

**Objective:** To discuss in depth the derivation of the Fleetwood Model of drug regimen review (DRR) as it is to be applied in Phase II of the Fleetwood Project.

**Data Sources:** On-line health services abstracts from 1987 forward were searched, as were pharmacy abstracts from 1970 to the present, selecting only English-language articles. In addition, archival research produced a number of relevant books, and an on-line search of government Web sites disclosed several germane federally sponsored investigative reports.

**Study Selection:** All potentially relevant articles were reviewed. However, in defining the terms of the high-risk assessment instrument, only quasi-experimental and experimental studies were accepted for full evaluation. Pre-experimental studies were eliminated from consideration.

**Data Synthesis:** The results of an extensive literature review were married with the empirical findings of several research projects in addition to the advice of various advisory groups. The outcome was the evocation of the Fleetwood Model infrastructure.

**Conclusion:** Elderly home care patients, as evaluated by a comprehensive in-home nutrition assessment, are a group at high nutritional risk. Increased use of medications, coupled with poor dietary intake and multiple medical diagnoses, may affect the level of nutrition in this population. Further study is warranted to document the beneficial effects of targeted interventions by a multidisciplinary team in the areas of cost savings, health status, and quality of life.

**Key Words:** Consultant pharmacy, Drug regimen review, Fleetwood Project.

**Abbreviations:** DRP = adverse drug event; APR =

A principal focus of recent research has been the determination of health-related and economic outcome measures associated with consultant pharmacists' services in nursing facilities.<sup>1-3</sup> While members of the profession are themselves keenly aware of the merits of consultant services, such research promotes their efforts to receive appropriate remuneration for their accomplishments. In recognizing a need to demonstrate consultant pharmacists' value to public policymakers and the managed care industry, the Fleetwood Project Research Initiative was born. The initiative was envisioned by members of the Niemerow Institute Council of Advisors, an advisory body to the ASCP Research and Education Foundation, as a means to gather quantifiable evidence of consultant pharmacists' impact. The precise objectives of the project were articulated by a national advisory board consisting of long-term care pharmacy providers as well as experts in outcomes, pharmacoeconomics, and geriatrics research.

Until recently, outcome studies examining the effects of drug regimen review (DRR) defined cost savings strictly in terms of reduction in medication costs.<sup>4-6</sup> Phase I of the Fleetwood Project went a step further than prior research by clearly demonstrating the total costs that are avoided in having consultant pharmacists conduct monthly retrospective DRRs in nursing facilities.<sup>1</sup>

Phase II of the Fleetwood Project proceeds from that point with the following three goals. The first is the development and feasibility testing of a new model for consultant pharmacists' clinical services. The second goal is to describe the pharmacists' impact in terms of the more global outcome measures of functional and

Assessment for Potential Risk index; DRR = drug regimen review; HCFA = Health Care Financing Administration; OIG = Office of the Inspector General; p.r.n. = as needed.

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health status as well as the more typical dimensions (e.g., number of drug orders, number of successful pharmacist interventions). The third goal is to serve as the pilot study for the larger, multicenter project slated for Phase III. Results and analyses from the pilot study will pinpoint what works best about the model, both in terms of affecting health outcomes and in terms of adapting the model for use in other pharmacies. These data will guide refinement of the model for Phase III of the Fleetwood Project. Phase III will, in turn, rigorously test the model under controlled conditions and in a larger population.

The purpose of this paper is to describe the theoretical foundation of the model that was used at the test sites. Hereafter, the model will be referred to as the "Fleetwood Model." The actual methodology of Fleetwood Phase II and the day-to-day activities of the consultant pharmacist will be presented at a later time. In the final design of the model, we consulted a number of sources and polled many experts. First and foremost, the Fleetwood Model is based on input from consultant pharmacists, the long-term care pharmacy community, and the Fleetwood Project Advisory Group. In addition, we were mindful of market and governmental demands placed on the profession and on research of drug-related problems. As such, we attempted to formulate a model that was responsive to some of these issues as well.

There are four components to the model:

- Prospective Review
- High-Risk Assessment
- Direct Contact with the Physician
- Patient Assessment

### **Prospective Review**

Consultant pharmacists have envisioned the ideal DRR to be a prospective, rather than retrospective or concurrent, endeavor.<sup>7</sup> This perspective remained paramount as the framework for the Fleetwood Model began to be constructed. The push to develop a prospective model came from outside the profession as well. Government expectations of pharmacy leave the profession with prospective review as the only reasonable response to the issue of drug-related problems.<sup>8</sup> In the reports recently released by the Office of the Inspector General (OIG), entitled Prescription Drug Use in Nursing Homes,<sup>3</sup> findings suggest that "...patients may be experiencing unnecessary adverse medication reactions as a result of inadequate monitoring of medications." Moreover, recommendations of the OIG include the proposal that "HCFA [Health Care Financing Administration] should require pharmacists' direct input to achieving optimal clinical outcomes for residents...." This assessment is not theirs alone. In comments to the OIG, R. Tim Webster, ScD, ASCP Executive Director, reiterated ASCP's position when he stated, "...prospective drug review can be an effective means of preventing or correcting drug-related problems."<sup>9</sup> As such, it became imperative that the model strongly embrace a prospective means of intervention.

To keep the medication review as prospective as possible, the Fleetwood Project Advisory Group recommended that the consultant pharmacist see each high-risk patient within 72 hours of their status change to "high risk." In practice, the 72-hour period was only necessary to determine what their final orders would be. The consultant pharmacist found that patients who had lived in the nursing facility for some time could be evaluated within hours of a change in risk status. In addition to the above guidelines, all medication orders for residents who were already high risk were held until the consultant could evaluate them.

### **High-Risk Assessment**

The first step in applying the Fleetwood Model to any nursing facility population is a determination of those patients at greatest risk for drug-related problems (DRPs). For the purpose of this study, operational definitions of DRPs are based on the Professional Pharmacy Service (PPS) codes that were implemented by the national Council for prescription Drug programs as a guideline for billing of cognitive services.<sup>10</sup> These codes describe a variety of undesirable drug-related situations, including underprescribing or overprescribing, additive toxicity, drug interaction, drug allergy, and suboptimal regimen, to name a few.

The intent of high-risk assessment is to economically and efficiently focus the most concentrated clinical attention on those at greatest risk of DRPs. However, because the Fleetwood Model has a prospective review component, it was necessary to be able to make such assessments quickly and at any point in time so that drug therapy changes could be evaluated before the orders took effect. Thus it became essential to use an assessment instrument that was capable of handling the dynamic clinical nature of the nursing facility population.

The biggest problem facing anyone who attempts to assess those at highest risk of DRPs is the choice of criteria. Among the choices available, the Beers criteria<sup>11</sup> are well-known and have been used extensively. Beers used explicit criteria such as drugs to be avoided (propoxyphene, dipyridamole, reserpine), dosing limits (digoxin), and condition-specific concerns (beta blockers in diabetics) to formulate his criteria for evaluating medication use. However, considering the vast array of new drugs on the market, our experience suggested that those criteria were becoming somewhat dated for this population, even with the refined and expanded 1997 version of the Beers criteria.<sup>12</sup> For example, two of the medications mentioned in the final criteria (disopyramide and reserpine) are rarely prescribed anymore. In addition, phenylbutazone was removed from the market in January 1993<sup>13</sup> except for use as an extemporaneously compoundable powder.

In selecting criteria for high-risk assessment, we relied instead on the work of Fouts et al,<sup>14</sup> who developed their list of risk factors on the basis of a survey of an expert panel and the application of a modified Delphi technique. The development of this high-risk instrument was one result of a grant that the ASCP Foundation provided to the Duke University Center for the Study of Aging and Human Development to identify factors that place nursing facility residents at high risk for DRPs. From the original list of factors determined by Fouts et al (Table 1), we eliminated the following two items because reliable data were not available for our study: history of prior adverse drug reaction and decreased renal function. We also removed chlorpropamide as a risk factor. Though its use in the elderly should clearly be discouraged, that particular medication is rarely prescribed anymore, especially with the recent introduction of agents from the biguanide, thiazolidinedione, and meglitinide classes. Last, we eliminated advancing age as a factor. Though common knowledge suggests that age is a risk factor, this assumption is never borne out in the research. Studies offer no evidence to support the use of age as an independent predictor of adverse drug reactions.<sup>15-22</sup> For purposes of our study, this modified version of the Fouts et al criteria is known as the Assessment for Potential Risk index (APR).

**TABLE 1. Risk Factors**

<b>As Determined by Survey<sup>14</sup></b>	<b>Retained for Fleetwood Model</b>
<b>Specific Medications</b>	<b>Specific Medications</b>
Digoxin	Digoxin
Warfarin	Warfarin
Lithium	Lithium
Chlorpropamide	

**Medication Classes**

Anticonvulsants  
 Antipsychotics  
 Sedative/hypnotics  
 Long-acting benzodiazepines  
 (T1/2 >24 hours)  
 Intermediate-acting benzodiazepines  
 (T1/2 = 10-24 hours)  
 Narcotic analgesics  
 Anticholinergics

**Patient Characteristics**

> 6 active chronic medical diagnoses  
 > 12 doses of medication per day  
 ,, 9 active medications  
 Prior adverse drug reaction  
 Low body weight or body mass index  
 (< 22 kg/m<sup>2</sup>)  
 Advanced age  
 Decreased renal function

**Medication Classes**

Anticonvulsants  
 Antipsychotics  
 Sedative/hypnotics  
 Long-acting benzodiazepines  
 (T1/2 > 24 hours)  
 Intermediate-acting benzodiazepines  
 (T1/2 = 10-24 hours)  
 Narcotic analgesics  
 Anticholinergics

**Patient Characteristics**

> 6 active chronic medical diagnoses  
 > 12 doses of medication per day  
 ,, 9 active scheduled medications  
 Low body weight or body mass index  
 (< 19 kg/m<sup>2</sup> for females and < 20 kg/m<sup>2</sup>  
 for males)  
 (> 85 years)  
 (< 50 ml/min)

The APR may easily be used as a pencil-and-paper measure. However, the pharmacy serving the test sites had already integrated many aspects of the high-risk assessment, in general, into their computer system. Because of this, they chose to rewrite their existing program to incorporate the APR into their system, providing them with a computerized version of the APR instrument. An advantage to computerization of the APR was that the system automatically flagged high-risk patients so that orders could be held for further evaluation. One of the assessment measures that the pharmacy had been gathering prior to becoming a study site was body mass index. However, their thresholds were set to any point below 19 kg/m<sup>2</sup> for females and below 20 kg/m<sup>2</sup> for males, rather than the 22 kg/m<sup>2</sup> used by the Fouts group.

Since this threshold had been operational for some time and because it was thought that the differences between the two would not be clinically significant, the cutoff points were left at 19 and 20. Second, Fouts et al defined active medications as the number of active scheduled medications plus any p.r.n. drug used within the last month. The software at the study site did not enable us to determine p.r.n. medication administration; therefore, we included only scheduled medications in screening for the number of medication orders.

**Direct Physician Contact**

In developing the physician contact component of the Fleetwood Model, we began with the assumption that direct communication between the pharmacist and the physician, rather than through the nurse, would (1) increase the likelihood that the pharmacist's recommendations would be accepted, and (2) resolve medication-related questions and concerns prospectively, before medication is dispensed. This assumption was based on two diverse areas of the literature: studies on disseminating information to physicians and research on human inference theory as it applies to prescribing behavior.

**Information Dissemination**

Numerous studies have examined the various means of disseminating information to physicians. Some of the

research analyzes communication methods used to instruct doctors on more appropriate prescribing. For example, educational programs have been compared with distribution of printed material to determine the most effective means of altering physicians' behavior. Other research has focused on the type of communication, such as computer feedback, that works best to elicit a specific change in a patient's order.<sup>2,23-31</sup>

Mailing or giving printed materials to physicians, especially when used as the only method of distributing information, is typically associated with no change in prescribing behavior.<sup>23,24,27,28,32,33</sup> There were two exceptions in which a positive correlation was reported between distribution of printed matter and physicians' prescribing habits.<sup>27</sup> However, neither resulted in a lasting effect. In their review of the literature, Soumerai et al<sup>33</sup> discovered evidence to suggest that printed material will alter attitudes but not behavior.

Despite the prevalence of group educational programs as a means of providing information, there is a paucity of well-controlled studies measuring the effect of this format.<sup>33</sup> Of the research available, results either border on the equivocal<sup>27</sup> or tend toward the disappointing.<sup>31</sup>

The studies that focused on efforts to change physicians' prescribing patterns indicate that the use of academic detailing is generally quite successful in altering prescribing habits.<sup>23,27,28,31,33</sup> One well-controlled study also reports that the effects may be long-lasting.<sup>23</sup>

Rigorous experimental trials of clinical pharmacists' interventions and their effect on physician prescribing habits are scarce. Those available suggest a positive correlation with improved prescribing.<sup>33</sup> One recent randomized, controlled study of clinical pharmacist activities demonstrated significantly decreased scores on a measure of inappropriate prescribing.<sup>2</sup> Moreover, the effect was still evident at 12 months post-initiation.

Thus direct interaction, as demonstrated through academic detailing, is the one proven method of modifying physicians' prescribing behavior.<sup>23,24,31,33</sup> Clinical pharmacist intervention, as yet to be fully tested, offers a potentially strong second means of influencing doctors.

The elements of academic detailing that are pertinent to a prospective review model of DRR include direct communication with the physician because recommendations do not go through a third party; there is the potential for greater immediacy of action; and the recommendation can be specifically tailored to fit the situation and the physician.

## Human Inference Theory

Raisch,<sup>27</sup> in his notable articles on human inference theory, explains why we may expect to find some of the results outlined above.<sup>27</sup> He points out that people rely on certain heuristics, inherent resource tools, as they categorize and consider new information in the process of making a decision. The chief classes of judgmental heuristics that Raisch discusses are those of representativeness, availability, framing, and anchoring ([Table 2](#)).

**TABLE 2. Heuristics of Decision Making**

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**Representativeness** - entails looking at an event and making a judgment as to how closely it corresponds to other events as found in the general population

**Availability** - evaluation about frequency, probability, and causality relationships that relies on how easily information is recalled from memory

**Framing** - with reliance on how information is presented, a judgment is made on the benefit of a choice

**Anchoring** - reflects the degree to which the initial judgment about an event or situation prohibits one from deviating from that position regardless of new Information to the contrary

*Source: Raisch.<sup>27</sup>*

In using the availability heuristic to make inferences about the probability of an event, people rely on the ease with which information about that event, or a similar event, can be recalled from memory.<sup>34</sup> How easily that information can be recalled depends, in turn, on other factors such as the amount of exposure to that event. For instance, if you are asked to estimate the proportion of people greater than 6 feet tall in the American population, you are likely to begin thinking about friends and relatives who are over 6 feet and form an estimate based on what you can recall. If you are acquainted with a number of tall people, you are more likely to suggest a higher proportion than someone whose friends and family tend to be shorter.

Associated with the availability heuristic is another aspect of inference called "vividness." Vividness is the tendency to apply greater weight to incidents and facts that are either more engaging or more specific than other pieces of information.<sup>27,34</sup>

On the basis of inference theory, it is not surprising that one-to-one encounters, much like those found with academic detailing, tend to be more forceful. Such communication tends to be more vivid than printed information or group programs.<sup>27</sup> In the Fleetwood Model, the consultant pharmacist applies the vividness principle to clinical pharmacy interventions by contacting the physician directly. When the pharmacist's recommendation is crucial to the patient's welfare, that contact will be made by phone or in person. Furthermore, the delay between when the order was written and when the physician is contacted will be dramatically reduced by contacting the physician directly. In shortening the time between the two events, the model makes further use of the availability heuristic.

Since communication with the physician will entail use of patient-specific information, the technique will also make good use of the second part of the vividness principle-use of information that is of particular interest to the physician. That, in turn, will affect the availability heuristic by making the information more memorable. Last, the model makes efficient use of the framing heuristic. Research shows that physicians respond more favorably to recommendations regarding patient care than to those addressing cost issues<sup>27,29</sup> because they perceive a greater benefit for the patient.

There are two more reasons to contact the physician directly: physician preference and promptness. In their research on physicians' acceptance of pharmacists' recommendations, Segal and Pathak<sup>29</sup> found that the means of communication used was second only in importance to the clinical significance of a recommendation. When the recommendation involved a serious therapeutic issue, the majority of physicians preferred to be contacted by phone. When the concern was not serious, no communication method stood out as the most favored. Interestingly, a note in the chart was considered unacceptable under both scenarios.

Promptness alone could serve as a crucial reason to contact the physician directly. The quicker the physician's response time, the more likely that DRR approaches the status of prospective. Leaving a note in the chart or with the nurse introduces too great a delay into the process. Moreover, there is little question that patients benefit when decisions are made and recommendations are acted upon as quickly as possible. As

stated in the Health and Human Services report on Texas nursing facilities, the OIG advocates that pharmacists take measures to "...strengthen and enforce coordination and communication among the involved healthcare team members..."<sup>3</sup>

## Patient Assessment

Patient interviews have taken on an added depth and dimension of importance ever since the originators of Comprehensive Pharmaceutical Care began to espouse the essentiality of patient-centered therapeutic assessment.<sup>35</sup> Interviews not only offer a means for discovering undocumented facts about a resident, but they also provide the foundation for a mutually beneficial professional relationship between pharmacist and patient.

In their study of systems failures that lead to adverse drug events, Leape et al<sup>36</sup> discovered the second most common cause of errors could be attributed to insufficient knowledge about the patient. (Unfamiliarity with the medication was the most frequent cause of errors.) In the nursing facility, a number of factors may contribute to this problem. Many patients are cognitively impaired, have constantly changing functional abilities, or are aphasic, thereby rendering medical histories suspect. In addition, records are frequently missing or incomplete.<sup>3</sup>

In their research on the detection of pain in nursing facility residents, Sengstaken and King<sup>37</sup> found that physicians had not detected chronic pain in 34% of communicative patients determined to have pain. It was only upon direct questioning that their condition was discovered. Furthermore, in their research on the quality of care given to the cognitively impaired, Fleishman et al<sup>38</sup> demonstrated that staff were less knowledgeable about the presence of medical problems in residents with mental impairment.

In an actual hands-on study of the effect of patient interviews, Twitty and Gardner<sup>39</sup> recorded initial recommendations made by a consultant pharmacist following traditional DRR procedures. In the next step of the research, the consultant visited each patient and then recorded any subsequent suggestions. The researchers found that the pharmacist uncovered enough new information from the patient visits to make additions or changes to the original recommendations in 61% of the cases. Discussing the role of consultants in the nursing facility, Martin<sup>40</sup> mentions two compelling reasons for resident interviews. First, elderly patients tend to reveal their wants and desires through behavior. Second, an interview may provide crucial clinical information, whether it be a behavior that needs to be treated (e.g., anxiety) or one that is the result of an adverse drug event.

Of the patients studied in the OIG report,<sup>3</sup> pharmacists found that 31% of the records were not sufficiently intact even to allow determination of whether medications were appropriate to the residents' diagnoses. If information as basic as diagnosis is absent, it is likely that less concrete information (such as history of falls, nursing notes, etc.) is missing. In fact, the OIG recommends "encouraging consultant pharmacists to interact with (counsel and inform) patients as part of their medication reviews" as an attempt to "more vigorously pursue enforcement of positive resident outcomes."<sup>3</sup> The problem of missing or misleading information is a main topic of Meade's discussion on the failure of recommendations.<sup>26</sup> Meade asserts that patient interviews might not only provide the consultant pharmacist with missing information, but also point to instances in which charts and notes do not agree with the facts of the matter.

## Conclusion

The intent of Phase II of the Fleetwood Project was twofold. The first objective was to develop a new model of DRR that emphasizes prospective review and screening for those nursing facility residents at greatest risk

for DRPs. The second objective was to compare the new model with retrospective review in terms of therapeutic outcome measures and costs. With the development of the Fleetwood Model complete, pilot testing was initiated in three test facilities for a 12-month period. The testing period has just come to a close. The task that remains is to analyze the data from that pilot phase. Tangential to the pilot study, predictive and construct validity testing of the high-risk assessment instrument (or APR) is being completed. When data from these projects have been collected and analyzed and the last of the model refinement procedures have been completed, Fleetwood Phase III will be initiated.

While the focus of Phase II is developing and testing the model, the essence of the research lies elsewhere. The ultimate purpose of Phase II of the Fleetwood Project is to demonstrate the power of prospective review on patient outcomes. The successive movement of consultant pharmacists toward prospective review for high-risk patients not only represents a shift in practice standards, but also in professional *raison d'être*.

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