IDENTIFYING NURSING HOME RESIDENTS AT HIGH RISK FOR PREVENTABLE ADVERSE DRUG EVENTS: MODIFYING A TOOL FOR USE IN THE FLEETWOOD PHASE III STUDY

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Objective: To modify and test a screening tool for identification of nursing home residents at high risk for preventable adverse drug events.
Design: Retrospective descriptive study.
Setting: 30 skilled nursing facilities in North Carolina receiving pharmacy benefits from one provider.
Patients, Participants: All patients residing in these homes.
Interventions: Modification of high-risk screening tool for use in the Fleetwood Phase III Study.
Main Outcome Measure: Proportion of residents who trigger high-risk screen for preventable adverse drug events.
Results: The median proportion of residents triggered was one-third; in some facilities only about 15% of the residents were deemed high-risk while in others the estimate was as high as 48%. The most likely medication classes triggering a chart review was use of seven or more medications, with one medication being an antidepressant.
Conclusion: The modified high-risk screening tool proved to be practical and clinically relevant. It will be used to maximize pharmacists' time and skills in preventing adverse drug events in nursing home residents in the Fleetwood Phase III evaluation.
Key Words: Adverse drug events, Fleetwood Phase III study, Geriatrics, High-risk screening, Long-term care.
Abbreviation: ADE=adverse drug effects.
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INTRODUCTION

Prescribing of drugs is the most common medical intervention that older patients will experience. This is particularly evident in the nursing home setting where the population is characterized by experiencing polypharmacy and multiple morbidities.[1-3] In nursing homes, the average resident uses six different medications, and 20% use at least 10 different medications.[4] Improvements in health-related quality of life in older patients can be achieved by minimizing inappropriate drug use and maximizing evidence-based prescribing.[5] Yet, changes in pharmacokinetics and pharmacodynamics, as well as multiple comorbid conditions, make older persons more vulnerable to adverse medication effects.[6]

A report by the Office of the Inspector General (OIG) entitled *Prescription Drug Use in Nursing Homes*[7] states that "…patients may be experiencing unnecessary adverse medication reactions as a result of inadequate monitoring of medications." This report notes that "HCFA (Health Care Financing Administration [now the Centers for Medicare & Medicaid Services]) should require pharmacists' direct input to achieving optimal clinical outcomes for residents…." Medication-related problems continue in nursing facilities despite the fact that the federal government requires consultant pharmacists to perform a monthly drug regimen review of each resident. The pharmacist then must report any "irregularities" to the attending physician and director of nursing, and these reports must "be acted on." Gurwitz et al.[8] estimated that 1.89 adverse drug effects (ADEs) per 100 resident-months occurred in 18 Massachusetts nursing homes, of which half were deemed preventable. Bootman et al.[9] estimated that for every dollar spent on medications in nursing facilities, two dollars were spent treating

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medication-related problems.

To address this problem, the American Society of Consultant Pharmacists Research and Education Foundation developed a new model for long-term care pharmacy—the Fleetwood Model—which incorporates prospective review, direct communication with the prescriber, and formalized pharmaceutical care planning in patients at highest risk for medication-related problems. The feasibility of incorporating such a model has already been proven,[10] and Phase III implementation of the Fleetwood model is underway.[11] This model of care theorizes that elderly nursing home residents at greatest risk for medication-related problems can be identified so that pharmacists can focus on making clinical recommendations in the people most likely to benefit from them.

The ASCP Foundation provided a grant to identify factors that place elderly nursing facility residents at high risk for medication-related problems.[12] This risk screening was used in the Phase II study of the Fleetwood Model and was based on specific patient characteristics or characteristics of their drug regimen (e.g., the number of medications or the particular classes of medications used, including those with narrow therapeutic indexes). However, in the years since the development of the risk screen used in the Phase II study, research identifying medications related to *preventable* ADEs emerged.[13] The purpose of this paper is to describe the process of development of the Fleetwood Phase III study high-risk screen, to discuss its implementation, and to provide descriptive information regarding the proportion of residents triggered.

METHODS

The Fleetwood Phase III Study has gained approval by the Institutional Review Board of Brown University.

DEVELOPMENT OF THE HIGH-RISK SCREEN

We first met with the pharmacy-system software vendor to understand the intricacies of collecting pharmacy data and the usefulness of the data for implementing a "real-time" algorithm to identify residents at high risk for medication-related problems. The algorithm developed would rely completely on information included in the commercial pharmacy software. The pharmacy vendor provided a snapshot of the data from nursing facilities likely to be targeted for recruitment into the Fleetwood Phase III Study.

We performed an extensive review of the literature on medication-related problems in nursing home settings and identified a recent study that identified risk factors of *preventable* ADEs in nursing home settings.[13] We focused on this article because we could use the Fleetwood Phase III high-risk screen to identify the residents most likely to benefit from a pharmacist-driven intervention. Second, this work extends (and confirms in most instances) work based on expert opinion and reviews of the literature.[12]

ADAPTING RESEARCH FINDINGS FOR PRACTICAL USE

We approached the study's authors[13] (Field and Gurwitz) for assistance in developing the Fleetwood Phase III high-risk screen. We needed their assistance for several reasons. First, the data available from the pharmacy vendor involved in the Fleetwood study were not identical to that used in Field's study.[13] For example, the Fleetwood Phase III pharmacy data do not include measures of comorbidity (e.g., Charlson comorbidity index); specific chronic conditions such as dementia, liver disease, renal disease; or measures of activities of daily living. Second, Field et al.[13] identified two factors that appeared to afford a protective effect on preventable ADEs: use of nutritional supplements and male gender.

That the use of nutritional supplements appeared to reduce the risk of preventable ADEs was an unexpected finding, which to date remains unexplained. After discussing this finding with the authors, we agreed that this variable more likely than not captures some aspect of quality of care, rather than something inherent in the supplements. As such, we did not want to include it in the Fleetwood Phase III high-risk screen. Furthermore, supporting a risk screen that would proportionately exclude men from receiving the intervention would be unethical.

Field agreed to analyze the data in ways that mirror the type of data availability in the Fleetwood Phase III study and not to include use of nutritional supplements and gender in the analysis. Field performed logistic regression analyses. In these models, the dependent variable of interest was preventable ADEs (yes/no). In the absence of the comorbidity index, several classes of medications that previously were not strong predictors became predictive of preventable ADEs. Additionally, because the analytic strategy used by the authors was not sufficiently powerful to show statistically significant differences in drugs used relatively infrequently, we asked that the authors rerun the analysis based on the clinical relevance of the associations. Field disregarded statistical significance in the building of the model. This was necessary because the underlying prevalence of such medications in the nursing homes included in the Fleetwood Phase III study may be different than in the nursing homes included in Field's study. Finally, based on discussions with the clinical team of the Fleetwood Project, we wanted to explore the effect of cardiovascular medications on preventable ADEs in a more complex way. As a result, Field explored the relation between number of cardiovascular medications and preventable ADEs, as opposed to just any cardiovascular medication (yes/no).

TABLE 1. RISK FACTORS FOR PREVENTABLE ADVERSE DRUG EVENTS AMONG ELDERLY NURSING HOME RESIDENTS (USED TO DEFINE THE FLEETWOOD PHASE III HIGH-SCREEN)

Resident is on:
- Any antidepressant
- An antibiotic or an anti-infective
- ≥ Seven medications (including OTC and prescription medications)
- An antipsychotic
- An antiseizure medication
- An opioid
- A sedative/hypnotic
- An anticoagulant
- A muscle relaxant
- > Three cardiovascular medications

Based on all standing orders (prescription and over-the-counter [OTC] medications); > four risk factors = patient is considered high-risk.

RESULTS

FLEETWOOD PHASE III HIGH-RISK ALGORITHM

Based on the rationale provided in the methods section, as well as analyses of pharmacy transaction data provided by the commercial pharmacy software vendor, the following algorithm was developed to determine the residents who would receive the Fleetwood model of pharmaceutical care. The evaluation of residents was based on all standing orders (prescription and over-the-counter medications).

Table 1 shows the risk factors included in the high-risk screen. Each resident has a counter for the number of risk factors for a preventable adverse event. For each of the risk factors on Table 1, one risk factor is added, capturing the sum of the number of risk factors. If it is greater than or equal to four, the resident is labeled high risk. For example, if a resident receives an opioid, an

TABLE 2. PROPORTION OF RESIDENTS WITHIN TARGET NURSING HOMES FOR THE FLEETWOOD III PROJECT ESTIMATED TO TRIGGER THE HIGH-RISK MEDICATION SCREEN

Facility ID	% of residents triggered as high risk*
0	31.1
1	45.9
2	26.1
3	45.1
4	38.2
5	35.7
6	33.3
7	32.5
8	36.5
9	14.0
10	45.7
11	16.7
12	31.0
13	48.1
14	30.5
15	27.7
16	29.2
17	37.9
18	24.0
19	26.3
20	20.5
21	30.4
22	34.6
23	32.3
24	33.8
25	30.4
26	41.1
27	42.4
28	30.8
29	39.3
30	39.1

* Defined as having four or more risk conditions.

antidepressant, a muscle relaxant, and five other medications, the residents would be labeled as high risk.

The proportion of residents within each facility identified as high risk is shown in Table 2. Overall, the median proportion of residents triggered was 33%. However, there was great variation among facilities in this measure. In some facilities approximately 15% of the residents were deemed high-risk, while in other facilities the estimate was as high as 48%. An evaluation of the distribution of the risk factors included in the risk screen revealed considerable variability by facility. These data are shown below in Table 3.

These data represent the distribution of facility level measures of medication use. For example, on average 7.3% of residents of all facilities were on a standing order for an antibiotic or anti-infective agent in a given month. In some facilities, the proportion of residents on an antibiotic/anti-infective was as low as 2.5%, while in others, as high as 20%. This table shows that certain medication classes (e.g., muscle relaxants) are infrequently used in this setting. The most likely medication class triggering a chart review was use of seven or more medications, with one medication being an antidepressant.

DISCUSSION

Pharmacists working within the long-term care setting must ensure that prescribing meets the federal standards as dictated by the regulations implementing the Omnibus Budget Reconciliation Act of 1987,[14] and this limits the time that can be spent on other aspects of pharmaceutical care. At present, there is no incentive to encourage the pharmacist's role in optimizing pharmacotherapy in nursing home residents, yet the Fleetwood model will demand greater involvement of pharmacists in planning and delivering pharmaceutical care. It may not be feasible or

necessary to provide such care to all residents—nor are payers likely to pay for this level of pharmacist services for all patients.[11] A more focused approach on residents at highest risk for medication-related problems may be realized through the use of the modified, high-risk screen tool. This should maximize resources in terms of the pharmacists' input and their time.

However, what is particularly critical in the context of the Fleetwood model is the use of the high-risk screen in "real time" pharmacy practice. Although the screening should make identification of high-risk residents more efficient, pharmacists (both dispensing and consultant) will still require protected time to perform interventions. Although the data presented in this paper suggest that the modified screening is practical and clinically relevant, using it in real time may not address the need for protecting time for pharmacists to intervene. It is envisaged that the dispensing pharmacists would be alerted to the high-risk status of residents and begin making recommendations for interventions immediately. Such interventions would be communicated to the consultant pharmacists to allow them to continue developing the pharmaceutical care plan for high-risk residents. However, staff shortages, particularly with respect to dispensing pharmacists, may work against this; the extent to which this model of pharmaceutical care is practical and effective will be evaluated in the Fleetwood Phase III study.

It is unclear if the high-risk screening will identify those residents who will most likely derive benefit from interventions. This can only be judged by meeting the objectives of the Fleetwood Phase III study.[11] Although this work has been grounded in findings generated from a nursing home population, the original research was based in Massachusetts in nursing homes.[13] Thus, what predicts an adverse event in this geographical setting may not be generalizable to those sites being used for the Fleetwood evaluation in North Carolina.

In summary, the modification of a high-risk screening has been undertaken and field-tested in nursing homes participating in the Fleetwood Phase III study. The next stage will involve integrating this screening with the other elements of the Fleetwood Model as part of the definitive evaluation of this comprehensive approach to pharmaceutical care.

TABLE 3. FREQUENCY OF RISK FACTORS OBSERVED IN THE SAMPLE POPULATION

Risk Factor	Median % of residents per facility	Range
On seven or more medications (OTC and prescription)	31.6	(15.7-49.2)
Antidepressant use	25.0	(9.5-50.0)
Antipsychotic use	14.5	(0-22.7)
Antiseizure medication use	13.1	(0-23.8)
Antibiotic or anti-infective use	7.3	(2.5-20.3)
Sedative/hypnotic use	6.5	(0-13.0)
Use of ≥ three cardiovascular medications	6.1	(0-10.2)
Anticoagulant use	5.7	(0.8-16.7)
Opioid use	5.3	(0-12.1)
Muscle relaxant use	1.6	(0-8.8)

Abbreviation: OTC = over the counter