The purpose of this booklet is to provide guidance in establishing, national, provincial and facility operational plans for Medicine Use Evaluations (MUE) within the health care system. It will describe and illustrate a proposed role for an MUE Subcommittee and its interface with the provincial PTC in line with National Core Standards. This booklet proposes a process that aims to identify, resolve, and prevent actual and potential medicine-related problems that could interfere...
with achieving optimum patient outcomes from medicine therapy¹.

Why is MUE important?

MUE programs play a key role in helping health care systems understand, interpret, evaluate and improve the prescribing, administration and use of medicines. Pharmacists play a key role in this process because of their expertise in the area of medicine therapy management. MUE affords the pharmacy department the opportunity to identify trends in prescribing within groups of patients whether by disease-state such as those with asthma, diabetes or high blood pressure, or by medicine specific criteria. Pharmacists can then, in collaboration with prescribers and other members of the health care team, initiate action to improve medicine therapy for patients.

What is the Definition of an MUE?

A Medicine Use Evaluation is a performance improvement method that focuses on evaluating and improving medicine-use processes with the goal of improving patient health outcomes¹. 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 medicine review in the health care setting². 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 Medicine Use Evaluation (MUE). MUE may be applied to a medicine or therapeutic class, disease state or condition, or a medicine-use process (ordering and transcribing, preparing and dispensing, administration, and monitoring).
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 MUE as the program gains acceptance and sufficient resources become available.
A. Prospective MUE

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

**Issues addressed by prospective MUE:**

- Irrational use
- Medicine-disease contraindications
- Medicine dosage modification
- Medicine interactions
- Medicine-patient precautions
- Therapeutic & generic substitution
- Inappropriate duration of medicine treatment

*Example:* Identification of medicine interactions are a common outcome of a prospective MUE. For example, a patient being treated with warfarin to prevent blood clots may be prescribed a new medicine by another specialist to treat arthritis. If taken together, the patient could experience internal bleeding. Upon reviewing the patient’s prescriptions, the pharmacist would note the potential medicine interaction and contact the prescriber to alert him/her to the problem.

B. Concurrent MUE

Concurrent review is performed during treatment and involves the ongoing monitoring of medicine 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 medicine-medicine 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.

**Issues addressed by concurrent MUE:**

- Medicine-disease interactions
- Medicine-medicine interactions
- Medicine dosage modifications
- Medicine-patient precautions
- Over and underutilization
- Therapeutic substitution

*Example:* Concurrent MUE often occurs in institutional settings, where patients often receive multiple medicines. Periodic review of patient records can detect actual or potential medicine-medicine interactions or duplicate therapy. It can also alert the pharmacist to the need for changes in medicines, such as antibiotics, or the need for dosage adjustments based on laboratory test results. The key prescriber(s) must then be alerted to the situation so corrective action can be taken.

C. Retrospective MUE

Most MUEs fall into the retrospective review category. A retrospective MUE is the simplest to perform since medicine therapy is reviewed after
Often, a hospital will begin a program using the retrospective method, and switch to prospective MUE as the program gains acceptance and sufficient resources are available.

the patient has received the medicine. A retrospective review may detect patterns in prescribing, dispensing, or administering medicines to prevent recurrence of inappropriate use. In retrospective MUEs, patient medical charts or computerized records are screened to determine whether the medicine therapy met approved criteria.

**Issues addressed by retrospective MUE:**

- Appropriate use
- Medicine-disease contraindications
- Medicine-medicine interactions
- Inappropriate duration of treatment
- Incorrect medicine dosage
- Use of formulary medicines
- Compliance with standard treatment guidelines
- Over and underutilization
- Therapeutic appropriateness
- Therapeutic duplication

**Example:** An example of a retrospective MUE may be the identification of a group of patients whose therapy does not meet approved guidelines. For example, a pharmacist may identify a group of patients with asthma, who according to their medical and pharmacy history should be using orally inhaled steroids. Using this information, the pharmacist can then encourage prescribers to utilize the indicated medicines.
The success of a formalized MUE program is largely dependent on the coordination of efforts between several working groups that comprise the MUE committee.
Provincial MUE Sub-committee

1. **Manage MUE programs**
   
a. Identify medicine or therapeutic class, disease state or condition, or medicine process to be examined. These may stem from concerns that arise from expenditure reports, ADR reports or from facility pharmacists or patients.

   b. Identify and/or solicit sites or districts for participation in MUE projects.

   c. Work collaboratively with hospital PTCs to collect, analyze, and evaluate patient-specific data to identify, resolve, and prevent medicine-related problems.

   d. Ensure that data privacy and security standards are complied with during data abstraction, inter-facility transfer, and analysis.

   e. Acquire ethics approval if and when required.

2. **Serve as resource for hospital PTCs**
   
a. Provide up-to-date information on MUE requirements for regulatory and/or policy purposes (e.g. National Core Standards, EDL committee).

   b. Provide guidance on MUE processes (e.g. MUE policies and procedures).

3. **Serve as an MUE “clearing house”**
   
a. Maintain current electronic online listing of local MUEs and results.

   b. Delineate, which MUEs pertain to medicine or therapeutic classes for which provincial criteria for use or guidance exist.

   c. Format for submission should follow a standard template (See example in Figure I)

4. **Report to Provincial PTC**
   
a. Present recommendations for provincial MUE projects.

   b. Present results, conclusions, and recommendations of national MUE projects.

Hospital MUE Sub-committee

1. A collaborative, multi-disciplinary group including a medical officer, pharmacist, nurse and other ancillary services as deemed necessary contribute a unique perspective to the MUE process. Chaired by a clinical coordinator for the pharmacy department or his/her designee, this subcommittee will help guide the facility MUE process.

2. Work collaboratively with the facility’s PTC Committee to identify potential areas where medicine processes can be enhanced and make recommendations to optimize patient safety and health outcomes.
3. Review each MUE design prior to implementation and review the results at the conclusion of the MUE before presentation to the PTC Committee.

4. Make recommendations to the facility's PTC and hospital CEO based on the MUE findings; request the provincial PTC to modify guidelines, policy or procedures; recommend actions to other governing bodies; make suggestions for conducting a follow-up MUE if necessary.

5. Serves as an MUE resource to the provincial MUE sub-committee.

6. Obtain ethical approval when collaborating with the provincial MUE sub-committee on multi-site projects if there is an intention to publish results outside of the provincial department of health.

Figure 1 Template for MUE Submission

<table>
<thead>
<tr>
<th>Template for MUE Submission</th>
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</thead>
<tbody>
<tr>
<td>Medicine-Use Evaluation Title:</td>
</tr>
<tr>
<td>Completed by:</td>
</tr>
<tr>
<td>Facility:</td>
</tr>
<tr>
<td>Phone Number:</td>
</tr>
<tr>
<td>E-mail:</td>
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<tr>
<td>Date Results Presented to PTC:</td>
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<tr>
<td>MUE Objective(s):</td>
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<td>Background:</td>
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<td>Conclusions:</td>
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<tr>
<td>Recommendations:</td>
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<tr>
<td>Limitations:</td>
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<tr>
<td>References:</td>
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</tbody>
</table>
Many studies have indicated that performing a medicine use evaluation and distributing the results to the doctors concerned has a beneficial effect on the appropriateness of drug use and provides an important tool for identifying the main problems in prescribing, so that educational efforts can be focused.
Quality Assurance and Quality Improvement

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

Clinical Governance Tool

An MUE program can also be considered an EDL or Standard Treatment Guidelines clinical governance technique by examining compliance with, deviations from, and effects of, national and provincial treatment guideline decisions.

Research and Publication

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, then review, oversight, and approval will become necessary. Moreover, the majority of peer-reviewed journals require a statement regarding ethics approval upon submission of a protocol.
CHAPTER 5
GOALS & OBJECTIVES

The main objectives of an MUE program are to provide a comprehensive and cyclical process of review, evaluation and intervention, which should operate as part of a broader program to improve the quality, safety and cost effectiveness of medicine use.
The MUE program should achieve the following goals if implemented properly:

1. **Promote optimal medicine therapy.**

   MUE is often conducted in conjunction with pre-established standard treatment guidelines or criteria for use of certain medicines. By measuring prescribing practices against evidence-based standards, 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 medicine-use processes.

2. **Prevent medicine-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 medicine. As such, problems can be identified and solutions constructed to prevent medicine problems in a similar patient population. Areas for further education of healthcare professionals may be identified through this process as well.

3. **Evaluate the effectiveness of medicine therapy.**

   Although all approved medicines have been reviewed for efficacy, the effectiveness of approved medicines remains to be established in real world experiences. Post-marketing studies are expensive and not carried out for all approved medicines. MUE provides a practical means for evaluating a medicine’s effectiveness, taking into account the practice environment, structure of the healthcare system, various patient-specific factors, and pharma-coeconomic issues.

4. **Enhance opportunities, through standardization, to assess the value of innovative medicine-use practices**

   Standardization in medicine prescribing, transcribing, evaluation, preparing, dispensing, administration, and monitoring has widely been used to improve patient safety, prevent adverse medicine events, or improve resource utilization. MUE provides the opportunity to evaluate the outcome of standardized processes in the healthcare system.

5. **Minimize costs of medicine therapy.**

   Medicine costs apart from the costs associated with medicine acquisition, storage, and administration need to be calculated into overall cost minimization initiatives. Although full economic analyses are often beyond the scope of an MUE project, it is reasonable to acknowledge that when medicines are selected and managed optimally from the outset, the costs of complications and wasted resources are minimized, and overall costs are decreased.
...the minimum driving force behind the execution of an MUE is to fulfill quality standards required of healthcare providers.

6. **Meet or exceed internal and external quality standards** (e.g., professional practice standards, national core standards, accreditation, 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 required of healthcare providers.

A recent example of an accrediting body in South Africa is that of the SA Office of Standards Compliance. This office has developed National Core Standards (NCS) for health establishments in South Africa, which aims to assist in setting the benchmark for quality care against which delivery of health services can be monitored. One of the five domains of the National Core Standards; namely Domain 3 outlines the minimum standards for clinical governance. Included in this domain is the functionality of the PTC Committee and how well it monitors compliance with standard treatment guidelines as well as the number of medicine use evaluations that have been conducted per annum.
CHAPTER 6

THE PLANNING

The following steps in the MUE process have been adapted from the ASHP Guidelines on Medicine Use Evaluation and serve to guide in planning a MUE program.¹
1. Establish organizational authority

a. The provincial MUE Subcommittee should be set up as a subcommittee of the provincial PTC.

b. The district or sub district MUE Subcommittee should be set up as a subcommittee of the district PTC.

c. The hospital MUE Subcommittees is generally a subcommittee of the hospital PTC.

d. Recommendations should be approved by the PTC Committee, which has the overall responsibility for the medicine-use processes the province and or districts as the case may be.

d. The medicine or medicine-use process is a critical component of care for a specific disease, condition, or procedure.

e. The medicine is potentially toxic or causes discomfort at normal doses.

f. The medicine is most effective when used in a specific way.

g. The medicine is being considered for national EDL retention, addition, or deletion.

h. The medicine or medicine-use process is one for which suboptimal use would have a negative effect on patient outcomes or system costs.

i. Use of the medicine is costly.

j. The medicine has a high potential for misuse (complexities in dosing, administration, titration, etc.).

k. The medicine is identified as a cost avoidance initiative.

l. Implications of therapeutic substitutions.

2. Select medicines and medicine-use processes for evaluation

The following list identifies medicines or medicine-use processes which may be selected for evaluation.

a. The medicine is known or suspected to cause adverse reactions, or it interacts with another medicine, food, or diagnostic procedure in a way that presents a significant health risk.

b. The medicine is used in the treatment of patients who may be at high risk for Adverse Medicine Reactions (ADRs).

c. The medicine-use process affects large number of patients or the medicine is frequently prescribed.

d. The medicine or medicine-use process is a critical component of care for a specific disease, condition, or procedure.

e. The medicine is potentially toxic or causes discomfort at normal doses.

f. The medicine is most effective when used in a specific way.

g. The medicine is being considered for national EDL retention, addition, or deletion.

h. The medicine or medicine-use process is one for which suboptimal use would have a negative effect on patient outcomes or system costs.

i. Use of the medicine is costly.

j. The medicine has a high potential for misuse (complexities in dosing, administration, titration, etc.).

k. The medicine is identified as a cost avoidance initiative.

l. Implications of therapeutic substitutions.

3. Examine potential indicators suggesting the need for an MUE

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

a. Adverse medicine events, including medicine errors, preventable adverse medicine reactions, and toxicity.

b. Signs of treatment failures, such as unexpected readmissions and bacterial resistance to anti-infective therapy.
c. Pharmacist interventions to improve medicine therapy, categorized by medicine and type of intervention.

d. Non-formulary / EDL medicines used or requested.

e. Patient dissatisfaction or deterioration in quality of life.

4. Establish the criteria or protocols for specific medicines and/or medicine-use processes for which the MUE will be conducted

a. Criteria should be developed to measure the safety, appropriateness, timeliness, continuity, efficiency, and effectiveness of medicine use.

b. 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 medicine use.

c. Objective criteria should reflect current knowledge, clinical experience, and relevant literature.

5. Collaborate with key stakeholders about objectives and expected benefits of the MUE to be conducted

a. Present MUE Criteria to the healthcare providers concisely.

b. Solicit comments from the staff and incorporate when appropriate into the MUE design.

6. Educate on the criteria or protocols for specific medicines and medicine use processes for which the MUE will be conducted.

a. Disseminate criteria for use, level of care etc 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 medicines or effectiveness of medicine use processes.

b. Establish mechanisms for communication among health care professionals

Medicine use criteria may be diagnosis-related, prescriber-related, or medicine-specific:-

**Diagnosis-related DUE criteria** identify indications for which select medicine(s) may be appropriate for a given disease state. For example, the use of selected antibiotics for community acquired pneumonia. Use of other antibiotics would fall outside the approved list and require follow-up.

**Prescriber-related DUE criteria** identify specific physicians whom the P&T committee has determined may use certain medicines. For example, selected antibiotics may be limited to infectious disease specialists or limited to critical care specialists.

**Medicine-specific DUE criteria** focus on specific aspects of a select medicine such as the dose or dosing frequency. For example, the dosage regimen of a low molecular weight heparin might be reviewed. Dosage regimens outside the criteria would...
CHAPTER 7

EXECUTING THE PROGRAM

An MUE Template Figure 2 provides a step-by-step approach to guide the MUE author in the development and implementation of the MUE.
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)

Evaluate criteria for the medicine’s use. These criteria may include:

1. Appropriate indication (primary criteria)
2. Appropriate dosage (process criteria)
3. Appropriate duration of therapy (process criteria)
4. Appropriate labs or other measure monitored (process criteria)
5. No contraindication for use (process criteria)
6. Adverse effects found while on the medicine (outcome criteria)
7. Known medicine interaction with other medicines prescribed for the patient (process criteria)
8. Did the patient’s treated condition improve as a result of the medicine’s use? (outcome criteria).

Investigate need for ethics and research approval

1. If the intent is to only share the findings within the provincial department of health, local facility PTC approval should suffice.
2. If the intent is to share the findings outside of department of health (e.g., poster presentation, article publication), or to conduct the MUE as part of a provincial multi-site project or as a research project, approval research and ethics committees will be necessary.
3. Discuss project with local ethics and research representatives first to determine actions necessary and route of approval.

Initiate and Conduct the MUE

1. Collect data
2. Analyze the data
3. Formulate conclusions and recommendations
4. Present completed MUE to the MUE committee and PTC
5. Disseminate results

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 medicine related problems (Newsletters, e-mails, circulars).

3. Create reminder dialogs that mirror EDL guidelines.

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, standard treatment guidelines etc.

3. Repeat cycle of planning, evaluating, and action taking for ongoing improvement in medicine use processes.
Objective(s):
What are the objective(s) of the evaluation?

Background:
What is the current medicine 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, provincial 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 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 medicine reactions?
            Tolerability? Side Effects?
            Safety?
            Medicine Monitoring? (Acquisition of appropriate lab results or other monitoring 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 EDL, standard treatment 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 medicine 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?
MUE is an ongoing process that can take place daily in the medicine use 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 de-
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.

fined, 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.

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 ethics approval is necessary, the process may take 6 weeks to 6 months.

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 afterwards 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.

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.
REFERENCES


