GUIDELINES FOR IMPLEMENTING DRUG UTILIZATION REVIEW PROGRAMS IN HOSPITALS

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PREFACE

This manual has been written as a practical guide for implementing a basic drug utilization review (DUR) program in a hospital setting. The methodology described here could be adapted and applied to outpatient clinics and other institutionalized health care settings as well.

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INTRODUCTION

One of the most pressing problems facing public health providers and administrators in many countries is ensuring the rational use of drugs. The Conference of Experts on the Rational Use of Drugs, convened by the World Health Organization (WHO) in Nairobi in 1985, defined rational use as follows: The rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.

Rational drug use implies an individual approach to patient treatment. Success of treatment largely depends on the ability of a physician to diagnose the major health problem(s) of a patient, select the correct drug, dosage form and route of administration, foresee probable adverse reactions and drug interactions, and prevent unnecessary or dangerous duplication therapy. Further, rational drug use depends on the performance of the pharmacy and nursing departments in preparing and administering drugs.

Implementation of hospital drug formulary systems helps to optimize treatment, make essential drugs available, and control costs of therapy. The drug formulary can be considered the basis of rational drug use. However, the existence of a rationally derived list of drugs approved for procurement and use in a hospital does not ensure that they are prescribed and used correctly. One mechanism to ensure correct prescribing and use is the drug utilization review (DUR) process; although often considered a component of a drug formulary system, DUR programs can exist in the absence of other formulary activities.

DUR programs should be carefully planned by the medical staff to include the drugs considered to be most problematic if not used correctly. By comparing actual drug use to predetermined standards, DUR can detect inappropriate and/or unnecessarily costly drug therapy. Programs can be designed to monitor individual drugs, or drug classes, as well as to monitor drug use in specified diseases. Most of the examples used in this guide are related to DUR for individual drugs. When problems are identified, interventions are designed and implemented to improve drug use. Interventions can include educational programs, provision of drug information, changes in hospital policies and procedures, and changes in the drug formulary.

Definitions

Criteria are predetermined parameters of drug prescribing and use established in a DUR program for comparison to actual practice. Criteria should be developed or selected by qualified health professionals, and supported by official drug compendia, unbiased drug information, and peer reviewed literature.

Threshold is a percentage, established by the DUR committee, that identifies the point at which a drug therapy problem exists. For example, a threshold of 95% means the DUR committee has determined that a problem exists if less than 95% of the data collected for a given criteria shows compliance.

Prospective DUR involves comparing drug orders with criteria before the patient receives the drug. This type of evaluation is ideal for its preventive potential, and for its individual patient-centered interventions.

Concurrent DUR involves reviewing drug orders during the course of therapy. This type of evaluation is ideal where adjustments to drug therapy may be necessary based on ongoing diagnostic and laboratory tests.

Retrospective DUR involves reviewing drug prescribing and use after they have occurred. Although the easiest and least costly approach, with retrospective DUR there is no opportunity to modify therapy for the patients on whom the data were collected.

Interventions are the activities selected by the DUR committee to correct drug therapy problems identified during DUR monitoring and evaluation.

STEPS IN ESTABLISHING A BASIC HOSPITAL DUR PROGRAM

The steps included in establishing a basic hospital DUR program are listed below. The process is divided into four phases: planning, data collection and evaluation, intervention, and program evaluation. The steps involved in each phase are discussed in detail later in the manual.

PHASE 1: PLANNING

Step 1. Form the DUR Committee.

Step 2. Write policies and procedures.

Step 3. Define all areas or departments of the hospital where drugs are used (e.g., emergency room, intensive care unit, radiology, surgical department, medical department).

Step 4. Identify drugs for possible inclusion in the program.

Step 5. Assess resources available for criteria development, data collection, and evaluation, and choose drugs to be included in program.

Step 6. For each drug, select aspects (indications, dosing, dosage form chosen, etc.) of drug use to monitor and evaluate.

Step 7. Select criteria and establish performance thresholds.

Step 8. Establish methodology for data collection and evaluation and create a schedule.

Step 9. Educate hospital staff about DUR program and current criteria.

PHASE 2: DATA COLLECTION AND EVALUATION

Step 10. Collect data.

Step 11. Evaluate data and determine if drug use problems exist.

PHASE 3: INTERVENTION

Step 12. Disseminate results to hospital staff.

Step 13. If a drug use problem was found, design and implement interventions.

Step 14. Collect new data on problem drug to determine if drug use has improved as a result of the intervention.

Step 15. Disseminate results of re-evaluation.

PHASE 4: PROGRAM EVALUATION

Step 16. Evaluate all DUR program activities at end of the evaluation year, and plan program activities for the next year.

PHASE I: PLANNING

Step 1. Form the DUR Committee

As with the development and maintenance of hospital formularies, DUR is primarily a medical staff function, with pharmacists and nurses providing valuable expertise. In a hospital setting, the body responsible for planning and implementing a drug utilization review program is the DUR Committee. If a Hospital Formulary Committee already exists, they may be given responsibility for DUR, or they may form a DUR subcommittee. Regardless of the structure, the body responsible for DUR should be composed of professionals with an interest in improving drug therapy in the hospital, and have ready access to experts in medicine, surgery, and all major hospital specialties. The DUR committee should establish and maintain adequate means of communication with the hospital administration and other relevant hospital committees.

The most critical task of the DUR Committee is the development or selection of the criteria that will serve as the basis for monitoring, evaluation, and interventions, which are described in Step 7. The committee may require input from a variety of hospital specialists in this step. As discussed in Annex One "The Importance of Clinical Pharmacology," the success of DUR as a means to improving drug use and controlling costs depends largely on the active participation of physicians, clinical pharmacologists, or clinical pharmacists with detailed, current knowledge of pharmacotherapy and pharmacokinetics.

The committee is responsible for the initial establishment of DUR policies and procedures, and planning and implementing all DUR activities, as explained in the following steps. Data collection is rarely the direct responsibility of committee members, however, they should ensure that data collectors are qualified and adequately trained.

Step 2. Write Policies and Procedures

Prior to monitoring and evaluation, the committee should draft and approve the policies and procedures that will govern its work. Inclusion of a clear statement of the goals and major activities of the committee is important because dissemination of the policies and procedures may be used as a means of educating hospital personnel about the program. Below are key elements recommended for inclusion in DUR policies and procedures.

Designation as a "program"

"The Order of the Chief Physician on Establishing DUR" should specify that DUR is a *program* that is *continuous*. It is important this requirement be stated as a policy, so that the medical staff understand that the hospital is committed to ensuring safe and effective drug use, and that the review of drug use is not an activity that takes place on an ad hoc basis after problems are identified.

Mission statement

A sample statement, including goals and major activities of a hospital DUR program is given below. Any hospital beginning a program should discuss and arrive at its own goals, and determine the types of activities that are needed or possible in their own setting.

"The DUR Committee, in conjunction with the Pharmacy Department, will be responsible for ensuring appropriate, safe, and effective drug use within the hospital. This will be accomplished through the development and maintenance of a systematic, ongoing, criteria-based monitoring and evaluation program in cooperation with the Formulary Committee. Findings from monitoring and evaluation may warrant several actions, including the addition of new drugs to the formulary, deletion of current formulary drugs, restriction of certain drugs to use in particular patients or disease states, or educational interventions, when necessary, to improve use."[1]

Committee makeup

The makeup of the committees should be specified, in accordance with decisions made in Step 1 above. Normally, a DUR committee consists of authoritative representatives responsible for drug use in medicine, surgery, specialty areas such as emergency medicine or pediatrics, pharmacy, drug information, and nursing, if appropriate. Ad hoc representatives may be invited to participate in development of criteria, data evaluation, and designing and implementing interventions.

A chairman and secretary should be appointed or elected according to the policies of the hospital. Normally, a pharmacy representative or clinical pharmacologist serves as secretary.

Frequency of meetings

The frequency of meetings will largely depend on the scope of the program, which is determined by the resources available, and clinical need. The schedule should minimally include a yearly planning meeting, and meetings for selecting and approving criteria, evaluating data, designing interventions, and reviewing the program. Initially, monthly meetings may be necessary to discuss start-up problems and make corrections in the program. Later, quarterly meetings may be sufficient.

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[1] Adapted from the *Arizona Health Sciences Center Drug Formulary Manual, 1994-1996*

Program cycle

The program cycle for DUR should include the following major activities:

1. Planning (including choice of drugs/criteria/thresholds)
2. Data collection and evaluation
3. Interventions
4. Program Evaluation

A yearly cycle is strongly recommended. The cycle may begin in January, although hospitals may choose other key dates if complete data for drug purchase and use are available at these times.

Aspects of drug use to be evaluated

The aspects of drug use that will be evaluated will differ among drugs, and hospitals, because of differences in known or suspected problems, patient mix, laboratory capabilities, specialties, and drug budgets. A DUR Committee may wish to identify *key aspects of care* that should be given first consideration when developing criteria, and include them in a policy statement. One approach is to classify aspects of care into *justification for use*, *process indicators*, and *outcome indicators.*

Justification for use parameters specify under which conditions the drug being evaluated should be prescribed, that is, the drug's indications. For example, an indication for ceftazidime may be documented *pseudomonas aeruginosa* infection; or for digoxin, a justification for use may be documented presence of atrial tachyrhythmia.

Process indicators are parameters describing various aspects of the therapy being evaluated, which should be monitored during standard therapy. The main drug-related aspects are:

- Documented appropriate indication
- Adverse effects
- Management of overdose
- Dosing
- Preparation
- Administration
- Drug-drug and drug-food interactions
- Monitoring/laboratory tests
- Patient education

Outcome indicators are the anticipated results of therapy. For example for the drug ceftazidime outcome indicators may be: fever reduction of at least 1°C within three days of the first dose; bacteriologic eradication as verified by negative cultures within 24 hours after discontinuation of ceftazidime; and white blood count (WBC) is within normal range. Outcome indicators could also include the cost of course of therapy. See Annexes Four and Five for further examples of justification for use, process indicators, and outcome indicators.

Requirements for development of criteria

A policy should be included that requires that drug use criteria be developed using a variety of resources, including scientific literature, hospital experience, and guidelines from professional societies, and that the list of references used in developing criteria should be made available to the medical staff.

Dissemination of information

The results of monitoring and evaluations are disseminated to appropriate hospital personnel. This policy is important because it will help prevent the perception among the medical staff that problem identification was made based on anecdotal information, or that interventions are unnecessary or chosen arbitrarily.

Types of interventions

A policy should be developed that specifies the major types of interventions to be employed to correct drug use problems. Such interventions might include:

- In-service/continuing education programs
- Written guidelines for drug use
- Development of special drug order forms
- Changes in hospital policies and procedures
- Formulary additions and deletions
- Prescribing restrictions
- Formal and informal counseling

Program evaluation

Policy should specify that the *DUR Program* be evaluated at the end of each cycle, so that improvements can be made, and to assess the clinical and economic impact to the hospital.

Step 3. Define All Areas or Departments of the Hospital Where Drugs are Used

As a starting point in designing a *comprehensive* DUR program, the committee should identify all areas or departments of the hospital where drugs are used (e.g., emergency room, intensive care unit, radiology, surgical department, and medical department). Generally, available DUR program resources do not permit inclusion of drugs used in all areas of the hospital in every monitoring cycle. Some departments, such as medicine, surgery, and pediatrics, will be involved in the DUR program in every cycle. Other departments, such as radiology, where drug use is not extensive, may be included only every three or four years. A DUR program can only be comprehensive when it addresses drug use in all areas of the hospital.

Step 4. Identify Drugs for Possible Inclusion in Program

It is impossible, and unnecessary, to monitor and evaluate every drug used in a hospital. Therefore, the DUR Committee must define priority drugs, where improvement in use will result in the greatest clinical and economic impact. These can be drugs with the following characteristics:

- High cost, high volume, clinically important drugs (identified and selected by performing ABC/VEN analyses or reviewing procurement documents);
- Used in high-risk patients (elderly, intensive care, pediatric, etc.);
- Significant side effects, narrow therapeutic index;
- Used in most common diagnoses;
- Under consideration for formulary addition; and
- Recently added to formulary.

High cost, high volume, clinically important drugs (identified by performing ABC/VEN analysis or reviewing procurement documents)

One tool particularly useful in identifying drugs for inclusion in a DUR program is ABC/VEN analysis.

ABC analysis is a method by which drugs are divided according to their annual usage (unit cost times annual consumption), into Class A items (10 - 20% of the items that account for 75-80% of the funds spent), Class B items (10 - 20% of items and 15 - 20% of expenditures), Class C items (60 -80% of items and 5 -10% of expenditures). ABC analysis can be used to give priority to Class A items in making drug selection and procurement decisions, as well as for inclusion in DUR.

VEN analysis is a system of setting priorities for drug selection, purchasing and review, in which drugs are classified, according to their health impact, Vital drugs, Essential drugs and Non-essential drugs:

Vital drugs:	Drugs that are potentially life-saving (e.g., vaccines), that have significant withdrawal side effects such that a regular supply is mandatory (e.g., propranolol, insulin, steroids)
Essential drugs:	Drugs that are effective against less severe, but nevertheless significant, forms of illness
Non-essential drugs:	Drugs for minor or self-limiting illnesses, drugs that are of questionable efficacy, and drugs that have a high cost for a marginal therapeutic advantage

An example of ABC/VEN analysis is provided in Annex Two.

If desired, a more detailed classification can be done. For example, rather than Vital, Essential or Non-essential designations, the following may be used:

Ethiothrope Therapy: Therapy directed at elimination of disease cause

Pathogenic Therapy: Therapy directed at elimination or suppression of disease development mechanisms

Symptomatic Therapy: Therapy directed at elimination or decrease of certain disease manifestations

Replacement Therapy: Therapy directed at the insufficiency of natural biologically active substances

Preventive Therapy: Therapy directed at disease prevention

For example, ABC/VEN analyses in a hospital may reveal that the following high cost, essential drugs are included in Class A:

- Cyclosporine 100mg tablet $284.00/50 tablets
- Immunoglobulin 1ml ampule $120.00/ampule
- Ondensetron 4mg tablet $83.00/10 tablets
- Nimodipine 30mg tablet $75.00/100 tablets
- Lovastatin 40mg tablet $38.00/28 tablets
- Imipenem/Cilastatin 500mg vial $18.00/vial
- Ceftazidime 1.0 gm vial $10.00/vial

Correct usage of these drugs may have both clinical and economic impact, and the DUR Committee in that hospital should strongly consider their inclusion in a program.

Used in high-risk patients (elderly, intensive care, pediatric, etc.)

For example, a hospital may identify the following as important drugs used in elderly patients:

- Theophylline
- Cimetidine
- Nitroglycerine
- Heparin
- Chlorpromazine
- Carbamazepine
- Fenoterol

Similar lists should be developed for intensive care, pediatric, or other high risk patients.

Significant side effects, narrow therapeutic index

Normally drugs with a narrow therapeutic index also cause significant side effects, and usually require careful initial dosage calculation, routine laboratory monitoring, dosage adjustments, and management of side effects during the course of treatment. A typical list of drugs with significant side effects and narrow therapeutic index might include:

- Gentamicin
- Chloramphenicol
- Phenylbutazone
- Sulfadimezine
- Quinidine
- Phenacetin
- Digoxin
- Metamizole

Used in most common diagnoses

Depending on clinical services provided, drug use varies greatly between hospitals. Concentrating DUR efforts on drugs used for the most common diagnoses can also have positive clinical and economic effects. Information on diagnoses is often available from the health administration statistics department.

Under consideration for formulary addition

The Formulary Committee typically handles written requests for addition to the formulary. A summary of requests for addition should be forwarded to the DUR Committee. The Formulary Committee may request that the DUR Committee design a DUR evaluation for a particular drug before making the decision to include it in the formulary. The drug would be purchased on a non-formulary basis while awaiting DUR results.

Recently added to formulary

Highly effective drugs may be added to the hospital formulary before they are routinely used by the general medical staff. This lack of experience makes these drugs a priority for DUR.

A drug may be included in more than one of these categories. These drugs should be given the highest consideration when choosing drugs for inclusion in a DUR program.

Step 5. Assess Resources Available for Criteria Development, Data Collection, and Evaluation, and Choose Drugs to be Included in Program

Usually, more drugs will be identified in the previous step than can be included in a typical one-year DUR cycle. The final plan will ultimately be determined by the resources available for criteria development, data collection, and evaluation. The committee may develop criteria itself, utilize hospital specialists and clinical staff, or use established criteria from unbiased drug reference literature. Data collectors should be chosen carefully, and should be familiar with how information is arranged in the patient's history, since data are often collected from the case history. Knowledge of drug names, strengths, and the way orders are written is also important. Depending on their availability, physicians, pharmacists, and nurses make ideal data collectors.

It is reasonable to begin a DUR program by choosing about 12 drugs, and completing monitoring and evaluation of one drug each month. Obviously, as interventions and reevaluations begin, the workload of the committee increases. If the hospital is starting a DUR program for the first time, the DUR committee may decide to complete one drug evaluation; using that experience the committee can then establish the DUR schedule.

Step 6. For Each Drug, Select Aspects (Indications, Dosing, Dosage Form Chosen, Etc.) of Drug Use to Monitor and Evaluate

Just as it is impossible to monitor and evaluate all drugs used in a hospital, it is impossible to address all aspects of use for each drug finally selected. Therefore, after the committee has selected drugs for inclusion in DUR, it must select only the *most important* aspects of use to monitor and evaluate.

For each drug, the committee should consider problems identified in the past, and problems with the most serious clinical and financial consequences.

The main aspects of drug use to consider are listed below:

- Indications
- Contraindications
- Side/adverse effects
- Management of overdose
- Dosing
- Duplicate therapy
- Preparation
- Administration
- Drug-drug and drug-food interactions
- Monitoring/laboratory tests
- Patient education/instructions
- Anticipated results of therapy
- Cost of course of therapy

For example, a committee may have selected ceftazidime, heparin, and salbutamol for evaluation. For each drug, the committee identified important aspects of care, and the reasons for choosing these aspects:

Ceftazidime is an expensive, wide spectrum, bactericidal, third generation cephalosporin. Widespread usage of this drug has a significant impact on the drug budget. It is known to be frequently prescribed for minor infections, and often, a culture and sensitivity test is not ordered. Under these circumstances, it is well known that bacterial resistance can develop, jeopardizing effectiveness when needed for future serious nosocomial infections. Additionally, it is frequently prescribed concurrently with bacteriostatic antibiotics such as erythromycin. For these reasons the most important aspects of use are indications, laboratory testing, and drug-drug interactions.

Heparin is a frequently used drug that has potentially fatal consequences if not used correctly. Additionally, it is often used for critically ill patients. Internal bleeding, or death, can occur if heparin is used when contraindicated, if side effects or overdosage are not managed correctly, or if dosing, which requires laboratory testing, is not done properly. Patients on heparin usually receive several other drugs concurrently, with significant potential for drug-drug interactions. For these reasons, the committee decided to monitor contraindications, side effects, dosing, management of overdose, laboratory testing, and drug interactions.

Salbutamol is a selective, sympathomimetic bronchodilator frequently used for asthma and chronic obstructive pulmonary disease. Expiration force testing is recommended to determine if a patient is responding favorably to salbutamol therapy. Although selective for bronchial receptors, incorrect dosing can result in tachycardia, and cardiac arrhythmia. Some patients cannot use the inhaler dosage form, necessitating use of an oral dosage form. Patients frequently use salbutamol inhalers after discharge from the hospital. The drug is ineffective if not inhaled properly. Also, overuse can cause tachyphylaxis. Therefore, patient education for proper inhalation is particularly important with this drug. For salbutamol, respiratory testing, dosing, dosage form selection, and patient education are important aspects of use.

Step 7. Select Criteria and Establish Performance Thresholds

Criteria are statements about correct drug use. A hospital DUR Committee may use one or more of the following methods to develop criteria for its program:

- Use existing criteria sets, such as Standard Treatment Guidelines developed under the auspices of the Health Insurance Fund, the World Health Organization *Guidelines for Treatment of Common Diseases*, or the American Society of Health System Pharmacists (ASHP) *Criteria for Drug Use Evaluation*. These criteria are unbiased, have been developed by experts, and have been field tested for acceptability of use.

- Adapt existing criteria sets according to the needs of the hospital.

- Select its own criteria, based on hospital-developed standard treatment guidelines.

Regardless of how they are developed, criteria should be supported by national drug compendia, unbiased drug information, and peer reviewed literature. The committee should provide its medical staff with information on the sources of information used to develop criteria.

Annex Four contains criteria developed by the ASHP for ceftazidime. A DUR committee could decide to use the criteria exactly as published, or could modify it to reflect existing standards for appropriateness in the hospital.

Below is an example of how a hospital may select criteria for nonsteroidal anti-inflammatory drugs. In this hospital, arthritic and inflammatory rheumatic conditions are among the most common diagnoses and many of its patients are on chronic therapy. ABC analysis revealed that the following drugs comprised 15% of the total drug budget:

- acetylsalicylic acid
- diclofenac
- flurbiprofen
- ibuprofen
- naproxen
- piroxicam

The medical staff knows that improper prescription of drugs in this class can lead to complications. As it is impossible to evaluate all aspects of drug use, the committee limited criteria to contraindications and drug interactions. The committee did not have access to existing criteria sets and developed the following criteria based on scientific literature available in the hospital, and experience of the chief rheumatologist:

Contraindications: chronic renal insufficiency, hypersensitivity to acetylsalicylic acid and NSAIDs, ulcer and erosive gastrointestinal disease, documented coagulopathy, congestive heart failure, pregnancy, breast-feeding, ascites, and cirrhosis.

Drug interactions: indirect anticoagulants, cyclosporine, methotrexate, ACE inhibitors, corticosteroids.

Once criteria have been selected, thresholds are set. A *threshold* is a percentage, established by the DUR committee, that identifies the point at which non-compliance with drug use evaluation criteria is of such magnitude to warrant an intervention. For example, a threshold of 95% means that a drug use problem exists if less than 95% of the data collected for a given criteria shows compliance.

If serious consequences could result from noncompliance with a given criteria, the threshold should be 100%. For example, the threshold for correct dosing of a drug such as heparin must be 100%, since prescribing an incorrect dosage of heparin could result in death. A threshold for correct dosing of acetylsalicylic acid may be set at 95%, because correct dosing of this drug is less critical. Thresholds set at less than 100% may signify the DUR committee has determined that some deviations are clinically justified, or that deviations are random occurrences that do not signify an ongoing problem.

Annex Five contains examples of criteria sets and thresholds for several drugs.

Step 8. Establish Methodology for Data Collection and Evaluation and Create a Schedule

Before the actual monitoring and evaluation of a drug begins, the DUR committee must establish methodology for data collection including: data elements, data sources, forms to use, persons responsible, and sample size.

Data elements — Describe each data element that must be collected during the evaluation. For example: prescriber name, prescriber specialty, drug name, drug dose, amount prescribed, duration of therapy, acquisition cost of the drug, etc. Data elements will vary with criteria. See Annex Three, Form 2 for examples.

Data sources: Indicate where the selected data elements can be found. For example, in patient history, laboratory records, pharmacy records, etc.

Forms: — Once the data elements are selected, design forms that can be used to report data in an orderly fashion, and to ensure that all necessary data are collected. Forms should be designed to organize the data for final analysis. See Annex Three for examples.

Persons responsible: — Indicate the persons who will be responsible for collecting, organizing, and reporting the data.

Sample size: — Decide how much data to collect, after considering the following aspects: objectives of the evaluation, dates to be evaluated, monthly or annual usage of the drugs, if seasonal variation could affect prescribing habits, time, and personnel and financial resources available.

Other considerations in choosing sample size: For drugs that are *frequently* purchased, it may only be necessary to sample a minimum of 30 to 50 cases, or a certain percentage of cases, as long as the data are collected in a random manner. For *infrequently* prescribed, but costly or clinically important drugs, it may be necessary to collect data on all cases during a specified period of time (e.g., three months, six months, or a year).

Whether data will be evaluated prospectively, concurrently, or retrospectively is a key decision. A description of the three types is found below. Often, a hospital will begin a program using the retrospective method, and switch to prospective DUR as the program gains acceptance and sufficient resources are available.

Prospective DUR involves comparing drug orders with criteria and conducting the intervention before the patient receives the drug. Its main advantage is its preventive potential, and it should be used when non-compliance with criteria will have the most serious consequences. The impact of this approach is noticeable immediately, and physicians may become accustomed to the monitoring as a "double check." Therefore, continuity of staffing is an important issue with prospective DUR. Various drug use problems can be detected and *prevented from occurring* with prospective monitoring, such as:

- incorrect dosage
- inappropriate dosage form/route of administration
- incorrect duration of therapy
- drug-drug interactions
- therapeutic duplication
- drug-disease contraindications
- drug-allergy and other side effects
- incorrect laboratory/monitoring orders

For example, criteria may be established that it is a contraindication for a patient to concurrently receive a bacteriostatic and bactericidal antibiotic. If a patient is on gentamicin, and the pharmacist receives an order for erythromycin, the pharmacist would not dispense the erythromycin, and would contact the prescribing physician to have the order changed.

Similarly, a criteria may be established that patients should not concurrently receive gentamicin and furosemide. In this case, the pharmacist should contact the physician and warn of the possible nephrotoxic effects of gentamicin.

Concurrent DUR monitoring involves comparing drug use with criteria *during* therapy, like prospective monitoring. The main difference between the two types is that with concurrent monitoring, interventions are corrective.

For example, a criteria may be established in a hospital stating that gentamicin dosage should be calculated based on ideal body weight, and adjusted based on renal and hearing tests. The clinical pharmacologist or pharmacist would check these parameters daily, contacting the prescribing physician when dosage was calculated incorrectly, or dosage adjustments were not made.

Retrospective DUR Monitoring involves reviewing prescribed drugs *after* they are dispensed to the patient. Its chief drawback is that interventions cannot be made to improve drug use for the patients whose records were reviewed. It can be used to monitor the same aspects of drug use listed for prospective DUR, as well as:

- identifying prescribing frequency of a single drug or class of drugs
- comparing drug prescribing among physicians
- comparing prescribing to standard treatment guidelines
- monitoring the therapeutic use of high cost drugs

For example, a hospital performs a DUR on gentamicin, with a criteria that states that use is contraindicated in renal failure. Records for patients discharged during the previous month are reviewed in the medical records department and the review may show that a prescribing problem exists. The medical staff decides to do a more intensive review of all aminoglycosides, with similar results. An education program is conducted for the entire medical staff on antibiotic use in renal failure.

Based on the information obtained in the previous steps, the committee should develop an annual DUR schedule. The schedule will show the drugs to be evaluated, and when the evaluations will be conducted. A sample form for establishing a schedule is included as part of Annex Three.

Step 9. Educate Hospital Staff about DUR Program and Current Criteria

Prior to data collection in the first program cycle, it is important to educate the medical and pharmacy staffs about the objectives of the DUR program, and build support for the program. Informal meetings with hospital opinion leaders may be used to build support. Physician/pharmacist education may best be accomplished by disseminating all or part of the DUR program's policies and procedures, the monitoring and evaluation schedule, and the criteria for each drug. Dissemination may be done by various methods including memo or newsletter, but using the staff meeting setting would allow discussion of the subject matter and interaction among staff members.

Before subsequent DUR cycles, distribution of the monitoring schedule and criteria may be sufficient, but the medical staff should always be informed about changes in DUR policies and procedures.

PHASE II: DATA COLLECTION AND EVALUATION

Step 10. Collect Data

The method of data collection will vary greatly with the approaches (prospective, concurrent or retrospective) chosen in the previous step. In all cases, forms will be necessary for documenting results.

Prospective

In prospective DUR, "data collection" usually requires a review of physicians' orders and comparison to criteria prior to administration of the drug. How this is accomplished, or if it is even feasible, will vary greatly between hospitals. In western-style distribution systems, where drug orders are reviewed by a pharmacist in an organized pharmacy department prior to distribution of the first dose of drug, data collection can be done in the pharmacy. In the ward-stock systems frequently seen in Russian hospitals, prospective DUR is only possible if a qualified "data collector" is available to review orders prior to administration by a nurse. In systems where the department chief reviews all drug orders prior to administration, this individual could also function in the capacity of DUR data collector.

Concurrent

Concurrent DUR data collection is similar to prospective in that it may be done in the pharmacy, or on the wards. It differs from prospective in that the data collection does not have to occur prior to administration of a first dose. This method of data collection is most suitable when staffing permits a daily review of case histories.

Retrospective

Retrospective DUR presents the fewest problems with data collection, and therefore is often the method of choice in new programs. Since almost all required data elements are contained in case histories, data collectors typically work in cooperation with the medical records department. Retrieval of data elements that are not contained in the case history, such as drug prices, may require visits to ancillary departments.

Step 11. Evaluate Data and Determine if Drug Use Problems Exist

Data evaluation is one of the most critical steps in a DUR program. Conclusions drawn from data analysis could result in changes in hospital policies, formulary additions or deletions, prescribing restrictions, and counseling of hospital staff. Information must be carefully aggregated when determining if thresholds were exceeded. Whenever feasible, a DUR committee member should review the data collection forms for completeness, and verify questionable data with the case history, or other hospital records.

If a threshold set at 100% is met (indicating complete compliance with the criteria), it is usually sufficient to simply report the results to the DUR committee.

If a threshold set at less than 100% (e.g., 95%) is not actually exceeded (e.g., 98%), the DUR committee should decide if it is necessary to review those cases that were not in compliance with the criteria. The main purpose of any such review is to determine if there was a *justifiable reason for non-compliance*. It is not uncommon for a DUR committee to justify cases of non-compliance. In this case, they may decide to change the criteria prior to re-evaluation of the drug. If non-compliance is determined to be justified, a recalculation of the threshold percentage should be done.

If a threshold is not met, it indicates a drug use problem. As above, cases of non-compliance should be reviewed to determine if drug use was actually appropriate. If the committee determines that a drug use problem does exist, the data should be evaluated to determine if the problem is widespread or limited to a few individuals, if the problem is localized to a particular ward or department, and even if the problem occurs on one particular hospital shift.

PHASE III: INTERVENTION

Step 12. Disseminate Results to Hospital Staff

As DUR data analyses are completed, the results should be reported to physicians and other relevant staff such as pharmacists and nurses. Results can be disseminated using any of the following mechanisms:

- weekly prescribers' conference
- dissemination of written DUR committee meeting minutes
- newsletters
- ad hoc meetings
- posting results in meeting places such as nurses' station on each ward

Step 13. If a Drug Use Problem is Found, Design and Implement Interventions

Interventions can be *educational* or *operational*, and can target *groups*, or only those *individuals* whose performance was not in compliance with drug use criteria. When the committee decides that a drug use problem exists, it should:

Choose one or more interventions that will result in improved drug use

a. Educational interventions can include the following:

- in-service/continuing education programs
- informal and formal counseling
- letters to the physician
- newsletters, guidelines on drug use, and other informational materials

b. Operational interventions can include:

- development of drug order forms
- changes in hospital policies and procedures
- formulary additions and deletions
- prescribing restrictions
- implementing or revising standard treatment guidelines
- purchasing new equipment
- staffing changes

Identify the target audience

The target audience for an intervention depends primarily on the extent of the problem. If non-compliance with criteria is widespread, the intervention may be aimed at the entire medical staff, or at groups of specialists. If a small number of prescriber or staff are non-compliant, interventions may be directly aimed at only those who did not meet criteria. In prospective DUR, the intervention target is always the prescriber.

Assign responsibility for designing and carrying out intervention

Interventions may be designed and carried out by a combination of committee members, hospital staff, or outside experts. The committee chairman is usually responsible for sending letters and counseling activities. Other interventions, such as writing an informational newsletter, or drafting new policies, may be assigned to specialists on the committee or on the hospital staff. Outside experts are usually used to conduct lectures for hospital staff. The chief physician may be involved if intervention requires hiring additional staff, or purchasing equipment.

Step 14. Collect New Data on Problem Drug to Determine if Drug Use Has Improved as a Result of the Intervention

Monitor physician prescribing to determine effectiveness of interventions. Typically, the reevaluation is done six to twelve months after the intervention was put in place, and should involve collecting the same data as in the original DUR evaluation. If a comprehensive evaluation with multiple criteria revealed a small number of problems, the committee may decide to narrow the focus of the re-evaluation to problematic criteria.

Step 15. Disseminate Results of Re-Evaluation

Disseminate results of the re-evaluation DUR to the medical staff as per Step 12.

PHASE IV: PROGRAM EVALUATION

Step 16. Evaluate All DUR Program Activities at End of the Evaluation Year and Plan Program Activities for the Next Year

At the end of an evaluation cycle, the DUR Committee should perform an evaluation of the DUR program, and if necessary, make policy and procedural changes to reflect actual practices, or to facilitate desired changes. Other considerations when evaluating the program are:

- Were appropriate drugs chosen for inclusion?
- Were important aspects of care addressed by the program?
- Were criteria developed according to hospital policy?
- Were thresholds appropriate?
- Were problems identified?
- Were interventions appropriate?
- Were drug use problems solved/did drug therapy improve?
- Did DUR have an impact on the incidence of adverse drug reactions, drug-drug interactions, or medication administration errors (if there is a system already in place for monitoring them)?
- Were results disseminated according to policy?
- Did the DUR program have a financial impact on the hospital?

ANNEX ONE: IMPORTANCE OF CLINICAL PHARMACOLOGY IN THE DUR PROCESS

ANNEX ONE: IMPORTANCE OF CLINICAL PHARMACOLOGY IN THE DUR PROCESS

Clinical pharmacology is a medical discipline that links pharmacological and clinical expertise in order to promote rational use of drugs. The likelihood of a DUR program being accepted by the hospital medical staff, and becoming a tool for optimizing drug therapy will be greatly increased if members of the committee have adequate knowledge of clinical pharmacology. This is especially true when selecting or developing criteria. This annex very briefly introduces various types of specialized knowledge that can enhance the effectiveness of a DUR program. These types include:

- Disease etiology
- Dosage forms, and routes of administration
- Differences in drug requirements depending on severity of disease
- Drug-disease contraindications
- Adverse drug reactions
- Pharmacokinetics
- Combination therapy

Disease etiology

When developing criteria it is necessary to consider and recognize the main pathogenic mechanisms of disease development, since various mechanisms can be involved in producing the same manifestations. For example, the development of arterial hypertension may originate from fluid retention, increased cardiac output, or an increase in total peripheral vascular resistance. In each case, a different drug would be initially prescribed:

- A diuretic is the drug of choice for treatment of volume-dependent forms of arterial hypertension.
- In hemodynamic forms of arterial hypertension, beta-blockers, which decrease cardiac output, are considered to be the most effective.
- If the history of arterial hypertension development shows prevalence of total peripheral vascular resistance, vasodilators are indicated.

Rational prescribing of antibiotics depends on knowledge of penetration through the blood-brain, placenta, pleura, and peritoneum barriers; accumulation in organs, tissues and cells; the antimicrobial spectra; minimum inhibitory concentrations (MIC); and susceptibility of various microorganisms to antibiotics. For example:

- In patients with *Hemophilus* influenza meningitis, ceftriaxone concentration in cerebrospinal fluid is 10,000 times higher than the MIC. For *Pneumococcal* meningitis, it is 1,000 times higher than the MIC. Therefore, this drug is a good choice for bacterial meningitis.
- Concentrations of cefaclor and cefuroxime axetil in sputum are 25-50 times higher than MIC for the majority of respiratory pathogenic organisms (*H. influenza, M. catharrhalis, Pneumococci*), which determines the high clinical effectiveness of these drugs (up to 90%), and eradication of pathogenic organism from bronchi and lungs.

- After administration of a 500 mg dose of ciprofloxacin, drug concentration in urine in patients with pyelonephritis reaches 400 mcg/ml, greatly exceeding the MIC for the main pathogenic microorganisms that cause urinary tract infections (*E. Coli, Proteus, Pseudomonas aeruginosa*). This explains the high effectiveness of ciprofloxacin and other fluoroquinolones in urogenital infections.

Dosage forms and routes of administration

Some drug use criteria often include dosage forms and routes of administration. Many drugs are available in several dosage forms with different biotherapeutic characteristics. For example:

- Knowledge of the fact that an oral or sublingual dose of nifedipine produces high plasma concentrations and a rapid response can be useful in treating hypertensive emergencies. The therapeutic effects of a sublingual dose of nifedipine are comparable to an injection of clonidine. The oral route is safer than an injection, and may be more applicable in outpatient or ambulatory settings.

- Special oral dosage forms are available that cause the active substance to be gradually released into the GI tract, achieving therapeutic plasma concentrations without reaching peak plasma concentrations, and therefore avoiding "acute" side effects. Examples of drugs available in these extended release dosage forms are theophyllines and calcium antagonists such as verapamil, diltiazem, and nifedipine. Therefore, sustained release calcium antagonists are more acceptable for maintenance therapy of hypertension and prevention of angina.

- The severity of disease should be considered in development of drug use criteria, including the route of administration. In severe conditions, such as sepsis, endocarditis, severe pneumonia, and acute cardiovascular failure, it may be necessary to use a parenteral route of administration in order to rapidly achieve maximum or therapeutic plasma concentrations.

Differences in drug requirements depending on severity of disease

The severity of a condition is a factor in determining whether a patient requires mono or combination drug therapy. Normally, it is preferable to prescribe only one drug to produce a therapeutic effect, and increase or decrease the dosage to modify the dose-related effect. There are some exceptions, such as when the dose-related effect is unclear or where increases in dose produce little change in therapeutic effect, but increase side effects (e.g., hydrochlorothiazide, antiarrhythmic agents, and psychotropic drugs).

Monotherapy is recommended when treating a moderate infection caused by a known pathogenic organism to avoid antibiotic-induced side effects. However, multiple antibiotics may be necessary in known or suspected mixed infections.

The dose-related approach should be utilized so as to allow modification of therapy when a drug's effectiveness appears to be insufficient, but given in normal dose ranges. However, in serious conditions, and in conditions where multiple mechanisms, organs, and systems are involved in the pathological process, monotherapy, even with maximum doses, may be insufficient. In such cases, combination therapy may be appropriate and necessary although additive therapeutic and side effects must be carefully considered in dosing.

Drug-disease contraindications

Optimal drug therapy requires consideration of a patient's total medical condition. In patients with multiple

diseases, the drug of choice for one condition may be absolutely contraindicated, or should be used with caution due to another preexisting condition. Pregnancy and breast-feeding will also influence selection of drugs.

- If a patient is newly diagnosed with arterial hypertension, and also suffers from bronchial obstruction syndrome or has a risk of bradycardia development, adrenergic blockers, especially nonselective ones, would be contraindicated in the treatment of hypertension.

- In pregnancy, the potential for a drug to be embryo toxic, teratogenic or organotoxic in the fetus, as well as cause adverse effects on blood circulation and uterine tone in the mother, should always be weighed against the benefits of using the drug.

Adverse drug reactions

Rational drug use requires consideration of adverse drug reactions, which are defined here as any unexpected reaction to a drug. This definition distinguishes adverse drug reactions from side effects, which are drug reactions that could occur, since the incidence has been documented in the literature. Because adverse effects are addressed only after they appear, they can contribute significantly to morbidity and mortality, as well as add to the overall cost of health care.

According to WHO statistics, up to 10% of the total number of hospital admissions are due to drug-induced adverse reactions.[2] While it may not seem possible to prevent adverse reactions, many are actually caused by incorrectly prescribed drugs.

- For example, use of gentamicin for treatment of urinary tract infections in patients with serious renal disease, such as pyelonephritis, diabetic nephropathy, or renal amyloidosis, is not always justified due to the fact that this drug may cause further progression of nephropathy. In such cases it is reasonable to replace gentamicin with azolide antibiotics such as azithromycin.

- It is recommended to avoid the prescription of drugs that are actively metabolized in the liver of patients with severe hepatocellular failure. For example, ketoconazole, long-acting benzodiazepines, nitrofuranes, and sulfonamides can increase hepatocellular injury.

Pharmacokinetics

It is essential to know the pharmacokinetic properties for each drug in order to be able to make rational decisions. The main indicators of a drug's behavior in a human organism are data on the drug's plasma half-life (T ½), elimination metabolism, distribution, and concentrations in plasma and tissues. Knowledge of drug metabolism and elimination is very important, since it can help avoid severe side effects in some cases. These data should always be considered when developing drug use criteria for DUR. For example:

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[2] *Guide to Good Prescribing,* WHO, 1995, p.25.

- In elderly patients there is a senile involution of kidneys where the volume of glomerular filtration is reduced by one-third in comparison with younger patients. This fact leads to prolongation of drug action and to a decrease in clearance for those drugs that are mainly eliminated through the kidneys. For example, it may be necessary to reduce the daily doses of the histamine H_2-blockers ranitidine and famotidine, and the antibiotics cefaclor and cefuroxime, as much as one-third to one-half of normal daily doses.

- In patients with renal failure it is mandatory to adjust daily doses of drugs based on creatinine clearance in the kidneys. For example, in patients with severe chronic renal failure, the daily dose of ciprofloxacin, histamine H_2-blockers, and digoxin, may need to be reduced by up to 75% of normal doses.

Combination therapy

As discussed previously, a patient may have multiple medical problems requiring use of several drugs. Even in patients with one disease or condition, in some cases the use of a single drug does not always produce the desired therapeutic effect, necessitating combination therapy.

For example, favorable additive therapeutic effects are seen when a β-adrenergic blocker and a thiazide diuretic are used together.

Similarly, the antibacterial spectrum can be broadened by concurrent use of cephalosporin and amino glycoside antibiotics, with the exception of cephalothin, which has been associated with increased incidence of nephrotoxicity.

In cases of multiple drug use physicians and pharmacists should be aware of significant drug-drug interactions.

As seen above, a given combination of drugs can have both positive (desired additive effects, synergism, etc.) and negative (antagonism, adverse effects, etc.) results because of pharmacodynamic and pharmacokinetic principles. For example, a combination of drugs with similar mechanisms of action, such as hydrochlorothiazide and furosemide, can result in a desired additive effect of controlling hypertension. However, this combination could also lead to an increase in the number and severity of side effects, such as hypokalemia, glucose intolerance, and myocardial infarction.

Just as combinations of drugs with similar mechanisms of action can lead to additive therapeutic effects, combinations of drugs with similar side effects can increase the risk of side effects. Concurrent use of drugs with similar side effects should be done with extreme care. For example, patients with severe ventricular arrhythmia may require use of procainamide and disopyramide, both of which can cause A-V block.

Below are more examples of drug-drug interactions:

- The potassium-sparing diuretic spironolactone may increase plasma concentration of digoxin and its elimination half-life, increasing the risk of arrhythmias.

- Cephalosporins and amino glycosides can have nephrotoxic effects when used with loop diuretics.

- Nonsteroidal anti-inflammatory drugs (NSAIDs), especially indomethacin, used with furosemide or hydrochlorothiazide, can reduce diuretic effects, possibly due to inhibition of renal prostaglandin synthesis.

- NSAIDs used with methotrexate can cause fatal methotrexate concentrations in plasma and tissues.
- Indomethacin decreases the hypotensive effect of the α-adrenergic blocker prazosin, the ACE inhibitor captopril, and the vasodilator hydralazine.

- Theophylline use with erythromycin, cimetidine, propranolol, and allopurinol (dosage ≥600 mg), will inhibit theophylline hepatic clearance, resulting in an increase in plasma theophylline concentrations, and leading to side effects such as tachycardia, nausea, tremor, and confusion.

The success in therapy is very much stipulated by the physician's ability to recognize the main components of an individual patient's disease, and in turn to select a drug correctly, to define a drug dose and dosage schedule, to foresee possible unfavorable side effects (including those induced by drug-drug interactions), and to consider the cost of treatment.

ANNEX TWO: EXAMPLE OF ABC/VEN ANALYSES

ANNEX TWO: EXAMPLE FOR CONDUCTING ABC/VEN ANALYSES

While these analyses can be done manually, use of a computer spreadsheet application immensely reduces the time required to perform the activities, as well as the potential for math errors. This example was prepared using Quattro Pro spreadsheet software. For demonstration purposes it is assumed the following 21 drugs are the only ones used in the hospital.

Step 1. Prepare a list of all drugs used in the hospital.

For each drug list the name, strength, package size, dosage form, package price, quantity dispensed (annual consumption) and total cost. Determine the total cost for each drug by multiplying the quantity dispensed in 1995 (number of packages consumed annually) times the price per package. For this hospital the list of drugs will appear in the following way:

Drug Name Strength Package Size	Dosage Form	Price Per Package US$	Quantity Dispensed in 1995	Total Cost US$
Ranitidine Hydrochloride 150 mg N100	tab	$8.00	500	$4,000.00
Bendazol 0.5% 2 ml N10	inj	$0.50	5000	$2,500.00
Cocarboxylase 50 mg 3 ml N3	inj	$1.25	1000	$1,250.00
Metoclopramide Hydrochloride 10 mg N40	tab	$1.67	1200	$2,004.00
Solcoseril 2 ml N25	inj	$20.12	700	$14,084.00
Verapamil Hydrochloride 80 mg N100	tab	$5.00	1200	$6,000.00
Nandrolone Decanoate 50 mg 1 ml	inj	$1.74	800	$1,392.00
Metamizole 50% 1 ml N10	inj	$0.30	2000	$600.00
Nitrofurantoin 100 mg N10	tab	$0.15	3000	$450.00
Inosine 200 mg N100	tab	$20.00	800	$16,000.00
Insulin HM 10 ml 40 IU/ml	inj	$5.50	2000	$11,000.00
Cefotaxime Sodium 1 g	inj	$2.40	2000	$4,800.00
Prednisolone 30 mg N3	inj	$1.21	1900	$2,299.00
Digoxin 0.25 mg N50	tab	$1.00	600	$600.00
Drotaverine Hydrochloride 0.04 N100	tab	$2.15	5000	$10,750.00
Nystatin 500,000 U N25	tab	$0.73	3000	$2,190.00
Ampicillin 250 mg N24	tab	$1.25	1500	$1,875.00
Allylestrenol 5 mg N20	tab	$1.63	300	$489.00
Inosine 2% 5 ml N10	inj	$1.57	3000	$4,710.00
Chlordiazepoxide 10 mg N50	tab	$0.56	800	$448.00
Isradipine 5 mg N30	caps	$16.21	600	$9,726.00
TOTAL				**$97,167.00**

Step 2. Categorize each drug as vital, essential, or non-essential.

This step is the VEN analysis and is conducted for the purpose of increasing effectiveness of drug utilization, and for determining which drugs to include in the hospital formulary or drug list. The classification is based on a drug's importance in treating the patient, for example:

Vital drugs: Drugs that are life saving (e.g., vaccines), and those necessary for life support (e.g., insulins, digoxin, some antibiotics, cytotoxics, anti-shock, etc.).

Essential drugs: Drugs that are effective for treatment of less life threatening, but still severe, diseases (e.g., antibiotics, ranitidine, chloroquine, phenytoin, etc.).

Non-essential drugs: Drugs used for treatment of mild diseases, drugs with questionable effectiveness, and high cost drugs used for symptomatic therapy.

Adding the VEN Category column to the previous table, it would look like this:

VEN Category (VEN)	Drug Name Strength Package Size	Dosage Form	Price Per Package US$	Quantity Dispensed in 1995	Total Cost US$
E	Ranitidine Hydrochloride 150 mg N100	tab	$8.00	500	$4,000.00
N	Bendazol 0.5% 2 ml N10	inj	$0.50	5000	$2,500.00
N	Cocarboxylase 50 mg 3 ml N3	inj	$1.25	1000	$1,250.00
E	Metoclopramide Hydrochloride 10 mg N40	tab	$1.67	1200	$2,004.00
N	Solcoseril 2 ml N25	inj	$20.12	700	$14,084.00
V	Verapamil Hydrochloride 80 mg N100	tab	$5.00	1200	$6,000.00
E	Nandrolone Decanoate 50 mg 1 ml	inj	$1.74	800	$1,392.00
E	Metamizole 50% 1 ml N10	inj	$0.30	2000	$600.00
E	Nitrofurantoin 100 mg N10	tab	$0.15	3000	$450.00
N	Inosine 200 mg N100	tab	$20.00	800	$16,000.00
V	Insulin HM 10 ml 40 IU/ml	inj	$5.50	2000	$11,000.00
V	Cefotaxime Sodium 1 g	inj	$2.40	2000	$4,800.00
V	Prednisolone 30 mg N3	inj	$1.21	1900	$2,299.00
V	Digoxin 0.25 mg N50	tab	$1.00	600	$600.00
N	Drotaverine Hydrochloride 0.04 N100	tab	$2.15	5000	$10,750.00
E	Nystatin 500,000 U N25	tab	$0.73	3000	$2,190.00
V	Ampicillin 250 mg N24	tab	$1.25	1500	$1,875.00
E	Allylestrenol 5 mg N20	tab	$1.63	300	$489.00
N	Inosine 2% 5 ml N10	inj	$1.57	3000	$4,710.00
E	Chlordiazepoxide 10 mg N50	tab	$0.56	800	$448.00
E	Isradipine 5 mg N30	caps	$16.21	600	$9,726.00
TOTAL					**$97,167.00**

Step 3. Rearrange drugs according to decreasing total cost to the hospital.

Using total cost as the basis, list drugs according to their decreasing cost to the hospital. This will place the most costly drugs at the top of the list. If using a computer spreadsheet, the sort function will rapidly perform this task. The sorted table now looks this way:

VEN Category (VEN)	Drug Name Strength Package Size	Dosage Form	Price Per Package US$	Quantity Dispensed in 1995	Total Cost US$
N	Inosine 200 mg N100	tab	$20.00	800	$16,000.00
N	Solcoseril 2 ml N25	inj	$20.12	700	$14,084.00
V	Insulin HM 10 ml 40 IU/ml	inj	$5.50	2000	$11,000.00
N	Drotaverine Hydrochloride 0.04 N100	tab	$2.15	5000	$10,750.00
E	Isradipine 5 mg N30	caps	$16.21	600	$9,726.00
V	Verapamil Hydrochloride 80 mg N100	tab	$5.00	1200	$6,000.00
V	Cefotaxime Sodium 1 g	inj	$2.40	2000	$4,800.00
N	Inosine 2% 5 ml N10	inj	$1.57	3000	$4,710.00
E	Ranitidine Hydrochloride 150 mg N100	tab	$8.00	500	$4,000.00
N	Bendazol 0.5% 2 ml N10	inj	$0.50	5000	$2,500.00
V	Prednisolone 30 mg N3	inj	$1.21	1900	$2,299.00
E	Nystatin 500,000 U N25	tab	$0.73	3000	$2,190.00
E	Metoclopramide Hydrochloride 10 mg N40	tab	$1.67	1200	$2,004.00
V	Ampicillin 250 mg N24	tab	$1.25	1500	$1,875.00
E	Nandrolone Decanoate 50 mg 1 ml	inj	$1.74	800	$1,392.00
N	Cocarboxylase 50 mg 3 ml N3	inj	$1.25	1000	$1,250.00
E	Metamizole 50% 1 ml N10	inj	$0.30	2000	$600.00
V	Digoxin 0.25 mg N50	tab	$1.00	600	$600.00
E	Allylestrenol 5 mg N20	tab	$1.63	300	$489.00
E	Nitrofurantoin 100 mg N10	tab	$0.15	3000	$450.00
E	Chlordiazepoxide 10 mg N50	tab	$0.56	800	$448.00
TOTAL					**$97,167.00**

Step 4. Calculate the percentage of total hospital drug budget spent for each drug.

This step involves two calculations for each drug:

(1) **Total Cost %** is determined by dividing the amount in the total cost column for each drug by the total cost for all 21 drugs.

(2) **Cumulative %** is a sum calculated by adding the total cost % of a drug to the cumulative % of the previous drug as you descend the drug list. For example, the total cost % of inosine is 16.5%; since there is no previous drug in the list, the cumulative % for this drug is also 16.5%. However, the total cost % for insulin is 11.3% and the cumulative % for all previous drugs (inosine and solcoseril) is 31.0%; to get the cumulative % for insulin add 31.0% + 11.3% = 42.3%.

Append the two new columns to the table, which will appear in the following way:

VEN Category (VEN)	Drug Name Strength Package Size	Dosage Form	Price Per Package US$	Quantity Dispensed in 1995	Total Cost US$	Total Cost %	Cumulative %
N	Inosine 200 mg N100	tab	$20.00	800	$16,000.00	16.5%	16.5%
N	Solcoseril 2 ml N25	inj	$20.12	700	$14,084.00	14.5%	31.0%
V	Insulin HM 10 ml 40 IU/ml	inj	$5.50	2000	$11,000.00	11.3%	42.3%
N	Drotaverine Hydrochloride 0.04 N100	tab	$2.15	5000	$10,750.00	11.1%	53.4%
E	Isradipine 5 mg N30	caps	$16.21	600	$9,726.00	10.0%	63.4%
V	Verapamil Hydrochloride 80 mg N100	tab	$5.00	1200	$6,000.00	6.2%	69.6%
V	Cefotaxime Sodium 1 g	inj	$2.40	2000	$4,800.00	4.9%	74.5%
N	Inosine 2% 5 ml N10	inj	$1.57	3000	$4,710.00	4.8%	79.4%
E	Ranitidine Hydrochloride 150 mg N100	tab	$8.00	500	$4,000.00	4.1%	83.5%
N	Bendazol 0.5% 2 ml N10	inj	$0.50	5000	$2,500.00	2.6%	86.0%
V	Prednisolone 30 mg N3	inj	$1.21	1900	$2,299.00	2.4%	88.4%
E	Nystatin 500,000 U N25	tab	$0.73	3000	$2,190.00	2.3%	90.7%
E	Metoclopramide Hydrochloride 10 mg N40	tab	$1.67	1200	$2,004.00	2.1%	92.7%
V	Ampicillin 250 mg N24	tab	$1.25	1500	$1,875.00	1.9%	94.7%
E	Nandrolone Decanoate 50 mg 1 ml	inj	$1.74	800	$1,392.00	1.4%	96.1%
N	Cocarboxylase 50 mg 3 ml N3	inj	$1.25	1000	$1,250.00	1.3%	97.4%
E	Metamizole 50% 1 ml N10	inj	$0.30	2000	$600.00	0.6%	98.0%
V	Digoxin 0.25 mg N50	tab	$1.00	600	$600.00	0.6%	98.6%
E	Allylestrenol 5 mg N20	tab	$1.63	300	$489.00	0.5%	99.1%
E	Nitrofurantoin 100 mg N10	tab	$0.15	3000	$450.00	0.5%	99.6%
E	Chlordiazepoxide 10 mg N50	tab	$0.56	800	$448.00	0.5%	100.0%
TOTAL					**$97,167.00**	100.0%	

Step 5. Review the ABC/VEN-analyses results:

The hospital X spent $97,167 for purchases of drugs in 1995. When placing the drugs according to the VEN system, six of the 21 drugs were included in the category of (V)ital drugs (insulin, verapamil, cefotaxime, prednisolone, ampicillin, digoxin). Nine drugs were included in the category of (E)ssential drugs (isradipine, ranitidine, nystatin, metoclopramide, nandrolone, metamizole, allylestrenol, nitrofurantoin, chlordiazepoxide). The group of (N)on-essential drugs was represented by six drugs (bendazol, drotaverine, inosine, solcoseril, cocarboxylase).

The ABC analysis was conducted with the purpose of reducing expenditures and increasing effectiveness of drug utilization. This analysis showed that the largest portion of money, 79%, was spent for purchases of eight drugs (Class A-up to 80% of total costs). When analyzing the drugs from this class, it was found that it included both vital drugs (insulin, verapamil, and cefotaxime --22.2% of total budget spent), as well as non-essential drugs, (inosine, solcoseril, and drotaverine, representing 46.9% of budget). For the drugs from Classes B and C, 20.6% of the budget was spent. These classes also included vital drugs (prednisolone, ampicillin, and digoxin), essential drugs (nystatin, ranitidine, etc.), as well as non-essential drugs (bendazol and cocarboxylase).

The analysis shows the structure of drug expenditures in the hospital, and allows for introduction of reforms in drug purchasing policy, and for shifting budget funds for the purchase of vital drugs. By limiting the use of such ineffective drugs as solcoseril, inosine, and drotaverine, expenditures can be significantly reduced.

This example of ABC-analysis demonstrates that such an analysis may become an effective tool for selecting drug classes for the initial formulary list review, and for corrections in purchasing policy.

ANNEX THREE: DESIGNING A DUR EVALUATION: EXAMPLE OF FORMS TO USE

FORM 1: DESIGN TYPE AND SIZE OF DUR EVALUATION

Date: _____

Drug to be Evaluated: _____

Department or Location of Evaluation: _____

Type of Data Collection: _____ **prospective** ____ **concurrent** ____ **retrospective**

Planned Study Size: _____ **number of cases to collect** ***or***

_____ **number of days or weeks to collect**

Source of Data Elements: _____**Patient charts** _____**Laboratory ledgers**

_____**Insurance claim forms** _____ **other:** _____

Rationale for Performing DUR for this Drug:
(Check all that apply)

___ **ABC/VEN analysis**
___ **budget trend report**
___ **potential for adverse drug reaction**
___ **potential for interaction with drugs or food**
___ **drugs that caused problems in the past**
___ **cost**
___ **one of most frequently prescribed drugs (therefore error prone)**
___ **staff recommendation**
___ **other:**_____

FORM 2: ESTABLISH DUR CRITERIA AND DATA ELEMENTS TO COLLECT

Date: **Drug:** **Data collector's initials:**

	Patient Chart No.						
	Diagnosis						
	Age/Sex/Weight						
	Date Treated						
CRITERIA AND INDICATORS	**Threshold**	**Observed**					
Justification for Drug Being Prescribed: 1. 2.			Yes No	Yes No	Yes No	Yes No	Yes No
Process Indicators: 3. 4. 5. 6.			Yes No	Yes No	Yes No	Yes No	Yes No
Outcome Indicators: 7. 8.			Yes No	Yes No	Yes No	Yes No	Yes No

FORM 3: COMPILE SURVEY RESULTS

DRUG_____ DIAGNOSIS_____

DATE_____ TOTAL NO. ENCOUNTERS_____

CRITERIA AND INDICATORS	TOTAL NO. MET		TOTAL NO. THRESHOLD MET		SPECIFIC COMMENTS
	YES	NO	YES	NO	
Justification for Drug Being Prescribed:					
Process Indicators:					
Outcome Indicators:					
Other Indicators or Criteria:					
Percentage of Total Encounters:					

FORM 4: REPORT RESULTS OF DUR EVALUATION

Date of Evaluation: _____ to _____

Drug Evaluated: _____

Objective of Evaluation: _____

Cost Savings Attributable to Evaluation: _____

_____

Results of Data Analysis:

Conclusions:

Recommendations: (Interventions and Persons Involved)

Follow-up of Recommendations:

Date Reported to Formulary and Therapeutics Committee: _____

DUR Committee Person Responsible for Evaluation: _____

FORM 5: ESTABLISH CALENDAR FOR DUR EVALUATIONS

EVALUATION YEAR: _____

NAME OF DRUG OR EVALUATION	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC

P = PLANNED
C = COMPLETED
FP = FOLLOW-UP PLANNED
FC = FOLLOW-UP COMPLETED
U = UNPLANNED BUT DEEMED NECESSARY BY DUR COMMITTEE

ANNEX FOUR: PUBLISHED DUR CRITERIA FOR CEFTAZIDIME

ANNEX FOUR: PUBLISHED DUR CRITERIA FOR CEFTAZIDIME

The following DUR criteria for ceftazidime is adapted from, *Criteria for Drug Use Evaluation:* Volumes 1-4, ASHP, Bethesda, MD, 1989-1993.

CRITERIA AND INDICATORS
Justification for prescribing ceftazidime: 1. A culture and sensitivity test documenting *pseudomonad* infection 2. An indication of at least one of the following: (a) the invading organism is resistant to piperacillin but sensitive to ceftazidime and an amino glycoside (b) the invading organism is more sensitive to an amino glycoside and ceftazidime than piperacillin and amino glycoside
Critical indicators to consider when prescribing ceftazidime: 3. Appropriate cultures were obtained within 48 hours prior to initial ceftazidime dose 4. Complete blood count with differential was obtained within 48 hours prior to initial ceftazidime dose 5. Serum creatinine (SCr) or urine creatinine clearance (CrCl) was obtained within 48 hours prior to or 8 hours after initial ceftazidime dose 6. Liver function tests (aspartate aminotransferase) and alanine aminotransferase were obtained within 7 days prior to or 1 day after initial ceftazidime dose 7. No history of anaphylaxis or other immediate hypersensitivity reaction to penicillins or cephalosporins 8. Appropriate ceftazidime dosage for *adult* patients: (a) with uncomplicated urinary tract infection--250 mg IM or IV every 12 hours (b) with complicated urinary tract infection--500 mg IM or IV every 8 to 12 hours (c) with uncomplicated pneumonia or skin/skin structure infections--500 mg to 1 gram(g) IM or IV every 8 hours (d) with bone and joint infections--2 g IV every 8 hours *Exceptions* to these doses are when the patient underwent successful antibiotic desensitization, or if the patient has renal dysfunction 9. Appropriate ceftazidime dosage for *pediatric* patients: (a) for neonates of 2-4 weeks--30 mg/kg IV every 12 hours (b) for infants and children--25-50 mg/kg IV every 8 hours not to exceed 6 g/day *Exceptions* to these doses are when the patient has renal dysfunction 10. Appropriate ceftazidime dosage for renal dysfunction: (a) if based on creatinine clearance: for CrCl of 31-50 ml/min/1.73m²--1 g every 12 hours; for CrCl of 16-30 ml/min/1.73m²--1 g every 24 hours; for CrCl of 5-15 ml/min/1.73m²--0.5 g every 24 hours; and for CrCl <5 ml/min/1.73m², 0.5 g every 48 hours (b) if patient is in hemodialysis: 1 g loading dose, and 1 g after each dialysis session (c) if patient is in peritoneal dialysis: 1 g loading dose, and 500 mg every 24 hours *Exceptions* to these doses are when a physician consult recommends alternative dosage for a particular patient 11. Vital signs are monitored at least three times daily during ceftazidime therapy 12. White blood cell (WBC) count is monitored at least twice weekly during first week of ceftazidime therapy, and at least once weekly thereafter, if WBC count remains above normal range 13. SCr or urine CrCl is obtained at least twice weekly during ceftazidime therapy 14. Blood chemistry, 12-test profile, is monitored at least once weekly during ceftazidime therapy 15. Duration of therapy is 7-14 days or for 2 days after the signs and symptoms of infection have disappeared

CRITERIA AND INDICATORS

Complications that could occur during therapy with ceftazidime, and how to respond if the complication presents, as follows:

16. Anaphylaxis with difficulty breathing, wheezing, laryngeal edema, flushing, tachycardia, bronchospasm, and/or hypotension--treat symptomatically with epinephrine and/or antihistamine with or without supportive care, such as cardiopulmonary resuscitation, assisted ventilation and fluids; switch to other antibiotic; or discontinue ceftazidime
17. Cutaneous reaction with urticaria, angioedema, maculopapular eruptions, pruritus and/or Stevens-Johnson syndrome--treat symptomatically with antihistamine and/or corticosteroid if mild reaction; if severe reaction, discontinue ceftazidime and treat symptomatically with epinephrine and/or antihistamine with supportive care if necessary (cardiopulmonary resuscitation and assisted ventilation)
18. Superinfection with overgrowth of another organism like enterococcus, *Candida*, *Pseudomonas*, *Acinetobacter*--treat with alternate antibiotic for primary infection and initiate therapy for superinfection
19. Gastrointestinal effects like nausea, vomiting, diarrhea, abdominal cramping, gastritis, and/or abdominal pain--with mild reaction, decrease dosage and treat symptoms; with severe reaction, discontinue ceftazidime and use other antibiotic
20. Taste disturbances like metallic taste or loss of taste--depending on severity, either decrease dosage or switch to another antibiotic
21. Antibiotic-associated pseudomembranous colitis characterized by at least two of the following: fever, diarrhea, abdominal pain or ileus, proctoscopy or colonoscopy revealing yellow-white exudative plaques or pseudomembranes, biopsy showing histologic changes, positive culture for *Clostridium difficile*--discontinue ceftazidime and switch to other antibiotic
22. Phlebitis characterized by redness, warmth, pruritus, tenderness, edema, stiffness, and pain at injection site --treat by changing infusion site, apply heat or cold therapy, increase amount of diluent, change type of diluent, use larger gauge needle, alternate injection sites every 24 hours
23. Elevation in serum liver transaminase greater than two times the upper limit of normal--no treatment if elevated less than three times the upper limit of normal, just repeat transaminase test within 2 weeks; if elevated three or more times the upper limit of normal, discontinue antibiotic or switch to another antibiotic
24. Non-bleeding hematologic effects like neutropenia (count <1500/cu mm), leukopenia (WBC <500/cu mm), eosinophilia (count >500/cu mm), megaloblastic anemia, hemolytic anemia, or aplastic anemia--provide supportive care and monitor blood counts with differential analysis on a daily basis

Outcomes that can be measured which demonstrate successful drug therapy with ceftazidime:

25. Fever reduction of at least 1°C within 3 days of the first ceftazidime dose
26. Bacteriologic eradication as verified by negative cultures within 24 hours after discontinuation of ceftazidime
27. WBC count is within normal range

Although not included above, the criteria monograph lists additional exceptions to the indicator considerations and measurable outcomes.

ANNEX FIVE: EXAMPLES OF ESTABLISHED DUR CRITERIA ON DATA COLLECTION FORMS

EXAMPLE OF ESTABLISHED DUR CRITERIA ON DATA COLLECTION FORM FOR AMIKACIN

Date: **Drug: AMIKACIN** **Data collector's initials:**

	Patient Chart No.						
	Diagnosis						
	Age/Sex/Weight						
	Date Treated						
CRITERIA AND INDICATORS	**Threshold**	**Observed**					
Justification for Drug Being Prescribed:			Yes No	Yes No	Yes No	Yes No	Yes No
1. Serious infections caused by susceptible strains of aerobic gram-negative bacteria resistant to gentamicin and tobramycin	100%						
2. Suspected serious gram-negative infections acquired in the hospital with high resistance rates to gentamicin and tobramycin	100%						
3. In combination with an anti-*pseudomonad* penicillin when treating serious *pseudomond* infections	100%						
Process Indicators:			Yes No	Yes No	Yes No	Yes No	Yes No
4. Obtain serum creatinine prior to therapy or within 24 hours of initiation of therapy	100%						
5. Loading dose of 7.5 mg/kg (IV or IM) based on ideal body weight	100%						
6. Maintenance dosage range of 15 mg/kg/day ideal weight (exception: renal compromise)	100%						
7. Therapy changed to tobramycin, gentamicin, or other drug if culture and sensitivity indicates less expensive or more appropriate drug	100%						
Outcome Indicators:			Yes No	Yes No	Yes No	Yes No	Yes No
8. Clinical improvement noted in patient medical records	100%						
9. Fever reduction to normal within 72 hours	100%						

EXAMPLE OF ESTABLISHED DUR CRITERIA ON DATA COLLECTION FORM FOR IV AMINOPHYLLINE

Date: **Drug: AMINOPHYLLINE (INTRAVENOUS)** **Data collector's initials:**

	Patient Chart No.						
	Diagnosis						
	Age/Sex/Weight						
	Date Treated						
CRITERIA AND INDICATORS	**Threshold**	**Observed**					
Justification for Drug Being Prescribed:			Yes No	Yes No	Yes No	Yes No	Yes No
1. Shortness of breath, wheezing and dyspnea, acute status asthmaticus, or other evidence of bronchospasm after a failure to respond to epinephrine	100%						
2. Poor response to oral bronchodilators or inability of patient to take oral bronchodilators	100%						
Process Indicators:			Yes No	Yes No	Yes No	Yes No	Yes No
4. Theophylline serum level obtained prior to initiation of therapy in patients on oral theophylline drugs	100%						
5. Loading dose (use lean body weight): 6.25 mg/kg (IV) or 3 mg/kg IV if received theophylline in previous 24 hours	100% 100%						
6. Initial maintenance dosage (use lean body weight): (a) children 1-9 years: 1.0 mg/kg/hr (b) children >9 years (and adult smokers): 0.75 mg/kg/hr (c) adolescents and adults (non smokers): 0.5 mg/kg/hr (d) adults with congestive heart failure or liver dysfunction: 0.25 mg/kg/hr	100%						
7. Serum levels obtained and adjusted to maintain levels of 10 to 20 mcg/ml (1st level obtained after 24 hours of therapy)	100%						
8. Therapy changed to oral theophylline within 48 hours if patient able to take oral therapy (theophylline dose = 80% of aminophylline dose; this is a cost containment measure)	100%						
Outcome Indicators:			Yes No	Yes No	Yes No	Yes No	Yes No
9. Clinical improvement noted in patient medical records	100%						

EXAMPLE OF ESTABLISHED DUR CRITERIA ON DATA COLLECTION FORM FOR DIGOXIN

Date: **Drug: DIGOXIN** **Data collector's initials:**

	Patient Chart No.						
	Diagnosis						
	Age/Sex/Weight						
	Date Treated						
CRITERIA AND INDICATORS	**Threshold**	**Observed**					
Justification for Drug Being Prescribed:			Yes No	Yes No	Yes No	Yes No	Yes No
1. Congestive heart failure	100%						
2. Atrial tachyarrhythmias	100%						
Process Indicators:			Yes No	Yes No	Yes No	Yes No	Yes No
3. Determine following tests prior to therapy: serum creatinine, electrolytes, and electrocardiogram (low potassium levels may decrease threshold for toxicity)	100%						
4. Maintenance dose: 0.125 to 0.5 mg daily	100%						
5. Serum levels are drawn at least eight hours after an oral dose (preferably in the AM prior to scheduled dose for patients on maintenance therapy)	100%						
6. Serum levels are drawn if disease worsens or: (a) suspected non-compliance, confirmation of overdose or suspected toxicity (b) unstable renal function or change in renal function during therapy (c) possible interaction with other drug (e.g., quinidine, amiloride, calcium channel blocker, amiodarone, amrinone, thiazides, thyroid hormones)	100%						
7. Therapy is evaluated/adjusted for: anorexia, nausea, visual disturbances, agitation, nervousness, psychoses, and disrhythmias (ventricular, atrial and brady arrhythmias)	100%						
Outcome Indicators:			Yes No	Yes No	Yes No	Yes No	Yes No
8. Clinical improvement noted in patient medical records	100%						

EXAMPLE OF ESTABLISHED DUR CRITERIA ON DATA COLLECTION FORM FOR METAPROTERENOL

Date: **Drug: METAPROTERENOL** **Data collector's initials:**

	Patient Chart No.						
	Diagnosis						
	Age/Sex/Weight						
	Date Treated						
CRITERIA AND INDICATORS	**Threshold**	**Observed**					
Justification for Drug Being Prescribed:			Yes No	Yes No	Yes No	Yes No	Yes No
1. Symptomatic treatment of asthma and acute bronchospasm	100%						
2. Symptomatic management of chronic bronchospastic pulmonary diseases	100%						
Process Indicators:			Yes No	Yes No	Yes No	Yes No	Yes No
3. Use no longer than 24 hours in acute setting (IPPB, nebulized)	100%						
4. Nebulized inhalation solutions changed to inhalation aerosol when patient able to use self-therapy	100%						
6. Patient instructed on appropriate use of inhaler when on aerosol	100%						
7. Dosage reduced if side effects are bothersome or clinically evident: e.g., tachycardia, tremor, headache, nervousness, palpitation, hypertension, dizziness, nausea and vomiting	100%						
8. Caution is noted when administered concomitantly with beta agonists, sympathomimetics or with beta-blockers (may antagonize activity)	100%						
9. Dosage is adjusted or therapy discontinued in response to: adverse effects, drug interactions, poor response to therapy, or poor compliance to therapy	100%						
Outcome Indicators:			Yes No	Yes No	Yes No	Yes No	Yes No
10. Breathing improvement noted in patient medical records	100%						
11. Clinical improvement in pulmonary function (FEVI)	100%						

EXAMPLE OF ESTABLISHED DUR CRITERIA ON DATA COLLECTION FORM FOR USE OF ANTIBIOTIC IN SURGICAL PROPHYLAXIS

Date: **Drug: ANTIBIOTIC USE IN SURGICAL PROPHYLAXIS** **Data collector's initials:**

	Patient Chart No.						
	Diagnosis						
	Age/Sex/Weight						
	Date Treated						
CRITERIA AND INDICATORS	**Threshold**	**Observed**					
Justification for Drug Being Prescribed:			Yes No	Yes No	Yes No	Yes No	Yes No
1. Class of surgery: clean contaminated, dirty contaminated, ruptured, or gangrenous	100%						
2. Antibiotic on approved list for surgical prophylaxis	100%						
Process Indicators:			Yes No	Yes No	Yes No	Yes No	Yes No
3. Dose given only one time, and not more than 45 min. before incision	100%						
4. Antibiotic administered if surgery is prolonged, 4 or more hours later	100%						
5. Post operative doses specified for no more than 24 hours	100%						
6. Antibiotic change recommended due to:	100%						
(a) adverse reaction							
(b) decreased renal function							
(c) drug interaction							
(d) cost effectiveness increased							
(e) documented infection							
7. Nosocomial infection is documented prior to non-surgical prophylaxis use of antibiotic	100%						
Outcome Indicators: None							