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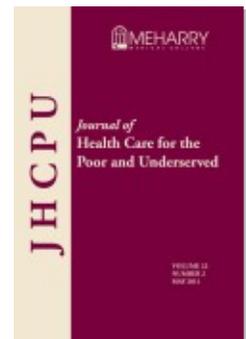
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Magaly Rodriguez de Bittner, Roxanne Ward Zaghab

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Improving the Lives of Patients with Chronic Diseases: Pharmacists as a Solution

Magaly Rodriguez de Bittner, PharmD
Roxanne Ward Zaghab, MSW

Abstract: Positive health outcomes hinge on the effective use of medications especially among vulnerable, chronically ill, and aging populations. Yet, increasingly powerful and complex drug combinations are used to treat patients with chronic diseases and multiple health conditions. As treatment complexity increases the potential grows for non-adherence to medications due to side-effects, drug-disease interactions, costs, and patient confusion about medicines. Pharmacists are the medication experts on a health care team. Working in collaboration with the patient and the prescriber, pharmacists offer solutions that foster medication adherence, improve clinical outcomes and decrease drug-related adverse events. Their accessibility, extensive knowledge of drug therapy, and trustworthiness in the minds of consumers open many opportunities for pharmacists to expand their reach in preventing drug-related problems in patients with chronic diseases.

Key words: Pharmacists, drug safety, chronic disease management, medication therapy management.

In a previous issue of the *Journal of Health Care for the Poor and Underserved (JHCPU)*, Dingham, Glenn and Leal¹ brought to light a common but significant problem in our current health care system—preventable adverse drug events in patients with chronic diseases. The tragedy of one individual recounted in that Association of Clinicians for the Underserved (ACU) column highlights the human toll that drug mismanagement can have on patients, and creates an opportunity for pharmacists as a solution in medication safety and chronic disease management.

To address the immediate problems of patient safety and multiple medication management, we stand with ACU in urging new models of care for the underserved with chronic disease. The University of Maryland School of Pharmacy participates in two

DR. RODRIGUEZ DE BITTNER directs the Maryland P³ Program™, is professor and chair of the Department of Pharmacy Practice in the University of Maryland School of Pharmacy, is Executive Director of the Center for Innovative Pharmacy Solutions, and provides leadership to the profession of pharmacy through national service on professional organizations, presentations, publications, and scholarship. As research and special projects administrator with the Center for Innovative Pharmacy Solutions at the University of Maryland School of Pharmacy Department of Pharmacy Practice and Science, **MS. ZAGHAB** provides leadership in research initiatives and strategic assistance to innovative program development. Please address correspondence to Magaly Rodriguez de Bittner, Pharmacy Practice and Science, University of Maryland School of Pharmacy, 20 N. Pine Street, Suite 400, Baltimore, MD 21201; mrodrigu@rx.umaryland.edu.

projects of the Health Resources and Services Administration (HRSA) Patient Safety and Clinical Pharmacy Services Initiative (PSPC). One PSPC team collaborates with a Baltimore HIV clinic and engages pharmacists to address adverse reactions, improve adherence, and manage complex medications for co-infections in this at-risk population. In one Washington, D.C. area safety-net clinic, pharmacists help patients (most of them Spanish-speaking) manage diabetes and other chronic diseases. The collaborative team model operating in these two clinics provides a useful framework to address patients' pharmacotherapy issues; in the short time since these clinics were established, our pharmacists have observed dramatic improvements in patients' clinical outcomes. Yet pharmacists remain an untapped resource for improving safety and patient outcomes in a range of health care delivery settings.

Pharmacists and the Health Care System

According to the Institute of Medicine's (IOM) 2006 report,² adverse drug events account for more than 1.5 million preventable medication-related incidents each year. Adverse reactions experienced by patients with poorly managed chronic diseases have severe consequences, resulting in increased suffering and costing an estimated \$177 billion dollars annually.³ Non-adherence to medication has also been shown to result in increased health risks and costs of up to \$290 billion.⁴ Among patients with chronic disease, poor adherence results in poor outcomes and increased medical costs. Almost one half of the U.S. population suffers from one or more chronic conditions, a situation that accelerates as the population ages.⁵ This commentary will provide evidence of pharmacist-provided programs that improve medication adherence in chronic disease management, reduce hospitalizations and prevent the need for emergency treatment.

The Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148 (March 23, 2010) is expected to expand significantly the proportion of medically underserved community residents who gain coverage through either Medicaid or health insurance reform plans. Growth is also expected in the number of individuals with chronic diseases who gain access to the health care system, ironically exacerbating the existing shortage of primary care providers. The projected shortage of primary care physicians (including pediatricians) ranges from 46,000 to 90,000 over the next 10 to 15 years.⁶⁻⁷ Such shortages open the door to new team-based models of primary care which include pharmacists, and encourage them to share their skills and medication expertise in medical systems, clinics and doctors' offices, and community pharmacies. The medical home under health care reform presents a platform and structure to maximize the knowledgeable contribution of pharmacists in chronic disease management. In addition, new service models suggest pharmacists can deliver care through telephone interaction and through collaboration in other technological venues such as telemedicine to reach rural and underserved populations.⁸

Pharmacists and Patients

Positive health outcomes hinge on the effective use of medications, especially among vulnerable, chronically ill, and aging populations. Increasingly powerful and com-

plex drug combinations are used to treat patients with chronic diseases and multiple health conditions. Though prescription medications represent an expanding portion of health care costs in chronic disease, potency of drug therapy has the potential to increase both cost and side-effects. This does not translate directly into improved patient outcomes.

Poor medication adherence may be due to the cost of drugs, side-effects and drug interactions, fear of allergies, and patient confusion about how to dose and self-administer multiple medications.⁹⁻¹² Patients' questions and doubts about their medications can lead to non-adherence, which occurs in 20% of all patients immediately, and nearly 50% of all patients after six months on long-term drug therapy.⁹ The complexity and lack of continuity in patient care for those with chronic conditions may be increased by the existence of multiple prescribers for the same patient or possibly the same conditions. Research studies have shown pharmacist effectiveness in promoting medication adherence among their patients with chronic disease as described later in this commentary.¹²⁻¹⁵

Any patient with questions about his or her medication, regardless of income or condition, can consult with a medication expert—the pharmacist—without an appointment or out-of-pocket expense. Pharmacists work with the patient to answer questions, to address concerns about symptoms and potential side-effects, as well as to educate patients about diseases and purpose of particular medications. There are 161,940 pharmacists working in retail drug stores in 61,000 communities across the U.S.²⁴ Not only are these medication experts located in patients' neighborhoods, they are accessible up to 24 hours per day at no direct cost to the patients. In addition to accessibility, pharmacists continue to be trusted as indicated in consumer ranking of pharmacists in the top two health professions for trust and honesty in a Gallup Poll.²⁵ With this trust and accessibility, pharmacy schools have a responsibility to prepare trainees to overcome the challenges of educating patients across varying languages, literacy levels, and cultural backgrounds.²⁶

Proper medication use is particularly relevant for underserved patients, the elderly, and culturally diverse patients who are at risk for drug safety problems.²⁷ Pharmacists' training and advanced continuing education prepares them to take an active role in patient education, counseling in proper medication use, and addressing barriers to adherence in the treatment of chronic disease. The pharmacist's goal is to improve patients' safe use of medication and also to prevent health crises due to non-adherence to prescribed drug therapy.

Patients who receive pharmacist services achieve better clinical outcomes than national standards for chronic disease, across-the-board.^{10,27-33} Many experts agree that strategic use of a pharmacist's medication knowledge can improve clinical outcomes in chronic disease, promote medication adherence, and avoid unnecessary breaches in medication safety.^{12-14,19-27} Pharmacists' involvement in the health care of chronically ill patients not only results in better health and safety for the patient, but also ensures documented savings for payers and patients.^{29,33}

Pharmacist-delivered Programs

Pharmacist-provided medication therapy management (MTM) services have been recognized by the Center for Medicare and Medicaid Services since the Medicare Modernization Act of 2003. Medicare beneficiaries gain access to affordable medications as well as to MTM services which include: a) gathering medical and drug therapy information; b) assessing the patient and reviewing pertinent laboratory data; c) calculating liver and kidney function; d) conducting a comprehensive medication review; e) formulating a medication treatment plan; f) recommending additions and modifications to medication therapy; g) monitoring drug therapy outcomes; h) detecting adverse drug events; i) providing patient education and fostering empowerment; j) documenting treatment plans; and k) communicating treatment plans to other providers. Medication therapy management services reduce adverse drug events and improve patient adherence. These services may be available on a limited basis as an out-of-pocket expense for those who are not Medicare beneficiaries. The first step in ensuring a standard of care and safety for patients with chronic diseases is to increase the availability of MTM services to all patients, particularly vulnerable populations with multiple chronic diseases.

Improvement in clinical outcomes and a decrease in overall health care costs have been observed in many programs that utilize the pharmacist as a medication expert and health care coach. One such program is the Maryland P³ Program™, in which pharmacists coach patients with diabetes to increase the patient's knowledge of their disease, ensure medication adherence, and improve the patient's ability to monitor warning signs and better self-manage their disease. The Maryland P³ Program™ was designed to address growing pressure on patients to manage their own chronic diseases, as well as their medications.

The University of Maryland School of Pharmacy's P³ Program™ participated in the *Ten City Challenge*^{32,33} in cooperation with the American Pharmacists Association. This study found reductions in cost, increases in adherence, and overall improvements in the quality of care as indicated by the number of patients with diabetes achieving American Diabetes Association (ADA) *Medical Standard of Care Guidelines* for average blood glucose levels (HbA1c).³⁴ Patients participating in the Maryland P³ Program™ showed clinical, economic, and humanistic improvements on key indicators in comparison with their ratings prior to enrollment. The Diabetes Ten City Challenge³³ reported statistically significant changes in 528 patients for all major clinical parameters (reductions in HbA1c, LDL cholesterol, blood pressure and body mass index) after one year of receiving pharmacist-delivered diabetes management. In addition, the study demonstrated dramatic improvements in the percentage of patients reaching Healthcare Effectiveness Data Information Set (HEDIS) standards—indicating compliance with the ADA standard of care for good HbA1c, blood pressure, lipid control, influenza vaccinations, and foot and eye exams. Most importantly, these same pre-post comparisons show that 72% of the patients with diabetes demonstrated proficiency or advanced skill in self management of their disease, such as operating the blood glucose meter and taking a blood pressure reading. Cost savings were achieved as a result of improved patient adherence. The Diabetes Ten City Challenge resulted in mean annual savings of \$1,079 per patient when compared with projected total health care costs.

Collaborative Drug Therapy Management (CDTM) practice between pharmacists and health care providers is an emerging practice model used in 46 states in 2009.^{27,28} Collaborative Drug Therapy Management is defined as an agreement between pharmacists and one or more physicians/health care providers working under a previously approved protocol.³⁵ According to the protocol, both practitioners define the functions and responsibilities that the physician/health care prescriber agree to delegate to the pharmacists for the management of the patients' medical conditions or drug therapy regimen. The protocol may delegate certain functions such as medication dose adjustments, ordering laboratory data to monitor and adjust drug therapy, as well as selecting, adjusting, continuing or discontinuing drug therapy. Collaborative Drug Therapy Management is regulated separately by each state.

The literature contains examples of the impact of collaborative-types of services on patients' clinical outcomes for all income levels.^{15,19–25} The chronic diseases managed as part of these CDTM services include diabetes, asthma, hypertension, depression, hyperlipidemia, pain, coagulation disorders, and heart failure. One such CDTM practice involves tobacco cessation and drug therapy services for homeless men receiving primary care in a Baltimore clinic.

Another example of CDTM practice involves the Veterans Administration (VA) outpatient diabetes treatment team. In a recent study of this collaboration, Rochester and colleagues demonstrated improvements in HbA1c and a decrease in the delay for insulin therapy initiation when pharmacists work under a collaborative protocol.³⁴ This study noted a mean reduction in HbA1c of 2.63%. This decrease can be translated as more than an 80% reduction in microvascular complications attributed to diabetes.

Pharmacist-delivered programs engage patients' providers and foster better communication among providers, and between patients and their providers. Research indicates that programs guided by patient-centered care and increased communication can improve the health of the patient and reduce health care costs.²⁸ In summary, pharmacists play a critical and effective role in ensuring patient safety, improving health outcomes, and cost savings for the patient and the payer.

Pharmacists as a Solution

In addition to supporting continuation of the PSPC initiative, we call upon providers to incorporate pharmacists as integral and active members of the health care team—to optimize their expertise in chronic disease management and MTM in community clinics, safety-net clinics, physician practices, long-term care, and hospital settings. In addition to collaborative practice, our experience suggests the Maryland P³ Program™ employer model can be extended into state Medicaid populations for diabetes, hypertension, and metabolic syndrome. Primary care providers can also access pharmacist expertise. Every consultation between a health care provider and a pharmacist regarding medication interactions and adverse effects has the potential to prevent problems and to ensure patient safety.

Pharmacists are health care providers available to serve all patients with chronic diseases in their own neighborhoods. We call on community pharmacists to fortify their knowledge in chronic disease and patient safety through continuing education

programs. Equally critical is training to ensure that our community pharmacists possess the ability to address cultural and language barriers to patient education at the counter and in the clinic. Cultural competency is at the core of patient-centered medical care.¹⁸ Pharmacy research has examined the impact of language and health literacy barriers to the provision of quality pharmacist-delivered care. Pharmacists face extraordinary challenges when serving culturally diverse, multi-lingual, and limited English proficiency (LEP) populations. This is illustrated by one study where up to a dozen languages (Spanish, French, Arabic, Korean, Chinese, Vietnamese and others) were spoken in a single community pharmacy.²¹ Pharmacists have taken steps to promote patient safety through multilingual and LEP communication including the use of language-specific labels¹⁶⁻¹⁷ and patient medication use leaflets.^{16-17,21} In one study telephone-accessible translation services were also available in some pharmacies.²⁰ Up to 34.9% pharmacies had no translation or alternative language materials, a situation not exclusive to small or rural pharmacies.²⁰ Pharmacy educators, such as those at the University of Maryland School of Pharmacy²² have forged an aggressive agenda to prepare student pharmacists as culturally competent practitioners through rigorous standards and a relevant curriculum.^{19,23}

Our expert pharmacists volunteer throughout the U.S. at local safety-net clinics, health fairs, and medical missions to serve patients at-risk. But volunteer professionals are not a long-term sustainable solution. Adequate recognition and reimbursement of pharmacists by private and government payers are essential to ensuring a permanent role for pharmacists in the continuity of care for patients fortunate enough to have coverage under Medicaid, Medicare, or other state insurance programs. As health care reform becomes a reality, pharmacists in every setting must be prepared to respond to this call to help address the overwhelming chronic disease problems that challenge patients and systems of care.

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