

Medication Use Evaluation (MUE) Toolkit

**VA National
Research Steering
Committee**

VA PBM SHG – VACO



Date: September 2007

TABLE OF CONTENTS

<i>Preface</i>	4
I. What is the Purpose of the MUE Toolkit?	5
II. What is the Definition of an MUE?	5
III. What are the Roles and Responsibilities of the National and Local MUE Subcommittees?	6
A. National MUE Subcommittee’s Responsibilities	6
B. Local MUE Subcommittee’s Responsibilities	8
IV. What is the Scope of an MUE Program?	9
V. What are the Objectives of an MUE Program?	10
A. Promote Optimal Medical Therapy	10
B. Prevent Medication-related Problems/Improve Patient Safety	10
C. Evaluate Effectiveness of Medication Therapy	10
D. Enhance Opportunities to Assess Value of Innovative Medication-Use ... Practices	11
E. Minimize Cost	11
F. Meet or Exceed Quality Standards	11
VI. What are the Steps to the MUE Planning Process?	12
A. Establish Organization Authority	12
B. Select Medications and Medication-Use Processes for Evaluation	12
C. Examine Potential Indicators Suggesting Need for an MUE	13
D. Establish Criteria or Protocol for Specific Medications and Medication-Use Processes	14

TABLE OF CONTENTS (CON'T)

E. Collaborate with Key Stakeholders About Objectives and Expected Benefits	14
F. Educate on Criteria or Protocol for Specific Medications and Medication-Use Processes	14
VII. What are the Steps to Executing the MUE Program?	15
A. Formulate MUE Design	15
B. Investigate Need for IRB Approval	15
C. Initiate and Conduct the MUE	16
D. Develop and Implement Improvement Processes Based on MUE Findings	16
E. Assess Effectiveness Of Actions Taken and Document Improvements	16
F. Regularly Assess Effectiveness of MUE Process Itself and Make Improvements	16
VIII. What is the Anticipated Commitment to Complete an MUE?.....	17
IX. References	18
Appendix I Flow Chart of National MUE Committee and Local MUE Subcommittee Interface	19
Appendix II Template for National MUE Clearinghouse Submission.....	20
Appendix III Medication Use Evaluation Template.....	21
Appendix IV Basic Elements of a Medication Use Evaluation Protocol for IRB Submission	23

PREFACE

Dear Clinical Coordinators, Chiefs of Pharmacy, Residency Directors, and Formulary Management Personnel,

We would like to introduce the first version of the VA Pharmacy Benefits Management Strategic Healthcare Group (PBM-SHG) National Medication Use Evaluation (MUE) Toolkit. This toolkit was designed for individuals, such as yourselves, who are faced with the tasks of ongoing management of processes designed to ensure that drugs are used appropriately, safely, and effectively. This toolkit will provide specific resources to develop, implement, and measure well-designed MUE programs, as well as provide resources for corroboration between the National MUE Subcommittee and Local MUE Subcommittees. Organized as a set of user questions, the toolkit represents step-by-step recommendations and resources for managing an MUE program at your VA Medical Center and provides a forum for the exchange of information between Local and National MUE Committees, as well as among the Local Subcommittees themselves. We hope you will find this product practical and resourceful in meeting your pharmacy quality assurance and improvement needs.

Sincerely,

Muriel Burk, Pharm.D

Clinical Pharmacist Specialist

National MUE Program Director/Co-Chair National MUE Subcommittee

VA PBM SHG VACO Outcomes Research/Center for Medication Safety

1st Ave & Cermak Road. Bldg 37, Rm 139.

Hines, IL 60141

Muriel.Burk@va.gov

Dorothy Jenrette, Pharm.D., BCPS

Clinical Pharmacy Coordinator and Residency Director/Co-Chair National MUE Subcommittee

Ralph H. Johnson VA Medical Center

109 Bee Street (119)

Charleston, SC 29401

Dorothy.jenrette@va.gov

Mary Beth Low, Pharm.D.

Clinical Pharmacy Specialist, Pharmacoeconomics/Co-Chair National MUE Subcommittee

VISN 10 PBM / Louis Stokes Cleveland VAMC

10701 East Boulevard

Pharmacy 119(W)

Cleveland, OH 44106

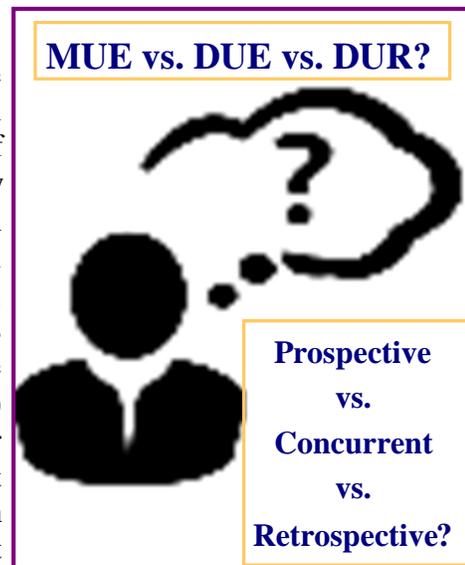
Mary.Low@va.gov

I. What is the Purpose of the MUE Toolkit?

The purpose of this toolkit is to provide guidance in establishing both national and facility operational plans for Medication Use Evaluations (MUE) within the VA health care system. It will describe and illustrate the roles of the VA PBM National MUE Subcommittee and its interface with Local MUE Subcommittees. The toolkit will outline the processes that aim to identify, resolve, and prevent actual and potential medication-related problems that could interfere with achieving optimum patient outcomes from medication therapy.¹

II. What is the Definition of an MUE?

A Medication Use Evaluation is a performance improvement method that focuses on evaluating and improving medication-use processes with the goal of improving patient outcomes.¹ The terminology referring to these processes has varied over time and in different settings. The term Drug Use Evaluation (DUE) has been used to indicate a prospective review, while the term Drug Utilization Review (DUR) has been used to indicate a retrospective review. The Academy of Managed Care Pharmacy (AMCP) believes that DUE is the most common designation for processes of prospective, retrospective, and concurrent medication review in the health care setting.² In contrast, the nomenclature espoused by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the American Society of Health-System Pharmacists (ASHP) is Medication Use Evaluation (MUE). MUE may be applied to a medication or therapeutic class, disease state or condition, or a medication-use process (ordering and transcribing, preparing and dispensing, administration, and monitoring).



The following provides a description for the various types of MUE:

A. Prospective MUE

Prospective review involves evaluating a patient's planned drug therapy *before* a medication is dispensed and allows for identification and resolution of problems before the patient has received the medication. Pharmacists routinely perform prospective reviews in their daily practice by assessing a prescription medication's dosage and directions and reviewing patient information for possible drug interactions or duplicate therapy.

CHAPTER 3

MUE: ROLES AND RESPONSIBILITIES OF NATIONAL AND LOCAL MUE SUBCOMMITTEES

B. Concurrent MUE

Concurrent review is performed *during* treatment and involves the ongoing monitoring of drug therapy to ensure positive patient outcomes. This provides the pharmacist with the opportunity to alert providers to potential problems and to intervene in areas such as drug-drug interactions, duplicate therapy, over or underutilization, and excessive or insufficient dosing. This type of review allows therapy for a patient to be altered if necessary.

C. Retrospective MUE

Most MUEs fall into the retrospective review category. A retrospective MUE is the simplest to perform since drug therapy is reviewed *after* the patient has received the medication. A retrospective review may detect patterns in prescribing, dispensing, or administering drugs to prevent recurrence of inappropriate use. In retrospective MUEs, patient medical charts or computerized records are screened to determine whether the drug therapy met approved criteria.

III. What are the Roles and Responsibilities of the National and Local MUE Subcommittees?

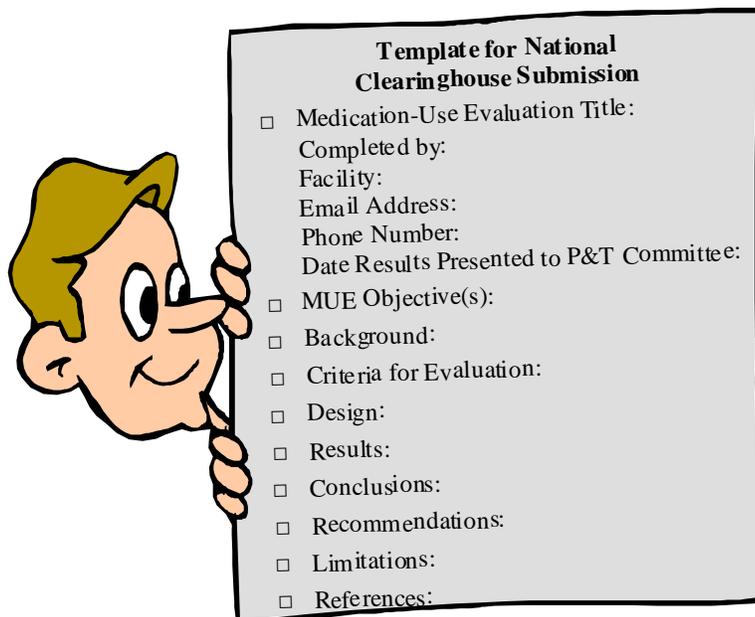
The success of a formalized MUE program is largely dependent on the coordination of efforts between several working groups that comprise the VA organizational body. MUEs are conducted at the local VA facility level as well as at the national level. Thus, there are two general types of MUE governing bodies that exist within VA: 1) The National MUE Subcommittee formed as a subcommittee of the National Research Steering Committee (RSC) in July of 2006; and 2) the Local MUE Subcommittee. Appendix I illustrates the interface between the National MUE Subcommittee and Local MUE Subcommittees, as well as the channels of communication that exist among other national groups.

A. National MUE Subcommittee's Responsibilities

1. Manage National Multi-center MUE programs

- a. Identify medication or therapeutic class, disease state or condition, or medication process to be examined as national multi-site MUE projects. These may stem from concerns that arise from the VHA Clinical Pharmacist electronic mailgroup, VISN Formulary Leaders (VFL) discussion, PBM/MAP (Medical Advisory Panel) discussion, or VA-wide therapeutic interchanges that require particular monitoring or multiple sites identifying similar medication issues.
- b. Identify and/or solicit sites for participation in national multi-site

- MUE projects.
- c. Work collaboratively with local VAMCs to collect, analyze, and evaluate patient-specific data to identify, resolve, and prevent medication-related problems.
 - d. Serve as liaison with VA Central Office for conducting national multi-site residency MUE projects.
 - e. Ensure that data privacy and security standards are complied with during data abstraction, inter-facility transfer, and analysis.
 - f. Acquire IRB approval for multi-site projects through Hines VAMC R&D and IRB Committees.
2. Serve as MUE resource for VAMCs nationwide
 - a. Provide up-to-date information on MUE requirements for regulatory purposes.
 - b. Provide guidance on MUE processes (e.g. MUE toolkit).
 3. Serve as clearing house for local MUEs
 - a. Maintain current electronic online listing of local MUEs and compilation of results.
 - b. Delineate which MUEs pertain to medication or therapeutic classes for which national criteria for use or guidance exist.
 - c. E-mail Contact for all submissions: Muriel.Burk@va.gov
 - d. Format for submission should follow template provided in Appendix II.



4. Report to National Research Steering Committee (RSC)
 - a. Present recommendations for national MUE projects.
 - b. Present results, conclusions, and recommendations of national MUE projects.
 - c. The National RSC is under the direction of the VA PBM and Center for Medication Safety, with collaborative efforts with the MAP and VFL Group.

B. Local MUE Subcommittee's Responsibilities

1. A collaborative, multi-disciplinary group including a prescriber, pharmacist, nurse and other ancillary services as deemed necessary contribute unique perspective to the MUE process. Chaired by the Clinical Coordinator for Pharmacy Service or his/her designee, this subcommittee will help guide the facility MUE process.
2. Work collaboratively with the facility's P&T Committee to identify potential areas where medication processes can be enhanced and make recommendations to optimize patient safety and outcomes.
3. Review each MUE design prior to implementation and review the results at the conclusion of the MUE before presentation to the P&T Committee.
4. Make recommendations to the facility's P&T and Medical Executive Committees based on the MUE findings; request Pharmacy Service to modify policy or procedures; recommend actions to other governing bodies of the Medical Center; make suggestions for conducting follow-up MUE if necessary.
5. Serves as an MUE resource to the national MUE Subcommittee via the Subcommittee Chairperson.
6. Acquire IRB approval when collaborating with the National MUE Subcommittee on a multi-site projects due to intent to publish results outside of VA.

IV. What is the Scope of an MUE Program?

A. Quality Assurance and Quality Improvement

An MUE program applies continuous quality improvement (QI) methods to the drug use process with an emphasis on improving patient outcomes. MUE should be a part of every VAMC's overall quality assurance (QA) program.

B. Formulary System Management Technique

An MUE program can also be considered a formulary system management technique by examining compliance with, deviations from, and effects of, national and local formulary decisions.

C. Research and Publication (IRB approval)

Although not inherent to its purpose, an MUE may sometimes fall within the scope of research when it seeks to answer a research question or confirm a hypothesis. In such cases, or in the event the intent is to share the results of the MUE with the general scientific and healthcare community, review, oversight, and approval from the Institutional Review Board (IRB) and Research and Development (R&D) committees become necessary. This is based on the scope outlined in the VHA Handbook 1108.04 Section 4.a(5) (Oct. 14, 2005).

*The IRB Committee at VA facilities (or their designated University affiliate) may conduct an expedited review of QI projects when it has been determined that the project incurs no more than minimal risk to the patient, or when previously approved research requires only minor changes in accordance with 38 CFR §16.110. This is essential to allow publication and dissemination of the results outside of VHA settings. **NOTE:** This requirement includes approved pharmacy resident research projects.*

Moreover, the majority of peer-reviewed journals require a statement regarding Institutional Review Board approval upon submission of a manuscript.

V. What are the Objectives of an MUE Program?

The following objectives have been adapted from the ASHP Guidelines on Medication Use Evaluation.

A. Promote optimal medical therapy

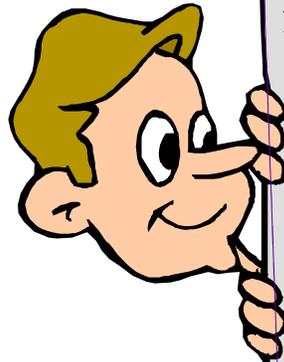
MUE is often conducted in conjunction with pre-established guidelines or criteria for use of certain medications. By measuring prescribing practices against evidence-based standards, the facilities will be able to promote prescribing that is consistent with evidence-based medicine, and thereby ensure that the patient is receiving optimal therapy. Implementing and measuring the impact of pre-established criteria may also result in standardization and improvements in the medication-use processes.

B. Prevent medication-related problems and improve patient safety

MUE can be used as a problem-identification tool when evaluating a patient's experience following prescribing of a drug. As such, problems can be identified and solutions constructed to prevent medication problems in a similar patient population. Areas for further education of healthcare professionals may be identified through this process as well.

C. Evaluate the effectiveness of medication therapy

Although all FDA-approved drugs have been reviewed for efficacy, the effectiveness of approved medications remains to be established in real-world experiences. Post-marketing studies are expensive and not carried out for all FDA-approved drugs. MUE provides a practical means for evaluating a drug's effectiveness, taking into account the practice environment, architecture of the VA healthcare system, various patient-specific factors, and pharmacoeconomic issues.



Objectives of an MUE Program

- Promote optimal medical therapy
- Prevent medication-related problems and improve patient safety
- Evaluate the effectiveness of medication therapy
- Enhance opportunities to assess the value of innovative medication-use practices
- Minimize costs of medication therapy
- Meet or exceed internal and external quality standards

- D. Enhance opportunities, through standardization, to assess the value of innovative medication-use practices from both patient-outcome and resource-utilization perspectives

Standardization in medication ordering and transcribing, preparing, dispensing, administration, and monitoring has widely been used to improve patient safety, prevent adverse medication events, or improve resource utilization. Examples may include standardized drug concentrations, list of abbreviations, order sets, templates, specialized drug consults, and monitoring clinics. MUE provides the opportunity to evaluate the outcome of standardized processes in the VA healthcare system.

- E. Minimize costs of medication therapy

Medication costs apart from the costs associated with drug acquisition, storage, and administration need to be calculated into overall cost minimization initiatives. However, full economic analyses are often beyond the scope of an MUE project. Nevertheless, it is reasonable to acknowledge that when medications are selected and managed optimally from the outset, the costs of complications and wasted resources are minimized, and overall costs are decreased.

- F. Meet or exceed internal and external quality standards (e.g., professional practice standards, accreditation standards, or government laws and regulations).

While MUE is useful in accomplishing the previously stated objectives, the minimum driving force behind the execution of an MUE is to fulfill quality standards imposed upon all healthcare organizations by accrediting bodies such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). JCAHO Standard MM.8.10 indicates that the medical center evaluates its medication management system which includes: 1. The medical center evaluates its medication management system for risk points and identifies areas to improve safety; 2. The medical center acts to implement improvements; 3. The performance of new and modified medication management processes is measured; and 4. The medical center uses information from data analysis to identify subsequent changes to improve its medication management system.³

CHAPTER 6
STEPS TO THE MUE PLANNING PROCESS

VI. What are the Steps to the MUE Planning Process?

The following steps to the MUE process have been adapted from the ASHP Guidelines on Medication Use Evaluation and serve to guide the organization's MUE program.¹



Steps in MUE Planning

- Establish Organization Authority
- Select Medications and Medication - Use Processes for Evaluation
- Examine Potential Indicators
- Establish Criteria or Protocol
- Collaborate with Key Stakeholders
- Educate on Criteria or Protocol

A. Establish organizational authority

1. The National MUE Subcommittee is a subcommittee of the PBM Research Steering Committee (RSC). Recommendations are approved by the VA PBM Center for Medication Safety and presented to the PBM/MAP and VFL Committees.
2. The Local MUE Subcommittee is generally a subcommittee of the Local P&T or Medication Management Committee. Recommendations are approved by the P&T or Medication Management Committee which has the overall responsibility for the medication-use processes of the medical center.

B. Selecting medications and medication-use processes for evaluation

The following list identifies medications or medication-use processes which may be selected for evaluation.

1. The medication is known or suspected to cause adverse reactions, or it interacts with another medication, food, or diagnostic procedure in a way that presents a significant health risk.
2. The medication is used in the treatment of patients who may be at high risk for Adverse Drug Reactions (ADRs).
3. The medication-use process affects large number of patients or the medication is frequently prescribed.

4. The medication or medication-use process is a critical component of care for a specific disease, condition, or procedure.
5. The medication is potentially toxic or causes discomfort at normal doses.
6. The medication is most effective when used in a specific way.
7. The medication is being considered for national formulary retention, addition, or deletion by the VHA PBM.
8. The medication or medication-use process is one for which suboptimal use would have a negative effect on patient outcomes or system costs
9. Use of the medication is costly.
10. The medication has a high potential for misuse (complexities in dosing, administration, titration, etc).
11. The medication is identified as a national VA cost avoidance initiative.
12. Implications of therapeutic interchanges/conversions.

C. Examine potential indicators suggesting the need for an MUE

Certain indicators, events, or flags may be used to identify potential opportunities to improve medication use. Indicators may include:

1. Adverse medication events, including medication errors, preventable adverse drug reactions, and toxicity.
2. Signs of treatment failures, such as unexpected readmissions and bacterial resistance to anti-infective therapy.
3. Pharmacist interventions to improve medication therapy, categorized by medication and type of intervention.
4. Non-formulary medications used or requested.

5. Patient dissatisfaction or deterioration in quality of life.
- D. Establish the criteria or protocols for specific medications and/or medication-use processes for which the MUE will be conducted
 1. Criteria should be developed to measure the safety, appropriateness, timeliness, continuity, efficiency, and effectiveness of medication use.
 2. Criteria must be based on local or national guidelines, published standards, primary literature, local policy or other accepted standard. When criteria are not available, work collaboratively with appropriate prescribers to develop criteria for use or processes for effective medication use.
 3. Objective criteria should reflect current knowledge, clinical experience, and relevant literature.
 - E. Collaborate with key stakeholders about objectives and expected benefits of the MUE to be conducted
 1. Present MUE Criteria to the healthcare providers concisely.
 2. Solicit comments from the staff and incorporate when appropriate into the MUE design.
 - F. Educate on the criteria or protocols for specific medications and medication use processes for which the MUE will be conducted.
 1. Disseminate criteria for use, PBM guidances, medical center procedures in advance of performing the MUE. Healthcare providers must be aware of the criteria for evaluation and the standard of practice expected before an MUE can evaluate the use of specific medications or effectiveness of medication use processes.
 2. Establish mechanisms for communication among health care professionals

VII. What Are the Steps To Executing the MUE Program?

A MUE Template (Appendix III) provides a step-by-step approach to guide the MUE author in the development and implementation of the MUE.

A. Formulate the MUE design

1. Prospective vs. retrospective vs. concurrent
2. Identify the setting: Inpatient vs. Outpatient
3. Determine data gathering capabilities (chart review, computerized database search)
4. Evaluate elements of the medication's use. These elements may include:
 - Appropriate indication (primary criteria)
 - Appropriate dosage (process criteria)
 - Appropriate duration of therapy (process criteria)
 - Appropriate labs or other measure monitored (process criteria)
 - No contraindication for use (process criteria)
 - Adverse effects found while on the drug (outcome criteria)
 - Known drug interaction with other drugs prescribed for the patient (process criteria)
 - Did the patient's treated condition improve as a result of the drug's use? (outcome criteria).
5. Write MUE protocol (A sample of the basic elements of a database/chart review protocol for IRB submission can be found in Appendix IV).

B. Investigate need for Institutional Review Board (IRB) and Research and Development (R&D) Approval

1. If the intent is to only share the findings within VA, local facility P&T Committee approval should suffice.
2. If the intent is to share the findings outside of VA (e.g., poster presentation, article publication), or to conduct the MUE as part of a VA national multi-site project or as a resident's research project, approval from local human subjects and research & development committees will be necessary. The intent of such projects is to submit for publication outside VA.

3. Discuss project with local IRB and R&D representative to determine actions necessary and route of approval.

C. Initiate and Conduct the MUE

1. Collect data
2. Analyze the data
3. Formulate conclusions and recommendations
4. Present completed MUE to the MUE Subcommittee and P&T Committee
5. Disseminate results

D. Develop and implement improvement processes based on MUE findings

1. Involve key stakeholders in implementing process changes that evolve from the MUE.
2. Identify multi-faceted approaches to solving medication related problems (Newsletters, e-mails, pocket cards).
3. Create reminder dialogs that mirror PBM guidelines.
4. Use CPRS to generate note text and orders. Restrict order entry.

E. Assess effectiveness of actions taken and document improvements

1. Document actions taken and define measures and timeframe for re-evaluation in the future.
2. Incorporate improvements into criteria, protocols, etc.
3. Repeat cycle of planning, evaluating, and action taking for ongoing improvement in medication use process.

F. Regularly assess effectiveness of MUE process for needed improvements

1. Modify the initial actions taken if the effectiveness of these actions are not noted upon re-evaluation.

VIII. What is the Anticipated Commitment to Complete an MUE?

MUE is an ongoing process that can take place daily in the medication process. The steps involved with MUE can vary in time. Much of the time it takes to complete an MUE depends on how much time the author has to commit to the process, what types of criteria are used to stage the MUE, how data collection is to be accomplished and how quickly data can be analyzed. Certainly if established criteria for use have already been developed or if monitoring parameters are well defined, the development of the design may only take a short time. If criteria for the MUE depend on collaboration amongst prescribers, then development of the design may take longer and could be more rigorous. The use of the VHA PBM CFU's is a great resource.

- Plan for 2-4 weeks for design development. Time for data collection may vary based on the method used. Chart review is often needed and can be labor intensive. Database searches have limitations but can provide a faster mode of data collection if available.
- If IRB approval is necessary, the process may take 6-10 weeks, depending on the need for revisions and tabling due to concerns with design and/or human subjects protection issues.
- Depending on the author's time availability, plan 4-6 weeks for data collection. Data collection is often the most time consuming part of MUE. When formulating the design and data collection, be sure to capture data in a way that is easy to analyze, count, display and describe. It is better to have captured the data than to discover that it needed to be collected.
- Plan 2-4 weeks for analysis and presentation formatting. Analysis of results is often the exciting part of evaluation.

Overall, the MUE process will take as long as one is able to commit. Remember the importance of why the MUE is being performed and that will help set the timeline for the project.



General Anticipated Time Commitments

- Design and development: 2 – 4 weeks
- IRB review and approval (if necessary): 6 – 10 weeks
- Data collection: 4 – 6 weeks
- Analysis and presentation: 2 – 4 weeks

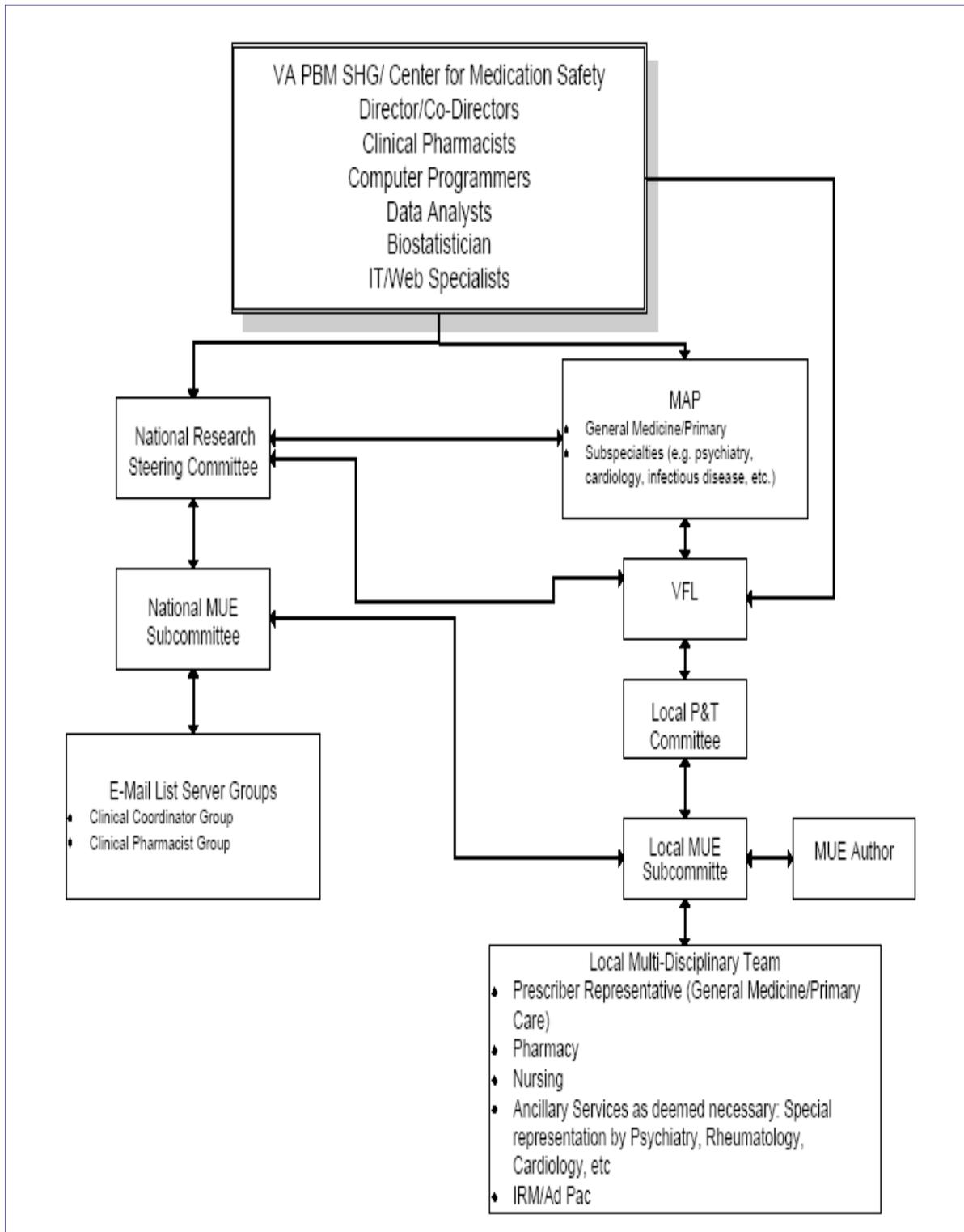
CHAPTER 9
REFERENCES

IX. References

1. The American Society of Health-Systems Pharmacists. ASHP guidelines on medication-use evaluation. *Am J Health-Syst Pharm.* 1996; 53: 1953-5.
2. Academy of Managed Care Pharmacy. Concepts in managed care pharmacy series. *Pharmaceutical Care.* 1997.
3. Joint Commission on the Accreditation of Healthcare Organizations. 2006 comprehensive accreditation manual for hospitals. Oakbrook Terrace (IL): Joint Commission on the Accreditation of Healthcare Organizations; 2006.

APPENDIX 1

NATIONAL MUE SUBCOMMITTEE AND LOCAL MUE SUBCOMMITTEE INTERFACE



**APPENDIX II
TEMPLATE FOR NATIONAL MUE CLEARINGHOUSE SUBMISSION**

Medication-Use Evaluation Title:

Completed by:

Facility:

Email Address:

Phone Number:

Date Results Presented to P&T Committee:

MUE Objective(s):

Background:

Criteria for Evaluation:

Design:

Results:

Conclusions:

Recommendations:

Limitations:

References:

(Please limit entire submission to 1-2 pages)

**APPENDIX III
MEDICATION USE EVALUATION TEMPLATE**

Medication-Use Evaluation Title:

Completed by:

Medical Staff Collaborator:

Date Design Presented to MUE Subcommittee:

Date Design Presented to P&T Committee:

Date Results Presented to MUE Subcommittee:

Date Results Presented to P&T Committee:

Objective(s):

What are the objective(s) of the evaluation?

Background:

What is the current medication use situation being evaluated?

Define the hypothesis and the rationale for the MUE.

What is the baseline performance? If no current performance is available as a baseline measure, consider what “performance” or “usage” has helped to identify the need for this MUE.

Criteria for Evaluation:

Define the criteria being used for the evaluation.

Where was the criteria developed (ie. local or national)?

Use referenced criteria as much as possible.

Define a threshold and the acceptable performance level expected.

Design:

In detail, define the data that will be collected to evaluate the MUE criteria.

Include how the data will be obtained (ie. chart review of VISTA/CPRS patient records, database search)

Define the timeframe for data collection or date range for which historical data will be captured if appropriate

Identify patient selection: who will be reviewed (ie. all active patients versus all patients, active prescriptions versus all prescriptions)

Include: Indications for Use? (by ICD-9 code or chart documentation?)

Prescription Characteristics: prescriber, clinic, dosing, length of therapy?

Measures of Efficacy

Track adverse drug reactions?

Tolerability? Side Effects?

Safety?

Drug Monitoring? (obtainment of appropriate labs or other monitoring

APPENDIX III (CONT)

MEDICATION USE EVALUATION TEMPLATE

parameters like BMI, blood pressure, etc)

Outcome criteria – identify objective parameters for evaluation of improvement, compliance with criteria

References:

Cite any references used to define the MUE.

Use the PBM Monographs, criteria for use, clinical guidelines, local criteria, published consensus statements, etc.

Results:

Data collection period: how long did it take to obtain the data?

Number of charts reviewed:

Number of charts included in MUE:

Provide the results on the parameters defined in the Design of the MUE.

Best to provide descriptive information in outline format and/or through charts and graphs.

Conclusions:

What conclusions can be made from the data collected?

What are the answers to the objectives defined at the beginning of the MUE?

Was there anything additional that was surprising?

Limitations:

What was difficult to ascertain during data collection?

Were there any unexpected challenges in the process of analysis?

Was there data that was not obtainable?

Recommendations:

What interventions can be made to improve the medication use process?

Identify specific actions that will impact the results/conclusions identified.

Identify a plan for reassessment of performance to determine if intervention was successful.

What is a reasonable timeframe for follow-up?

APPENDIX IV

BASIC ELEMENTS OF A DATABASE/CHART REVIEW PROTOCOL FOR IRB SUBMISSION

Adapted from Office for Human Research Protections (OHRP) Instructions for
Preparing a Database/Chart Review Study*

1. PURPOSE AND BACKGROUND

- ___ a. Brief references to literature and statements of the problem, purpose of the study, research question (and hypothesis if appropriate)
- ___ b. Relevance and importance of the problem stated
- ___ c. Justification for study involving humans
- ___ d. Specific aims of the research: state concisely and realistically what the research is intended to accomplish.
- ___ e. Background: briefly state the background of the study. Include a critical evaluation of existing knowledge, and specifically identify the gaps which the project is intended to fill.

2. STUDY DESIGN

- ___ a. Type of study design
- ___ b. Principle variables or outcome measures stated

3. SUBJECTS

- ___ a. Subjects defined and subject sampling method described
- ___ b. Number, reason for choosing this sample size
- ___ c. Source of subject population (i.e., clinic, private practice, general population)
- ___ d. Criteria for inclusion and exclusion
- ___ e. How will subjects be identified for study inclusion? By review of medical records or hospital database, advertisement, previous research participation?
- ___ f. Will your method of identification and/or recruitment violate subjects expectations of confidentiality regarding their medical records or history in ANY way?
If yes, how are you addressing the issue?
If no, how are you assuring this?

4. METHODS

- ___ a. Methods clearly described
- ___ b. Validity and reliability of measurement tools addressed
- ___ c. Potential biases or problems identified and addressed

5. DATA ANALYSIS

- a. If the study is designed to test a hypothesis, sample size derivation explained and appropriate power issues addressed
- b. Specific statistical analysis methods stated and appropriate
- c. Dependent and independent variables stated or variables to be analyzed stated

6. POTENTIAL BENEFITS

- a. Benefits to the individual subjects and/or parent, if any.
- b. Benefits to the population from which the subject is drawn
- c. Benefits to science, society, humanity in general

7. POTENTIAL RISKS

- a. Psychological, social, physical, economic, violations of normal expectations

8. PRECAUTIONS TAKEN TO MINIMIZE RISKS

- a. If confidentiality is an issue, specify how it will be managed, i.e., coding procedures; storage of and access to identifying data; when data will be destroyed.
 - Please note that management of risks does not change “risk” classification to “no risk.”

9. OTHER INVESTIGATORS

- a. Will there be other investigators involved in the study, other than those you have listed on the application form? If yes, how will you assure they are qualified and trained to participate as an investigator?

10. INVESTIGATOR QUALIFICATIONS AND EXPERIENCE

Send one copy each of C.V./resume for all investigators to the IRB Office.

11. INSTRUMENTS (attach all questionnaires, test batteries, etc.)

- a. How will this information be stored to assure limited access?
- b. Will any subjects identifiers be stored separately?

APPENDIX IV (CONT)

BASIC ELEMENTS OF A DATABASE/CHART REVIEW PROTOCOL FOR IRB SUBMISSION

12. CONSENT FORM

- ___ a. A sample consent form and Assent form are almost always available at every Research Office.

- ___ b. Fill out the Verification of Consent Procedures form and include it in your package.

* http://www.hines.med.va.gov/research/forms/OHRP_protocol.doc