DEVELOPMENT OF A PROVINCIAL DRUG FORMULARY

by

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DEVELOPMENT OF A PROVINCIAL DRUG FORMULARY

ABSTRACT

The adoption of the Lions Gate Hospital Drug Formulary by the British Columbia Hospital Association for distribution and use in all provincial hospitals endorses the growing trend toward regionalization of drug information. Several aspects of this Formulary were investigated in the present study with the objective of designing a text even more applicable to the varied needs of the province. The format of the Formulary and a mechanism for regularly evaluating and updating the information therein were the major areas receiving consideration.

One major change in format proposed is the increase in the number of drug monographs to approximately 600 from the present 300 entries. This increase is based on the requests for additional drugs from the representative hospitals sampled in the province. Changes in the format of individual monographs include an expansion of information under the heading "Mode of Action", that an additional section on "Instructions to the Patient" be added to facilitate effective instructions for self-administration in ambulatory services, that each monograph receive a Canadian Drug Identification Code reference and that the information in each monograph be referenced where possible to the primary literature source.

Changes in the format of the overall Formulary include a cross-index of monographs to manufacturers' brand names, a bibliography of the referenced information and a "Mini" Formulary format for use on individual hospital wards. The latter recommendation is made in recognition of the potential bulk of the overall Master Formulary which would make it awkward for efficient and frequent use. In this respect, it is anticipated that one Master Formulary containing all 600 eventual monographs, the bibliography for each and the various indices be made available in each hospital for resource reference. On each ward a complete Formulary of all drug monographs but not the accompanying bibliographies would be available. Studies showed that something less than 100 of these drugs (less than 20 percent) were used with any frequency on any specialty ward studied. Therefore, a "Mini" Formulary containing only the monographs of drugs frequently used in a specialty area would make the information more readily available in that service. Changes in printing format also are recommended with the objective of reducing the bulk of the proposed Formulary.

A regular updating mechanism must be activated to keep the information in the Formulary current. Such a mechanism related to an annual literature evaluation assignment by the senior students of the Faculty of Pharmaceutical Sciences, University of British Columbia, is proposed. Based on this academic exercise, two types of updating are identified. First, a complete evaluation and referencing of the existing monograph information is required. Second, annual updating of this information from

current literature should be maintained. To evaluate, revise and condense the students' evaluations to monograph format, a "service" component of faculty instructor time and of stenographer time have been projected. It is anticipated that the provision of approximately one-half time instructor per year and one-tenth time stenographer will be required on a "service" basis to enable the regular updating of the current Formulary as defined above. The arrangement for a Medical Review Board to review the evaluated monographs from a clinical validity standpoint also should be made. The above projections are based on studies related to the evaluation and updating of 100 drug monographs during 1972-73. A final recommendation is that the basis for generating, updating and additional referencing of the Drug Formulary should be a provincial Drug Information Centre.

Signature of Supervisor

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LITERATURE SURVEY

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> "Accurate and unbiased information about drugs is essential if good medicine is to be practiced. In these days when many new and potent drugs are being introduced such information must be readily available and should include all facts relevant to the use of the drug, including both efficacy and adverse reactions." (1).

(a) Volume of Drug Literature

The volume and diversity of drug literature and the problems of compiling and distributing drug information have been widely expressed (2-15). A World List of Pharmacy Periodicals which was compiled in 1963 contains over 900 entries. In addition to pharmaceutical publications, drug information is also found in other journals such as medicine, dentistry, biology, agriculture and engineering (3). Dr. A. F. Langlykke in 1958 estimated that 200,000 original papers were published yearly in regard to pharmacy and drugs (4). Dr. D. Burkholder projected in 1967 that 33 percent of published biomedical literature dealt with drugs (6). Since Burkholder was referring to documented sources of drug information such as textbooks, review articles, journals and product literature, his estimate was probably considerably larger than Langlykke's which dealt only with original papers.

In addition to the literature regarding new drugs, new applications of drugs, dosages and therapeutic indications previously mentioned, a great deal of information has been accumulated regarding adverse drug reactions by several organizations including the World Health Organization (9, 10). In the first three years of operation, the Canadian Drug Adverse Reaction Program received 11,000 reports of suspected adverse reactions (9). Unfortunately, much of this valuable information is unpublished and the published portion is often not representative of the overall picture (13). For example, although the number of reports of an adverse reaction is published, it is almost impossible to determine the number of people exposed to the particular problem. For this reason it is difficult to obtain a clear picture of the importance of adverse drug reactions.

The existence of a list of pharmacy periodicals containing over 900 entries, the estimates of Langlykke and Burkholder, and the amount of information collected in regard to adverse drug reactions are some indications of the volume of drug literature which must be effectively dealt with in providing "...accurate and unbiased information about drugs" (1). Dr. C.S. Keefer (11), in recognition of the vast and diverse sources of drug information, expressed it well when he said "...there is no dearth of information about drugs."

(b) Compiling Drug Literature

It became apparent that any limitations in drug information today are not due to a shortage of drug literature but rather to an inadequate organization and evaluation of the existing information (16). The need for better dissemination of the existing literature has been recognized by the development of various drug information and abstracting subscription services. Three of the major drug information services include: the deHaen series "Drugs in Use", "Drugs in Combination" and "Drugs in Research"; the Iowa Drug Information Service microfliche system and International Pharmaceutical Abstracts. Other services less specifically involved with pharmaceuticals are: Chemical Abstracts, Biological Abstracts, Index Medicus and specialized index services such as Cancer Chemotherapy Abstracts and Mental Retardation Abstracts.

The major subscription services have the common feature of being abstracting systems which are similar in the services offered. The deHaen system abstracts information from 400 journals in the health care field as well as various medical association meetings (17). The cards of the deHaen service contain significant information from the original article including the sample size, duration of the study, dosage information and the statistical study performed as well as the results and comments of the author. International Pharmaceutical Abstracts, published by the American Society of Hospital Pharmacists, is a semi-monthly bulletin containing abstracts from over 1000 periodicals dealing with

pharmacy, medicine and related fields (18). The International Pharmaceutical Abstracts publication compiles the title of the original article and an informative abstract which is categorized under one or more of the 25 sections which cover the practical, theoretical, economic and scientific aspects of pharmacy literature.

In contrast to the abstracting services, the Iowa Drug Information Service presents the complete original article on microfilm, indexed by 64 two-digit "descriptors" on accompanying file cards. The "descriptors" are terms used to define the contents, structure and results of the study. The significant items of each paper are coded by the "descriptors" before the article is microfilmed. This process allows the user to pinpoint his areas of interest firstly from the index card and secondly on the microfilmed article (19). It also makes available the complete article for immediate evaluation by the user. One drawback of this system is that a microfilm reader or reader-printer is required to make use of the information.

The advantage of systems such as those described above lies in the fact that they cover a large number of information sources, organizing them into a usable format and making them available to the users of drug information. One disadvantage is that they do not present evaluated information (14) but rather present all information regardless of the validity or significance. Another disadvantage of these systems is the cost (see Appendix I). The price, the storage area needed and the equipment

necessary to make use of systems such as the Iowa Drug Information Service limit the ability of the individual hospital to acquire and maintain them.

As explained by Burkholder (14) and supported by others (12, 16, 20, 21) the problem is to make available to members of the health professions valid and useful drug information when and where it is needed. A corollary to the problem could be that the information also should be unbiased (1).

II. Hospital Drug Formularies

(a) Definition

The major approach taken by hospitals to overcome the problem of not having the right drug information available at the right time is the development of hospital drug formularies in conjunction with the Pharmacy and Therapeutics Committees of the individual institutions (23-31). A formulary is defined by the American Society of Hospital Pharmacists as:

> "...a continually revised compilation of pharmaceuticals which reflects the current clinical judgment of the medical staff" (34).

"Mirror to Hospital Pharmacy" indicates that about 60 percent of hospitals in the United States operate under a formulary system, defining a formulary system as:

> "...a method whereby the medical staff of a hospital, working through a pharmacy and therapeutics committee..., evaluates, appraises and selects from among the numerous medicinal agents available those that are considered most useful in patient care, together with the pharmaceutical preparations in which they may be administered most effectively." (32).

The usefulness of the formulary system is acknowledged by both the Canadian Society of Hospital Pharmacists and the American Society of Hospital Pharmacists in publishing statements of guidelines for the use of the hospital formulary system (33, 34). In additional support of the formulary system, the Canadian Council on Hospital Accreditation (35) requires participation in the development of a hospital formulary as part of the requirements for pharmaceutical services of a hospital seeking accreditation.

The use of formularies is not a new concept. They have been used in North America since the early nineteenth century (36). Some formularies, for example the previous Vancouver General Hospital formulary (37), were lists of drugs and dosage forms available for use in the hospital. Other formularies contained additional information on therapeutic indications, side effects, and standard doses as in the formulary of the Ottawa Civic Hospital (25) and the formulary of the University of Pennsylvania Hospital (28). A third format is that of the Lions Gate Hospital Drug Formulary (see Figure 1) which contains indications, side effects and dosages as well as additional information on contraindications, drug inter-

Figure 1. Example of the format and content of the drug monographs of the Lions Gate Hospital Drug Formulary.

GLUTETHIMIDE DORIDEN 28:24

ACTION

A sedative-hypnotic structurally similar to barbiturates.
Greater degree of hypotension than barbiturates.
Onset: 20 minutes.
Duration: Approximately 6 hours.

INDICATIONS

Sedative, hypnotic.

CONTRAINDICATIONS

None known. Use with caution when impending depression or suicidal tendencies exist.

DOSAGE

ADULTS: Daytime sedation: 125-250 mg. t.i.d.
Insomnia: -.5 gm. h.s., may be repeated not less than 4 hours before arising. In long term use the total daily dose should not exceed 1 gm.

SIDE EFFECTS

Nausea, vomiting, anorexia, headache, dizziness, confusion, generalized skin rash. Rarely acute allergic reactions, blood dyscrasias, porphyria and jaundice. Hypotension and circulatory shock represent the major problem in toxic doses. Psychic and physical dependence with prolonged use.

DRUG INTERACTIONS

Inhibits action of oral anticoagulants increasing the risk of thrombus formation during therapy and bleeding tendency on withdrawal. CNS depressant effects of glutethimide are potentiated by narcotics, alcohol, phenothiazines (Largactil, Stelazine, Phenergan, etc.), MAO inhibitors (Parnate, Nardil, etc.), anaesthetics, and Reserpine. Glutethimide inhibits (by enzyme induction) analgesics, antihistamines (Benadryl, Perazine), phenylbutazone, diphenlyhydantoin, griseofulvin (Grisactin, Fulvicin), meprobamate, (Equanil), corticosteroids (oral contraceptives, hydrocortisone, etc.) other hypnotics.

NURSING IMPLICATIONS

Periodic blood counts and liver function tests are advisable. With prolonged use, withdrawl from drug should be gradual to minimize withdrawal reactions. Give with food to reduce gastric irritation. Monitor vital signs if being taken regularly. Exaggerated potentiation by alcohol. Does not produce sedation in highly disturbed patients or those in pain. May produce physical and psychological dependence.

PRESENTATION

Tablets: 500 mg.

FIGURE 1

actions and nursing implications.

As well as developments in the format and content of formularies, advances have been made in the field of formulary production. Electronic Data Processing (E.D.P.) is being used in formulary production in both Canada and the United States (25, 27, 28, 38, 39, 40, 41). The Iowa Drug Information Service used E.D.P. to produce a drug formulary from their automated drug information file (27). At the University of Pennsylvania Hospital (28) and the Ottawa Civic Hospital (25, 38) formularies were produced from decks of computer cards on which the information had been key-punched. At present, the Ottawa Civic Hospital has converted their production of the formulary to automated photocomposition and magnetic tape for information storage (38). These operations have demonstrated that in the several ways of applying E.D.P. to formulary printing (28), the cost of long-term production of the formularies by E.D.P. was less than the cost of conventional printing methods (27, 38). Editing and updating of drug information contained in the formularies also was faster and easier (25, 28, 38).

(b) Limitations

From the wide-spread use of drug formularies it appears that they have been fairly successful in providing drug information to the health practitioners at the point of use in their respective hospitals. However, there are also some specific limitations in their effectiveness.

It has been recognized that a true formulary has to be more comprehensive than merely a drug list (27). It has been identified also that the cost of the drug information resources (see Appendix I) required to evaluate and compile information for a formulary limits the ability of each individual hospital to maintain the resources to back-up their formulary with additional information when necessary. It should be noted that the smaller non-teaching hospital is perhaps at a greater disadvantage in this regard since access to large medical libraries is limited (42). Nevertheless, these smaller hospitals require drug information as much as, or more than the large teaching institutes (31).

A second obstacle to the effective production of individual formularies is the considerable time and expertise required to evaluate the literature and produce the drug monographs (43). The responsibility for producing the drug monographs rests with the pharmacists who in their spare time evaluate the literature and produce the drug monographs (43).

Francke recognized these obstacles to the preparation of a drug formulary in his own hospital (43). He also recognized that the purchase of the costly information sources, and the time and effort required to produce the formulary were being duplicated many times by pharmacists everywhere (43). Francke suggested that much of the duplication mentioned above could be eliminated if the American Society of Hospital Pharmacists would sponsor a national hospital formulary service and make it available to the hospitals at a reasonable cost (43). This perhaps was the first step

to regionalized formulary production.

III. Regional Drug Formularies

(a) The American Hospital Formulary Service

Although the Physicians' Desk Reference* (P.D.R.) had served the general medical practitioners' needs for drug information for many years (47), it represents a national compilation of drug manufacturers' literature (44). Perhaps the first, and still most popular regional drug formulary that provides accurate and unbiased information is the American Hospital Formulary Service**(A.H.F.S.). The drug monographs of the A.H.F.S. are prepared by the Committee on Pharmacy and Pharmaceuticals of the American Society of Hospital Pharmacists. The director of the committee edits the monographs to ensure a constant format and they are reviewed by three subcommittees of practitioners, pharmacists and manufacturers for suggestions and comments. Supplements to the A.H.F.S. are published and distributed to the subscribers at regular intervals containing both new drug monographs and updated information on existing monographs. The monographs produced are believed to represent accurate, evaluated and unbiased information (46).

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*The Physicians' Desk Reference, 23rd. edition, Medical Economics, Inc., subsidiary of Litton Publications, Inc., Oradell, New Jersey, 1969.

**The American Hospital Formulary Service, Committee on Pharmacy and Pharmaceuticals of the American Society of Hospital Pharmacists; The Hamilton Press, Hamilton, Illinois.

The Committee on Pharmacy and Pharmaceuticals recognized two important uses for the A. H. F. S.:

(1) As a basis for preparing individual hospital formularies;

(2) As a comparatively complete drug reference useful to practitioners and teachers in all the health professions concerned with drugs (46).

The first objective intended that each hospital Pharmacy and Therapeutics Committee would accept the responsibility to adapt the A. H. F. S. to the specific needs of the individual hospital (57). Promoting this concept Francke suggested that the respective pharmacists also might maintain on file all additional drug monographs supplied by the A. H. F. S. as additional drug information. This practice would enable the pharmacist to provide information to the Pharmacy and Therapeutics Committee investigating a new formulary addition or to other staff members requesting a non-formulary drug.

(b) Hospital Drug Information Centres

The second projected use of the A. H. F. S. became more popular with the development of hospital drug information centres (24, 30, 31, 49, 50). These centres were initiated to provide accurate, detailed and up-to-date information on drugs to all members of the patient care staff of the hospitals (31) and "...to support, assist and promote a rational drug therapy program" (24). Although other formularies such as the A. H. F. S. (51, 52) adequately provided evaluated, accurate and unbiased information

(46), it was difficult for these services to provide up-to-date information. This problem was due largely to the time lag between the original publication of the literature and the production of the respective supplements. An active drug information centre on the other hand with information resources similar to those listed by Burkholder (6), better enabled the pharmacist to provide up-to-date information, to answer questions that were beyond the scope of the formulary and to provide information on non-formulary drugs (27, 29, 30, 31, 42, 48, 49, 50).

Again, as with the production of hospital formularies, the smaller community hospital with limited access to literature resources, facilities and staff is at a disadvantage in operating a drug information centre (42, 53). In order to overcome duplication and inadequate efforts by small hospitals in this respect, it was recognized that such needs for drug information might better be served by developing one large drug information centre at a university-affiliated hospital to serve a specific region of smaller institutions (42).

(c) Regional Drug Information Centres

The development of Regional Drug Information Centres, like the production of the regional American Hospital Formulary Service, resulted in a centralized service supporting smaller services at the local level (42, 7, 54, 55, 56) and, consequently, the elimination of some of the duplication of costs, facilities, and staff. There have been two major trends in the

development of Regional Drug Information Centres based on decentralized and centralized approaches. These may be exemplified by the Michigan Regional Drug Information Network and the Kentucky Regional Drug Information Centre respectively.

The Michigan Regional Drug Information Network with its main centre at the University of Michigan supplies drug information to nine affiliated hospitals throughout the state. Various sources of drug information including the American Hospital Formulary Service, the deHaen systems, the Federal Drug Administration (F.D.A.) Clinical Experience Abstracts, the F.D.A. Suspected Adverse Reaction, International Pharmaceutical Abstracts and several journals serve as resources (57, 58). Each affiliated centre is responsible for answering drug information requests from its own area whenever possible (58). The main centre is available as a referral centre or clearing house for more complex requests that cannot be answered adequately at the local centre (59) as well as answering requests from the University of Michigan Medical Centre. This system has attempted to maintain as much autonomy as possible at each affiliated centre within the framework of a regional system and is therefore an example of the decentralized trend in Regional Drug Information Centres.

The system in operation at the University of Kentucky and, similarly, in the Appalachian Regional Hospitals System is designed to provide medical library and drug information services on a regional basis from a single centralized source (55, 56). In the Kentucky Regional Drug Infor-

mation Centre, the central information source is available to the health professionals in the state by a toll-free, direct-dial telephone line (called a Wide Area Telephone Service or WATS) for incoming calls. When a return call is necessary the information is provided via the existing telephone lines. By using the existing telephone system instead of the WATS network for out-going calls the Kentucky Regional Drug Information Centre has reduced the high cost of communication inherent in a centralized system (55, 68). In the Appalachian region, communication between the main centre and the regional hospitals is maintained by a teletype network, newsletters, and telephone conferences (56).

The popularity of the A.H.F.S. and Drug Information Centres in general, is reflected by the increasing use and development of both of these concepts (24, 31, 38, 45, 51, 59, 60, 61, 62, 63, 64). Although the combination of the A.H.F.S. and a Drug Information Centre has resulted in the Drug Information Centre being labelled as the "...guardian of the formulary" (48), the A.H.F.S. alone still has definite limitations for use in general and, more specifically, in Canada.

(d) Limitations of the A.H.F.S.

Some of the general limitations of the A.H.F.S. which have been cited include:

1. The A.H.F.S. has expanded to include, (as of 1967) 1030 drug monographs and 2766 pages in a two-volume set (43). As a result of the size, the A.H.F.S. is a very bulky and awkward book to use (47, 65). The

bulkiness alone can impede rapid information retrieval (47);

2. Many products covered in the A.H.F.S. may not be used in a specific hospital. Burkholder showed that the average number of drug monographs required by a hospital is about 400 (66) while the A.H.F.S. contains 1030 (43). This implies that a set of the A.H.F.S. in the average hospital is about two and one-half times larger than necessary;

3. The format of the A.H.F.S. is a third potential problem. The format of paragraphs rather than point form requires that the user read whole sentences to find the required information. Also, the information does not seem to be divided into enough subsections. This requires that the user must refer to the subsection on "pharmacology and action" to find information on side effects.

4. Finally, the drug monographs are not referenced and to supply additional information on a specific point of interest becomes quite difficult without the starting point of the original reference.*

In the United States, attempts to overcome the bulkiness of the A.H.F.S. have taken the form of modified formularies as suggested by the producers of the A.H.F.S. (46). However, this is a very time consuming task (46) and the resulting formulary printed on small pages to match the A.H.F.S. is still bulky (65).

In addition to the above, there are at least two drawbacks to the use of the American Hospital Formulary Service in Canadian hospitals:

1. The A.H.F.S. uses American brand names which in many instances do not correspond to the brand names commonly in use in Canada. Some examples of this problem are: chlorpromazine which is Thorazine^{R} in the United States and Largactil^{R} in Canada; cyclophosphamide which is Cytoxan^{R} in the United States and Procytox^{R} in Canada; isoniazid which is Dinacrin^{R} in

* Presently being undertaken.

the United States and Rimafon^{R} in Canada; and diethylstilboestrol diphosphate which is Milestrol^{R} in the United States and Honvol^{R} in Canada (70.67).

2. A second problem of the use of any American drug reference in a Canadian hospital is the possibility of different formulations of products bearing the same brand name. This problem is represented by the different formulations of a Canadian and an American product which both have the brand name Infantol. The Canadian product is a dietary supplement containing vitamin A, vitamin D, thiamine, riboflavin, vitamin C, niacinamide and pyridoxine (70) while the American product is an antidiarrheal containing, pectin, zinc phenosulphonate, bismuth subsalicylate and Irish Moss Extract (67). This is possibly one of the most significant formulation differences.

Although there is no regional formulary in Canada comparable to the A.H.F.S., one publication which overcomes some of the above limitations is the Compendium of Pharmaceuticals and Specialties* (C.P.S.). The C.P.S. is a compilation of information on pharmaceutical products and is commonly used in Canadian hospitals, clinics, community pharmacies and physicians' offices (68). However, some of the characteristics of the C.P.S. make it somewhat inadequate in a hospital setting:

1. The format of the C.P.S. is not thought to be suitable for rapid reference since it is prepared in paragraphs rather than point form;

2. The information in the drug monographs is not divided into enough subsections to enable the users to rapidly find the desired information;

3. The monographs of the C.P.S. are arranged alphabetically by both brand and generic names. As a result of this practice, there may be

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* Compendium of Pharmaceuticals and Specialties, Rotenberg, G.N. and Hughes, F.N., ed. Canadian Pharmaceutical Association, Toronto 1972.

several separate monographs for one generic name drug. An example of this problem is Ampicillin which is monographed five times under different brand names and once as the generic name drug (70);

4. The C.P.S. does not contain any references for the monographs so that it is not possible to evaluate the original information source on a specific statement or point of interest;

5. The C.P.S. does not include specific subsections regarding drug administration and use.

The popularity of use of the A.H.F.S. and the C.P.S. in Canada endorse the need for a regularly produced formulary on current drug information. Recognizing the limitations of the above two services, however, it would appear that a need still exists for a Canadian hospital formulary service.

IV. Provincial Hospital Drug Formulary

The development of clinical pharmacy services and the increased involvement of the Lions Gate Hospital* pharmacy staff in drug information led to the recognition of the limitations of the A.H.F.S. and the C.P.S. in this hospital (71, 72). Between the years 1965-1970, the pharmacists at the Lions Gate Hospital prepared a drug formulary containing one or two typewritten pages of clinically relevant information on about 300 drugs in use at the hospital (37). Working from many sources of drug information, the authors were able to compile for their drug monographs information on

*Lions Gate Hospital, North Vancouver, British Columbia.

pediatric dosages, dosages in kidney and liver failure, intravenous incompatibilities, drug interactions and nursing implications which for the most part had been unavailable in the monographs of the A.H.F.S. and the C.P.S. This information was added to the basic drug information commonly available on indications, dosages, side effects and contraindications to produce the drug monographs of the Lions Gate Hospital Drug Formulary (see Figure 1). Although much of this information was available in journals, textbooks and handbooks, the resulting formulary was unique in compiling all of this information into one usable source of drug information for the health professionals in the hospital (71, 72).

For the Lions Gate Hospital, the production of the Lions Gate Hospital Drug Formulary* also overcame the conflict between Canadian and American brand names that is inherent in using an American reference such as the A.H.F.S. in a Canadian hospital. The authors also attempted to reduce the search time for information by preparing their formulary in point form rather than paragraphs and by dividing the monographs into subsections of specific information. The subsections included action, indications, contraindications, dosage, side effects, intravenous incompatibilities, drug interactions and nursing implications. With these alterations and additions to the format and content of the A.H.F.S. and the C.P.S., some of the limitations previously mentioned were overcome. However, the Lions Gate Hospital Drug Formulary still had one major drawback to

*Lions Gate Hospital Drug Formulary, Lions Gate Hospital, Pharmacy Department, North Vancouver, 1971.

its continuing use as a source of drug information. There was no established mechanism for regularly updating the drug monographs. The previous work of updating the monographs and the production of new monographs when necessary soon proved to be a monumental task (71).

Recognizing the unique features of the Lions Gate Hospital Drug Formulary to the province as a whole, the British Columbia Hospital Association (B.C.H.A.) adopted the text as a provincial Drug Formulary and it was made available to approximately 100 British Columbia hospitals (37). Also recognizing that the monographs represented only those drugs used at one hospital and that a regular updating mechanism was required to maintain the potential of the new Drug Formulary, the B.C.H.A. supported a study at the Faculty of Pharmaceutical Sciences, University of British Columbia, directed at designing a mechanism to overcome these limitations.

V. Academic Role

One of the major assignments for senior pharmacy students at the Faculty of Pharmaceutical Sciences, University of British Columbia, requires an extensive literature evaluation of the scientific and clinical validity of new drug information. Accordingly, the information relative to about 100 drugs is evaluated annually. Although these assignments were not extended to produce the results in drug monograph format, it became apparent that much of the time and effort expended by students and

instructors represented the type of resource updating required to annually revise the provincial Drug Formulary.

It was further recognized that to revise, condense, edit and compile the academic assignments into useful Formulary monograph format, some "service" committment in terms of pharmacist and stenographic personnel would be required. The degree of this committment in terms of "service" to annually update and revise the Drug Formulary is the objective of the present study.

STATEMENT OF OBJECTIVES

The distribution of the Drug Formulary, originally produced at the Lions Gate Hospital, to the provincial hospitals by the British Columbia Hospital Association reflects the need for a formal provincial Drug Formulary. The objectives of the present study are to:

1. Identify how the present Drug Formulary may become more useful on a provincial basis through modification of the monograph and Formulary formats;

2. Define a mechanism whereby the Formulary may be evaluated and updated on a regular basis;

3. Project personnel requirements to achieve the above.

METHODOLOGY

This research was instituted with the realization that the Drug Formulary when adopted and distributed by the British Columbia Hospital Association (B.C.H.A.) would possibly require some alterations in format and content to make it more acceptable and useful to the provincial hospitals. It was recognized also that the Drug Formulary should be updated at regular intervals from the current literature with information that is both scientifically and clinically valid.

I. Identifying the Provincial Needs

In an attempt to determine the acceptability of the present Drug Formulary and what modifications were desirable in regard to format and content, three studies were undertaken. Firstly, a questionnaire was distributed to the chief pharmacists of the provincial hospitals to determine the extent of use of the Drug Formulary and their opinions in regard to the format and contents. Secondly, a survey of four major hospitals of the province was conducted to determine how many additional drug monographs were desired which would eventually influence the size of the Formulary. Thirdly, a study was conducted of the drug usage patterns in specific care areas of five hospitals to determine if a condensed version of the Formulary could be made to facilitate a more effective use of the Drug Formulary at the ward level.

(a) Popularity of Use

A questionnaire was sent to the chief pharmacists of all British Columbia hospitals which listed a chief or director of pharmacy in the 1971 edition of the "Canadian Hospital Directory"*. The questionnaire was designed to give the Formulary users the opportunity to express their own opinions and those of their colleagues on the content and format of the present Drug Formulary. It also gave these professionals a chance to suggest changes in the format and content and additional drug monographs for inclusion in the Formulary. Figure 2 illustrates the questionnaire.

All questionnaires that were completed and returned were reviewed to determine the number of hospitals that were using the Formulary and to obtain suggestions for future changes in the Formulary format and the monograph format. The lists of additional drug monographs requested by the chief pharmacists for inclusion in the Formulary were included in the results of the Additional Drugs Survey.

(b) Number of Drug Monographs

Before requesting which additional drug monographs were needed by the Formulary users, it was deemed necessary to determine the number of drug monographs in the existing Drug Formulary and the number of

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*Canadian Hospital Directory, Vol. 19, The Canadian Hospital Association, Toronto, 1971.

Figure 2. Example of the questionnaire sent to the chief pharmacists of the provincial hospitals.

THE UNIVERSITY OF BRITISH COLUMBIA

VANCOUVER 8, CANADA

FACULTY OF PHARMACEUTICAL SCIENCES

November 21st, 1972

Dear Fellow Pharmacists:

The Faculty of Pharmaceutical Sciences is undertaking a provincially sponsored study to "update" and make "more provincial" the present Drug Formulary (Lion's Gate) being distributed by the B.C.H.A. The objective here is to design and maintain on a regular basis a provincial formulary for all hospitals in British Columbia.

Accordingly, so that the design might represent "provincial" thinking, we are asking for your support and the contribution of your ideas as related to the following questions:

1. Is the Drug Formulary in general use in your hospital? _____
2. If the answer to question 1 is no, please comment in regard to the reasons in your hospital for not using the Drug Formulary. _____
   _____
   _____
   _____
3. Did you previously have a formulary of your own in your hospital? _____
   If yes, is it still being used? _____
4. Is the formulary satisfactory in regard to:
   (a) overall format _____
   (b) monograph format _____
   (c) introductory information _____
   (d) monograph information _____
   (e) other _____
   as related to the physicians, pharmacists and nursing views in your hospitals.
5. Are there any additional monographs you would like to see included? if yes, please list them _____
   _____
   _____

As the information that you supply to us will be used to determine the cost and usefulness of regular updating and making the formulary more provincially useful, we request that you reply before the 15th of December, 1972. A reply by that date will enable us to evaluate your comments and to incorporate your ideas into our project in early 1973.

Thank you for any assistance which you can give to us and for your interest in promoting better drug information to your hospital in the future.

Yours sincerely,

EAP/cs

Elizabeth A. Page, B.Sc.(Pharm).
Division of Clinical Pharmacy

cc. Dr. J. Hlynka, Chairman, Division of Clinical Pharmacy

FIGURE 2

drugs and drug products listed in the Formulary alphabetical index.

The drug monographs in the Formulary were counted, excluding the specialized monographs on "Ear, Eye, Nose and Throat Preparations", "Skin and Mucous Membrane Preparations", and "Intravenous and Irrigation Solutions". The above listed sections were excluded because the monographs represent specialized uses of drugs which are usually monographed in the main section of the Formulary under generic names. To determine the number of drugs and drug products listed in the Formulary alphabetical index, most of the brand names of the drugs which are included in the index as a cross-reference to the generic drug name were eliminated. The remaining drug names were counted and arranged in alphabetical order. The resulting drug list was later used in the study of drug usage patterns in special care areas of five provincial hospitals.

Additional Drugs Survey

To determine which, if any, additional drug monographs were needed to make the Drug Formulary more adequately reflect the drug information needs of the provincial hospitals, a sample survey was conducted in four major hospitals of the province. Vancouver General Hospital, St. Paul's Hospital (Vancouver), Victoria General Hospital and Royal Jubilee Hospital (Victoria) were chosen because they all offer hospital pharmacy residency programmes and therefore expected to have sufficient staff to complete the survey.

The hospital pharmacy resident in each hospital was asked to review the drugs stocked in his hospital and to list all drugs used which were not monographed in the present Drug Formulary. They were asked also to indicate whenever possible which drugs in the lists their hospital would like to see included in the Formulary. The results of this survey were correlated with the lists of additional drug monographs requested by the chief pharmacists. The additional drug monographs requested were categorized according to the frequency of requests received for each drug from the four hospitals and the chief pharmacists. From the results, the eventual size and content of the Drug Formulary could be estimated providing that the additional drugs suggested above were representative of the other provincial hospital needs as well.

(c) Format of the Drug Monographs

In completing the chief pharmacists questionnaire (see page 26) the chief pharmacists were asked to comment on the acceptability and usefulness of the drug monograph format. Suggestions for changes and additions were reviewed in addition to those that were identified from an analysis of the literature and from the comments of the members of the Faculty of Pharmaceutical Sciences, University of British Columbia who were involved in the current revisions. All of these were noted and some of them were adopted for further evaluations in the present study.

Canadian Drug Identification Code

The recent publication by the federal Health Protection Branch of the Canadian Drug Identification Code stimulated interest in adding to the drug monographs a drug code which was specifically Canadian in nature. This would supplement the existing American Hospital Formulary Service (A.H.F.S.) therapeutic classification number. Since the Canadian Drug Identification Code contains four unique drug codes, the Health Protection Branch publication was studied to determine which of the four codes would be most useful to the Formulary users for drug identification as well as stock control and other procedures.

Ambulatory Considerations

In recent years, hospitals and hospital pharmacists have become increasingly involved in ambulatory and outpatient services (60). In attempting to produce a Drug Formulary which might be useful to all health professionals of the province, consideration was given to those areas which deal with ambulatory patients in an outpatient clinic as well as in the inpatient setting. For this reason an attempt was made to supply information on the drug monographs to assist the health care professionals in instructing the ambulatory patients about the proper handling and use of their medications. The mechanism that is being evaluated as a means of updating the Drug Formulary monographs was adopted as the basis for also accomplishing the objective of supplying instructions to the patients.

Electronic Data Processing and Formulary Production

Because the present method of printing the Drug Formulary requires that the whole monograph be re-typed each time that it is updated, it was decided that another means of producing the Formulary should be investigated.

The use of electronic data processing (E.D.P.) and computerization is becoming more common in medical and pharmacy practice and several drug formularies have been produced by these means. To investigate the possibility of computerized production of the Drug Formulary in future years, the recent literature on this subject was reviewed. A letter was also sent to Mr. H. Smythe, Director of Pharmacy at the Ottawa Civic Hospital, (Ottawa, Ontario) requesting information on the costs, storage of information, and the method used to update the monographs by E.D.P. The Ottawa Civic Hospital was chosen as the source of this information because it is a Canadian hospital using E.D.P. to produce a drug formulary and it was thought that the costs and procedures at a Canadian hospital would more closely resemble the possible costs and methods also available in British Columbia. A comparison between the costs of E.D.P. formulary printing as supplied by Mr. Smythe and the costs of the conventional methods as used to produce the British Columbia Drug Formulary was done.

(d) Monograph Utilization Survey

One of the limitations of the American Hospital Formulary Service is that the two-volume set is too bulky for easy use (47, 65). Similarly, the present Drug Formulary also is awkward due to its size. For this reason and because the content of the Formulary may have to be further increased to cover the drug information needs of the province, an attempt was made to find a method(s) by which the wards of the hospitals could be supplied with useful, compact formularies through identifying the unique drug use patterns in each patient care area.

A study was conducted in this regard in five provincial hospitals to determine the frequency of use of the drugs and drug products listed in the alphabetical index of the Formulary according to specialty wards. The complete drug list was typed (first page exemplified in Figure 3) and distributed to Vancouver General Hospital, St. Paul's Hospital, Lions Gate Hospital, Victoria General Hospital and Royal Jubilee Hospital.

Information in this respect was generated on the frequency of use of the listed drugs in the specific care areas of Pediatrics, Emergency, Psychiatry and Extended Care. These areas were chosen to exemplify specialties because of the wide variety of drugs that might be used in each of them. For each listed drug the frequency of use was determined as "frequently", "occasionally" or "rarely" in each of the four areas. "Frequently Used Drugs" were defined as those drugs which were supplied to

Figure 3. Sample of Drug Lists used for Monograph Utilization Survey.

DRUG	PEDIATRICS			EMERGENCY			PSYCHIATRIC			EXTENDED CARE		
	F	O	R	F	O	R	F	O	R	F	O	R
Acetaminophen												
Acetazolamide												
Acetycholine												
Acetylcysteine												
Acetylsalicylic acid												
Achromycin												
ACTH												
Adephinine												
Adrenalin												
Aerosporin												
Aerosporin (Ear)												
Agarol												
Airbron												
Alcohol												
Alkeran												
Allopurinol												
Alpha-Chymotrypsin												
Alpha-Tocopherol												
Aluminum Hydroxide												
Americaine												
Amesec												
Amethopterin												
Aminocaproic acid												
Aminophyllin												
Aminophyllin Compounds												
Amitriptyline												
Ammonium Carbonate Mixture												
Ammonium Chloride												
Ammonium Chloride Mixture												
Amobarbital Sodium												
Amphotercin												
Amphyl												
Ampicillin												
Amyl Nitrite												
Anectine												
Anileridine												
Annanase												
Antepar												
Anusol												
Apresoline												
Argyrol												
Ascorbic acid												
Atropine (eye)												

FIGURE 3

an area as ward stock, used daily or several times a week. "Occasional Used Drugs" were those used in an area only once or twice a month, and "Rarely Used Drugs" were interpreted as those drugs used in an area only once or twice a year, or never. To obtain this information, records were reviewed and pharmacists and nurses were interviewed according to specific drug use patterns (see Figure 4).

The lists from each hospital were analysed according to the specific treatment areas to determine the number of drugs and the approximate percentage of the drugs used "frequently", "occasionally" and "rarely" for each hospital. It was anticipated that the results could then be used to propose a system whereby the monographs of the "Frequently Used Drugs" could be made more readily available to the health professionals on the nursing ward without sacrificing the availability of the remaining monographs for drugs used "Occasionally" and "Rarely" in each area. It was hoped also to keep the potential bulk of a provincial Drug Formulary to a minimum.

II. Evaluation and Updating the Formulary

For the past two years a limited number of senior year pharmacy students at the Faculty of Pharmaceutical Sciences, University of British Columbia have been participating in a programme of literature evaluation in conjunction with a pilot course in Clinical Pharmacy. It was recognized that the work done by the students was valuable and that much of this work

FIGURE 4

INSTRUCTIONS FOR MONOGRAPH UTILIZATION SURVEY

SURVEY OF DRUG USE FOR SPECIALTY FORMULARIES

Hospital Name _____

Resident's Name _____

INSTRUCTIONS:

1. Complete the following charts with regard to the frequency of drug use in specialized care areas in your hospital.

2. F = Frequently - floor stock to area or used daily, several times a week?

   O = Occasionally - used in specific area only once or twice a month.

   R = Rarely - used in specific area only once or twice per year - or never..

   Other than floor stock, frequency of use is to be determined by Resident's experience, pharmacists' opinions and nurses' opinions.

3. A section on the last page is provided for evaluation of the frequency of use of drugs that are not listed here, but are used in your hospital.

4. Drugs are listed by generic name only, to prevent confusion with brands that may not be used in all hospitals. (Exception: those medications which are combination products).

5. Please complete and return forms before December 20, 1972.

could be further applied to a practical use in fulfilling the need of updating the present Drug Formulary. Accordingly a mechanism was proposed to the Medical Services Foundation of British Columbia whereby the monographs of the Drug Formulary could be updated as a clinically related educational assignment to the senior year pharmacy class in 1972-73.

The proposed mechanism of updating the drug monographs to be evaluated in the present study represents a sequence of senior year Clinical Pharmacy student assignments and instructor review, both as an "academic" responsibility and on a "service" basis to ensure the accuracy of the student work. The instructor "service" input represents the revision and condensing of the literature evaluation report to suitable monograph format. The above Foundation approved a one-year grant to enable the financing of this "service" component by the instructor as well as some stenographic assistance.

The questions that were to be answered before a continuing programme of this nature could be undertaken on an annual basis include:

1. Is there a need for regular updating of the drug monographs?
2. What are the time requirements of the students and what is the extent of their contribution to the updating mechanism?
3. What is the time requirement of the instructors beyond their academic involvement?
4. What is the time requirement of the stenographic staff to type the updated monographs on an annual basis?

(a) Mechanism of Updating

Student Assignment

Each student in the senior year pharmacy class was assigned three drugs (see Appendix III) to completely evaluate the existing monograph information and reference from original literature all statements in the monograph sections of "Drug Interactions" and "Intravenous Incompatibilities". The students were supplied with a statement of the type of papers and references which were acceptable literature sources and were instructed to use only scientifically valid information to update the monographs. In addition the section of the monograph concerning "Action" was to be expanded to include the mechanism of action, absorption, distribution, metabolism and excretion of the drug. A new section of "Instructions to the Patient" was added also to fulfill the objective of supplying drug information to ambulatory care areas. Throughout the assignment the students were required to add any new information from the literature of the past year as well as to evaluate existing monograph information from earlier years. The students also were directed to record any changes or corrections that were found from the literature and to reference these alterations on a Change Sheet (see Figure 5) which were presented to the instructor with both the original and evaluated monographs.

Throughout the assignment the students recorded the time required to update each monograph. The results of the time study were

Figure 5. Sample of a Change Sheet as distributed to the students, with sections for the updated information similar to the monograph format.

Pharmacy 403

Drug and Poison Information Centre

Revisions and Updating of Drug Monograph

GENERIC NAME OF DRUG _____

1. General Information
2. Action
3. Spectrum of Activity
4. Indications
5. Contraindications
6. Cautions
7. Dosage
8. Side Effects
9. Drug Interactions
10. Intravenous Incompatibilities
11. Nursing Implications
12. Instructions to the Patient
13. Presentation

FIGURE 5

used to project the student involvement in annual updating and a time schedule for future revisions.

Pharmacist Involvement

The required instructor involvement in total revision of the drug monographs represents the participation of the instructors beyond their "academic" responsibility. The "academic" responsibility included being present at the student presentations of the evaluated monographs and grading the work on the basis of academic merit. For Formulary purposes, the instructors then reviewed the revised monographs for all changes, additions and corrections made by the students, and evaluated the work and cited references for scientific validity on a "service" basis. When the instructors had completed the evaluation of the revised monographs they then edited and condensed the monographs into the standard format of the Drug Formulary.

The instructors were requested to maintain a record of their time requirements beyond their "academic" involvement. These time records were used to project the pharmacist "service" requirements for updating the monographs on a future annual basis.

Stenographic Requirements

The revised, corrected and condensed monographs were required to be typed in a uniform format for duplication and distributed to the

participating hospitals. Accordingly, a stenographic service input was required for this purpose. As for other personnel, the time required for the stenographic work was recorded to enable a projection of this service on a potential annual basis.

(b) Nature and Frequency of Changes

One hundred completed Change Sheets (see Figure 5, page 39) were selected and reviewed to estimate the need for regular revision of the Drug Formulary monographs. These one hundred Change Sheets were analyzed to show the average total number of changes in each monograph and the average number of changes which appeared specifically in the sections of "Drug Interactions" and "Intravenous Incompatibilities". The latter two sections were segregated since it was expected that the majority of the future updating time might be required in these areas.

(c) Time Evaluation

From each of the time records of the above three groups (students, instructors and stenographers) one hundred records were evaluated. These records were used to determine the average approximate time needed for updating the monographs on a "service" basis, to propose a schedule for future revisions and to project the personnel that might be needed to accomplish this objective.

RESULTS AND DISCUSSION

The three basic issues to be resolved in the present study included the definition of the drug monograph and Formulary format changes required to present a more provincially useful reference, the projection of an evaluation mechanism which could effectively update the Formulary on a regular basis, and a description of the type and number of personnel required to produce such updated drug monographs.

I. Identifying the Provincial Needs

Three approaches were used to determine the necessary format changes and how to implement these changes to produce a more provincially useful Drug Formulary.

(1) A questionnaire was sent to the chief pharmacists of all British Columbia hospitals which listed a chief or director of pharmacy in the 1971 edition of the Canadian Hospital Directory*.

(2) A sample of four hospitals of the province were surveyed to determine which, if any, additional drug monographs were needed.

(3) An evaluation of the drug use patterns of the drugs listed in the alphabetical index of the Formulary in specialty care areas of five provincial hospitals was conducted to determine if more effective use could be made of the Formulary at the ward level.

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* Canadian Hospital Directory, Vol. 19, The Canadian Hospital Association, Toronto, 1971.

By reviewing the results of these three approaches, some format and content changes that would make the Drug Formulary more useful to all hospitals of the province were identified.

(a) Popularity of Use

Of the 46 hospitals monitored in the chief pharmacists questionnaire, 32 or approximately 70 percent replied to the questionnaire and of these, 19 or approximately 60 percent reported using the Drug Formulary (see Table I). The major reasons for not using the Formulary and the incidence of these reasons are presented in Table II. Since the majority of the respondents appear to be using the Formulary and since the limitations forwarded can be overcome, it would appear to be worthwhile to pursue an attempt to make the Formulary more provincially acceptable.

Those hospitals using the Drug Formulary submitted some excellent recommendations for improvements and the following list of recommended modifications represent a summary of these as well as those from the other sources mentioned on page 42:

(1) that additional drug monographs be added to the Formulary to cover the drug information needs of the province;

(2) that the mode of action be included on the drug monographs and that more extensive information on some drugs be added;

(3) that consideration be given to supplying information to those areas of practice that deal with the ambulatory patient in a hospital setting

TABLE I

DRUG FORMULARY UTILIZATION

As Determined By a Survey of Chief Pharmacists

	Number of Hospitals	Percentage[1]
Hospitals in British Columbia	104	
Hospitals Surveyed	46	44
Hospitals which replied	32	70
Hospitals which use the Provincial Drug Formulary[2]	19	60

1. Determined to the nearest percentage point.

2. Of those hospitals which replied.

TABLE II

REASONS FOR NOT USING THE

DRUG FORMULARY[1]

Reason	Number of Hospitals
Using American Hospital Formulary Service	4
Using Compendium of Pharmaceuticals and Specialties	2
Do not have sufficient Copies for all areas (more on order)	3
Specialized Hospitals (Mental Health, Rehabilitation)	3
Use it but as Back-up Reference only	1
Total	13

1. As determined from the survey of chief pharmacists.

such as the Outpatient Clinic, Nursing Stations in remote areas and the Mental Health Clinics;

(4) that references of the drug monographs would assist the users in obtaining additional information as required;

(5) that a Canadian Drug Code be included on the monographs for drug identification;

(6) that the Drug Formulary is too bulky and cumbersome for quick reference;

(7) that electronic data processing (E.D.P.) be considered as a means of producing the Drug Formulary which might be cheaper and facilitate quicker updating and editing;

(8) that the Formulary should be updated at regular intervals so that it remains an accurate, up-to-date source of drug information to the users.

Some of the above recommendations were implemented in the current revision of the Formulary. Others have been investigated in the present study for possible future adaptations. The results in each area are considered as follows under the sub-headings of "Number of Drug Monographs", "Format of Drug Monographs", "Format of the Formulary" and "Evaluation and Updating of the Formulary".

(b) Number of Drug Monographs

Before requesting which additional drug monographs might be needed by the provincial hospitals, the number of drug monographs included in the present Drug Formulary was determined. This was done to enable a

projection of the possible size of the Formulary if additional drug monographs are required. The total number of drug monographs in the existing Formulary is 306.

The alphabetical index of the Formulary, however, lists 483 drugs and drug products. The discrepancy that exists is due to the fact that the latter number includes the various salts of the generic name drugs as well as some brand names of combination products which may be monographed in the Formulary under a single generic name.

In recognition of the fact that the present Drug Formulary contains monographs of only those drugs used at one hospital, a survey was conducted in four additional provincial hospitals of varying size to determine what additional drug monographs might be required to supply comprehensive drug information in the province. The hospitals included in this study (see Methodology, page 27) were requested to list the drugs that they stock which are not included presently in the Drug Formulary It was felt that by correlating these lists with those submitted by five chief pharmacists on the chief pharmacists questionnaire (see Methodology, page 24), the final result would reflect most of the drug monographs needed by the provincial hospitals.

Of a total of 904 drug monographs eventually requested in addition to the existing monographs, 592 received one request, 204 were requested by two hospitals, 71 were requested by three hospitals, 32 others

were requested by four institutions and five drug monographs were requested by five hospitals (see Appendix II). In terms of priorities for new drug monographs to be produced in the future, it is recommended that those drugs which received two or more requests should be considered firstly. On this basis, a future provincial Drug Formulary might be expected to contain in excess of 600 drug monographs; 306 existing monographs, plus approximately 300 new monographs requested by two or more institutions.

(c) Format of the Drug Monographs

Among the many ways in which the format of the present drug monographs were recommended to be changed to obtain a more provincial Formulary, the inclusion of "Mode of Action", ambulatory use instructions, bibliography references and the Canadian Drug Identification Code were some which were adopted during the current Formulary revision. Figure 6 and Figure 7 present copies of the monographs of Erythromycin, respectively, before and after revision featuring the above additions.

Mode of Action

Although the existing monographs have a section for information on the action of the drug, it is often only a statement of the therapeutic classification of the drug (see Figure 6). In view of the request that the mode of action be included on the monographs, each revised monograph now contains information on the mechanism, absorption, distribution,

Figure 6. Sample monograph of Erythromycin from the existing Drug Formulary before revision.

ERYTHROMYCIN

ILOSONE
ERYTHROCIN

8:12:12

ACTION:
Primarily bacteriostatic antibiotic. Spectrum similar to Penicillin, i.e., mainly gram positive bacteria. Excreted mainly in bile. Peak of Action: 2-4 hours. Duration 6 hours. Normal serum half-life: 1.5 hours. Serum half-life in renal failure: 5 hours.

BACTERIAL SPECTRUM:
Staphylococci, B-hemolytic streptococci, clostridia, D. pneumoniae, H. pertussis, *C. diphtheriae, treponema, *Mycoplasma pneumoniae (Eaton agent), viruses causing trachoma and lymphogranuloma venereum. (*Generally considered antibiotic of 1st choice.) Other principal use is against group A, beta-hemolytic streptococci and pneumococcal infections in patients allergic to Penicillin.

INDICATIONS:
Bacteriostatic against staphylocci, pneumococci, beta-hemolytic streptococci. Used in soft tissue, respiratory and skin infections.

CONTRAINDICATIONS:
Hypersensitivity. Erythromycin estolate (Ilosone) is contraindicated in cholestatic jaundice or liver disease. Kidney disfunction is not a contraindication to use of Erythromycin.

DOSAGE:
ORAL: ADULTS AND CHILDREN over 23 kg: 250 mg. every 6 hours. Severe infections: 500 mg. every 6 hours. Taken 1-1-1/2 hours prior to or after meals. Dosage range 1-4 gm. daily.
CHILDREN 11.5-23 kg: 125 mg. q.6.h.
CHILDREN 4.5-11.5 kg: 11 mg./kg. q.6.h.

I.V.: ADULTS: Reserved for severe infections: 1-4 gm. daily in divided doses q.6.h.
CHILDREN: 12 - (24)- 48 mg./kg/24 hours divided q.8.h.
Maximum single dose: 0.5 gm. Maximum daily dose: 1.5 gm.
In renal failure (creatinine clearance 10 ml./min. or less): Normal initial dose followed by half-doses at intervals of 8 hours.

SIDE EFFECTS:
Nausea, vomiting, diarrhea, skin rash, jaundice, I.M. injection of more than 100 mg. produces severa and persistent pain. I.V. infusion of 1 gm. doses frequently causes phlebitis.

DRUG INTERACTIONS:
Erythromycin antagonizes action of Penicillins.

NURSING IMPLICATIONS:
Oral solutions must be refrigerated, stability varies with product. Injection stable 14 days under refrigeration. I.V. injection must be mixed with water for injection without preservative otherwise the drug precipitates. It is advisable to give oral preparations between meals unless gastric irritation is too severe. Periodic blood cell counts are advisable. Liver function tests are advisable in prolonged therapy with the estolate salt.

I.V. INCOMPATIBILITIES:
Loss of activity in solution is rapid at a pH below 5. Compatible with most I.V. solutions but may be precipitated by addition of high concentrations of inorganic salts. Incompatible with B complex with C, barbiturates, heparin, Tetracycline, Ceporan, Diphenylhydantoin (Dilantin), Chloramphenicol, Aminophyllin, Streptomycin.

PRESENTATION:
Capsules or Tablets: 250 mg.
Suspension: 125 mg./5 cc.
Drops: 100 mg./cc.
Vial: 1 gm.

Figure 7. Sample monograph of Erythromycin including the bibliography after revision, showing the Canadian Drug Identification Code Active Ingredient Group Number in the top left-hand corner and the American Hospital Formulary Therapeutic Classification number in the top right-hand corner.

00431 ERYTHROCIN (STEARATE) ILOSONE (ESTOLATE) E-MYCIN (BASE) ERYTHROMYCIN AND ITS ESTERS 8:14:12

ACTION: Bacteriostatic Antibiotic.

Mechanism: Primarily bacteriostatic. Inhibits protein synthesis at ribosomal level (1).

Absorption: Oral - readily, primarily from upper part of small intestine. The base and stearate salt absorption decreases if taken with food but the estolate salt is unaffected (3). Highly protein bound, peak blood levels in about two hours with estolate salt, in about four hours with stearate salt or with base in acid resistant coated tablets (3). Blood levels are at least twice as high (1), more predictable and more prolonged (3) when an equivalent dose of estolate given as compared with base or stearate.

Distribution: All tissues except brain contain higher concentrations than in blood (1); into peritoneal, pleural, ascitic and amniotic fluids; into saliva; across mucous membrane of the tracheo-bronchial tree; into placental circulation (3). Poorly into spinal fluid unless meninges inflamed (3).

Metabolism: Normal serum half-life 1.5 hours. Half-life in renal impairment up to five hours (11).

Excretion: The drug is concentrated in the liver and is mainly excreted in the active form in the bile (1). Also excreted in the urine, feces and milk (3).

SPECTRUM OF ACTIVITY:

Similar to penicillins, i.e., mainly Gram positive bacteria. Bacteriostatic against Staphylococci, B-hemolytic streptococci, clostridia, D. pneumoniae, H. pertussis, *C. diphtheriae, treponema, *Mycoplasma pneumoniae (Eaton agent), viruses causing trachoma and lymphogranuloma venereum. * - generally considered antibiotic of 1st choice. No cross resistance with penicillin. Cross resistance with carbomycin, oleandomycin and spiramycin. Staphylococci strains develop resistance fairly rapidly (3).

INDICATIONS:

Principal use is in group A beta-hemolytic streptococcal and pneumococcal infections in patients who are allergic to penicillin (2). Prophylactically - for prevention of bacterial endocarditis prior to dental or other operative procedures on patients with a history of rheumatic re fever or congenital heart disease (2). Used in soft tissue, respiratory infections.

CONTRAINDICATIONS:

Hypersensitivity. Estolate salt is contraindicated in cholestatic jaundice or liver disease, and in chronic disorders (e.g., acne and furunculosis) (3). Kidney dysfunction is not a contraindication to use (1).

CAUTIONS:

Patients with pre-existing liver dysfunction (4).

DOSAGE:

Oral: Adults and children over 23 Kg.
250 mg every 6 hours. Severe infection - 500 mg every 6 hours. Taken 1 hour prior to or 2 hours after meals. Dosage range 1-4 Gm daily.

Children: 11.5 to 23 Kg: 125 mg q.6.h.; 4.5 to 11.5 Kg: 11 mg/Kg q.6.h.

IV.: Reserved for severe infections. Adults: 1-4 Gm daily in divided doses q.6.h. Maximum single dose: 0.5 Gm. Maximum daily dosage: 1.5 Gm. In renal failure (creatinine clearance 10 ml/min or less): Normal initial dose followed by half dose at intervals of 8 hours.

SIDE EFFECTS:

Rarely serious adverse reactions (5), infrequently nausea, vomiting, diarrhoea, skin rash, jaundice (only with estolate salt and extended therapy (3, 8)). I.M. injection of more than 100 mgm produces severe and persistent pain. I.V. infusion of 1Gm doses frequently causes phlebitis.

INTERACTIONS:

Erythromycin antagonizes action of penicillin (12). Antibacterial effect in the urine appears to be enhanced by agents which alkalinize the urine - e.g., acetazolamide, sodium bicarbonate (6, 7). The drug should not be administered prior to fruit juice or other acid drink - activity of drug greatly decreases in acid solution (3).

I. V. INCOMPATIBILITIES:

Erythromycin is extremely pH dependent - most stable above pH 6-8. Loss of activity in solution is rapid at a pH below 5 - avoid concurrent use of additives which will result in an admixture pH below 5 (9). Compatible with most I. V. solutions but may be precipitated by addition of high concentrations of inorganic salts. Incompatible with: Vitamin B complex with C, barbiturates, heparin, tetracycline, cephaloridine, diphenylhydantoin, chloramphenicol, aminophyllin, streptomycin, ascorbic acid, dextrose in lactated Ringer's injection (10).

NURSING IMPLICATIONS:

Oral solutions must be refrigerated, store in a cool place, protected from light (4); stability varies. Injection stable 7 days under refrigeration (4). I. V. injection must be mixed with water for injection without preservatives, otherwise the drug precipitates. I. M. injections irritating and too painful and should not exceed 100 mg. It is advisable to give oral preparations between meals unless gastric irritation is too severe. Antacid may be given for gastric irritation. Periodic blood counts are advisable in prolonged therapy with the estolate salt. Venous irritation and thrombosis may occur if I. V. solution extravasates - watch site of infusion, stop flow before removing needle (4). Observe for symptoms of overgrowth of nonsusceptible organisms (black furry tongue, enteritis) during prolonged therapy (4). The commercial I. M. product is not miscible with water, so only a dry syringe and needle should be used (2).

INSTRUCTIONS TO PATIENT:

Take one tablet one hour before meals (or two hours after) and at bedtime - 4 a day. Take antacid if stomach gets upset after taking medication. Don't drink fruit juice or any acid drink with or after taking tablet. Store medication in a cool place, protected from light.

PRESENTATION:

Capsules or Tablets	250 mgm
Suspension	125 mgm/5 cc
Drops	100 mgm/cc
Vial	1 Gm

Date Prepared: March, 1973

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metabolism and excretion of the drug where applicable (see Figure 7). As well as adding the above information to the monographs, the revised monographs now also include more extensive information in each of the other sections of the monograph on "Indications", "Side Effects", Contraindications" and "Intravenous Incompatibilities". Such additional information contained in the drug monographs should better meet the needs of most users in the future.

Ambulatory Use Instructions

Since the Drug Formulary is in use in hospitals in all parts of the province, and since some of these hospitals are active in many services including outpatient clinics, it was determined that a section should be added to this year's revised monographs on "Instructions to the Patient" (see Figure 7). This section also is expected to be of use within the hospital setting itself to assist in the instruction of patients receiving discharge medications. The addition of this section may further prove useful if an Ambulatory Drug Formulary is produced at some future date for use in Community Health Centres. In an Ambulatory Formulary the section on "Instructions to the Patient" could be used in place of the sections on "Intravenous Incompatibilities" and "Nursing Implications" which at present deal primarily with information required in the hospital setting.

References and Bibliography

From previous experience with the American Hospital Formu-

lary Service (A.H.F.S.) and other reference sources such as standard textbooks, difficulty is experienced frequently in conducting additional information searches on the presented information because these sources contain no indication of where the original information was found. Although it is possible to obtain the references to the A.H.F.S. by writing to the American Society of Hospital Pharmacists, experience dictates that this system is too awkward and time consuming for efficient utilization. For these reasons, it was decided to reference the contents of the drug monographs and to provide a complete bibliography for each monograph in the Drug Formulary (see Figure 7). The presence of the references and bibliography is expected to enable the user to further research information and to identify the information source quickly.

Canadian Drug Identification Code

The Health Protection Branch of the Canadian government has recently published the Canadian Drug Identification Code. The publication contains four sections of different codes - the Sequential Identifier; an alphabetical listing by Trade names; the Manufacturers' Assigned Code and the Active Ingredient Group Number.

After reviewing the above four codes, it was decided to adopt the Active Ingredient Group Number for inclusion in the drug monographs because it appeared to be the most useful code without limiting identification to only one manufacturer's product (see Figure 7, top left). It was felt that as well

as having the Canadian Drug Identification Code Active Ingredient Group Number however, the American Hospital Formulary Service (A.H.F.S.) Therapeutic Classification number (8:12:12) should be retained on the monograph (see Figure 7, top right) as a correlation to the A.H.F.S. and for those hospitals which wish to file the monographs by the A.H.F.S. Therapeutic Classifications.

(d) Format of the Formulary

The major criticism of the present Drug Formulary format as determined from the chief pharmacists questionnaire, from the members of the Faculty of Pharmaceutical Sciences who were involved with the current revisions and from the comments of the Formulary users, is that it is too bulky. The Formulary, if expanded in its present format to approximately 600 monographs as anticipated (see page 48) would be further reduced in usefulness, particularly on the nursing station where limited time and space is available. It would appear that the larger the reference book, the less it is likely to be used.

Monograph Utilization Survey

In an attempt to reduce the bulk and to increase the usefulness of the Drug Formulary, a survey was conducted to determine the frequency of use of the 483 drugs and drug products listed in the Formulary alphabetical index (see pages 31-35). This approach should reflect the frequency

of monograph requirements in specialty areas within the hospitals and accordingly, the minimum number required in each. The survey was conducted in five British Columbia hospitals (see Methodology, page 31). The study requested information on the frequency of use of the drugs and therefore drug monographs in the following four specialized care areas: Pediatrics, Emergency, Psychiatry and Extended Care. The information evaluated at the five hospitals was compiled into the following tables under the headings of "Frequently", "Occasionally" and "Rarely" used drugs. It was assumed that should some format of the Drug Formulary eventually be designed for specific ward areas, only those drugs identified as "Frequently" and/or "Occasionally" used might be included for use in those areas. The anticipated advantage of such a system would be to reduce the bulk of the Formulary while supplying the required drug information on the drugs most frequently used in the ward area.

In the area of Pediatrics, five hospitals replied whereas in Extended Care and Psychiatry only three hospitals supplied the necessary information because the other two hospitals do not have facilities for these services. In regard to Emergency care, one institution,the Royal Jubilee Hospital, was unable to supply complete information on drug usage and therefore was not included in the results.

Table III shows the frequency of use of the 483 drugs listed in the Formulary alphabetical index on Pediatric wards. The number of drugs

"Frequently" used ranged from 63 at Lions Gate Hospital to 111 at the Vancouver General Hospital. The difference in these figures may be attributable to the large teaching atmosphere of the latter hospital. The average number of "Frequently" used drugs in the five hospitals was 86 or approximately 18 percent of the total number of drugs listed. This would seem to indicate that a Formulary of 600 monographs would not only be cumbersome but of little value for use on Pediatric wards.

Table IV shows similar results for four hospitals on the study of Emergency Ward drug use. Lions Gate Hospital again had the lowest number of "Frequently" used drugs at 68 while St. Paul's Hospital indicated that 178 drugs were "Frequently" used. The reason for this difference was difficult to determine but may have been due to the urban, central setting of the latter hospital which might require a more diverse pattern of emergency care. In Emergency Wards the average number of "Frequently" used drugs in the four hospitals was 122 or approximately 25 percent of the total number of drugs listed in the current Formulary alphabetical index. Again, the limited number of monographs apparently used in this area further supports the apparent needlessness of the complete Drug Formulary in any specialty area.

In Extended Care (Table V), Vancouver General Hospital recorded the lowest number of "Frequently" used drugs at 43, and Lions Gate Hospital had the highest number at 106. It is thought that the Vancouver General Hospital had the lowest number in this category because they had just opened

TABLE III

FREQUENCY OF USE OF PROVINCIAL FORMULARY DRUGS (483) IN PEDIATRIC WARDS OF VARIOUS HOSPITALS

Hospital	FREQUENTLY[1] Number (%)[4]	OCCASIONALLY[2] Number (%)[4]	RARELY[3] Number (%)[4]
Vancouver General	93 (19)	111 (23)	279 (58)
St. Paul's	75 (16)	88 (18)	320 (66)
Lions Gate	63 (13)	40 (8)	387 (79)
Victoria General	111 (23)	134 (27)	238 (50)
Royal Jubilee	86 (18)	103 (21)	294 (61)
Average[5]	86 (18)	93 (20)	304 (62)

1. Drugs used daily.

2. Drugs used once or twice a month.

3. Drugs used once or twice a year or never.

4. To nearest percentage point, of total 483 drugs.

5. Averaged to nearest whole number and percentage point.

TABLE IV

FREQUENCY OF USE OF PROVINCIAL FORMULARY DRUGS (483) IN EMERGENCY WARDS OF VARIOUS HOSPITALS

Hospital	FREQUENTLY[1] Number (%)[4]	OCCASIONALLY[2] Number (%)[4]	RARELY[3] Number (%)[4]
St. Paul's	178 (37)	53 (11)	252 (52)
Vancouver General	137 (28)	112 (23)	234 (49)
Lions Gate	68 (14)	65 (13)	350 (73)
Victoria General	103 (21)	125 (26)	255 (53)
Average[5]	122 (25)	89 (18)	272 (57)

1. Drugs used daily.
2. Drugs used once or twice a month.
3. Drugs used once or twice a year or never.
4. To nearest percentage point, of total 483 drugs.
5. Averaged to nearest whole number and percentage point.

their new facility and therefore medication requirements were quite low. The average number of "Frequently" used drugs for the three hospitals with Extended Care facilities was 83 or approximately 17 percent of the 483 drugs. Should a future Drug Formulary contain as many as 600 monographs, some mechanism for separating those monographs "Frequently" used in specialty areas, such as Extended Care, should be designed for ease of use.

In the field of Psychiatry (Table VI), Lions Gate Hospital and the Vancouver General Hospital had similar drug use needs with 50 and 53 drugs "Frequently" used respectively. The Royal Jubilee Hospital listed 193 drugs "Frequently" used. The large difference seen here may be due to the fact that the Royal Jubilee Hospital operates a very large Psychiatric facility while both Lions Gate Hospital and the Vancouver General Hospital operate considerably smaller units. The average number of "Frequently" used drugs for the three hospitals was 98 or approximately 20 percent of the number of drugs listed in the alphabetical index of the present Drug Formulary. Again, the complete Drug Formulary on psychiatric wards would appear to prove unnecessary and awkward as demonstrated throughout Tables III to VI.

The major criticism of the present Formulary is that it is too bulky for convenient use at the ward level. Attempts to make the Formulary more provincial in nature (see page 46) suggest that this problem may be increased with the addition of approximately 300 additional monographs in the future. The data presented in Tables III to VI, however, reveal that

TABLE V

FREQUENCY OF USE OF PROVINCIAL FORMULARY DRUGS (483) IN EXTENDED CARE WARDS OF VARIOUS HOSPITALS

	FREQUENTLY[1]	OCCASIONALLY[2]	RARELY[3]
Hospital	Number (%)[4]	Number (%)[4]	Number (%)[4]
Vancouver General	43 (9)	73 (15)	367 (76)
Lions Gate	106 (22)	67 (14)	310 (64)
Victoria General	100 (20)	120 (25)	463 (55)
Average[5]	83 (17)	86 (18)	314 (65)

1. Drugs used daily.
2. Drugs used once or twice a month.
3. Drugs used once or twice a year or never.
4. To nearest percentage point, of total 483 drugs.
5. Averaged to nearest whole number and percentage point.

TABLE VI

FREQUENCY OF USE OF PROVINCIAL FORMULARY DRUGS (483) IN PSYCHIATRIC WARDS OF VARIOUS HOSPITALS

	FREQUENTLY[1]	OCCASIONALLY[2]	RARELY[3]
Hospital	Number (%)[4]	Number (%)[4]	Number (%)[4]
Vancouver General	53 (11)	116 (24)	314 (65)
Lions Gate	50 (10)	49 (10)	384 (80)
Royal Jubilee	193 (40)	91 (19)	199 (41)
Average[5]	98 (20)	85 (18)	300 (62)

1. Drugs used daily.
2. Drugs used once or twice a month.
3. Drugs used once or twice a year or never.
4. To nearest percentage point, of total 483 drugs.
5. Averaged to nearest whole number and percentage point.

considerably fewer drugs than those that might appear in a future Formulary are used with any degree of frequency in any given specialty ward. This would suggest that there is no need for the bulk of the complete Formulary in these areas. It also suggests that "Specialty Formularies" for specialty areas may function well in relation to a "Master Formulary" for the entire hospital.

Master-"Mini" Formulary

The previous results project that each hospital might have a Master Formulary of all provincial drug monographs as well as "Mini" Formularies designed for and containing monographs for only those drugs "Frequently" used in specialty ward areas. These two types of Formularies within a hospital would be further differentiated according to the individual monograph content. For example (see Figure 7, page 51), the Master Formulary would contain the complete monograph plus the bibliography whereas the "Mini" Formulary in use on the ward would not be encumbered by the bibliography.

Another feature that might be included in a future Master (but not "Mini") Formulary is a cross-index. In recognition of the large number of different manufacturers and brand names for each generic name drug or drug product, it is suggested that a complete cross-index of brand to generic names be produced. In this index it is suggested also that the Canadian Drug Identification Code Active Ingredient Group Number shown on the present revised monographs be included to facilitate the use of national electronic

data processing indexing and stock control systems when these are introduced into the hospitals at some future date. It is recommended further that this cross-index be produced as soon as possible and updated as new brand name drugs are introduced and as new monographs are produced for inclusion in the Drug Formulary.

As can be deduced from the increased amount of information proposed for addition to the Formulary as well as a complete bibliography for each monograph and a cross-index, the Master Drug Formulary could become a massive volume. The value of such a volume for resource information and research, however, becomes apparent. On the other hand, it becomes apparent also that the Master Formulary as described here would not be effectively used at the ward level due to its bulk.

From this study there appear to be four ways to reduce the bulkiness of the Drug Formulary on the ward by using a "Master"-"Mini" Formulary arrangement. Firstly, by removing the bibliography from the "Mini" Formularies located at the ward level the bulk should be decreased by one-third to one-half. In this respect, it is proposed that the monographs with the reference numbers be kept on the ward while the bibliographies be maintained in the Master Formulary in the Central Pharmacy or Drug Information Centre. This would enable the reduction of the Drug Formulary on the ward while still allowing the users access to the bibliographies when necessary by contacting the pharmacy.

A second approach to reducing the bulk of the Formulary would be to produce "Mini" Formularies for each specific ward, including only those drugs which are "Frequently" used in each area. Unfortunately, this solution if undertaken by the producers of the Drug Formulary would probably be too costly to become feasible. If a specific "Mini" Formulary was to be produced for each ward of each hospital of the province (100 provincial hospitals with an average of 8 to 10 wards each) there could be from 800 to 1000 specific formularies to collate separately. This would greatly increase the personnel required to produce the Drug Formulary and increase the costs possibly beyond the present costs.

A third approach to producing a "Mini" Formulary could overcome this problem by having the pharmacists of each hospital conduct surveys similar to the Monograph Utilization Survey (see pages 31-34) on the wards of their hospital to determine those drugs most frequently used in each patient care area. Once this has been determined, it is suggested that the monographs for these drugs (without the bibliography) could be removed from a complete Formulary and be placed in clear plastic envelopes and inserted in a three-ring binder which could be permanently affixed to either a counter or wall at the location of greatest use. In this manner, the monographs would be available to the users but could not be removed from the place of use, resulting in less possibility of the monographs being lost. The remaining monographs could be maintained in the original binder and stored on the nursing station in a drawer or cupboard. These monographs should be kept on the nursing station so that they are available when occasionally

or rarely used drugs are being administered and information on these medications is required by the medical or nursing staff.

The above proposed system might be expected to cost approximately $10.00 per ward beyond the cost of the basic Drug Formulary. (This is based on $2.50 for a hard cover, three-ring binder and $0.15 x 50 = $7.50 for 50 plastic envelopes). This system would allow between 50 and 100 monographs to be placed in the "Mini" Formulary. Another system along similar lines was investigated using Kardex frames of 8-1/2 x 11 inch size to contain the monographs. The cost of this type of system was approximately 40 times greater than the above system and therefore was thought to be prohibitive for widespread use.

The fourth suggestion for reducing the bulk of the Formulary is to print the monographs of two pages or more in length on both sides of a page (see Figure 7, page 51). The bibliographies of two or more pages also could be printed on both sides of a page. This suggestion could have the possible effect of reducing the size of the Formulary by up to one-half.

Under the proposed conditions, the Master Formulary would be maintained in the pharmacy (containing the monographs of all drugs used in the hospital, the bibliographies for each monograph and the complete cross-index of the Formulary). The "Mini" Formulary would contain only the drug monographs of the drugs frequently used on the ward with the remaining monographs being stored in the original binder in a drawer or cupboard on the ward.

Present Publication and Electronic Data Processing.

As Electronic Data Processing (E.D.P.) and the use of Cathode Ray Tube (C.R.T.) reader-printers become more acceptable in hospitals, another means of reducing the bulk of the present Drug Formulary will become feasible. This would enable the removal of the printed Formulary completely from the ward areas and the maintenance of all drug information in a central data bank which would be connected to each area by a C.R.T. reader-printer. The present cost of this system is prohibitive, but as the system becomes more available and less expensive, the use of C.R.T. reader-printers may become a more feasible means of supplying drug information to health practitioners.

Another approach to E.D.P. however, might reduce the present cost of Formulary production. The production of the Drug Formulary presently is being undertaken by the British Columbia Hospital Association at a cost to the hospitals of about $15.00 per copy or approximately four cents a page. This cost represents only the duplication and distribution costs and does not include personnel and stenographic expenses in researching and preparing the information for each monograph. The Ottawa Civic Hospital was contacted in regard to the production costs of E.D.P. Formulary printing. The cost of producing each Formulary at the Ottawa Civic Hospital was $5.00 or about two cents per page. This cost represents approximately one-half the cost of printing the Drug Formulary by a conventional method. It is felt that the cost difference can be attributed to three

factors: the method of production; the number of pages; and finally, the number of formularies printed. The Ottawa Civic Hospital Formulary is printed by E.D.P. methods which, from the literature (27, 38) were noted to be less expensive for long-term printing, while the provincial Drug Formulary is produced by conventional methods. The Ottawa Civic Hospital prints about 600 copies of approximately 270 pages each, whereas the current Drug Formulary contains 400 pages and the number of Formularies printed is about 250. Accordingly, the adoption of E.D.P. printing for the Provincial Formulary should not be considered before the major revisions are made and the regulation publication is decided upon.

The above studies reflect that several modifications of the present Drug Formulary should be considered in addition to updating, in making it more useful on a provincial basis. The future number of monographs, additional information in each, an extensive bibliography, a Master-"Mini" format for more effective hospital use and production aids such as electronic data processing, all would assist in producing a Formulary of a more valuable format.

II. Evaluating and Updating the Formulary

Perhaps the greatest limitation of the present Drug Formulary is that no mechanism exists for updating and evaluating the drug monographs or for reviewing the scientific and clinical validity of the information con-

tained therein.

The proposed method that was evaluated in the present study is the one which was used to produce 100 existing monograph revisions based on a senior pharmacy student assignment (see Methodology, page 37) during 1972-73. To evaluate the proposed mechanism, two points were studied:

(1) The number and nature of changes in the monographs as suggested from the student updating assignment (see Methodology, page 37);

(2) The time requirement for student, instructor and stenographer input for monograph updating (see Methodology, page 41).

From the results of these studies, projections were made regarding a schedule for updating the monographs on an annual combined education and "service" basis and regarding the personnel which might be required to continue the annual updating of the Formulary.

(a) Nature and Frequency of Changes

For each updated monograph the students completed a Change Sheet (see Methodology, page 39) which indicated all additions, corrections and changes to the original monograph. One hundred of these Change Sheets were analyzed to determine the need for annual updating of the existing monographs. The results of this study are presented in Table VII.

Because in some cases, three to five years had elapsed since the original monograph was produced, a great deal of new information and,

TABLE VII

MONOGRAPH CHANGES[1]

Based on Information From the Literature in 1969-73

	Average[2]	Range
Total Changes	13.26	3-30
Changes in sections on Drug Interactions and Intravenous Incompatibilities[3]	5.77	2-18

1. As determined by reviewing the Change Sheets for 100 randomly selected existing monographs during the updating assignment.

2. The average number of required changes found on one monograph.

3. The number of changes found on the monograph sections thought to be most required in annual updatings.

therefore, changes appeared in the updated monographs. This became apparent when the Change Sheets were studied.

Due to the significant number of changes required, two forms of updating should be identified in the total revision requirements - complete evaluation and annual updating. Complete evaluation includes referencing of the existing monograph information, addition of the new sections on "Mode of Action" and "Instructions to the Patient", and the addition of any additional information from previous and current literature to the existing monograph (see Methodology, pages 37-38). This definition of complete evaluation is consistent with the assignment completed by the senior pharmacy students in 1972-73. Once this complete evaluation has been done on all monographs, only annual updating from current literature would be required in future years.

The proposed annual updating, a part of the total revision, consists of proofreading the revised monograph against standard reference sources such as the American Hospital Formulary Service, textbooks and the Compendium of Pharmaceuticals and Specialties, as well as updating the monograph from the literature of the previous year only, with emphasis on the sections of "Drug Interactions" and "Intravenous Incompatibilities". The determination to place the emphasis on these sections was made because the number of changes which occurred in these two sections was greater than one-third of the total number of changes per monograph in most cases (see Table VII).

(b) Time Evaluation

The purpose of studying the time requirements of the students, instructors and stenographers for updating and typing the drug monographs was to determine an approximate personnel requirement for updating the Drug Formulary on a continuing "service" basis in the future. The individual as well as collective times were analyzed to enable flexibility in any suggested system.

One hundred time sheets again were analyzed for each of the three groups (students, instructors, and stenographers) for inclusion in the time evaluations. The results of this study are presented in Table VIII.

TABLE VIII

REVISION TIMES[1]

	AVERAGE TIME FOR MONOGRAPHS ± Standard Deviation (Hours)
A. STUDENTS	
1. Total Revision	13.13 ± 9.09
2. Annual Updating	4.50 ± 3.72[2]
B. INSTRUCTORS' REVIEW	
1. Review and Evaluate	3.26 ± 1.06
2. Edit and Condense for monograph format	0.84 ± 0.31
C. SECRETARIAL WORK	
Typing	0.68 ± 0.44[3]

1. As determined from 100 randomly selected updating time sheets.

2. Portion of the Total Revision time requirement representing "Drug Interactions" and "Intravenous Incompatibilities" as described on page 73 .

3. Does not consider time required to make corrections or typographical errors.

As can be seen from the Table of Revision Times, approximately 13 hours per monograph was required by the students to evaluate the complete monograph. To update only the sections on "Drug Interactions" and "Intravenous Incompatibilities", the students required between four and five hours. By correlating these results with the definitions of complete evaluation and annual updating on page 73 , it seems reasonable to estimate that the annual updating would required approximately one-third of the time required for the initial complete evaluation of the monograph.

The determination of instructor time required concerns only the time necessary to complete the "service" portion of their work and does not consider their academic input to the updating assignment (see Methodology, page 37). This "service" part includes the evaluation of the original reference as cited by the student for scientific validity, editing and condensing the updated monograph for typing. It can be seen that this portion of the instructors' commitment required about four hours per monograph. Once all of the Formulary monographs have been completely evaluated however, it can be expected that approximately one hour will be required to review the annual updating done by the students.

The time required by the stenographic staff to type each monograph in the standard format (see Figure 7, page 51), with its corresponding bibliography, was approximately 40 minutes. This figure does not include the time necessary to correct any typographical errors which were discovered while proofreading the evaluated monographs.

In total, the time required for student, instructor, and stenographer input was about 18 hours for each monograph based on the 1972-73 complete evaluation format.

Proposed Future Revision Schedule

By using the results of the time evaluation, a schedule of complete evaluation and annual updating of the remaining and future monographs might be made on a combined education and "service" basis. This proposal is made on the assumption that the educational time and credit value of the student assignment will be continued. It is made also on the assumption that a "service" component of instructor time will be made available. The proposed schedule is presented in Table IX.

Assuming that the educational assignment will be similar in 1973-74, it is proposed that the senior year pharmacy students be assigned complete evaluations (and annual updating) of the remaining 88 monographs not done in 1972-73 as well as the annual updating of the 218 monographs evaluated in 1972-73. On this proposed schedule, the revision of the existing monographs will reach a maintenance level by the end of the academic term 1973-74. Thereafter, the student assignment would consist only of annual updating of the existing drug monographs and perhaps the complete evaluation of new monographs.

In 1972-73, the instructors reviewed, edited and condensed 100 of the 218 evaluated monographs. It is proposed that in 1973-74, the instructors

TABLE IX

FUTURE REVISION SCHEDULE[1]

for Drug Formulary Monographs

	Number of Revised Monographs		
Academic Terms	1972-73	1973-74	Total
Complete Evaluation[2]	218	88 (306)[4]	306
Annual Updating[2]	218	306	
Instructor Review and Condense[3]	100	206 (306)[4]	306

1. On a proposed education and "service" basis.

2. As related to student assignment in 1972-73 and as defined on page 73 .

3. Instructor committment on a "service" basis only.

4. The total number of drug monographs in the present Formulary.

complete the remaining 118 monographs evaluated in 1972-73 and review and condense the 88 monographs evaluated in 1973-74. As with the student assignments, the "service" commitment of the instructors would reach a maintenance level by the end of the academic term 1973-74 should no additional monographs be added. However, it is proposed that the instructors' commitment thereafter should be to produce new monographs as requested in the Additional Drugs Survey (see Methodology, pages 27, 28 and Appendix II).

Future Personnel Requirements

To continue the updating of the Formulary on a "service" basis for distribution to the hospitals of British Columbia, certain personnel requirements must be quantitated. This projection is based on a continued student involvement and, therefore, no professional staff requirement will be assigned to the portion of evaluation presently undertaken by the students. However, "service" staff will be needed to continue the instructors' review and condensing of the updated monographs as well as the typing of the same.

From the Time Evaluation studies, it was noted that the instructors required an average of four hours to review and condense each monograph (see Table VIII). Therefore, it might be expected that approximately 800 hours would be required for the instructors to review and condense the remaining 206 monographs (four hours times 206 monographs). On this basis it is expected that about one to one and one-half additional hours per monograph will be necessary to review the 218 monographs which will require

annual updating in 1973-74. This represents approximately an additional 300 hours. Therefore, to fulfill the "service" committment as projected, a total of approximately 1100 instructor "service" hours will be needed in 1973-74. For this reason, it is anticipated that one-half of a pharmacist's time will be required in 1973-74 for this committment.

Recognizing that there might be 206 additional monographs prepared for typing in 1973-74 (see Table IX), and that each monograph took approximately 40 minutes to type during 1972-73 (see Table VIII), it is projected that about 140 hours of stenographic time might be required in 1973-74. Since this extrapolation does not account for corrections of typographical errors, it is recognized that this time estimate is a very minimum.

The results of the above studies identify that the monographs of the existing Drug Formulary require complete evaluation of the present information as well as annual updating of new information. Student, instructor and stenographic time required to evaluate and update 100 monographs during the 1972-73 academic term were recorded and analyzed.

Such analyses are used to project a continued evaluation and updating revision of the remaining monographs during 1973-74. On this basis, it is expected that at least one-half of a pharmacist's time will have to be made available other than for academic instruction, and that about 140-150 hours of stenographic time, similarly, will be required to complete the

revision of the remaining Drug Formulary monographs during the next year. It can be expected that annual updating thereafter, will require a similar committment.

RECOMMENDATIONS

If the present Drug Formulary distributed for use in British Columbia hospitals is to retain its present value, and perhaps realize a greater potential, several changes in format and a regular updating mechanism should be effected. Based on the present study, these include:

1. The addition of approximately another 300 drug monograph entries to make the Formulary more useful to all hospitals;

2. The addition of more information under each monograph, specifically in the "Mode of Action" and "Instructions to the Patient";

3. The evaluation and referencing of the existing information and the annual updating of the same;

4. The adoption of a Master Formulary containing all provincially used drugs, a complete bibliography for each monograph and a cross-index of generic to manufacturers' brand names;

5. The adoption of a "Mini" Formulary derived from the Master and containing only the monographs for those drugs frequently used in the individual hospital ward areas;

6. The arrangement for a printing rather than typing production of the Formulary;

7. The provision of at least one-half time pharmacist on a "service" basis to edit, revise and condense student drug literature evaluation projects to Formulary format;

8. The provision of a minimum of 200 hours per year stenographer time;

9. The arrangement for a Medical Review Board to judge the clinical significance of proposed new information to be added;

10. The establishment of a central Drug Information Centre in the province to coordinate the above functions and to serve as a resource centre for additional information required on a daily basis for the effective use of the Formulary.

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APPENDIX I

COST OF THREE MAJOR DRUG INFORMATION SERVICES

1. deHaen Services, Paul deHaen Inc., 11 West 42nd Street, New York, N.Y., 10036.

   A. "Drugs in Use and Combination" $700.00/year

   B. "Drugs in Research" $150.00/year

   C. "Drugs in Use Product Profile Index" $100.00/year

   D. "Drugs in Prospect" $450.00/year

2. International Pharmaceutical Abstracts, American Society of Hospital Pharmacists, 4630 Montgomery Ave., Washington, D.C., 20014.
   $150.00/year

3. Iowa Drug Information Services, College of Pharmacy, Iowa State University, Iowa City, Iowa.

   A. Current Subscription Year (1973) $900.00/year*

   B. Retrospective File (1966-1972) $1500.00*

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* Subscription Charges, Iowa Drug Information Services, College of Pharmacy, Iowa State University, Iowa City, Iowa, February, 1973.

APPENDIX II

LISTS OF DRUGS RECEIVING TWO OR MORE REQUESTS FOR INCLUSION IN THE DRUG FORMULARY

Drugs receiving 5 requests

Ethacrynic acid

Ethchlorvinyl

Perphenazine

Protriptyline

Vinblastine

Drugs receiving 4 requests

Clofibrate
Cycloserine
Cycrimine
Cytosine Arabinoside
Dehydrocholic acid
Dienestrol
Dihydroergotamine
Echothiophate Iodide
Erythrityl Tetranitrate
Ethambutal
Ethanolamine Oleate
Fluocinolone
Fluphenazine
Hydroxychloroquine
Iron-Sorbitol Complex
Meclizine
Methallenestril
Methsuximide
Methyltestosterone
Nitrofurazone
Nortriptyline
Orciprenaline
Orphenadrine Hydrochloride
Oxacillin
Oxazepam

APPENDIX II (Continued)

Drugs receiving 4 requests (Continued)

Oxytetracycline
Phenelzine
Pseudoephedrine Hydrochloride
Terpin Hydrate
Triethylenethio Phosphoramide (Thio-tepa)
Trimethadione
Vancomycin

Drugs receiving 3 requests

Acenocoumarol
Alphaprodine Hydrochloride
Aluminum Acetate
Ambenonium Chloride
Ammoniated Mercury
Bendroflumethiazide
Blood and Blood Components
Butabarbital Sodium
Carbinoxamine
Carisoprodol
Chlorcyclizine
Chlormezanone
Chlorphenoxamine Maleate
Chlorprothixene
Chlorthalidone
Chlorotrianisene
Clindamycin
Cyclandelate
Cyclizine Hydrochloride
Cyclopentolate
Dactinomycin
Dapsone
Dextrose
Dextrothyroxine
Dichlorpheniramine
Dicloxacillin
Dicyclomine
Dimethylpolysiloxane
Dioxyline Phosphate
Doxycycline
Estradiol Valerate
Ethamival

APPENDIX II (Continued)

Drugs receiving 3 requests (Continued)

Ethinyl Estradiol
Ethisterone
Fludrocortisone
Gitalin
Glycerin Enema
Hydroxyprogesterone Caproate
Indomethacin
Influenza Vaccine (Polyvalent)
Inositol Niacinate
Isopropamide
Isoproterenol Sulphate
Liothyronine
Methdilazine Hydrochloride
Methocarbamol
Methylprednisolone
Methysergide Bimalate
Metapryone
Nandrolone Phenpropionate
Nicotinamide
Novobiacin
Oxymetholone
Paramethadione
Phenmetrazine
Prednisolone
Procarbazine
Pyrimethamine
Quinacrine
Quinidine Phenylethyl Barbaturic Acid
Saccharin Sodium
Sodium Tetradectyl Sulphate
Stanozolol
Succinylsulfathiazide
Sulfamethiazole
Sulfinpyrazone
Tetanus Antitoxin
Thiomersol
Triamcinolone
Trifluopromazine
Trimepramine
Trimethobenzamine
Trimipramine
Triple Sulfa Cream (equivalent)
Trolnitrate Phosphate
Witch Hazel

APPENDIX II (Continued)

Drugs receiving 2 requests

Acetic Acid
Acetohexamide
Acnomel
Alcaroid Pulvules
Alkavervir
Allylbarbaturic Acid
Alophen
Alphosyl Lotion
Amaranth
Aminopryine
Amphetamine Sulphate
Antivert
Atasorb
Azapetine Phosphate
Azuresin (Diagnex Blue)
Belladonna Leaf
Benzoate
Benzononate
Benzyl Peroxide
Betahistine
Biperiden
Bismuth Formic Acid Compound
Bismuth Sodium Triglucollamate
Blephamide
Brucellergan
Butaserpine
Butobarbitone
Calcium Bromodolactobionate
Calcium Undecylenate
Carcholin
Cassia Oil
Chlorophylline
Chlorophenesin
Chlorquinaldol
Chorionic Gonadotropin
Citri-cerose
Climacterone
Clindinium Bromide
Coccidioidan
Collodion
Cophylac Drops
Creta Pulvules
Cremosuximide
Cyclamate

APPENDIX II (Continued)

Drugs receiving 2 requests (Continued)

Cyclobarbitone
Cyclomethylcaine
Cyclopentamine
Dextromethorphan
Diasol
Diatroate Sodium
Dihexylverine Hydrochloride
Dihydrotachysterol
Dill Oil
Diperidolate
Diperidon
Dipianone
Dimethisoquin
Dimethylsterone
Disodium Hydrogen Citrate
Doxylamine
Dromoran
Duo-CVP
Entoral
Eosine
Estradiol Lipropionate
Etrafedrine
Ethopropazine
Ethylenediamine Tetra-acetate
Ethylene Glycol
Etrafon
Eucalyptus Oil
Euflavine
Evans Blue
Fat Emulsion
Festol
Fibrinogen
Flucinonide
Fluoescite
Flurandrenolone
Folinic Acid
Framycetin Sulphate
Furazalidone
Gall and Opium Ointment
Glauber Salts
Glycothmoline
Gold Salts

APPENDIX II (Continued)

Drugs receiving 2 requests (Continued)

Hemocebrin
Heptobarbital
Hetacillin
Histamine Azoprotein
Histoplasmin
Hydromorphone
Hygroton-Reserpine
Ichthyl
Immune Serum Globulin
Imuvac
Iodoform Compounds
Iopanoic Acid
Iophendylate
Isoflurophate
Isometheptene
Itramine Tosylate
Ketamine
Lactated Pepsin Elixir
Lactostat (Testosterone Estradiol)
Lanatoside C
Levopromazine
Magenta
Magnesium Trisilicate
Mefenamic Acid
Menadione
Mepenzolate
Mephenytoil
Mephobarbital
Mepivacaine
Mercuric Oxide
Mercury Bichloride Ointment
Metaxalone
Methacholine
Methantheline
Methycellulose
Metimyd
Myocrysine
Nandrolone Decanoate
Neomedrol
Nifuroxime
Norethandrolone
Norisodrine
Oil of Cajaput
Oral Proteolytics

APPENDIX II (Continued)

Drugs receiving 2 requests (Continued)

Oxalic and Maloric Acid
Para-amino Benzoic Acid
Papain Pulvules
Penicillamine
Penthienate Methobromide
Pentylenetetrazole
Pericyazine
Pertussis Immune Globulin
Phenaglycodol
Phenol
Phenoxymethylpenicillin
Pimacrin Compound
Piperoxan
Podophyllin
Potassium Bromide
Potassium Phosphate
Proflavine
Progfesterone
Proguanil
Protamide
Protein Hydrolysate
Pyrimethamine
Pyrithen
Pyrrobutamine Compound
Quandrinal
Quinidine Compound
Raudixin
Rautractyl #2 #4
Resorcinol Monoacetate
Resteclin
Restropin
Restropinal
Rimactane
Roniacol
Salbutamol
Salicylamide
Ser-Ap-Es
Silver Nitrate
Sodium Citrate
Sodium Iodide
Sodium Free Salt
Sulfasuxidine
Sodium Oxychlorosene

APPENDIX II (Continued)

Drugs receiving 2 requests (Continued)

Sodium Para-amino Hippurate
Staphlococcus Antitoxin
Stilboestrol Diphosphate Sodium
Sulfamerazine
Surfacaine
Testolactone
Tetrahydrazoline
Theobromine Calcium Salicylate
Theophylline
Thyroglobulin
Thyrotropin
Trichloroacetic Acid
Trifluoperazine
Triprolidine and Compounds
Troxidone
Trypsin
Tuberculin PPD
Typhoid, Paratyphoid and Tetanus
Tyrothricin
Urethan
Vagisec
Valerian Root
Vitamin A and D Ointment
Viomycin
White Pine Syrup
Xanthinol Niacinate
Zeobarb
Zincafrin
Zylene

APPENDIX III

STUDENT MONOGRAPH UPDATING ASSIGNMENT - 1972-73

Drug and Poison Information Centre

Monograph Assignment Pharmacy 403

1. Each student will be assigned to prepare three drug monographs and one poison monograph.

2. The completed monographs will be typewritten (double-spaced - including references) on 8-1/2" x 11" white bond paper.

3. Each page of the monograph shall have the name of the drug or poison and the name of the student.

4. DRUG MONOGRAPHS

   (a) Update the Lion's Gate Hospital Formulary monograph using the most recent monograph of the American Hospital Formulary Service. Reference all changes or additions.

   (b) Search Index Medicus for all new information on the particular drug or poison which has been published during the previous 12 months. Reference all new information with original reference sources. Restrict the search to pertinent clinical data (do NOT include animal data) - deHaen information cards may be used but not quoted as reference source.

   (c) The following sections must be completely referenced with original reference sources:

   Section IX: Drug Interactions

   Section X: I.V. Incompatibilities

Only clinically significant drug interactions should be included in the monograph. ("Drug Interactions" by Hansten categorizes the clinical significance of the various drug interactions quite well).

"Hazards of Medication" by Martin and "Drug Interactions" by Hansten are tertiary reference sources and the student must review the original article and use the original article as the reference source.

(d) Section XI: Nursing Implications.
Every statement should be referenced.

The American Hospital Formulary Service and/or references used in preparing Sections I - X may be repeated.

(e) Section XII: Instructions to Patient
Every statement should be referenced.

A useful reference is "Drugs and Nursing Implications" by Govoni and Hayes. The reference sources may be either primary (original articles) or tertiary (textbooks and formularies).

(f) Section XIII: Presentation

A. Dosage Forms Available - "CPS" is recommended reference.

B. Identi-Code Number - if applicable.

C. Cost - the cost to the community pharmacist for 100 tablets or capsules is obtained from the Drug Benefit List in the Student Health Service Pharmacy, Cunningham Building, U.B.C.

6. General

(a) The metric and centigrade scales should be used.

(b) The following format should be used for the bibliography:

JOURNAL: Billig, N., Propoxyphene Hydrochloride (Darvon) Poisoning in a Three Year Old Child, Amer. J. Dis. Child. 116: 187-189 (August).

TEXTBOOK: Goodman, L.S. and Gilman, A., The Pharmacological Basis Therapeutics, 4th edition, MacMillan Co.: New York, 1970.

The abbreviations of journal names should conform to that of Index Medicus.

(c) In reviewing clinical case reports, the study should have a randomized double-blind trial with a sample size of approximately 20 patients before the results can be considered statistically significant. One exception is adverse drug reactions in which case, the sample size can be reduced to only one patient.

(d) In clinical case reports, it is important to consider pertinent patient factors:

i) kidney function

ii) liver function

iii) age, weight, sex

iv) other coinciding diseases

v) placebo effect

vi) spontaneous remission of the disease (if applicable)
i.e., rheumatoid arthritis

vii) seasonal variation of the disease (if applicable)
i.e., hayfever

PHARMACY 403

DRUG AND POISON INFORMATION CENTRE (DPIC)

Format for DRUG MONOGRAPH

1. General Information:

   A. Heading: AHFS Pharmacologic - Therapeutic Classification Number.

   B. Non-propriatory name.

   C. Trade name or synonyms.

II. Action :

   A. Absorption - includes absorption by usual routes of administration but should not be confined only to routes used for commercially available preparations; onset; duration of action; peak blood levels following various routes; factors affecting absorption.
   B. Distribution - usual distribution in body tissues and fluids; indicate protein binding, penetration of blood-brain barrier, transfer across placental barrier.
   C. Metabolism - half-life and factors affecting; sites of biotransformation; metabolic products and their activity.
   D. Excretion - route(s) of elimination from the body; factors affecting elimination; form in which eliminated.

III. Spectrum of Activity:(if applicable; e.g., bacterial, fungal, etc.).

IV. Indications: Statement of indications and use

   (Indicate prophylactic, therapeutic, palliative, curative, supportive use, etc.).

V. Contraindications: (include pregnancy if information known).

VI. Cautions: e.g. use in patients with certain diseases or under certain conditions.

VII. Dosage:

A. Include minimum, maximum and maintenance dosage.

B. State routes of administration and dose schedule.

C. Give adult and children's dosage.

VIII. Side Effects

A. Include incidence (if available).

B. Group according to body system (e.g., G.I.).

C. Report changes in renal or hepatic changes - function, blood dyscrasins, etc.

IX. Drug Interactions: (include OTC's)

A. Drug - drug.

B. Drug - food.

C. Drug - lab. test.

X. I.V. Incompatibilities: (if applicable)

XI. Nursing Implications: (not all categories will be applicable).

A. Observation for adverse reactions, hypersensitivity reactions, toxicity.

B. Monitoring of vital signs, cardiac status.

C. Lab. tests for renal, and/or hepatic function, blood counts, blood chemistry, etc.

D. Observation for physical changes in drug - e.g., discolouration.

E. Method, route, time of administration.

F. Storage.

XII. Instructions to Patient:

A. Correct methods of administration.

B. Drug-food and drug-drug (including OTC) interactions.

C. "Selected" side effects.

D. Contraindications for continued use.

E. Specific storage instructions.

XIII. Presentation:

A. Dosage forms available.

B. Identi-code number.

C. Cost.

XIV. References:

XV. Date Prepared: