Reliability testing of a case-leveling framework for assigning level of difficulty of pharmacist’s initial patient medication assessments

Natalie Kennie and Lisa Dolovich

Abstract

Objective: To develop and test the reliability of a case-leveling framework for assigning level of difficulty of the pharmacist’s task for initial medication assessments conducted by pharmacists integrated into family physician offices.

Design: Descriptive study.

Setting: Seven family practice sites in Ontario from June 2004 to July 2006.

Patients: Patients referred by their family physician for pharmacist assessment.

Intervention: Individual medication assessments, monitoring, and follow-up by pharmacists. A case-leveling framework was developed with three levels of complexity (graded as I, II, or III) including specific descriptors and practice-based examples. Reliability was assessed between two standardized assessors and between one assessor and project pharmacists. Project pharmacist feedback was elicited through an e-mail survey. Reliability is reported using the kappa statistic.

Main outcome measures: Reliability of a case-leveling framework and helpfulness of the framework as reported by pharmacists.

Results: 53 patient cases were evaluated for interrater reliability between standardized assessors. The mean (± SD) case level assigned was 1.8 ± 0.68, and the kappa was 0.62 (95% CI 0.44–0.79), indicating a substantial strength of agreement between raters. For the second reliability test, 52 cases were rated, with a level of agreement between project pharmacists and the external assessor of 0.46 (95% CI 0.27–0.65), indicating moderate agreement. Feedback resulted in slight revisions to the original framework.

Conclusion: The case-leveling framework was a reliable method and can be used to determine the level of difficulty of patient cases in primary care.

Keywords: Primary care, case management, drug therapy assessment.


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Natalie Kennie, BSc(Pharm), PharmD, was Primary Care Pharmacist, Department of Family and Community Medicine, St. Michael’s Hospital, Toronto, and Assistant Professor, Faculty of Pharmacy and Department of Family and Community Medicine, University of Toronto, Toronto, at the time this study was conducted; she is currently a pharmacist with the Summerville Family Health Team, Mississauga, ON, Canada. Lisa Dolovich, BScPhm, PharmD, MSc, is Associate Professor, Departments of Family Medicine, Medicine, and Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, ON, Canada; Pharmacotherapy Specialist and Associate Director, Centre for Evaluation of Medicines, St. Joseph’s Healthcare, Hamilton, ON, Canada; and Associate Professor, Faculty of Pharmacy, University of Toronto, Toronto.

Correspondence: Lisa Dolovich, BScPhm, PharmD, MSc, Centre for Evaluation of Medicines, St. Joseph’s Healthcare, 105 Main St. East, Level P1, Hamilton, ON L8N 1G6, Canada. Fax: 905-528-7386. E-mail: ldolovic@mcmaster.ca

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The foundation of a medication consultation conducted by a pharmacist involves an initial medication assessment. The complexity of conducting patient medication assessments can be influenced by many factors, including those related to the patient or the health care provider (such as knowledge and skill level of the health care provider) and interrelational and environmental factors. Studies that have investigated the effectiveness of the provision of pharmacist medication assessments have generally described the patient population studied by age, medication use, number or types of medical conditions, or number or types of drug-related problems per patient. Taken together, these characteristics provide a representation of the complexity of the patients receiving a pharmacist intervention. However, patient characteristics do not fully account for or explain the entirety of factors that influence the task of conducting a medication assessment. Workload for the pharmacist when conducting a medication review has also been used and has generally been captured as the time to complete a review. Other factors that can affect the complexity of a medication assessment that could be considered include how well defined the pharmacist’s task is in conducting the medication assessment, whether patient factors can be easily interpreted (i.e., diagnosis, complete medical history), the complexity of the patient situation (i.e., communication, cognition), whether the drug-related issue is common or routine in primary care, and whether managing the problem is straightforward.

A greater understanding of the complexity of patient cases related to the task of medication assessments would help improve comprehension or prediction of complexity in relationship to patient characteristics or health outcomes, design of pharmacy curriculum and training, estimation of pharmacist workload, and integration of complexity into pharmacist payment for cognitive services.

Few methods for identifying the level of difficulty or complexity of the tasks or patient cases used in different contexts have been described. Cipolle et al. described a “pharmaceutical care reimbursement grid” as a method to determine the level of reimbursement for pharmacist services; the grid included levels of payment based on the patient needs and resources required. The level of payment is based on five categories of case complexity that take into account the following main criteria: number of medical conditions for which the patient is currently being treated, number of drug therapy problems present, number of medications the patient is taking, and whether the work-up is problem focused at the simplest level or comprehensive at the most complex level. Additionally, a competency framework originally developed by Bajcar and Boyd was created as part of the Association of Faculties of Pharmacy of Canada (AFPC) Educational Outcomes for a Post-Baccalaureate Pharmacy Graduate in Canada. This competency framework was proposed as a method to define the expected level of performance for a PharmD graduate. The framework defines the level of difficulty of a task by the amount and complexity of knowledge required and the complexity inherent in the specific situation in which the application occurs. The level of complexity is characterized according to three levels (I, II, and III). These frameworks are useful for determining complexity; however, alone they may not fully describe patient complexity related to conducting a medication assessment to inform both pharmacy curriculum and workload measurement.

**Objectives**

The goal of this study was to develop and test the reliability of a case-leveling framework to assign a level of difficulty to the pharmacist’s task for initial medication assessments conducted by pharmacists integrated into family physician offices. The specific objectives were to describe the development of a case-leveling framework, test the reliability of the framework, and collect formative feedback on the use of the case-leveling framework by pharmacists who used it in practice.
Methods

This descriptive study involved two assessments of reliability and a brief e-mail survey. The study was approved by the McMaster University Research Ethics Board. The pharmacists and patients in this study were participants in the Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics (IMPACT) project. This demonstration project examined the effect of pharmacist integration into family physician group practices on patient health outcomes and the processes of interdisciplinary care provision. Seven nondispensing pharmacists were integrated into seven different family physician group practices from June 2004 to July 2006. The pharmacists provided the following services: patient medication assessments, drug information and education, and office system enhancements to optimize drug therapy. Further information is available at www.impactteam.info. Three pharmacists had fewer than 5 years of experience, two had between 5 and 10 years of experience, and two had more than 10 years of experience. All had community pharmacy experience, and many of the pharmacists had practiced in more than one practice setting in their career.7

Case-leveling framework development

A case-leveling framework for assigning the level of difficulty of the pharmacist’s task was developed to determine the complexity of a key pharmacist activity in the IMPACT project—initial patient medication assessments. During a medication assessment, the pharmacist conducted a comprehensive patient interview to identify actual and potential drug-related problems for patients referred to the project. In addition, the pharmacist provided solution-focused recommendations to the physician, patient, and health care team. The case-leveling framework that was developed for this study is an application of the competency framework of the APIC Educational Outcomes for a Post-Baccalaureate Pharmacy Graduate in Canada8 that has been made specific to the task of conducting a medication assessment in the primary care family practice setting, as encountered in the IMPACT project.

The case-leveling framework developed (Table 1) comprised specific descriptors and practice-based examples for the patient case or task based on three main components: (1) complexity of the application required for the patient case or task, (2) complexity of the clinical knowledge/skills required to address the task, and (3) burden of drug-related problems. The latter component was added to recognize that the number of drug-related problems occurring within one patient increases the level of difficulty of the pharmacist’s task as a result of identifying, prioritizing, and solving multiple drug-related problems.

The difficulty of the pharmacist’s task for the initial medication assessment for each case was categorized according to three levels (I, II, and III), which were defined as follows:

- Level I: A task in which the patient case or task and the clinical knowledge required to address the case or task is straightforward and a low burden of drug-related problems exists.
- Level II: A task in which the patient case or task is complex or ill defined, or the clinical knowledge is complex, or a high burden of drug-related problems exists.
- Level III: A task in which both the patient case or task and the clinical knowledge are complex, or multiple codependent drug-related problems exist.

Reliability testing

Interrater reliability between standardized assessors. A sample of 53 medication assessments was reviewed to evaluate the interrater reliability of the case-leveling framework between two standardized assessors (N.K. and L.D.). The sample included approximately eight patient cases assessed by each of the seven participating pharmacists during the first months of the project in 2004. Raters independently reviewed pharmacist clinical documentation notes to rate the cases. Documentation notes included structured sections documenting pharmacist recommendations, lists of medications and medical conditions, detailed justifications for the drug-related recommendations, and follow up and monitoring plans. Interrater reliability was estimated using the kappa statistic. Disagreements in the assigned level of the cases were resolved by consensus. Refinements based on this pilot were then made to the descriptors and examples in the case-leveling framework to produce the original framework (Table 1).

Case level assignment by project pharmacists. Project pharmacists used the framework (Table 1) to assign case levels to all of their initial assessments for patients enrolled in the IMPACT study as part of their project activities at the 3-month follow-up appointment. The pharmacists recorded their rating in the project computer database.

Project pharmacists were trained to use the case-leveling framework during a 15-minute meeting and then asked to rate 10 sample cases. A follow-up group meeting was held to review the case levels assigned for the sample cases and to discuss areas of disagreement in order to achieve consensus.

Interrater reliability between a standardized assessor and project pharmacists. Reliability between a standardized assessor and project pharmacists was determined to evaluate the usability of the case-leveling system in practice by testing it across a set of pharmacists. To obtain a representative sample of patient cases over a 1-year period in the project with a similar number of patients as the first reliability sample (n = 53), one new patient initially seen by the pharmacists between January and December 2005 was chosen from the sites for each month. These cases formed the second reliability sample (n = 52).

Workload comparisons

Workload for initial medication assessments was estimated by the project pharmacists during their patient care activities and entered into their study database. Pharmacists were asked to record the time taken for initial
assessments. The components of the initial medication assessment workload were time taken to perform the chart review, patient interview, research into therapeutic issues, and documentation. Pharmacist total time allocation (where available) for cases sampled in the initial reliability testing (n = 53) was used to provide a preliminary analysis of workload differences per case complexity level.

### Analysis

Descriptive statistics (mean ± SD) for case levels and workload data were calculated. Reliability testing was estimated using the kappa statistic and 95% CIs based on the three categories of levels (level I versus level II versus level III). A kappa of 0.21 to 0.40 was considered fair strength of agreement, a kappa of 0.41 to 0.60 was considered a moderate level of agreement, and a kappa of 0.61 to 0.80 was

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Table 1. Case-leveling framework for assigning the difficulty of the pharmacist’s task for initial medication assessments

<table>
<thead>
<tr>
<th>Level of difficulty of task</th>
<th>Descriptor</th>
<th>Example</th>
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<tbody>
<tr>
<td><strong>Level I</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient case or task</td>
<td>The task (e.g., medication assessment, focused drug question) is clear (well defined).</td>
<td>Patient has uncontrolled chronic pain and is not using pain medication regularly.</td>
</tr>
<tr>
<td>AND</td>
<td>All patient-related factors are present and easily interpreted. The issue or problems are routine (common) in primary care.</td>
<td>Patient with suboptimal hypertension control and diabetes is not using an ACE inhibitor and has no contraindications to this class of medications.</td>
</tr>
<tr>
<td>Clinical knowledge</td>
<td>Managing the problem is straightforward, and clear treatment guidelines are available and readily accessible.</td>
<td>Patient with diabetes with uncontrolled lipids and not currently on adequate dose of a statin. Patient with uncontrolled asthma and having difficulty using inhalers.</td>
</tr>
<tr>
<td>AND</td>
<td>Original description: The number of DRPs the pharmacist must address is three or less. (Note that cases with one DRP can fall under level II if the patient care or task or clinical knowledge is complex.)</td>
<td>Patient is not receiving the optimal benefit of a medication due to a food–drug interaction or inappropriate administration time. Patient has three or fewer straightforward DRPs that the pharmacist must address.</td>
</tr>
<tr>
<td>Drug-related problems</td>
<td>Revised description: The DRPs identified are common or routine in primary care. If more than one DRP is identified, prioritization is straightforward.</td>
<td></td>
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<tr>
<td><strong>Level II</strong></td>
<td></td>
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<tr>
<td>Patient case or task</td>
<td>The task referred to the pharmacist is unclear or not well defined. The pharmacist has to collect initial information before clearly defining the task.</td>
<td>Patient has uncontrolled chronic pain and is not using pain medication regularly, has early dementia, lives alone, and his/her social and economic supports are not well known.</td>
</tr>
<tr>
<td>The patient is taking multiple medications and has multiple medical conditions requiring drug therapy. The patient is complex (communication difficulties, difficult ethical issues, patient affect, cognition, or attitude).</td>
<td>Patient with suboptimal hypertension and diabetes is not using an ACE inhibitor, has had an ACE inhibitor cough in the past and has increasing serum creatinine.</td>
<td></td>
</tr>
<tr>
<td>Some patient factors are not present, unclear, or not well described, requiring interpretation and inferences to be made.</td>
<td>Patient with marked dyslipidemia and previous intolerance to statins.</td>
<td></td>
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<tr>
<td>The issues or problems are uncommon (nonroutine) in primary care.</td>
<td>Patient has anxiety and depression, has been taking benzodiazepines on a long-term basis, and is at risk for falls, and the physician and patient are interested in tapering the benzodiazepine.</td>
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<tr>
<td><strong>OR</strong></td>
<td></td>
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<tr>
<td>Clinical knowledge</td>
<td>The clinical knowledge/skill required to address the task is complex. The clinical knowledge requires an in-depth understanding of multiple issues (e.g., drugs, diseases).</td>
<td>Patient is on multiple prescription medications (e.g., &gt;12) with potential drug interactions and dosing administration issues.</td>
</tr>
</tbody>
</table>

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### Table 1 (continued from previous page)

<table>
<thead>
<tr>
<th>Drug-related problems</th>
<th>Original description: The number of DRPs the pharmacist must address is four or more.</th>
<th>Revised description: The DRPs identified are complex. The DRPs are nonroutine (uncommon) in primary care.</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug-related problems</td>
<td>Original description: The patient is taking a medication with a narrow therapeutic index, may be experiencing adverse effects secondary to a supratherapeutic dose, and is taking drugs that may be interacting with the medication.</td>
<td>Revised description: The DRPs identified are complex. The DRPs are nonroutine (uncommon) in primary care.</td>
</tr>
<tr>
<td>Level III</td>
<td>Original description: Both the patient case or task and the clinical knowledge required are complex and ill-defined or multiple DRPs that are codependent are present.</td>
<td>Revised description: Both the case scenario and the clinical knowledge are complex and ill-defined and multiple DRPs that are codependent are present.</td>
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</table>

Abbreviations used: A1C, glycosylated hemoglobin; ACE, angiotensin-converting enzyme; DRP, drug-related problem.

*DRPs may relate to use of over-the-counter products (i.e., self-medication), prescription medications, and/or complementary therapy but exclude routine monitoring instructions, referrals to health care providers, and general medication education.

*The complexity of the patient may be difficult to accurately rate based on the pharmacist’s assessment documentation alone. However, raters should assign a level based on the complexity of the patient as described in the documentation.
considered a substantial strength of agreement. All analyses were conducted using SAS 9.0 (SAS Institute, Cary, NC).

Feedback on the use of the case-leveling framework

Project pharmacist feedback on the case-leveling framework was gathered using a brief e-mail survey containing two open-ended questions. The project pharmacists commented about its perceived usefulness and ease of use when assigning the level of difficulty to their patient cases. Specifically, the pharmacists were asked which aspects of the framework were (1) most helpful and (2) most challenging when assigning the case level for the initial medication assessments in practice.

Feedback was also sought from the original developers of the AFPC competency framework (N.K., oral communication, August 2006) to further the revisions made to the case-leveling framework. Additionally, project pharmacist feedback and standardized assessor experience were incorporated into the revised framework. Cases from the first sample were rerated by one of the original standardized assessors (N.K.) using the revised case-leveling framework. The level of agreement was recalculated to compare the case levels assigned using the original and modified case-leveling frameworks.

Results

Reliability testing

Interrater reliability between standardized assessors. A total of 53 patient cases were evaluated using the original case-leveling framework shown in Table 1. Complete agreement between raters on case level occurred in 41 of 53 (77%) cases. The kappa estimate was 0.62 (95% CI 0.44–0.79; P < 0.0001), indicating substantial agreement between raters. All disagreements were within one level of difference and were distributed evenly between cases rated at lower (level I) or higher (level III) levels. One assessor did not consistently rate the cases higher or lower than the other. The mean (± SD) case level assigned was 1.8 ± 0.68. Table 2 presents the distribution of cases (based on standardized assessor consensus) according to level.

Interrater reliability between a standardized assessor and project pharmacists. For the second reliability test, 52 cases were rated using the original case-leveling framework (Table 1) by the project pharmacists and standardized assessor. Complete agreement between project pharmacists and the standardized assessor occurred in 37 of 52 cases (71%). The level of agreement between the project pharmacist case assignment and the standardized assessor was 0.46 (95% CI 0.27–0.65; P < 0.001), indicating moderate agreement. Most disagreements were within one level of difference. Pharmacists did not appear to rate cases consistently higher or lower than the standardized assessor. The average case level assigned by the standardized assessor was 1.54 ± 0.54 and that by project pharmacists was 1.56 ± 0.69. Table 2 shows the distribution of cases according to level for the pharmacists and standardized assessor.

Workload comparison

For the 44 cases with available workload data from the initial sample, the average time spent on the initial assessment by project pharmacists was 4.6 ± 2.9 hours (range 1.3–15.5). Table 3 shows pharmacist time allocation according to case level. Workload estimates increased with case level.

Formative feedback

Feedback was received via an e-mail survey from five of seven project pharmacists. Pharmacists reported that the “patient case or task” complexity component was the most helpful aspect of the case-leveling framework. The pharmacists appreciated that there were examples for each case level, which helped in their assignment of the level of difficulty.

Two respondents indicated some difficulty in assigning case levels for therapeutic situations in which they had less experience/familiarity. They also indicated that they had difficulty with the case assignment incorporating “clinical knowledge,” as they believed they were continually building their skills in the practice setting. As the pharmacist’s clinical knowledge and skills improved, the difficulty level could have been rated lower than that assigned originally. The respondents felt that this shift may have affected the case level assigned to the medication assessments conducted earlier in the study.

Two respondents indicated that the drug-related problem burden was helpful in assigning case levels but, at the same time, were concerned that it might lead to errors in case assignment if not considered in relationship to the other components (patient case or task and clinical knowledge). In this situation, some respondents felt that the number of drug-related problems may have been relied on too heavily for the case-leveling assignment. One respondent also commented that varying values or beliefs between the physician and pharmacist as well as relationship or interaction between them may also affect case-leveling assignment; however, these elements were not taken into account within the framework developed in the current study.

Revisions made to the case-leveling framework

Based on the case-leveling assignment experience, pharmacist feedback, and consultation with the AFPC

<table>
<thead>
<tr>
<th>Case level</th>
<th>First case sample rated by standardized assessors</th>
<th>Second case sample rated by standardized assessor</th>
<th>Second case sample rated by pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>53</td>
<td>52</td>
<td>52</td>
</tr>
<tr>
<td>Level I, no. (%)</td>
<td>17 (32)</td>
<td>25 (48)</td>
<td>29 (56)</td>
</tr>
<tr>
<td>Level II, no. (%)</td>
<td>28 (53)</td>
<td>26 (50)</td>
<td>17 (33)</td>
</tr>
<tr>
<td>Level III, no. (%)</td>
<td>8 (15)</td>
<td>1 (2)</td>
<td>6 (11)</td>
</tr>
</tbody>
</table>

Table 2. Distribution of sample cases according to level
was initially considered a useful descriptor for the task of component in the assignment of case level of difficulty number of drug-related problems per case as an additional accessible. Data or tasks are defined, and whether the clinical knowledge primary care practice, the degree to which available patient alternative factors, including whether the issue is routine in specific patient case or pharmacist's task by considering method is that it can describe the level of complexity of the number of medications used by a patient or the number medication assessments conducted by pharmacists (such as long-term care setting).

**Table 3. Pharmacist time allocation according to level**

<table>
<thead>
<tr>
<th>Case level</th>
<th>Estimated time (h) Mean ± SD (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1 (n = 14)</td>
<td>2.7 ± 1.4 (1.3–6.0)</td>
</tr>
<tr>
<td>Level 2 (n = 23)</td>
<td>5.2 ± 2.4 (2.0–9.5)</td>
</tr>
<tr>
<td>Level 3 (n = 7)</td>
<td>6.5 ± 4.8 (1.5–15.5)</td>
</tr>
</tbody>
</table>

competency framework developers (N.K., oral communication, August 2006). Revisions were made to the third component of the framework related to drug-related problems for each of the three levels (Table 1). The number of drug-related problems was removed as a method for assigning complexity for levels I and II. Descriptors related to complexity were added for each of these levels. Level III case complexity was changed to reflect that the case scenario, clinical knowledge, and multiple drug-related problems that are codependent were required to assign a case at this level. The level of agreement between the original case level and that assigned using the modified case-leveling framework by the standardized assessor was 0.78 (95% CI 0.61–0.94; P < 0.001), indicating substantial agreement.

**Discussion**

The case-leveling framework developed in the present study was a reliable method for assigning level of difficulty of a pharmacist's task in conducting an initial medication assessment in primary care. This reliability was demonstrated by substantial agreement between the standardized assessors and by moderate agreement between project pharmacists and a standardized assessor. The pharmacists found that brief training was helpful in assigning case level of difficulty, and they were able to provide useful feedback about the framework after using it in practice. In addition, the pharmacist's time allocation in patient care activities was observed to increase according to level of complexity, demonstrating some initial yet promising congruence between the case levels and pharmacist workload.

Use of the case-leveling framework could be considered complementary to previous patient case descriptions for medication assessments conducted by pharmacists (such as the number of medications used by a patient or the number of drug-related problems per patient). The advantage to this method is that it can describe the level of complexity of the specific patient case or pharmacist's task by considering alternative factors, including whether the issue is routine in primary care practice, the degree to which available patient data or tasks are defined, and whether the clinical knowledge required to address the task is straightforward or easily accessible.

A few modifications were made to the original framework (Table 1) based on the pilot process. Including the specific number of drug-related problems per case as an additional component in the assignment of case level of difficulty was initially considered a useful descriptor for the task of conducting a medication assessment. However, some of the study pharmacists believed that this component might have been relied on too heavily for the case assignment. To address this issue, an alternative description of the drug-related problem component was suggested that presents specific examples of levels of complexity of the drug-related problems identified in the initial medication assessment rather than the number identified (Table 1). An additional factor perceived as relevant by the pharmacists that added to the complexity of the patient case or task was when the physician held values or priorities that differed from those of the pharmacist. This factor was also added as a descriptor of the complexity of a drug-related problem (Table 1).

To enhance the case-leveling framework and increase standardization of use, further study in the following areas is needed: describing routine situations or problems in primary care, identifying straightforward clinical knowledge (based on evidence and clinical guidelines), and providing additional practice-based examples. The flexibility of the AFPC competency framework facilitated its application in the context of initial medication assessments. The case-leveling framework could also be adapted (e.g., by changing the examples) to other environments, such as the hospital or long-term care setting.

This method for assigning case level of difficulty could be beneficial for a variety of purposes. Understanding the level of complexity and relative distribution of cases in primary care can assist pharmacy curriculum design and/or training of pharmacists who are new to providing medication assessments and clinical services in primary care or family practice settings. For example, this information could inform the development of patient scenarios for case-based learning or simulated patient interviews and help define the level of expected performance for pharmacists providing patient care in this setting. Case-level assignment also may be helpful for improving understanding of pharmacist workload per patient case and thus resource use, as case complexity can have a large impact on the time spent on initial medication assessments. For example, level I patient cases would be expected to require less pharmacist time than level III cases. Therefore, case complexity could help determine pharmacist resource allocation based on population requirements. Future research should also investigate whether case level may affect the ability of pharmacists and health care providers to change patient outcomes.

**Limitations**

The case-leveling framework developed here has limitations. Because case-level assignment was based on the clinical documentation notes of the project pharmacists, the standardized assessors needed to assume that the pharmacist identified and documented all relevant data and problems in the assessment note. Documentation format and level of detail differed among pharmacists and according to the needs of the clinical practice setting. In addition, potentially relevant complexity information based on the specific patient.
case (e.g., cognition, attitudes) may not have been included or stressed in the clinical documentation notes to enable the standardized assessor to weigh in a manner comparable with the project pharmacist. Therefore, in some situations (e.g., level III cases in which more case complexity exists), the standardized assessor may have assigned a lower level than the study pharmacist. Nevertheless, the use of clinical documentation is applicable when using the case-leveling framework to rate cases in practice and future research studies. Another limitation of using this method is that the framework is somewhat subjective and dependent on the knowledge and skills of the pharmacist involved. Pharmacists who are unfamiliar with a therapeutic topic area may assign a higher case level rating compared with pharmacists with experience in that therapeutic area. However, a comparison of case level ratings did not reveal obvious differences between the ratings of the project pharmacists and standardized assessor. More work needs to be done to explore this further.

**Conclusion**

The case-leveling framework developed was a reliable method for assigning level of difficulty of the pharmacist’s task in conducting an initial medication assessment for the IMPACT project. Although future research is needed, the congruence observed between case levels and pharmacist workload is promising. This framework can be used as a method for assigning the level of difficulty of patient cases or describing case complexity from a medication perspective for patients in primary care practice. Further experience using the framework, including adaptation to other practice areas, should occur.

**References**