

# TOPICS

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## **F-329: Unnecessary Drugs Adverse Drug Consequences**

**By Rich Januszewski, M.S., Pharm., C.G.P.**

According to a recent study, it is estimated that about 120 adverse drug events (ADE) should be identified each year in an average 105-bed long-term care facility (LTCF) (1). The authors of this study went on to state that, if extrapolated nationally, their results would translate into 1.9 million ADE each year in all U.S. LTCF residents of which about 42% should be preventable. Of these ADE an estimated 86,000 would be fatal or life threatening with about 70% being preventable.

Giving any drug in the presence of adverse consequences which indicate the dose should be reduced or discontinued is an *unnecessary drug* according to OBRA-87. An *adverse drug consequence* refers to an unpleasant symptom or event that is due to or associated with a medication (2). Adverse drug consequence is a very broad regulatory term and comprises many medication related categories. A few examples of adverse drug consequences include adverse drug reactions, drug side effects, drug-drug interactions, and drug-disease reactions. Minnesota LTCFs are frequently cited for not adequately monitoring for the emergence or presence of adverse drug consequences. Most studies within the medical and pharmacy literature characterize medication adverse consequences as adverse drug events (ADE) or adverse drug reactions (ADR). An ADE is a response to a drug that is noxious and unintended and occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for modification of physiologic function (2). An ADR is an appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment or alternation of the dosage

regimen or withdrawal of the product. The purpose of this article is to focus on ADE with an emphasis on the ADR sub-category.

### **Scope of the Problem**

The Food and Drug Administration has operated the Adverse Event Reporting System since 1998. From 1998 to 2005 serious ADE reports increased 2.6-fold and fatal ADE increased 2.7-fold. Those over the age of 65 accounted for a disproportionate 34% of the reported serious ADE (3). Recent FDA activities such as taking propoxyphene off the market and expanding the warnings regarding the use of Avandia are two examples of FDA involvement with ADE. Due to differences in study designs and patient demographics, studies have revealed a wide and inconsistent range of ADE rates going from 2.5% to 35% (4, 5, 6, 7). ADE have been studied mostly among hospitalized patients and it has been estimated that 5-25% of hospital admissions are drug-related (8, 9). In community-dwelling elderly up to 34% experience ADE each year and up to 30% of hospital admissions in older people are related to ADE (6, 10). A study in 2003 involving elderly ambulatory patients discovered that 27% of all ADE were preventable. Thirty-eight percent of the ADE were considered serious, life threatening, or fatal with 42% of them considered preventable (11). Fatal events included intracranial hemorrhage, (related to what? aspiration pneumonia related to oversedation, digoxin toxicity, and a drug associated metabolic abnormality (hypercalcemia). The most common preventable ADE involved oversedation, confusion, hallucinations, and delirium and the most common drugs included warfarin, antipsychotics, loop diuretics, opioids,

antiplatelets, and ACE inhibitors (52%). The stages of pharmaceutical care in which a preventable ADE occurred were during monitoring (80%), prescribing (59%), administration (13%) and dispensing (5%). The most frequent ADE in nursing homes are ADRs and range from 1.2 to 7.3 per 100 patient-months (12). Two studies conducted in Georgia, found about two thirds of LTCF residents experienced an ADE over a 4-year period of time, with 1 in 7 of these residents requiring hospitalization (13, 14). In 2000 a study involving 18 LTCFs over a 12 month period of time discovered that 13.7% of the residents experienced an ADR with nearly 44% of the ADR being fatal, life threatening, or serious. Fifty-one percent of these ADRs were deemed preventable (15). A more recent study within two LTCFs by the same author found 42% of ADE were preventable (1).

## Preventing ADES

A review of 29 studies involving preventable ADES found rates of 21% for ambulatory patients, 35% for inpatients, and 42% to 51% in LTCFs (19). Interventions that have shown some success in preventing ADE include prescriber education, pharmacist intervention, comprehensive geriatric assessment, and computerized decision support tools (17, 187). One study found a high positive predictive value for detecting ADRs by computerized clinical event monitors using pharmacy order signals and laboratory test result signals (19). These signals involve abnormal laboratory values, elevated medication concentrations, and antidotes used. This study found that 30% of ADR were preventable and that 88% of the preventable ADR were in the monitoring stage of the medication use process. However, such interventions are resource intensive and not universally available (20). The majority of preventable ADRs occur at the monitoring (80%) and prescribing (59%) stages of the medication use process (1). A recent study suggests that serum concentration monitoring for narrow therapeutic window drugs (e.g. digoxin, anticonvulsants) may be underutilized (21). Performance measures and interventions targeting warfarin, insulin, and digoxin use could prevent more emergency department visits due to ADE (22).

Particular medications have been identified as risk factors and closer scrutinizing their use may minimize ADE. When it comes to hospital admissions, 9 of the 10 most commonly implicated medications may be categorized into 3 classes: anticoagulant/antiplatelet agents, antidiabetic agents, and narrow therapeutic index agents (e.g. digoxin and phenytoin). Together these 3 classes accounted for an estimated 32%-48% of all emergency department visits for ADE among older adults (22, 23). The drug groups most frequently associated with preventable ADE-related hospital admissions were cardiovascular drugs (47%), CNS-active drugs (15%), and respiratory drugs (12%). In ambulatory studies 86% of preventable ADE were from cardiovascular drugs, analgesics, and hypoglycemic agents (16). Numerous studies have implicated the Beers medications with ADE. But some studies have questioned whether the Beers criteria pose an increased risk for ADE or account for only a small proportion of ADE in older patients (22, 24, 25, 26). For now, the debate continues regarding the Beers criteria utility as risk factors for ADE.

## Detecting Adverse Drug Reactions

Detecting an ADE in progress is paramount in maintaining the health of LTCF residents. It is frequently difficult to distinguish an ADE from an exacerbation of an existing disease or a new medical problem. ADE in older patients often manifest themselves with non-specific symptoms or geriatric syndromes such as cognitive impairment or falls. Not correctly identifying the occurrence of an ADE may lead to the prescribing of another drug (cascade effect) and unnecessary poly-pharmacy. *Prescribing cascade* is a known problem, where a medication-caused ADE is mistaken as a separate diagnosis and treated with more medications, which puts the patient at risk for additional ADE (27). The key frequently involves recognition of a change in a resident's function, as this may be an early sign of an ADR. Various approaches can be used to detect ADE. One study in two LTCFs found 78% of ADE were detected by periodic medical record reviews, 20% via computerized signals, but only 2% through incident reports (1). The *Naranjo Criteria* is the most widely used tool for assessing ADE causality and determining the likelihood of whether an ADR was actually due to the drug

identified (28). This tool scores a potential ADR from 0 (doubtful) to 9 or 10 (definite). Unfortunately, the results are often difficult to interpret in older residents.

The Trigger tool, developed in part by the Institute of Healthcare Improvement, increases the rate of ADE detection 50-fold over traditional reporting methods (29). It was recently modified for LTCFs. This LTCF tool includes 40 triggers: 15 lab./medication combinations, 12-medication concentrations, 10 antidotes, and 3 Resident Assessment Protocols. It is recommended that this tool be used to measure the number of ADE in a LTCF over time, and determine whether or not the changes a facility is making result in improvement. This information can then be reported to the Quality Assurance and Assessment Committee (QAAC), which can then develop and implement plans of action to prevent future ADE. The Trigger tool requires about 20 minutes per resident for record review by an experienced person.

### **Predicting ADE**

A better approach to preventing ADRs is to identify residents who are at a high risk for ADE and then devote resources toward that group. One way to do this is to identify inappropriate medications and eliminate their use. Drugs-to-avoid criteria may best be used to warn prescribers of potential problems prior to prescribing and also as a means to identify medications needing follow-up during individualized reviews. Frequently studies have utilized explicit (criterion based) or implicit (judgment based) criteria to define inappropriateness. Explicit criteria are easy to use and intended to be universally applicable while implicit measures are highly patient specific. A major limitation of both types is that they frequently leave room for disagreement as to what defines appropriateness. Some of the tools developed to identify inappropriate medications are listed below.

### **Beers Criteria (30)**

The Beers' criteria are the most widely cited explicit tools and have dominated the medical/pharmacy literature since they first came out in 1991. The criteria were revised in 1997 and more recently in 2003. A number of studies using explicit measures, mainly the Beers criteria, have reported significant relationships with ADE risks

(31, 32, 33). But, one study found that the Beers criteria accounted for only 3.6% of emergency department visits due to ADE and failed to identify more than 85% of actual inappropriate prescribing (8). Another study (34) found that 61% of the medications identified as potentially inappropriate by the Beers criteria were not judged to be problematic by a group of expert reviewers. Moreover, the Beers criteria identified only 8% of the drugs that experts judged to be problematic. This study suggests limited accuracy of drugs-to-avoid criteria when applied at the level of the patient. A systematic review concluded that Beers criteria were associated with some adverse health effects, but the studies analyzed were too heterogeneous to support formal meta-analysis (35).

### **Zhan Criteria (34)**

The Zhan criteria start by using the 1997 version of the Beers criteria but do not include considerations for drug dosages, or drug-disease interactions. Medications are placed into 3 categories: drugs to avoid, drugs that are rarely appropriate, and drugs that are sometimes appropriate but often misused.

### **Screening Tool of Older Persons (STOPP) (36)**

This tool identifies potentially inappropriate medications according to physiological systems. It includes reference to drug duplication and various interactions. These criteria address more domains of prescribing appropriateness than the Beers' criteria. One study found that the STOPP criteria identified a significantly higher proportion of patients requiring hospitalization as a result of potentially inappropriate medicine related ADE than the Beers criteria (37).

### **Medication Appropriateness Index (MAI) and Modified MAI (38, 39)**

The MAI tool is the most frequently used implicit measure of medication appropriateness. Each medication's appropriateness is given a value of 0 to 18 by using ten criteria involving indications, effectiveness, dose, administration, interactions, and cost. Recently a modified MAI tool has been tested and demonstrated that it can significantly predict ADE risks and may even be more utilitarian than the original MAI. The major problem with the MAI is the time it takes to use

(about 10 minutes per medication) and the need for a well trained individual. The modified MAI employs only six criteria and is therefore more user friendly.

### **ARMOR: A Tool to Evaluate Polypharmacy in Elderly Persons (40)**

The ARMOR (Assess, Review, Minimize, Optimize, Reassess) is an attempt to consolidate a number of tools into a functional and interactive tool. It approaches polypharmacy in a systematic and organized fashion. The tool emphasizes quality of life as a factor for making decisions. Functional status and mobility is held up as the essential final outcome measure for any medication change. The author of this tool states results include a decline in the use of poly-pharmacy, psychotropics, falls, and behaviors.

### **The Drug Burden Index (41)**

Medications with high anticholinergic and/or sedative properties have been identified as causing ADE in the elderly. This tool quantifies the anticholinergic and sedative burden based upon the specific medications a resident is receiving. The drug burden index has demonstrated that anticholinergic and sedative drug exposure is associated with poorer function in community-dwelling older people. This study also found that the association between the number of drugs taken and poorer functioning is lost if anticholinergic and sedative drugs are excluded. Thus, in order to prevent ADE it may be more important to assess specific medications a resident is receiving than the total number they are receiving (i.e. poly-pharmacy).

### **GerontoNet ADR Risk Score (42)**

This recently developed tool assesses risk utilizing more than just medications. This tool identifies and quantifies a resident's ADE risk level using variables including: number of drugs, a history of an ADR, heart failure, liver disease, presence of 4 or more conditions, and renal failure. Risk scores with the tool range from 0 (doubtful) to 9-12 (definite). The researchers believe their tool to be a practical, efficient and a simple method of identifying patients who are at increased risk for an ADR and may represent individuals justifying preventive interventions.

### **The Good Palliative-Geriatric Practice Algorithm (43, 44)**

This is an implicit criteria algorithm tool that has been tested within a LTCF and community-dwelling for older patients with dramatic results. The algorithm has been shown to be effective in reducing polypharmacy, costs, and improving mortality and morbidity. Overall, discontinuation rates were 2.5 and 2.8 medications per patient in the LTCF and community settings. In the community-dwelling residents 47% of all medications were discontinued, and after a mean follow-up of 19 months only 2% were restarted. Within the LTCF only 10% of discontinued medications were restarted.

### **Conclusions**

It is not easy to determine if a resident is experiencing an ADE or ADR from a medication, let alone determine what type of ADE is occurring. Whenever a resident is experiencing what appears to be an exacerbation of an existing condition, or when a new medical problem emerges while being treated for something else, the possibility of an ADR must be added to the differential diagnosis. Knowing that poly-pharmacy carries risks for ADE is insufficient because it provides no guidance for determining which drugs should be discontinued. Based upon a systematic review involving 19 studies published between 1990 and 2006, one author reports on five ways by which inappropriate prescribing and ADE can be reduced. (18) Four of these approaches are supported by some evidence and include: incorporating pharmacist recommendations, using computerized alerts, focused medication reviews using such techniques as "brown bag" assessments involving a multi-disciplinary approach, and patient education. LTCFs wishing to reduce ADE may want to consider one or more of these approaches along with one or more of the previously discussed tools.

In addressing ADE any of the previously mentioned tools could be used by a prescriber or designated LTCF employee, but, the best way for a LTCF to proactively address ADE may be via an interdisciplinary committee combining both explicit and implicit criteria. Some of the tools previously mentioned are quite time consuming, but, a LTCF could create an interdisciplinary committee with the charges of reviewing the available tools and

modifying one or two to suit the facility's objectives. Computerized explicit criteria could be used by the committee to identify residents receiving high-risk medications, or residents meeting other agreed upon criteria such as nine or more drugs. Then the committee could use an implicit criteria tool to evaluate the medications' appropriateness and ADE potential. An interdisciplinary committee approach would have the advantage of capitalizing upon the various disciplines' areas of expertise and do so in a more structured approach than is currently done in most LTCFs.

The elderly are at an increased risk for ADE due to physiological decline, and comorbidity. Hence risk-benefit analyses that apply to the healthy middle-aged adult population may not translate well to the elderly. Most ADE studies have justifiably focused on significant ADE consequences such as hospitalization and death. But it is possible that in the greater scheme of things these ADE are just the tip of the iceberg and that less significant, but more frequent, ADE may be occurring and are being overlooked. Such ADE as falls, increased confusion, incontinence, increased behavior, and worsening dementia may in aggregate have a more profound impact on residents' quality of life and functionality than we realize. These ADE may include another category of medications that do not get as much attention: the "medications of minimal benefit". Many medications are prescribed in older adults to prevent illness by decreasing risks that may never affect them. Conditions such as hypertension, hyperlipidemia, osteoporosis and others are treated the same as in younger patients.

The benefits of these treatments in older residents either have not been evaluated or, if they have, may be extremely small at the level of the individual resident. Thus, the ADE (e.g. falls, fractures, sedation, GI distress, etc.) may not be balanced by the potential for benefits. The simplest way to avoid ADE may therefore be to avoid the use of any inappropriate medication and assure that there are obvious benefits with the use of each medication administered. All medications have risks and ADE potential. If a medication's benefits are not obvious it may be prudent to practice *Primum Non Nocere* - First, Do No Harm.

## About the Author

Rich is the President of Health Care Consultants of Minnesota and has been a consultant pharmacist for 30 years. He is nationally certified as a geriatric pharmacy and, as an independent consulting pharmacist, he provides consulting services to 40 long-term care facilities throughout Minnesota and Wisconsin.

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"...Linnaeus was the first who said that all our principle medicines are poisons; that physicians ought not to condemn poisons, but to use them, as surgeons their knives, cautiously."

*Hektoen L. Journal of AMA 1902; 39 (11): 593-598. Linnaeus as physician.*

## President's Column By John Mielke, MD

The annual MMDA fall conference was well attended and packed with informative and often entertaining speakers. We were in the dark at times – the power went out for nearly two hours. We heard, but did not see, Senator Durenberger speak on health care financing. He spoke by flashlight. Nick Schneeman took us from the dark to the light. Well actually he was in the dark, and then the lights came on.

Those who attended the Thursday session were blessed with Val Ulstad's presentation on adaptive leadership. This process of dissecting difficult problems facing groups of people continues to impress me as insightful and very practical. I am beginning to teach these principles in my nursing homes, and it is changing the relational dynamic.

There is another adaptive process unfolding in the metro area that I want our readership to be aware of: The Metro Alliance of Geriatric Primary Care Providers. This group of long term care providers (TCUs, LTC, and AL) has met three times this past year with the goal of improving care in nursing facilities by cooperating across provider groups. The groups represented are: Allina SeniorCare Transitions, Bluestone Medical, Evercare, Fairview Partners, HealthPartners Geriatrics, Hennepin County Extended Care, Geriatric Services of Minnesota, Park Nicollet, and University of Minnesota Geriatrics. We have recognized that cooperation and coordination of certain practices in the nursing homes would benefit the efficiency and quality of care for all our residents. The "output" of this group will likely be a set of "white papers" reflecting evidence based practices that our respective providers will adhere to thereby reducing variation in practice styles. We also hope to promote quality approaches in areas that have suffered from lack of agreement among providers.

The projects underway at this time include: Antipsychotic reduction in dementia residents, after hours INR protocols, and benchmarking the use of POLST forms for LTC residents. A new effort is just underway, collating the various standing house order sets to develop a single SHO for use throughout all our organizations. This should simplify life for the nursing staff, and make SHOs more user friendly. Any input about any of these projects would be welcome. Send me your thoughts at: [jmielke@comcast.net](mailto:jmielke@comcast.net). It has been very gratifying to see these multiple "competitors" come together to work cooperatively on quality issues.

MMDA is also planning a strategic planning meeting in January to help chart the future course of our fine organization. I'll keep you informed about this in future TOPICS.

The Minnesota Medical Directors Association would like to thank the following for their support of our Annual Fall Conference.

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Executive Director: Rosemary Lobeck

Editor: C. Dwight Townes, M.D.

E-mail: [rlobeck@mnmeddir.org](mailto:rlobeck@mnmeddir.org)

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