

# 1 DRAFT ASHP Guidelines on Medication-Use Evaluation

## 2 Purpose

3 These guidelines describe essential elements of the medication-use evaluation (MUE) process  
4 for healthcare organizations. These elements include a formal definition of MUE, a description  
5 of indicators suggesting the need for an MUE, how to select medications and processes for  
6 evaluation, common objectives of an MUE, typical steps in the process, the roles and  
7 responsibilities of the interdisciplinary team, common problems and pitfalls, and useful  
8 resources.

9

## 10 Goals, objectives, and definitions of MUE

11 MUE is an ongoing, systematic, and interdisciplinary performance improvement method that  
12 has an overarching goal of optimizing patient outcomes through evaluating and improving  
13 medication-use processes across all practice settings.<sup>1</sup> Various terms have been employed to  
14 describe programs intended to achieve this goal; in addition to MUE, drug use evaluation (DUE)  
15 and drug utilization review (DUR) have also been used.<sup>1-3</sup> Although these terms are sometimes  
16 used interchangeably, MUE may be differentiated in that it emphasizes improving patient  
17 outcomes and quality of life, whereas DUE and DUR generally refer to a criteria-based  
18 assessment of appropriate medication-use processes and prescribing.<sup>3</sup>

19 Historically, ASHP has considered MUE to encompass DUE in its broadest application,<sup>1</sup>  
20 so these guidelines use MUE as the preferred term. The distinction between the terms may be  
21 viewed as somewhat arbitrary, as the results of any specific MUE can suggest improvements in

---

**This draft is intended for review purposes only; it is not official ASHP policy. This document may not be reproduced, circulated (except for review purposes), or quoted without prior written permission from ASHP. Copyright © 2019, American Society of Health-System Pharmacists. All rights reserved.**

22 therapeutic outcomes or medication-use processes, or both. For example, an MUE may focus  
23 on patient-centered therapeutic outcomes (e.g., clinical events, quality of life), falling under  
24 some definitions of MUE, or the MUE may focus on elements of the medication-use process  
25 (e.g., prescribing, dispensing), falling under some definitions of DUE. The initial MUE may  
26 identify suboptimal therapeutic outcomes experienced by patients, which may trigger a  
27 separate MUE (or DUE, depending on one's preferred terminology) focused on aspects of the  
28 medication-use process, and vice versa. Specific objectives, examples of MUE designs, and their  
29 foci (i.e., therapeutic or process outcomes) are presented in Table 1.

30

### 31 **Performance improvement framework**

32 Healthcare organizations routinely use specific performance improvement methods (e.g., Lean  
33 or Six Sigma) to improve safety, efficacy, quality, and efficiency in patient care. These methods  
34 may be applied in the setting of MUE, which can be considered one component of a  
35 performance improvement program. Performance improvement methods generally consist of  
36 steps that may fall in the Plan-Do-Study-Act (PDSA) model framework (Figure 1).<sup>4</sup> These steps  
37 include:

- 38 • **Plan:** define or clarify the problem, measure the baseline performance, analyze the root  
39 cause, and identify corrective actions;
- 40 • **Do:** implement improvements;
- 41 • **Study/check:** evaluate the results; and
- 42 • **Act:** determine what changes are needed moving forward and implement those  
43 changes.

44 The steps in the PDSA model may need to be repeated in an ongoing, systematic manner.

45

#### 46 **Indicators suggesting a need for an MUE**

47 The occurrence of certain events in a stage of the medication-use process may indicate  
48 opportunities to improve medication use and justify undertaking an MUE (Table 2).<sup>1,5</sup> Generally,  
49 these events may represent trends or deviations in medication use within a health system,  
50 availability or discontinuation of drugs, or new knowledge regarding drug therapy.

51

#### 52 **Prioritizing medications and medication-use processes for evaluation**

53 The indicators described above may reveal specific medications or medication-use processes  
54 that should be evaluated in an MUE. The following characteristics may help prioritize the  
55 selection of a particular medication or medication-use process, based on its magnitude or  
56 severity of effect on patients or the medication-use system.

57

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

- 66 • The medication is potentially toxic or causes discomfort at normal doses.
- 67 • The medication is most effective when used in a specific way.
- 68 • The medication is under consideration for formulary retention, addition, or deletion.
- 69 • The medication has been the subject of a Food and Drug Administration recall, safety  
70 alert, or market withdrawal.
- 71 • The medication or process is one for which its use would have a negative effect or no  
72 impact on patient outcomes.
- 73 • Use of the medication or process is expensive.

74

#### 75 **Steps of the MUE process**

76 Although specific approaches vary with the practice setting and patient populations being  
77 served, many steps common to MUE fall within the previously mentioned cyclical PDSA model  
78 framework for process improvement (Figure 1). In addition, the organizational authority for the  
79 MUE process itself should be established, and subject matter experts and representative  
80 stakeholders should be engaged.<sup>6,7</sup> Healthcare professionals (and others as necessary) in the  
81 affected practice setting(s) should be informed about the objectives and expected benefits of  
82 the MUE. An in-depth analysis of important aspects of medication use should be used to set  
83 priorities for the MUE. The effectiveness of the MUE process itself should be regularly assessed,  
84 and improvement should be incorporated as necessary.

85 The success of an MUE process should be assessed in terms of improved patient  
86 outcomes. Medication-use system changes that evolve from MUE findings should be developed  
87 by the departments and medical services with responsibility for providing care, rather than

88 solely through a committee having oversight for MUE (e.g., pharmacy and therapeutics [P&T]  
89 committee). Typical follow-up actions based on MUE findings include information-sharing and  
90 education (e.g., newsletters, seminars, clinical care guidelines) and changes to existing policies,  
91 but some MUEs may suggest more reliable and sustainable tools for change, such as software  
92 technology, forcing functions (e.g., hard stops, automatic conversions), standardization of  
93 equipment, and visual aids. Punitive reactions to quality concerns are often counterproductive;  
94 it is important to communicate and commend positive achievements (care that meets or  
95 exceeds expectations) and improvements as well.

96         Because MUEs generally fall within the scope of quality assurance or quality  
97 improvement (QA/QI) and are typically not designed to expand the knowledge base of a  
98 scientific discipline, they generally do not constitute research.<sup>8</sup> However, although not  
99 inherent to its purpose, an MUE may sometimes fall within the scope of research when it is  
100 designed to develop or contribute to generalizable knowledge. Individual institutions should  
101 obtain the necessary approvals based on the institution's guidelines for QI assessments and  
102 research protocols. Furthermore, it is not beyond the QA/QI scope to have the results  
103 published or shared at professional meetings outside the institution. Local governing groups  
104 should be consulted for external publication and presentation requirements. Most peer-  
105 reviewed journals do require, at a minimum, a statement regarding review or exemption by an  
106 institutional review board.

107

### 108 **Roles and responsibilities in the MUE process**

109 The roles of pharmacists and other healthcare professionals in MUE may vary according to

110 practice setting, organizational goals, and available resources. The organizational body (e.g.,  
111 quality management or QI committee, P&T committee) responsible for the MUE process should  
112 have, at a minimum, prescriber, pharmacist, nurse, and administrator or healthcare system  
113 representation. Other healthcare professionals and subject matter experts should contribute  
114 their unique perspectives when the evaluation and improvement process addresses their areas  
115 of expertise and responsibility. Ad hoc committees or temporary working groups, which include  
116 at a minimum a pharmacist and subject matter expert(s) can be assigned to develop MUEs for  
117 specific QI efforts.

118 QI programs with a high degree of interdisciplinary participation provide an optimal  
119 mechanism to conduct MUEs. Although other disciplines should be encouraged to assist in  
120 development of MUEs, pharmacists, by virtue of their expertise and mission to ensure  
121 appropriate medication use, remain the primary healthcare professional responsible for the  
122 development and coordination of MUEs. Pharmacists should continue to exert leadership and  
123 work collaboratively with other members of the healthcare team in the ongoing MUE process.

124 The responsibilities of pharmacists in the MUE process should include:

- 125 • Developing an operational plan for MUE programs and processes that are consistent  
126 with the health system's overall goals and resource capabilities.
- 127 • Working collaboratively with prescribers, subject matter expert(s), and others to  
128 develop criteria for specific medications and to design effective medication-use  
129 processes and assessments.
- 130 • Ensuring optimal input from subject matter expert(s) and interdisciplinary groups in the  
131 design of the MUE efforts, when possible.

- 132 • Reviewing individual medication utilization against medication-use criteria and  
133 consulting with prescribers and others in the process as needed.
- 134 • Managing MUE programs and processes.
- 135 • Collecting, analyzing, and evaluating patient-specific data to identify, resolve, and  
136 prevent medication-related problems, enhance medication effectiveness, and improve  
137 patient outcomes.
- 138 • Ensuring the integrity of the collected data.
- 139 • Interpreting and reporting MUE findings and recommending changes in medication-use  
140 processes.
- 141 • Providing information and education based on MUE findings.
- 142 • Assisting in implementation of optimal findings in the facility or healthcare system.
- 143 • Ensuring that development of MUEs emphasizes QI versus research.

144

### 145 **Common problems and pitfalls**

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

151

### 152 **Conclusion**

153 These guidelines describe essential elements of the MUE process for healthcare organizations.

154 MUE is an ongoing, systematic, and interdisciplinary performance improvement method that  
155 has an overarching goal of optimizing patient outcomes through evaluating and improving  
156 medication-use processes. MUE may be considered one component of a performance  
157 improvement program, and its steps may be described using the PDSA model framework. The  
158 occurrence of certain events in a stage of the medication-use process may indicate  
159 opportunities to improve medication use and justify undertaking an MUE, and the  
160 characteristics provided may help prioritize the selection of a particular medication or  
161 medication-use process for MUE. The success of an MUE process should be assessed in terms  
162 of improved patient outcomes, one of which may be lower cost. Interdisciplinary participation  
163 is crucial to successful MUEs. Although other disciplines should be encouraged to participate  
164 in MUEs, pharmacists remain the primary healthcare professional responsible for the  
165 development and coordination of MUEs due to their expertise and mission to ensure  
166 appropriate medication use.

## References

1. Phillips MS, Gayman JE, Todd MW. ASHP guidelines on medication-use evaluation. *Am J Health-Syst Pharm*. 1996; 53:1953-5.
2. Academy of Managed Care Pharmacy. Drug utilization review (2009). <http://www.amcp.org/workarea/downloadasset.aspx?id=9296> (accessed 2019 Mar 27).
3. World Health Organization. *Drug and Therapeutics Committees – A Practical Guide* (2003). <http://apps.who.int/medicinedocs/en/d/Js4882e/8.5.html> (accessed 2019 Mar 27).
4. Agency for Healthcare Research and Quality. Health literacy universal precautions toolkit, 2nd ed. Plan-do-study-act (PDSA) directions and examples. <https://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlitoolkit2-tool2b.html> (accessed 2019 Mar 27).
5. Ninno MA, Ninno S. Chapter 14. Performance improvement and the medication use process. In: Malone PM, Kier KL, Stanovich JE. eds. In: *Drug Information: A Guide for Pharmacists*. 4th ed. New York, NY: McGraw-Hill; 2012. <http://accesspharmacy.mhmedical.com/content.aspx?bookid=466&sectionid=40064980>



- (accessed 2019 Mar 27).
6. Faley B, Fanikos J. Best practices for medication utilization evaluations in postsurgical pain management. *Curr Emerg Hosp Med Rep.* 2017; 5:33-40.
  7. Institute for Healthcare Improvement. Science of improvement: testing changes. <http://www.ihl.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx> (accessed 2019 Mar 27).
  8. U.S. Department of Veterans Affairs. Office of Research & Development Program Guide: 1200.21. VHA operations activities that may constitute research. October 28, 2011. <https://www.research.va.gov/resources/policies/ProgramGuide-1200-21-VHA-Operations-Activities.pdf> (accessed 2019 Mar 27).

## 167 Resources

168

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

171

- 172 • Veterans Affairs Center for Medication Safety. VA Medication use evaluation (MUE)  
173 toolkit. Updated July 2012.  
174 <https://www.pbm.va.gov/PBM/vacenterformedicationsafety/tools/MUEToolkit.pdf>.  
175 Accessed December 4, 2018.
- 176 • World Health Organization. Introduction to drug utilization research. 2003.  
177 <http://apps.who.int/medicinedocs/en/d/Js4876e/4.6.html>. Accessed December 4, 2018.
- 178 • Academy of Managed Care Pharmacy. Drug utilization review. 2009.  
179 <http://amcp.org/WorkArea/DownloadAsset.aspx?id=9296>. Accessed December 4, 2018.
- 180 • Institute for Healthcare Improvement. Science of improvement: testing changes.  
181 <http://www.ihl.org/resources/Pages/HowtoImprove/ScienceofImprovementTestingChanges.aspx>.  
182 Accessed December 4, 2018.
- 183 • Fanikos J, Jenkins KL, Piazza G, Connors J, Goldhaber SJ. Medication use evaluation:  
184 pharmacist rubric for performance improvement. *Pharmacotherapy.* 2014;34(Suppl  
185 1):5S-13S.
- 186 • Nau DP. Performance improvement and the medication use system. In: Malone PM, Kier  
187 KL, Stanovich JE, Malone MJ, eds. *Drug Information: A Guide for Pharmacists.* 5<sup>th</sup> edition.  
188 New York, NY: McGraw-Hill; 2014.
- 189 • Anderson KC, Brown C. Medication use policy and performance assessment. In: Gabay  
190 M, editor. *The Clinical Practice of Drug Information.* 1<sup>st</sup> edition. Burlington, MA: Jones &  
191 Bartlett; 2016.
- 192 • Faley B, Fanikos J. Best practices for medication utilization evaluations in postsurgical  
193 pain management. *Curr Emerg Hosp Med Rep.* 2017;5(1):33-40.

When approved, these guidelines will supersede the ASHP Guidelines on Medication-Use Evaluation dated April 24, 1996.

Copyright © 2019, American Society of Health-System Pharmacists, Inc. All rights reserved.

**Table 1. Common MUE objectives, example MUEs, and type of outcome (therapeutic or process)**

Objective	Example MUE	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, 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 therapy to reduce 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 international normalized ratio range in patients treated with warfarin	Therapeutic
	Evaluate the frequency of appropriate warfarin dose changes when an interacting medication was 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

---

**This draft is intended for review purposes only; it is not official ASHP policy. This document may not be reproduced, circulated (except for review purposes), or quoted without prior written permission from ASHP. Copyright © 2019, American Society of Health-System Pharmacists. All rights reserved.**

**Table 2. Indicators of need for MUE at different steps in the medication-use process**

Step	Indicator
Prescribing	Market entry or withdrawal of approved drug products used in the medication-use system 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 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
Administration	Medication misadventures related to medication delivery systems
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	Drug shortages requiring replacement of therapeutic substitution Diversion of controlled substances Lack of standardization or confusion within the medication use process Changes in cost or spending on drugs used within the medication use system

**Table 3. Problems, pitfalls, and barriers to completing a successful MUE**

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	Without a clear definition of the roles and responsibilities 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.
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 readily retrievable data or discrepancies in data abstraction	Collaboration with analytics or information solutions teams should occur to ensure the majority of discrete data fields are generated through reporting mechanisms. MUE group members completing chart abstraction should be trained so their collection methodologies are accurate and consistent.

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.

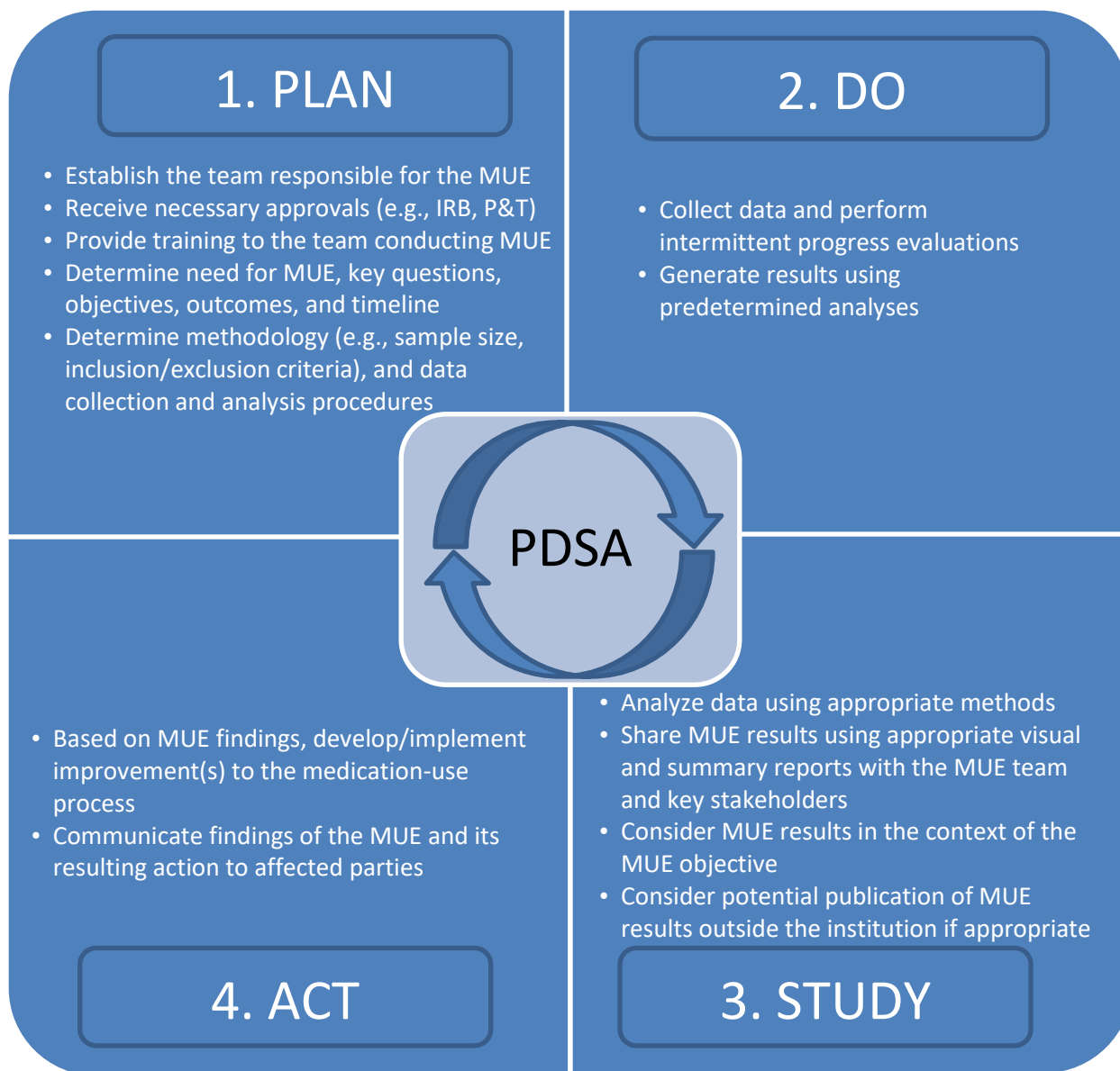


Figure 1. Components of the plan-do-study-act (PDSA) model applied to MUE. IRB, internal review board; P&T, pharmacy and therapeutics committee.