

FLEETWOOD PROJECT

Phase III Moves Forward

The ASCP Research and Education Foundation will join forces with Brown University's Center for Gerontology and Health Care Research to conduct Phase III of the Fleetwood Project. Fleetwood Phase III is the culmination of seven years of research activities on re-engineering long-term care pharmacy practice to demonstrate the value of pharmacist services and to improve patient outcomes. Fleetwood Phase III will test the effectiveness of the "Fleetwood Model" in reducing inappropriate medication use, adverse drug events, and the undertreatment of common diseases experienced by nursing facility residents. The ultimate goal of the Fleetwood Project is to improve health outcomes and reduce health care costs resulting from medication-related problems among nursing facility residents.

In 1995, ASCP launched the Fleetwood Project, a landmark, three-phase initiative to demonstrate the impact of consultant pharmacist services on patient outcomes and health care costs (see sidebar on next page). The Fleetwood Project may be the most important research initiative ever undertaken on behalf of pharmacy practice, and its significance and relevance have been validated by the private foundation funding obtained to conduct Phase III.

The first two phases of the Fleetwood Project were funded by the ASCP Foundation through contributions from ASCP and its members, chapters, and affiliates; long-term care pharmacy providers; and pharmaceutical companies. Two internationally recognized private foundations—the Commonwealth Fund and the Retirement Research Foundation—have provided grants totaling more than \$750,000 to fund Phase III of the Fleetwood Project (see page 184).

PHASE I: DEMONSTRATING THE VALUE OF CONSULTANT PHARMACISTS' SERVICES

Fleetwood Phase I was the first pharmacoeconomic study to quantify the cost of medication-related problems in U.S. nursing facilities, and the value of consultant pharmacists' services in reducing medication-related problems. The study found that consultant pharmacist-conducted drug regimen review increases the number of patients experiencing an optimal therapeutic outcome by 43% and saves \$3.6 billion annually in costs



THE FLEETWOOD PROJECT

DEMONSTRATING THE VALUE OF CONSULTANT PHARMACISTS

Launched in 1995, the Fleetwood Project is a three-phase initiative to demonstrate the impact of consultant pharmacist services on patient outcomes and health care costs:

■ **Phase I**—A pharmacoeconomic analysis of the costs of medication-related problems in U.S. nursing facilities and the impact of consultant pharmacist services on those costs. The study found that consultant pharmacist-conducted drug regimen review increases the number of patients who experience an optimal therapeutic outcome by 43% and saves as much as \$3.6 billion annually in costs associated with medication-related problems. Even with these savings, for every dollar spent on medications in nursing facilities, two dollars are spent treating medication-related problems.

■ **Phase II**—A feasibility study to test the Fleetwood Model of prospective drug regimen review and formalized pharmaceutical care planning in elderly patients at highest risk for medication-related problems.

■ **Phase III**—Evaluation of the Fleetwood Model, including identification of *pharmacist-sensitive outcomes*—those outcomes most sensitive to pharmacist intervention—for the frail elderly at highest risk for medication-related problems. The Phase III study will evaluate the effectiveness of the Fleetwood Model in reducing potentially inappropriate medication use, under-treatment of common diseases, potential adverse drug events, and indicators of common geriatric problems associated with medication use.

from avoided medication-related problems. The study also showed, however, that despite the cost savings from retrospective drug regimen review, for every dollar spent on medications in nursing facilities, two dollars are spent treating medication-related problems.¹

Other studies examining medication-related problems in nursing

facilities have yielded similar results. A 1997 report from the U.S. Department of Health and Human Services' Office of the Inspector General on prescription drug use in nursing homes stated that "patients may be experiencing unnecessary adverse medication reactions as a result of inadequate monitoring of medications." That report concluded

that "[t]he Health Care Financing Administration [now the Centers for Medicare & Medicaid Services] should require pharmacists' direct input to achieving optimal clinical outcomes for residents."²

More recently, a study conducted in 18 Massachusetts nursing homes estimated 1.89 adverse drug events per 100 resident-months, of which half were deemed preventable.³

The Fleetwood Advisory Group recognized that the Fleetwood Project had to go beyond traditional retrospective drug regimen review, which has not been shown to be adequate to prevent avoidable adverse medication effects, and dared to create a new model of consultant pharmacy practice—a model that is prospective rather than retrospective; a model that focuses on patients at highest risk for medication-related problems. From this vision the *Fleetwood Model* was developed and tested in Phase II.

PHASE II: PROVING THE FEASIBILITY OF THE FLEETWOOD MODEL

The Fleetwood Project Technical Advisory Group—which included representatives from consultant phar-

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FLEETWOOD PHASE III FUNDERS

The Commonwealth Fund, based in New York, New York, is a private foundation that supports independent research on health and social issues and makes grants to improve health care practice and policy. The Fund is dedicated to helping people become more informed about their health care, and improving care for vulnerable populations such as elderly people. The Fund's two national program areas are improving health insurance coverage and access to care and improving the quality of health care services.

The Retirement Research Foundation (RRF), based in Chicago, Illinois, is the nation's largest private foundation devoted solely to serving the needs of older Americans and enhancing their quality of life. For more than 20 years, RRF has been at the forefront of efforts to meet the ever-changing needs of older Americans. The organization supports efforts that enable older adults to live at home or in residential settings that facilitate independent living, improve the quality of care at nursing homes, leverage the wisdom and experience of older adults and promote community involvement, and increase understanding of the aging process and age-associated diseases.

macy practice, geriatric medicine, geriatric pharmacy, nursing, health economics and health services research, and long-term care pharmacy providers—met in 1997 to develop the “intervention” to be studied in Fleetwood Phase II. The goal was to develop a model that could be operationalized in the “real world” of pharmacy, and that relied on the skills and knowledge of pharmacists currently practicing in long-term care.

The Fleetwood Project Advisory Group developed a new model for long-term care pharmacy: the Fleetwood Model. This model

has four broad components: (1) prospective medication review and intervention, (2) direct communication between the pharmacist and prescriber, (3) patient assessment by the consultant pharmacist, and (4) formalized pharmaceutical care planning for patients at highest risk for medication-related problems.⁴ Ultimately, the Fleetwood Model provides a framework for pharmacists to re-engineer their practice; shift their focus from the drug regimen alone to the *patient*; and play a more active role in identifying, resolving, and preventing medication-related

COMPONENTS OF THE FLEETWOOD MODEL

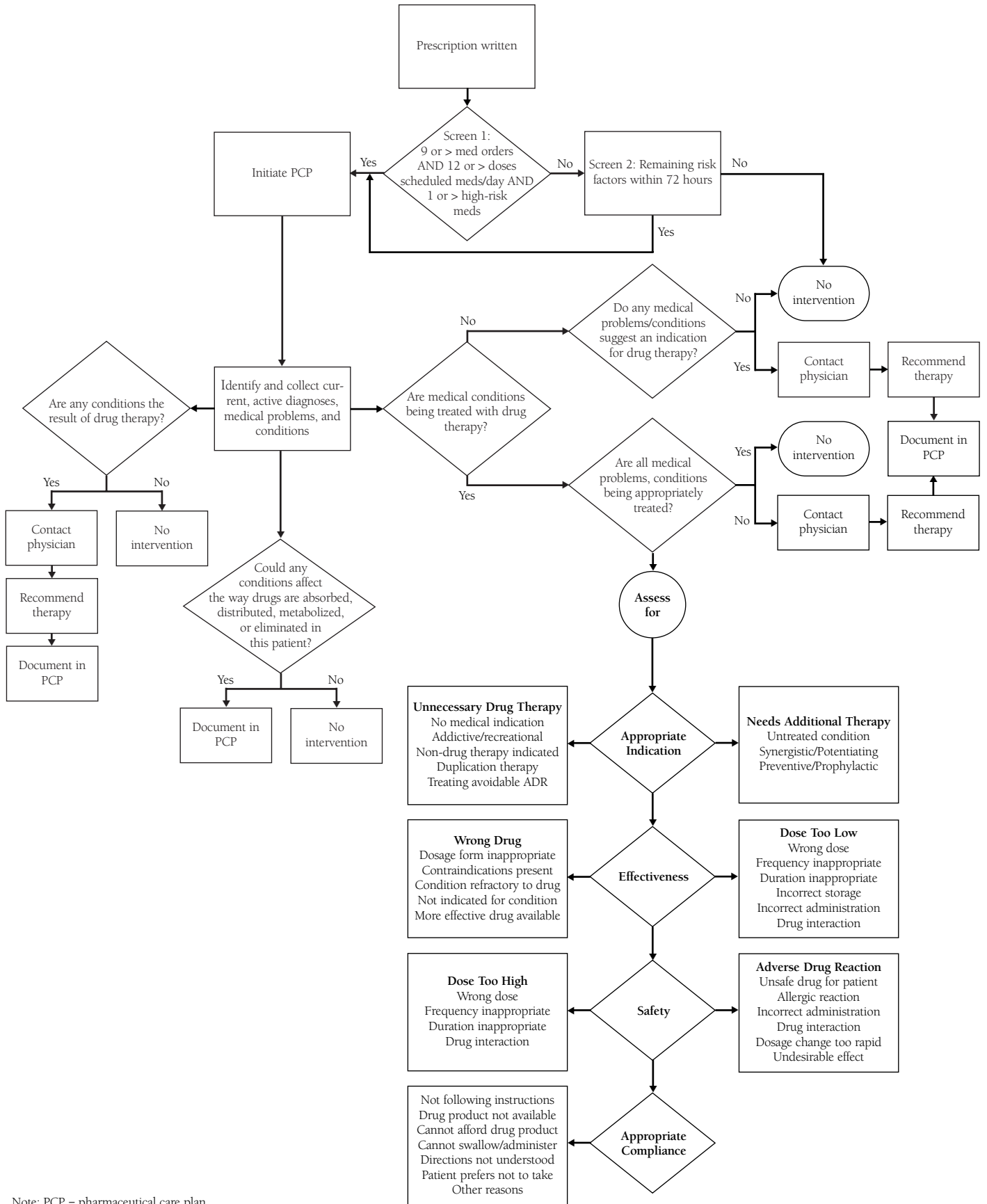
- Screening for high-risk patients
- Prospective medication review
- Pharmacist intervention and direct communication with the prescriber
- Patient assessment by the consultant pharmacist
- Formalized pharmaceutical care planning

problems. Figure 1 is a schematic of the Fleetwood Phase II intervention that incorporates the components of the Fleetwood Model.

The Fleetwood Model is based on the following assumptions:

- Transaction-related payment for pharmacist services is unlikely.
- Targeting patients at highest risk for medication-related problems will demonstrate the greatest impact of pharmacist services.
- Physicians are more likely to accept pharmacist recommendations if they are made prospectively, before therapy is initiated.

FIGURE 1. FLEETWOOD PHASE II INTERVENTION



Note: PCP = pharmaceutical care plan



TABLE 1. RISK FACTORS FOR MEDICATION-RELATED PROBLEMS AMONG ELDERLY NURSING FACILITY RESIDENTS

Specific Medication

Digoxin
Warfarin
Lithium
Theophylline
Chlorpropamide
Glyburide

Class of Medication

Anticonvulsants
Antiarrhythmics
Antipsychotics
Antidepressants
Sedative/hypnotics
Benzodiazepines
Histamine₂-antagonists
Nonsteroidal anti-inflammatory drugs
Anticholinergics
Angiotensin-converting enzyme inhibitors
Diuretics
Antibiotics (new prescription)
Narcotic analgesics

Patient Characteristics

Number of chronic health diagnoses (> 6)
Doses of medications per day (> 12)
Recent transfer from hospital
Advanced age (> 85)
Prior adverse drug reaction
Cancer
Depression
Low body weight or body mass index (< 22 kg/m²)
Use of nine or more medications
Cognitive impairment, including dementia
Decreased renal function (estimated creatinine clearance < 50 mL/min)

■ Physicians are more likely to accept pharmacist recommendations if the pharmacist communicates directly with the prescriber—rather than through a nurse—to resolve actual or potential medication-related problems.

■ Intervention must include patient assessment and formalized pharmaceutical care planning.

■ The most costly negative outcomes due to medication-related problems should be targeted in order to demonstrate the greatest impact on health care costs.⁶

The first step in Fleetwood Phase II was the identification of factors that place frail, elderly nursing facility residents at highest risk for medication-related problems (Table 1). Not all patients experience preventable medication-related problems that result in costly negative outcomes. It is difficult to demonstrate the value of consultant pharmacist interventions in avoiding negative outcomes and associated costs when looking at the entire nursing facility population. In addition, it may not be feasible or reasonable to provide pharmaceutical care to all patients receiving medications, nor are payers likely to pay for this level of pharmacist services for all patients. Focusing on patients at highest risk for medication-related problems that result in the most costly negative outcomes allows pharmacists and other health care professionals to more efficiently and economically focus their attention on patients who have the greatest

Source: Reference 4.



need and may thus realize the greatest benefit.

The study to identify risk factors for medication-related problems among nursing facility residents was conducted by Joseph Hanlon, PharmD, and colleagues at Duke University Center for the Study of Aging and Human Development, and published in the October 1997 issue of *The Consultant Pharmacist*.⁵

The Fleetwood Phase II feasibility study was conducted over a six-month period, May 1–October 31, 1998, in cooperation with Vitalink Pharmacy Services' Appleton, Wisconsin site. The study sites were six nursing facilities (three intervention and three comparison facilities) serviced by the Vitalink Appleton pharmacy site.

Fleetwood Phase II found that the Fleetwood Model can be successfully implemented in long-term care pharmacy. The Fleetwood Model enables the pharmacist to play a more active role in patient care through greater interaction with other members of the interdisciplinary team, the patients, and their families. The most significant operational findings from implementation of the Fleetwood Model in Phase II are described in the sidebar on page 190. The complete operational results were published in the October 2000 issue of *The Consultant Pharmacist*.⁶

Wide-scale implementation of the Fleetwood Model is particularly important as the average age of the



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population increases, the number of people at risk for medication-related morbidity and mortality increases, and consultant pharmacists expand their practices into the broader senior care marketplace. The Fleetwood Model will be further refined and tested in Phase III, prior to widespread implementation.

**PHASE III: PROVING THE
EFFECTIVENESS OF THE
FLEETWOOD MODEL**

The feasibility of implementing the Fleetwood Model in long-term care pharmacy practice was demonstrated in Phase II. The effectiveness of the Fleetwood Model in improving patient outcomes through identifying, resolving, and preventing medication-related problems will be investigated in Phase III. The evaluation of the Fleetwood Model in Phase III will focus on the prevalence of potentially inappropriate medication use, undertreatment of common diseases and conditions, potential adverse drug events, and indicators of common geriatric problems associated with medication use; process measures, such as acceptance of pharmacist recommendations, incorporation of medication monitoring recommendations into the care plan,



FLEETWOOD PHASE II: KEY OPERATIONAL FINDINGS

- The consultant pharmacist and internal or dispensing pharmacist—even the pharmacy technicians—shifted their focus from the drug to the *patient*. This greater sense of connection to patients led to enhanced job satisfaction.
- The internal pharmacists became more confident in their clinical skills and knowledge and more involved in the clinical decision-making process. Actual and potential medication-related problems were handled prospectively by the internal pharmacist prior to dispensing medications.
- The consultant pharmacist spent less time on traditional retrospective drug regimen review and had more time for patient assessment, clinical interventions, pharmaceutical care planning, involvement with residents and their families, and interaction with the interdisciplinary team.
- Physicians and nursing staff viewed the consultant pharmacist as an integral member of the interdisciplinary care team and recognized the valuable contributions of the consultant pharmacist regarding medication information, clinical expertise, and the positive impact on drug therapy. The consultant pharmacist was called on to assist in clinical decision making for high-risk residents, including selection of appropriate therapies and participation in care planning. Over time, the consultant pharmacist was increasingly consulted about drug therapy for all residents, not just those identified as being at high risk.
- The consultant pharmacist spent more time in direct contact with the residents and their families, which involved patient interviews and assessments, education on medication therapy, and discussion of alternatives to optimize drug therapy and improve patient outcomes. This interaction was often the most significant factor in successfully making changes in drug therapy.
- Communication among the pharmacy staff, as well as communication among the pharmacy, physicians, and the nursing facilities, improved greatly.
- Procedures allowing nurses to take orders from the pharmacist were implemented to support direct communication between the prescriber and the pharmacist.
- All pharmacists documented patient recommendations, which were accessible to all staff.
- Pharmacy workflow was studied, and many processes were streamlined for efficiency and duplicate steps eliminated. The workflow changes needed to implement the Fleetwood Model did not require additional personnel in the long-term care pharmacy.

and linking of pharmacist interventions with specific patient outcomes; and staff efficiency, productivity, workload, and satisfaction. The specific aims of Fleetwood Phase III are listed in the sidebar on page 193.

RESEARCH PARTNERS

The ASCP Foundation's research partner for Phase III is the Center for Gerontology and Health Care Research at Brown University, Providence, Rhode Island. The center's primary mission is to advance the fields of gerontology and health services research through both methodological and substantive research, informed by basic theories of aging, human development, and the illness experience. The goal of these efforts is to enhance the quality of life of persons with chronic illness, especially older adults. The center's research focus, both basic and applied, draws upon the social sciences, as well as the clinical disciplines. It is among the leading academic research centers in the country addressing issues pertaining to the quality of care and the outcomes of policy interventions experienced by frail elders and persons with chronic illness. As an integral part of the Brown Medical School, the center coordinates multidisciplinary educational and research efforts in aging and long-term care.

Kate Lapane, PhD, will serve as principal investigator for the Fleetwood Phase III study. She will work closely with ASCP Foundation

staff, who will serve as co-investigators. Lapane has more than 10 years of research experience in both pharmacoepidemiology and multi-site intervention studies, and is the director of the Systematic Assessment of Geriatric Drug Use via Epidemiology (SAGE) Study Group. The SAGE group is an international, multidisciplinary group of investigators—including physicians from a range of specialties, pharmacists, epidemiologists, and biostatisticians—using the SAGE Minimum Data Set (MDS) database. Lapane has published extensively on pharmacotherapy in long-term care settings, including studies examining under-treatment and inappropriate treatment of common geriatric conditions in nursing facilities.

Fleetwood Phase III will be conducted in cooperation with Neil Medical Group, Kinston, North Carolina, and the nursing facilities it serves. Neil Medical Group's Kinston site serves approximately 6,000 residents of nursing facilities, assisted living facilities, and group homes.

PHASE III METHODOLOGY

Fleetwood Phase III is a three-year randomized trial to test the effectiveness of the Fleetwood Model in nursing facilities. Twenty-six nursing facilities served by Neil Medical Group will be recruited for the study. The nursing facilities will be randomized, with half receiving the intervention and half receiving the standard of care (i.e., retrospective drug regimen review). Existing data

sources will be used, including MDS data, pharmacy claims, and inpatient claims data. Throughout the study period, pharmacists will record specific aspects of their work to document their interventions.

In any randomized controlled study, the distinctiveness of the experimental and standard of care groups must remain intact throughout the intervention phase to avoid "contamination." To reduce the risk of such contamination in the Phase III research, the consultant pharmacists will provide services only to the intervention facilities or to the comparison homes; no consultant pharmacist will provide services to both.

THE PHASE III INTERVENTION

The three-year Fleetwood Phase III study includes pre-implementation tasks, a one-year implementation phase, and data analysis.

Pre-implementation tasks include:

- Nursing facility recruitment
- Evaluation and redesign of current pharmacy workflow to accommodate the Fleetwood Model
- Pharmacy and nursing facility staff orientation
- Identifying data needs and testing data transfer
- Development of a communication plan for facilities and prescribers
- Training for intervention pharmacists
- Collaboration with a pharmacy system software vendor to incorporate the Fleetwood Model risk screening criteria

The research team will work closely with Neil Medical Group staff to accomplish the pre-implementation tasks.

Intervention pharmacists will participate in a two-day interactive workshop, which will cover use of the high-risk screening criteria, communicating with members of the care team, writing recommendations to be incorporated into the nursing care plan, pharmaceutical care planning, documentation of interventions, and other relevant aspects of the Fleetwood Model. Clinical training for the intervention pharmacists will be provided through the ASCP Foundation's Disease Pharmacotherapy Traineeship.

IMPLEMENTATION OF THE MODEL

Once the pre-implementation tasks are completed, the one-year implementation phase will begin. The components of the Fleetwood Model will be operationalized for high-risk patients by the pharmacists serving the intervention nursing facilities. Based on experience with the screening algorithm in Fleetwood Phase II, it is anticipated that approximately one-third of the residents will be prospectively identified as being at high risk for medication-related problems.

EVALUATION OF THE MODEL

Evaluation of the effectiveness of the Fleetwood Model will focus on the six specific aims of the study, described below. A cost-effectiveness analysis will also be conducted.



SPECIFIC AIMS OF FLEETWOOD PHASE III

Specific Aim 1: Reduction of potentially inappropriate medication use. The study will seek to determine the extent to which the Fleetwood Model reduces the prevalence of potentially inappropriate medication use. The investigators will estimate the prevalence of potentially inappropriate medication use within each nursing home in each month of the study using the criteria established by Beers et al.^{7,8}

Specific Aim 2: Reduction of potential under-treatment of common diseases. The Phase III investigators will estimate the extent to which the Fleetwood Model reduces the potential under-treatment of

1. To determine the extent to which the Fleetwood Model reduces the prevalence of potentially inappropriate medication use
2. To determine the extent to which the Fleetwood Model reduces the potential under-treatment of common diseases
3. To determine the extent to which the Fleetwood Model reduces the rate of potential adverse drug events
4. To determine the extent to which the Fleetwood Model reduces the triggering of Resident Assessment Protocols (RAPs) related to medication use
5. To quantify the impact of the Fleetwood Model on the efficiency, productivity, workload, and satisfaction of the consultant pharmacists and staff of the nursing facilities
6. To differentiate nursing facilities that successfully incorporate the new role of the consultant pharmacist into ongoing routines from those that do not



common diseases experienced by nursing facility residents. The proportion of residents in a given month receiving any appropriate treatment for a given disease or condition (e.g., stroke, heart failure) will be determined.

Specific Aim 3: Reduction of rate of potential adverse drug events (ADEs). A key Phase III objective is to quantify the extent to which the Fleetwood Model reduces the rate of potential “severe” ADEs (defined as those requiring hospitalization) using surrogate markers from inpatient claims data. Based on a recent study of the incidence of common ADEs in nursing homes,³ hospitalizations for the following primary diagnoses will be considered potential ADEs: gastrointestinal hemorrhage, non-traumatic intracranial hemorrhage, allergic urticaria, diabetic hypoglycemia/coma, acute liver failure, fractures, falls with or without fracture, and drug-induced delirium. (Because delirium experienced by nursing facility residents often does not result in hospitalization, delirium [determined from MDS data] will be considered a potential severe ADE, whether or not it results in hospitalization.)

Specific Aim 4: Reduction of “triggering” of Resident Assessment Protocols (RAPs) related to medication use. Specific Aim 4 is to determine the extent to which the Fleetwood Model reduces the “triggering” of RAPs, such as delirium and falls, potentially related to medication use.

Specific Aim 5: To quantify the impact of the Fleetwood Model on the efficiency, productivity, workload, and satisfaction of the pharmacists and staff of the nursing facilities. To evaluate this aim, pharmacists and nursing facility staff will complete a survey regarding their perceptions of workload, efficiency, job satisfaction, and productivity prior to implementation of the intervention and at the end of the study.

Specific Aim 6: To differentiate nursing facilities that successfully incorporate the new role of the consultant pharmacist into ongoing routines from those that do not. The implementation of innovative models typically disrupts established organizational routines. As a result, such models are often difficult to implement. The research team from Brown University will attend the training processes associated with the Fleetwood Model implementation. During this time and during site visits to the nursing facilities and long-term care pharmacy, the research team will interview staff about their perceptions of the Fleetwood Model and what challenges they feel will need to be overcome for successful implementation. Additionally, existing tools developed to evaluate the organizational and team characteristics will be modified and used by the research team specifically for implementation of the Fleetwood Model. Findings pertaining to this specific aim will facilitate planned future replication of the Fleetwood Model.

PROCESS EVALUATION

An important adjunct to any intervention study is process evaluation. In the Fleetwood Phase III study, this type of evaluation will provide data for better understanding the role of the pharmacist in preventing ADEs in nursing facilities. Process outcomes to be measured include acceptance of pharmacist recommendations and incorporation of pharmacist monitoring recommendation into the care plan. In addition, pharmacists will document all interventions, which will be “classified” using a standard taxonomy. This analysis will facilitate the linking of pharmacist activities with specific patient outcomes and the identification of *pharmacist-sensitive outcomes*, those outcomes most sensitive to pharmacist intervention.

COST ANALYSIS

No large-scale randomized, controlled trial of a new intervention would be complete without a cost analysis. The costs associated with serious ADEs will be estimated and compared across the intervention and comparison facilities. Other costs that will be measured fall into four general categories: labor, facilities, equipment, and materials. Costs measured for this analysis will be specific to the intervention and will not include costs stemming from the research and evaluation of the intervention. The cost-effectiveness results can be used to estimate the cost of implementation in other settings.



A TESTAMENT TO PROGRESS

A great deal has been learned and accomplished since the Fleetwood Project was first conceptualized nearly a decade ago, when ASCP set out to demonstrate the value and positive impact of consultant pharmacist services on patient outcomes and health care costs. Fleetwood Phase III is the culmination of years of planning and work—a major return on investment for those who have generously supported the project through Phases I and II.

The ability of the ASCP Foundation to receive private foundation funding to conduct Phase III of the Fleetwood Project is a testament to the work previously accomplished in Phases I and II, and a validation of the course set by the Fleetwood Advisory Group in the formative days of the project.

Fleetwood Phase III will, for the first time, quantify the effect of professional pharmacist services within the framework of the Fleetwood Model on the rate of potential ADEs, prevalence of potentially inappropriate medication use, underuse of appropriate medications, and prevalence of indicators of common geriatric problems associated with medication use. In addition, process measures, including classification of phar-

THE FLEETWOOD PROJECT IS THE FOUNDATION FOR RE-ENGINEERING PHARMACY PRACTICE.

maciast interventions, acceptance of pharmacist recommendations, and incorporation of medication monitoring recommendations into the care plan, will be evaluated. This type of evaluation provides data for better understanding the role of the pharmacist in preventing adverse medication events, linking pharmacist interventions to patient outcomes, and identifying pharmacist-sensitive outcomes.

The significance and relevance of the Fleetwood Project today is a direct outgrowth of the bold and prescient vision of the Technical Advisory Group, which recognized the need and opportunity to conceptualize what consultant pharmacy practice had to look like in the future within the framework of the Fleetwood Project. The easier road would have ended with Fleetwood Phase I and the economic analysis of the benefits of federally mandated retrospective drug regimen review in nursing facilities. But the Advisory Board dared to step

beyond traditional drug regimen review in its vision for the Fleetwood Project, to create a new model of practice—a model that is prospective rather than retrospective, focuses on patients at highest risk for medication-related problems, identifies specific outcomes where pharmacists have a measurable impact, fosters integration of the pharmacist in the interdisciplinary team, removes arbitrary distinctions between the role of consultant and “dispensing” pharmacists, and, most importantly, better serves the needs of patients.

In short, the Fleetwood Project is the foundation for re-engineering pharmacy practice toward a more clinical, patient-centered orientation. ☉

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