2006 Rho Chi Lecture
San Francisco, California
March 20, 2006

Unparalleled Opportunities for Improving Medication-Related Health Outcomes

Milap C. Nahata, MS, PharmD
Professor and Chairman
Division of Pharmacy Practice and Administration
College of Pharmacy
Professor of Internal Medicine and Pediatrics
College of Medicine
Ohio State University (OSU)
Associate Director of Pharmacy
OSU Medical Center
Columbus, Ohio

Address for correspondence:

College of Pharmacy
Ohio State University
Parks Hall
500 W 12th Avenue
Columbus, OH 43210
E-mail: Nahata.1@osu.edu
Phone: 614-292-2472
Fax: 614-292-1335

It is a tremendous honor to be chosen to present the 2006 Rho Chi Lecture to the annual meeting of the Society, which "encourages and recognizes excellence in intellectual achievement and advocates critical inquiry in all aspects of pharmacy." It brings back fond memories of my induction into the Society as a graduate student. I am grateful for all the opportunities I have had in pharmacy education, practice, and research over the past 30 years. None of this would have happened without the support of my colleagues and administration at Ohio State, the hard work of my students and fellows, and a sense of community I have felt with my pharmacy friends across the country. I have been fortunate to be associated with the most advanced system of pharmacy practice, education, and research in the world. The reason we excel is because we are always pushing the frontiers and asking ourselves how we could do better. In that spirit, for this presentation, I have chosen to briefly describe the current health care needs in our society, within the context of pharmacotherapy, and discuss the role pharmacy must play to enhance medication-related health outcomes and quality of life of our citizens.

Enormous progress has occurred in clinical medicine during the past century. Just during my career, advances in pharmacotherapy, in part have led to increased life expectancy, decreased infant mortality, effective vaccines and antibiotics for the prevention and treatment of many deadly infectious diseases, and lower morbidity and mortality from cardiovascular disease by treating hypertension, hyperlipidemia, and heart failure. AIDS was fatal in nearly all patients two decades ago; now this disease has become a chronic illness in most patients due to the use of highly active antiretroviral therapy. Improved pharmacotherapy of benign prostatic hyperplasia has reduced the need for prostatectomies, disease modifying drugs have improved the course of rheumatoid arthritis, and aromatase inhibitors and herceptin have advanced the treatment of breast cancer.

Despite all the progress in pharmacotherapy, we face many challenges. The evidence presented in the 1999 Institute of Medicine (IOM) report demonstrated that thousands of patients receiving medications in our country were being harmed due to errors.[1] However, a much bigger problem is when adverse events occur despite the use of drugs

under FDA approved indications. Within the past year, rofecoxib (Vioxx) and valdecoxib (Bextra) were withdrawn from the market due to safety concerns; we also learned that antidepressants may be associated with suicidal ideation, that pseudoephedrine may be used to produce a drug of abuse, and that phenylpropanolamine may cause hypertension and hemorrhagic stroke.

The 2001 IOM report found that the nation's health-care system was fragmented and uncoordinated, and far too many were not receiving optimal pharmacotherapy: antibiotics were overused and vaccines under utilized, and many patients with mental illnesses received suboptimal therapies.[2] Three years later, the Rand Corporation reported that recommended care was being provided to only 39% of pneumonia patients, 45% of diabetes patients, 53% of asthma patients, 54% of patients with colorectal cancer, 63% of patients with congestive heart failure, and 65% of patients with hypertension.[3]

The 2005 State of Health Care Quality report from the National Committee for Quality Assurance (NCQA) showed areas where improvements in the treatment of chronic diseases are still needed. The data from Medicare, Medicaid and certain commercial health plans showed that the appropriate care was provided to only 19% of women treated for osteoporosis after fracture, 32% of patients treated for alcohol and other drug dependence treatment, 52% of patients managing their cholesterol after a heart attack, 60% of diabetics trying to control their hemoglobin A1c, 64% of patients trying to control their high blood pressure, and 69% of patients who used medications for asthma; it was good to know that 90% of patients received a beta-blocker after a heart attack .[4] The aggregate data suggest that health care including pharmacotherapy is still in need of marked improvement. I believe that the problems with the quality in health care may not be so much related to a lack of knowledge but rather in its application to get the right results. We have done a commendable job discovering new treatments and establishing evidence for best practices in using these treatments. However, we have done less well in translating this knowledge into practice modalities that actually help patients. The next challenge for us is to bring creativity to find ways to improve the delivery of health care

and close the gaps between what we know should be done and what actually happens in practice.

The current state of health care in the US provides unparalleled opportunities for pharmacists to make important contributions to patient care through practice, patient education, and scholarship. Let us examine how we are doing in hospital pharmacy at the national level. An ASHP survey has shown between 83 and 90% of hospitals provide pharmacist consultations for drug information, dosage adjustments, pharmacokinetics, and antibiotics but only 38 to 51% provide consultations for nutrition support, patient education, pain management, and anticoagulation, and only meager 14% provide consultations for medication history and compliance. Between 71 and 98% of hospitals are engaged in medication use evaluation activities track and assess the trend of adverse drug events, evaluate retrospective drug use, identify high-risk therapies, routinely review culture and sensitivity reports, and track and assess the trend of pharmacist interventions, and evaluate compliance with clinical practice guidelines, but only 20% evaluate tracking and monitoring their patients' quality of life, and 35% track and assess the trend of treatment failures.[5] These percentages may be on the right track compared to previous data, but are far from ideal in many areas.

Effective use of technologies can increase efficiency and quality of care, and allow pharmacists more time to perform patient care activities. The technology and computerized prescription order-entry systems may also decrease medication errors. A 2005 ASHP survey, however, showed that only 9.4% of hospitals used bar code technology, 21% used electronic medical records, 32% used smart infusion pumps, and 72% used automated dispensing cabinets.[6] There is some urgency to make improved use of technology. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has implemented two important standards to improve patient care: a 24/7 prospective review of prescription orders and medication reconciliation by pharmacists can improve patient safety and therapeutic outcomes. Given the limited resources and shortage of pharmacists, successful implementation of this standard may require remote prescription order entry, contracting for after-hours review, and collaborating with other

institutions for cross-coverage. Medication reconciliation is defined as "the process of comparing what the patient is taking at the time of admission or entry to a new setting with what the organization is providing to avoid errors of transcription, omission, duplication of therapy, drug-drug and drug-disease interactions."[7] In one study, medication reconciliation decreased medication errors by 70% and adverse events by 25%.[8] Another study published last week showed that medication reconciliation and counseling by pharmacist decreased preventable adverse drug events.[9] Starting January 2006, all accredited organizations including ambulatory care, hospitals, home care, long-term care and managed care are expected to fully comply with this standard, including collecting medication lists for all new and returning patients taking prescription and nonprescription drugs, reconciling these lists with new medication orders, and communicating the complete lists at all interfaces.

One concern is lack of pharmacist's presence in the emergency departments; only 3.5% of emergency departments had fulltime pharmacists. Since emergency departments are the points of entry into the health system for many patients, it is critical to correctly reconcile medications. We have all seen patients giving medication history with three white pills, one purple pill and one yellow pill. There is a potential for missing or duplicating medications or identifying history of allergy unless we correctly reconcile medications at all points of entry. Although it is a challenge, this activity provides a great opportunity for pharmacists to make a positive impact on health care.

Considering the current status of our health care, we should not be surprised that Americans are not entirely satisfied with their health care despite the fact that we spend more on health care than any other country in the world. The costs to both payors and patients are rising at a staggering pace. People want to know more and take control of their health care—they deserve better care than we are able to currently deliver. The gap between the excellent care provided to some and the average care received by the majority is too large. We must close this gap by enhancing patient care services in all practice settings. Academic pharmacy led the development of clinical pharmacy in

hospitals decades ago; now it's time for the profession to foster innovations and make a commitment to provide patient care in ambulatory and community settings.

There is an immediate need to improve medication use and health outcomes among patients suffering from both acute and chronic diseases. The existing data clearly suggest that despite the availability of effective medications, expected health outcomes are not achieved in an unacceptably large number of patients. Numerous studies have shown patients do not take their medications as prescribed and drugs do not work unless they are taken as intended. Frequent problems include the wrong number of doses, wrong administration times, and the premature discontinuation of medications. This is a serious concern in elderly patients who routinely take 10 or more drugs daily; one of our faculty who provides medication therapy management services to the elderly in their homes found that the average age of these patients was 72 and the average number of medications used daily by these patients was 12. The most common reasons for misusing medications is poor understanding of instructions by patients and patients making wrong decisions; these problems can be avoided by pharmacists helping patients make the best use of their medications. Active participation of pharmacists in patient care can increase medication adherence, assuring effectiveness and safety and achieving desired health outcomes. Patient report, pill count, refill record, and electronic monitoring systems can be used to document adherence, but there are limitations associated with the use of any single approach. A multidimensional approach is needed to improve medication adherence, including simplification of dosage regimens, adherence aids, patient education, patient-, disease-, and therapy-related factors, and monitoring of treatment outcomes.[10] Pharmacists are in the best position to make a difference with the outcomes of drug therapy.

The Asheville project supported by the City of Asheville, NC in the community pharmacy setting led to improved health outcomes and decreased costs related to diabetes among its employees. Patients were given free medications in return for an appointment with a pharmacist each month to assure adherence and monitor therapy. These positive results led to the funding of further research on medication therapy management by

American Pharmacists Association Foundation across the country. Last week, our local newspaper, The Columbus Dispatch, had an Editorial "Take Your Medicine" emphasizing the importance of adherence. On March 18, 2006, Detroit Free Press had an article about the Plans of Blue Cross to cut copays for brand medications from $40 to $10 (current copay for generics) for patients with asthma. The expectation is that this action will increase adherence and thus reduce overall health care costs from decreased emergency department or clinic visit or hospitalizations among patients currently not taking their medicines due to high cost.

The need for patient care in all settings is obvious. However, this also evokes a general response from many: There is a lack of time, payment, interest, training and support for providing patient centered care. However, there are a number of examples of excellence in practice in various community, ambulatory and institutional settings, demonstrating we can do better.[11] Our two ambulatory care clinics (Clinical Partners and University Health Connection) at Ohio State have achieved far better results with medication therapy than the national data for treating chronic diseases including hypertension, high cholesterol, and diabetes. The Clinical Partners program received the Best Practice Award in 2004 and the UHC program was recognized with the Best Practice Award in 2005 both from the American Society of Health-System Pharmacists (ASHP). These programs were selected based on well-documented provision of exemplary health-care services and education to pharmacy students and residents. The data from our faculty's clinical practices have demonstrated much better health outcomes in patients compared with either baseline or national data. In patients with diabetes, marked reductions in HbA1c, cholesterol, and blood pressure occurred; a larger number of patients received influenza vaccine and had renal, eye, and foot exams. In an anticoagulation clinic, the numbers of complications and hospitalizations were reduced among patients managed by our pharmacy faculty. [12]

The Kaiser Permanente (Colorado region) Pharmacy Department offers comprehensive and innovative pharmacy services. Pharmacy operations and support services include medical office pharmacies, emergency care center pharmacy, long-term care pharmacy,

home IV pharmacy, and oncology pharmacies. Clinical pharmacy services include primary care services, centralized services (such as cardiac risk service), specialty services (such as infectious diseases), disease statement management (asthma, for example), drug information, and research. These pharmacists utilize technology for operations and support services such as Pharmacy Automated Refill Center and ScriptPro in their medical office pharmacies to increase the time they can devote to patient care services. Information technology supports patient care activities of pharmacists. Reengineered pharmacy distribution and work flow have also added efficiency. Electronic medical records are available for all patients. These clinical pharmacy services have led to improved health outcomes and patient satisfaction.[13]

An important question is: how do we transition from some pockets of excellence today to a day when all patients requiring medication therapy management routinely get it in all practice settings? Improving medication-related health outcomes and quality of life for all patients in various settings will require bold leadership and actions. The need for leadership in practice, education, and scholarship is greater than ever before. We need to attract and educate the best students as well as train the existing pharmacists about patient-focused care. Tomorrow's pharmacists should be able to understand and implement evidence-based therapies to attain maximum effectiveness and safety at minimum cost while considering patient's needs, preferences and values; work effectively independently as well as in interdisciplinary teams; incorporate technology and informatics in their practice; and achieve and document improved medication-related health outcomes and quality of life in patients.

Our practitioners need to take a leadership role in reshaping the core function of pharmacists—the provision of optimal pharmacotherapy to improve health outcomes and quality of life. This leadership will require articulating a clear vision which is shared, realistic, and achievable. They will need to understand the environment and the people at all levels. They must lead by example and surround themselves with people who can challenge the status quo. They will need to be enthusiastic, curious, persistent, flexible, team players, humble, compassionate, optimistic, caring and supportive, and be able to

share their influence with others. They must lead, not for their benefit, but because the organizations and people need their leadership. Such leaders are needed at each level in various practices (e.g., the staff leaders, the student leaders, the technician leaders, the pharmacist leaders, and the manager leaders).

There are many opportunities to enhance various practice environments including community, medical centers, long-term care, clinics, managed care, industry, pharmacy benefit management, government, community health centers, home care and private practice. Meeting the professional mission will require personal commitment, redesigned workflow, the use of technology and supportive personnel, easy access to patient data, collaboration and coordination of efforts and documentation of interventions and outcomes, while assuring appropriate payment for professional services. These efforts are critical to reduce prescription misuse and medication-related adverse events. We have learned that the FDA drug approval process and postmarketing voluntary reporting of adverse events are far from perfect. Postmarketing surveillance can be best done by pharmacists under realistic conditions of medication use for both approved indications and off-label use. Proper management of chronic conditions like diabetes, asthma, hypertension, coronary artery disease, and osteoporosis can substantially reduce their serious consequences. Improvement in medication ordering, administration, and monitoring can reduce adverse events. Appropriate use of medications can markedly decrease overall total cost of health care. We need to not only focus on disease control and cure but also on the social and quality–of-life aspects of medication use. Under this scenario, patients would share their values and beliefs in both traditional and alternative/complementary therapies and take responsibility for their care. We need to engage in community outreach activities to improve medication-related health outcomes.

Medication Therapy Management services supported by the Centers for Medicare and Medicaid Services (CMS) offer a great opportunity for pharmacists to demonstrate their essential role while receiving payment for patient care. Although there are questions about the definition of MTM which should be readily understood by CMS, payors and patients, how MTM should be delivered and what payment will be received by

pharmacists, it is a step in the right direction. For the first time, pharmacists are now health care providers approved by CMS. It is an example of leadership by pharmacy practitioners and associations. This will require assisting patients with the selection of the most desirable health plan among dozens while considering their formularies, payment structure, and coverage of clinical services. As we provide MTM, we need to consider data from the American Medical Association Foundation survey on health care literacy. Nearly one-half of Americans have low literacy and 20% are functionally illiterate. Elderly often lack knowledge about their therapies with multiple drugs and also take complementary medicines without knowledge of their effects and safety. We need to involve, educate, reassure, and confirm their understanding of expected and unexpected outcomes of drug therapy. We must understand the concerns and priorities of both patients and payors and assess the quality, efficiency, safety, and cost of pharmacy services being provided. It is a better value to pay $100 for a pharmacist consultation than to pay out thousands of dollars to take care of prolonged illness and its complications due to inadequate therapy or an adverse event associated with the medication. I am pleased to see that the new ACPE accreditation standards for PharmD program (released February 17, 2006 and effective July 1, 2007) focus on the need for education in MTM and patient safety.

Pharmacy should be an integral component of an advanced health-care system to achieve excellence in patient care. The institutions incorporating pharmacists should reap bigger rewards from the "Pay for Performance" initiative of the CMS and several insurance companies. CMS will offer bonuses ($1.2 billion over 3 years) to hospitals using established clinical practice guidelines to improve 34 quality-of-care measures to treat various diseases including pneumonia, heart attack, and congestive heart failure. Of course, the next question is: did adherence to clinical practice guidelines lead to improved health outcomes and quality of life? Wellness and preventive care should also be emphasized and rewarded with appropriate payments to reduce total health care costs.

In closing, we have many challenges and opportunities to improve medication-related health outcomes and the quality of life of our patients. It is also the time when the

society and payors are concerned about the quality and cost of health care. Fortunately, we are in an excellent position to enhance the quality of cost-effective health care through our well-prepared pharmacists, our quest for continued learning and creating new knowledge, and our ability to lead the profession. These goals are consistent with the values of the Rho Chi Society which "seeks universal recognition of its members as lifelong intellectual leaders in pharmacy, and as a community of scholars, to instill the desire to pursue intellectual excellence and critical inquiry to advance the profession." I am looking forward to the day when every patient's pharmacotherapy needs will be met by pharmacists. Thank you so much for this recognition.

References

1. Institute of Medicine. To Err is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS (eds) Washington, DC: National Academy Press, 1999.

2. Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, DC: National Academy Press, 2001.

3. Rand Corporation Report, Wall Street Journal. September 17, 2004.

4. The State of Health Care Quality. Industry Trends and Analysis. National Committee for Quality Assurance. Washington, DC, 2005: 1-74.

5. Pedersen C, Schneider P, Scheckelhoff D. ASHP National Survey of Pharmacy Practice in Hospital Settings: Prescribing and Transcribing—2004. American Journal of Health-System Pharmacy 62:378-390, 2005.

6. Pedersen C., Schneider P, Scheckelhoff D. ASHP National Survey of Pharmacy Practice in Hospital Settings: Dispensing and Administration—2005. American Journal of Health-System Pharmacy 63:327-45, 2006.

7. Joint Commission on Accreditation of Healthcare Organizations 2006 National Patient Safety Goals FAQs URL: http://www.jointcommission.org/NR/rdonlyres/4CF20AC5-B125-4B22-9D0C-9C39B0EBD57B/0/06_npsg_faq8.pdf. Accessed by: March 9, 2006.

8. Whittington J, Cohen H. OSF Healthcare's journey in patient safety. Quality Management in Health Care 13:53-59, 2004.

9. Schnipper JL, Kirwin JL, Cotugno MC, Wahlstrom SA, Brown BA, Tarvin E, Kachalia A, Horng M, Roy CL, McKean SC, Bates DW. Role of pharmacist counseling in preventing adverse drug events after hospitalization. Archives of Internal Medicine 166:565-71, 2006.

10. Balkrishnan R. The Importance of Medication Adherence in Improving Chronic-Disease Related Outcomes What We Know and What We Need to Further Know. (Editorial) Medical Care 43:517-20, 2005.

11. Cohen J, Nahata MC, Roche VF, Smith RE, Wells BG, Helling D, Maine LL. Pharmaceutical Care in the 21st Century: From Pockets of Excellence to Standard of Care: Report of the 2003-04 Argus Commission. American Journal of Pharmaceutical Education 68(3) S9: 1-9, 2004.

12. Mehta B, Rodis J, Nahata M, Bennett M. Advancing patient care through innovative practice: The Clinical Partners Program. American Journal Health-System Pharmacy 62:2501-2507, 2005.

13. Helling D, Nelson K, Ramirez J, Humphries T. Kaiser Permanente Colorado Region Pharmacy Department: Innovative Leader in Pharmacy Practice. Journal of American Pharmacists Association 46:67-76, 2006.