

Serving vulnerable populations

Am J Health-Syst Pharm.
2023;80:1535-1541

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<https://doi.org/10.1093/ajhp/zxad160>

Editor's note: The following was adapted from Dr. Nahata's remarks in acceptance of the 2023 Harvey A.K. Whitney Lecture Award at the ASHP Summer Meetings & Exhibition, held in June in Baltimore, MD.

This is indeed a tremendous honor to receive a recognition carrying the name of a courageous and transformational leader in health-system pharmacy, Harvey A.K. Whitney. His vision and lasting impact on health-system pharmacy have been unmatched. Although I never met Mr. Whitney, I feel fortunate to have had the opportunity to work with and learn from his son, Harvey A.K. Whitney Jr.

I have been influenced and inspired by the exceptional contributions of the past winners of this award, including many here tonight, and feel grateful to them for considering me worthy of this distinction. I want to express my heartfelt appreciation to John Murphy for leading my nomination along with Henry Mann, Robert Parsons, and Matthew Sapko, and to John Armitstead, Jannet Carmichael, Fred Eckel, John Gans, Henri Manasse, and William Zellmer for supporting it.

Humble beginnings. When [ASHP Chief Executive Officer] Paul

Abramowitz called to inform me about my selection for this honor, I was at a loss for words and felt a deep sense of gratitude. I could not have imagined how my life would unfold from humble beginnings. I faced vulnerabilities of limited education and resources in the family and a difficult childhood. My father had schooling up to the sixth grade, and mother never attended a school. Three of my 4 grandparents had passed before the age of 55 years, and financial hardship affected our access to basic necessities from running water to healthcare. My family emphasized education with the hope that it might change our lives, so that became my critical goal. Living through adversities and graduating from college in India were my early lessons on hope, perseverance, and gratitude—thanks to my parents and grandparents.

Coming to the United States for an MS degree in pharmaceuticals at Duquesne University was a life-changing opportunity wrapped with numerous challenges. Since I had received most of my education in Hindi, later adapting to English, a different education system and new culture seemed insurmountable at times. Performing well in the MS program gave me the confidence that I could explore an opportunity in industry. I had never considered an academic career until I discovered my love for teaching while being a teaching assistant in the lab. A chance meeting with a PharmD student raised my curiosity about the role of a pharmacist in patient care, which I had never heard of or encountered in India. The next day I was at Mercy Hospital and saw the value of PharmD students taking medication histories and counseling patients about medication use and clinical faculty offering consultations to physicians about drug therapies. I had found my purpose and passion to pursue a postbaccalaureate PharmD instead of a pharmaceuticals PhD degree. Thanks to Sister Gonzales Duffy—a past Whitney

Award recipient who would go on to be the first woman president of ASHP—and Thomas Mattei for allowing me to enroll into the postbaccalaureate PharmD program after all 5 positions had been filled. Completing both the MS and PharmD programs at Duquesne and a residency at Buffalo General Hospital directed by Donald McLeod reaffirmed my enthusiasm for health-system pharmacy practice, teaching, and clinical research to improve the outcomes of medication use among patients. I was so energized to have a direct and immediate impact on people's lives. It was exciting to start an academic career at The Ohio State University and gain experiences in developing and teaching pharmacotherapy courses, establishing a clinical practice site, and implementing a patient-centered research program. I had seen many gaps in serving vulnerable pediatric and elderly populations in India and the US, so it became apparent that a dedication to practice, education, and research was essential to close those gaps.

Vulnerabilities of pediatric and older adult patients

It has been a privilege for me to serve the healthcare needs of both pediatric and older adult patients during my 46-year career. These two age groups of patients share some vulnerabilities. As an example, dosage requirements for effective and safe drug therapy in these groups can often differ from those for adults 18 to 64 years of age, and yet they are generally excluded from studies for most drug approvals unless the conditions are prevalent in these cohorts (eg, otitis media in children, Alzheimer's disease in older adults). The very young and very old can also be dependent on a caregiver, which brings additional challenges of communication and care coordination. Further, patients within the pediatric and adult age groups can be markedly different in terms of optimal dosage requirements (eg, differences

Milap C. Nahata, PharmD, MS, FASHP, FCCP, FAPhA, FPPA, is professor emeritus of pharmacy, pediatrics, and internal medicine at The Ohio State University (OSU) colleges of pharmacy and medicine. His clinical practice and patient-focused research have fundamentally shaped the field of pediatric pharmacy, encompassing all aspects of providing comprehensive medication management for children.

Nahata has published over 650 peer-reviewed articles and book chapters. Notably, his studies with azithromycin were pivotal in its approval by the Food and Drug Administration (FDA) for use in children. He is an author and coeditor of 5 books, including *Pediatric Drug Formulations*, one of the most widely used resources in health-system practice, and *Pediatric Pharmacotherapy* and *Pediatric Pharmacotherapy Self-Assessment*. He also contributed to 2 reports of the Institute of Medicine: *Emergency Care for Children: Growing Pains* and *Safe and Effective Medicines for Children*. He has presented over 400 invited lectures in the United States and abroad. He is the editor-in-chief of the *Annals of Pharmacotherapy*.

He has received many honors for his research and practice, including the ASHP Foundation Literature Award for Sustained Contributions, the ASHP Best Practices Award, the American College of Clinical Pharmacy (ACCP) Russell Miller Award for Sustained and Outstanding Contributions, and the American Pharmacists Association (APhA) and American Association of Pharmaceutical Scientists Research Achievement Award in Clinical Sciences. He is also a recipient of the American Association of Colleges of Pharmacy (AACCP) Lifetime Achievement and Robert Chalmers Distinguished Educator awards, the ACCP Paul Parker Medal and Education Award, the Pediatric Pharmacy Association (PPA) Sumner Yaffe Lifetime Achievement and Richard Helms Excellence in Pediatric Pharmacy Practice awards, the APhA Gloria Francke Leadership Mentor Award, the Ohio Pharmacists Association (OPA) James Beal Award, and the Ohio Society of Health-System Pharmacists (OSHP) Walter Frazier Award. He has been recognized for significant impact on pharmacy education with the Alumni Award for Distinguished Teaching conferred by OSU and with 8 Teacher of the Year awards from the OSU College of Pharmacy.

In addition to his research and clinical practice, Nahata also has a long record of service in pharmacy associations. He is a past president of ACCP and AACCP and has served on committees of ASHP, ACCP, APhA, PPA, FDA, NIH, USP, and FIP. He is among a select group of elected pharmacist members in the National Academy of Medicine and is a Fellow of ASHP, ACCP, APhA, PPA, and several other organizations.

Nahata is also the founding director of the Institute of Therapeutic Innovations and Outcomes (ITIO) at OSU. The ITIO provides medication therapy management services via telephone to more than 100,000 patients annually. The services are provided by pharmacists, pharmacy technicians, and students/trainees.

He received a BS degree in chemistry, physics, and math from the University of Jodhpur, a BS degree in pharmacy from the University of Bombay (Mumbai), and an MS degree in pharmaceuticals and a PharmD from Duquesne University School of Pharmacy. He completed a residency at Buffalo General Hospital.



between an infant, child, and adolescent in the pediatric group and between 70-, 80-, and 90-year-olds in the older group). Given a lack of data for

many drugs about the specific dose requirements in children and the elderly, it was clear to me that the needs of these vulnerable populations could be best

met by developing an integrated program grounded in both clinical practice and research. My goal here is to briefly describe some of the healthcare trends affecting pediatric and elderly patients, my experiences in serving their therapeutic needs, and the opportunities to enhance medication use in these 2 vulnerable populations—a call to action for the profession.

Trends in children's health.

The Children's Defense Fund tells us that "A society must be judged by how it treats its most vulnerable—and most valuable—members: its children."¹ The organization's 2020 *State of America's Children* report concluded that we are "falling shamelessly short" by many measures, including poverty, income inequality, food and nutrition insecurity, lack of proficiency in reading and math, and the number of children without health coverage.¹ A compilation of data for the 2018-2020 period revealed some important concerns. The prevalence of obesity, attention deficit/hyperactivity disorder, and major depressive episodes and other mental health diagnoses, as well as teen firearm and homicide death rates and the percentage of children with disability, had gone up.² A recent publication reported an increase in all-cause mortality among US children and adolescents, primarily from injuries due to causes including drug misuse, self-harm, and violence, offsetting gains made by effective treatment of lethal conditions such as premature births, cancers, and congenital disorders.³ The authors stated, "A nation that begins losing its most cherished population—its children—faces a crisis like no other."³ An estimated 109,000 people in the United States, including those in the pediatric age group, died from drug overdose in 2022.⁴ The current scenario is simply unacceptable and requires immediate actions by all stakeholders, including healthcare professionals, educators, payors, policy makers, insurance providers, and community leaders, to ensure the health and well-being of our children.

Serving therapeutic needs of pediatric patients. Being the first clinical pharmacist in the late 1970s at the Nationwide Children's Hospital in Columbus, OH, made it challenging for me to begin my work at the hospital. The PharmD degree was an unknown credential to physicians, nurses, and the administration at the hospital. It was also not a desirable degree with which to become a principal investigator on research projects with approval of the institutional review board and to obtain external funding. Obviously, the value of a pharmacist's contributions needed to be demonstrated to establish credibility with the healthcare team and administration. (It is heartening to say that there are now 50 pediatric clinical pharmacists for inpatient care and 10 for outpatient care with full funding from the hospital.)

Many drugs approved by the US Food and Drug Administration (FDA) for adults lacked labeling with specific dosage guidelines for use in pediatric patients. Thus, many medications were used off-label in these patients. We found approximately one-fourth of the medication orders in an emergency department were for off-label use,⁵ and 80% of patients with sleep difficulties received a prescription medication although none of those medicines had received FDA approval for use in pediatric patients.⁶ Our call to action was clear: develop evidence for effective and safe therapies in children. An epidemic of Reye's syndrome occurred soon after I started my practice. Glycerol was being used to lower the intracranial pressure, but its effective and safe dosage were unknown. Our collaboration was successful in identifying appropriate dosage regimens.⁷ We were able to determine safe and effective dosage regimens for several classes of medications, including antimicrobial,⁸⁻¹⁸ anticonvulsant,¹⁹ antihyperglycemic,²⁰ antihypertensive,²¹ and analgesic/anti-inflammatory²²⁻²⁴ agents, and optimal ways to administer intravenous medications in children.^{25,26}

Drugs not approved for children were often unavailable in suitable

Harvey A. K. Whitney Lecture Award

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Harvey A. K. Whitney (1894–1957) received his Ph.C. degree from the University of Michigan College of Pharmacy in 1923. He was appointed to the pharmacy staff of University Hospital in Ann Arbor in 1925 and was named Chief Pharmacist there in 1927. He served in that position for almost 20 years. He is credited with establishing the first hospital pharmacy internship program—now known as a residency program—at the University of Michigan in 1927. Harvey A. K. Whitney was an editor, author, educator, practitioner, and hospital pharmacy leader. He was instrumental in developing a small group of hospital pharmacists into a subsection of the American Pharmaceutical Association and finally, in 1942, into the American Society of Hospital Pharmacists. He was the first ASHP President and cofounder, in 1943, of the *Bulletin of the ASHP*, which in 1958 became the *American Journal of Hospital Pharmacy* (now the *American Journal of Health-System Pharmacy*). The Harvey A. K. Whitney Lecture Award was established in 1950 by the Michigan Society of Hospital Pharmacists (now the Southeastern Michigan Society of Health-System Pharmacists). Responsibility for administration of the award was accepted by ASHP in 1963; since that time, the award has been presented annually to honor outstanding contributions to the practice of hospital (now health-system) pharmacy. The Harvey A. K. Whitney Lecture Award is known as “health-system pharmacy’s highest honor.”

dosage forms for use in this population. As an example, many intravenous medications intended for adults were too concentrated to measure small doses accurately. In these cases, the IV products needed to be diluted up to 10-fold, which required proof of the stability and sterility of the modified dosage forms for safe and effective use in infants and young children. Similarly, many drugs not approved for children were available only in tablet or capsule form for oral use. Infants and young children could not swallow solid dosage forms and required liquid formulations for ease of administration and body weight-based doses rather than the fixed doses routinely used in older children and adults. Thus, we documented stability and dose uniformity for over 70 drugs compounded in liquid formulations for these patients.²⁷

Opioid use disorder continues to affect too many adolescents and young adults in our society. Our office-based medication-assisted treatment program markedly decreased acute opioid-related events and led to an over 50% reduction in emergency visits among these patients.²⁸ Longer retention in medication-assisted treatment decreased healthcare utilization; however, retention in the program was shorter among patients with a diagnosis of anxiety, depression, nicotine use disorder, stimulant or cocaine use disorder, and poor insurance coverage, as well as among those of minority race.^{29,30}

Even with implementation of technology, disparities in care provided to children persisted. Medication prescribing was being done electronically with systems such as an Epic electronic medical record and with the aid of decision support systems.³¹ We found 86% of dosing alerts to be inappropriate, which could have led to alert fatigue whereby important alerts could have been overridden without intent, potentially leading to adverse outcomes. This led to incorporation of dosage ranges customized at our institution to enhance the sensitivity of rules for the detection of dosing errors and to reduce unnecessary alerts.

Trends in the health of older adults. The federal Healthy People 2030 initiative has estimated that older adults will account for almost one-quarter of the population in the US by 2060.³² Chronic conditions such as hypertension, diabetes, osteoporosis, dementia and Alzheimer's disease, and fall-related injuries occur frequently in this population. Approximately two-thirds of older adults take 5 or more prescription or over-the-counter medications. Optimal use of medications can improve health outcomes and quality of life for many chronic conditions, and inappropriate use can lead to a variety of adverse outcomes. Older adults in the community setting are largely responsible for managing their own medications, and yet their growing medication lists are not routinely scrutinized for appropriateness, emphasizing the need for patients to be actively involved with decisions about their medication use.³³ Anticoagulant, antidiabetic, antihypertensive, anticholinergic, opioid, sedative, hypnotic, and antipsychotic drugs have been associated with adverse effects in this population. Over 750 older adults may be hospitalized daily in the US due to serious adverse effects of medications.³⁴ Although the US spends more money on healthcare than any other high-income country, our population continues to experience poorer health and have shorter lives.³⁵ There is an immediate call for action to pharmacists to optimize use of medications and vaccines to improve the health and well-being of older adults.

Serving therapeutic needs of older adults. Having observed numerous gaps in the prescribing and use of medications in the US and the early preventable deaths of my grandparents from uncontrolled hypertension, diabetes, and asthma in India, I was compelled to lead the development of a telephonic medication management program that offered comprehensive medication reviews or targeted medication reviews for community-based older adults in 2013. The goals of our program have been to ensure that

medication regimens are evidence based for cost-effectiveness and that barriers to adherence and appropriate use are minimized. Records of all medications being prescribed to our patients are provided by the insurance companies or health plans. Our teams of pharmacists, pharmacy technicians, and students speak with patients to reconcile medications, address questions and concerns about their health and well-being, ensure appropriateness of medication regimens and supplements relative to the most recent treatment guidelines, and communicate recommendations to the prescribers.

Patients frequently served by us across the US are typically 70 to 80 years old, with 4 to 9 chronic conditions, using 10 to 15 medications prescribed by 3 to 5 prescribers, and receiving those medications from 2 to 4 pharmacies. One can only imagine the potential for significant medication-related problems. Poor control of blood pressure and glucose levels, medication nonadherence, and use of medications for anxiety and sleep have been frequently encountered among patients served by this program.

The research mission of our medication management services has been to directly improve patient care, and our findings have emphasized the need for expansion of our services. For example, we found over 50% of 13,250 older adults with evidence of heart failure had been prescribed at least 1 medication associated with worsening of heart failure. Polypharmacy, the numbers of prescribers and pharmacies, and poverty level were associated with increased odds of receiving a potentially inappropriate prescribed medication (PIPM).³⁶

A study of nearly 18,000 older adults with dementia served by our program and collaborating medication therapy management centers found nearly 8,000 patients who were on a medication that could worsen dementia and needed to be discontinued. PIPM prescribing increased with poverty level and the numbers of medications, prescribers, and

pharmacies used by patients.³⁷ Among 3,624 patients with chronic kidney disease (CKD), over one-third were prescribed at least 1 medication that was supratherapeutically dosed or contraindicated based on renal function. The presence of CKD at stage 4 or 5 increased the odds of having an inappropriate medication by 7 to 14 times when compared to the odds among patients with stage 3 CKD.³⁸

In a cohort of 3,500 older adult patients receiving chronic opioid therapy, approximately 25% were prescribed daily opioid therapy at 50 morphine milligram equivalents or higher. These patients were also more likely to be prescribed antidepressants and hypnotics, which could increase adverse effects in this cohort of patients. Importantly, only 9% of patients were prescribed naloxone to reverse a potential overdose of an opioid. The prescriptions were most often written by primary care physicians.³⁹

Finally, social determinants of health can influence medication adherence and access to and quality of healthcare, and these factors are amplified in minority populations of all ages. We found that the most prevalent social needs of Medicare/Medicaid dually enrolled patients nonadherent to medications were not having money to pay bills, lacking support to perform daily activities, lacking companionship, feeling isolated and left out, running out of food, and transportation barriers.⁴⁰

A call to action. Examples of our work in pediatric and geriatric pharmacy summarized above illustrate the importance of implementing an integrated program with the capabilities to offer clinical services, with the support of conducting research, to serve the medication therapy needs of these vulnerable patient populations. This has been my call to action, as it has been for many others. Although we have made substantial progress with advances in practice, research, and federal regulations for drug approval, it is time to lead and do far more to ensure the best use of medications by our patients. I would

like to end with a few additional calls to action for the profession:

1. All patients with acute and chronic conditions should be monitored in real time to ensure optimal use of medications. Treatment of chronic conditions should require reassessment with each change in medication regimen or the patient's response to therapies through comprehensive or targeted medication reviews supported by accurate and precise decision support systems. Data including patients' diagnoses, medications, and laboratory and clinical findings, as well as social determinants of health, and an assurance of understanding of medication benefits and risks by patients and caregivers would be needed to ensure optimal medication use.
2. Reliable medication risk scoring systems and predictive software should be developed and applied for patients on multiple medications to determine which patients need special attention to promptly identify and prevent adverse effects and maximize safety.⁴¹
3. Value-based care models should be expanded, with pharmacists playing an important role in optimizing medication use. Over 500 accountable care organizations (ACOs) have been serving over 10 million Medicare- and Medicaid-enrolled patients and were rewarded for meeting or exceeding the quality targets.³³ Our hospital has had the largest Medicaid ACO for children—Partners for Kids—with pharmacists actively involved in patient care.⁴²
4. Drug shortages continue to compromise medication access and use. It is surprising that a drug like amoxicillin has been unavailable in some areas for use in children. Thus, essential and commonly used medications need to be manufactured in the US, and supply chains should be diversified and reliable. To ensure access to effective, safe, and equitable healthcare, we need to oppose rising drug costs and oppose interference by judges and legislators in framing health policies.

5. ASHP national surveys should include specific questions about pharmacy practice and transitions of care programs (eg, transitions within a health system or from hospital to home or extended care facilities, transitions from adolescent to adult care and from younger to older adult care) being provided to pediatric and older adult patients in various health systems, and the data should be shared for benchmarking and continuous quality improvement. The ASHP Foundation should prioritize funding of impactful research on the efficacy and safety of medications in the most vulnerable populations.

Expression of gratitude.

Based on where I came from, with all the challenges and vulnerabilities, my only goal was to seek education and a position that would support my family. The recognition I have received tonight was beyond imaginable and speaks more to the qualities of my personal and professional families than to my own. I am most grateful to my family: my grandparents and parents, for showing me how to lead life while facing adversities; my wife Suchitra, for her love and support during our journey of 45 years; and our daughter Leena, son-in-law Amit, grandson Saavan, and granddaughter Ishani, who have brought so much joy to my life. In addition to those I mentioned earlier, I would like to express my appreciation to Paul Abramowitz, Roger Anderson, Daniel Cobaugh, Harold Godwin, Dennis Helling, Robert Kuhn, Clifton Latiolais, Lucinda Maine, William Miller, Max Ray, and William Smith; deans John Cassidy, Robert Brueggemeier, and Henry Mann; chairs Richard Reuning and Bella Mehta; colleagues Marialice Bennett, Chet Kaczor, Jennifer Rodis, Jerry Siegel, and Robert Weber; staff members Joni Warren and Ashley Knackstedt; and the students, residents, fellows, other colleagues, and collaborators at OSU and Nationwide Children's Hospital, for their inspiration and confidence in me.

In closing, an Italian immigrant who came to the US over 2 centuries ago said, “Well, I came to America because I heard that the streets were paved with gold. When I got here, I found out three things—first, the streets weren’t paved with gold; second, they weren’t paved at all; and third, I was expected to pave them.” Well, I came to America nearly 50 years ago because I had correctly heard that it was a place with possibilities and opportunities for one to succeed with hard work, dedication, and perseverance. What I did not know was that there would be so many generous and kind people to lift me up when I needed them. I am grateful for your encouragement, support, friendship and affection, and for this incredible honor!

Disclosures

Dr. Nahata has declared no potential conflicts of interest.

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