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## EDITORIAL

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# The Role of Pharmacists in Clinical Care: Where Do We Go from Here?

Americans fill over 3 billion prescriptions annually, and there are more than 10,000 prescription products available today (compared with 650 in the 1960s).<sup>1</sup> Patients with chronic disease are often on more complex regimens, which can result in lower medication adherence and increased morbidity, adverse drug events, hospital admission, death, and health care costs.<sup>2-4</sup> The importance of drug-related events has, in part, led the pharmacy profession to redefine its role in the health care delivery system, particularly through pharmaceutical care. Pharmaceutical care is “the responsible provision of drug therapy for the purpose of achieving outcomes that improve a patient’s quality of life.”<sup>5</sup> Thus, pharmaceutical care represents a fundamental paradigm shift emphasizing that pharmacists can help improve patients’ health-related quality of life, rather than simply providing a product or service.

To prepare for the pharmacist’s expanded role, all accredited pharmacy schools now require students to complete a Doctor of Pharmacy (PharmD) degree, which requires 4 years of education beyond prepharmacy studies. In addition, pharmacists can now obtain board certification in several specialty areas, including nutrition support, oncology, and pharmacotherapy.<sup>6</sup> This training and certification permits pharmacists expanded responsibilities, including collaborative drug therapy management with physicians, disease state management, immunization services, and patient education. Over 30 states currently allow some form of collaborative management that “allows physicians to enter into agreements with pharmacists to jointly manage a patient’s drug therapy.”<sup>7</sup> Pharmacists may be involved in selecting, initiating, modifying, and monitoring a patient’s drug therapy. They also may order, perform, and interpret laboratory-related tests, assess patient response to therapy, counsel patients concerning medications and potential adverse effects, monitor patient adherence, and work to prevent adverse drug reactions.<sup>7</sup> Pharmaceutical care activities are particularly important when caring for patients with chronic disease, where it is estimated that over 50% of patients do not take their medication properly.<sup>1</sup> A recent position paper by The American College of Physicians–American Society of Internal

*This paper is available at [ecp.acponline.org](http://ecp.acponline.org).*

TABLE 1

## ACP Positions on Pharmacist Scope of Practice and Potential for Research

ACP-ASIM POSITION*	RATIONALE*	FURTHER RESEARCH TO EXAMINE
Supports research into the effects of pharmacy automation and the move to the PharmD degree	Store-based pharmacists currently spend over 60% of their time processing and dispensing orders; automation and pharmacy technicians will free up this time PharmD degree has expanded clinical training	Expanding roles of community pharmacist Level of autonomy for community pharmacists Impact of PharmD training
Supports physician-directed collaborative practice agreements between the pharmacist and the physician, limited to pharmacist involvement in patient education and hospital rounds	Pharmacist interventions in the hospital setting have been successful in improving clinical outcomes, reducing cost, and reducing adverse events	Organizational structures to enhance physician-pharmacist communication Technologies (e.g., Internet, automated phone systems, home monitoring equipment) that can improve this communication Pharmacist role in community-based, disease state management in the outpatient setting Practical programs and protocols that are acceptable to patients, pharmacists, and physicians
Opposed independent pharmacist prescription privileges and initiation of drug therapy	Question if pharmacist training is sufficient for independent initiation of medications No evidence to support this activity	Pharmacist prescribing under close guidelines and supervision
Supports the use of the pharmacist as immunization information source. . . immunizer, as appropriate	30 states already allow pharmacists to give immunizations Pharmacies are a readily accessible site and can increase immunization rates	Effect of these programs on improving patient outcomes and cost-effectiveness
Reiterates its support of its 1990 therapeutic substitution position	Supports previous position In accordance with American College of Clinical Pharmacy	Effect of these actions on improving patient outcomes and cost-effectiveness

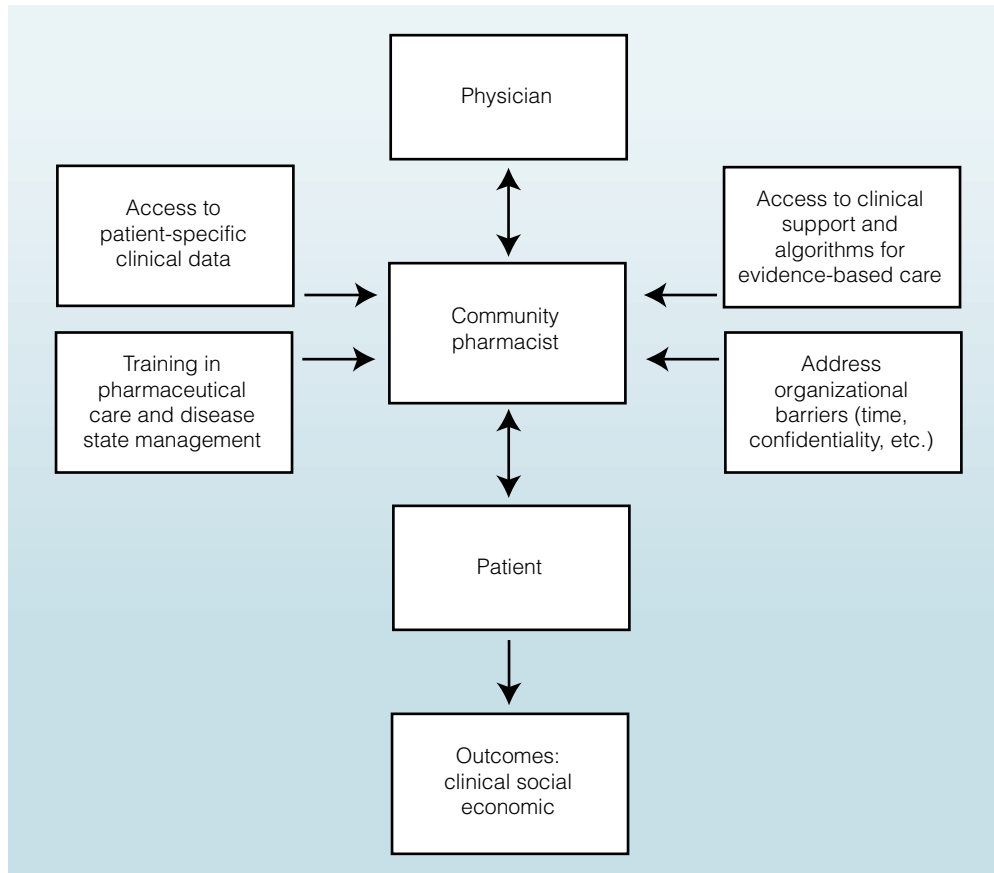
\*Adapted from Pincus and colleagues.<sup>6</sup> ACP-ASIM = American College of Physicians-American Society of Internal Medicine.

Medicine (ACP-ASIM)<sup>6</sup> recognizes the increasing scope of pharmacists and outlines “how the medical profession can work with pharmacists to enhance patient safety and quality of care.” **Table 1** describes these positions, their rationale, and areas for future research.

Empirical evidence about the benefits of pharmaceutical care has been generally positive, but the strength of the evidence is problematic. Several randomized trials have shown that clinical pharmacists can play a key role in disease management models for anticoagulation treatment, hypertension, hyperlipidemia, asthma, and other chronic conditions.<sup>8-11</sup> However, several recent literature reviews suggest that the enthusiastic reports are often plagued by serious design flaws, lack of controls, absence of appropriate controls, incorrect analyses (e.g., reporting within-group rather than between-group comparisons), small sample sizes, short follow-up periods, and lack of patient outcome data.<sup>12-15</sup> These reviews

suggest that there is evidence supporting the effectiveness of pharmaceutical care delivered during hospital admissions, less evidence in outpatient settings, and no well-designed studies supporting the effectiveness of pharmaceutical care in retail pharmacies. One recent review<sup>13</sup> identified 21 studies conducted in community pharmacy settings that measured the impact of pharmaceutical services on patient outcomes. The authors found that many of these studies had significant methodologic problems, and none evaluated the impact of pharmaceutical care on economic, clinical, and humanistic outcomes. The authors recommend that pharmaceutical services in community and ambulatory care settings should be evaluated using multisite randomized trials that attend to the foregoing issues.<sup>13</sup>

In this issue of **ecp**, Fischer and colleagues<sup>16</sup> take a step toward evaluating the impact of community pharmacists on patient outcomes. In this nonrandomized but



**FIGURE 1. Model for community-based pharmaceutical care.**

controlled trial, pharmacists identified drug therapy problems in 69% of the intervention patients and provided some level of intervention for 87% of these patients. This comprehensive drug management intervention appeared to result in a small but significant increase in the number of unique medications (1.0 vs. 0.4;  $P = 0.03$ ) and a trend toward increased clinic visits and overall charges. This increase in utilization is consistent with a randomized, controlled trial that evaluated the impact of pharmaceutical care delivered by community pharmacists to patients with asthma or chronic lung disease.<sup>17</sup> The interpretations of these findings are hindered by major research design limitations, most of which the investigators acknowledge. The nonrandomized design, combined with nonspecific definitions of disease conditions and selection bias, make it difficult to evaluate the true effectiveness of the intervention. In addition, the exact nature of the intervention is not well defined, and as the investigators concede, it may not have been potent enough. It is not clear whether the intervention allowed the pharmacists to make improvements in a proactive rather than a reactive manner. Finally, one of the most important limitations is the emphasis on utilization of services as the primary outcome without any evaluation of patient-centered outcomes, such as quality of care, or clinical outcomes.

Although the study suggests that patient use of services is increased, we do not know if this improved quality or outcomes of care.

Despite these limitations, this study provides us with some important research on community-based pharmaceutical care and points to several research questions that need to be more adequately addressed. For example, what models of pharmaceutical care are the most successful? What are the specific roles that pharmacists can perform? What outcomes are improved by these interventions? What methods should be used to best evaluate this research?

There has been a fair amount of research on the role of pharmacists in the inpatient and selected outpatient settings. However, we believe that well-designed, randomized, controlled trials in retail pharmacies are critical because that is the venue where patients and pharmacists most often interact. A major benefit of conducting research in large retail chains is that they possess the capability to rapidly implement effective programs throughout their stores. In **Figure 1**, we propose a conceptual model for the design and evaluation of community-based pharmaceutical care. These innovative programs will need to be evaluated in terms of patients' clinical outcomes (e.g., disease status, health-related quality of life) and cost-effectiveness. Barriers to the

proper design, implementation, and evaluation of this research will be considerable. Interventions will require partnerships between academic and private enterprise. Successful interventions will need to be potent enough to effect change, without placing too much responsibility on the pharmacists or being too cumbersome economically. Long-term implementation will require the intervention to be reliably replicated under uncontrolled conditions.<sup>18</sup> In addition, we will need to determine reimbursement strategies that allow pharmacists to provide pharmaceutical care. We support The Agency for Healthcare Research and Quality statement that the challenge for the next generation of outcomes and effectiveness research is the acceleration of the process by which findings impact policy and practice.<sup>19</sup> Given patients' increasingly complex medication regimens, we believe that developing creative ways to increase community-based pharmacist involvement in patient care represents an important direction for research.

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