ASHP Guidelines on Medication-Use Evaluation

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Purpose

These guidelines describe essential elements of the medication-use evaluation (MUE) process for healthcare organizations. These elements include the goals and objectives of a MUE, performance improvement methods, a description of indicators suggesting the need for an MUE, how to prioritize and select medications and processes for evaluation, typical steps in the process, the roles and responsibilities of the interdisciplinary team, common problems and pitfalls, and useful resources.

Goals, objectives, and definitions of MUE

MUE is a systematic and interdisciplinary performance improvement method with an overarching goal of optimizing patient outcomes via ongoing evaluation and improvement of medication utilization.[1] Various terms have been employed to describe programs intended to achieve this goal; in addition to MUE, *drug use evaluation* (DUE) and *drug utilization review* (DUR) have also been used.[1-3] Although these terms are sometimes used interchangeably, MUE may be differentiated in that it emphasizes improving patient outcomes and quality of life through assessment of clinical outcomes via a multidisciplinary approach, whereas DUE and DUR generally refer to an ongoing, systematic, criteria-based, drug- or disease-specific assessment that ensures appropriate medication utilization at the individual patient level.[3] Historically, the American Society of Health-System Pharmacists (ASHP) has considered MUE to encompass DUE in its broadest application,[1] so these guidelines continue to use MUE as a preferred term.

When developing a MUE, clinicians should also take into consideration its focus. For example, a MUE may focus on patient-centered therapeutic outcomes (eg, clinical events, quality of life) or on process elements related to appropriate medication usage (eg, prescribing, dispensing). In this way, an initial MUE may identify suboptimal therapeutic outcomes experienced by patients, which may trigger a separate MUE focused on aspects of the medication-use process and vice versa. Specific objectives, examples of MUE designs, and their foci (ie, therapeutic or process outcomes) are presented in Table 1.

Performance improvement framework

Healthcare organizations routinely use performance improvement methods to improve safety, efficacy, quality, and efficiency in patient care. Many accreditation bodies, such as the Joint Commission, require annual reviews of a hospital formulary along with other quality and safety improvement strategies that would benefit from such a framework. These methods may be applied in the setting of MUE, which can be considered one component of a performance improvement program. One performance improvement framework that aligns with the MUE process is the FOCUS-PDCA model (Figure 1).[4] The steps include:

- **F**ind the process to be targeted for improvement.
- **O**rganize the team that knows the process.
- **C**larify current knowledge of the process.
- **U**nderstand causes of process variation.
- **S**elect process improvement.
- **P**lan: Develop a solution.
- **D**o: Implement improvements.
- **C**heck: Evaluate the results.
- **A**ct: Determine what changes are needed moving forward and implement those changes.

The steps in the FOCUS-PDCA model may need to be repeated in an ongoing, systematic manner.

Indicators suggesting a need for an MUE

The occurrence of certain events in a stage of the medication-use process may indicate opportunities to improve medication use and justify undertaking an MUE (Table 2).[1,5] Generally, these events

Table 1. Common MUE Objectives, MUE Examples, and Type of Outcome (Therapeutic or Process)

Objective	MUE Example	Therapeutic or Process Outcome
Promoting optimal medication therapy	Compare efficacy before and after introduction of a biosimilar therapeutic substitution policy	Therapeutic
	Evaluate the frequency of patients who qualified for, but did not receive, an approved therapeutic substitution	Process
Improve patient safety	Evaluate the incidence of major bleeding in patients treated with thrombolytic therapy	Therapeutic
	Evaluate the frequency of use of thrombolytic therapy in inappropriate candidates	Process
Standardize to reduce unnecessary variation	Compare rates of adverse events in patients receiving standard vs highly concentrated vasopressor infusions	Therapeutic
	Evaluate the prescribing frequency of concentrations outside of the standard concentration policy for vasopressors	Process
Optimize drug therapy	Determine the time in therapeutic range for patients treated with a medication requiring pharmacokinetic therapeutic drug monitoring	Therapeutic
	Evaluate the frequency of appropriate dose changes when an interacting medication is introduced	Process
Assess value of innovative practices	Compare the rates of blood pressure control in a physician- vs pharmacist-managed hypertension service	Therapeutic
	Evaluate the frequency of physician referral to a pharmacist-led hypertension management service	Process
Meet quality or regulatory standards	Determine the percentage of patients with heart failure readmitted after discharge	Therapeutic
	Determine the percentage of patients receiving required medication discharge education	Process
Minimize costs	Compare infection cure rates before versus after involvement of an antimicrobial stewardship pharmacist	Therapeutic
	Compare costs of antimicrobial therapy before versus after involvement of an antimicrobial stewardship pharmacist	Process

Abbreviation: MUE, medication-use evaluation.

may represent trends or deviations in medication use within a health system, availability or discontinuation of drugs, or new knowledge regarding drug therapy.

Prioritizing medications and medication-use processes for evaluation

The indicators described above may reveal specific medications or medication-use processes that should be evaluated in an MUE. The following partial list of characteristics may help prioritize the selection of a particular medication or medication-use process, based on its magnitude or severity of effect on patients or the medication-use system (other characteristics will likely emerge with the introduction of new medications and technologies):

- The medication is known or suspected to cause adverse events or is used in the treatment of patients who may be at high risk for adverse events.
- The medication interacts with another medication, food, or diagnostic procedure in a way that presents a significant health risk.
- The medication or process affects a large number of patients, or the medication is frequently prescribed.
- The medication or process is a critical component of care for a specific disease, condition, or procedure.

- The medication is potentially toxic or causes discomfort at normal doses.
- The medication is most effective when used in a specific way.
- The medication is under consideration for formulary retention, addition, or deletion.
- The medication has been the subject of a Food and Drug Administration (FDA) recall, safety alert, or market withdrawal.
- The medication has not been approved by FDA.
- The medication has not been evaluated in a high-risk population (pregnant females, pediatric patients, obese patients, etc).

Figure 1. Components of the FOCUS-PDCA process improvement model as applied to medication-use evaluation.
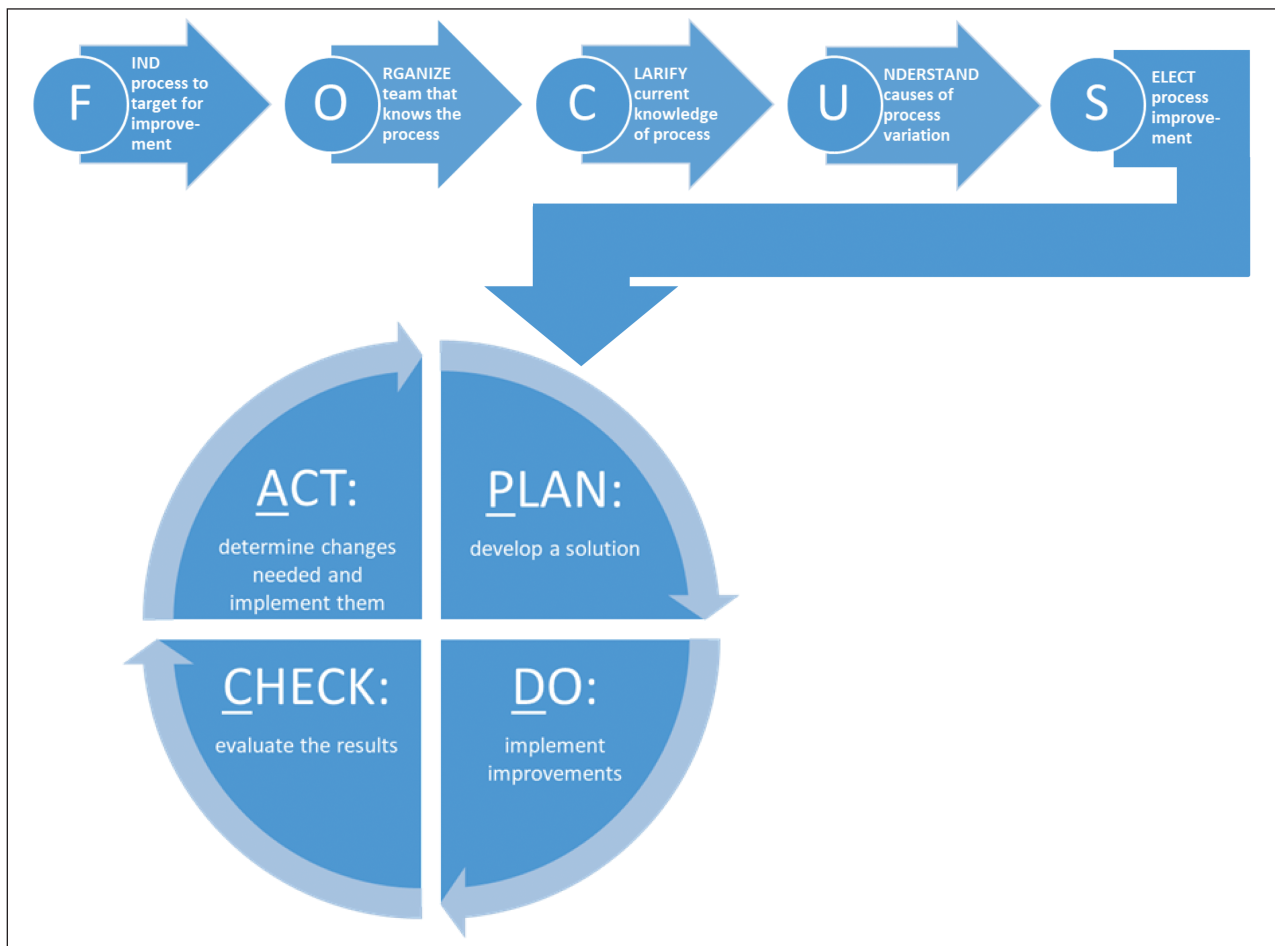
- The medication or process is one for which its use would have a negative effect or no therapeutic impact on patient outcomes.
- The process is an innovative or newly initiated practice and its effects on patient care are unknown.
- Use of the medication or medication process is considered expensive and the cost benefit is unknown.
- To determine if clinicians are complying with medication formulary restrictions or facility guidelines for use.
- To evaluate pharmacist-directed collaborative practices, such as dosing protocols and algorithms (pharmacy per protocol or pharmacy to dose) to verify appropriate action steps.
- Analytic tools (eg, failure mode and effects analysis, risk priority numbers, cause and effect diagrams,

control chart) or scoring systems (eg, harm criteria) suggest the need for intervention.

Steps of the MUE process using FOCUS-PDCA

While the specific approach varies with the practice setting and patient population being served, many steps common to MUE fall within the FOCUS-PDCA model framework for process improvement mentioned earlier (Figure 1). However, the following common steps often occur in an ongoing MUE process.

1. Find the process to target for improvement:
   - Establish the need for the MUE (see Table 2 for indicators of need for MUE).

2. Organize the team:
   - Establish organizational authority for the MUE process and engage subject matter experts and representative stakeholders:
     ◦ Inform healthcare professionals (and others as necessary) in the practice setting(s) about the objectives and expected benefits of the MUE process.
     ◦ Set priorities for in-depth analysis of important aspects of medication use.
     ◦ Educate healthcare professionals involved with the MUE on the guidelines, treatment protocols, and standards of care.
     ◦ Establish mechanisms for timely communication among healthcare professionals.
   - Decide on the team for the MUE:

Table 2. Indicators of Need for Medication-Use Evaluation at Different Steps in Medication-Use Process[a]

Step	Indicator
Prescribing	• Market entry or withdrawal of approved drug products • Regulatory actions such as drug recalls, market withdrawals, or safety alerts • Publication of guidelines or high-impact studies that may change treatment patterns • New organizational interventions to improve medication therapy, such as changes to protocols or formularies • Changes in use of, or requests for, nonformulary medications • Changes to pharmacy clinical services to improve medication therapy • Introduction of or changes in quality indicators, such as those published by the Centers for Medicare & Medicaid Services, or other regulatory or accrediting bodies
Dispensing	• Signs of process failures, such as wasted medication or delayed medication delivery • Incorrect medication preparation • Dosing that requires clinician preparation or compounding • Ensuring compliance with regulatory requirements (eg, *United States Pharmacopeia* chapters 795, 797, 800)
Administration	• Medication misadventures related to medication delivery systems • Multiple medication concentrations, units of measure, or infusion rates
Monitoring	• Adverse events, including medication errors, preventable adverse drug reactions, and toxicity • Signs of treatment failures, such as unexpected readmissions and bacterial resistance to anti-infective therapy • Patient dissatisfaction or deterioration in quality of life attributable to drug therapy
Systems management and control	• Procurement requirements, specialty pharmacy requirements, risk evaluation and mitigation strategies (REMS) programs, restricted distribution channels, or other access challenges • Drug shortages requiring replacement or therapeutic substitution • Diversion of controlled substances • Lack of standardization or confusion within the medication-use process • Changes in contracts, cost, or spending on drugs • Organizational priorities such as budget constraints or cost-saving initiatives

[a]This table does not provide an exhaustive list of characteristics.

◦ Core teams tend to include pharmacists, pharmacy residents, student pharmacists, pharmacy technicians, and key stakeholders such as nurses, physicians, and other allied health professionals.

◦ Consider engaging experts in informatics, data analytics, performance improvement, and/or biostatistics whenever possible.

• Provide training to the staff involved with the MUE.

3. Clarify current knowledge:

• Build MUE criteria using the above guidelines, treatment protocols, and standards of care in the medication-use process.

• Identify the key question to answer, measurable objectives, and the timeline for the MUE. Objectives must be measurable, relevant, and easy to obtain or collect. See Table 1 for details.

• Design MUE by deciding on methodology and selecting sample population, sample size, and inclusion and exclusion criteria.

• Create a data collection plan. Include a data dictionary to standardize definitions for collected variables and sources utilized for collection:

◦ Generate reports from the electronic medical record (EMR) whenever possible in order to limit manual chart abstraction.

◦ Determine sample size and variables to collect. Estimate the potential time required for manual chart reviews and the ideal number of team members. Any set sample size should represent a larger group or population.

◦ Establish thresholds for evaluating achievement of targeted measures by using past performance and/

or utilization reports or published benchmarks, if available.

◦ Conduct data collection and schedule intermittent progress evaluations as needed, depending on project timeline. Look for outlying data (eg, 80 lbs accidentally entered instead of 80 kg for 55-year-old, 6-foot, healthy male).

• Analyze data using appropriate statistical tests.

◦ Descriptive statistics are appropriate for many MUEs (eg, measures of central tendency, measures of variability, percentage of patients meeting a certain outcome). If there are 2 or more distinct groups within the analysis, inferential statistics may also be considered.

• Document results and compare them to your anticipated outcomes.

• Share MUE results using appropriate text and visuals (eg, figures,

tables) with the MUE team and key stakeholders.

4. Understand the causes of process variation:
   - If outcomes do not meet desired thresholds, conduct root cause analyses to determine the source of the problem.
   - Consider using tools that assist in identifying variation in the process (eg, Five Whys).[6]
   - Punitive reactions to quality concerns are often counterproductive. It is important to communicate and commend positive achievements as well.

5. Select process improvement:
   - Brainstorm and engage key stakeholders to develop ideas that would address the root cause of the process variation:
     ◦ Whenever possible, solutions that "hard-wire" workflows and those that do not rely on someone to remember to do something during particular circumstances are preferred.
     ◦ Ensure the selected solution aligns with the department and organization's goals, adds value, and is both technically and financially feasible.
     ◦ Consider using a tool such as the FACES tool[7] to evaluate and prioritize recommendations:
   - **F**easibility: How easily and quickly can the change be made?
   - **A**cceptability: How willing are those impacted to make the change?
   - **C**ost/benefit: How much does the cost outweigh the benefit?
   - **E**ffectiveness: How effectively will this change solve the problem?
   - **S**ustainability: How will the change last over time?

6. Plan:
   - Create a plan to specify what actions will be taken, how it will be done, who is responsible for each task, and what the desired timeline will be.
   - Establish a plan for data collection and measuring success once the solution is implemented. Success should be assessed in terms of improved healthcare outcomes, which

may include but are not limited to morbidity, mortality, adverse events, quality of life, healthcare resource utilization, and cost savings.

7. Do:
   - Implement the identified solution(s).

8. Check:
   - Complete follow-up data collection on the new process following implementation of corrective actions.
   - Obtain feedback from the MUE team and other disciplines regarding lessons learned in order to brainstorm solutions to overcome obstacles, challenges, and inefficiencies of MUE methods.

9. Act:
   - Take steps necessary to maintain the improvement. If the identified solution was pilot tested, develop a plan to roll out the optimized solution to the entire process.
   - When sustained reproducible improvement is seen, revise criteria, guidelines, treatment protocols, standards of care policies, or point-of-care tools in the EMR (eg, hard stops, automatic conversions) when indicated.
   - Communicate findings of the MUE and the newly implemented processes to affected parties (eg, newsletters, seminars).
   - Consider publishing MUE results (eg, poster, manuscript) outside of the institution if appropriate. Although MUEs are within the scope of operational activities, this type of quality assurance (QA) or quality improvement (QI) work does not preclude publication. It is important that MUE results be accurately presented either as research or nonresearch, depending on whether the MUE was designed to contribute to generalizable knowledge, which would then fall within the realm of research.[8] Most peer-reviewed journals do require, at minimum, a statement regarding review and/or exemption by a human subjects protection committee or institutional review board. Local governing groups should be consulted

for external publication and presentation requirements.

Roles and responsibilities in the MUE process

The roles of pharmacists and other healthcare professionals in MUE may vary according to practice setting, organizational goals, and available resources. The organizational body (eg, quality management or QI committee, pharmacy and therapeutics committee) responsible for the MUE process should have, at a minimum, a prescriber (most commonly a physician), pharmacist, nurse, and an administrator or health-system representative. Pharmacist extenders, including pharmacy technicians, student pharmacists, and pharmacy residents, should also participate in conducting MUEs in facilities and healthcare systems where allowed. Other healthcare professionals and subject matter experts should contribute their unique perspectives when the evaluation and improvement processes address their areas of expertise and responsibility. Ad hoc committees or temporary working groups, which include at a minimum a pharmacist as the MUE lead and subject matter expert(s), can be assigned to develop MUEs for specific QI efforts. Best practices should be established in settings whenever possible to enhance the structure around how MUE committees conduct, report, implement, and complete evaluations. In addition, systematic evaluations should be conducted when possible to assess the attributes of the interdisciplinary team in regard to subject matter expertise, leadership in the program or healthcare system, and overall ability to implement and sustain the MUE findings. In settings in which only a small number of healthcare professionals are available (eg, some community hospitals, rural hospitals, or clinics), extensive MUEs conducted by a large interdisciplinary team may not be an option. In such instances, the pharmacist at the smaller facility may be responsible

for the design, conduct, analysis, and reporting of an MUE. Implementation of findings from the MUE may require assistance from the hospital administration in such facilities.

QI programs with a high degree of interdisciplinary participation provide an optimal mechanism to conduct MUEs. Although other disciplines should be encouraged to assist in development of MUEs, pharmacists, by virtue of their expertise and mission to ensure appropriate medication use, remain the primary healthcare professional responsible for the development and coordination of MUEs. Pharmacists should continue to exert leadership and work collaboratively with other members of the healthcare team in the ongoing MUE process. The responsibilities of pharmacists (with the assistance of pharmacist extenders such as pharmacy technicians, student pharmacists, and pharmacy residents) in the MUE process should include:

- Developing an operational plan for MUE programs and processes that is consistent with the health system's overall goals and resource capabilities
- Working collaboratively with prescribers, subject matter expert(s), and others to develop criteria for specific medications and to design effective

Table 3. Problems, Pitfalls, and Barriers to Completing a Successful Medication-Use Evaluation

Category	Explanation
Lack of authority	An MUE process that does not involve the medical staff is likely to be ineffective. Authoritative medical staff support and formal organizational recognition of the MUE process are necessary to support changes and incorporate best practices.
Lack of organization, structure, or leadership	Without a clear definition of the roles, responsibilities, and accountabilities of individuals involved to complete tasks and reach milestones, an MUE process may not succeed.
Poor communication	Everyone included in the MUE process should understand its importance to the health system, its goals, and its procedures. The pharmacist should manage the MUE process and have the responsibility and authority to ensure timely communication among all professionals involved in the MUE process. Criteria for medication use should be communicated to all affected professionals prior to the evaluation of care. MUE activity should be a standing agenda item for appropriate quality-of-care committees responsible for aspects of medication use.
Poor documentation	MUE activities should be well documented, including summaries of MUE actions with respect to individual medication orders and the findings and conclusions from collective evaluations. Documentation should address recommendations made and follow-up actions.
Lack of involvement	The MUE process is not a one-person task, nor is it the responsibility of a single department or professional group. Medication-use criteria should be developed through an interdisciplinary consensus process. Lack of administrative support can severely limit the effectiveness of MUE. The benefits of MUE should be conveyed in terms of improving patient outcomes and minimizing health-system costs.
Data integrity	Data collection efforts are often interdisciplinary and can involve student pharmacists, pharmacy interns, pharmacy residents, and others. Data are often found in different medical record locations and can be interpreted differently, often resulting in discrepancies. Teams should agree on sources and interpretation before data collection begins.
Lack of follow-through	A one-time study or evaluation independent of the overall MUE process will have limited success in improving patient outcomes. The effectiveness of initial actions must be assessed and the action plan adjusted if necessary. It is important not to lose sight of the improvement goals.
Evaluation methodology that impedes patient care	Data collection should not consume so much time that patient care activities suffer. Interventions that can improve care for an individual patient should not be withheld because of the sampling technique or evaluation methodology.
Lack of scope	Consider inclusion of unique or under-represented populations (e.g., neonates, pediatric patients, pregnant women, etc.) in project scope.
Lack of readily retrievable data	Collaboration with analytics or information solutions teams should occur to ensure the majority of discrete data fields are generated through reporting mechanisms.
Lack of hard-wired corrective actions	When sub-optimal processes are uncovered, corrective actions should be hard-wired (e.g., forcing functions in the electronic health record) whenever possible. Remedies relying on education and provider memory are often ineffective in promoting lasting change.
Lack of education	If results from a MUE are not disseminated through the education of appropriate staff, a change in process or patient care will not occur.

Abbreviation: MUE, medication-use evaluation.

medication-use processes and assessments

- Ensuring optimal input from subject matter expert(s) and interdisciplinary groups in the design of the MUE efforts, when possible
- Reviewing individual medication utilization against medication-use criteria and consulting with prescribers and others in the process as needed
- Collecting, analyzing, and evaluating patient-specific data to identify, resolve, and prevent medication-related problems, enhance medication effectiveness, and improve patient outcomes
- Ensuring the integrity of the collected data
- Interpreting and reporting MUE findings, as well as recommending and facilitating changes in medication-use processes
- Providing information and education based on MUE findings
- Assisting in implementation of optimal findings in the facility or healthcare system
- Evaluating the outcomes of implemented MUE findings when appropriate and assessing the effect on the facility or healthcare system
- Ensuring that systems are in place to sustain the implemented MUE findings in the facility or healthcare system whenever possible
- Ensuring that MUEs emphasize QI vs research

Common problems and pitfalls

Common problems and pitfalls to avoid in performing MUE activities are presented in Table 3. These pitfalls often involve lack of interdisciplinary involvement, including authoritative medical staff; poor documentation and communication of the MUE process; and inadequate education of affected staff regarding outcomes of the MUE and improvements to the medication-use system.

Conclusion

These guidelines describe essential elements of the MUE process for healthcare organizations. MUE is an ongoing, systematic, and interdisciplinary performance improvement method that has an overarching goal of optimizing patient outcomes through evaluation and improvement of medication-use processes. MUE may be considered one component of a performance improvement program, and its steps may be described using the FOCUS-PDCA model framework. The occurrence of certain events in a stage of the medication-use process may indicate opportunities to improve medication use and justify undertaking an MUE, and the characteristics provided may help prioritize the selection of a particular medication or medication-use process for MUE. The success of an MUE process should be assessed in terms of improved patient outcomes, one of which may be lower cost. Interdisciplinary participation is crucial to successful MUEs. Although other disciplines should be encouraged to participate in MUEs, pharmacists remain the primary healthcare professionals responsible for the development and coordination of MUEs due to their expertise and mission to ensure appropriate medication use.

Resources

Resources that may be helpful in the design and implementation of MUEs include the following.

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Disclosures

Dr. Fanikos declares having served as the lead investigator for the RE-VECTO surveillance study (for which Boehringer Ingelheim provided research support) and as a consultant to Portola and Ipsen. The other authors have declared no potential conflicts of interest.

Additional information

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