

# Adverse Drug Reactions and Current State of Drug Regimen Review in Nursing Facilities: Need for a Change?

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**Objective:** To review the salient issue of adverse drug reactions in nursing facilities.

**Setting:** Nursing facilities across the United States.

**Practice Description:** Federally mandated, retrospective drug regimen reviews (DRRs) performed by consultant pharmacists are discussed as the impetus for change.

**Practice Innovation:** A prospective process of medication therapy management that involves pharmacists interacting with the interdisciplinary care team is described as a way to deliver high-quality, medication-related health care at the point of care. The paper presents the Fleetwood model as an exemplar of the proposed care model and—as well as the recent revisions to the interpretive guidelines for the State Operations Manual (SOM)—as a means of changing the way medication therapy management is deployed in nursing facilities.

**Main Outcome Measures:** Change in nursing facility pharmacy practice.

**Results:** In settings where the Fleetwood model has been implemented, researchers have observed numerous changes, including increased clinical involvement by dispensing and consultant pharmacists, reduced time spent on traditional DRR, increased time spent on pharmaceutical care planning, improved communication among the interdisciplinary team, and more efficient processes within the nursing facility pharmacy. Changes in the Pharmacy Services Tags (F425, F428, F431) and Unnecessary Medications Tag (F329) in the interpretive guidelines for the SOM, released by the Centers for Medicare & Medicaid Services, have significant implications for the way consultant pharmacists practice.

**Conclusions:** Application of prospective medication therapy management, such as that contained in the Fleetwood model, and changes to the interpretive guidelines support greater pharmacist involvement at the point of care, which has potential to dramatically decrease adverse drug reactions in nursing facilities.

**Key Words:** Adverse drug reactions, Consultant pharmacist, Drug regimen review, Fleetwood model, Interpretive guidelines, Nursing facility, Nursing home, Prospective medication therapy management, State Operations Manual.

**Abbreviations:** ADR = Adverse drug reaction, ASCP = American Society of Consultant Pharmacists, CMS = Centers for Medicare & Medicaid Services, DRR = Drug regimen review, SOM = State Operations Manual.

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## Introduction

Medications play an important role in the prevention, cure, and palliation of disease. Medication therapy is an integral part of the care provided to residents of nursing facilities and a key determinant of resident outcomes. Despite their positive attributes, all medications can be dangerous, even when they are used according to approved labeling. A medication-related problem is defined as an event or circumstance involving a patient's medication that actually or potentially interferes with the achievement of a desired patient outcome<sup>1,2</sup> or leads to a deleterious outcome such as hospitalization, fall, functional decline, or cognition change.<sup>3</sup> Eight categories of medication-related problems have been identified (Table 1); their operational definitions have been described elsewhere.<sup>1,2</sup> Medication errors are defined as any error occurring in the medication use process.<sup>4</sup> Most often, medication errors occur at the stages of prescribing<sup>5-9</sup> and monitoring.<sup>5-7,10</sup> Medication errors may result in medication-related adverse events, which include adverse drug reactions (ADRs), adverse drug withdrawal events, and therapeutic failures.<sup>11</sup> For the purpose of this commentary, the focus is on ADRs, defined as a response to a drug that is noxious and produces unintended consequences, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy for disease or for modification of physiologic function.<sup>11,12</sup>

The purpose of this article is to review the salient issue of ADRs in nursing facilities. The problem is framed by describing the incidence and economic impact of ADRs in that setting. The discussion section evaluates pharmacist-conducted, retrospective drug regimen reviews (DRRs),

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**Table 1. Categories of Medication-Related Problems**

- Untreated indication
- Improper drug selection
- Subtherapeutic dose
- Failure to receive drugs
- Overdose
- Adverse drug reactions
- Drug interactions
- Drug use without indication

Source: References 1, 2.

and reviews the Fleetwood Project and revisions of the interpretive guidelines for the State Operations Manual (SOM), released by the Centers for Medicare & Medicaid Services (CMS) in December 2006. To conclude, the paper calls for a change in the pharmacy profession that will foster innovative ways to improve the delivery of medication-related health care in nursing facilities. Specifically, the author suggests a prospective process of medication therapy management that involves pharmacists interacting with the interdisciplinary care team to deliver high-quality, medication-related health care at the point of care rather than through a retrospective audit of residents' profiles.

### Incidence and Risk Factors

Handler et al.<sup>11</sup> recently performed an exhaustive review of the available literature on medication-related adverse events in the nursing facility setting during the past two decades. The incidence rates reported across the sample of studies ranged from 1.2 to 7.3 per 100 resident-months;<sup>11</sup> the marked variability is most likely explained by the heterogeneous study designs<sup>11</sup> and underreporting of medication errors in nursing facilities.<sup>13</sup> Therefore, the true incidence of ADRs in nursing facilities may be greater than that reported. Although certain iatrogenic responses to some medications are inherently unavoidable, adverse events may largely be preventable. The incidence of preventable medication-related adverse events varies across health care settings, with reported estimates ranging

from 25% to 60%,<sup>5-8,10</sup> and among residents of nursing facilities, as many as half of these events are considered preventable.<sup>5,6</sup> Ironically, the more serious adverse events are more likely to be of the preventable type.<sup>5</sup>

Data from the National Nursing Home Survey indicate that in 1999 an estimated 1.6 million Americans received care in nursing facilities nationwide. Of these residents, 90.3% were older than age 65, and 46.5% were older than age 85.<sup>14</sup> The increasing proportion of nursing facility residents aged 85 years and older mirrors the growth of this segment of the United States population.<sup>14</sup> Not surprisingly, because of the number and severity of chronic comorbid medical conditions that coexist among the frail elderly, there has been a growth in medication use in nursing facilities. In fact, nursing facility residents are prescribed more medications than patients in any other medical setting.<sup>11</sup> Specifically, these residents take an average of 8.8 medications per day (7.6 regularly scheduled and 1.2 as needed), and 32% take  $\geq 9$  medications.<sup>15</sup> The number of regularly scheduled medications has been strongly correlated with increased risk of ADRs in all settings of care.<sup>10,16-19</sup> Several investigators have demonstrated that use of  $\geq 9$  medications imposes significant risk to nursing facility residents (odds ratio, 2.3 to 3.3).<sup>5,20,21</sup> Equally formidable, several classes of medications commonly used in these residents have been directly linked to ADRs. The most frequently cited include cardiovascular and psychoactive or central nervous system agents;<sup>5,6,19-22</sup> the latter are among the therapies most often implicated in adverse events such as falls and fractures.<sup>5,6,20,21</sup>

In the nursing facility population, the use of psychoactive medications, which include antidepressants, anxiolytics, sedative hypnotics, and antipsychotics, has risen: between 1997 and 2004 their use increased by 60%.<sup>23</sup> In addition to the number and type of medications taken by nursing facility residents, the physiological changes associated with aging may further increase older adults' susceptibility to ADRs. The pharmacokinetics and pharmacodynamics of certain medications are affected by renal and hepatic function, body mass, and/or plasma albumin levels, all of which diminish with age. One study estimated that more than two-thirds of older nursing facility residents have at least four risk factors for ADRs.<sup>3</sup> Thus, it stands to reason that a sizable number of nursing facility residents are at increased risk for experiencing one or more ADRs.

## Economic Impact

Medication-related adverse events are often associated with substantial morbidity, mortality, and increased health care resource utilization. The occurrence of an ADR in residents of nursing facilities frequently increases both the intensity of care requirements and consumption of additional resources to treat the medication-related event. The cost of medication-related morbidity and mortality in the nursing facility is estimated at \$7.6 billion.<sup>24</sup> For every dollar spent on medications in this setting, an average of \$1.33 in health care resources is consumed to treat the effects of medication-related problems.<sup>24</sup> The economic impact of treating medication-related problems emanating from nursing facility care is particularly noteworthy when compared with other settings. For example, in the ambulatory setting the ratio is reported as dollar for dollar.<sup>25,26</sup> Clearly, as the population of older adults increases in the coming decades, and the number living in nursing facilities grows, the human and economic costs associated with medication-related problems such as ADRs are potentially staggering.

## Discussion

### DRR

While physicians, nurses, and other health professionals also contribute to effective medication therapy management, consultant pharmacists have a unique, mandated role in appropriate medication use. For Medicare/Medicaid-certified nursing facilities, federal regulations require that each resident's medication regimen be (retrospectively) reviewed at least once a month by a consultant pharmacist. The pharmacist must report any "irregularities" to the attending physician and director of nursing, and these reports must be "acted on." In addition, each resident's medication regimen must be "free of unnecessary drugs."<sup>27</sup> This model of medication oversight is known as the DRR process.

The medical literature is replete with findings pertaining to the impact of consultant pharmacists on reducing inappropriate medication use and polypharmacy in nursing facilities.<sup>24,28-34</sup> Although these studies have contributed to an understanding of the role of consultant pharmacists in the nursing facility environment, most were narrow in scope, measuring only avoided medication costs and failing to consider the range of possible adverse clinical outcomes

associated with medications.<sup>24</sup> Recognizing the need to describe the role of consultant pharmacists' practice beyond the economic effects, the American Society of Consultant Pharmacists (ASCP) initiated the Fleetwood Project, the largest research initiative designed to examine the impact of consultant pharmacists' services on patient outcomes and health care costs in nursing facilities. The project was a three-phase, multicenter study. Phase I of the project was the first pharmaco-economic study to quantify the costs of medication-related morbidity and mortality in United States nursing facilities, as previously mentioned, and to quantify the value of consultant pharmacy services in reducing medication-related problems.

The study found that consultant pharmacists' retrospective DRR under the current federal mandate helped to reduce annual health care costs from avoided medication-related problems by \$3.6 billion (52.6%).<sup>24</sup> This research represents an improvement over previous investigations of pharmacists' impact in that it simultaneously incorporated clinical and economic effects of medications in the nursing facility setting rather than estimating only direct drug-cost savings.

Nevertheless, retrospective DRR programs have not been shown to improve clinical outcomes.<sup>35</sup> Although the purpose of the federally mandated monthly DRR is to improve medication use and to avoid medication-related adverse events in nursing facility residents, current DRR guidelines focus on a limited selection of medications and indications (a medication list) rather than on patient health outcomes. Accordingly, the clinical correlates of DRR are neither measured nor reported.<sup>36</sup> While this medication list has been updated since its original development, it focuses on a limited number of medications and fails to address the overall health of the resident. There is growing concern about ADRs in older nursing facility residents involving medications that might not be on this list.<sup>36</sup>

Additionally, there is a financial disincentive to pharmacists to widen the scope of their DRR evaluations, as payment is based solely on this medication list.<sup>36</sup> Finally, adhering to DRR guidelines does not guarantee a decrease in medication-related morbidity. For instance, a comparison of institutional practice patterns before and after implementation of CMS's policy for nursing facility certification revealed that mandated, retrospective DRRs—as designed and currently implemented through the surveyor process—provide no greater protection against receiving potentially inappropriate medication in nursing facilities than

no reviews at all.<sup>37</sup> Furthermore, despite the current system of DRR, medication-related hospitalizations may affect as many as one of every seven nursing facility residents.<sup>38</sup> Collectively, these studies highlight the problems of trying to improve patient safety and quality of care in nursing facilities through nationally mandated, retrospective DRRs. The question then raised is: could a different model of care be designed that is both economically feasible and improves clinical outcomes in nursing facility residents?

### The Fleetwood Model

Appreciating the value of consultant pharmacists' services in reducing medication-related problems, yet recognizing that current practices have not been adequate to prevent avoidable medication-related adverse events, ASCP developed a new model for nursing facility pharmacy services, subsequently referred to as the Fleetwood model. The new model was designed to be a *prospective* rather than retrospective medication review and to focus on patients at highest risk for medication-related problems.<sup>39</sup>

As mentioned, the results of Phase I of the Fleetwood Project provided valuable baseline cost-of-illness data concerning medication-related morbidity and mortality within the nursing facility setting against which the provision of prospective medication therapy management by consultant pharmacists could be evaluated. In turn, Phase II of the Fleetwood Project was a two-part feasibility study and pilot implementation of the prospective Fleetwood model. The first part was designed to identify risk factors for medication-related problems among older nursing facility residents.<sup>3</sup> The second part of Phase II compared outcomes associated with the traditional retrospective DRR approach to those associated with the prospective process of medication review and formalized pharmaceutical care.<sup>40</sup>

Implementation of the Fleetwood model:

- Increased clinical involvement by dispensing and consultant pharmacists
- Reduced time spent on traditional DRR and increased time spent on pharmaceutical care planning
- Afforded greater recognition of the pharmacist's contribution to patient care by physicians and nursing staff, which subsequently led to increased pharmacist consultations
- Improved communication among the interdisciplinary team

- Established more efficient processes within the pharmacy

These pilot data were the basis for continuing evaluation of the model in multiple nursing facilities.

Phase III of the Fleetwood Project was a three-year, multicenter, randomized trial to test the effectiveness of the Fleetwood model in reducing medication-related problems in nursing facility residents and to identify outcomes most sensitive to pharmacists' intervention. While the final phase of the Fleetwood Project is complete, the results are yet to be published. Nonetheless, Lapane and Hughes<sup>41</sup> recently provided a glimpse into how pharmacists conducted their practice before and after the implementation of the Fleetwood Phase III study. In the past year, dispensing pharmacists at the intervention site (Fleetwood model) were more likely than those at the control site (usual practice) to perform resident assessments (60% versus 0%) and prospective medication therapy management (71% versus 50%), and provide formalized pharmaceutical care planning (71% versus 0%), most or all of the time. More consultant pharmacists at the intervention site, compared with their consultant colleagues at the control site, provided prospective medication therapy management to nursing facility residents (60% versus 40%), participated as part of interdisciplinary health care teams (60% versus 20%), and provided formalized pharmaceutical care planning (80% versus 60%), most or all of the time; however, consultant pharmacists at the intervention site were less likely to perform resident assessments (40% versus 80%), most or all of the time. These data demonstrate that nursing facility-pharmacy practice can change within a study context<sup>41</sup> and that significant shifts in the focus of practice can be achieved within a short period of time, with a dramatic impact on process measures of pharmacy practice.

### Revisions of the Interpretive Guidelines

CMS has recently revised the SOM, which outlines the standards that state surveyors must consider when reviewing pharmacy services provided in nursing facilities as part of the annual review required by federal regulation. These revisions signify important changes in consultant pharmacists' accountability for medication use in nursing facilities.<sup>42</sup> Of particular importance to consultant pharmacists are the release of the new Pharmacy Services Tags (F425, F428, F431) and Unnecessary Medications Tag

(F329) in Appendix P and PP of the SOM. In general, the revisions to the F-Tags encourage a more holistic view of the medication regimen and assessment of the patient. For example, the new approach mandates an evaluation of medication-specific, risk-benefit ratios; expands reviews of medication indications beyond simply matching diagnoses with medications; and provides guidance on monitoring for efficacy and safety, which involves ongoing vigilance by pharmacists, among others.<sup>42</sup> More specifically, Tag F425 (Pharmaceutical Services and Procedures) clearly details the consultant pharmacist's responsibilities, providing specific examples of activities that the consultant pharmacist and facility may collaborate on to ensure the provision of these services.<sup>42</sup>

The revised guidelines also provide the first formal definition of medication regimen review: "a thorough evaluation of the medication regimen of a resident with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication." According to the new guidelines, Tag F428 (Medication Regimen Review) emphasizes that pharmacists are expected to perform medication regimen reviews more often than every 30 days, if necessary (e.g., short-stay residents). Additionally, consultant pharmacists may identify and report concerns in several medication-related problem categories.<sup>42</sup>

A thorough understanding of the changes to the interpretive guidelines is critical for consultant (and dispensing) pharmacists servicing nursing facilities. The reader is encouraged to review the recent publication by Martin and McSpadden<sup>42</sup> for a more in-depth evaluation of the revisions to the SOM. These changes will undoubtedly challenge consultant and senior care pharmacists to demonstrate their worth and to take responsibility for the efficacy and outcomes of medication therapy in nursing facilities.

### Call for a Change

Despite pharmacist-conducted DRRs, aggregate data suggest that ADRs are remarkably common in nursing facility residents, and medication-related health care in the nursing facility setting is still in need of marked improvement. Although the majority of patient outcomes are not influenced by any one discipline alone, the current state of health care in the United States provides unparalleled opportunities for pharmacists to make important

contributions to patient care in nursing facilities. Through innovative technological tools and models that support prospective medication therapy management, consultant pharmacists have a tremendous opportunity not only to break the mold of the currently mandated retrospective DRR process, but also to significantly affect the health-related and economic outcomes of their patients. The current capitated payment system for nursing facilities elevates the importance of achieving positive clinical outcomes, and it supports a prospective medication therapy management approach that aligns financial incentives between payers and providers. Residents stand to benefit from further research on quality, especially with regard to the effects of newer models for prospective medication therapy management on clinical outcomes.

Usual practice that consists of dispensing services and federally mandated DRR contains some elements of the Fleetwood approach, but is not as comprehensive and structured. The Fleetwood model:

- Requires participation of dispensing pharmacists and consultant pharmacists
- Incorporates the elements of prospective review, direct communication with the prescriber, and formalized pharmaceutical care planning
- Integrates a computerized system to identify residents receiving potentially inappropriate medications, provide treatment algorithms for alternative therapies, document the formalized pharmaceutical care plans, and allow sharing of information between dispensing and consultant pharmacists at the point of care

The Fleetwood model was the first to demonstrate that pharmacy practice in nursing facilities could be re-engineered to capitalize on pharmacists' clinical expertise while also improving workflow and economic efficiencies.<sup>39</sup> Findings from Lapane and Hughes<sup>41</sup> are encouraging in that they suggest that dispensing and consultant pharmacists can integrate elements of the Fleetwood model into their current practices. However, this study and others of the Fleetwood model have not assessed how the improvements translate into clinical outcomes for nursing facility residents. Furthermore, barriers that may limit the extent to which the elements of the model of care can be diffused into practice must be further evaluated. In the meantime, the nursing facility community eagerly awaits additional findings from the Fleetwood Project with anticipation that an evidence-based approach will improve

practice, and ultimately improve outcomes for the burgeoning number of individuals in nursing facilities.

Modifying the current system to achieve greater efficiency within its current mandate will likely be insufficient to improve outcomes in nursing facility residents. The recent revisions to the SOM provide a foundation for optimizing the services of consultant pharmacists in the nursing facility setting, thereby re-engineering practice toward a more clinical, patient-centered orientation—one that focuses on the patient as a whole and not on the medication profile as a silo. Regardless of the resolution, it is time to move beyond studying the problems; it is time for the pharmacy profession to make meaningful progress toward implementing an evidence-based, feasible, preventive, and prospective approach to assure the safe and appropriate use of medications in nursing facilities. Now is the time for the pharmacy profession to foster innovative ways to improve the delivery of medication-related health care in nursing facilities and close the gaps between best practice and usual care. The Fleetwood model and revisions to the SOM are steps in the right direction.

## Conclusion

Application of prospective medication therapy management, such as that contained in the Fleetwood model, and changes to the SOM interpretive guidelines, support greater pharmacist involvement at the point of care, which has potential to dramatically decrease ADRs in nursing facilities.

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