GUIDELINES FOR THE IMPLEMENTATION OF A DRUG USE EVALUATION PROGRAM

PREFACE

This is the original edition of the Guidelines for the Implementation of Drug Use Evaluation. These Guidelines were developed as a tool to assist hospital pharmacists with the development and implementation of a drug use evaluation program.

1. SCOPE

1.1
These Guidelines are intended as a tool to develop and implement a Drug Use Evaluation (DUE) program.

2. DEFINITIONS

The following definitions are used in these Guidelines:

Concurrent Evaluation - evaluation and intervention, if necessary, are completed while the patient is undergoing therapy.

Criteria - predetermined elements of drug use against which aspects of quality, medical necessity, clinical and pharmacoeconomic outcome may be compared.[2] Criteria are easily measured (e.g., numerical or nominal decision point, yes or no answer, presence or absence of a specific condition, specific number).

Drug Use Evaluation (DUE) Program - a multidisciplinary, structured, ongoing program that uses predetermined standards to monitor and evaluate drug therapy. DUE should be outcome-oriented with the intent to assure safe and effective drug use.[4]

Drug Use Review (DUR) Program - a multidisciplinary, structured, ongoing system for improving the quality of drug use within a health care organization. It includes a mechanism for measuring the effectiveness of corrective actions.[1] One difference between Drug Use Review (DUR) and DUE is that DUE evaluates only qualitative aspects of drug use while DUR may be a quantitative or a qualitative evaluation. The other difference is that DUE is outcome-oriented while DUR is process-oriented.

Exceptions - a list of valid conditions which are exempt from the standard.[2]

Prospective Evaluation - evaluation and intervention, if necessary, are begun before the patient receives the first dose of the prescribed drug.[2,4]

Qualitative DUR - evaluation of drug use in a given health care environment against predetermined criteria and standards to assess the appropriateness of drug therapy.[2] It is a onetime event that provides limited feedback to staff.

Quantitative DUR - determination of quantities and types of drugs used during a defined period of time, by type of patient or prescriber.[1,3] It may be used as a budgetary indicator and for targeting drugs to be reviewed.

Retrospective Evaluation - evaluation and intervention, if necessary, are performed after the patient completes therapy.[2]

Standard - statement of expected level of performance (e.g., 0%, 100%).[2] When the data indicate a practice which differs from a criterion, it is reflected in the degree of compliance with the standard.[5]

3. RESOURCE REQUIREMENTS

3.1
The pharmacy department should plan for adequate resources for DUE, taking into account the following:
(a) number of drugs to be evaluated;
(b) number of criteria to be developed;
(c) absence or presence of a therapeutic controversy surrounding the subject;
(d) type of DUE study chosen;
(e) computerization of certain stages;
(f) delegation of certain tasks; and,
(g) number of records to be reviewed.

4. DRUG USE EVALUATION COMMITTEE

4.1
The mandate of a DUE committee is to:
(a) select the drugs and populations to be studied;
(b) develop explicit criteria and have them approved by the Pharmacy and Therapeutics (P & T) Committee;
(c) evaluate the records selected;
(d) suggest and participate in the implementation of corrective measures; and,
(e) verify their impact.

4.2
The members of the DUE committee must possess recognized expertise in pharmacology, a professional interest in the rational use of drugs, objectivity and impartiality, and must observe confidentiality in all circumstances.[6]

5. SELECTION OF DRUG(S)

5.1
In choosing drugs for evaluation, the following criteria must be considered based on clinical experience, relevant literature, and current knowledge:
(a) frequency of prescribing;
(b) level of risk to patients if not properly used; and,
(c) drugs known or suspected to be problem-prone.

6. DEVELOPMENT OF EVALUATION CRITERIA

6.1
Criteria shall be clear, concise and complete, so that they may be

applied consistently in different situations and by different persons. A criterion should describe one issue at a time. Criteria should reflect the optimal use of the drug and must be based on objective information. A consensus approach should be the goal; otherwise, the legitimacy of the DUE may be lost.[7,8]

6.2
An effective and productive way to develop explicit criteria is to use existing criteria published in the literature. However, it is important to ensure that published criteria are up-to-date and are applicable to the proposed study.

7. DETERMINATION OF THE PARAMETERS OF THE EVALUATION

7.1 Number of Records

7.1.1
The number of records to be studied should be a function of the resources available and the volume of use of the drug studied.[9] The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has recently established standards for the performance of DUEs which are[6]:

(a) if the average number of cases per quarter is more than 600, at least 5% of cases are reviewed; and,
(b) if the average number of cases per quarter is less than 600, at least 30 cases are reviewed.

7.2 Timeframe for Data Collection

7.2.1
A definite period of time should be selected for data collection. Prescribing patterns may change as a result of seasonal variations in the incidents of certain diseases or the publication of clinical studies and state-of-the-art review articles. For example, seasonal variations in the incidence of certain diseases or publication of clinical studies or state-of-the-art review articles which may alter prescribing patterns.[10,11] Since these factors cannot always be controlled, the analysis has to account for them in the discussion section of the report.

7.3 Type of Evaluation

7.3.1
Reviews may be retrospective, concurrent or prospective. (See Appendix C)

7.3.1.1
Retrospective evaluation implies no direct contact with the prescriber. It relies on data from the medical record and is after the fact. It is less time consuming and may be perceived as less aggressive by the prescriber.[1,3,4,12]

7.3.1.2
Concurrent and prospective evaluation both imply direct contact with the prescriber, use of ongoing collection of clinical data and are more time consuming. Only prospective evaluation allows immediate intervention on the medication order.[2,3,13,14]

7.3.2
Evaluation criteria should serve as a guide in choosing the data collection method. Clinical outcome criteria are best suited for a concurrent or prospective design. If general information on prescribing habits is needed to document that a problem exists, retrospective review is recommended. Usually, the more experience the institution has with DUE, the easier the evolution to prospective evaluation.[4,10,12,15]

8. APPROVAL OF THE DRUG USE EVALUATION

8.1
The selected target drug(s) and the parameters of the study should be approved by the P&T Committee of the facility. The head of the Quality Assessment Program should also be informed.[1,3,8,11,12,14,16-21]

9. DATA COLLECTION PROCESS

9.1
A data collection form should be developed, based principally on the explicit criteria. The form should not introduce bias by the data collector. The form should be tested and validated on a small number of cases. If necessary, improvement to the form can then be made.

9.2
The number of individuals involved in the data collection process should be restricted. This will decrease the amount of inter-individual variability in the data retrieved.[5]

10. COMPILATION OF DATA

10.1
Once data collection is complete, the data is organized to allow comparison with explicit criteria. The results of the study should be presented in the form of tables for ease of interpretation.

11. DATA ANALYSIS

11.1
Every discrepancy detected in compilation of data must be peer-reviewed in committee.

11.2
Results are analyzed to isolate usage problems and identify their most plausible cases. This analysis is done in committee (DUE or P&T Committee). Cost analysis should be done, at least in terms of cost avoidance calculations.

11.3
More sophisticated pharmacoeconomic studies, such as cost-effectiveness analysis, could be designed if resources are available.

12. REPORTING OF RESULTS

12.1 Formulation and Approval of Recommendations and Action Plan

12.1.1
Recommendations should be developed to resolve the drug use problems detected.[11] As a first step, the focus should be educational. Restrictive measures should not be used until educational ones have failed. Recommendations should be part of an overall action plan which should identify the individuals responsible for implementing the recommendations, the time-frame and the follow-up required.

12.1.2
The action plan must be ratified by the P&T Committee and the Medical Advisory Committee (MAC) before it is implemented. Prior to this approval, heads of department and medical services affected by the results should be consulted and involved in the preparation of the action plan.

12.1.3
The plan should describe the follow-up interventions to be made in order to change prescribing habits. The most effective interventions are step-wise and allow prescribers to read about the problem, hear about it and discuss it with peers or opinion leaders. Targeted educational meetings should be organized with the physicians concerned. Acceptance of the recommendations is facilitated by involvement of the physicians at this level.[4,6,10,17]

12.2 Preparation and Submission of Reports

12.2.1
Regular progress reports on each study should be submitted to the members of the P&T Committee. In addition, an annual report summarizing the year's activities should be prepared.[3,8,11,12,14,17-24] These reports should subsequently be submitted to the Medical Advisory Committee (MAC) and to the relevant department heads and the committee responsible for quality assessment.

12.2.2
Progress reports should be concise, briefly describing the DUE Committee's activities, the methodology used, the results of the study (in the form of tables), the analysis and discussion of these results and the resulting action plan.

13. FOLLOW-UP ON RECOMMENDATIONS

13.1
In order to assess improvement in the quality of drug use, the action plan should define ways to evaluate the impact of the recommendations made. Usually, it is advisable to repeat the evaluation 3 to 12 months after the recommendations have been made, depending on the type and frequency of the problems identified.[8,10,12]

14. REFERENCES

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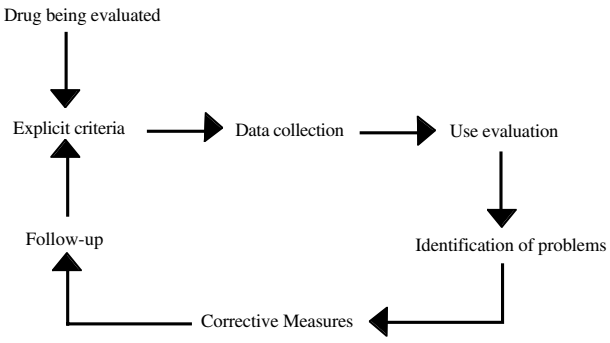
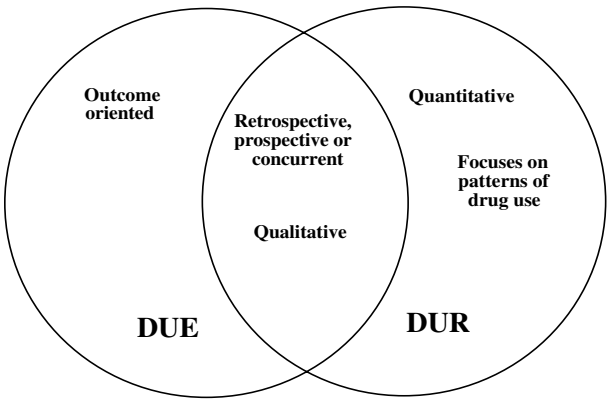
APPENDIX A: STAGES OF A DRUG USE REVIEW[3]



NOTE: *This appendix is not a mandatory part of this standard but is written in mandatory language to accommodate its adoption by anyone wishing to do so.*

APPENDIX B: FEATURES OF A DRUG USE EVALUATION AND DRUG USE REVIEW



The area of overlap represents features shared by both DUE & DUR.

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APPENDIX C: THE RELATIONSHIP BETWEEN THE METHOD OF DATA COLLECTION AND DRUG USE

Selection and ordering of medication	Administration of first dose	Administration of subsequent dose	Discontinuation of medication

Prospective review

Concurrent review

Restrospective review

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APPENDIX D: RESOURCES FOR DEVELOPING DRUG USE CRITERIA

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