug variables, and his ability to interact closely on a personal basis with other health professionals. Academic training in such areas as toxicology, pathophysiology and therapeutics, as well as extensive clinical experience, provide the background for a pharmacist to function in this clinical role.

These services include (1) drug information, which encompasses the collection, organization, retrieval, interpretation and evaluation of the applicable literature and the ability to present the excerpted data in an appropriate fashion; (2) collection of the pharmacy patient data base; (3) patient education; (4) the monitoring (either subjectively or objectively) and auditing of therapeutic regimens; (5) drug use review; (6) the monitoring of specific adverse drug reactions to decrease their incidence; and (7) other similar functions designed to improve patient care by optimizing drug use. Further, clinical functions may extend to the pharmacist's role in primary care as well as in the management of chronic care patients.

VI. Conduct of and Participation in Educational Activities

A wide range of educational activities is performed routinely in the institution and involves all health practitioners and students of the various health professions. The director of pharmacy services, or his designee, is responsible for coordinating the department's contribution to these educational activities. Further, he is responsible for training new personnel and for carrying on a continuous educational program for pharmacists and pharmacy supportive personnel. In institutions having a pharmacy residency program, the pharmacist must develop a well planned and coordinated program so that the residency is a meaningful educational experience in the development of future practitioners. In institutions offering a pharmacy residency program in conjunction with an academic program, the pharmacist must have a thorough understanding of his own program and the course material and objectives of the academic phase to assist in coordinating one with the other.

VII. Development and Conduct of a Quality Assurance Program for Pharmaceutical Services

A major responsibility of the department must be the assurance of the quality of its services and of products dispensed, coupled with a control program for the distribution of drugs throughout the institution.

The pharmacist must conduct service audits, either by process or outcome, or both, to assure the quality of patient care services rendered and to assure the appropriate patient benefit of all pharmaceutical services offered.

RESEARCH IN HOSPITAL PHARMACY

It has been stated that for hospital pharmacy to continue its advancement as a contributing member of the health professions, it must encourage its practitioners towards greater participation in research.

To achieve this objective the American Society of Hospital Pharmacists issued the following guidelines.[9*]

The promotion of scientific research in institutional pharmacy and in pharmaceutical problems in general is an objective of the American Society of Hospital Pharmacists, as stated in its Constitution and Bylaws. In keeping with this objective, institutional pharmacists should, therefore, have the ability to conduct and participate in research.[1]

There are differing views about the proper function of scientific research. Some feel that the purpose of research is to improve things, while others say that the proper function of research is to establish general laws regarding the behavior of events or objects which may be used to predict. All of these functions are apropos institutional pharmacy research activities. The institutional pharmacist should, to the extent possible, participate in clinical research with other health care disciplines, in pharmaceutical sciences research, and in operations research in pharmaceutical services and systems.

The Nature of Scientific Research

Scientific research is the systematic, controlled, empirical and critical investigation of hypothetical propositions about the presumed relations among natural phenomena.[2]

It is a method of acquiring knowledge based on the faith that there are real things whose characteristics are entirely independent of our opinions about them, and that objective propositions can be stated about them and subject to empirical tests.

There are two broad views of science: the *static* and the *dynamic*.[1] The static view, held by most students and laymen, is that science is an activity that contributes systematized information to the world. The scientist's job is to

*Approved by the ASHP Board of Directors, November 15, 1977.
This document replaces the ASHP Guidelines for Scientific Research in Hospital Pharmacy and the ASHP Statement on Research in Hospital Pharmacy.

discover new facts and to add them to the already existing body of information. Science is even conceived to be a body of fact. The emphasis is on the present state of knowledge and adding to it.

The dynamic view regards science more as an activity—what scientists do. The present state of knowledge is considered to be important, but mainly because it is a base for further scientific theory and research. This has been called the heuristic view (meaning serving to discover or reveal). The heuristic view in science emphasizes theory and interconnected conceptual schemata that are fruitful for further research. It is an emphasis upon discovery. The heuristic view stresses problem-solving rather than facts and bodies of information, and distinguishes scientific research from engineering and technology.

Although research is problem-solving, not all problem-solving is research. The difference that distinguishes research is a primary concern for theory, rather than just the immediate answer to one specific problem at one place at one time.

The basic aim of scientific research is theory.[4] A theory is defined as a set of interrelated constructs (concepts), definitions and propositions that presents a systematic view of phenomena by specifing relations among variables, for the purpose of explaining and predicting phenomena. Theory sets out the relationship between variables and explains phenomena by stating what variables are related and how the variables are related.

Theories are general explanations of natural events. Their value lies in their generality, because they can be applied widely and to many people in many places.

Realistically, much that has been identified as research in institutional pharmacy, although often quite valuable, is more accurately described as problem-solving through the use of research methods. The subject matter of such activity has included the development of new pharmaceutical dosage forms, the identification of unknown drugs in poisoning cases, the development of new drug tests and assays, exploratory studies of various aspects of the pharmacist's work role, attitudinal studies of acceptance of innovations, and descriptive studies of drug prescribing, drug use and adverse drug reactions. Many (but not all) of these research "studies" would probably be better identified by such terms as methods improvement studies, product development, demonstration projects with built-in evaluation, etc.

Scientific research in general can be divided by using many different classification schemes, for example:

1. Experimental/nonexperimental
2. Exploratory/descriptive/predictive
3. Whether or not stimulus-variables are under control of the experimenter.

Special Types of Research

Two special types of research are historical research and methodological research.

Historical research is the critical investigation of events, developments and experiences of the past, the careful weighing of evidence, the validating of sources of information on the past and the interpretation of the weighed evidence. The historical investigator collects data, evaluates the data for validity and interprets the data. The historical method, or historiography, differs from scientific research only in its focus upon the past and the peculiarly difficult interpretative tasks imposed by the elusive nature of its subject matter.

Methodological research is the controlled investigation of the theoretical and

applied aspects of measurement and ways of attaining and analyzing data. Areas of investigation include the theoretical and practical problems of identifying and measuring variables, including reliability and validity. The application of mathematics (e.g., statistics and predictive equations) may be investigated. Methods of data collection and analysis may be studied.

Scope of Research

Pharmacy is based on the theories of the medical, pharmaceutical and social sciences. Therefore, every pharmacist has an obligation to support the advancement of these sciences through research in order that they may continue to grow. History has shown that the results of such research by practitioners can make a vital contribution to the improvement of patient care, and the support of such research has become one of the fundamental objectives of most health care facilities. It is, therefore, logical and in accord with the fundamental purposes of these facilities that they provide their pharmacists with at least a modest level of resources to control research. Institutions such as university teaching hospitals with a primary emphasis upon research objectives may be expected to provide more elaborate research facilities than other health care facilities.

The amount and quality of the education and training in research possessed by most institutional pharmacists are important, if temporary, limitations in the advance of research in institutional pharmacy. Those pharmacists who do have adequate preparation may, by reason of their training of interests, or both, wish to make their research contribution in any of the several sciences basic to pharmacy practice—pharmacology, pharmacognosy, the social sciences, etc. As research in these fields will require greatly differing needs for facilities and equipment, it is difficult to provide a general recommendation for institutional pharmacy research facilities.

No limit should be placed on the scope of scientific research to be undertaken by the institutional pharmacist. Free and unhindered inquiry is the basic tenet given to all research workers in keeping with skills and facilities available for research. The primary areas for research by institutional pharmacists are those areas in which pharmacists possess a body of knowledge which is uniquely theirs. A research problem involving the delivery of pharmaceutical services would be an example of such an area.

The Scientific Approach

Problem—Obstacle—Idea.[5] The scientist experiences an obstacle to understanding, or curiosity as to why something is as it is. His first step is to get the idea out in the open and express it in some reasonably manageable form. He states the problem, even if ill-defined and tentative.

Hypothesis. The scientist looks back on experience for possible solutions—his own experience, the literature and contacts with other scientists. He formulates an hypothesis, a tentative proposition about the relation between two or more variables. He says, "If such and such occurs, then so and so result

Reasoning—Deduction. The scientist deduces the consequences of the hypothesis he has formulated. He may find that the deductions formulated as consequence of his hypothesis cause him to arrive at a new problem quite different from the one with which he started. On the other hand, his deductions may lead him to believe that the problem cannot be solved with existing tech

nical tools. Such reasoning can help lead to wider, more basic, and more significant problems, as well as provide operational (i.e., testable) implications of the original hypothesis.

Observation—Test—Experiment. If the problem has been well stated, the hypotheses adequately formulated and the implications of the hypotheses carefully deduced, this next step is almost automatic for the competent investigator. To test an hypothesis is to test the relation expressed by the hypothesis, that is, the relation between the variables. All testing is for one purpose: putting the problem relation to an empirical test.

It is not the hypotheses that are tested, but the deduced implications of the hypotheses. On the basis of the research evidence, the hypothesis is either accepted or rejected.

Criteria for a Research Report

Area of the Study. The area selected leads meaningfully to some more encompassing concept or theory.

The hypothesis concerns specific problems which are capable of being solved.

The boundaries of the study are limited to practical proportions without being overly simplified to the point of being out of context to the overall problem.

Variables and terms used to identify variables are operationally defined.

Hypotheses are identified clearly and simply.

Evidence is given as to the relationship of this research to the work of others in this area.

Design of the Study. Procedures and methods used are clearly described in order to permit reproducibility. Where interview schedules or questionnaires are used, such items are included with the study report.

The overall plan of this design permits drawing a valid conclusion. Groups used for inferences are equated as to variables, or the inequalities among the groups are compensated for. The design eliminates the possibility of confusing the results or manipulating the desired variable and the results of other variables.

Assumptions underlying the study are given explicit recognition.

The plan of design permits collection of sufficient information to make reliable inferences.

The design allows equal opportunity for evidence that would prove and evidence that would disprove the hypotheses.

The methods of drawing the sample and the universe from which it was drawn are stated clearly.

The representativeness of the population studied to the population to which [illegible]e reslts are generalized is substantiated.

Consideration is given to the permanency of the results of the study.

Quantitative or qualitative measurements are appropriate for and applicable [illegible]he type of data collected.

[illegible]tatistical treatment is appropriate to the type of data collected, the popu[illegible]on and the sample involved.

The statistical results are interpreted correctly.

Evidence is given of the degree of probablility that the statistical results could [illegible]ave been chance variations or errors of measurement.

Conclusion of the Study. All conclusions are justified by the procedures used and the data obtained.

Conclusions *supported* by the data are clearly differentiated from conclusions *suggested* by the data.

The limitations imposed by underlying assumptions are readily admitted when drawing conclusions.

Personal opinions and impressions of the research worker are included only if they are identified as such.

Structure of a Research Report

The structure of a research report is relatively simple and is almost the same as the structure of the research itself: the problem, the methodology and the results. The general outline is as follows:

1. Problem
   a. Theory, hypotheses, definitions
   b. Previous research: the literature
2. Methodology—data collection
   a. Sample and sampling method
   b. How hypotheses were tested, experimental procedures, instrumentation
   c. Measurement of variables
   d. Methods of analysis, statistics
   e. Pretesting and pilot studies
3. Results, interpretation and conclusions

The statement of the general problem sets the general stage for the reader and is usually in question form. A good practice is to state the broader, general problem and then to state the hypotheses, both general and specific. All the important variables should be defined, both in general and in operational terms, giving a justification for the definitions used.

The two reasons for discussing the general and research literature related to the problem are (1) to explain the theoretical rationale of the problem and (2) to tell the reader what research has and has not been carried out on the problem and show that this particular investigation has not been conducted before.

The methodology-data collection section of the report should meticulously describe what was done so as to enable another investigator to reproduce the research, reanalyze the data and arrive at unambiguous conclusions as to the adequacy of the methods and data collection. This criterion may be difficult to meet in a published article in view of the lack of journal space; nevertheless, it remains valid, and such material should be made available in unpublished form to other researchers on request. This section should tell what samples were used, how they were selected and why they were selected. An account of the measurement of the variables of the study must be included.

An account of the data analysis methods used is sometimes included in the methodology section and sometimes in the analysis/interpretations section; in either case, the analysis methods must be outlined and justified. Where pilot studies and pretesting are used, they must be described; however, if the purpose of the pilot study was solely to try out instruments or the methodology on a small scale, little may be said.

Before writing the results and interpretations and conclusions, the author should reduce the data to condensed form, usually tables. The limitations and weaknesses of the study should be discussed. In writing this section, the question, "Do the data support the hypotheses?" must be foremost in mind, and everything written should be geared to letting the data bear on the problem and the hypotheses.

Facilities for Scientific Research

Facilities for scientific research in the institutional pharmacy should be appropriate for the type of research conducted. It is a mistake to identify the research function solely with the analytical chemistry function of the pharmacy, although the analytical equipment and facilities may be used for research. The single piece of equipment most commonly needed for research of all types is an electronic calculator.

Research Staff

Pharmacists conducting scientific research must have an adequate educational background in research methodology and in the preparation of research reports.

Summary

For institutional pharmacy to continue to be successful it must be able to adapt to an ever-increasing rate of change. The best type of scientific thinking will be required to attempt to understand these changes and to keep the profession relevant.*

SCOPE OF HOSPITAL PHARMACY RESEARCH

The hospital pharmacist who possesses adequate education and training can conduct a protracted investigation in the various scientific disciplines which comprise the profession of pharmacy. In addition, the hospital pharmacist may become involved in research pertaining to packaging, distribution, manufacture and storage of pharmaceutical preparations. There exists also the opportunity to develop new dosage forms, improve existing ones and to develop new and more accurate methods for analyzing the final product.

Some writers even suggest that the hospital pharmacist and/or the clinical pharmacist become involved, along with other members of the hospital's clinical research team, in studies on the absorption, distribution and excretion of drugs and their metabolites. The feeling being that these pharmacists possess the analytical chemical knowledge to make a worthy contribution in this type of applied research.

By the same token, many hospital pharmacists are capable of conducting a studious inquiry into problems of pharmaceutical adminis-

*(References to ASHP Guidelines for Scientific Research in Institutional Pharmacy) Anon: Statement on the competencies required in institutional pharmacy practice. Am. J. Hosp. Pharm., 32:917. (Sep.) 1975. Kerlinger, F.: Foundations of behavioral research. New York, Holt, Rinehart and Winston, Inc., 1964. p. 13. Conant, J.: Science and common sense. New Haven, Yale University Press, 1951. p. 23–27. Braithwaite, R.: Scientific explanation. Cambridge, Cambridge University Press, 1955. p. 1. Dewey, J.: How we think. Boston, Heath, 1933. p. 106–117, as adapted to the scientific framework by Kerlinger, op cit. p. 13–15.

tration, quality control, professional practice, and the sociological aspects of patient care as they relate to the practice of hospital pharmacy.

PHARMACEUTICAL SERVICES IN ACCREDITED HOSPITALS

The Joint Commission on Accreditation of Hospitals was incorporated in 1952 through a joint effort of the primary associations of North American medicine and hospitals for the purpose of encouraging the voluntary attainment of uniformly high standards of institutional medical care. The founding sponsors of the Joint Commission on Accreditation of Hospitals were the American College of Surgeons, the American College of Physicians, the American Hospital Association, the American Medical Association and the Canadian Medical Association. On December 15, 1979 the board of commissioners took the "unprecedented" action of expanding the commission by granting board membership and one voting seat to the American Dental Association. It was the first time that the board has been enlarged since the commission's inception in 1951.

JCAH STANDARDS FOR PHARMACEUTICAL SERVICES

The purpose of the Joint Commission on Accreditation of Hospital (JCAH) are:

1. to establish standards for the operation of hospitals and other health-related facilities and services;
2. to conduct survey and accreditation programs that will encourage members of the health professions, hospitals, and other health-related facilities and services voluntarily:
   a. to promote high quality of care in all aspects in order to give patients the optimum benefits that medical science has to offer,
   b. to apply certain basic principles of physical plant safety and maintenance, and of organization and administration of function for efficient care of the patient, and
   c. to maintain the essential services in the facilities through coordinated effort of the organized staffs and the governing bodies of the facilities;
3. to recognize compliance with standards by issuance of certificates of accreditation;
4. to conduct programs of education and research and publish the results thereof, which will further the other purposes of the corporation, and to accept grants, gifts, bequests, and devices in support of the purposes of the corporation; and
5. to assume such other responsibilities and to conduct such other

activities as are compatible with the operation of such standard-setting, survey and accreditation programs.

In 1965, Public Law 89-97 (Medicare) was enacted. Reference to JCAH in this law represented the confidence of Congress in the ability of the private health care sector to voluntarily assess the quality of care being provided. Written into the Medicare Act was the provision that hospitals participating in that program were to maintain the level of patient care that has come to be recognized as the norm. The standards of JCAH are specifically referred to in the law, and the Conditions of Participation for Hospitals, subsequently promulgated and published by the Social Security Administration, reflected the 1965 standards of JCAH. One result of the 1965 Medicare legislation was that hospitals accredited by JCAH were "deemed" to be in compliance with most of the federal Medicare Conditions of Participation for Hospitals and, thus, deemed to meet eligibility requirements for participation in Medicare. (The 1972 Amendments to the Social Security Act, Public Law 92-603, provide for "validation" surveys of JCAH-accredited hospitals. This means that, while JCAH-accredited hospitals continue to be deemed to meet eligibility requirements for participation in Medicare, the Secretary of the Department of Health and Human Services is authorized to validate JCAH findings, either on a selective sample basis or on the basis of substantial complaint.)

Recognizing that most of the nation's hospitals are eager to achieve a level higher than a required minimum, the Board of Commissioners, in August 1966, voted to review, reevaluate, and rewrite the accreditation standards to encourage hospitals to strive for excellence in the provision of patient care. Consequently, the standards underwent extensive revision, resulting in the 1970 edition, called, for the first time, the Accreditation Manual for Hospitals. Since then, the Accreditation Manual for Hospitals has undergone continuous review and revision to keep abreast of the state of the act.[10]

Accordingly, the following pharmaceutical service standards and their interpretations are published verbatim from the *Accreditation Manual for Hospitals 1985*.[10]

PRINCIPLE

The hospital shall maintain a pharmaceutical department/service that is conducted in accordance with accepted ethical and professional practices and all legal requirements.

Standard I

The pharmaceutical department/service shall be directed by a professionally competent and legally qualified pharmacist. It shall be staffed by a sufficient number of competent personnel, in keeping with the size and scope of services of the hospital.

The pharmaceutical department/service shall be directed by a competent pharmacist who is appropriately licensed and who is responsible to the chief executive officer of the hospital or his designee. The director should either be a graduate of a college of pharmacy accredited by the American Council on Pharmaceutical Education and be oriented and knowledgeable in the specialized functions of hospital pharmacies, or have completed a hospital pharmacy residency program accredited by the American Society of Hospital Pharmacists. Consideration may be given to graduates of foreign colleges of pharmacy who are appropriately licensed and otherwise qualified to perform the responsibilities of the job. The director may be employed full-time or part-time.

The pharmaceutical services provided shall be sufficient to meet the needs of the patients as determined by the medical staff. It is recommended that a pharmacist be available at all times. Whether this is on an on duty, on call, or consultative basis should be determined by the pharmacy work load.

When the hospital pharmaceutical department/service in decentralized, a licensed pharmacist, responsible to the director of the pharmaceutical department/service, shall supervise each satellite pharmacy or separate organizational element involved with the preparation and dispensing of drugs and with the provision of drug information and other pharmaceutical services.

The director of the pharmaceutical department/service should be assisted by additional qualified pharmacists and pharmacy supportive personnel commensurate with the scope of services provided. Nonpharmacist personnel shall work under the direct supervision of a licensed pharmacist and in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records. The duties and responsibilities of nonpharmacist personnel must be consistent with their training and experience, and they shall not be assigned duties that by law or regulation must be performed only by a licensed pharmacist. Clerical and stenographic assistance should be provided as needed to assist with records, reports, and correspondence.

The organizational structure of the pharmaceutical department/service will vary with the size and complexity of the hospital and the scope of services provided. The pharmacy shall be licensed as required.

If the hospital does not have an organized pharmacy, pharmaceutical services shall be obtained from another hospital having such services or from a community pharmacy. Prepackaged drugs then shall be stored in, and distributed from, the hospital drug storage area, under the supervision of the director of the pharmaceutical department/service. Prepackaged drugs obtained from pharmacies outside the hospital shall be identified and labeled so that recalls can be effected as necessary and the proper controls established. There shall be an approved written procedure for obtaining drugs from another hospital or community pharmacy on a routine basis and in emergencies.

Standard II

Space, equipment, and supplies shall be provided for the professional and administrative functions of the pharmaceutical department/service as required, to promote patient safety through the proper storage, preparation, dispensing, and administration of drugs.

Hospitals with an organized pharmaceutical department service shall have the necessary space, equipment, and supplies for the storage, preparation (compounding, packaging, labeling), and dispensing of parenteral products and radio-pharmaceuticals.

Drug storage and preparation areas within the pharmacy and throughout the hospital must be under the supervision of the director of the pharmaceutical department/service or his pharmacist-designee. Drugs must be stored under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security. Properly controlled drug preparation areas should be designated, and locked storage areas or locked medication carts provided, for each nursing unit as required. Drug preparation areas should be well-lighted and should be located where personnel preparing drugs for dispensing or administration will not be interrupted. The directors of the pharmaceutical department/service or his qualified designee must conduct at least monthly inspections of all nursing care units or other areas of the hospital where medications are dispensed, administered, or stored.

A record of all such monthly inspections shall be maintained to verify the following:

Antiseptics, other drugs for external use, and disinfectants are stored separately from internal and injectable medications.

Drugs requiring special conditions for storage to assure stability are properly stored. For example, biologicals and other thermolabile medications shall be stored in a separate compartment within a refrigerator that is capable of maintaining the necessary temperature. All drugs must be stored in accordance with current established standards (United States Pharmacopeia). Drugs not listed in the official compendia must be stored so that their integrity, stability, and effectiveness are maintained.

Outdated or otherwise unusable drugs have been identified and their distribution and administration prevented. The director of the pharmaceutical department/service, with the approval of the chief executive officer, shall designate one or more areas for the authorized storage of such drugs prior to their proper disposition.

Distribution and administration of controlled drugs are adequately documented by the pharmacy, nursing service, and other involved services or personnel, and are in accordance with federal and state law.

Any investigational drugs in use are properly stored, distributed, and controlled.

Emergency drugs, as approved by the medical staff, are in adequate and proper supply within the pharmacy and in designated hospital areas. The pharmacist should be responsible for both the contents of emergency medication carts, kits, and so forth, and for the inspection procedure to be used.

The metric weight system is in use for all medications. Metric-apothecaries' weight and measure conversion charts should be available to those professional individuals who may require them.

There should be a suitable area for the manipulation of parenteral medications. When laminar airflow hoods are used, quality control requirements shall include cleaning of the equipment used on each shift, microbiological monitoring as required by the infection control committee, and periodic checks for operational efficiency at least every 12 months by a qualified inspector. Appropriate records shall be maintained.

Materials and equipment necessary for the administration of the pharmaceutical department/service should be provided. Effective messenger and delivery service, when appropriate, should be provided for the pharmacy.

Up-to-date pharmaceutical reference materials shall be provided in order to

furnish the pharmaceutical, medical, and nursing staffs with adequate information concerning drugs. These should include official pharmaceutical compendia and periodicals, as well as current editions of text and reference books covering the following: theoretical and practical pharmacy; general, organic, pharmaceutical, and biological chemistry; toxicology; pharmacology; therapeutics; bacteriology; sterilization and disinfection; compatibility and drug interaction references; and other related matters important to good pharmaceutical practice in its relation to patient care. Authoritative, current antidote information and the telephone number of the regional poison control information center should be readily available in the pharmacy for emergency reference. Current federal and state drug law information should be readily available to the pharmaceutical department/service.

Standard III

The scope of the pharmaceutical department/service shall be consistent with the medication needs of the patients as determined by the medical staff.

All drugs, chemicals, and biologicals shall meet national standards of quality or shall be clearly and accurately labeled as to contents, and such information shall be disclosed to the medical staff. All drugs should be obtained and used in accordance with written policies and procedures that have been approved by the medical staff. Such policies and procedures should relate to the selection, the distribution, and the safe and effective use of drugs in the hospital, and should be established by the combined effort of the director of the pharmaceutical department/service, the medical staff, the nursing service, and the administration.

Within this framework, the director of the pharmaceutical department/service should be responsible for at least the following:

Maintaining an adequate drug supply.

Establishing specifications for the procurement of all approved drugs, and those chemicals and biologicals related to the practice of pharmacy.

Preparing and dispensing drugs and chemicals.

Preparing, sterilizing, and labeling parenteral medications and solutions that are manufactured in the hospital. There shall be an associated quality control program to monitor personnel qualifications, training and performance, and equipment and facilities. The end product should be examined on a sampling basis, as determined by the director of the pharmaceutical department/service, to assure that it meets with the required specifications. Appropriate records shall be maintained. The compounding and admixture of large volume parenterals should ordinarily be the responsibility of a qualified pharmacist. Individuals who prepare or administer large volume parenterals should have special training to do so. When any part of the above functions (preparing, sterilizing, and labeling parenteral medications and solutions) is performed within the hospital but not under direct pharmacy supervision, the director of the pharmaceutical department/service shall be responsible for providing written guidelines and for approving the procedure to assure that all pharmaceutical requirements are met. In the interest of safety of preparation and administration, and effective nutritional content, overall direction shall be provided by a qualified physician when total parenteral nutrition products (hyperalimentation) are required.

Participating in the initial orientation and subsequent in-service edu-

cation, including the provision of appropriate incompatibility information, of all personnel involved in the preparation or administration of sterile parenteral medications and solutions.

Any in-hospital manufacturing of pharmaceuticals, with proper control procedures.

Maintaining and keeping available the medical staff-approved stock of antidotes and other emergency drugs, both in the pharmacy and in patient care areas. Authoritative, current antidote information, as well as the phone number of the regional poison control information center, should also be readily available in areas outside the pharmacy where these drugs are stored.

Filling and labeling all drug containers issued to the departments/services from which medications are to be administered.

Maintaining records of the transactions of the pharmacy as required by federal, state, and local laws, and as necessary to maintain adequate control and accountability of all drugs. This should include a system of controls and records for the requisitioning and dispensing of pharmaceutical supplies to nursing care units and to other departments/services of the hospital.

Assuring the monitoring and evaluation, with medical staff input, of the quality and appropriateness of patient services provided by the pharmaceutical department/service.

Participating in the development and subsequent updating of a hospital formulary or drug list. The medical staff, through its pharmacy and therapeutics function, shall determine the hospital formulary to be used. When properly annotated, a formulary developed outside the hospital will suffice if it is maintained as a current document and if it has been approved by the medical staff. Any hospital formulary or drug list should be readily available to the professional staff who use it, and the staff should be kept informed of any changes. The formulary or drug list should also include the availability of non-legend medications. The existence of a formulary does not preclude the use of unlisted drugs, and there should be a written policy and procedure for their procurement.

Requiring and documenting the participation of pharmacy personnel in relevant education programs, including orientation of new employees, as well as in-service and outside continuing education programs. Frequency of programs and participation shall be related to the scope of the pharmaceutical services offered and shall be established with the approval of the chief executive officer.

Participating in those aspects of the overall hospital quality assurance program that relate to drug utilization and effectiveness. This may include determining usage patterns for each drug according to clinical department/service or individual prescribers, and assisting in the setting of drug use criteria. Refer also to the Quality Assurance section of the *JCAH Manual*.

Participating in all meetings of the pharmacy and therapeutics committee and implementing the decisions of that committee throughout the hospital.

Communicating new product information to nursing service and other hospital personnel, as required.

Performing an annual review of all pharmaceutical policies and procedures for the purpose of establishing their consistency with current practices within the hospital.

Maintaining confidentiality of patient/medical staff information.

Maintaining a means of identifying the signature of all practitioners authorized to use the pharmaceutical services for ambulatory care patient prescriptions, as well as a listing of their Drug Enforcement Administration numbers.

Cooperating in the teaching and research programs of the hospital.

Within the limits of available resources, the pharmaceutical department/service should provide drug monitoring services in keeping with each patient's needs. These may include, but are not necessarily limited to, the following:

The maintenance of a medication record of drug profile for each patient, which is based on available drug history and current therapy and includes the name, age, and weight of the patient, the current diagnosis(es), the current drug therapy, any drug allergies or sensitivities, and other pertinent information relating to the patient's drug regimen. This information should be available to the responsible practitioners at all times.

A review of the patient's drug regimen for any potential interactions, interferences, or incompatibilities, prior to dispensing drugs to the patient. Such irregularities must be resolved promptly with the prescribing practitioner, and, when appropriate, with notification of the nursing service and administration.

The instruction of the patient or of the appropriate nursing department/service personnel who advise the patient, verbally or in writing, on the importance and correct use of medication to be taken following discharge, in the interest of assuring safe and correct self-administration, when such instruction is requested by the responsible practitioner or as provided by written medical staff policy.

The director of the pharmaceutical department/service and staff pharmacists should be invited to participate on a regular basis in the education of medical staff and nursing service personnel in regard to drugs and biologicals in use in the hospital. This may include information on drug incompatibilities and sensitivities, on the monitoring of end-points for initial signs of toxicity or optimum drug effect, and on new drugs. Individuals who have responsibility for drug storage or administration should be instructed in the recognition of signs of drug deterioration. Greatest benefit occurs when qualified pharmaceutical department/service staffing permits the establishment of a drug information center in the hospital, which is available at all times to professional staff members.

Standard IV

Written policies and procedures that pertain to the intrahospital drug distribution system shall be developed by the director of the pharmaceutical department/service in concert with the medical staff and, as appropriate, with representatives of other disciplines.

Drug preparation and dispensing shall be restricted to a licensed pharmacist, or to his designee under the direct supervision of the pharmacist. A pharmacist should review the prescriber's order, or a direct copy thereof, before the initial dose of medication is dispensed (with the exception of emergency orders when time does not permit). In cases when the medication order is written when the pharmacy is "closed" or the pharmacist is otherwise unavailable, the medi-

cation order should be reviewed by the pharmacist as soon thereafter as possible, preferably within 24 hours.

The use of floor stock medications should be minimized; the unit dose drug distribution system which permits identification of the drug up to the point of administration, is recommended for use throughout the hospital.

Written policies and procedures that are essential for patient safety and for the control, accountability, and intrahospital distribution of drugs be reviewed annually, revised as necessary, and enforced. Such policies and procedures shall include, but not be limited to, the following:

All drugs shall be labeled adequately, including the addition of appropriate accessory or cautionary statements, as well as the expiration date when applicable.

Discontinued and outdated drugs, and containers with worn, illegible, or missing labels, shall be returned to the pharmacy for proper disposition.

Only a pharmacist, or authorized pharmacy personnel under the direction and supervision of a pharmacist, shall dispense medications, make labeling changes, or transfer medications to different containers.

Only prepackaged drugs shall be removed from the pharmacy when a pharmacist is not available. These drugs shall be removed only by a designated registered nurse or a physician, and only in amounts sufficient for immediate therapeutic needs. Such drugs should be kept in a separate cabinet, closet, or other designated area and shall be properly labeled. A record of such withdrawals shall be made by the authorized individual removing such drugs and shall be verified by a pharmacist.

There shall be a written drug recall procedure that can be implemented readily and the results documented. This requirement shall apply to both inpatient and ambulatory care patient medications.

Drug product defects should be reported in accordance with the ASHP-USP-FDA Drug Product Problem Reporting Program.

Medications to be dispensed to inpatients at the time of discharge from the hospital shall be labeled as for ambulatory care patient prescriptions.

A system designed to assure accurate identification of ambulatory care patients at the time they receive prescribed medications should be established.

Unless otherwise provided by law, ambulatory care patient prescription labels should bear the following information:

Name, address, and telephone number of the hospital pharmacy;

Date and pharmacy's identifying serial number for the prescription;

Full name of the patient;

Name of the drug, strength, and amount dispensed;

Directions to the patient for use;

Name of the prescribing practitioner;

Name or initials of the dispensing individual; and

Any required Drug Enforcement Administration cautionary label on controlled substance drugs, and any other pertinent accessory cautionary labels.

In the interest of effective control, the distribution of drug samples within the hospital should be eliminated if possible. Sample drugs brought into the hospital shall be controlled through the pharmaceutical department/service.

Standard V

Written policies and procedures that govern the safe administration of drugs and biologicals shall be developed by the medical staff in cooperation with the pharmaceutical department/service, the nursing service, and, as necessary, representatives of other disciplines.

Written policies and procedures governing the safe administration of drugs shall be reviewed at least annually, revised as necessary, and enforced. Such policies and procedures shall include, but not necessarily be limited to, the following:

Drugs shall be administered only upon the order of a member of the medical staff, an authorized member of the house staff, or other individual who has been granted clinical privileges to write such orders. Verbal orders for drugs may be accepted only by personnel so designated in the medical staff rules and regulations and must be authenticated by the prescribing practitioner within the stated period of time.

All medications shall be administered by, or under the supervision of, appropriately licensed personnel in accordance with laws and governmental rules and regulations governing such acts and in accordance with the approved medical staff rules and regulations.

There shall be an automatic cancellation of standing drug orders when a patient undergoes surgery. Automatic drug stop orders shall otherwise be determined by the medical staff and stated in medical staff rules and regulations. There shall be a system to notify the responsible practitioner of the impending expiration of a drug order, so that the practitioner may determine whether the drug administration is to be continued or altered.

Cautionary measures for the safe admixture of parenteral products shall be developed. Whenever drugs are added to intravenous solutions, a distinctive supplementary label shall be affixed to the container. The label shall indicate the patient's name and location; the name and amount of the drug(s) added; the name of the basic parenteral solution; the date and time of the addition; the date, time, and rate of administration; the name or identifying code of the individual who prepared the admixture; supplemental instructions; and the expiration date of the compounded solution.

Drugs to be administered shall be verified with the prescribing practitioner's orders and properly prepared for administration. The patient shall be identified prior to drug administration, and each dose of medication administered shall be recorded properly in the patient's medical record.

Medication errors and adverse drug reactions shall be reported immediately in accordance with written procedures. This requirement shall include notification of the practitioner who ordered the drug. An entry of the medication administered and/or the drug reaction shall be properly recorded in the patient's medical record. Hospitals are encouraged to report any unexpected or significant adverse reactions promptly to the Food and Drug Administration and to the manufacturer.

Drugs brought into the hospital by patients shall not be administered unless the drugs have been identified and there is a written order from the responsible practitioner to administer the drugs. If the drugs are not to be used during the patient's hospitalization, they should be packaged and sealed, and either given to the patient's family or stored and returned

to the patient at the time of discharge, provided such action is approved by the responsible practitioner.

Self-administration of medications by patients shall be permitted on a specific written order by the authorized prescribing practitioner and in accordance with established hospital policy.

Investigational drugs shall be properly labeled and stored, and shall be used only under the direct supervision of the authorized principal investigator. Such drugs should be approved by an appropriate medical staff committee. Investigational drugs should be administered in accordance with an approved protocol that includes any requirements for a patient's appropriate informed consent. On approval of the principal investigator, registered nurses may administer these drugs after they have been given, and have demonstrated an understanding of, basic pharmacologic information about the drugs. In the absence of an organized pharmaceutical department/service, a central unit should be established where essential information on such drugs is maintained.

Orders involving abbreviations and chemical symbols should be carried out only if the abbreviations symbols appear on an explanatory legend approved by the medical staff. In the interest of minimizing errors, the use of abbreviations is discouraged, and the use of the leading decimal point should be avoided. Each practitioner who prescribes medication must clearly state the administration times or the time interval between doses. The use of "prn" and "on call" with medication orders should be qualified.

Drugs prescribed for ambulatory patient use in continuity with hospital care shall be released to patients upon discharge only after they are labeled for such use under the supervision of the pharmacist and only on written order of the authorized prescribing practitioner. Each drug released to a patient on discharge should be recorded in the medical record.

Individual drugs should be administered as soon as possible after the dose has been prepared, particularly medications prepared for parenteral administration, and, to the maximum extent possible, by the individual who prepared the dose, except where unit dose drug distribution systems are used.

Unless otherwise provided by the medical staff bylaws, rules and regulations or by legal requirements, prescribing practitioners may, within their discretion at the time of prescribing, approve or disapprove the dispensing of a nonproprietary drug or the dispensing of a different proprietary brand to their patients by the pharmacist.

Refer also to the Anesthesia Services, Emergency Services, Functional Safety and Sanitation, Home Care Services, Hospital-Sponsored Ambulatory Care Services, Infection Control, Medical Record Services, Medical Staff, Nuclear Medicine Services, Nursing Services, Respiratory Care Services, and Special Care Units sections of this *Manual*.*

Standard VI

As part of the hospital's quality assurance program, the quality and appropriateness of patient care services provided by the pharmaceutical depart-

*Accreditation Manual for Hospitals, AMH85. Joint Commission on Accreditation of Hospitals, Chicago, Ill. 60611.

ment/service are monitored and evaluated, and identified problems are resolved.

Required Characteristics

A. The pharmaceutical department/service has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of patient care services and for resolving identified problems.
   1. The director of the pharmaceutical department/service is responsible for assuring that the process is implemented.

B. The quality and appropriateness of patient care services are monitored and evaluated in all major clinical functions of the pharmaceutical department/service. Such monitoring and evaluation are accomplished through the following means:
   1. Routine collection in the pharmaceutical department/service, or through the hospital quality assurance program, of information about important aspects of pharmaceutical services; and.
   2. Periodic assessment by the pharmaceutical department/service of the collected information in order to identify important problems in patient care services and opportunities to improve care.
      a) In B.1 and B.2, the pharmaceutical department/service agrees on objective criteria that reflect current knowledge and clinical experience.
         (1) These criteria are used by the pharmaceutical department/service or by the hospital quality assurance program in the monitoring and evaluation of patient care services.

C. When important problems in patient care services or opportunities to improve care are identified,
   1. actions are taken; and
   2. the effectiveness of the actions is evaluated.

D. The findings from and conclusions of monitoring, evaluation, and problem-solving activities are documented and, as appropriate, are reported.

E. The actions taken to resolve problems and improve patient care services, and information about the impact of the actions taken, are documented and, as appropriate, are reported.

F. As part of the annual reappraisal of the hospital's quality assurance program the effectiveness of the monitoring, evaluation, and problem-solving activities in the pharmaceutical department/service is evaluated.

G. When and outside source(s) provides pharmaceutical services, or when there is no designated pharmaceutical department/service, the quality and appropriateness of patient care services provided are monitored and evaluated, and identified problems are resolved.
   1. The chief executive officer is responsible for assuring that a planned and systemic process for such monitoring and problem-solving activities is implemented.

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2

The Hospital and Its Organization

"The hospital is a complex organization utilizing combinations of intricate, specialized scientific equipment, and functioning through a corps of trained people educated to the problems of modern medical science. These are all welded together in the common purpose of restoration and maintenance of good health.

The hospital, as an organization, provides special facilities and trained personnel to facilitate the work of the physician in his primary position involving care of the patient who is the focal point about which all activities of the hospital revolve. In the delivery of medical services to patients, therefore, the medical and associated technical staff of nurses, dietitians etc. become a most important factor. The character and extent of hospital services are adjusted continuously to keep abreast of changes and advances in medical science.

Although primary emphasis is placed on the care of bed patients, the frontier of the hospital in recent years has been extended from the sick person in the hospital bed, to the potentially sick person in his normal living situation. Hospitals have been assuming more and more responsibility for programs of preventive medicine. They serve as the medium in many communities through which the professional staffs and official health agencies pool their efforts for improvement of the public health."[1]

Because of the specific scope of this volume, only a general view of the complex organizational structure of a hospital will be presented.

CLASSIFICATION OF HOSPITALS

Hospitals may be classified in many different ways and any single institution may fall into more than one grouping. For example, the Peter Bent Brigham Hospital is a "private, non-profit, teaching hospital." The following is a brief general classification schedule which will serve to classify the great majority of hospitals.

HOSPITAL CLASSIFICATIONS

CLINICAL
General Medical & Surgical
Specialty
MEDICINE
Internal Medicine
Psychiatric & Nervous Diseases
Tuberculosis
Communicable Diseases
Pediatrics
SURGERY
Orthopedic
Gynecologic
Otolaryngologic
MATERNITY
Length of Stay
Short term
Long term (Chronic)
Custodial (Long term)

OWNERSHIP & CONTROL
Governmental
Army, Navy, Veterans Administration
Public Health Service
State
County
City
Non-Government
Private for profit
Non-profit
Church
Fraternal order
Community
Non-profit private
*BY ACCREDITATION**
Accredited
Non-accredited

*Joint Commission on Accreditation of Hospitals

What are teaching hospitals? A major teaching hospital is one which is used extensively for the clinical instruction of medical school students. A minor teaching hospital is used only for a limited amount of student instruction, such as occasional demonstrations or clinics.

Traditionally, teaching hospitals are places where the new medical graduate seeks postgraduate training. He almost always undergoes 1 year of hospital training as an intern. He may frequently spend 2 or more additional years in a hospital as a resident in some specialty, such as internal medicine, surgery, pediatrics or radiology. On the other hand, some community hospitals maintain intern and residency programs. When they exist, however, then tend to be far less complete than in the teaching institution.

Numerically, teaching hospitals represent approximately 400 of the nation's 6983 registered hospitals. However, they care for a little over one of every five hospitalized Americans.

Industry also recognizes the importance of the teaching hospital by virtue of the special coverage it receives from the company's medical service representatives as well as its desire to financially support both educational and research programs.

Because teaching hospitals act as referral centers for the more seriously ill patient, third party payors have been, in recent years, reimbursing these hospitals at a higher rate than small suburban institutions with no special programs for the care of these cases.

Most young physicians entering practice look for locations in a teaching hospital because such institutions assure them of the most contem-

porary educational opportunities coupled with broad experiences in the clinical care of patients, teaching and research.

ORGANIZATIONAL PATTERN

The organizational pattern of a hospital does not differ from that of any industrial plant. The apparent difference is superficial and deals only with the nomenclature of the positions. For example, the Director or Administrator of a hospital may be the Executive Vice-President or the General Manager of the commercial entity. Two organizational charts are presented in Figures 1 and 2. Obviously, the smaller the hospital the fewer the administrative positions of associate or assistant director and conversely, the large institutions may further sub-divide the general areas of clinical and administrative services into smaller units under the aegis of assistant directors. The corporation and the board of trustee segment of the organization is standard for all private hospitals. Governmental hospitals usually have a board of trustees but no corporate body.

GOVERNING BODY AND MANAGEMENT

Aside from licensure, most hospitals cherish recognition by the Joint Commission on Accreditation of Hospitals as "accredited" hospitals.

The Joint Commission on Accreditation of Hospitals (JCAH)[2] is an outgrowth of the *Hospital Standardization Program* established by the American College of Surgeons in 1918. Due to the fiscal drain which this program placed on the coffers of the College of Surgeons, participation by other national professional organizations was solicited in order to continue the program. In 1951, five major medical and hospital associations jointly created the JCAH. The founding members were the American College of Surgeons, the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association. The Canadian Medical Association continued its participation in the JCAH until 1959 when the Canadian Council on Hospital Accreditation activated its own program.

Recognizing that most of the nation's hospitals are eager to achieve a level higher than a required minimum, the Board of Commissioners, in 1966 voted "to review, re-evaluate, and re-write the hospitalization standards and their supplemented interpretations to attain the following two objectives":[3]

1. To raise and strengthen the standards from their present level of minimum essential to the level of optimal achievable and to assure their suitability to the state of the art.

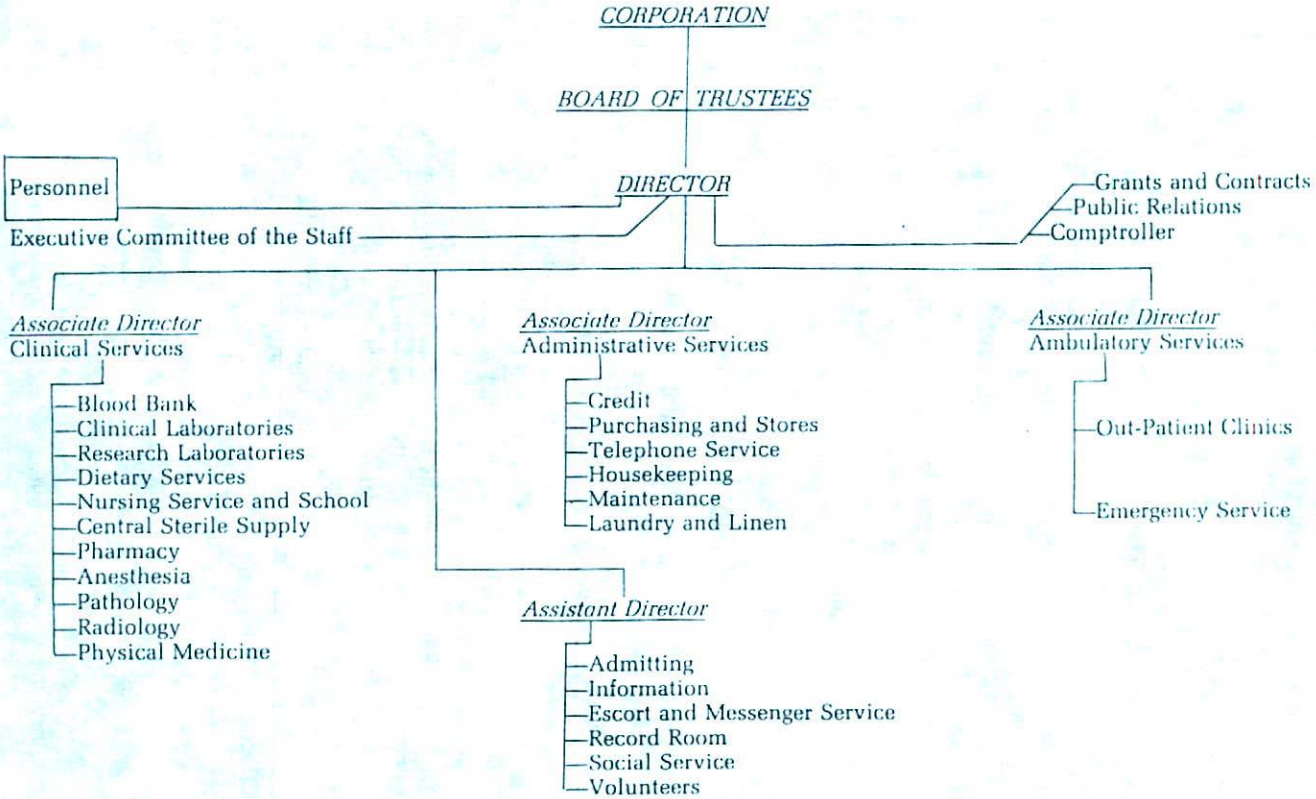


Fig. 1. Administrative Organization Chart.

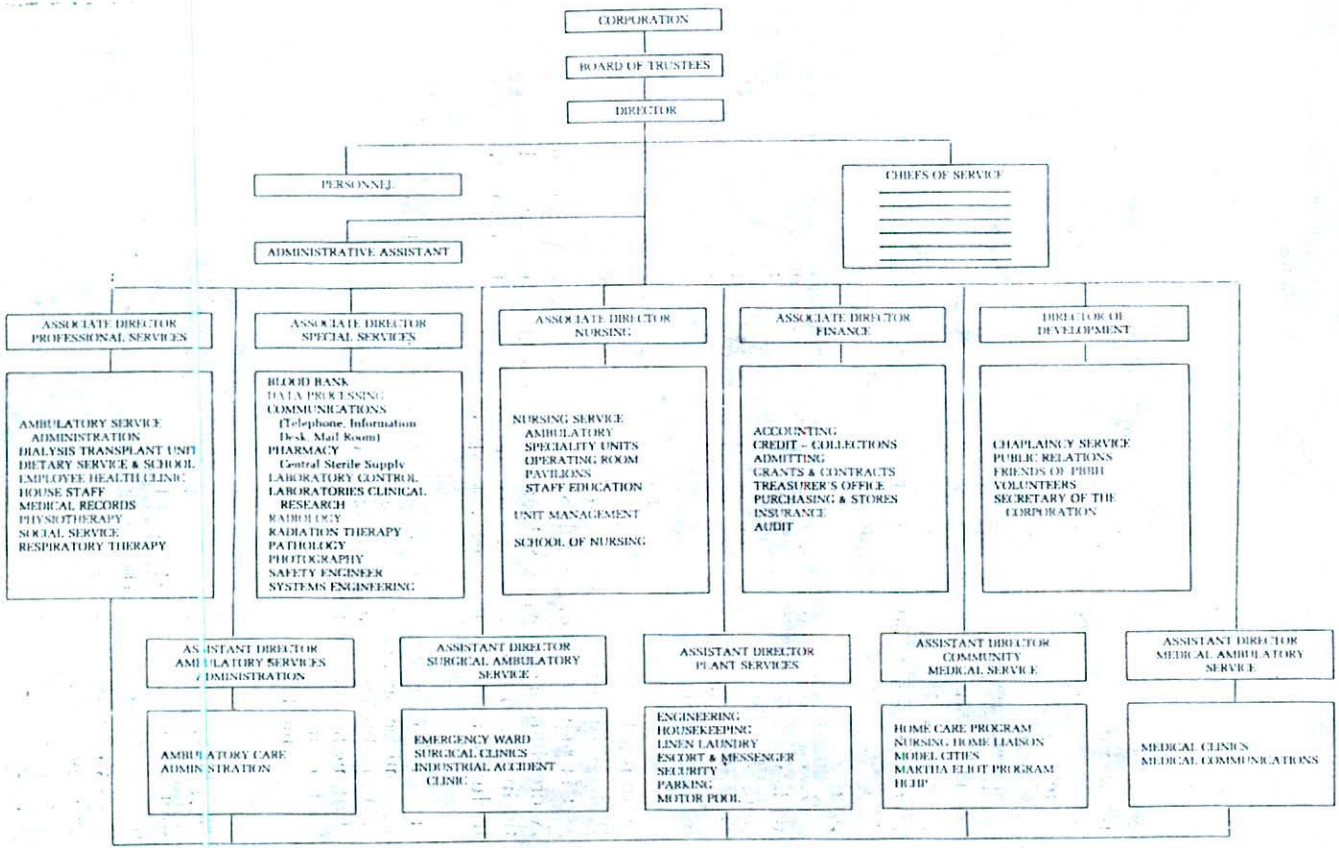


Fig. 2. Large Hospital Administrative Organization Chart.

2. To simplify and clarify the language of standards and interpretations to remove all possible ambiguities and misunderstandings.

With respect to the governing body, the JCAH adopted the following principle.[4]

There shall be an organized governing body, or designated person(s) so functioning, that has overall responsibility for the conduct of the hospital in a manner consonant with the hospital's objective of making available high quality patient care.

The resulting application of this principle is that hospitals, in general, are legally organized as CORPORATIONS according to the corporate laws of the State in which they operate, although a few of the privately owned and operated units still function under a partnership agreement. The total number of members in each corporation will vary from hospital to hospital.

Because the corporation may consist of a large number of people from widely scattered areas, a representative group, from within the corporation membership, is elected to a board of trustees. This group is also known as the governing board, board of governors, board of managers or board of directors.

Generally, the above board includes a broad representation of the community served by the hospital and its members are selected for their ability to contribute to its effective management.

It is required, both by State laws and the Joint Commission on the Accreditation of Hospitals, that the governing body adopt by-laws identifying the purposes of the hospital and the means of fulfilling them. Included in the by-laws are the following.[5]

(i) definition of the powers and duties of the governing body officers, committees and chief executive officer.
(ii) qualifications for governing body membership.
(iii) method of selection of membership.
(iv) tenure.
(v) committees—kinds, appointment and membership tenure.

The by-laws also describe the authority delegated to the chief executive officer (Director or Administrator) and to the medical staff. It should be clear to the student that such a delegation of authority does not preclude the governing body from exercising the control and authority required to meet its responsibility for the conduct of the hospital. The governing body always has the right to rescind any such delegation.

As part of the organizational process, the governing body elects its officers and causes to be appointed a wide variety of committees necessary for the discharge of its duties. These may include an Executive

Committee, Building Committee, Investment and Finance Committee and a Joint Conference Committee.

The governing body of the hospital has, through its chief executive officers, a number of obligations best exemplified by recording Standards I through X of the 1983 Accreditation Manual for Hospitals.[6]

Standard I

There shall be full disclosure of hospital ownership and control.

Standard II

The governing body shall adopt bylaws in accordance with legal requirements and its responsibility to the community.

Standard III

Governing body members shall be selected, unless otherwise provided by law, in accordance with the hospital's bylaws and, if applicable, articles of incorporation or charter.

Standard IV

The governing body shall provide for the selection of its officers, adopt a schedule of meetings, and define attendance requirements and the method of documenting governing body proceedings.

Standard V

The governing body shall provide mechanisms for fulfilling the functions necessary to the discharge of its responsibilities.

Standard VI

The governing body shall provide for institutional planning to meet the health needs of the community.

Standard VII

The governing body shall appoint a chief executive officer whose qualifications, responsibilities, authority, and accountability shall be defined in writing.

Standard VIII

The medical staff bylaws, rules and regulations shall be subject to governing body approval. This approval shall not be unreasonably withheld.

Standard IX

The governing body shall hold the medical staff responsible for making recommendations concerning initial medical staff appointments, reappointments, termination of appointments, the delineation of clinical privileges, and the curtailment of clinical privileges.

Standard X

The governing body shall require that the medical staff establish mechanisms designed to assure the achievement and maintenance of high standards of medical practice and patient care.

ADMINISTRATION

The active management of hospitals is delegated, by the board of trustees, to the administrator and his staff of associates, assistants, supervisors and department heads.

It should be noted that the Director of the Pharmacy Service (Pharmacist-in-Chief) reports to the assistant or associate director responsible for the clinical services of the hospital. Too often, the pharmacy is considered a business type of service and is assigned to the division of administrative services. Grouping the pharmacist with the housekeeper, laundry manager and maintenance group does irreparable harm to the professional stature of the pharmacist and damages his rapport with the other members of the clinical group.

The administrator of a hospital is especially trained for his position. Today, most of the new appointees to the top post in hospitals are graduates of special programs and hold the *Master of Hospital Administration* degree. The lack of such a degree does not preclude other qualified individuals from being appointed administrator. In addition, many boards of trustees require that the administrator be a *Fellow* of the American College of Hospital Administrators.

The main function of the administrator is to enforce trustee policy in the daily management routine. In addition, he is required to take all reasonable steps to assure that the hospital complies with applicable laws and regulations; establish an organizational structure to carry out the programs of the hospital and to meet the needs of the patients; to implement the governing body policy on the financial management of the hospital; and to develop and implement a comprehensive management reporting system throughout the hospital. The chief executive must also provide, maintain, and safeguard appropriate physical resources. In commenting upon the expanding role of the hospital administrator, Cordes[7] has stated . . .

". . . the hospital administrator of today must know and understand his community, its people, their historical traditions, the value structure that is at work, the resources available, and the weaknesses to be reckoned with in any course of action. Armed with this knowledge and understanding, he must educate the community to his enterprise, its goals, its problems, its needs, and its opportunities for contribution to the community. . ."

The modern hospital administrator can be described as a specialist in administration, as an educator, as a community adviser and as an

organizer. Reporting to the governing body, he bears responsibility for the operation of the entire institution, assuring the medical and scientific staffs, the trustees and the patients of the highest possible standards of both service and economy. Within the hospital he plans, directs and coordinates activities which outside the institution would be complete entities in themselves: food service, laundry, pharmacy, out-patient clinic. The future of the institution depends, in significant measure, on the vision of the hospital administrator.[8]

MEDICAL STAFF

Because the medical staff is the backbone of any hospital, it is essential that it be well organized and controlled. Accordingly, the JCAH has set forth the following *Principle* and *Standard*:[9]

> There is a single organized medical staff that has overall responsibility for the quality of the professional services provided by individuals with clinical privileges,[a] as well as the responsibility of accounting therefor to the governing body. There is a mechanism to assure that all individuals with clinical privileges provide services within the scope of individual clinical privileges granted.

Clearly, every hospital must have a medical staff that is responsible for the quality of all medical care provided to patients and for the ethical conduct and professional practices of its membership.

Generally, medical staff membership is limited to individuals who are fully licensed to practice medicine or dentistry. As a body, this group usually organizes itself to provide for the election or appointment of officers and committees whose function is to create and maintain an optimal level of professional performance of its membership.

The framework of the medical staff will vary from hospital to hospital due to the varying size and activities of the hospital and the staff. However, the staff may be divided into the following categories: active medical staff; associate medical staff; courtesy medical staff; consulting medical staff and honorary medical staff.

The active medical staff is responsible for the delivery of the preponderance of medical service within the hospital and is most involved in the organizational and administrative duties pertaining to the medical staff.

The associate medical staff consists of individuals who are being considered for advancement to the active medical staff. These practitioners are appointed and assigned to the various services in the same manner as are members of the active medical staff.

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[a]**clinical privileges** Permission to provide medical or other patient care services in the granting institution, within well-defined limits, based on the individual's professional license and his experience, competence, ability, and judgement.

The courtesy medical staff consists of practitioners who are eligible for staff membership, who are given privileges to admit an occasional patient to the hospital. Courtesy staff members may neither vote nor hold office in the medical staff organizaiton.

The consulting medical staff consists of medical practitioners of recognized professional ability who are not members of the preceding categories of staff membership.

The honorary medical staff consists of former staff members, retired or emeritus, and of other practitioners whom the medical staff chooses to honor.

CLINICAL DEPARTMENTS

The degree of departmentalization of the clinical divisions of the hospital depends almost entirely upon the degree of specialization of the medical staff. In small communities, one would expect to find two major departments in a hospital—medicine and surgery. Supportive services such as radiology and pathology are also offered but are generally limited in their capability to provide service. In those areas where there are two or more small hospitals, it is common to have a single department of pathology or radiology servicing both institutions. However, in the large metropolitan areas the hospital staff is highly specialized and therefore greater subdivisions within a particular department.

Generally, the department of medicine includes the following subdivisions:

Internal Medicine
Allergy
Cardiology
Infectious Diseases
Dermatology
Endocrinology
Geriatrics
Immunology
Pediatrics
Gastroenterology
Nephrology
Neurology
Psychiatry
Pulmonary Diseases
Rheumatology

The department of surgery is generally divided into the following:

General Surgery
Orthopedic Surgery
Neurologic Surgery
Obstetrics & Gynecology
Ophthalmology
Dental & Oral Surgery
Otolaryngology
Plastic Surgery
Proctology
Thoracic Surgery
Urology

In addition there may be a division of general practice as well as a division of physical medicine and rehabilitation within the hospital.

Each of these sub-divisions usually has a chief-of-service who in turn is responsible to the department chief. In addition, the medical staff is organized in such a manner as to provide fair representation of each individual on the staff through to the administration and the governing body.

It should be clear to the student that the larger and more specialized medical staff is indicative of the fact that the institution is a teaching hospital. Because the description "teaching hospital" has been misused, the American Hospital Association describes such an institution in the following manner.[10,11]

> A hospital that allocates a substantial part of its resources to conduct, in its own name or in formal association with a college or courses of instruction in the health disciplines that lead to the granting of recognized certificates, diplomas, or degrees, or that are required for professional certification or licensure, is a teaching hospital.

The association also placed the following interpretation on the definition:

> The allocation of resources and facilities, personnel, and funds must be adequate to demonstrate the discharge of teaching programs.

Educational programs or courses of instruction are "formal" when based upon published or recorded curricula covering specified periods of study and have faculty qualification and student admission requirements established or agreed to by the hospital. They are not work and learn or on the job training assignments that primarily augment the hospital's capability to provide services. Further, the hospital controls, or agrees to, the appointment of faculty and selection of students except during the term of agreements that gives a college or medical school exclusive authority therefore.

Certificates, degrees or diplomas must be recognized and accepted by national educational agencies, professional qualifying bodies or state approving authorities. This implies that the courses of educational programs meet standards generally recognized in the health field.

The teaching hospital affords the hospital pharmacists with innumerable opportunities to participate in and to develop educational programs. The literature is replete with articles describing endeavors by hospital pharmacists in the teaching of various subjects to student nurses, conducting inservice programs for graduate nurses and practical nurses, developing seminars on the pharmacology of drugs for interns, residents and senior staff physicians, training undergraduate and graduate students in hospital pharmacy and participating in the training of students in hospital administration.

Because of the unique training of the professional hospital pharma-

cist, he can make noteworthy contributions towards the fulfillment of the criteria required for an institution to qualify as a teaching hospital.

SUPPORT SERVICES

To those unfamiliar with the hospital environment, it would seem as though the hospital consisted of the clinical departments only. Actually, the clinical departments would not be able to function without the supporting services. Amongst the supporting services are the nursing department, the dietary service, laboratory services, the medical records department, the blood bank, the central sterile supply and the social service department.

There are other services clinically essential to the operation of the hospital such as the maintenance and engineering divisions. However, for the purpose of this text only the former will be discussed.

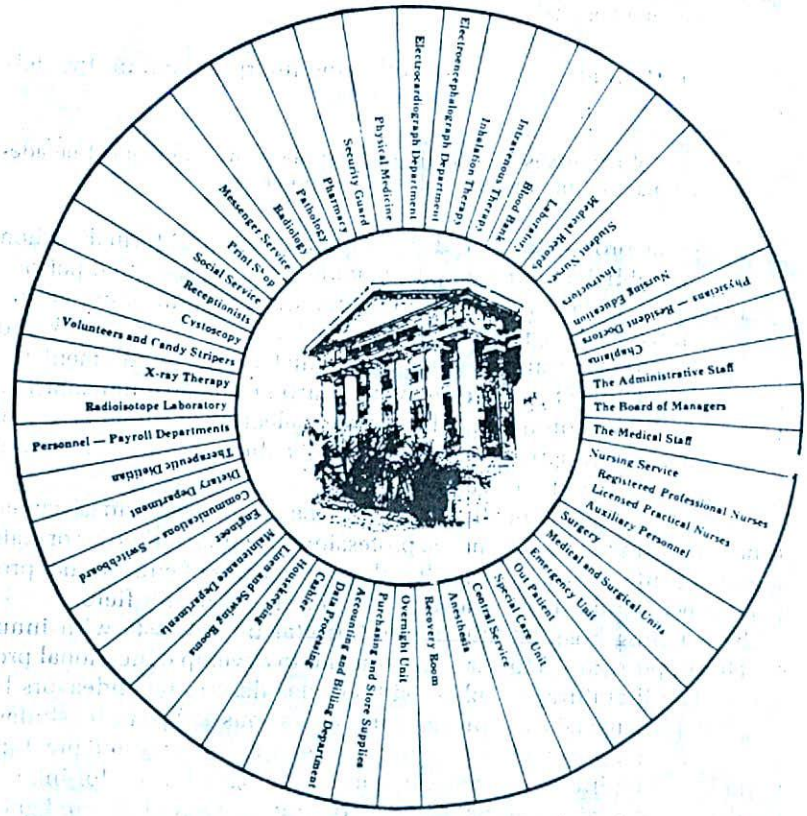


Fig. 3. The Hospital . . . A Multiple Service Unit.

NURSING SERVICE

Much has been written relative to the progress that has been made in the field of medicine during the past decade. The revolution in medical care has had its effect on the other health professions. For nursing, keeping pace with medicine has meant many changes in practice. The nursing team, made up of workers with varying degrees of nursing skill and directed by a professional nurse, now replaces the single nurse who once did everything for the patient. Today's nursing practitioner recognizes social, psychological, or religious problems with the patient that might influence his physical well being and refer those that lie outside the province of nursing to the person most competent to deal with them. Helping the patients to help themselves is another new element of nursing practice, added because of increased emphasis on self care by the patient as an aid to early recovery. The new patterns of nursing service thus brought about are often misunderstood by the public when the changes and the reasons behind them are not explained. Thus in 1964, The National League for Nursing directed a statement concerning the basic assumptions which one could make about nursing care to those engaged in various aspects of nursing service as a means of improving service wherever it is given; to allied professions because nursing care is only a part of the total health provided by many groups, whose ability to work together improves the mutual understanding; and to consumers of nursing service who, as members of the community, share the responsibility for seeing that the care necessary for regaining and maintaining health is made available to themselves and to their families. The following are the basic assumptions.[12]

1. Nursing care encompasses health promotion, the care and prevention of disease or disability, rehabilitation, teaching, counseling, and emotional support as well as the care of illness.
2. Nursing care is an integral part of total health care and is planned and administered in combination with related medical, educational, and welfare services.
3. Nursing personnel respect individuality, dignity, and rights of every person; regardless of race, color, creed, national origin, social or economic status.

The nursing service is organized similarly to any other large service in the hospital. There is at its head a Director of Nursing who is generally an experienced nurse with administrative talent. The administrative nursing services carries ultimate administrative authority and responsibility in one or more health facilities for the nursing services provided individuals and families. As a member of the administrative staff, the administrative nursing service participates in formulating policy, and

devising procedures essential to the achievement of objectives, and in developing and evaluating programs and services.

In some institutions, the Director of Nursing service is also responsible for the administration and operation of the School of Nursing. However, the modern trend is to separate the responsibility and assign it to an individual specifically trained in the educational aspect of nursing. In those institutions where the school of nursing has been separated from the nursing service, the individual heading the school assumes a position of responsibility similar to that of the Director of the Nursing Service and may be responsible directly to the Chief Executive Officer of the hospital.

DIETETIC SERVICES

An essential service of each institution is that of the dietary department. The JCAH requires that the dietetic service be organized in such a manner that it shall effectively apply the principles of the science of nutrition to the preparation of palatable and appropriate food. The services are generally directed by a qualified person and staffed by adequate numbers of dietitians and technical and clerical personnel. Qualified personnel in the dietary division are generally considered to be individuals who are registered by the American Dietetic Association or have met that Association's standards for qualification.

In addition to the purchasing, planning and preparation of menus, both for patients and employees, the dietitian is generally responsible for recording dietary histories of patients such as those with food allergies and those unable to accept a limited diet regimen; interviewing patients regarding their food habits; counseling patients and their families concerning normal or modified regimens, and encouraging patients to participate in planning their own normal or modified regimens; and participating in appropriate ward rounds and conferences.

MEDICAL RECORDS DEPARTMENT

Every hospital is required by law to maintain adequate medical records on their patients. These must be accurately documented, readily accessible and can be easily used for retrieving and compiling information.[13]

The purposes of the medical record are:

1. To serve as a basis for planning and for continuity of patient care;
2. To provide a means of communication among the physician and any professionals contributing to the patient's care;
3. To furnish documentary evidence for the course of the patient's illness and treatment during each hospital stay;

4. To serve as a basis for review, study and evaluation of the care rendered to the patient;
5. To assist in protecting the legal interest of the patient, hospital and responsible practitioner;
6. To provide data for use in research and education.

The medical record must contain all significant clinical information and should be sufficiently detailed to enable another practitioner to assume the care of the patient at any time, a consultant to give an opinion after his examination of the patient and the practitioner to give effective continuing care to the patient.

A complete medical record is one which includes identification and sociological data, personal family history, history of present illness, physical examination, special examination such as consultations, clinical laboratory data, x-ray and other examinations, provisional or working diagnosis, medical or surgical treatment, gross and microscopic pathologic findings, progress notes, final diagnosis, conditions on discharge, follow-up, and autopsy findings.

Identification data in the medical record are generally provided on what is known as the admission sheet. This sheet generally contains such perinent information as the unit record number, the patient's name, address, name of the patient's spouse, home telephone number, business telephone number, sex, date of birth, birth place, marital status, occupation, referring family physician's name and address, admission diagnosis, date and time of admission, and destination within the hospital. Attached to the admission sheet, one may generally find consent forms for the authorization for medical or surgical treatment, authorization for the release of information to insurance companies, and a general authorization for the release of information to other physicians or attorneys.

The admission history sheet usually provides space for recording the name of the informant as well as the name of the individual taking the history. The purpose of the admission history is to record the patient's chief complaint and a description of his present illness. In addition, it provides the opportunity of protecting the provisional or admitting diagnosis which is usually made on every patient at the time of admission.

The history and physical examination sheet provides the physician with such information as hospital admissions that have taken place in the past with their subsequent diagnosis, operations and major injuries that have been experienced by the patient, the history of childhood and adult infectious diseases, if applicable, pregnancies with dates, outcome and complications, immunization data, a history of transfusion with dates, reactions and complications, current medications, sociological data covering habits with alcohol or tobacco, diets, height,

weight, date of birth, country of birth, education, military history, occupational history, marital status, health of spouse, family history.

The physical examination sheet consists of a routine systematic review of skin, head and neck, cardiorespiratory, breast, gastrointestinal, urinary, genitalia, endocrine-metabolic, lymph nodes and hematological, muscular skeletal and extremities, urologic, psychiatric, and allergy.

Once the physician has obtained all of this information, he then proceeds to record in the medical record a suggested program to be followed during the hospitalization of the patient.

Signed laboratory sheets are entered into the patient's medical record. The laboratory reports include those obtained from chemistry, hematology, microbiology, serology, pathology as well as radiology. For this purpose, hospitals have a preprinted form which permits for the recording of data under each of the specific sections. However, some hospitals find it practical to paste the original laboratory reports into the medical record.

All treatment procedures performed upon the patient are recorded in the medical record. Operative notes are also included in the record and contain both a description of the findings as well as a detailed account of the technique used and the tissue removed.

Progress notes are made in the medical record for the purpose of providing the physician with a chronologic picture and analysis of the clinical course of the patient.

Upon the completion of all of the diagnostic procedures to be performed, it is mandatory that the physician enter into the medical record a definitive final diagnosis which is based on the terms specified in the standard nomenclature of diseases and operations.

Upon discharge from the hospital, the patient's record will have entered into it a discharge summary. The purpose of this is to provide a recapitulation of the patient's hospitalization. In some hospitals, a copy of this discharge summary is forwarded with the patient whenever he is transferred either to another hospital or to an extended care facility or nursing home. Some of the items contained within the discharge summary include a brief history, results of the physical examination, laboratory data, a description of the patient's hospital course, the diagnosis, the present condition, medications that have been sent with the patient, a listing of the operations performed, complications, disposition, and an estimated length of diability.

If the patient has died while in the hospital, and an autopsy has been performed, the medical record will contain a complete protocol of the findings that have resulted from the autopsy.

PATHOLOGY SERVICES

The JCAH requires that the pathology services shall be directed by a physician who is qualified to assume professional, organizational and

administrative responsibility for the facilities and for the services rendered and there shall be sufficient personnel who have had adequate training and experience to supervise and conduct the work of the laboratory. The Director of the Pathology Service is a member of the medical staff and has undertaken special training in pathology. Generally, he is certified by the American Board of Pathology or its equivalent. In addition to the cytologic and gross anatomic analysis performed within the department of pathology, most hospitals group clinical laboratories within this division. Laboratories such as clinical chemistry, microbiology, clinical microscopy, hematology, and serology are but a few examples.

BLOOD BANK

Because of the essential nature of blood as a therapeutic agent, most hospitals operate a blood bank. This service is generally under the supervision of a licensed physician who has a basic interest in hematology. However, some hospitals assign the blood bank to the department of pathology because of its laboratory-like operation. Most hospital's blood banks operate as an adjunct to the local Red Cross Blood Program.

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RADIOLOGY

One of the most important of the scientific and therapeutic facilities of the hospital is the department of radiology. Radiology is that branch of medicine which deals with the diagnostic and therapeutic application of radiant energy, chiefly in the form of roentgen rays and radium. The department is under the supervision of a qualified physician who has also obtained adequate training and experience in general radiology.

Radiology services are performed only upon the written order of a member of the medical staff who has been granted clinical privileges in the hospital. The therapeutic use of radium or sealed radioactive sources in the hospital is limited to physicians, who have been granted this privilege, after consultation with, and consideration of, the recommendations of the radiologist and/or a radiation safety committee. Only persons who have suitable training and experience are permitted to handle radioactive materials.

The department of radiology generally consists of physicians who are trained as radiologists, physicists, technicians, radiotherapists, isotopepharmacists, nurses, orderlies, and secretarial personnel.

MEDICAL SOCIAL SERVICE DEPARTMENT

The Medical Social Service Department is an important liaison between the hospital and the patient and his community. The qualified

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social worker represents a discipline whose professional focus is on the social aspects of the patient and his family. Social service personnel generally provide information relating to medical social study of appropriate patients; social therapy and rehabilitation of patients; home environmental investigations for attending physician; cooperative activities with community agencies; social service summaries; and follow-up reports of discharged patients, confirming disposition, when obtained.

ANESTHESIA SERVICE

The Anesthesia Service of a hospital is generally directed by a physician member of the medical staff who has had special training and is responsible for the following: quality of anesthesia care rendered by anesthetist in the surgical and obstetrical areas; availability of equipment necessary for administering anesthesia and for related resuscitative effects; development of regulations concerning anesthetic safety; and retrospective evaluation of all anesthesia care.

Anesthesia care is usually provided by anesthesiologists, other qualified physician anesthetist, qualified nurse anesthetist, or appropriately supervised trainees in an approved educational program. Whenever nurse anesthetists are employed, they generally provide general anesthesia under the overall direction of the departmental director or his designee.

CENTRAL SERVICE DEPARTMENT

The Central Service Department furnishes all supplies required for the nursing units. These supplies include sterile linen, sterile kits, operating room packs, needles, syringes, and other medical surgical supplies. In addition the personnel in this department clean, inspect, repair, assemble, wrap, and sterilize special treatment trays for the various nursing units. Reference to Chapter 22 will provide the student with a greater insight as to the functions of this department.

PHARMACY'S ROLE IN THE HOSPITAL

Reference to the Administrative Organization Charts (Figs. 1 and 2) will quickly support the claim that a hospital is truly a "city within a city." Within its four walls there is in operation: a hotel which manifests itself by the patient's room accommodations; a dormitory for the student nurses, residents and interns; a school for the training of nurses, technicians, dietitians; laboratories; a pharmacy; food vending operations; a laundry and linen service; housekeeping services; engineering and power generating services; delivery services; a post office; a massive

internal and external communications system; blood bank; accounting and credit services; a public relations department; a motor service and security patrols.

Although the pharmacy department is only one of the many divisions of a hospital, it exerts a great deal of influence on the professional stature of the hospital as well as upon the economics of the total operational costs of the institution because of its inter-relation with and the inter-dependency of these other services upon it.

In the community practice of pharmacy, the pharmacist is keenly aware of the doctor-patient-pharmacist triad. In this setting, the doctor diagnoses and prescribes, the pharmacist dispenses the medication and the patient administers the prescribed drug to himself or at most it is administered to him, under ordinary circumstances, by a member of his family.

This is not true in the hospital or in an extended care facility. In this setting we find interjected into the doctor-pharmacist-patient triad the professional nurse who assumes the major responsibility of administering all medications to the patient (unless the patient is on a self-medication regimen).

Clearly then, the pharmacist who practices his profession in an institutional environment must be aware of the forces operating around him, and he must learn not only to understand them, but to assist in marshalling them towards the ultimate goal of better patient care.

HOSPITAL CONTRACTUAL RELATIONS

Because of the high cost of delivering health care, governing boards of hospitals have resorted to various means of reducing operating costs. In some institutions this has been achieved via shared services agreement,[14] contract management,[15] and institutional management contracts.[16] Yet others have gone the corporate reorganization route.

SHARED SERVICES

Sharing of services offers a viable option to health care institutions in providing extensive and high-quality services in a cost-effective manner. Such services include both administrative and clinical activities. Shared services of an administrative nature can be defined as those support services that are not normally involved in the delivery of direct patient care and are not normally revenue producing. These services are easier to develop than clinical shared services programs because they do not directly involve the medical staff, have fewer external elements, and often can be implemented by the hospital's chief executive officer.[14]

Clinical shared services can be defined as those services that are

normally involved with the delivery of direct patient care, are usually revenue producing, and may have a significant impact on the financial resources of the participating institutions.[14]

Hospitals may develop and participate in various types of arrangements to organize and operate shared services programs, including:

(a) Referral service—a service maintained by one member of a group of health care institutions.
(b) Purchased service—any service for which an institution pays directly.
(c) Multisponsored service—a service jointly controlled and operated by a group of institutions generally involving a legal agreement among the sponsoring hospitals.
(d) Regional service—a service sponsored by an association of institutions through a community hospital council, a state hospital association or a special association or organization formed for a specific purposes.[14]

CONTRACT MANAGEMENT

The past decade has seen the evolution of a new industry in the health care field—contract management of the hospital's pharmacy department. A departmental management contract (DMC) is a formal agreement between a health care institution and a contractor, under which the contractor provides to the institution various management functions and which may include other services, in return for a fee.

A DMC differs from consultative services in several respects. Consultative services are most frequently specific in nature, limited in scope, and used only periodically. On the other hand, DMCs are ongoing and comprehensive, relate to day-to-day operation of a department, and combine consultation with the authority and responsibility for action and implementation.[15]

Once a contract has been agreed upon, the hospital and contractor must develop plans to ensure a close day-to-day working relationship. The initiator's management should commit itself to regular monitoring of the contractor's performance under the contract, just as it would evaluate the performance of any of its internally provided services.

Most hospital trustees and administrators believe that, with proper organization and supervision, the well-qualified department head who is provided with adequate resources should be able to equal or exceed any advantages claimed by contractors for services provided by them and, or the same time, provide additional benefits to the hospital.

Advantages of maintaining in-hospital services include—greater employee loyalty; scheduling flexibility; better interdepartment cooperation and teamwork and lower overhead costs. Advantages of contracting

for services include—reduced costs; provides skills not readily available to the hospital; improves efficiency of the department served and reduces the number on the payroll, thus lowering the cost of fringe benefits. Contractors claim that their services offer the following advantages: higher productivity, better supervision, custom designed services, familiarity with labor demands, research capability and provides equipment and supplies at a lower cost because he has the price advantage of a quantity discount.[15]

INSTITUTIONAL MANAGEMENT CONTRACTS

With tight fiscal constraints being placed on hospitals coupled with a shortage of highly trained business-type executives to management them, trustee have entered into institutional management contracts (IMCs).

The American Hospital Association defines an institutional management contract as one of many types of arrangements through which health care institutions can obtain the services of other organizations or provide services to other organizations. An IMC is a formal agreement in which a hospital or other organization contracts with the governing board of a hospital to assume the responsibility for general management of the hospital. This managing organization appoints the administrator and has overall day-to-day management authority and responsibility for the managed hospital, subject only to the direction of the governing body. Subject to the terms of the contract and local law, the managed hospital may retain total legal responsibility and ownership of the facility and its assets and liabilities.[16]

Potential contractors for this service include autonomous hospitals, tax-exempt multihospital systems, shared services organizations, investor-owned multihospital systems, hospital associations and firms specializing in management contracts.[16]

Among the reasons hospitals enter into management contracts are: economies of scale; access to specialized consultants in finance, reimbursement, and management systems; procurement of qualified management personnel; resolution of financial difficulties; and assistance in dealing with licensing, planning and related regulatory requirements.[16]

HOSPITAL REORGANIZATION

Regulatory and competitive pressures are requiring hospitals and other healthcare providers to examine their organizational structures, and to realign those structures to place themselves in a more flexible posture to compete on an as nearly equal basis as possible in a healthcare delivery system undergoing revolutionary changes.

Organizational and entity structure has come to be recognized as an important weapon in a healthcare facility's arsenal for confronting these regulatory and competitive pressures that will only intensify in the future.

As a result, institutions are now reassessing their modes of operations, and are restructuring or have restructured to protect present and future assets, develop and safeguard a wide variety of new sources of revenue, attract additional funds through philanthropy, and to raise venture and equity capital through cooperative ventures.

The pressures impelling reorganization are many but can be summarized as follows:

1. Regulatory pressures—best exemplified by the switch of Medicare/Medicaid from "reasonable cost" to "prospective payment."
2. Pronouncements by the administration that more cuts in healthcare financing are to be expected.
3. The prospective/capital payment systems have forced greater cooperation between hospitals and physicians in an effort to control costs,
4. The oversupply of physicians and hospital beds have caused sharp competition among physicians, hospitals and often between hospitals and physicians.
5. Cost conscious party payors.

The response of the industry has been a realignment of corporate structure.

Essentially, this has involved (a) the transformation of the existing hospital corporation into a parent corporation, deprived of its authority to operate a hospital; (b) the creation of a new subsidiary corporation to operate the hospital; and (c) the creation of other subsidiary corporations to operate various business enterprises.

HOSPITAL FINANCES

All too often, the hospital pharmacist lacks a thorough knowledge of the ways and means by which the operation of a hospital is financed. This situation is brought about by the pharmacist's lack of interest or his belief that it is a subject which does not concern him or his department. In reality, the finances of the hospital affect every patient, employee, staff member, trustee and the community at large.

Accordingly, the following is a brief resumé of the sources from which income may be derived to meet operating expenses.

The primary source of revenue is derived from the billing of patients for services rendered. A patient receiving such a statement may either pay it in full himself or he may have *third party coverage* which may pay the bill in full or pay a specified portion with the patient serving

as co-insurer. Since the phraseology "third party coverage" or "third party payor" is nonspecific in definition the student is reminded that it may mean that the bill, either in full or in part, will be paid by someone other than the patient. These "third party payors" may include agencies such as Welfare, Vocational Rehabilitation Services, Aid to Families of Dependent Children, Blue Cross, Medicare, Medicaid or private insurance carriers. Some of these payors pay charges as billed, while others reimburse the hospital on a fixed all-inclusive per diem rate.

HEALTH MAINTENANCE ORGANIZATIONS (HMO'S)

With the passage of the Health Maintenance Organization Act of 1973[17] Congress endorsed the Health Maintenance Organizations (HMO's) concept as a method of improving medical care efficiency. HMO's provide a uniquely competitive approach to health care delivery. The concept is based on the idea of providing comprehensive health services in exchange for prepaid annual fees. The management of HMO's and their affiliated medical staff strive to provide high quality care while eliminating wasteful and costly medical procedures. Because inpatient hospital charges constitute an HMO's largest expense, their greatest incentive is to reduce an enrollee's length of stay in a hospital.

HMO's differ from traditional fee for service insurance companies in two important respects. Insurance companies such as Blue Cross and Blue Shield reimburse hospitals and doctors for whatever medically reasonable hospital costs were incurred on behalf of the patients. HMO's on the other hand, are at risk for their enrollee's health costs; they receive a flat fee for all the medical treatments they provide. They achieve a competitive advantage by utilizing less expensive methods of treatment. The emergence of diagnostic related group (DRG) regulatory systems threaten the viability of HMO's by eliminating their competitive advantage. State-adopted DRG systems require hospitals to charge a fixed rate to all patients with similar diagnoses thereby eliminating the HMO's advantage of reducing a length of stay.[17] (See also Chapter 31, p. 663.)

DIAGNOSIS RELATED GROUPINGS (DRG's)

One of the most significant changes in health care reimbursement legislation was the passage of Title VI of the Social Security Amendments of 1983 and the implementation of a prospective payment system. This drastic change was forced upon the health care industry by spiraling inpatient hospital expenses which, at times escalated to three times the inflation factor in the general economy. The cost to the federal government of the Medicare program alone increased by 17%.[18]

It is of prime importance for hospitals to give serious study to the programs established by the federal government for the payment of Medicare claims because these represent approximately 40 to 45% of the institution's income. Additionally, private insurers will follow with similar prospective pricing programs.

A patient's health problem is described by diagnosis using one of two coding schemes: the *International Classification of Diseases Adopted, 8th Revision,* (ICDA-8), and the *Hospital Adaptation of ICDA, 2nd Edition,* (HICDA-2). These schemes classify patients with similar ailments, and allow the development of data for medical and statistical reporting, medical research and utilization review. These schemes are used to identify the various diagnoses of the patient as determined by the patient's physician. Although these methods have proved satisfactory for medical reporting purposes, there are shortcomings. For examples, other factors which affect treatment modalities are secondary diagnosis, surgery, age, prognosis, other medical procedures, and socioeconomic factors.[19]

As a result thereof, the ICDA-8 and HICDA-2 schemes have been replaced by an updated version, *International Classification of Diseases, Clinical Modification*—9th Revision—Clinical Modification (ICD-9-CM). This scheme expands and, in some cases, changes the labeling definitions and the amount of data abstracted for each patient, and as of January 1, 1979, hospitals are required to use this system when preparing discharge abstracts for Medicare and Medicaid patients.[19]

DRG's have been used in several applications requiring a measure of hospital output by case type. Currently, DRG's are being used in utilization review programs, hospital reimbursement experiments, development of a case mix index and to ascertain cost per case limits.

TAX EQUITY AND FISCAL RESPONSIBILITY ACT (TEFRA)

Because of what health care economists perceive as continued escalation of medical care costs, the federal government undertook a regulatory approach to change the retrospective payment system. The established goals for such a changeover were: (1) to provide immediate restraints on the growth of federal payments for health care, (2) to correct the instability of the Medicare Hospital Trust Fund, (3) to provide reliable predictions of expenditures in order to stabilize budgetary predictions, (4) to encourage beneficiaries to be cost conscious and (5) to be easy to administer and understand.[20]

The result was the passage of the Tax Equity and Fiscal Responsibility Act (TEFRA) in August 1982. The new law restructured Medicare payment for hospital inpatient services to include not only routine operating costs, but also ancillary and special care unit services, establishing

control over total inpatient costs, excluding capital and direct teaching costs. The method of calculating these costs was changed and is now based on a hospital's average total cost per case, rather than the average cost per diem. Thus, reimbursement is no longer dependent on the length of stay; instead, it has become a fixed payment per patient based on discharge diagnosis. Accordingly, hospital pharmacies will be affected and pharmacists will need to work closely with the administration and physicians to lower costs.

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3

The Pharmacy—Its Organization and Personnel

A number of years ago, Francke *et al.*[1] stated:

"The dispensing function of the pharmacist, while important and even vital, is essentially a superficial practice of the profession which, by itself, does not require knowledge or skills basic to merit professional recognition to the depth that lies within the grasp of hospital pharmacists."

Clearly, the above observation was a forecast of pharmacy's future new role for, less than a decade later, pharmacists have assumed important new roles—those of clinical pharmacist and drug consultant. To be able to assume these positions, it has become necessary to alter the pharmacist's educational program and work habits.

The *Task Force on Prescription Drugs*[2] made the following comments on the new role of pharmacy:

"The pharmacy profession currently faces a dilemma which is partly though not entirely of its own making. Many other aspects of health care—the practice of medicine and surgery, hospital operations and particularly drug manufacture—have developed and adopted new devices and techniques which have remarkably improved the provision of health services. In contrast, the number of important new methods introduced to enhance the efficiency of retail pharmacy operations, at least during the past two or three decades, has not been noteworthy . . ."

The role of the community or retail pharmacist is viewed by many people as simply transferring pills from a large bottle to a small one—counting tablets, typing labels and calculating the price. Much of his time is seen as devoted to routine merchandising of cosmetics, shaving supplies, stationery and other commodities which have little or no relationship to health care.

This has raised doubts concerning the relevance of modern pharmacy education. As with other members of health professions, on the one hand, it would seem that much of the traditional education is not utilized, since a nonprofessional person—working under the supervision of a licensed pharmacist—can effectively perform many of the

routine tasks of counting, labeling and pricing. At the same time, many pharmacists are seeking a new role as drug information specialists, and thus their formal education has taken this into account.

SUPPORTIVE PERSONNEL

Experience in numerous pharmacies—military and hospitals—has demonstrated that individuals without formal pharmacy education can effectively undertake many of the routine activities of pharmacists, under the supervision of a licensed pharmacist. Such activities have stimulated many hospitals to develop training programs to meet this need. In recognition of this development, the ASHP distributed the following Statement on Supportive Personnel in Hospital Pharmacy.[3]

ASHP STATEMENT ON SUPPORTIVE PERSONNEL IN HOSPITAL PHARMACY[a]

The increasing complexity of health care in the modern hospital is creating ever greater demands for the hospital pharmacy to broaden its scope of services. New health care legislation and rapid changes in health care technology are imposing new demands on hospital pharmacy which result in a need for increased manpower. These demands dictate for the hospital pharmacist a multifarious role which he can assume only when there is an adequate number of personnel within the pharmacy.

There is a growing concern about the present shortage of hospital pharmacists and an even greater concern about future shortages. The scope of pharmaceutical services being provided in most hospitals is limited largely by personnel shortages. Studies have indicated that many of the tasks performed in today's modern hospital pharmacy could be delegated to supportive personnel under the supervision of a pharmacist and, in fact, such personnel have long been used in most hospitals.

If the hospital pharmacist could be freed to a greater extent from performing routine tasks which could be delegated with supervision to trained supportive personnel, he would be able to direct more of his attention to professional tasks only, thereby expanding professional pharmacy service in the interest of patient care. Other professions—notably medicine, nursing, and dentistry—are in the process of delegating more and more functions to technicians and to other supportive personnel. Hospital pharmacy must do likewise if it is to keep pace

[a]Approved by the ASHP Board of Directors October 26–27, 1970 and by the AACP Executive Committee December 1970.

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with progress in the health field, meet the growing demand for hospital pharmacy manpower, make maximum use of the hospital pharmacists' unique body of knowledge, and provide an opportunity for developing a scope of pharmaceutical services yet undefined and unrealized in the institutional setting.

Observations

Careful consideration of this subject by representatives of the American Association of Colleges of Pharmacy and the AMERICAN SOCIETY OF HOSPITAL PHARMACISTS has led to the following observations:

1. Previous and current studies indicate a growing shortage of professional hospital pharmacy manpower now and in the future.
2. The performance by pharmacists of duties which might appropriately be assigned to supportive personnel results in a dilution of pharmaceutical talents and limits the scope of pharmaceutical services provided.
3. Supportive hospital pharmacy personnel are used in most hospitals today.
4. The accelerating development of expanded professional services by the hospital pharmacy emphasizes the need for supportive personnel to assume many of the routine, nonjudgmental duties traditionally associated with the delivery of pharmaceutical services.
5. There is a need to recognize and define several different levels, or categories, of supportive hospital pharmacy personnel.
6. There is a need to define those functions and responsibilities which can be assigned to each category of supportive hospital pharmacy personnel, as differentiated from those which can be carried out only by the pharmacist.
7. There is a need to define training requirements and to develop training programs for each category of supportive hospital pharmacy personnel.
8. There is a need to standardize nomenclature used in referring to supportive personnel in hospital pharmacy.

Recommendations

Based on these observations and consistent with the developments of pharmacy practice in hospitals, it is recommended that:

1. The term "supportive personnel" be adopted as standard nomenclature to be used in referring collectively to all nonprofessional personnel.
2. The American Association of Colleges of Pharmacy and the AMERICAN SOCIETY OF HOSPITAL PHARMACISTS give priority considerations to adopting standard nomenclature to be used in referring to the different levels, or categories, of supportive personnel.
3. The American Association of Colleges of Pharmacy cooperate with the AMERICAN SOCIETY OF HOSPITAL PHARMACISTS in developing hospital-based training programs for hospital pharmacy supportive personnel with consideration being given to the potential role of academic institutions and to the experiences of existing training programs.
4. The American Association of Colleges of Pharmacy continue to provide

consultation to the AMERICAN SOCIETY OF HOSPITAL PHARMACISTS to the development of training programs.

5. The American Association of Colleges of Pharmacy and the AMERICAN SOCIETY OF HOSPITAL PHARMACISTS support and participate in, where possible, projects defining the roles of, and the training requirements for, supportive personnel in hospital pharmacy.

Livengood and associates[5] conducted a regional survey to determine the utilization of hospital pharmacy supportive personnel. The survey showed that, within the region, a high percentage of the hospitals (92.4%) utilize pharmacy technicians and that, on the average, there is approximately one technician employed for each pharmacist.

PHARMACY SPECIALISTS

Major teaching hospitals require a diversified pharmacy staff. Professional personnel include clinical pharmacists (Chapter 11) and Drug Information Specialists (Chapter 25). The area of clinical pharmacy has undergone rapid change and its practitioners have undertaken to specialize in the sub-medical specialties of psychiatry, geriatrics, oncology, nuclear medicine and pediatrics. The ASHP has developed the appropriate supplemental standards and learning objectives for residency training in the sub-specialties of clinical pharmacy (Chapter 26).

Residencies in these specialties are defined as postgraduate programs of organized training that meet the requirements set forth and approved by the ASHP. The ASHP Accreditation Standard for Specialized Residency Training[6] together with special supplemental standards for each specialty are the basic criteria used in evaluating and accrediting these programs. For examples, see Chapter 26.

DRUG INFORMATION SPECIALISTS

At the other end of the spectrum, it is also becoming evident that appropriately trained pharmacists may become new and vital members of the total health team by serving as drug information specialists. Some hospitals—especially teaching institutions and those in major medical center complexes—are already using pharmacists as consultants on drug therapy. They serve not only as drug distributors, but also as sources of drug data for physicians, interns, residents and nurses. They may participate in ward rounds with the staff, providing valuable drug information on both old and new drug products. Although they do not prescribe for patients, they enable the physicians who do prescribe to keep up more effectively with drug information. While some pharmacists are already serving as drug information specialists, and others are probably competent to do so, not all pharmacists have adequate competency in this field. Some licensed pharmacists have received 5

or even 6 years of formal college training, but about 15% of those now in practice have received 2 years or less of formal pharmacy education, and nearly half of these have had courses lasting only about 5 months.

PHARMACY EDUCATION

The manner in which pharmacists, pharmacy associations, pharmacy schools and the pertinent state pharmacy agencies repond to increasing demands for pharmaceutical services will unquestionably determine in large measure how the pharmacy profession will evolve during the years to come. As a guide to the responses which should be made, there is a clear need for a broad study of pharmacy education similar to the famed Flexner study of medical education made half a century ago.

The Task Force therefore recommends that the Bureau of Health Manpower should support—

(a) The development of a pharmacist aid curriculum in junior colleges and other educational institutions.

(b) The development of appropriate curricula in medical and pharmacy schools for training pharmacists to serve as drug information specialists on the health team.

(c) A broad study of present and future requirements in pharmacy, adequacy of current pharmacy education, and the educational changes which must be made.

The department of pharmacy is typical of the majority of other departments in the hospital in that, depending upon its size and services rendered, it employs both professional and lay personnel. Therefore, it behooves the administrator or his pharmacist to ascertain the necessary number of employees in each category which will be required to render safe and prompt service. In addition, due to legal criteria the duties and responsibilities of each category of employee must be quite clearly defined.

JOB DESCRIPTIONS

The federal government, in a 1952 publication,[8] has clearly and adequately provided us with job descriptions for the positions of "Chief Pharmacist," "Pharmacist" and "Pharmacy Helper." Accordingly, the following is a direct excerpt of the job summary and performance requirements for the position of chief pharmacist.

"Compounds and dispenses medicines and preparations according to prescriptions written by physicians, dentists, and other practitioners authorized by law to prescribe. Prepares and sterilizes injectable medication manufactured in hospital, and manufactures pharmaceuticals. Furnishes information concerning medications to physicians, interns, and nurses. Plans, organizes, and directs pharmacy policies and procedures in accordance with established policies of

hospital. Implements decisions of pharmacy and therapeutics committee of which he is a member. Performs related duties.

PERFORMANCE REQUIREMENTS

"RESPONSIBILITY FOR: Preparation and sterilization of injectable medication manufactured in hospital; manufacture of pharmaceuticals; dispensing of drugs, chemicals, and pharmaceutical preparations; filling and labeling of all drug containers issued to services; inspection of all pharmaceutical supplies on all services; maintenance of an approved stock of antidotes and other emergency drugs; dispensing of all narcotic drugs and alcohol and maintenance of a perpetual inventory of them; specifications for purchase of all drugs, chemicals, antibiotics, biologicals, and pharmaceutical preparations used in treatment of patients; furnishing information concerning medications to physicians, interns, and nurses; establishment and maintenance, in cooperation with accounting department, of a system of records and bookkeeping in accordance with policies of hospital for charges to patients, and control over requisitioning and dispensing of drugs and pharmaceutical supplies; planning, organizing, and directing pharmacy policies and procedures in accordance with established policies of hospital; cooperation in teaching courses to students in school of nursing and in medical intern training programs; implementing decisions of pharmacy and therapeutics committee; and preparation of periodic reports on progress of department.

"Accuracy in use of chemical and pharmaceutical equipment for compounding and dispensing drugs and medicines. Follows prescription in details, and is accurate in labeling of containers and indicating directions for use."

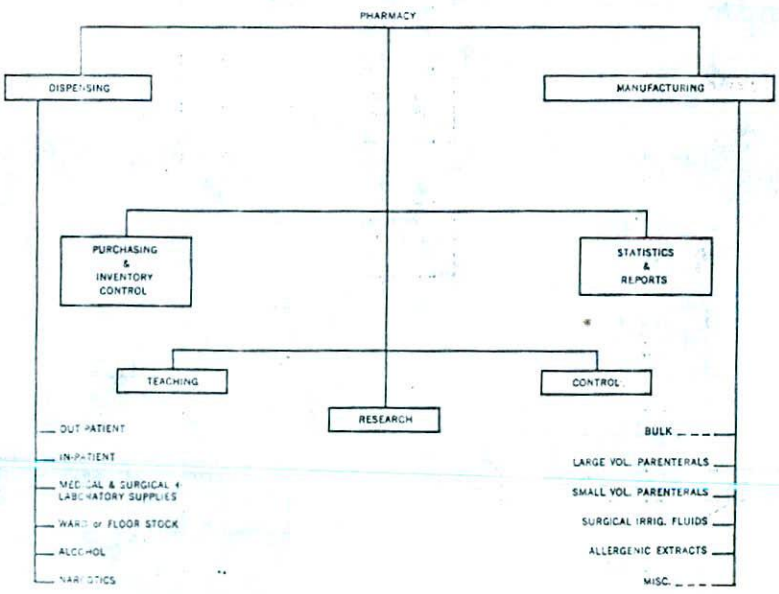


Fig. 4. Departmental activity chart.

DETERMINING THE DEPARTMENTAL STAFF—PROFESSIONAL

The number of professional and lay employees necessary cannot be determined until some thought has been given to the scope of service to be rendered. Is the department to serve in-patients only? How many? Is there to be any out-patient service? If so, how many patients per day? Is there to be a manufacturing section of the pharmacy? Is the pharmacy going to stock and dispense surgical and laboratory supplies?

Once these questions are answered, the pharmacist must then determine which of the duties must, by law, be assigned to pharmacists and those which are within the scope of reasonably intelligent lay personnel who are herein referred to as pharmacy helpers.

In order to understand and to ascertain the personnel requirements, it is recommended that the department's major activities be dia-

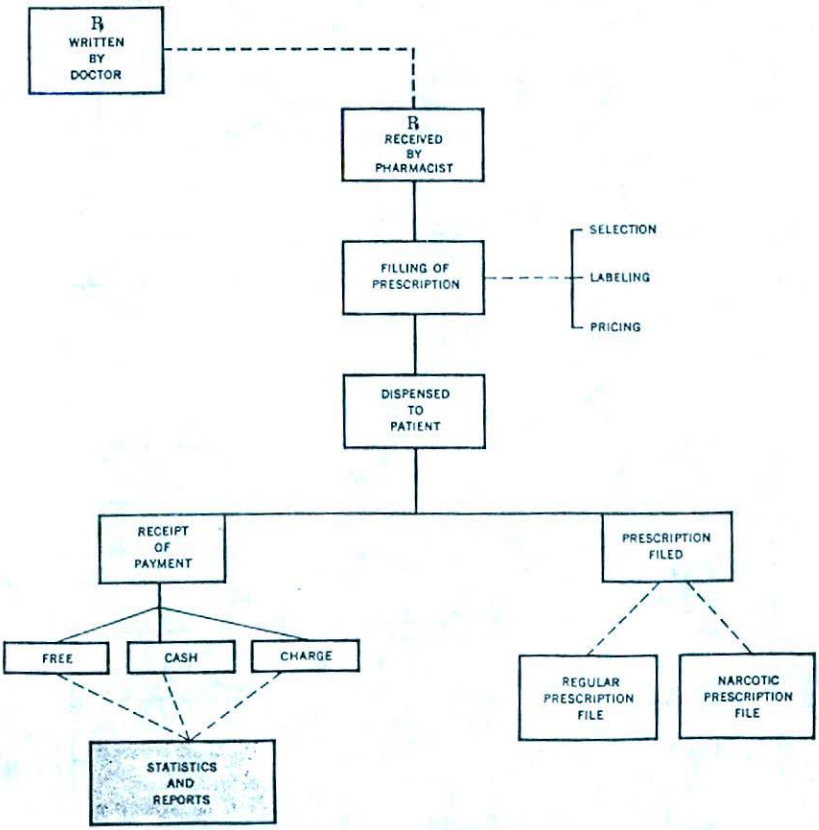


Fig. 5. Out-patient activity chart.

grammed. Examples of such a process are provided in Figure 4 which represents the over-all functions of a department of pharmacy in a university teaching hospital, Figure 5 which briefly presents the activity involved in the dispensing of an out-patient's prescription and Figure 6 which provides a diagrammatic representation of the various processes involved in accommodating in-patient drug needs.

Once these charts are prepared, the hospital pharmacist is ready to evaluate the job, so diagrammed, through the preparation of a Flow Process Chart, Figure 7. By so doing, the pharmacist will be able to evaluate the time and motion involved in the performance of each job in the department. In addition, he will have a unique opportunity to utilize more efficiently the time of his personnel through simplification of the job by applying to it the various interrogatories of work simplification, namely:

What is its purpose?
Why is it necessary?

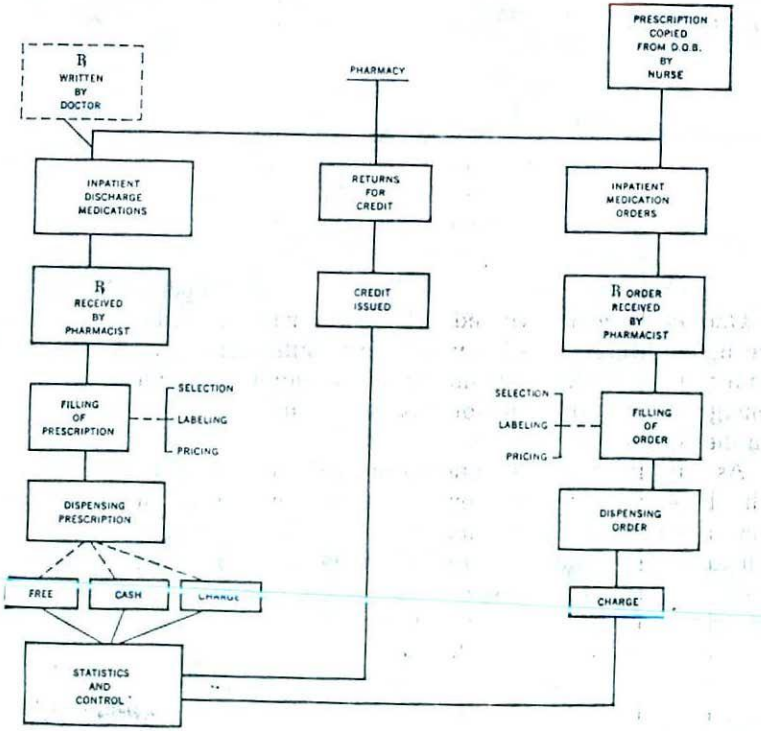


Fig. 6. In-patient activity chart.

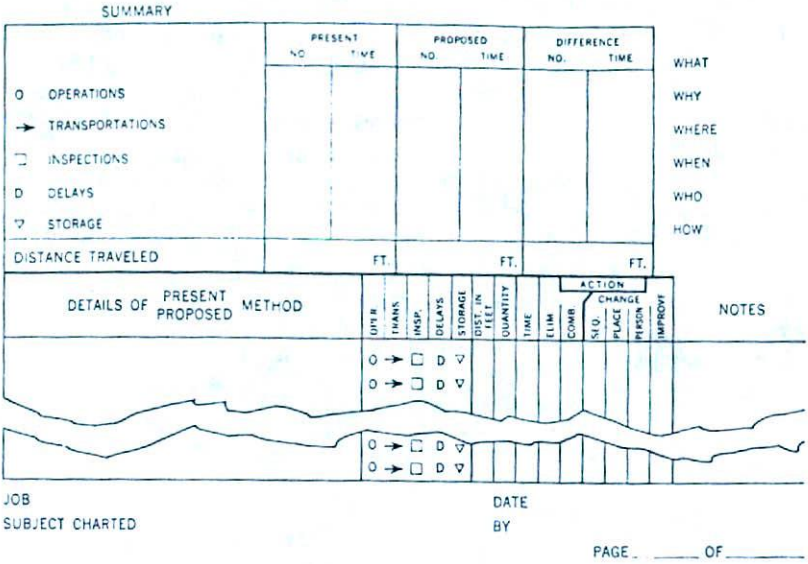


Fig. 7. Flow process chart.

Where should it be done?
When should it be done?
Who should do it?
How should it be done?

Once each detail involved in the performance of a particular job has been challenged, each job will become sufficiently streamlined so as to require a minimal expenditure of the employee's time, motion, and energy thereby providing for maximal production without any increase in the labor force on hand.

As a result of the preparation of these flow charts, the pharmacist should be in a better position to visualize the volume of activity in each category as well as the number of assistants necessary to dispense the medications and supplies to the correct area in the hospital.

There are no standard rules for the staffing of a hospital pharmacy which can be quoted. However, in the publication *Mirror to Hospital Pharmacy* the following reference to staffing is made.[9]

"... in hospitals with from 100 to 500 beds and over, about 100 to 150 prescriptions or orders are processed daily for each full-time pharmacist employed. While it is difficult to make precise comparison of this workload with those reported by others, the number of prescriptions and requisitions filled falls within the range of those handled in pharmacies of the Public Health Services. For example, a report by Archambault (Division of Hospitals Bulletin No. 60–86 [1960]), states that the Pharmacy Branch considers a daily measurable workload

of from 125 to 190 units plus a normal amount of non-measurable activities as reasonable for a pharmacist working with adequate non-professional assistance in hospitals utilizing 6 or less pharmacists. A daily range of 126 to 158 units per pharmacist is considered normal by Archambault for the one- or two-man pharmacies, while 168–181 units per man is considered normal in pharmacies employing 3 to 5 pharmacists."

Those individuals who are desirous of using the above quoted standards are reminded that the work units employed in the Public Health Service include a number of bulk compounded and pre-packaged items, as well as prescriptions and requisitions. In addition, the authors point out that the above standard omits consideration of a number of non-measurable workloads as well as the effect of non-professional assistance to the pharmacist.

Jeffries and Greenberg[10] in their study on prescription pricing, state that the average time required for the proper dispensing of a noncompounded prescription is 8 minutes and that 14 minutes is required for a compounded prescription.

Because the dispensing pattern within the hospital differs from that employed in the retail practice of pharmacy, a personally conducted survey of the dispensing time in the hospital pharmacy of a 300-bed teaching hospital was conducted. The results showed that a pre-packaged medication could be dispensed in an average time of 4 minutes (which coincides with the arbitrarily selected time of 4 minutes referred to in the *Mirror to Hospital Pharmacy).*[9] Accordingly, it should not be too difficult to ascertain the workload within the pharmacy and thereby arrive at the approximate number of pharmacists required. If this system is used, the reader is again cautioned to take into consideration the fact that not all of the services rendered by the pharmacist are reflected in the prescription or order workload. Time must be provided for administrative work, purchasing, teaching, sick time, and vacation time, to mention a few.

The following table, which may serve as a guide to those contemplating using this method of ascertaining staff needs, is reproduced from the *Mirror to Hospital Pharmacy.*[9]

Daily In-Patient Workload per Pharmacist

Bed Capacity			
Short-Term	*Prescriptions*	*Other Orders*	*Combined Work Load*
Under 50	10	10	20
50–99	45	17	62
100–199	96	44	140
200–299	101	50	151
300–399	100	52	152
400–499	89	38	127
500 and Over	61	35	96
Long-Term			
All sizes	39	38	77

Some investigators[11] have explored the applicability of the *queuing theory* as a mathematical tool in scheduling the pharmacist manpower needs of a hospital out-patient pharmacy. To apply this theory, it is necessary for the pharmacists to maintain time records to indicate "time in," "time start" and "time finish" or various types of prescriptions. The difference between "time in" and "time finish" is the waiting time (queue) of the patient.

Liebman *et al.*[12] suggest that the essential result of the use of the queuing theory is that the number of pharmacists on duty in the out-patient pharmacy should be synchronized to the fluctuations in the prescription order arrival rate.

With the introduction of clinical pharmacy activities into the institutional setting, the time spent on the product oriented services has decreased in favor of time devoted to clinical activities. This was borne out by a task analysis of a pharmacist's activities in a 45-bed rural hospital with comprehensive pharmaceutical services. The study[14] showed that almost one-third of the total work time was spent in clinical pharmacy activities. A major distinction between the activities of the pharmacist offering comprehensive services and those providing product-oriented services was the difference in the nonproductive amount of time. The latter group averaged 52.1% of its day in nonproductive time while the pharmacist in this study was nonproductive only 15% of the time.

DETERMINING THE DEPARTMENTAL STAFF—LAY PERSONNEL

Personnel falling into this category are secretarial or clerical workers, delivery men and hospital pharmacy technician-helpers.

The functions of secretarial or clerical workers would appear to be quite well defined and require no description here. Ascertaining the number of people required will depend on the amount of purchasing, inventory control and accounting procedures which are assigned to the pharmacy. Other factors which influence the need for secretrial assistance are the number of hospital committees upon which the pharmacist serves as secretary, the frequency of departmental publications such as pharmacy bulletins, frequency of updating the formulary, whether or not literature files are maintained and whether or not the pharmacist is active in teaching and research programs within the hospital.

Small hospital pharmacies usually have no need for delivery services or hospital pharmacy technician-helpers. The larger the unit, the more the need for this category of employee becomes. It can and has been argued that with modern means of communication, vertical conveyor systems and pneumatic tube devices, the pharmacy has little or no need for a delivery service. This is a sound argument and may be perfectly valid in departments which are located in new buildings with all of

the above refinements. But even in those departments, certain types and sizes of products must be transported by human beings. If the volume is not great, the pharmacist may arrange to share the services of one messenger with other departments or may utilize the services of the *central transport* and *messenger service* of the hospital, if one exists. If, on the other hand none of the above mentioned modern conveyance devices are available, then the need for human transporters becomes obvious. Because of the shortage of nurses, pharmacists, technicians and other specially trained personnel, they should be spared the inconvenience and waste of time picking up and delivering supplies. Oftentimes hiring a delivery staff saves countless man-hours throughout the hospital.

Because of the acute shortage of pharmacists in many areas of the country, many hospitals have been forced to utilize hospital pharmacy technician-helpers.[13] As this trend developed, it became evident that some standards for such a category of personnel were needed. Thus, the Joint Committee on Hospital Pharmacy of the American Society of Hospital Pharmacists and the American Association of Colleges of Pharmacy met and agreed upon the following.[13a]

1. The worker classificaiton of hospital pharmacy technician-helper exists in most hospitals today;
2. There may be a need for more formal methods of training to improve the quality and quantity of technician-helpers;
3. Recent publications stress the dilution of pharmaceutical talents resulting from the performance of non-professional duties by pharmacists;
4. Previous and current studies indicate the possibility of a grave shortage of professional manpower in the near future;
5. Attempts to establish similar programs in the past resulted in emotional outbursts which damaged professional unity.

It was also the consensus that the details of such a training program should be developed by the American Society of Hospital Pharmacists because of the unique need of this type of employee within the hospital.

The use of hospital pharmacy technician-helpers is strongly advocated only if they are properly trained and supervised. It should be clear that these people may not perform a "dispensing act" for this would be in violation of a majority of the state pharmacy codes.

As has been previously stated, there is in existence a need for supportive personnel in hospital pharmacy to assist in the newer programs of strip packaging, unit of use distribution systems and intravenous additive programs. However, no definitive guidelines for this type of personnel were available until the American Society of Hospital Pharmacies released its original *Statement on Supportive Personnel in Hospital Pharmacy* and subsequently its Competency Standard for Phar-

macy Supportive Personnel in Organized Health Care Settings which is reproduced[17] on page 61.

Beahm[15] in a study regarding the use of non-licensed personnel in pharmacy has reported that it is possible to ascertain which functions normally performed by a pharmacist may be done by a technician, those which may be done by a technician under supervision, and those which a technician is forbidden to do.

Among those which a non-licensed person is prohibited from doing are the following: take telephone orders for prescription refills from patients, weigh or measure ingredients to be used in compounding prescriptions, mix ingredients, already weighed or measured, to compound prescriptions, calculate percentages in prescription compounds, take telephone orders for new prescriptions, affix prescription labels to medication containers, provide information on use, precautions etc., to patients and professional personnel.

Those functions that may be done under supervision are as follows: type labels from prescription orders to be later attached to containers by pharmacist, assemble prescription ingredients immediately prior to pharmacist's filling of order, pre-package prescription drugs, print labels for pre-packaged drugs, affix pre-printed labels to containers of pre-packaged drugs, pre-package solid dosage forms in single unit packages, pre-package injectable dosage forms in single unit packages, prepackage all liquids in single unit packages, order and check in pharmaceuticals, calculate prices for prescriptions dispensed by pharmacists, maintain family prescription records, package finished dosage forms immediately prior to pharmacist's checking of prescription, weigh and measure ingredients in bulk compounding of pharmaceuticals, maintain narcotic drug inventory records, maintain drug inventory records.

Non-licensed personnel may perform the following duties independent of pharmacist's supervision: locate prescription order and file immediately prior to pharmacist's filling of prescription, routinely inventory supplies and re-stock prescription items, calculate the prices for prescriptions dispensed by pharmacists, clean bulk manufacturing and pre-packaging equipment, clean other prescription equipment, deliver prescription drugs to physicians and nurses in hospital or office for professional use, deliver prescriptions to patients but refer any quesitons to pharmacists, bill patients and/or third party and pay pharmacy accounts.

Although the foregoing classification is based upon responses from societies of hospital pharmacists, responses from colleges of pharmacy as well as boards of registration in pharmacy, it did not coincide with the entire breakdown. The variation in response relative to technician utilization in the various activities covered by the survey may have

been due to the tradition of certain activities in hospital and/or community practice.

Unfortunately there are no reliable criteria whereby a formula may be arrived at which, when properly applied to a set of statistics, will reveal the magic number of pharmacy helpers required in any given situation. This, then, requires some serious planning and evaluation on the part of the pharmacist-in-chief.

PROFESSIONAL SERVICES RENDERED

The primary function of the hospital pharmacist is to dispense drugs to the in-patients and out-patients where hospital policy permits. However, there are a large number of important ancillary areas of pharmacy in which the pharmacist should exercise his skills. Again, depending upon the size of the hospital, the pharmacist may develop such areas as bulk compounding, sterile product manufacturing, control laboratory, distribution of laboratory and medical and surgical supplies, as well as expanding his role as a teacher, drug consultant and clinical pharmacist. Another service worthy of consideration is the after-hour pharmacy service which will be discussed later under methods of drug distribution.

The bulk compounding and sterile manufacturing program are two areas which offer the hospital great financial savings and the pharmacist pride and prestige. These two areas will be discussed in greater detail in a later chapter.

CHARTING OF PHARMACY ORGANIZATION

With the selection and categorizing of the employees, it now becomes essential to develop a chart showing the flow of administrative authority. Obviously, in the very small departments, this is usually generally understood and no problems arise. However, in the large units with assistant chief pharmacists, supervisors, and lay personnel, authority must be delegated by the chief pharmacist.

Sample distributions are depicted in Figures 8 and 9. Clearly this can and should be tailored to meet the specific requirements of the department and hospital. Once prepared and approved, it should be conspicuously posted for each of the departmental employees to read and adhere to.

In large hospitals, departments of pharmacy have a more complex organization. Note for example, the Ohio State University Hospital's Department of Pharmacy organizational chart. It should seem obvious to the student that each of the subdivisions of the department are assigned specific responsibilities. The following are some of the responsibilities of each division.

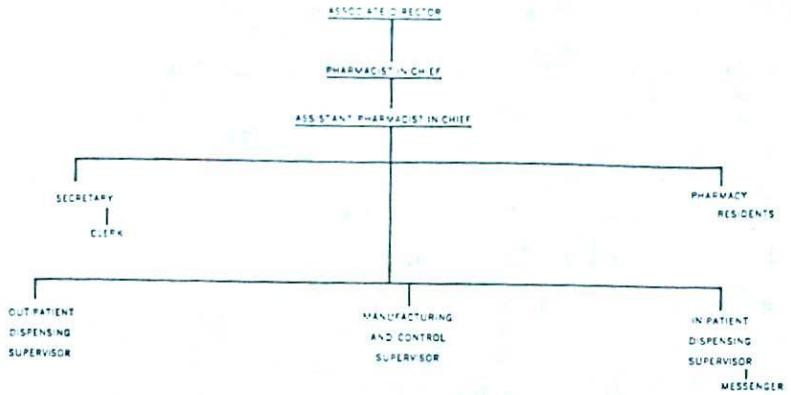


Fig. 8. Departmental organization.

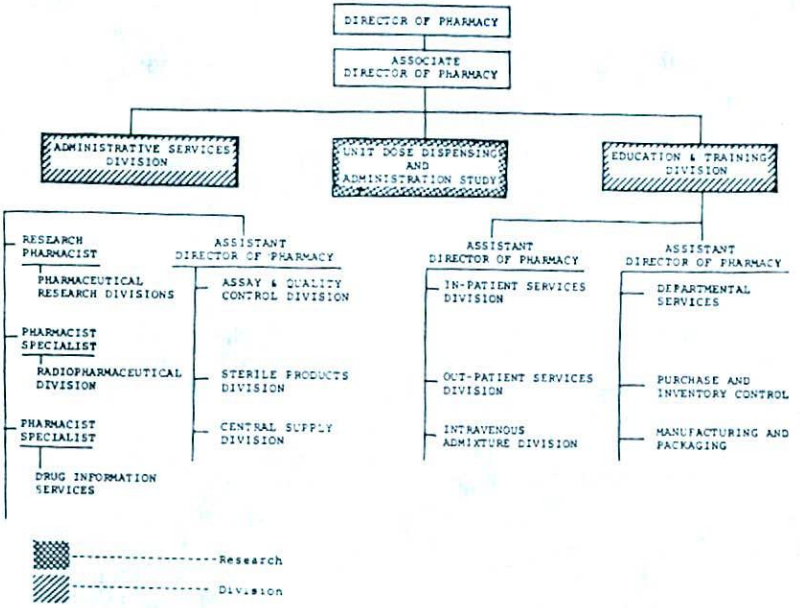


Fig. 9. Departmental organization in a large university hospital pharmacy operation.

Administrative Services Division

1. Plan and coordinate departmental activities.
2. Develop policies.
3. Schedule personnel and provide supervision.

4. Coordinate administrative needs of the Pharmacy and Therapeutics Committee.
5. Supervise departmental office staff.

Education and Training Division

1. Coordinate programs of undergraduate and graduate pharmacy students.
2. Participate in hospital-wide educational programs involving nurses, doctors etc.
3. Train newly employed pharmacy department personnel.

Pharmaceutical Research Division

1. Develop new formulations of drugs, especially dosage forms not commercially available, and of research drugs.
2. Improve formulations of existing products.
3. Cooperate with the medical research staff of projects involving drugs.

In-Patient Services Division

1. Provide medications for all in-patients of the hospital on a 24-hour per day basis.
2. Inspection and control of drugs on all treatment areas.
3. Cooperate with medical drug research. See Chapter 7.

Out-Patient Services Division

1. Compound and dispense out-patient prescriptions.
2. Inspect and control all clinic and emergency service medication stations.
3. Maintain prescription records.
4. Provide drug consultation services to staff and medical students.

Drug Information Services Division

1. Provide drug information on drugs and drug therapy to doctors, nurses, medical and nursing students and the house staff.
2. Maintain the drug information center.
3. Prepare the hospital's pharmacy newsletter.
4. Maintain literature files.

Departmental Services Division

1. Control and dispense intravenous fluids.
2. Control and dispense controlled substances.
3. Coordinate and control all drug delivery and distribution systems.

Purchasing and Inventory Control Division

1. Maintain drug inventory control.
2. Purchase all drugs.

3. Receive, store and distribute drugs.
4. Interview medical service representatives. See Chapter 10.

Central Supply Services Division

1. Develop and coordinate distribution of medical supplies and irrigating fluids. See Chapter 15.

Assay and Quality Control Division

1. Perform analyses on products manufacturered and purchased.
2. Develop and revise assay procedures.
3. Assist research division in special formulations.

Manufacturing and Packaging Division

1. Manufacture wide variety of items in common use at the hospital.
2. Operate an overall drug packaging and prepackaging program.
3. Undertake program in product development.
4. Maintain a unit dose program.

Sterile Products Division

1. Produce small volume parenterals.
2. Manufacture sterile ophthalmologics, irrigating solutions etc.
3. Prepare aseptic dilution of lyophylizal and other "unstable" sterile injections for administration to patients.

Radiopharmaceutical Services Division

1. Centralize the procurement, storage and dispensing of radioisotopes used in clinical practice. See Chapter 23.

Intravenous Admixture Division

1. Centralize the preparation of intravenous solution admixture.
2. Review each I.V. admixture for physio-chemical incompatibilities.

ASHP COMPETENCY STANDARD FOR PHARMACY SUPPORTIVE PERSONNEL IN ORGANIZED HEALTH CARE SETTINGS[21]*

This Standard describes the *minimum* competencies which the technician category of pharmacy supportive personnel in organized health care settings should be expected to demonstrate. This is a companion document to the ASHP Training Guidelines for Hospital Pharmacy Supportive Personnel which outlines a suggested program for training technicians.

For purposes of this Standard, the definition of a pharmacy technician is the same as that given in the Training Guidelines, namely, someone who, under the supervision of a licensed pharmacist, assists in the nonprofessional (i.e., nonjudgmental) aspects of preparing and dispensing medications. Also, as in

*Approved by the ASHP Board of Directors, November 14–15, 1977. Originally drafted by the ASHP Council on Education and Manpower in response to a recommendation from the Council on Organizational Affairs.

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the Training Guidelines, the duties of a "pharmacy technician" do not include those generally performed by secretaries, clerks, typists, delivery personnel or medication administration technicians. The Standard addresses itself to a "generalist" technician, one who can function appropriately in most hospitals, both small and large, in the kinds of activities for which there is generally the greatest need for supportive personnel manpower.

The competencies described in the Standard are representative ones and no attempt has been made to develop an exhaustive listing. It is believed that any technician who can demonstrate attainment of these competencies should be able to perform satisfactorily in any hospital or related health care facility after a reasonable period of orientation.

The competencies are described in behavioral terms; thus, it should be possible to evaluate the technician's attainment of each competency in the manner described in each statement. In some instances this can be by paper and pencil tests, in other instances it can be by oral statement, and in yet other instances, by actually performing the activity or function under the observation of the evaluator. In the latter instances, it is extremely important that the evaluator judges the technician's performance strictly on the basis of the training objectives previously established for the respective training activity relating to the competency.

Omitted from most of the competency statements are references to time or error limits. Obviously, these must be taken into account in the evaluation process. It is suggested that reasonable time and error limits be imposed where indicated, based upon the evaluator's experience.

Standard 1

The technician shall demonstrate appropriate knowledge and understanding of the health care institution and its pharmacy department.

Competencies:

1. The technician will be able to interpret the institution's organizational chart in terms of the name and title of the administrative person to whom the director of pharmacy reports and the administrative and professional relationship of the pharmacy department to any other departments in the institution.
2. The technician will be able to describe the general responsibilities and job status of personnel in other institutional departments with whom he will have contact in carrying out his assigned duties and activities.
3. The technician will be able to interpret the organizational chart for the pharmacy department in terms of names and general responsibilities of all departmental supervisory and administrative personnel.
4. The technician will be able to describe the location of every department shown on the institutional organizational chart and will be able to escort another person to any department.
5. The technician will be able to state at least three valid reasons why information about patients must be kept confidential.
6. The technician will be able to state at least five reasons for initiation of a disciplinary action in the institution (e.g., absenteeism, incompetency, dishonesty, etc.).

Standard 2

The technician shall demonstrate a thorough knowledge and understanding of the duties and responsibilities of his position.

Competencies:

1. The technician will be able to state all of his primary job responsibilities and the duties falling under each.
2. The technician will be able to state the institutional and departmental policies applicable to each of his primary job responsibilities and describe the procedures for each.
3. The technician will be able to define what is meant by "a decision requiring professional judgment" and will cite at least 10 examples.
4. The technician will be able to demonstrate the use of correct telephone communication technique and protocol both in receiving and in initiating calls.
5. The technician will be able to demonstrate the use of correct written communication by drafting a memorandum to his supervisor requesting a change in work assignment schedule to take care of personal business.
6. The technician will be able to state the general requirements of many local, state or federal laws which specifically affect any of his responsibilities.

Standard 3

The technician shall have a working knowledge of the pharmaceutical-medical terms, abbreviations and symbols commonly used in the prescribing, dispensing and charting of medications in the institution.

Competencies:

1. The technician will be able to interpret without error any 12 inpatient medication orders selected at random from at least four different patient units in the institution.
2. The technician will be able to define in lay terms the meaning of names of all the clinical, diagnostic and treatment units and services in the institution.

Standard 4

The technician shall have a working knowledge of the general chemical and physical properties of all drugs handled in manufacturing and packaging operations in the pharmacy department.

Competencies:

1. The technician will be able to designate from a list of 50 drug names those which are light-sensitive and those which must be refrigerated.
2. The technician will be able to list the titles of at least four reference books where he may find stability information on drug compounds.

Standard 5

The technician shall have a working knowledge of commonly used weight and volume equivalents and shall demonstrate an ability to carry out the arithmetic calculations required for the usual dosage determinations and solutions preparation.

Competencies:

1. The technician will be able to list without error the metric equivalents for the apothecaries doses and for household doses written in any 12 randomly selected medication orders.
2. The technician will be able to convert without error all metric or apothecary weights and volumes in at least four manufacturing formulas to the other system.
3. The technician will be able to perform the calculations necessary to prepare at least two different weight-in-volume and at least two different volume-in-volume solutions.

Standard 6

The technician shall demonstrate the ability to perform the essential functions relating to drug purchasing and inventory control.

Competencies:

1. The technician will be able to inventory a representative stock of pharmacy drugs and supplies using prepared forms and records.
2. The technician will be able to determine from existing reorder levels which inventoried items should be ordered and in what quantity.
3. The technician will be able to demonstrate an ability to check in a drug shipment using the packing list or invoice and purchase order, completing the receiving report, and adding the items to the inventory.
4. The technician will be able to demonstrate the ability to retrieve, without error, from the drug storeroom at least 10 randomly designated drug items.
5. The technician will be able to describe the procedure for returning outdated drugs to the manufacturer.

Standard 7

The technician shall demonstrate a working knowledge of drug dosages, routes of administration and dosage forms.

Competencies:

1. The technician will be able to list at least:
   a. Six routes of drug administration.
   b. Ten dosage forms and their respective routes of administration and
   c. Ten adverse effects encountered in drug therapy.
2. The technician will be able to state the lumen size, length and primary use for each of five different needles.
3. The technician will be able to identify, by name and use, each of five different syringes.

Standard 8

The technician shall have a working knowledge of the procedures and operation relating to the manufacturing, packaging and labeling of drug products.

Competencies:

1. The technician will be able to repackage and label 25 unit doses from a bulk supply of drugs and correctly complete all necessary control records.
2. The technician will be able to demonstrate for each of five randomly selected formulation and packaging requests:
   a. Correct selection of necessary equipment,

b. Proper assembly and use of the equipment,
c. Proper cleaning and storing of the equipment,
d. Proper selection of each ingredient,
e. Accurate calculation and measurement of each,
f. Proper completion of worksheet record of weights and volumes, manufacturers' lot numbers, and other required information,
g. Correct procedure for mixing and preparing product,
h. Proper selection and preparation of packages/containers and closures,
i. Proper packaging technique,
j. Correct selection and preparation of labels and
k. Proper quarantine procedure.

3. The technician will be able to identify from a list of 10 different steps in manufacturing and packaging operations, those functions which must be performed by a pharmacist only.

Standard 9

The technician shall have a working knowledge of the procedures and techniques relating to aseptic compounding and parenteral admixture operations.

Competencies:

1. The technician will be able to list five different possibilities for contamination of an injectable solution during its preparation and for each possibility a precaution which would prevent the contamination.
2. The technician will be able to demonstrate the proper technique for using a syringe and needle for aseptic withdrawal of the contents of:
   a. A rubber-capped vial, and
   b. A glass ampul.
3. The technician will be able to demonstrate the proper technique for aseptic reconstitution of an antibiotic injection.
4. The technician will be able to describe the occasions when hand washing is required and will demonstrate the proper technique.
5. The technician will be able to demonstrate the correct techniques and procedure for preparing at least three parenteral admixtures, including the proper preparation of the label and completion of the control records.
6. The technician will be able to identify the major components of a laminar air flow hood and state their functions.
7. The technician will be able to define and/or describe:
   a. Microbial growth and transmission,
   b. Origin, pharmacologic effect, and prevention of pyrogens,
   c. Sterility,
   d. Heat sterilization and
   e. "Cold" sterilization.
8. The technician will be able to designate from a list of 10 different sterile preparations those which may be safely heat-sterilized.
9. The technician will be able to demonstrate the proper technique for visual inpection of parenteral solutions.

Standard 10

The technician shall demonstrate the ability to perform the usual technician functions associated with a unit dose drug distribution system.

Competencies:

1. The technician will be able to prepare the drug profile for five newly admitted patients.
2. The technician will be able to pick all doses for one patient unit and complete the necessary dispensing records.
3. The technician will be able to describe the special dispensing and record-keeping procedures which apply to the dispensing of:
   a. Controlled drugs,
   b. Investigational drugs and
   c. Nonformulary drugs.
4. The technician will be able to list for each of 30 commonly prescribed drug trade names:
   a. The generic name,
   b. The common therapeutic use and
   c. The usual dose.

Standard 11

The technician shall demonstrate the ability to perform the manipulative and record-keeping functions associated with the dispensing of prescriptions for ambulatory patients.

Competencies:

1. The technician will be able to carry out the following functions for any 10 randomly selected ambulatory patient prescriptions:
   a. Correctly type the label,
   b. Select the proper drug from the dispensing rack,
   c. Accurately count or measure the product and place in the proper container,
   d. Complete the necessary records and documents and
   e. Calculate the charge for the prescription.
2. The technician will be able to describe the special procedures and documentation required in dispensing ambulatory patient prescriptions for:
   a. Controlled drugs,
   b. Investigational drugs and
   c. Alcohol.
3. The technician will be able to designate from a list of 10 steps involved in ambulatory patient prescription dispensing, those functions which only a pharmacist may carry out.

CONTROL OF PERSONNEL

This section is not intended as an invitation to the hospital pharmacist to subrogate the established personnel policies or procedures of the hospital. The purpose is to present a few relatively simple procedures whereby the pharmacist who is located in the smaller hospital and either functions alone or with lay help or who may be responsible for more than one department may maintain, in the absence of an active personnel director, reasonable employee records for accounting and administrative purposes.

The *Application for Employment* should elicit from the prospective employee vital information relative to his personal history, education,

military service, office skills when applicable, previous employment record, interviewer's comments and the employment contract. It would seem necessary to obtain all of the above information in order to make an intelligent decision whether or not the applicant has the necessary qualifications for the position which he seeks or for which he is being interviewed. Certainly, if the question ever arose as to whether or not due care was used in the selection of the employee, a record, such as the one illustrated, properly completed, would serve as *prima facie* evidence.

It is essential that the director of pharmacy services evaluate the personnel in the department on a regular basis. In so doing, he must remain objective and impartial. To perform this important management responsibility the director should become familiar with such personnel appraisal systems as ranking, person-to-person comparison, grading, graphic scales, checklists, forced choice description, selection of critical incidents and management by objective.

Figure 10, the *Performance Rating Form,* can be used effectively in determining whether or not the employee is worthy of a pay increase. In addition, it can serve as a warning to the employee of his deficiency in certain areas. Many department heads in using this form assign a numerical value of 4 for each check mark under "excellent," 3 for "good," 2 for "fair" and 1 for "poor." A total is taken of the points and then divided by 10. The figure obtained determines where the category of "Overall Rating" is checked.

Figure 11, entitled *Paid Vacation,* is an example of a form which may be used within the department to keep an accurate record of those important fringe benefits due the employee, namely paid vacation or sick leave time. Improper records, particularly in the area of sick time, have been used to the detriment of the hospital in claims arising out of industrial accidents involving the employee or they may prove to be a great asset to him in his claim for insurance disability payments and income tax deductions.

HIRING OF PHARMACISTS

The hiring of pharmacy personnel is an extremely important function of the director of pharmacy service and requires special consideration.[16]

The State Board of Registration in Pharmacy is empowered to make rules and regulations for the enforcement of administration of the pharmacy law. Such regulatory and enforcement procedures must be in accord with the expressed or implied purposes of the enabling statutes. In view of the fact that the Board is an administrative, not legislative agency, it may not exercise any power of authority not delegated to it, or which, by reasonable implication is necessary to the proper functioning of the pharmacy law.



Brigham and Women's Hospital

EMPLOYEE PERFORMANCE REVIEW

Employee No. _____

Name _____ Department _____ Cost Center _____

Position _____ Review Date _____ Date Started in Present Position _____ ☐ Anniversary ☐ Transfer/Promotion

Please see Remarks Section for additional explanation of the areas evaluated below.

I. QUALITY OF WORK – Accuracy and neatness of work performed regardless of volume

1 ____ Does very poor work
2 ____ Work barely acceptable. Frequent errors
3 ____ Usually does acceptable work
4 ____ Better than average work. Very few errors
5 ____ Outstanding work. Exceptionally accurate

Remarks _____

II. QUANTITY OF WORK – Volume of work performed regardless of accuracy

1 ____ Volume of work unsatisfactory. Seldom completes work on schedule
2 ____ Barely passable volume of work
3 ____ Usually accomplishes satisfactory volume of work. Average turned in producing results
4 ____ Better than average volume of work
5 ____ Outstanding volume of work. Completes jobs quickly.

Remarks _____

III. KNOWLEDGE OF JOB – Employee's knowledge in his particular field, his mastery of all phases of the job

1 ____ Inadequate knowledge of job
2 ____ Limited knowledge of job. Often needs explanation
3 ____ Adequate knowledge of most phases of the job
4 ____ Thorough knowledge of all phases of the job
5 ____ Exceptional mastery of all phases of the job

Remarks _____

VI. INTERPERSONAL RELATIONSHIPS – Ability to get along with fellow employees and his supervisor, i.e. cooperation, tact, sincerity, thoughtfulness and courtesy.

1 ____ Frequently does not get along with others. Inclined to create friction. Cannot accept criticism
2 ____ Indifferent to others. Cooperates occasionally. Fair teamworker
3 ____ Accepts criticism with appropriate change in behavior. Gets along satisfactorily with others
4 ____ Actively promotes harmony within a group. Flexible. Very good cooperation
5 ____ Outstanding ability to create harmony in all situations. Goes out of way to cooperate

Remarks _____

V. DEPENDABILITY – Reliability of employee and the extent to which employee can be counted on to carry out instructions

1 ____ Completely unreliable. Has to be closely supervised
2 ____ Not fully dependable. Needs more supervision than others
3 ____ Dependable on routine work. Needs some supervision
4 ____ Requires only occasional supervision.
5 ____ Needs no supervision.

Remarks _____

VI. ATTENDANCE – Attendance at work and work area. (Explain exact nature of any attendance problem.)

1 ____ Frequently absent
2 ____ Some difficulty in attendance.
3 ____ Attendance is adequate
4 ____ Consistently present
5 ____ Attendance records are outstanding.

Remarks _____

VII. PUNCTUALITY – Arrival and departure for work and/or break periods.

1 ____ Frequently late
2 ____ Sometimes late
3 ____ Adequate punctuality
4 ____ Consistently on time.
5 ____ Punctuality records are outstanding.

Remarks _____

VIII. GROWTH POTENTIAL – Ability to assume more responsibility and authority

1 ____ Does not demonstrate ability to cope with present responsibilities
2 ____ Does not demonstrate ability to grow and adapt.
3 ____ Demonstrates limited ability for growth and development in present job
4 ____ Demonstrates considerable ability for growth and development in present job
5 ____ Demonstrates ability to accept more responsibility and authority in other areas

Remarks _____

FOR SUPERVISORY EVALUATION OR PROMOTION TO SUPERVISORY POSITION ONLY

JUDGMENT – Ability to make decisions by sound reasoning and the drawing of correct conclusions

1 ____ Inclined to be illogical. Neglects and misinterprets facts.
2 ____ Makes frequent errors in judgment
3 ____ Good common sense. Decisions seldom cause difficulty
4 ____ Excellent judgment. Decisions are logical and sound
5 ____ Outstanding ability to think quickly and logically and to use sound judgment

Remarks _____

PLANNING AND ORGANIZING – Success in planning and organizing work to complete assignments on schedule

1 ____ Inefficient. Work is poorly planned and organized
2 ____ Planning ability is inadequate when under pressure
3 ____ Effective under normal circumstances
4 ____ Careful and effective planning
5 ____ Exceptionally systematic, inventive and creative.

Remarks _____

LEADERSHIP – Ability to train, supervise and get results through personnel

1 ____ Antagonizes subordinates. Gets poor results
2 ____ Fails to command respect and confidence
3 ____ Meets minimum leadership requirements
4 ____ Gets good results through motivation of subordinates
5 ____ An extremely capable and forceful leader in directing and training subordinates.

Remarks _____

Additional Comments _____

_____ Evaluator _____ Date _____ Department Head/Vice President/Assistant Vice President _____ Date

FOR EMPLOYEE ONLY

I understand that my signature neither confirms nor denies the validity of this performance rating but merely means that I have seen the report in its completed form. Upon inspection and discussion of this evaluation with my supervisor, my personal opinion:

_____ A Fair Evaluation _____ An Unfair Evaluation

Remarks _____

_____ Employee _____ Date _____ Reviewed by _____ Personnel Representative _____ Date

Fig. 10.

PAID VACATION

Date of Employment _____

Name _____

Credit Balance 2/1/80
Starting 2/1/80
Period

1	2/ 1/80– 3/ 7/80
2	3/ 8/80– 4/11/80
3	4/12/80– 5/16/80
4	5/17/80– 6/20/80
5	6/21/80– 7/25/80
6	7/26/80– 8/30/80
7	8/31/80–10/ 3/80
8	10/ 4/80–11/ 7/80
9	11/ 8/80–12/12/80
10	12/13/80– 1/31/81

Added Credit	Paid Vac. Hours	Hours Balance

VACATION DAYS

DATE TAKEN	HRS.	DATE TAKEN	HRS.	DATE TAKEN	HRS.

Fig. 11.

One of the clearly defined responsibilities of the State Board of Registration in Pharmacy is to establish the educational and experience qualifications which individuals must meet at the time of examination or registration.

Once an individual has successfully qualified for practice he is generally awarded a certificate of registration which enables him to practice pharmacy in the setting of his choice—community or institutional.

The American Society of Hospital Pharmacists through its Minimum Standard for Pharmacies in Hospitals prescribes that the department be under the direction of a "—professionally competent, legally qualified pharmacist—he shall be well trained in the specialized functions of hospital pharmacy and shall be a graduate of an accredited college of pharmacy or meet an equivalent standard of training or experience—."

Because of the fact that many of the approximately 7000 hospitals registered by the American Hospital Association are minus the services of a trained pharmacist, too many administrators are prone to overlook or ignore the mandates of good hiring procedure. The same applies to the overworked pharmacist in the larger hospital who is anxious to hire "another pair of hands" for peak periods in the operation of the department. Both of these "short-cuts" may prove to be disastrous from a legal point of view.

In practice, the hospital administrator, personnel director or director of pharmacy services, should insist that applications for pharmacist positions should show—

Proof of graduation from an accredited college/school of pharmacy.

Proof of licensure in the state in which the individual desired to practice.

Proof of professional competency.

Proof of good moral character.

In addition, a 6-month probationary period satisfactorily completed would be further evidence of the quality of the hiring procedures of the hospital in the selection of the pharmacist.

Should an unfortunate accident then occur, a charge of negligence might be defended successfully in some states.

State pharmacy laws, hospital licensing acts, Food and Drug laws, and state public health laws and agency regulations are clear on the issue that the use, as pharmacists, of those not skilled and experienced in the practice of pharmacy, as evidenced by state registration, is a criminal offense. In this connection, it should be borne in mind that neither the hospital administrator nor the director of pharmacy services are relieved by law of their responsibility where pharmacists are employed yet the work-load is so great that non-registered personnel must perform duties that the law limits to the registered practitioner of pharmacy.

DePiro et al.[15] studied the extension of unproductive and under-

productive staff pharmacist activity to identify opportunities to improve use of pharmacists' time. The study noted the following percentages of time devoted to such areas as: (1) dispensing activities requiring professional judgment 19.5%; (2) dispensing activities not requiring professional judgment 37.8%; (3) therapy related activities 6.5%; (4) idle time 13.2%; (5) absent 8.9%; (6) communication and coordination 9.4% and (7) outpatient activities 0.5%.

As reasonable and prudent individuals, the hospital administrator and the director of pharmacy services know or should know the relationship between the work-load and the number of qualified staff necessary to handle it—expertly and on schedule.

Also of serious import is the civil liability that attaches to the institution in malpractice or negligence suits arising from injuries or deaths resulting from medication errors committed by a non-pharmacist acting in the capacity of a licensed pharmacist with the consent, implied or expressed, of the hospital management.

Accordingly, it behooves all pharmacists who are delegated the responsibility of managing the institution's pharmacy to exercise due care in the selection and hiring of personnel as well as the determination of acceptable work-loads and work assignments for the employees.

WOMEN IN PHARMACY

Although women are averaging 50% of pharmacy school enrollments, they represent only 15 to 20% of all practicing pharmacists. This segment of the work should not be ignored by hospital pharmacy directors when recruiting to fill vacant positions. Kirk[20] in a study of women in male dominated professions shows that even though women pharmacists are paid the same as men, have the same job responsibilities, and work the same hours, they are subconsciously stereotyped therefore precluding the occurrence of true equality for women pharmacists in many hospitals. Hospital pharmacy directors should make every effort to provide opportunities for female pharmacists to become actively involved in professional organizations to facilitate their gaining a professional identity. In addition, these women need to be encouraged to seek out managerial positions and to be given a clearer understanding that being a manager can be combined with family responsibilities.

SALARIES

At nearly every meeting of hospital pharmacists, the subject of salaries is discussed. Many of the state associations have conducted surveys amongst their membership in an attempt to determine the wage levels within the area and, when possible, to promote higher salaries.

The instigators of the salary survey movement are usually those in-

dividuals within the lower salary brackets. Some of these pharmacists may be doing an exceptionally fine job within their institutions but are harnessed by an unrealistic wage range within the hospital or even governmental salary structure.

On the other hand, there is a small segment of the profession which is continually advocating higher personal recompense even though they offer very little in return for the higher salary.

Because the hospital pharmacist is a highly trained professional member of the health team, his salary requirements should not be arrived at in the same manner as other members of the hospital staff. Neither should his salary be restricted by what other institutions in the area are paying.

It is generally agreed that no two hospitals are alike in their operation. By the same token, no two hospital pharmacists can be evaluated by what they do in neighboring institutions. They must be evaluated on their own performance standard within the particular institution they serve.

As a result of the economic pressures that are being exerted upon the hospital, many members of the professional staff are being subjected to unionization activities. Many pharmacists would prefer not to become involved with organizations whose sole goal is economic security but would demonstrate interest in a group combining both professional and economic goals.

Thus, the *Economic Status Program of the American Society of Hospital Pharmacists* came into being and is hereinafter reproduced.[18]

ECONOMIC STATUS PROGRAM OF THE AMERICAN SOCIETY OF HOSPITAL PHARMACISTS[a]

Policy on Economic Status

The professional and economic goals of the professional person are closely interrelated. Only in attainment of these goals can he assume the leadership role expected of him in the community by his colleagues, and by other health professions. When satisfactory economic status is achieved, the professional can realize his maximum potential and apply his full energies to the needs of the society.

The American Society of Hospital Pharmacists has, since its inception, concentrated on the professional responsibilities of hospital pharmacists through promotion of high standards of professional ethics, education and attainments. Nevertheless, the economic interests of members of the Society were acknowledged several years ago when the

[a]Approved by the Board of Directors on January 11, 1970.
Approved by the House of Delegates on March 29, 1971.

Mirror to Hospital Pharmacy and the Society's Commission on Goals counselled the ASHP to involve itself in activities dealing with the economic status of hospital pharmacists. Indeed one of the goals of the Society's statement, "Goals for Hospital Pharmacy" adopted in 1964, was to "Promote payment of realistic salaries to hospital pharmacists in both staff and managerial positions in order to attract and retain the services of career personnel." More recently, the Society conducted a salary survey to obtain factual data on the economic status of pharmacists in institutional practice.

The Society's concern for the economic welfare of its members complements the professional and scientific objectives presently set forth in the Constitution of the American Society of Hospital Pharmacists. Involvement by the Society in the economic well-being of its members is in the public interest since assurance of economic satisfaction tends to attract highly qualified pharmacists to institutional practice.

Salaries, working hours and fringe benefits of hospital pharmacists should be commensurate with professional education, responsibility and status and with the increased participation by hospital pharmacists in the actual planning and administration of pharmacy service and in the determination of policies which directly affect them. Both employers and employed pharmacists have an obligation to resolve employment issues fairly and in good faith.

The responsibility of the individual is primary. However, as institutions and the delivery of health care grow in size and complexity, collective effort may be necessary to solve group economic problems. With this view, the Society must meet the needs of its members by embarking on a broad program of economic status which may include such activities as the compilation of statistical data, the preparation of model contracts and, when necessary, mediation, conciliation and arbitration. When economic problems of employment cannot be resolved by the individual practitioner or the pharmacy staff of a hospital, the Society's Affiliated Chapters, with the legal and financial assistance of the ASHP, may find it necessary to engage in collective bargaining.

The Board of Directors of the American Society of Hospital Pharmacists, at its meeting of January 10–11, 1970 voted:

> To engage in collective bargaining by assisting Affiliated Chapters, upon request, in accordance with policies and guidelines as established by the House of Delegates of the AMERICAN SOCIETY OF HOSPITAL PHARMACISTS; further,
> To adopt the statement, "Economic Status Program of the American Society of Hospital Pharmacists."

In accordance with this action, the following are guidelines for individual members, Affiliated Chapters and the ASHP.

Guidelines for Collective Bargaining

Individual Members

1. Hospital pharmacists must recognize their obligation to the patient, the institution, the profession, the allied health professions and society.
2. Hospital pharmacists shall not deprive patients of pharmaceutical services by withholding their services in any form, including strikes, in support of economic demands.

Affiliated Chapters

1. Affiliated Chapters may engage in collective bargaining, preferably through the statewide Affiliated Chapter. Any such activity shall be conducted solely in the name of, and by, the Affiliated Chapter.
2. Affiliated Chapters may engage in collective bargaining when:
   a. professional prerogatives of the pharmacists are endangered by lack of effective representation; or
   b. wages or conditions of employment are below acceptable levels; or
   c. the environment in which the profession is practiced is not conducive to good patient care; and
   d. good faith attempts have failed to remedy the above situation(s).
3. Affiliated Chapters will make available the services of negotiating contracts to active ASHP members. All hospital pharmacists who practice at the contracting institution may be represented. Hospital pharmacists being represented who are not members of the Affiliated Chapter and the American Society of Hospital Pharmacists must become members, if permitted by all applicable laws.
4. Affiliated Chapters will accept or reject contracts as determined by a majority of the members in the bargaining unit.
5. Affiliated Chapters will assess each hospital pharmacist a service fee for each contract negotiated, as determined by and paid to the ASHP, to the extent permitted by applicable laws.
6. Affiliated Chapters must follow procedures outlined by the ASHP.

American Society of Hospital Pharmacists

The Society will coordinate collective bargaining activities of Affiliated Chapters by providing:

a. statistical information and research assistance;
b. legal assistance; and
c. financial assistance when necessary.

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4

The Pharmacy and Therapeutics Committee

In these days of modern medicine when numerous agents are available for the treatment of disease, the judicious selection of drugs for use in the hospital has become an important administrative and therapeutic tool. During the last half century, there has been a dynamic change in the medical profession's attitude toward therapeutic agents. Fifty years ago there were few really worthwhile medicinal substances available; however, if one examines the formularies of that period, it is amazing to see the hundreds of preparations that were recommended. Perhaps one of the finest things that Sir William Osler did was to lead the endeavor to rid the profession of such valueless items.

Following Osler's period of clinical evaluation, there came a period of near therapeutic nihilism when most physicians were skeptical about nearly all therapeutic measures. As a consequence, it was difficult to get individuals deeply interested in the problems of reliable therapeutics. If an examination were made of the texts on therapy between 1920 and 1940, one notes that there was a definite lack of interest in therapeutics, and to a great extent, the use of various prescriptions and preparations was curtailed. Many of the medical graduates of this period had little idea about good therapy and received poor instruction in the subject during their clinical training in the hospital.

However, during this period, definite standards for improving drug therapy were established. Rules to guide manufacturers, as well as physicians, were established by the American Medical Association which did much to put drug therapy in a more desirable position. The Council on Pharmacy and Chemistry of the American Medical Association had been well established and was successfully operating when we were suddenly thrust into the modern era of therapeutics. This came about as a result of the discovery of the sulfa compounds and was quickly followed by the discovery of penicillin, streptomycin and the other antibiotics. In the 1950s, there was a flood of new substances of high potency and activity in many fields of pathologic physiology. This deluge of new therapeutic agents made it a nearly impossible task for

the physician to become knowledgeable about more than a relatively few products.

Because of this profusion of agents, some excellent, some not so good, and some practically useless, it was necessary for the hospital to establish a system to bring the best medicinal agents to the attention of the staff, and thus assist them in the proper selection of therapeutic substances for the treatment of the hospitalized patient. This educational program was best brought about through the formation of a good Pharmacy and Therapeutics Committee whose responsibility was to include the preparations of a hospital formulary, the publishing of a pharmacy educational bulletin, the establishment of automatic stop orders for dangerous drugs, the supervision of investigational use drugs, the development of a program for reporting and investigating adverse drug reactions and assisting in the preparation of emergency kits or carts for medical emergencies.

Despite the creation of these hospital oriented committees, there appeared to be a need for a systematic evaluation of the entire drug system in the country. Thus, in May of 1967, acting upon a directive from the President, John W. Gardner—then Secretary of Health, Education, and Welfare—established the Task Force on Prescription Drugs. The charge to the Task Force was—

"Undertake a comprehensive study of the problems of including the cost of prescription drugs under medicare."

To achieve the goal set by the charge, the Task Force was obliged to seek objective data on the health needs of the elderly; the present patterns of drug use; the nature of drug research, production and distribution; current drug insurance programs in the United States and abroad; reimbursement methods and administrative approaches; legal and fiscal aspects; and the pharmacological and clinical aspects, including the intricate problem of chemical and clinical equivalency of generic products.[1]

In addition, a more drastic approach was taken. Under the authority granted to the Secretary of HEW by the Drug Amendments of 1962, the *National Academy of Sciences-National Research Council* (NAS-NRC) in 1966, at the request of the FDA, initiated a study to evaluate the effectiveness of new drugs marketed between 1938 and 1962. During that period of time, the law required only that a new drug be demonstrated to be safe. The requirement that a new drug be effective, as well as safe, was added by the Drug Amendments of 1962.

An advisory committee of the NAS-NRC created 27 panels of non-government experts to evaluate the efficacy of approximately 3000 drugs. On the basis of its findings, the *Drug Efficacy Study Group*

classified the drugs as: *effective, probably effective, possibly effective, effective but,* or *ineffective.*

It has been stated[2] that the hospital Pharmacy and Therapeutics Committee is a tool for maintaining medical staff self-government. It is responsible to the medical staff as a whole and its recommendations are subject to medical staff approval. The Pharmacy and Therapeutics Committee is a mandatory committee under the **Conditions** of **Participation** of the Hospital Insurance Program—Medicare. Composed of physicians and the pharmacist, it serves as the organizational line of communication of liaison between the medical staff and the Pharmacy Department. This committee assists in the formulation of broad professional policies regarding the evaluation, selection, procurement, distribution, use, safety procedures and other matters relating to drugs in hospitals.

In 1959, the American Hospital Association and the American Society of Hospital Pharmacists approved a **Statement on the Pharmacy and Therapeutics Committee**[3] which has been superseded by the following ASHP Statement on the Pharmacy and Therapeutics Committee.

ASHP STATEMENT ON PHARMACY AND THERAPEUTICS COMMITTEE

The multiplicity of drugs available and the complexities surrounding their safe and effective use make it necessary for hospitals to have an organized, sound program for maximizing rational drug use. The pharmacy and therapeutics committee, or its equivalent, is the organizational keystone of the program.[a]

The pharmacy and therapeutics committee is an advisory group of the medical staff and serves as the organizational line of communication between the medical staff and pharmacy department. This committee is composed of physicians, pharmacists, and other health professionals selected with the guidance of the medical staff. It is a policy-recommending body to the medical staff and the administration of the hospital on matters related to the therapeutic use of drugs.

Purposes

The primary purposes of the pharmacy and therapeutics committee are as specified in the following.

[a]Approved by the ASHP House of Delegates, June 6, 1984. Approved by the ASHP Board of Directors, November 17–18, 1983. (The previous version was approved by the House of Delegates, May 15, 1978.) Revised by the ASHP Council on Clinical Affairs.

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1. **Advisory.** The committee recommends the adoption of, or assists in the formulation of, policies regarding evaluation, selection, and therapeutic use of drugs in hospitals.
2. **Educational.** The committee recommends or assists in the formulation of programs designed to meet the needs of the professional staff (physicians, nurses, pharmacists, and other health-care practitioners) for complete current knowledge on matters related to drugs and drug use.

Organization and Operation

While the composition and operation of the pharmacy and therapeutics committee might vary from hospital to hospital, the following generally will apply:

1. The pharmacy and therapeutics committee should be composed of at least three physicians, a pharmacist, a nurse, and an administrator. Committee members are appointed by a governing unit or elected official of the organized medical staff.
2. A chairman from among the physician representatives should be appointed. A pharmacist usually is designated as secretary.
3. The committee should meet regularly, at least six times per year, and more often when necessary.
4. The committee should invite to its meetings persons within or outside the hospital who can contribute specialized or unique knowledge, skills, and judgments.
5. An agenda and supplementary materials (including minutes of the previous meeting) should be prepared by the secretary and submitted to the committee members in sufficient time before the meeting for them to properly review the material.
6. Minutes of the committee meetings should be prepared by the secretary and maintained in the permanent records of the hospital.
7. Recommendations of the committee shall be presented to the medical staff or its appropriate committee for adoption or recommendation.
8. Liaison with other hospital committees concerned with drug use (e.g., infection control, medical audit) shall be maintained.

Functions and Scope

The basic organization of the hospital and medical staffs will determine the functions and scope of the pharmacy and therapeutics committee. The following list of committee functions is offered as a guide:

1. To service in an advisory capacity to the medical staff and hospital administration in all matters pertaining to the use of drugs (including investigational drugs).
2. To develop a formulary of drugs accepted for use in the hospital and provide for its constant revision. The selection of items to be included in the formulary will be based on objective evaluation of their relative therapeutic merits, safety, and cost. The committee should minimize duplication of the same basic drug type, drug entity, or drug product.

3. To establish programs and procedures that help ensure cost-effective drug therapy.
4. To establish or plan suitable educational programs for the hospital's professional staff on matters related to drug use.
5. To participate in quality-assurance activities related to the distribution, administration, and use of medications.
6. To review adverse drug reactions occurring in the hospital.
7. To initiate or direct (or both) drug-use review programs and studies and review the results of such activities.
8. To advise the pharmacy in the implementation of effective drug distribution and control procedures.
9. To make recommendations concerning drugs to be stocked in hospital patient-care areas.

PURPOSE OF THE COMMITTEE

Pharmacy departments utilize the committee structure to coordinate and effectively integrate requisite aspects of planning, development, implementation, and control of designated activities. In both the interdepartmental and intradepartmental pathways, the resourceful hospital pharmacy manager will use the committee as an effective management tool.[4]

Longest[5] suggests the following as prerequisites for an effective committee:

1. The committee's tasks should be clearly defined.
2. Members should be selected from among those who have some definite relationship to the tasks to be accomplished.
3. For optimal effectiveness, superiors and subordinates should not serve on the same committee. Furthermore, the fact that a manager holds a position at a given level should not, in and of itself, be a basis for inclusion or exclusion.
4. Committees must have time to evolve interpersonal relationships before they can move on to effective problem-solving.
5. To function most effectively, committees require the support of the groups of individuals to whom the results of their deliberation are to be submitted.
6. Committees with a task to perform—for example, a pharmacy and therapeutics committee—should be clearly differentiated from staff groups whose major role is to communicate events and to develop the managerial competence of members.

The Pharmacy and Therapeutics Committee is a committee of the medical staff and serves as liaison between the medical staff and the pharmacy service on all matters pertaining to the use of drugs in the hospital. Its prime objective is to achieve optimal patient care and safety through rational drug therapy.

COMMITTEE NAME

The actual name given to this type of committee is irrelevant. For the sake of clarification, the following nomenclature has been applied to that committee acting in an advisory capacity to the hospital and its staff on all matters pertaining to drugs and pharmaceuticals: **Pharmacy Committee; Formulary Committee; Therapeutics Committee** and **Pharmacy and Therapeutics Committee.**

COMMITTEE MEMBERSHIP

Although the approved statement by the American Hospital Association and the American Society of Hospital Pharmacists provides for a membership of not less than three physicians and the pharmacist, the majority of the larger hospitals list committees which often include representatives of the following groups:

Surgery

Anesthesiologist
Urologist
General Surgeon

Medicine

Allergist
Cardiologist
Dermatologist
Endocrinologist
Gastroenterologist
Pharmacologist
Phychiatrist
Internist

Pharmacist
Administrator
Nurse

It is admitted that this constitutes a large committee; however, this is justifiable since no single individual is competent to rule on all categories of drugs which are being developed. A committee of these specialists can certainly provide a learned opinion as to the merit of any pharmaceutical agent.

Flack[6] has observed that too many hospitals had pharmacy and therapeutics committees with only two or three physician members and that such committees were not truly representative of all medical staff services. In describing the Pharmacy Committee of the attending medical staff at the Jefferson Medical College Hospital, it was shown to consist of three physicians, all of whom were department heads. However, there existed an Advisory Subcommittee to the Pharmacy Committee consisting of the head of each of the divisions of the department of medicine. Such an arrangement is beneficial in that it provides the parent committee with advisory input derived from a broad base of clinical expertise.

On occasion, the issue is raised as to whether or not the pharmacist should serve as a full voting member of the committee or serve in an *ex officio* capacity. The pharmacist should serve as a full voting member

of the committee. Furthermore, he should serve as the secretary of the group and should, therefore, be fully responsible for developing the agenda and the preparation and distribution of the minutes of the meetings.

FREQUENCY OF MEETINGS

The number and frequency of meetings of this Committee depend upon the size of the hospital and the volume and variety of drugs used. Clearly, the Committee should meet at least once per quarter, and in the busier institutions at least monthly. Notices of the meeting date and accompanying agenda should be distributed by the secretary of the Committee in ample time to assure attendance and knowledgeable participation in the discussion of the agenda items.

THE COMMITTEE AGENDA

A successful meeting depends upon the preparation of an interesting agenda which is made available to the committee members reasonably far in advance of the scheduled meeting. Because of the broad scope enjoyed by this committee, many interesting subjects may, rightfully, be placed upon the agenda for discussion.

A typical agenda may consist of the following general categories:

1. Minutes of the previous meeting.
2. Review of a specified section of the Formulary for up-dating and deletion of products.
3. New drugs which have become commercially available.
4. Investigational use of drugs currently in use in the hospital.
5. Review of adverse drug reactions reported in the hospital since the last meeting.
6. Drug safety in the hospital.

FUNCTIONS OF THE COMMITTEE

Committees having as diversified a membership as the Pharmacy and Therapeutics Committee need to have a set of guidelines which delineate its activity. The following demonstrate this point:

A. To serve in an advisory capacity to the Medical Staff, to hospital administration, and to the Pharmacy Department on all matters pertaining to the use of drugs in the hospital. Actions taken by the Committee are subject to review and approval by the Executive Committee of the Medical Staff.

B. To assist the Pharmacy Department in the development and review of policies, rules, and regulations regarding the use of drugs in the hospital

in accordance with local, state, and federal regulatory and accreditation agencies.

C. To evaluate, approve, or reject drugs proposed for inclusion in or deletion from the Hospital Formulary.
D. To define categories of drugs used in the hospital and assign each drug to a specified category. (See section on "Policies" for a list of these categories.)
E. To review drug utilization in the hospital and promote optimum standards for rational drug therapy.
F. To collect and review adverse drug reaction reports.
G. To develop and disseminate pertinent educational materials and programs regarding drugs to members of the Medical and Nursing Staffs.

Policies of the Committee

In order that there be no misunderstanding amongst the membership and subsequently by the medical staff, it is essential that the Committee establish policies under which it proposes to control the use of drugs in the hospital. These policies should be comprehensive and should be reviewed periodically to ensure that they are current and are placed in the Pharmacy Procedural Manual.

The following are presented as an example of the thoroughness required:

A. Proposal of a new drug for the Hospital Formulary shall be submitted on a Formulary Request Form to the Pharmacy Department. These forms may be obtained from the Pharmacy. Such requests may be submitted by any member of the medical staff. The Committee will evaluate the request and notify the proposer as to acceptance or rejection. The proposer shall have the opportunity to appeal the decision of the Committee.
B. Drugs evaluated and approved by the Committee will be assigned to one of the following four categories:
   1. *Formulary Drug*
      An FDA approved drug which is recommended as being essential for good patient care with a well established usage. Once accepted as a Formulary Drug, it may be prescribed by all members of the attending and house staffs.
   2. *Drugs Approved on a Conditional Trial Period*
      A drug which has been approved by the FDA for general use but which the Committee will evaluate for a 6- or 12-month period before final consideration. During that period, the drug may be prescribed by all members of the attending and house staffs.
   3. *Specialized Formulary Drug*
      An FDA approved drug which is recommended for use in specialized patient care. The drug may be placed in this category by the proposer or the Committee and either may designate those persons authorized to prescribe Specialized Formulary Drugs.
   4. *Investigational Drugs*
      A drug which has been approved by the FDA for a specific use by its principal investigator and designated associates. Such drugs are not commercially available. They must be approved by the Human Sub-

jects Committee, the Pharmacy and Therapeutics Committe, and, if applicable, the Isotope Committee. A protocol of the study must be submitted to the Pharmacy if it is to be used in the hospital. The drug may be stored and dispensed by the Pharmacy if desired by the principal investigator.

C. Drugs which do not qualify for the four categories listed shall be considered as "Non-Formulary Drugs" and will not be stocked in the Pharmacy. A "Non-Formulary Drug" may be prescribed only by members of the attending staff and chief residents, or their designees in their absence. The Pharmacy will obtain and dispense a limited quantity of the drug.

D. The pre-signing of prescription blanks or drug orders for any purpose is prohibited.

E. The Pharmacy Department is authorized to dispense drugs according to policies and procedures of the Committee. According to the Formulary System, all drugs will be dispensed on the basis of generic names to avoid duplicate inventory and achieve a cost savings. Physicians may specify a specific brand name drug when deemed necessary. Authority for the routine selection of drug brands is delegated to the Pharmacy Department, utilizing a fair and equitable bid process when necessary.

F. The Committee is responible for the rules and regulations which govern pharmaceutical company representative activities within the hospital. These rules and regulations are available from the Pharmacy.

G. *Drug Recall*

Drug recalls may emanate from manufacturers, regulatory agencies, or the Pharmacy Department, and may be of a general nature or a specific recall for one or more lot numbers. Once a recall notice is received, the drugs will be removed and replaced; and this information will be sent to staff and pertinent hospital departments. (See chart in Pharmacy and Policy Manual.) All recall drugs, if stocked, will be held in quarantine in the Pharmacy until directions for return or final resolution are received.

H. *Inpatient Prescribing*

1. *Routine Drug Orders*

A physician's medication order written on inpatient order form is deemed a legal prescription. A legible copy of the medication order must be forwarded to the Pharmacy and must include the following information:

a. The patient's addressograph information.
b. The name of the nursing unit.
c. The name and strength of each drug.
d. The directions for frequency of administration.
e. The route of administration.
f. The signature of the prescribing physician.
g. The date and time that the order was written.

Orders written by medical students must be countersigned by a member of the medical staff. Quantities of drugs to be dispensed need not be specified since the pharmacist will determine the optimum amounts in keeping with greatest economy to the patient and efficiency in handling and storage by the nursing and Pharmacy staffs.

2. *I.V. Orders*

Orders for intravenous medications must be written in the same manner as routine drug orders and must include the following additional information:

a. The exact quantity of the drug(s) which must be added.
b. The exact volume and name of the infusate solution.

c. Specific directions for administration such as IV drip, IV bolus, IV push, etc.
d. Specific times to hang infusate solution and drip rate.
e. Specific directions for continuing or discontinuing any IV medications.

3. *Total Parenteral Nutrition (TPN)*
   a. TPN has been designed to serve as a nutritional infusion providing essential amino acids, carbohydrates, and electrolytes for patients incapable of ingesting, digesting, or absorbing food substances given by mouth. Since a standard hyperalimentation solution must always be prepared extemporaneously, the Pharmacy Department shall be responsible for the preparation of these solutions.
   b. *Ordering*
      (1) The TPN mixture may only be prescribed by an authorized House Staff physician in conjunction with a Dietician through consultation.
      (2) The written order must be sent to the Pharmacy for verification including the basic solution and all additives.
      (3) Following the original order, subsequent orders must be confirmed every morning and recorded on a card designated for that specific patient.
      (4) A 24-hour supply is to be ordered by the physician each morning.
      (5) Only electrolytes and vitamins may be added to hyperalimentation solutions.

4. *Self Medication*[8]
   Only nitroglycerin and antacids may be left at the patient's bedside for self administration if so ordered by the physician. The quantity of nitroglycerin is limited to 10 tablets which must be counted by the nurse at the conclusion of each shift and charted in the patient's medical record. Antacids must be recorded and replenished in the same manner.

5. *Medication Brought to the Hospital by Patients*
   Medications brought into the hospital by the patient may not be kept at the patient's bedside. Medications are shown to the physician, then sent home with a responsible family member or friend. If the latter is not possible, the medication container must be labeled with patient's name, locked in the medication cabinet and with physician's permission sent home with patient when discharged.

6. *Automatic Stop Orders*
   Automatic stop-order requirements for medications are:
   1. 24 hours for Schedule II Control drugs
   2. 7 days for all other drugs

   P.R.N. and standing orders for all medications except Schedule II Control drugs expire at 10:00 A.M. of the following Tuesday morning. All orders shall be renewed between the hours of 4:00 P.M. Monday and 10:00 A.M. Tuesday. Orders which are written on Monday become effective at 10:00 A.M. Tuesday.

7. A new medication order must be written by the physician if a change is wanted in route of administration or in dosage.

8. *Prescribing Schedule II Control Substances*
   a. Routine orders for Schedule II Control substances must be written on the inpatient's order form and signed by the physician. The physician's full name is required. The order must include the

name of drug strength, route of administration, and frequency of administration.

b. Pro Re Nata (prn) orders of Schedule II drugs are acceptable if a specific dose and a specific minimum interval is written.

c. Telephone and verbal orders may be given by the physician in an emergency situation. The nurse will make the appropriate entry on the inpatient's order form, sign the physician's name, and initial the verbal or telephone order. It is the responsibility of the physician to sign the order prior to the next shift count.

d. Discharge prescriptions for Schedule II drugs are restricted to a 30-day supply, no refills, patient's home address, and the physician's DEA number (See Discharge Prescriptions).

9. *Prescribing Methadone*

a. The FDA has issued new regulations governing the use of methadone for analgesia in severe pain and for detoxification and temporary maintenance treatment of heroin addicts.

b. Methadone is permitted to be administered for analgesia in severe pain, detoxification, or temporary treatment of the acute withdrawal symnptoms for *hospitalized patients* for a period *not to exceed three weeks.* If the Hospital does not operate a maintenance program, an outside agency may be contracted. (See Outpatient Prescribing)

10. *Alcoholic Beverages*

Whiskey, wine, and other alcoholic beverages may be ordered from the Pharmacy. The order must specify the prescribed dose for the patient and bear the personal signature of the physician. The maximum quantity which may be dispensed on any one prescription is 240 ml. Alcoholic beverage prescriptions cannot be refilled. A new prescription must be written for each 240 ml quantity dispensed. Alcoholic beverages obtained from the Pharmacy may not be removed from the hospital. Unused quantities must be returned to the Pharmacy.

11. *Discharge Prescriptions*

A separate prescription is required for each medication which the patient is to take home. Each prescription must contain the following information:

a. Patient addressograph information. (Home address for Schedule II drugs).
b. Name of drug and strength.
c. Quantity to be dispensed.
d. Specific instructions for patient administration.
e. Number of refills (none for Schedule II drugs).
f. Signature and printed name of physician.
g. For narcotic prescriptions, see Schedule II prescribing.

Discharge prescriptions must be received in the Pharmacy the day prior to discharge, so that they may be processed and returned to the nursing station. Delays may result in the patient having to wait which is not consistent with good patient care.

12. *Emergency (STAT) Orders*

Bona fide emergency (STAT) orders should be rare and in most cases obtained from the nursing station emergency drug supplies. When necessary, these orders should be transmitted in writing on the Pharmacy copy of the inpatient order form. This procedure prevents unnecessary delay and confusion which results from hurried verbal

transmission orders. If it is necessary to phone the Pharmacy for emergency drugs, calls should be placed either by the physician or the nurse in order to avoid delay and error.

I. *Outpatient Prescribing*
   1. The hospital requires that a prescription be written for any drug or medical supply which is to be dispensed for hospitalized patients at discharge, clinic patients, and employees. Such prescriptions may *only* be written on hospital prescription forms in compliance with all regulatory agencies.
   2. Information required on prescriptions:
      a. Addressograph patient information
      b. Date
      c. Name and strength of medication
      d. Quantity to be dispensed
      e. Specific information for patient administration
      f. Specific number of refills
      g. Signature and printed name of the physician
   3. Prescriptions for Control Drugs have special requirements, which are as follows:
      a. All Control Drug prescriptions require the physician's DEA number.
      b. Schedule II drugs (narcotics) are limited to a 30-day supply and *no* refills. These prescriptions are valid for 5 days and are not valid if there are crossouts, erasures, or any evidence of tampering.
      c. Schedule III drugs, such as paregoric and medium acting barbiturates, are limited to a 30-day supply and may be refilled up to 5 times within 6 months of issuance date.
      d. Schedule IV and V, such as benzodiazepines and cough preparations, may be refilled 5 times within 6 months of issuance date.

GENERIC VS. BRAND NAMED DRUGS[9]—A COMMITTEE DILEMMA

A quarter century ago, approximately 75% of all prescriptions were extemporaneously compounded by pharmacists. Today the reverse is true; nearly 90% are written for manufactured entities which usually bear a brand name. During this same 25-year period, material, labor and operational costs have steadily risen and industry has spent many millions of dollars in research for new drugs. Because of this increasing cost spiral, each newly released prefabricated brand name medication appeared to be closely associated with high prices. Thus the concept of brand name prescribing and dispensing has been erroneously linked with such descriptive adjectives as "expensive," "highly priced" and "exorbitantly priced" in comparison to generic prescribing and dispensing which is supposedly "inexpensive" and "money saving."

The advocates of generic prescribing and dispensing have been vociferous and have commanded much space in our drug journals. In addition, they have monopolized administrative and legislative sessions at both the federal and state levels. Their lobbyists have proposed

that the government require generic prescribing and dispensing in all welfare programs. Others contend that the federal government offer the States a bonus payment with its Federal welfare payments whenever generic drugs are dispensed in state-operated programs. Still others suggest that the Federal government approach the issue by penalizing the State through lower welfare reimbursement rates if the State advocated the use of brand named drugs in its welfare programs. Some welfare departments have already succumbed to the pressure thus forcing pharmacists to become involved with the purchasing and dispensing of generic drugs.

Because hospitals with large active clinics usually carry a high welfare census in order to maintain an adequate resource of teaching cases, the hospital pharmacist will be faced with the problem of generic vs. brand named drug. Furthermore, the hospital administrator and many members of the medical staff will advocate generic prescribing and dispensing. They will do this in good faith and with good intentions. They want the clinic patients and the welfare agencies to pay as little as possible for medications.

At each meeting of the Pharmacy and Therapeutics Committee the hospital pharmacist will be, and in many institutions already has been, faced with the allegation that if several medications made by different companies conform to the standards of the U.S.P., then all of those medications will have identical effects on patients and the least expensive one will be just as good as the most expensive.

Hospital pharmacists know that this is not wholly true. Two preparations each labeled with the generic name and the symbol U.S.P. may be generic equivalents from a chemical point of view but the important question is whether the two products are *clinically effective equivalents.*

It should be noted at this point that clinicians advocate a comparison of the clinical effectiveness of a drug. Too often this is confused with a drug's pharmacologic activity which manifests itself by means of a specific physiologic response, whereas the clinical effectiveness of a drug includes not only its pharmacologic activity, but also such criteria as ease of application or removal, flavor and odor, allergic manifestations, tissue irritation, caloric values, disintegration and absorption rate to mention a few.

It should be common professional knowledge that the active ingredient alone does not make a medication. This chemical entity must be made into one of the accepted medicinal forms—tablet, capsule, injection, cream, ointment, elixir, syrup, a sustained release form or a suppository. This then means that other materials must be used to produce the pharmaceutical form desired. The choice of ingredients and method of combining is left to the judgment and experience of the manufacturer. The U.S.P. itself states that the actual formulating processes, by which

the active ingredient becomes a medication, "are in general, beyond the scope of the Pharmacopeia."

Reference to any pharmacy textbook will show that the producer of a medication must concern himself with such things as potency, strength, purity, compatibility, solubility, particle size, choice of vehicle or base, pH, tonicity, melting point, surface tension, viscosity, storage factors, packaging and control. Deviation from accepted standard or omission of any of these may result in a product which because of its active chemical component is a generic equivalent but not a clinically effective equivalent.

By the same token, two products may both meet U.S.P. standards but, because of differences in composition or the way they are compounded, may not be clinically effective equivalents.

It should be emphasized at this point that all generic drugs are not being condemned. An observation is being made to the extent that if a manufacturer applies all of the standards of high quality ingredients, rigid manufacturing and control procedures, adequate packaging and supports medical research and development programs, the final product will be a generic equivalent with clinical effectiveness. However, its production cost will probably be the same as that of the brand name equivalent and therefore it will have the same retail price to the consumer.

Some hospital pharmacists operating in large metropolitan teaching and research hospitals may well be in a position to purchase generic products from manufacturers who are unfamiliar to them, because they have adequately staffed and equipped control laboratories and clinical testing programs in which they are able to make the assays necessary to ascertain the quality and effectiveness of the product purchased. It should be noted here that oftentimes when the cost of the hospital conducted analyses is added to the purchase price of the product, little financial advantages remains.

Pharmacists certainly realize that there are both high and poor quality pharmaceuticals available under both generic names and brand names. The hospital pharmacist by virtue of this educational background and general familiarity with the reputation, integrity and facilities of pharmaceutical manufacturers is in an excellent position to evaluate the merits of brand named drugs vs. their generic equivalents. He should not relinquish this position of professional authority and competence to any administrator, physician, politician or welfare agency commissioner. He should, on the other hand, make himself available to all of these people to advise and teach them that the quality of a drug and its subsequent clinical effectiveness are quite independent of its name.

The hospital pharmacist can carry on his teaching program in a number of ways. As a member of the Pharmacy and Therapeutics Committee, he can make available to the Committee membership various articles

dealing with the therapeutic implications of brand interchange, publications pertaining to clinical ineffectiveness of drugs due to faulty formulation and the various reports of the FDA in which they describe drug seizures due to faulty labeling or improper strengths.

As the editor of the hospital pharmacy newsletter, the hospital pharmacist should avail himself of the opportunity to editorialize his views on the subject.

As a lecturer in pharmacology in the school of nursing and as a lecturer in the in-service training programs for nurses and interns, the hospital pharmacist should deliver knowledgeable lectures on the subject in order that the doctors and nurses—particularly those in training—may keep in clear perspective the relationship between quality pharmaceuticals and therapeutic efficacy.

EVALUATION OF DRUGS

The evaluation, approval or rejection of drugs and biological agents from the hospital formulary is a time consuming task that dominates the committee agenda. Because no two institutional committees use the same drug evaluation criteria, it is suggested that the ASHP Technical Assistance Bulletin on the Scientific and Therapeutic Evaluation of Drugs for Hospital Formularies[7] be utilized.

ASHP TECHNICAL ASSISTANCE BULLETIN ON THE SCIENTIFIC AND THERAPEUTIC EVALUATION OF DRUGS FOR HOSPITAL FORMULARIES[a]

Preamble

One of the major roles of the Pharmacy and Therapeutics Committee is to develop and maintain a hospital drug formulary system. The hospital formulary can be used as the basis for promoting optimal pharmacotherapy because it contains only those drugs judged by the Pharmacy and Therapeutics Committee to be in the best interest of the patient's health needs in terms of efficacy and consideration of cost. The pharmacist is a key member of the drug evaluation team because of his knowledge of pharmacology, pharmacokinetics, toxicology, therapeutics, and drug purchasing.

The evaluation of comparative data associated with a drug's efficacy, adverse effects and cost, and the determination of its potential therapeutic advantages and deficiencies require specific attention by the

[a]Developed by the ASHP Council on Clinical Pharmacy and Therapeutics. Approved by the ASHP Board of Directors, April 30, 1981.

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pharmacist. Products may be admitted to or rejected from entry into the hospital formulary based on the initial evaluation by the Pharmacy and Therapeutics Committee. Alternative recommendations might include either conditional approval for a specific time period, with subsequent re-evaluation, or temporary limitation of a drug's use to an individual medical service specialty with future reassessment.

Evaluation Process Considerations

Standardization forms should be developed for use in the evaluation process. It is recommended that each form should include the following information:

1. Generic Name
   - List the officially approved name of all chemical entities in the drug product.
2. Trade Name(s)
   - List the most common trade name(s) of the drug product, as used in the local area.
3. Sources(s) of Supply
   - Identify the pharmaceutical companies from which the drug product could be procured.
   - For a generic drug product, identify the actual manufacturer: if applicable, identify the pharmaceutical company marketing the product.
4. *American Hospital Formulary Service (AHFS)* Classification Number
   - List number for quick access and retrieval for information.
5. Pharmacologic Classification
   - State which pharmacologic class to which the drug belongs and any similar properties it possesses in comparison to existing drugs.
   - State the mechanism of action; if the mechanism of action is unknown, so state. If applicable, the mechanism of action may be compared with that of another drug or class of drugs.
   - List the potential nonapproved uses for the drug, based on an expanded description of its pharmacological activity (preferably in humans).
   - List bacterial spectrum and clinical effectiveness for an antimicrobial agent, comparing properties to existing formulary agents.
6. Therapeutic Indications
   - State the uses of the drug as approved by the Food and Drug Administration (FDA); indicate if use is prophylactic, therapeutic, palliative, curative, adjunctive or supportive.
   - Evaluate uses of the drug in comparison with other established forms of therapy using, if possible, human studies for comparison. Comparisons should emphasize therapeutics, i.e., efficacy, incidence of treatment success, remission, sansitivity, ease of monitoring and treatment periods required, and include critical analysis of clinical studies in such areas as patient population, methodology, statistics, and conclusion.
   - State potential drug-drug interactions.

- Identify non-FDA approved uses for the drug, and those uses that show promise in investigational studies.

7. Dosage Forms
   - List all dosage forms available as approved by the FDA; list unit costs.
8. Bioavailability and Pharmacokinetics
   - List bioavailability data for the most common route of administration and dosage of the drug. Other bioavailability data should be available upon request by the Pharmacy and Therapeutics Committee.
   - List pharmacokinetic data for absorption, distribution, metabolism, and excretion of drug.

   Absorption—Include information on the extent and rate of absorption of the drug by the usual routes of administration; the factors that might effect rate or extent of absorption; the therapeutic, toxic and lethal blood levels; the period of time required for onset, peak, and duration of therapeutic effect; the half-life and factors affecting it.

   Distribution—Include information on the usual distribution of the drug in body tissues and fluids; the drug's propensity to cross the blood-brain barrier, placenta, or appear in human milk; protein binding and volume of distribution.

   Metabolism—Include information on sites of metabolism and extent of biotransformation; metabolic products and their activity.

   Excretion—Include information on routes of elimination from the body; factors affecting elimination; form in which drug is eliminated.
9. Dosage Range
   - List dosage for different routes of administration of drug.
   - List initial, maintenance, maximum, and pediatric doses for the drug.
10. Known Side Effects and Toxicities
    - Discuss side effects of the drug and their frequency of occurrence from research data of human studies.
    - Discuss means or methods of prevention or treatment of side effects and toxicities. Benefits of disease treatment to risk of side effects should be emphasized.
11. Special Precautions
    - List precautions and contraindications for certain disease states or other conditions.
    - Compare all of the preceding with existing similar agents where applicable.
    - List potential drug-drug interactions if deemed clinically significant.
12. Advantages
    - Compare and list all advantages of the drug with existing products, using information from sections 5–10 as basis of comparison.
13. Disadvantages
    - Compare and list any disadvantages of the drug with existing products, using information from sections 5–10 as basis of comparison.
14. Comparisons
    - List therapeutic comparisons with other drugs or treatment regimens.
    - List cost comparison data of a standard treatment regimen with the new drug versus currently used drugs.
15. Recommendations
    - Formulate recommendations from analysis of all the preceding data, and consideration of other factors such as medical staff preference,

distribution problems, availability of drug, and manufacturer. Determine action to be taken in regard to hospital formulary status:

Uncontrolled—Available for use by all medical staff.

Monitored—Available for use by all medical staff, but use monitored by a department.

Restricted—Available for use by medical staff of a specific service or department.

Conditional—Available for use by all medical staff for a specific time period.

Deletion—Delete from current formulary.

RECOMMENDED REFERENCE MATERIALS

The development of a comprehensive data base is essential for evaluating drugs proposed for admission to a hospital formulary. A thorough review of the pharmaceutical and medical literature is necessary when accumulating these data. The list of recommended references include those sources that commonly provide useful information in drug evaluation; however, review of additional specialty journals may be required.

Texts:

1. *American Hospital Formulary Service*
2. *Drug Topics Redbook*
3. *Facts and Comparisons*
4. *Martindale—The Extra Pharmacopoeia*
5. *Physicians' Desk Reference*
6. *The Pharmacological Basis of Therapeutics*—Goodman and Gilman

Periodicals and Abstracting Systems:

1. *American Journal of Hospital Pharmacy*
2. *Annals of Internal Medicine*
3. *Archives of Internal Medicine*
4. *Antimicrobial Agents and Chemotherapy*
5. *Clinical Pharmacology and Therapeutics*
6. Drugdex
7. *Drugs*
8. Drug Intelligence and Clinical Pharmacy
9. *Hospital Formulary*
10. Iowa Drug Information Service
11. *International Pharmaceutical Abstracts*
12. *Journal of the American Medical Association*
13. *Lancet*
14. *Medical Letter on Drugs and Therapeutics*

15. *New England Journal of Medicine*
16. Paul de Haen Information Systems

RECOMMENDATIONS

"ASHP Guidelines for the Scientific and Therapeutic Evaluation of Drugs for Hospital Formularies" are supplementary to "ASHP Guidelines for Hospital Formularies"[1] and "ASHP Statement of Guiding Principles on the Operation of the Hospital Formulary System,"[2] which should be consulted for further information on the formulary system. These guidelines are recommended as an aid to the pharmacist responsible for the selection of drugs to be included in a hospital formulary.

REFERENCES

1. ASHP guidelines for hospital formularies. *Am. J. Hosp. Pharm.* 1978; *35*:326–8.
2. ASHP statement of guiding principles on the operation of the hospital formulary system. *Am. J. Hosp. Pharm.* 1964; *21*:40–1.

The Committee's Role in Drug Safety

With the advent of each new class of therapeutic agents, the scope, knowledge and responsibility of the hospital pharmacist increases commensurately. Hand-in-hand with this increased responsibility goes the moral, legal, and professional obligation of insuring safety in the handling and administration of drugs.

Unfortunately, too many pharmacists and physicians take drug safety for granted. They are lulled into a false state of complacency by the fact that pharmacy "accidents" resulting in serious injury to or death of patients are relatively infrequent.

However, with the first press release describing a tragic drug "accident" in a neighboring hospital, every trustee, administrator, physician, and pharmacist suddenly awakens to the fact that their policies governing the pharmacy ought to be reviewed in the light of modern dispensing and prescribing trends.

This function could well be the responsibility of the Pharmacy and Therapeutics Committee and should be an on-going program. The following may serve as a guide to this Committee in ascertaining the safeness of the hospital pharmacy.[10]

1. Does the hospital employ a qualified registered pharmacist to supervise the pharmacy?
2. Does the hospital permit non-pharmacist personnel to dispense drugs and allied materials?
3. Does the hospital employ a sufficient number of qualified per-

sonnel to allow for adequate coverage of the pharmacy seven days per week?

4. Does the hospital employ personnel commensurate with the pharmacy work load?
5. Does the hospital provide adequate, safe work space, and safe storage facilities for the pharmacy?
6. Does the pharmacy have the equipment necessary to safely and adequately carry out the modern practice of pharmacy?
7. Does the hospital have an automatic stop order regulation for dangerous drugs such as narcotics, hypnotics and anticoagulants?
8. Does the hospital have a firm policy regarding the use of research drugs in the hospital and its clinics?
9. Does the hospital have a drug formulary? If so, is it periodically revised and kept up-to-date?
10. Does the hospital permit anybody other than a licensed pharmacist into the pharmacy "after hours"?
11. Are poisonous materials adequately segregated from non-poisonous materials in the pharmacy and on the nursing stations?
12. Are external use preparations separated from internal use medications in the pharmacy and on the nursing stations?
13. Does the pharmacy manufacture products for patient's use? If so, are these products checked for accuracy and asepsis by chemical and bacteriologic means?
14. Does the hospital allow the pharmacist sufficient help to permit him to engage in a teaching program to acquaint the nursing and resident staff with new drugs and to teach the student nurses the basic courses of pharmaceutical mathematics and pharmacology?
15. Are all nursing stations periodically inspected for the purpose of removing deteriorated and outdated drugs as well as to check all labels for legibility?
16. Does the pharmacy have an adequate reference library which contains texts on pharmacology, toxicology and posology?

COMMITTEE'S ROLE IN THE ADVERSE DRUG REACTION PROGRAM

A consequence of recent advances in drug therapy is the proportionate increase in drug reactions. In order to gain an understanding of these problems and to formulate competent opinions as to the best type of prevention and treatment, the Pharmacy and Therapeutics Committee must assume the responsibility for developing and instituting a procedure for the prompt reporting of an adverse drug reaction.

An adverse drug reaction has been defined by the Food and Drug Administration as follows:[11]

"An adverse drug reaction includes any pathological condition precipitated by a drug regardless of its nature or the circumstances of its occurrence, *i.e.*, toxicity caused by overdosage (therapeutic, accidental, homicidal); hypersensitivity; allergy; or injury from improper technique of administration, use of the wrong drug, error in compounding, labeling, or packaging, or from other error in the manufacture of the drug, or in its preparation for use in the hospital. Reactions caused by blood and plasma products need not be reported unless a chemical agent other than the basic substance is responsible."

An *Adverse Drug Reaction Report Form*, such as that shown in Figure 12, should be prepared by the Committee and made available on every nursing station.

A simple yet effective reporting program may be established by adopting the following criteria:

Every case of adverse drug reaction must be reported by the attending physician to the clinical pharmacologist, if one is available on the staff, otherwise to the Chairman of the Pharmacy and Therapeutics Committee. The attending physician should complete an *Adverse Drug Reaction Report Form* on any patient having an adverse reaction. The Medical Record Room will, upon the patient's discharge, remove the *Adverse Drug Reaction Form* from the medical record and forward it to the clinical pharmacologist or to the Chairman of the Pharmacy and Therapeutics Committee. Adverse drug reactions should be listed in the medical record as a diagnosis whenever such applies.

DRUG EXPERIENCE REPORTING

The FDA has in use a Drug Experience Report (Form FDA 1639.4/81) which seeks to gather information on drug defects and adverse drug reactions. The form states that the identity of the patient and the individual making the report will be held in confidence. The form is divided into three sections—Reaction Information, Suspect Drug(s) Information and Recent/Concomitant Drugs and Medical Problems. The forms are available from the FDA and it is recommended that Pharmacy and Therapeutics Committees make use of them in reporting drug incidents.

DRUG PRODUCT DEFECT REPORTING PROGRAM

In 1971, the ASHP, the USP and the FDA initiated a drug product defect reporting program. Since then, the program has been expanded to include, in addition to ASHP members who were in active practice,

Addressograph

ADVERSE DRUG
REACTION REPORT

Directions:

Every case of drug reaction (unusual or unexpected reactions), including acute poisonings by narcotics, barbiturates and amphetamines and industrial poisonings is to be reported by the attending physician to the Division of Pharmacology. The physician in charge of the patient is also responsible for notifying the allergist, dermatologist and others interested in the problem. Diagnostic procedures and therapy when such exist, will be instituted.

1. Drug or agent involved: _____

_____

_____

2. Type of reaction: _____

_____

_____

3. Therapy and Results: _____

_____

_____

4. Age

__Under 20
__21–30
__31–40
__41–50
__51–60
__61 and Over

5. Sex:

__M. __F.

5A. Color:

__Negro
__White
__Other

6. Source of drug:

__Prescription
__Over the counter
__Other

_____
Attending Physician

Fig. 12. Adverse Drug Reaction Report.

HOSPITAL PHARMACIST'S DRUG DEFECT REPORT

Form Approved: OMB No. 57-R0059
DO NOT USE THIS SPACE
DATE RECEIVED
REFERENCE NO.

1. TRADE NAME, DOSAGE FORM, STRENGTH

2. LOT NUMBER(s)

3. DATE PURCHASED (If known)

4. SOURCE OF PRODUCT (Where purchased, if known)

5. NAME AND ADDRESS OF DRUG MANUFACTURER

6. REPORTING PHARMACIST'S NAME

7. NAME AND ADDRESS OF HOSPITAL (Include ZIP Code) 1/

8. PHONE NUMBER OF HOSPITAL (Include Area Code)

9. DEFECTS NOTED OR SUSPECTED

1/ Additional forms and postage-paid envelopes will be mailed to you automatically at this address when this report is received.

RETURN TO

United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852
Attention: Dr. Joseph G. Valentino

FD FORM 2519 (2-72)

Fig. 13. Hospital Pharmacist's Drug Defect Report Form.

community pharmacists, the American Nurses' Association and hospital pharmacists who are not members of the ASHP.

Reporting forms (Fig. 13) are automatically sent to all those participating in the program. Reportable defects include inadequate packaging; confusing or inadequate labels or labeling; deteriorated, contaminated, or defective dosage forms; inaccurate fill or count of a drug product; faulty drug delivering apparatus etc. Obviously, the participants should report anything which, in their professional opinion, is considered to be defective or undesirably associated with the product.

The completed report forms are sent directly to the USP. The staff of the USP then forwards copies of the reports to the FDA and to the manufacturer or distributor involved for their information and use.

AUTOMATIC STOP ORDER FOR DANGEROUS DRUGS

The Pharmacy and Therapeutics Committee should develop a means whereby dangerous drugs may be properly administered under reasonable medical staff control.

The questionnaire for accreditation by the Joint Commission on Accreditation of Hospitals specifically determines whether or not the hospital has an automatic stop order in force.

The way two hospitals handle this matter is shown below. Either may be copied in principle by any hospital desiring to do so:

"All drug orders for narcotics, sedatives, hypnotics, anticoagulants, and antibiotics (administered orally or parenterally) shall be automatically discontinued after 48 hours, unless (1) the order indicates an exact number of doses to be administered, (2) an exact period of time for the medication is specified, or (3) the attending physician reorders the medication."

The second example of an automatic stop order is:

"All orders for narcotics, sedatives and hypnotics must be rewritten every 24 hours.

"All P.R.N. (pro re nata) and standing orders for all medications except narcotics, sedatives and hypnotics shall expire at 10:00 a.m. on the seventh day unless renewed."

COMMITTEE'S ROLE IN DEVELOPING EMERGENCY DRUG LISTS

Because in most true emergencies time is of the essence, it is imperative that emergency drug or "Stat" boxes containing drugs and supplies be readily available for use by the bedside. The Pharmacy and Therapeutics Committee should develop a list of supplies and drugs which ought to be in an emergency box and instruct the pharmacist and nursing service supervisors of their joint responsibility to have the box ready for use at all times.

Once the content of the box has been established and the responsibility for its stocking assigned, the units should be prepared and placed on each pavilion, in the clinic, in the emergency ward and in the special procedures room of the department of radiology.

After the emergency boxes have been placed on the wards, it is mandatory that a program be developed whereby they are checked daily either by the hospital pharmacist or by the nursing supervisor responsible for the ward.

The following list of contents is provided to serve as a guide.

Supplies to be Maintained in Emergency Box:

Syringes:
4– 2 ml
4– 5 ml
1–20 ml
1 insulin

Needles:
2 #16
2 #18
2 #20
2 #23
2 cardiac, #20, 4"

Files, ampul.
Airway
Tourniquets

Drugs for the Emergency Box:

Aminophylline 0.25 gm/10 ml
Amphetamine Sulfate 20 mg/ml
Amyl Nitrite Inhalation
Atropine Sulfate 0.4 mg/ml
Caffeine Sodium Benzoate 0.5 gm/2 ml
Calcium Gluconate 1 gm/10 ml
Chloroprophenpyrimadine Maleate 50 mg/ml
Digoxin 0.25 mg/ml
Diphenylhydantoin Sodium 50 mg/ml
Epinephrine HCl 1:1000
Heparin 10,000 Units/ml
Hydrocortisone 100 mg
Isoproterenol 1:100
Magnesium Sulfate Injection 10% and 50%
Metaraminol Bitartrate 10 mg/ml
Mannitol Injection 25%
Nalorphine HCl 10 mg/2 ml
Neostigmine Methylfulfate 0.25 mg/ml
Nor-epinephrine Injection 0.2%
Pentobarbital 50 mg/ml
Pentylenetetrazol Injection 0.1 gm/ml
Phenobarbital 120 mg/ml
Phenylephrine HCl 10 mg/ml
Phytonadione Injection 50 mg/ml
Picrotoxin Injection 3 mg/ml
Procaine Amide 100 mg/ml
Protamine Sulfate 10 mg/ml
Saline for Injection 30 ml
Sodium Molar Lactate Solution
Water for Injection 50 ml

Supplies for Cabinet or Pavilion Utility Room:

1 Venous cannulization set
2 each—#14 and #17 venous catheters
2 6" shock blocks
2 Oxygen catheters
3 Sterile suction catheters
1 Sengstachen-Blakemore tube
1 Razor with blades
1 pkg. sterile gelatin sponge
1 Resuscitation tube

Other Emergency Supplies:

Resuscitation carts
Phlebotomy sets
Oxygen equipment
Tracheostomy sets
Dextran and tubing
Burn sheets

Drug Utilization Review

Drug utilization has been defined as the prescribing, dispensing, administering, and ingesting of prescription drugs.[12] Clearly, the magnitude of the problems associated with drug utilization is of great public concern and warrants the attention of health care practitioners. Yet, as a result of this study of the problem Brodie[2] concluded that "there is

no organized mechanism for what can properly be called drug utilization review in the private sector of medical care."

Within the hospital, the Pharmacy and Therapeutics Committee provides the institutional authority for the formulary system of drug-use control as well as the mechanism for the continuing education of physicians, nurses and pharmacists. Thus, some institutions have initiated *patient drug utilization profiles* and medication history taking as part of their clinical pharmacy programs thereby enabling the pharmacists to monitor drug utilization within the hospital.

Medication histories are taken by pharmacists of every patient admitted to the hospital or seen in the ambulatory care section. These may be accomplished by personal interview or via a computerized questionnaire specifically designed for the purpose. In addition to personal identification and general diagnosis, the following information is elicited:

1. Medications being taken at time of admission.
2. Medications taken during the recent past. (Including antibiotics.)
3. Home remedies (OTC Drugs) used.
4. Drug allergies.
5. Laboratory tests performed out of the hospital during which diagnostic agents were ingested.
6. Idiosyncrasy towards food products.

The Patient Medication Profile (Fig. 14) is developed by the pharmacist for the following purposes.[13]

1. To help improve drug prescribing practices by promoting the safe and rational use of drugs.
2. To detect and help prevent potential drug interactions.
3. To help detect and prevent adverse drug reactions in sensitive patients.
4. To detect and prevent IV additive incompatibilities.
5. To detect drug-induced laboratory test abnormalities.
6. To detect possible drug-induced diseases.
7. To help detect and prevent potential drug toxicities.

When the Patient Medication Profile, Patient History and Laboratory Procedure Profile are compared, the pharmacist is in an excellent position to monitor proper drug utilization.

It should be obvious to the student that the compilation of drug utilization is a tedious responsibility that can be automated. A computer-based system provides for the entry of the information into the computer through the use of punch cards, magnetic tape, scanning device, or an electronic input terminal device. In the National Center for Health Services Research and Development Study[12] it was pointed

PATIENT MEDICATION PROFILE

Name_____ Location_____ Physician_____

Admitted_____ Source of Admission_____ Home____ Other hospital

_____ Nursing Home _____ Emergency Service

Admission Diagnosis_____

Other Pathology_____

Operative Procedure Required_____

Pre-Op Medications Used_____

DRUG PROFILE
(includes I.V.'s)

DATE	MEDICATION	DOSE, ROUTE FREQUENCY	DISCONT. DATE	LAB. TESTS	PHARM. NOTE

DISCHARGED_____ PHARMACIST_____

Fig. 14. Patient Medication Profile for use by clinical pharmacists.

out that the ideal system should provide for both retrospective and prospective review.

Retrospective analysis is provided through the use of the punch cards and magnetic tapes whereas when electronic terminal devices are employed, both retrospective and prospective analyses are possible. Control of drug utilization by prospective review is possible when a computer read-out station is located on the patient pavilion. This device can display the profile of a patient's regimen (and others if desired) at

the time a new drug is prescribed or when changes are made in therapy. In either case, the entry to the computer is made through an input station utilizing a typewriter keyboard, thereby making an instant entry into the on-line system.

Generally, the input information for an electronic data processing system is taken in a codified form from the source documents which, in this instance, are the prescription, medication order or doctor's order book. The following provides an idea of the type and scope of information utilized: patient's name, age, sex, ethnic background, diagnosis, drug product, manufacturer, therapeutic class, dosage form, strength, route of administration, directions for use, amount dispensed, days of therapy, drug effectiveness, toxicity, adverse reactions, reasons for termination of therapy, prescriber's name and specialty, etc.[12]

In those hospitals and nursing homes where it is not possible to develop patient drug profiles for the continuing surveillance of drug utilization, it may be advisable for the pharmacist to become a member of the Utilization Review Committee. Membership on this committee of a pharmacist is possible because it is required to be broadly representative of the entire scope of professional practice carried out in the institution. The pharmacist's training and experience in drug problems uniquely qualifies him to sit on such a committee and review patient drug utilization while physicians review clinical utilization of hospital services.

The ASHP has developed Guidelines on the Pharmacist's Role in Drug-Use Review and Patient-Care Audits[14] hereinafter reproduced.

ASHP GUIDELINES ON THE PHARMACIST'S ROLE IN DRUG-USE REVIEW AND PATIENT-CARE AUDITS[a]

Drug-use review (DUR) is "an authorized, structured, ongoing system for improving the quality of drug use within a health care organization."[1] This can be accomplished by the development of an evaluation process that uses predetermined criteria and leads to corrective measures that will improve use of drugs. DUR is a responsibility of the pharmacy and the medical staff; it is not unilaterally a pharmacy or medical staff function.[2]

DUR can either be a "freestanding activity"[3] or be incorporated in current patient-care audits performed by the medical staff. Patient-care audits use explicit and measurable process and outcome criteria applied to a sufficiently large number of patient records to evaluate the quality of care being provided for (most commonly) a certain disease state or

[a]Developed by the ASHP Council on Clinical Pharmacy and Therapeutics. Approved by the ASHP Board of Directors, April 30, 1981.

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surgical procedure. Drug use is often an important component of the care provided and should be appropriately reviewed.

DUR may be performed retrospectively, concurrently, or prospectively, and can use patient outcomes or therapeutic processes or both as basis for judgments about the appropriateness of drug use. The basic requirements of a DUR program are as follows:

1. Authority for the program (This derives from the medical staff or hospital administration).
2. Adequate data bases for study.
3. Use of predetermined criteria.
4. Use of appropriate audit methodology in data retrieval.
5. Data analysis.
6. Education or corrective action or both (when appropriate).
7. Reaudit.
8. Documentation and report of all activities and results.

Responsibilities of the pharmacist in these activities include the following:

1. Preparing, in cooperation with the medical staff, drug use criteria and standards.
2. Obtaining quantitative data on drug use (e.g., information on the amounts and types of drugs used, prescribing patterns by medical services, and types of patients). These data will be useful in setting priorities for the review program.
3. Reviewing medication orders against the drug use criteria and standards.
4. Consulting with prescribers on the results from (3) above.
5. Participating in the follow-up activities of the review program (e.g., educational programs directed at prescribers, development of recommendations for the formulary, and changing drug control procedures in response to the results of the review process).

Quantitative data used to pick topics for qualitative studies can be found in such pharmacy records as: purchasing records, monthly usage data, drug profiles for inpatients and outpatient, patient charge, adverse drug reaction reports, and others. Review of these data bases usually leads to the study of drugs that are of substantial clinical or financial import.

The intent of these guidelines is to provide a framework for pharmacists to follow in developing individual DUR programs or participating in patient care audits at their own hospitals. Pharmacists should assume an active role in any quality assurance activities in their institution that deal with the use of drugs.

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The following is offered as a starting point for the pharmacist to review the patient's drug therapy record in order to ascertain whether or not his stay was affected by drug therapy. Obviously, good therapy coupled with good clinical care can reduce the patient's length of stay whereas poor therapy, which leads to complications, may increase the patient's hospital stay.

I. Proper Choice of Therapeutic Agent
   1. Was the drug employed one with a special effect upon the diagnosed ailment? If not, why was it prescribed? If the medication prescribed was of multiple composition, was there contained therein a sufficient amount of the principal ingredient to produce a therapeutic effect?
   2. If the drug employed was a sulfonamide or antibiotic, were cultures of the infecting organism taken for the purpose of identification? Were sensitivities performed?
   3. Was any effort made to ascertain the patient's sensitivity to the drug?
   4. Did administration of the drug have any effect upon subsequent laboratory analyses essential to the diagnosis of the ailment?

II. Proper Choice of Dosage Form
   1. Did the patient receive his therapy via the parenteral route when the enteral should have been employed or vice versa?
   2. Were enteric coated tablets used when indicated?
   3. If time disintegrating dosage forms were employed, was there any evidence to indicate that the medication was being properly released?
   4. If intravenous fluids were employed, what drugs were administered simultaneously? Were they compatible with each other? With the intravenous vehicle?

III. Proper Route of Administration
   1. Was the route of administration preferable to another?
   2. If the oral route was selected, was the medication prescribed for administration at the recommended times, *i.e.* pre- or postprandially?

IV. Drug Allergy
   1. Were there any manifestations of drug allergy?
   2. Were tests for predicting drug allergies done on patients with a suspicious history?
   3. Were the drug allergies subsequently managed adequately?

V. Drug Idiosyncrasy and Pharmacogenetics
   1. If there was an abnormally prolonged drug effect, were steps taken to reduce dosage frequency?
   2. If there was evidence of increased drug sensitivity, were steps taken to reduce dosage?
   3. Were any novel or unusual drug effects noted?
   4. If there was evidence of decreased responsiveness to the drugs employed, were counter measures taken?
   5. Was there any evidence of the development of physical dependence upon the drug?

VI. Effect upon Utilization of Hospital Facilities
   1. As a result of improper drug therapy, was the length of stay increased? How many days? At how much additional cost?
   2. What additional laboratory tests were necessary? At how much additional cost?
   3. What additional diagnostic and therapeutic measures were necessary due to the improper therapy? At what additional cost?
   4. What additional medication was necessitated? At what additional cost?

VII. Follow-up and Discharge Medications
   1. Were discharge medications prescribed?
   2. Were they necessary? If yes, were the label instructions adequate to insure proper administration to the patient by law or semi-professional personnel?
   3. If a follow-up visit is scheduled, were sufficient drug doses prescribed to carry the patient until the visit date? If not, does the prescription order indicate that a refill is permissible?

NURSING AND THE PHARMACY AND THERAPEUTICS COMMITTEE

In a large teaching hospital, it is not uncommon for members of the medical staff to request nurses to administer drugs with which they are not familiar.[15] More frequently than not the medication requires administration by the intravenous route. Because these requests invariably bring anxiety and frustration to the nurse, it is vital that the Pharmacy and Therapeutics Committee devise a system whereby these requests are reviewed and if appropriate the necessary educational and training programs be instituted.

It is suggested that any nurse or physician wishing to delegate to nurses the responsibility for the administering of an intravenous drug to a patient submit to the Pharmacy and Therapeutics Committee the following information on the drug or drug product.

Names
Method of Administration
  I.V. Push
  I.V. Bolus
  I.V. Drip
Dosage
Diluent
Administration Time
Necessary Blood Work and/or other laboratory data
Contraindications
Stability of the Drug
Incompatibilities
General Precautions
Special Indications Concerning Preparation
  a. By nursing
  b. By physician only
  c. By pharmacy only

If the Pharmacy and Therapeutics Committee approves, then the educational and training effort should include the above as part of the program.

DRG'S AND THE PHARMACY AND THERAPEUTICS COMMITTEE

The term, "DRG" refers to a methodology, developed at the Center for Health Studies, at Yale University, for compressing the entire range of inpatient diagnoses into a manageable and medically meaningful number of major categories according to certain patient attributes such as age, primary diagnosis, primary surgical procedure, secondary diagnosis (if present), and secondary surgical procedure (if present). DRG's are attracting intense interest from hospitals, regulators, PSROs, and planners because of their potential for describing hospitals' casemix on a common basis.

DRG's are used by hospitals for casemix accounting for budgeting and cost control, inhospital utilization review, reimbursement appeals and resource scheduling and control. Regulators use DRG for "per case" reimbursement determinations, interhospital groupings and cost comparisons and health planning. PSRO's use DRG's for concurrent review of utilization, length of stay profiles, focused review and national PSRO reporting.

With the acceptance of the DRG methodology, hospitals will be able to compare drug therapy for the major categories of diagnoses on an interhospital basis. Presumably, reinbursement by third party payors may be based upon a predetermined schedule of drugs for the respective

diagnostic categories. Pharmacy and Therapeutics Committees should be aware of this development and should use it in performing drug utilization reviews as well as in the preparation of the hospital formulary.

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5

The Hospital Formulary

American hospital and pharmaceutical literature is replete with both favorable and unfavorable comments and views on the use of the formulary system in hospitals. This chaotic state has been brought about because of the complete misunderstanding by certain minority groups of the purpose, scope and function of the hospital formulary system.

Those who denounce the system often cite the following reasons to make valid their claims:

(a) The hospital formulary system deprives the physician of his prerogative to prescribe and obtain the brand of his choice.

(b) The hospital formulary system, in many instances, permits the pharmacist to act as the sole judge of which brand of drug is to be purchased and dispensed.

(c) The hospital formulary system allows for the purchase of inferior quality drugs, particularly in institutions where there is no staff pharmacist.

(d) The hospital formulary system does not reduce the cost of drugs to the patient or to the third party payor because most institutions purchase large volumes of drugs at reduced rates but do not pass on to the patient any reductions in their cost.

The potential benefits of a formulary system are threefold: (1) therapeutic, (2) economic and (3) educational. The therapeutic aspect of a formulary system provides the greatest benefit to the patient and physician in that only the most efficient products are listed and available. The economic merit also has a double benefit in that the formulary eliminates duplication thus reducing inventory duplication and the opportunity for volume purchasing means lower charges to the patient. The passage of the Tax Equity and Fiscal Responsibility Act (TEFRA) and other cost containment laws and regulations will have major impact on the formulary system as hospitals seek an effective mechanism to reduce drug expenses. The educational benefit is also significant for the resident staff, nurses and medical students because many good formularies contain various prescribing tips and additional drug information of educational value.[1]

With the advent of Medicare, the hospital formulary system has taken

on a new measure of importance in the hospital's economy. This is due to the fact that the Federal government will reimburse hospitals for the drugs administered or dispensed to a Medicare covered patient if the drugs were approved and listed in certain specified compendia or the hospital's formulary.

The concept of a hospital formulary system was endorsed by major health care associations in 1964 in the form of an ASHP Statement of Guiding Principles on the Operation of a Hospital Formulary System. This document has been retired in favor of the following ASHP Statement on the Formulary System.[2]

ASHP STATEMENT ON THE FORMULARY SYSTEM[a]

Preamble

The care of patients in hospitals and other health-care facilities is often dependent upon the effective use of drugs. The multiplicity of drugs available makes it mandatory that a sound program of drug usage be developed within the institution to ensure that patients receive the best possible care.

In the interest of better patient care, the institution should have a program of objective evaluation, selection, and use of medicinal agents in the facility. This program is the basis of appropriate, economical drug therapy. The formulary concept[b] is a method for providing such a program and has been utilized as such for many years.

To be effective, the formulary system must have the approval of the organized medical staff, the concurrence of individual staff members, and the functioning of a properly organized pharmacy and therapeutics committee[c] of the medical staff. The basic policies and procedures governing the formulary system should be incorporated in the medical staff bylaws or in the medical staff rules and regulations.

The pharmacy and therapeutics committee represents the official organizational line of communication and liaison between the medical and pharmacy staffs. The committee is responsible to the medical staff

[a]Approved by the ASHP House of Delegates, June 7, 1983. Approved by the ASHP Board of Directors, November 18, 1982. Developed by the ASHP Council on Clinical Affairs. Supersedes the "ASHP Statement of Guiding Principles on the Operation of the Hospital Formulary System" approved by the Board of Directors, January 10, 1964. This former ASHP statement had the endorsement of the American Hospital Association, the American Medical Association, and the American Pharmaceutical Association. At the appropriate time, ASHP will pursue approval of the new document by these organizations.

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[b]The formulary system is adaptable for use in any type of health-care facility and is not limited to hospitals.

[c]For additional information, see the ASHP Statement on the Pharmacy and Therapeutics Committee, *Am J Hosp Pharm.* 1978; 35:813–4.

as a whole, and its recommendations are subject to approval by the organized medical staff, as well as to the normal administrative approval process.

This committee assists in the formulation of broad professional policies relating to drugs in institutions, including their evaluation of appraisal, selection, procurement, storage, distribution, and safe use.

Definition of Formulary and Formulary System

The *formulary* is a continually revised compilation of pharmaceuticals (plus important ancillary information) that reflects the current clinical judgment of the medical staff.[a]

The *formulary system* is a method whereby the medical staff of an institution, working through the pharmacy and therapeutics committee, evaluates, appraises, and selects from among the numerous available drug entities and drug products those that are considered most useful in patient care. Only those so selected are routinely available from the pharmacy. The formulary system is thus an important tool for assuring the quality of drug use and controlling its cost.

The formulary system provides for the procuring, prescribing, dispensing, and administering of drugs under either their nonproprietary or proprietary names in instances where drugs have both names.

Guiding Principles

The following principles will serve as a guide to physicians, pharmacists, nurses, and administrators in hospitals and other facilities utilizing the formulary system:

1. The medical staff shall appoint a multidisciplinary pharmacy and therapeutics committee and outline its purposes, organization, function, and scope.
2. The formulary system shall be sponsored by the medical staff based upon the recommendations of the pharmacy and therapeutics committee. The medical staff should adapt the principles of the system to the needs of the particular institution.
3. The medical staff shall adopt written policies and procedures governing the formulary system as developed by the pharmacy and therapeutics committee. Action of the medical staff is subject to the normal administrative approval process. These policies and procedures shall afford guidance in the evaluation or appraisal, selection, procurement, storage, distribution, safe use, and other matters relating to drugs, and shall be published in the institution's formulary or other media available to all members of the medical staff.
4. Drugs should be included in the formulary by their nonproprietary names, even though proprietary names may be in common use in the institution.

[a]For additional information, see the ASHP Guidelines for Hospital Formularies. *Am J Hosp Pharm.* 1978; 35:326–8.

Prescribers should be strongly encouraged to prescribe drugs by their nonproprietary names.

5. Limiting the number of drug entities and drug products routinely available from the pharmacy can produce substantial patient care and (particularly) financial benefits. These benefits are greatly increased through the use of *generic equivalents* (drug products considered to be identical with respect to their active components: e.g., two brands of tetracycline hydrochloride capsules) and *therapeutic equivalents* (drug products differing in composition or in their basic drug entity that are considered to have very similar pharmacologic and therapeutic activities: e.g., two different antacid products or two different alkylamine antihistamines.) The pharmacy and therapeutics committee must set forth policies and procedures governing the dispensing of generics and therapeutic equivalents. These policies and procedures should include the following points:
   - That the pharmacist is responsible for selecting, from available generic equivalents, those to be dispensed pursuant to a physician's order for a particular drug product.
   - That the prescriber has the option, at the time of prescribing, to specify the brand or supplier of drug to be disoensed for that particular medication order prescription. The prescriber's decision should be based on pharmacologic or therapeutic considerations (or both) relative to that patient.
   - That the pharmacy and therapeutics committee is responsible for determining those drug products and entities (if any) that shall be considered therapeutic equivalents. The conditions and procedures for dispensing a therapeutic alternative in place of the prescribed drug shall be clearly delineated.
6. The institution shall make certain that its medical and nursing staffs are informed about the existence of the formulary system, the procedures governing its operation, and any changes in those procedures. Copies of the formulary must be readily available and accessible at all times.
7. Provision shall be made for the appraisal and use of drugs not included in the formulary, by the medical staff.
8. The pharmacist shall be responsible for specifications as to the quality, quantity, and source of supply of all drugs, chemicals, biologicals, and pharmaceutical preparations used in the diagnosis and treatment of patients. When applicable, such products should meet the standards of the *United States Pharmacopeia.*

Recommendation

A formulary system, based upon these guiding principles, is important in drug therapy in institutions. In the interest of better and more economical patient care, its adoption by medical staffs is strongly recommended.

ASHP TECHNICAL ASSISTANCE BULLETIN ON HOSPITAL FORMULARIES[1*]

The hospital formulary system is an ongoing process whereby a hospital's[a] medical staff, working through its pharmacy and therapeutics committee (or

*Approved by the ASHP Board of Directors, November 14–15, 1984. Revised by the ASHP Council on Clinical Affairs. Supersedes the previous version, which was approved on November 15, 1977.

[a]It should be noted that the formulary system is adaptable for use by any type of health care facility and is not limited to hospitals.

its equivalent), evaluates and selects from among the numerous drug products available in the market place, those it considers to be most useful in patient care. These products then are routinely available for use within the hospital. The formulary system is a powerful tool for improving the quality and controlling the cost of drug therapy, and its use is strongly encouraged. Central to the operation of the formulary system is the hospital formulary, a continually revised compilation of the drug products selected by the P & T committee, plus important ancillary information about the use of those drugs and relevant pharmacy policies and procedures.

Since the formulary is the vehicle by which the medical and nursing staffs make use of the system, it is important that it be complete, concise and easy to use. These guidelines are offered as an aid to pharmacists who will be preparing a formulary for their institution or who wish to improve an existing formulary. They do not deal with the specific drug products which might be included in a formulary or with the selection process, but, rather, with the formulary's format, organization and content.

"Guidelines for Hospital Formularies" is complementary to the "Statement of Guiding Principles on the Operation of the Hospital Formulary System"[a] which should be consulted for further information on the formulary system.

Formulary Content and Organization

The primary objectives of the formulary are to provide the hospital staff with: (1) information on what drug products[b] have ben approved for use by the pharmacy and therapeutics committee, (2) basic therapeutic information about each approved item, (3) information on hospital policies and procedures governing the use of drugs and (4) special information about drugs such as drug dosing rules and nomograms, hospital-approved abbreviations, sodium content of various formulary items, etc. In accordance with these objectives, the formulary should consist of three main parts:

Part One—Information on hospital policies and procedures concerning drugs,
Part Two—Drug products listing and
Part Three—Special information.

A more detailed look at each section follows.

Information on Hospital Policies and Procedures Concerning Drugs. The material to be included in this section will vary from hospital to hospital. Generally, the following items may be included:

1. Formulary policies and procedures, including such items as restrictions on drug use (if any) and procedures for requesting that a drug be added to the formulary.
2. *Brief description of the pharmacy and therapeutics committee,* including its membership, responsibilities and operation.
3. *Hospital regulations governing the prescribing, dispensing and administration of drugs,* including the writing of drug orders and prescriptions,

[a] Anon: Statement on the operation of the formulary system. *Am. J. Hosp. Pharm.*, *40*:1384–1385, 1983.

[b] "Drug product" refers to a specific drug entity/dosage form/strength/packaging/package size combination. Only certain dosage forms, for example, of a given drug entity might be included in a formulary.

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controlled substances considerations, generic and therapeutic equivalency policies and procedures, automatic stop orders, verbal drug orders, patients' use of their own medications, self-administration of drugs by patients, use of drug samples, policies relative to "stat" and "emergency" drug orders, use of emergency carts and kits, use of floor-stock items, requests by staff for medications for their own use, rules to be followed by medical service representatives, standard drug administration time and the reporting of adverse drug reactions and medication errors. Other topics should be included as deemed appropriate.

4. *Pharmacy operating procedures* such as hours of service, out-patient prescription policies, pharmacy charging systems, prescription labeling and packaging practices, inpatient drug distribution procedures, the handling of drug information requests, and specialized services of the pharmacy (e.g., patient education programs, pharmacy bulletins).
5. *Information on using the formulary,* including how the formulary entries are arranged, the information contained in each entry and the procedure for looking up a given drug product. Reference to sources of detailed information on formulary drugs (e.g., *American Hospital Formulary Service,* pharmacy drug information service, etc.) should be included here.

Drug Products Listing. This section is the heart of the formulary and consists of one or more descriptive entries for each formulary item plus one or more indexes to facilitate use of the formulary.

Formulary Item Entries. The entries can be arranged in several ways: (1) alphabetically by generic name, with entries for synonyms and brand names containing only a "see (generic name)" notation; (2) alphabetically within therapeutic class, usually following the *American Hospital Formulary Service (AHFS)* classification scheme; (3) a combination of the two systems whereby the bulk of the drugs are contained (alphabetically) in a "general" section which is supplemented by several "special" sections such as ophthalmic/otic drugs, dermatologicals and diagnostic agents.

The type of information to be included in each entry will vary. At a minimum, each entry must include:

1. Generic name of the basic drug entity or product; combination products may be listed by generic, common or trade name;
2. Common synonym(s) and trade name(s); there should be a note in the "directions for use" section of the formulary explaining that inclusion or omission of a given brand does not imply that it is or is not stocked by the pharmacy;
3. Dosage form(s), strength(s), packaging(s) and size(s) stocked by the pharmacy;
4. Formulation (active ingredients) of a combination product; and
5. *AHFS* category number.

Additional information which may be part of the drug entries includes:

1. Usual adult or pediatric dosage ranges, or both;
2. Special cautions and notes such as: "do not administer i.v." or "refrigerate";
3. Controlled substances symbol; and
4. Cost information; this generally will be most useful where the therapeutic classification system is used or, alternatively, lists of similar drugs (e.g., oral steroids) may be presented showing relative cost data.

Indexes to the Drug Products Listing. There are two indexes which can be included at the beginning or end of this section which will facilitate the use of the formulary. They are:

1. *Generic Name-Brand/Synonym Cross Index.* The proper page number reference should be included in each entry. An example of this type of index is:
   Ophthaine: brand of proparacaine, p 114
   Ophthetic: brand of proparacaine, p 114
   Opium tincture, camphorated: synonym for paregoric, p 103
   Paragoric: p 103
   Proparacaine: p 114
   This index also could be integrated into the drug products listing rather than being a separate entity. The listing, in this event, must be arranged alphabetically.
2. *Therapeutic/Pharmacologic Index.* This index is a listing of all formulary items within each therapeutic category. It is useful in ascertaining what therapeutic alternatives exist for a given situation such as patient allergy to a particular drug. An example of this type of index is:
   4:00 Antihistamine drugs
   Brompheniramine maleate, p 14
   Chlorpheniramine maleate, p 14
   Diphenhydramine HCl, p 14
   Promethazine HCl, p 20
   8:00 Anti-infective agents
   8:04 Ambecides
   Chloroquine, p 43
   Diiodohydroxyquin, p 22

The entries should include the *AHFS* code number.

Special Information. The material to be included in this section will vary from hospital to hospital. However, what is included should be of general interest to the hospital staff and not readily available from other sources. Examples of the type of items often found in the special information section of hospital formularies are:

1. Nutritional products list.
2. Tables of equivalent dosages of similar drugs (e.g., corticosteroids).
3. List of hospital-approved abbreviations.
4. Rules for calculating pediatric dosages.
5. Table of the sodium content of antacids.
6. List of sugar-free drug products.
7. List of items available from central supply.
8. List of the contents of emergency carts.
9. Lists of dialyzable poisons.
10. Pharmacokinetic dosing and monitoring information.
11. Metric conversion scales and tables.
12. Examples of blank or completed hospital forms such as prescription blanks, request for nonformulary drug forms and adverse drug reaction report forms.

13. Tables of drug interactions, drug interferences with diagnostic tests and parenteral drug incompatibilities, and
14. Poison control information.

FORMAT AND APPEARANCE OF THE FORMULARY

The physical appearance and structure of the formulary is an important influence on its use. Although elaborate and expensive artwork and materials are unnecessary, the formulary should be visually pleasing, easily readable, and professional in appearance. The need for proper grammar, punctuation, correct spelling, and neatness is obvious.

There is no one single format or arrangement which all formularies must follow. A typical formulary must have the following composition:

1. Title page
2. Names and titles of the members of the pharmacy and therapeutics committee
3. Table of contents
4. Information on hospital policies and procedures concerning drugs
   - 4.1 The pharmacy and therapeutics committee of XYZ hospital
   - 4.2 Objectives and operation of the formulary system
   - 4.3 Hospital regulations and procedures for prescribing and dispensing drugs
   - 4.4 Hospital pharmacy services and procedures
   - 4.5 How to use the formulary
5. Products accepted for use at XYZ hospital
   - 5.1 Items added and deleted since the previous edition
   - 5.2 Generic-brand name cross reference list
   - 5.3 Pharmacologic/therapeutic index with relative cost codes
   - 5.4 Descriptions of formulary drug products by pharmacologic therapeutic class
6. Appendix
   - 6.1 Central service equipment and supply list
   - 6.2 Rules for calculating pediatric doses
   - 6.3 Nomogram for estimating body surface area
   - 6.4 Schedule of standard drug administration times

Several techniques can be used to improve the appearance and ease of use of the formulary. Among these are:

1. Using a different color paper for each section of the formulary,
2. Using an edge index,
3. Making the formulary pocket size (approximately 4" × 7") and
4. Printing the generic name heading of each drug entry in boldface type or using some other method for making it stand out from the rest of the entry.

DISTRIBUTION OF THE FORMULARY

Copies of the formulary should be placed at each patient care unit, including clinics and other outpatient care areas such as the emergency room. Each division of the pharmacy (inpatient dispensing, outpatient dispensing, drug information service, etc.) should receive a copy. Heads of departments providing direct patient care should receive a copy as should hospital administration. Each member of the medical staff should receive a copy.

The necessary steps should be taken to insure that the nursing and medical staffs are familiar with the formulary and know how to use it.

Enough formularies should be printed to allow for replacement of copies which become lost or worn.

KEEPING THE FORMULARY CURRENT

Generally, the formulary will need to be revised annually. Additions and deletions to the formulary, changes in drug products, removal of drugs from the marketplace and changes in hospital policies and procedures all will necessitate periodic revision of the formulary. There should be a system for including "between revision" changes in the current edition of the formulary. One method is to attach formulary supplement sheets to the inside back covers of the formulary books.

Another means of keeping a formulary current is through an organized system of soliciting changes in the formulary from the medical staff. One institution[3] utilizes a form as exhibited in Chart A.

USE OF NON-FORMULARY DRUGS

In many institutions, a non-formulary drug will not be dispensed from the out-patient pharmacy. The patients are instructed to obtain the medication from their local pharmacy.

With respect to in-patients, a physician is allowed to order a non-formulary drug for a specific patient by the use of a special non-formulary drug request form Chart B.

PATIENT PACKAGE INSERTS (PPI)

The Food and Drug Administration has proposed regulations requiring that prescription drugs be accompanied by a non-technical explanation informing patients about the drug. The purpose of this is to promote the safe and effective use of prescription drugs by patients. In addition, this proposal would ensure that patients have the opportunity to be informed of the risks/benefits involved in the use of the prescription drug. It has been estimated that the cost of the system will be $90 million.[5] Industry and pharmacy costs will be 97% of that total or 6.3¢ per prescription.[2] Pharmacy costs will be $20 million initially and within 5 years rise to $75 million.[5]

Because PPI's distributed to hospitalized patients would create many logistical and practical problems, the hospital association and the professional pharmaceutical society have compaigned to exempt hospitals from compliance. The FDA took into consideration the facts that hospitalized patients may be too ill to read the labeling; that many institutions already have programs providing drug information; that patients have hospital staff readily available to them to answer questions about drugs; and that patients often take several drugs at once. Because of these problems, the FDA exempted hospitals from the labeling distribution requirement if the patient (or patient's agent) is

DEPARTMENT OF PHARMACY SERVICES
REQUEST FOR FORMULARY CHANGE

Request for: ..... Admission ..... Deletion

Generic Name: Trade Name(s):

Manufacturer:

Pharmacologic Class:

Dosage Form(s):

Oral: ..... Parenteral: .....Topical: ..... Other: .....
(Specify)

Strength:

List vehicles, preservatives, and solubilizers where applicable.

Similar products currently stocked:

Similar products by other manufacturers:

Justification with references:

Will new drug be used:
A. Widely for inpatients?
B. Widely for outpatients?
C. On a limited basis?

Requestor's Name Printed: ..... Signature .....

Department: ..... Telephone: .....

Date: .....

Cost of drug (to be completed by Pharmacy Services):

Completed forms should be directed to the Department of Pharmacy Services

1. Accepted a) For general formulary
   b) For conditional formulary
   c) For restricted use
2. Restricted: Reason
3. Deferred: Reason
4. Date action taken: .....

.....
Secretary, Pharmacy & Therapeutics Committee

Chart. A. Request for formulary change initiated by members of the medical staff.

informed at the time of admission—or as soon thereafter as possible—that drug descriptions are available on request. Further, institutions are not required to provide patients with personal copies of any specific information. However, the information ought to be available to the patient. Some suggested ways are to maintain the information in a compendium, a file or via the use of audio or audio-visual tape recordings.

Other exemptions include instances of: legally incompetent patients;

BRIGHAM & WOMEN'S HOSPITAL
NON-FORMULARY MEDICATION REQUEST

This form must accompany a copy of physician's order sheet for each non-formulary drug ordered.

This form is to be used by house officers only when attending physicians or chief resident countersigns.

THIS FORM IS FOR INPATIENT DRUG ORDERS ONLY.

Patient Name:

Floor and Room: Use addressograph or print.

Drug Name:

Manufacturer:

Dosage Schedule and Route:

Number Doses Required (Approximate):

..... M.D. Date: .....
Signature of House Officer

..... M.D. Date: .....
Signature of Attending Staff or Chief Resident

NOTE: By ordering a non-formulary drug, you are obliging your patient to pay for the entire package of medication. *Twenty-four hours* may be required to obtain a non-formulary drug.

Completed forms should be directed to Pharmacy Administrative Office.

....
Pharmacist Sending Form Date & Time Form Sent

....
Pharmacist Receiving Completed Form Date & Time Completed Form Received

Chart. B. Form used by members of the medical staff to obtain a non-formulary drug for use by their patient.

a specific request by the doctor that the information be withheld; emergency treatment; blind patients and those whose primary language is not English.

In the preparation of the hospital formulary, the Pharmacy and Therapeutics Committee should give serious consideration to limiting the number of drugs admitted to the formulary in the light of the PPI regulations. Further, it is incumbent upon the committee members to give consideration to the content and preparation of the non-technical brochure which would be given to the patient should it be requested.

THE LEGAL BASIS OF THE FORMULARY SYSTEM

A written and signed prescription or a written and signed medication order in the Doctor's Order Book constitutes the only legal permit to

dispense or administer a prescription legend drug. If the physician in writing the prescription or medication order uses a generic or chemical name for the desired preparation, the pharmacist may then dispense the brand which, in his professional judgment, meets the therapeutic need, and there will arise no legal problems irrespective of whether or not the hospital has adopted a formulary system.

The problem usually arises when the hospital has in effect a formulary system yet the prescriber continues to use a proprietary name for the drug desired. In many instances, the prescriber is aware of the fact that the hospital is operating under the formulary system but, through habit, writes for brand-named drugs. Under these circumstances, if the prescriber had previously agreed to the policy that all prescriptions and medication orders will be dispensed without reference to brand identity, then the pharmacist may so dispense. On the other hand, if there had been no previous consent to the policy by the physician, the pharmacist is professionally and morally duty bound to honor the prescriber's wishes as to brand.

In general, this system of prior **blanket consent** is no longer recommended because it is established upon unsound legal principles.

In order to avoid such situations, hospitals have devised many ways of obtaining the prescriber's consent to the hospital formulary system of dispensing.

One common method is the use of a suitably worded imprint on the prescription form. Examples of such wording are: *"Generic Equivalent Permitted"* or *"Dispensed in accord with the hospital formulary system."* Any physician not desirous of the generic equivalent may obtain the selected brand merely by drawing a line through the permissive statement. In some hospitals, the consent statement is often followed by a check box with a "Yes" or "No," thereby giving the physician an option each time he prescribes. Although both methods are acceptable, I prefer the former since it takes the positive permissive approach and places the responsibility upon the physician of giving notice to the pharmacist of the deviation from accepted policy.

The second method of obtaining prior medical consent to the operation of a hospital formulary system is to incorporate the basic policy and procedures governing its use in the medical staff by-laws or in the rules and regulations. Therefore, as each physician accepts appointment or reappointment, he accepts the formulary system. It is strongly recommended that the acceptance of the appointment and the willingness to abide by the by-laws or the rules and regulations be executed in writing. Members of the intern and resident staffs who normally do not sign documents to abide by the by-laws or rules and regulations of the medical staff should be requested to execute separate consent agreements. Since this method is a modification of the blanket prior consent policy, it should be used with caution.

The third method of obtaining prior medical consent to the operation of a hospital formulary system is to express the policy and procedures governing the formulary system in a separate document and request that all physicians sign it.

The second and third methods have long been criticized on the basis that they abrogate the professional prerogatives of the clinician. This is no longer a valid argument since the adoption of the Statement of Guiding Principles on the Operation of the Hospital Formulary System which provides a means whereby a physician who, for clinical reasons, desires the brand-named product may still obtain it for his patient.

It is the opinion of some attorney[6] that whenever a physician accepts an appointment to a hospital staff, he "commonly yields to the medical staff as a whole, so far as his practice in that hospital is concerned, certain professional decisions which he is otherwise free to make for himself." It should be quite clear that if the physician does not wish to conform to all of the rules of the particular hospital, he is free to take his patients elsewhere and practice as he chooses. However, so long as he admits to and treats patients in the hospital, he may not disregard or willfully circumvent the accepted by-laws of the staff or the institution.

ANTISUBSTITUTION LAWS AND THE FORMULARY

The movement to modify state antisubstitution laws which interfere with the pharmacist's ability to exercise his professional judgment has gained momentum. As each state legislature has formulated its own approach to the problem, a wide variety of solutions have evolved. Hospital pharmacists should certainly be knowledgeable about the legislation affecting pharmacy practice in their state, and they may even wish to consider modifying the language in their hospital formulary systems to comply with that of the state legislation regarding physician specification of a certain brand; however, this would not appear to be an absolute necessity. The legal basis of the hospital formulary system remains intact regardless of the changes in state antisubstitution laws.[12]

PREPARATION OF THE FORMULARY

The preparation of the hospital formulary, although the prime responsibility of the Pharmacy and Therapeutics Committee, rests upon the Pharmacist-in-Chief. This is desirable for the sake of expediency. The Committee is here free to make the necessary decisions relative to the materials to be included in the formulary and the pharmacist undertakes the production aspects of preparation.

The initial step in the development of a formulary for any hospital, irrespective of size, specialty, or control, is the selection of a competent

Pharmacy and Therapeutics Committee. Because of the importance of this Committee, a separate chapter has been devoted to its organization, membership and functions. Suffice it to say here that, once established, this Committee must take the initial step in the preparation of the formulary.

Some of the decisions which must be reached by this Committee concern themselves with the following:

a. What type of publication will best suit the needs of the hospital?
   1. A hospital owned formulary?
   2. A simple drug list or catalogue?
   3. A purchased formulary service?

b. Irrespective of what decision is reached in the above, it will be necessary to promulgate a series of rules or guides which the Committee may use to evaluate drugs for admission to the formulary or drug list.

c. If the desirable end product is to be a formulary, a decision must be reached as to possible contents other than the sections on various therapeutic agents.
   1. Section on prescription writing?
   2. Section governing the use of drugs?
   3. Tables of metric weights and apothecary and household equivalents?
   4. Table of common laboratory values?
   5. Section on the calculation of dosages for children based on established rules and by use of the body surface method?
   6. Pharmacological index?
   7. Section on reagents?

d. What type of format should the formulary take?
   1. Size?
   2. Loose leaf or bound?
   3. Printed or mimeographed?
   4. Categorizing and indexing—to what extent?

Once answers to the above have been provided for the Pharmacist-in-Chief, the preparation of the formulary becomes a routine matter requiring diligence to detail, accuracy and perseverance.

FORMULARY VS. DRUG CATALOGUE OR LIST

Unfortunately, too many people use the terms *formulary* and *drug list* interchangeably. This is erroneous in view of the fact that there exists a vast difference in the scope and preparation of a formulary over a drug list.

A formulary usually consists of a listing of therapeutic agents by their generic names followed by informaiton on strength, form, posology, toxicology, use, and recommended quantity to be dispensed, whereas

a drug list usually consists of a listing of therapeutic agents by their generic names followed by data on strength and form. There may or may not be any additional information although some drug lists may provide the prescriber with recommended quantities to be dispensed.

Clearly then, the formulary is the more information type of publication and may exert an influential role in the educational aspects of drug therapy particularly in hospitals with an active intern and residency training program and a school of nursing.

If a formulary type of publication is desirable, then the Committee ha the option of either preparing a private formulary for the hospital or to subscribe to a perpetual drug monograph service such as the *American Hospital Formulary Service*, a publication of the American Society of Hospital Pharmacists.

Either a well-prepared private formulary or the *American Hospital Formulary Service* will provide the hospital with adequate information concerning drugs. Each has its own merits.

Some of the advantages of the private formulary are that it is prepared locally by the hospital's own clinical staff and thereby engenders in them a sense of pride and loyalty as well as a determination to make the system succeed; its contents with respect to the amount of information provided under each monograph is subject to local needs and desires; it may include sections on related clinical matters which are characteristic to the local hospital; it may be published in a more convenient size and format; drugs may be added or deleted with greater frequency; and finally certain drugs may be added to the formulary before they have attained sufficient stature to be considered on a national level.

Some of the advantages of the *American Hospital Formulary Service* are that it is a continuing drug monograph subscription service published by a national professional society of means; it has the official approval of the American Pharmaceutical Association, the Catholic Hospital Association, and the American Hospital Association; it is prepared by a reference panel of the nation's outstanding clinicians, pharmacologists and pharmacists; each monograph contains a complete rundown on drugs including physical and chemical properties, pharmacologic responses, uses, toxicology, contraindications, posology and preparations; and the drugs are classified and coded according to pharmacologic action and therapeutic indications by a system of numbers which can be adapted to the filing of all informative drug literature in the pharmacy library.

SELECTION OF GUIDING PRINCIPLES FOR ADMISSION OR DELETION OF DRUGS

Of all the tasks which face the Pharmacy and Therapeutics Committee, the selection of criteria by which to gauge the worthiness of a

drug for admission to the formulary is the most difficult and troublesome. This is due to the fact that no single member of the Committee is qualified to evaluate the therapeutic efficacy of every drug in every area of clinical specialization. Accordingly, from the outset, the Committee should feel free to invite staff specialists to attend specific committee meetings for the purpose of evaluating preparations commonly used in his specialized practice for inclusion into the formulary.

Thus one of the first criteria to be established is whether or not the local general and specialty staff consider the drug to be of proven clinical value based upon their experience with it.

A second may be that the drug must be recognized by the *United States Pharmacopeia,* the *National Formulary,* or their supplements.

A third may be that the manufacturer of the drug must be one of proven integrity and dependability as well as having the reputation of initiating and supporting research activities of merit.

A fourth criterion may be that no preparation of secret composition will be considered or admitted to the formulary.

A fifth criterion may deal with products of multiple composition. Some hospitals have adopted the policy that no preparation of multiple composition may be admitted if the same therapeutic effect can be achieved through the use of a single drug entity.

On the same subject, the **Drug Efficacy Study** considered questions of efficacy peculiar to combination drug products and in its 1969 Final Report to the FDA, the National Academy of Sciences stated:[7]

> It is a basic principle of medical practice that more than one drug should be administered for the treatment of a given condition only if the physician is persuaded that there is substantial reason to believe that each drug will make a positive contribution to the effect he seeks. Risks of adverse drug reactions should not be multiplied unless there be overriding benefit. Moreover, each drug should be given at the dose level that may be expected to make its optimal contribution to the total effect, taking into account the status of the individual patient and any synergistic or antagonistic effects that one drug may be known to have on the safety or efficacy of the other.
>
> One these grounds, multiple therapy using fixed dose ratios determined by the manufacturer and not by the physician is, in general, poor practice."

This general opinion of combination drugs is shared by other expert bodies. The Council on Drugs of the American Medical Association in a letter accompanying the first edition of AMA Drug Evaluation says:[7]

> "The effects of drugs are intrinsically so complex that it is generally advisable to administer multiple agents separately in order that the dosage and frequency of administration of the individual drugs may be varied in accordance with a patient's requirements. Therefore, most fixed-ratio combinations listed are not recommended. This reflects a long-standing policy of the Council."

The FDA is not opposed to combination drug products; it recognizes that many are safe and effective and provide important advantages to patient and physician.

For a combination to be approved under the law there must be substantial evidence that each active component contributes to the claimed effect of the product, a requirement since 1962. If this requirement is satisfied, two or more drugs may be combined in a single dosage form when, in good medical practice, they would be given concurrently and when putting them together in the same product in no way detracts from their safety and efficacy. Such a combination product should provide appropriate dosage for a significant patient population that can be defined in the labeling. A special case of this general rule is the addition of an ingredient that enhances the safety or effectiveness of the principal active component or minimizes its abuse potential.[7]

Obviously, the above criteria are merely presented as sample guides and should be either elaborated upon or restricted in their scope depending upon the requirements of the local committee and hospital.

Once the Pharmacy and Therapeutics Committee agrees upon a set of principles to guide them in their decisions relative to admissions or deletions from the hospital formulary, it is recommended that these principles be published and included in the finished formulary. In addition, it may be desirable to circulate these amongst the medical staff in order that they may have prior knowledge of them and therefore acquire an understanding of why a particular preparation may not have been included in the final publication.

CONTENTS

The decision as to the contents of the private formulary rests with those responsible for its publication. There are no published requirements for such which are established by an accrediting agency or professional association.

It would, therefore, appear that the Pharmacy and Therapeutics Committee should be guided and influenced by the role which they foresee or expect the formulary to take. If the formulary is to function merely as a control of what drugs may be used in the hospital by the staff, then all that is required is a listing of the drugs with whatever ancillary informaiton the Pharmacy and Therapeutics Committee deems desirable.

On the other hand, if it is the intent that the formulary in addition to its control value is to function as a useful helpful informative tool in the clinician's daily practice, then its contents should be expanded to meet this goal.[8]

Experience has demonstrated the fact that a section on prescription writing is a valuable asset to the young physician joining the intern

staff, for throughout his medical school education this facet of his training is relatively skimpy. The section should be brief yet should cover the important parts of the prescription, the use of the metric system, a list of acceptable abbreviations, and the essentials of a narcotic prescription. The following is a briefly written section on prescription writing which may serve as a guide to those contemplating such a chapter in a hospital formulary.

PRESCRIPTION WRITING

All prescriptions must be written clearly and correctly. Every prescription must bear the following information:

Name and address of the patient.

The date.

The medication prescribed.

(This should be written for in the terminology listed in the formulary.)

The strength of the medication prescribed.

(This must be given in the metric system, *e.g.* milligrams [mg.], grams [gm.], milliliters [ml.] or micrograms [μg. or mcg.].)

The total amount to be dispensed should be clearly indicated.

The signa, containing the instructions to the patient, should be in clear, concise and simple terminology. The physician hould avoid mixing Latin and English abbreviations. The term, "As directed," should seldom, if ever, be used.

When refills are desired, the number wanted should be indicated. If this is not done, the prescription will not be refilled.

Prescriptions calling for a controlled substance must have, in addition to all of the above information, the DEA number of the prescribing physician.

It is essential that all prescriptions be signed by the physician issuing them.

Schedule II drugs are limited to a 30-day supply and no refill. These prescriptions are valid for 5 days and are not valid if there are crossouts, erasures, or any evidence of tampering.

Schedule III, IV, and V drugs are limited to a 30-day supply and may be refilled up to 5 times within 6 months of issuance date.

Other important data such as normal laboratory values; tables of heights and weights; tables for the calculation of percentages, milliequivalents and dosages; formulas of the various diagnostic stains and reagents in common use in the hospital as well as a myriad of other factual informaiton may be considered for inclusion. Obviously, all of this material cannot be included without making the publication unwieldy and expensive. Therefore the judicious evaluation of each entry by the Pharmacy and Therapeutics Committee is vital.

FORMAT

The format is extremely important since it will determine the practicality of daily use of the formulary as well as the publishing costs.

Prior to commencing work on the development of the hospital formulary format, it is suggested that the hospital pharmacist gather for-

mularies from various hospitals. The hospital pharmacist may also obtain a representative sample of formularies from many different types of hospitals merely by requesting same from the American Society of Hospital Pharmacists. Needless to say, once the local hospital formulary is published, two copies should be forwarded to the Society in order that their collection continue to expand and therefore be of assistance to other pharmacists seeking ideas.

SIZE

Experience has shown that a formulary which is sufficiently small in size to permit its being carried in a uniform or laboratory coat pocket will, in all probability, enjoy widespread use in the hospital. A small-sized book also can be carried in the doctor's bag along with his prescription blanks. Many physicians who have become accustomed to using the formulary in their hospital practice often use the hospital formulary in their private office practice.

No specific size can be recommended at the present time, and therefore this determination must be arrived at after careful study of the local need as well as the formularies gathered from the Society and local hospitals.

LOOSE-LEAF VS. BOUND

Whether or not the hospital formulary should be loose-leaf or bound will depend upon a number of factors. The most important of these is the ease by which a loose-leaf formulary can be kept current. A bound volume is difficult to keep up-to-date and therefore requires more frequent revision. In comparison, a loose-leaf formulary can be revised at will simply by printing, distributing and inserting the necessary page or pages.

The type of loose-leaf binder is immaterial and is left to the decision of the Pharmacy and Therapeutics Committee. The local stationer, if consulted, will be able to provide sample binders in all price ranges.

Those desiring a permanently bound volume also have many selections to choose from ranging from paper to cardboard to plastic to leather or its substitutes. The controlling factor here will, in all probability, be the cost involved.

PUBLICATION

A printed hospital formulary is obviously more esthetic in appearance, easier to read, and imparts to the user the impression that the hospital considers the formulary as an extremely important document and therefore worthy of the cost of printing. This does not mean that

a mimeographed formulary will not be used or is not good. A study of a number of formularies will show that some of the better units are mimeographed. However, where it is possible, it is recommended that printing be the selection of choice.

Some formularies appear to have been developed by individuals with a flair for public relations or advertising. Drawings, colored ink, and colored paper should be avoided. The formulary is a professional publication and should reflect the high ethical standards of the hospital and its staff. Therefore, a white or slightly off-white paper should be used. Black ink is always in good taste.

Many authors have been concerned about the use of electronic data processing equipment in preparing and publishing the hospital formulary.[9–11] Reasons generally given for the utilization of the computer for this task are *(a)* to take advantage of the computer process to lower the cost of producing the formulary and *(b)* to adopt the formulary information for future applications resulting from computerized hospital information systems.[8]

Generally, the program has two phases. Phase-I produces the drug information file which is maintained on magnetic tape. Punched cards prepared from the source documents are used as the input to the drug information file. Phase-II produces the printed formulary using the magnetic tape drug information file.

A coding technique must be either developed or adopted for the purpose, as well as data concerning choice of paper, printing technique and photoreduction if necessary.

The American Society of Hospital Pharmacists has developed a computer-processable *Drug Products Information File* which is available to hospitals and nursing homes and from which a hospital formulary can be prepared. Because of the comprehensive nature of the Drug Products Information File (DPIF) it also may be used in drug-drug interaction and drug-laboratory interaction programs.

FORMULARY DRUG LISTING SERVICE

"FDLS" refers to the Formulary Drug Listing Service of the American Society of Hospital Pharmacists (ASHP). The service provides reproducible copy of a hospital's drugs in two parts: A Drug Listing Section and a Pharmacologic-Therapeutic Index. The hospital uses the printout to reproduce as many copies of its formulary drug list as are required for distribution to the hospital's professional staff, nursing units, outpatient clinics and libraries.

The Drug Listing Section contains each of the drug products selected by the subscriber, including the nonproprietary name of the drug; selected trade names, synonyms and/or abbreviations; the therapeutic category of the drug; and the specific dosage forms and strengths of the

drug selected by the hospital. Package sizes are included for injectable preparations. The ingredients of combination products are listed in tabular form. The section is alphabetically arranged by non-proprietary drug names. Trade names and synonyms are cross-referenced in alphabetical sequence. The Pharmacologic-Therapeutic Index consists of the non-proprietary drug names categorized according to the classification system of the American Hospital Formulary Service (AHFS). Only those drugs and categories included in the Drug Listing Section are included in the index.

All hospitals should have a list of drugs which the medical staff considers acceptable for use in the hospital (i.e., a formulary). Both the Conditions of Participation for "Medicare," and the Standards for Pharmaceutical Services of the Joint Commission on Accreditation of Hospitals (JCAH) stipulate the existence or development of a formulary or drug list.

Since the development of a formulary drug list requires a substantial investment in professional personnel time and because of limited budgets or staff shortages, many hospitals have not prepared a formulary drug list or have not revised an out-of-date edition. The amount of professional personnel time required, annually, to revise a formulary drug list can easily exceed 300 hours!

Under these circumstance, it behooves the hospital administration to approve a subscription to the ASHP's Formulary Drug Listing Service. By so doing, a substantial reduction in cost of personnel time can be realized by the hospital thereby permitting this valuable professional time to be allocated to other hospital programs.

FORMULARY DRUG LISTING SERVICE PREPARATIONS

The ASHP sends to the hospital a checklist containing about 3,000 "core" drugs—those found to be the most frequently approved by Pharmacy and Therapeutics Committees for use within the nation's hospitals. The description of these core drugs on the checklist includes nonproprietary name, trade name, route of administration, dosage form and strength. The format of the checklist includes an access number for ASHP use and a "check" column for use by the subscribing hospital. The checklist is arranged alphabetically by nonproprietary name.

The hospital pharmacist reviews and marks the checklist. Checks on the appropriate lines assure that the products so identified will be included in the drug list for that individual hospital.

The subscribing hospital writes in those additional drug products to be listed in its formulary drug list which do not appear on the checklist.

The checklist, with individual additions, is returned to the ASHP where the input codes for the products designated by the hospital are punched into machine readable form. The input data for a number of

uniquely identified hospitals are run against the ASHP's computerized Drug Products Information File and individualized formulary drug lists are output.

Each subscribing hospital receives a listing of only those drugs it has selected. The hospital receives a single computer printout of its formulary drug list.

The hospital then reproduces the desired number of copies required for distribution within the institution.

The reproduction masters (printout) provided by FDLS can be reproduced in any desirable page size. The masters can be reproduced at exact size (*e.g.*, xerography) on standard 8½" × 11" pages. If necessary the masters can be photo-reduced for the printing of pocket-sized lists.

CATEGORIZING AND INDEXING

The ease by which a physician may locate an item in the formulary will have an impact upon its usability. Too often, the formulary contains all of the desired information, but due to poor indexing data are not readily found. Therefore, since the index is the key to a good formulary, it behooves the pharmacist to expend effort on it.

Most formularies have a general index located at the end of the text. This index is usually alphabetical by generic name and is cross-indexed with brand names of drugs used in the text portion of the formulary. Although the general index is an essential and integral part of any text and cannot be eliminated, it presumes that the user knows what he is looking for. In a formulary, this presumption is not always valid. Here the physician knows that he has need for an anticholinergic drug and he obviously has knowledge of the generic or brand names of a number of drugs which bear this pharmacologic classification. This now means that he must search the index to find a familiar anticholinergic drug. Because this is a burdensome and time-consuming procedure, it is strongly suggested that the general index be implemented with a pharmacologic index which will alleviate similar occurrences.

SAMPLE PHARMACOLOGIC INDEX

The following pharmacologic classification represents main headings only and the pharmacist in conjunction with the Pharmacy and Therapeutics Committee should classify the drugs which are to be listed in the hospital formulary under each heading. This complete index should then be placed in the front or rear of the formulary.

- Amebicides
- Analgesics
  1. Narcotic
  2. Non-narcotic
- Anesthetics
  1. General
  2. Local
- Anthelmintics
- Antiallergenics
- Antibacterials
  1. Antibiotic
  2. Chemotherapeutic
- Antiepileptics
- Antihistaminics
- Antihypertensives
- Antimalarials
- Antiparkinsonism Agents
- Antisyphilitics
- Antituberculous Agents
- Cardiovascular Agents
  1. Cardiac Drugs
     a. Accelerators
     b. Depressants
     c. Glycosides
  2. Vascular Drugs
     a. Constrictors
     b. Dilators
     c. Sclerosing Agents
- Central Nervous System Drugs
  1. Depressants
     a. Analgesics
     b. Anesthetics
     c. Antispasmodics
     d. Hypnotics
     e. Sedatives
  2. Stimulants
  3. Tranquilizers
- Dermatological Agents
  1. Anhydrotics
  2. Antipruritics
  3. Antiseborrheics
  4. Antiseptics
  5. Astringents
  6. Bactericides
  7. Caustics
  8. Cleansers
  9. Emollients
  10. Fungicides
  11. Keratolytics
  12. Parasiticides
      a. Lice
      b. Scabies
  13. Protectives
- Deterrent Therapy
- Diuretics
  1. Mercurial
  2. Thiazide Derivatives
  3. Other
- Gastrointestinal Agents
  1. Anorexogenics
  2. Antacids
  3. Antidiarrheals
  4. Antinauseants
  5. Antispasmodics
  6. Cathartics
  7. Choleretics
  8. Digestives
  9. Emetics
  10. Emulsifiers
  11. Spasmogenics
- Genitourinary Agents
  1. Antibacterials
     a. Antibiotic
     b. Chemotherapeutic
  2. Antiseptics
  3. Antispasmodics
  4. Diuretics
  5. Oxytocics
  6. Spasmogenics
- Hematics
  1. Antianemics
  2. Anticoagulants
  3. Coagulants
  4. Expanders
  5. Hemostatics
  6. Neoplastics
- Hormones and Synthetic Substitutes
  1. Adrenal hormones
  2. Ovarian hormones
  3. Pancreas hormones
  4. Parathyroid hormones
  5. Pituitary hormones
  6. Placental hormones
  7. Testicular hormones
  8. Thyroid hormones
     a. Depressants
     b. Stimulants
- Muscular Relaxants
- Nutritional Aids
  1. Albumin preparations
  2. Amino acid preparations
  3. Carbohydrate preparations
  4. Choline preparations
  5. Fat preparations
  6. Gustatory aids
  7. Mineral preparations
  8. Nutritives
  9. Protein hydrolysates
- Parasiticides—Internal
  1. Amebicides
  2. Malaria Therapy
  3. Spirochete

4. Trichomoniasis
5. Worms

Respiratory Agents
1. Antihistaminics
2. Bronchial dilators
3. Cough preparations
   a. Depressants
   b. Expectorants
4. Respiratory stimulants

Sedatives and Hypnotics
1. Barbiturates
   a. Short duration
   b. Moderate duration
   c. Long duration
2. Non-barbiturates

Serums and Vaccines
Vitamin and Vitamin Mixtures

In addition to the general and pharmacologic index, the formulary may be divided into specific sections with each section segregated by a divider. A suggested subdivision of the formulary is as follows:

Ear
Eye
Nose
Rectal
Throat
Vaginal
Skin
Nutritional Aids
Oral and Injectable

By such a subdivision, the clinician can easily refer to the agents specifically used for either the anatomic entity or to the broad category of drugs used orally or by injection.

TEXT

Finally, the selection of the scope of the text material under each generic named drug should be given serious consideration. The amount of material published will depend upon the goals established by the Pharmacy and Therapeutics Committee. The membership of the committee is hereby cautioned that insufficient information does not enhance the use and acceptance of the formulary by the staff. On the other hand, the busy practitioner will also shy away from the formulary if it develops into a miniature text on pharmacology. The ideal situation obviously lies somewhere in between these extremes. As an aid to the hospital pharmacist, three examples are presented.

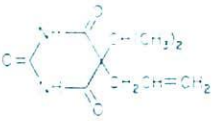
Figure 15 represents a sample page from the American Hospital Formulary Service. The important point to notice here is the detailed nature of the text material.

Figure 16 represents a sample page from the Formulary of the Peter

SEDATIVES AND HYPNOTICS *28:24*

Aprobarbital

Alurate®



Aprobarbital, 5-allyl-5-isopropylbarbituric acid, is classified as a short-acting barbiturate. It occurs as a bitter, white, crystalline powder and is very slightly soluble in water and soluble in alcohol.

Aprobarbital is useful as a hypnotic and for the treatment of conditions in which mild sedation is desirable, as in hypertension, preoperative apprehension, functional gastrointestinal disorders, anxiety neuroses, and coronary artery disease.

For the mode of action, cautions, and contraindications in therapy with aprobarbital, and for the treatment of acute or chronic toxic reactions, see the general statement on The Barbiturates 28:24.

Dosage

Aprobarbital is administered orally. The recommended sedative dosage for adults is 20 to 40 mg three times daily. The adult hypnotic dose is usually 80 to 160 mg. Dosage for children has not been established but, as for adults, the smallest effective dose should be used.

Preparations

APROBARBITAL
Elixir, 40 mg per 5 ml
Tablets, 20 mg and 40 mg

Only those Preparations underlined or checked above are included in the Formulary of this hospital

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Fig. 15. Sample page from the American Hospital Formulary Service.

NICOTINIC ACID
(Niacin)

FORMS AVAILABLE:	
Tablet:	50 mg
	100 mg
Injection:	100 mg/10 ml
USUAL DOSE:	25 to 50 mg
DAILY DOSE:	50 to 100 mg
ROUTE:	Orally.
	Intravenously.
	Intramuscularly.
CAUTION:	High doses produce a flushing of the skin.
PRESCRIBE:	25 Tablets (1) either strength.
	1 Ampul (1).
USE:	Vasodilator, correct nicotinic acid deficiency.

NITROFURANTOIN
(Furadantin)

FORM AVAILABLE:	
Tablet:	100 mg
USUAL DOSE:	5 to 10 mg per kg of body weight per 24 hours; given in 4 doses with meals and at bedtime.
PRESCRIBE:	25 Tablets (6).
USE:	Urinary antibacterial.

Fig. 16. Sample page from the Formulary of the Peter Bent Brigham Hospital, Boston, Massachusetts.

Bent Brigham Hospital. Note here the fact that although brief in nature, the practitioner is provided with all of the necessary information.

Figure 17 represents a sample page from the Formulary of the Massachusetts General Hospital. Note here the interesting presentation of each drug in the form of an individual prescription.

Figure 18 represents a sample page from the Formulary of the Newton-Wellesley Hospital. This presentation is of interest due to the fact

AUTONOMIC DRUGS

SYMPATHOMIMETIC DRUGS

(Adrenergic)

Ephedrine Sulfate Injection
1 ml. contains 50 mg
Disp.: 1 ml
Route: Subcutaneous, intramuscular
Dose: 25 to 50 mg every 4 hours

Epinephrine Injection
1 ml contains 1 mg
Disp.: 1 ml
Route: Subcutaneous
Dose: 0.2 to 1 mg every 4 hours

Epinephrine in Oil Injection, Suspension
1 ml contains 2 mg
Disp: 1 ml
Route: Intramuscular, only
Dose: 2 mg every 8 or 12 hours

Levarterenol Bitrate Injection
4 ml contains 4 mg Levarterenol
Disp: 4 ml
Route: Intravenous only, by infusion
Dose: 4 mg is added to 1000 ml 5% Dextrose solution. Each 1 ml of this dilution contains 4 mcg Levarterenol.

Metaraminol Bitartrate Injection
1 ml contains 10 mg
Disp: 10 ml
Route: Intramuscular, intravenous, not subcutaneous
Dose: Intramuscular 2 to 10 mg. Intravenous 15 to 100 mg added to 200 ml isotonic sodium chloride solution or 5% dextrose in water. Administered by drip.

Phenylephrine Hydrochloride Injection
1 ml contains 10 mg
Disp.: 1 ml
Route: Subcutaneous
Dose: 1 to 10 mg every 8 hours.

Fig. 17. Sample page from the Formulary of the Massachusetts General Hospital, Boston, Massachusetts.

CARDIOVASCULAR DRUGS

Vasodilators

Amyl Nitrite Pearles	
Glyceryl Trinitrate (Nitroglycerin)	
.3 mg H.T.	
.6 mg H.T.	
.4 mg H.T.	
Mannitol Hexanitrate	
30 mg Tablets	
Paveril Phosphate	
.1 gm Tablets	
Papaverine HCl	
30 mg Tablets	
30 mg Ampuls	
30 mg = 1 ml	For subcutaneous or intravenous use
Pentaerythritol Tetranitrate (Peritrate)	
10 mg Tablets	
Priscoline Hydrochloride	
25 mg Tablets	
10 ml vials 25 mg/ml	For subcutaneous, intramuscular, or intravenous use

Fig. 18. Sample page from a Formulary (Drug List) of the Newton-Wellesley Hospital, Newton, Massachusetts.

that it combines the brevity of a drug list with a pharmacological classification and the routes of administration for injectable preparations.

Figure 19 represents a sample page from the Commonwealth of Massachusetts formulary entitled *The Massachusetts Drug Formulary.* This formulary was prepared by a state drug formulary commission consisting of physicians, nurses and pharmacists and must be used for the prescribing of medications for patients on state welfare plans.

SPECIALTY FORMULARIES

With the increasing use of enteral nutrition products in hospitals and hospital-based home care programs, one university hospital has developed a formulary for use of the medical and dietetic staffs.[13]

The formulary reports product variables such as osmolality, caloric density, protein content and source, fat content and source, freedom

THE MASSACHUSETTS DRUG FORMULARY

Brand Name Generic Name	
Acidulin OTC	Glutamic Acid Hydrochloride
Acon OTC	Vitamin A Water Soluble USP
Acthar	
Acthar Gel	Corticotropin Gel USP
Adrenalin OTC	Epinephrine Hydrochloride USP
Adrenalin Injection	Epinephrine Hydrochloride USP
Adrenotrate	Epinephrine Bitartrate USP
Albolene OTC	Mineral Oil, Light NF
Alcon-Efrin OTC	Phenylephrine Hydrochloride USP
Almocarpine	Pilocarpine Hydrochloride USP
Alphalin OTC	Vitamin A USP
Alurate	Aprobarbital NF
Ambodryl	Bromodiphenhydramine Hydrochloride NF
Amnestrogen	Esterified Estrogens USP
Amphicol	Chloramphenicol USP

Fig. 19. Sample page from the Massachsetts Drug Formulary of 1972.

from lactose, and, for oral supplements, flavors. The products are categorized as follows: liquid supplemental feedings, isotonic supplemental feedings, isotonic tube feedings, high caloric/high nitrogen tube feedings, high nitrogen tube feedings and blenderized tube feedings.

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