

SPECIAL ARTICLES

Evolution of Self-Care Education

Nonprescriptions Medicine Academy Steering Committee,* Emily M. Ambizas, PharmD,^b Karen M.S. Bastianelli, PharmD,^c Stefanie P. Ferreri, PharmD,^d Seena L. Haines, PharmD,^e Katherine Kelly Orr, PharmD,^a Misty M. Stutz, PharmD,^f Jenny A. VanAmburgh, PharmD,^g and Miranda Wilhelm, PharmD^h

^aCollege of Pharmacy, The University of Rhode Island, Kingston, Rhode Island

^bCollege of Pharmacy and Health Sciences, St. John's University, Queens, New York

^cCollege of Pharmacy, University of Minnesota, Duluth, Minnesota

^dEshelman School of Pharmacy, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina

^eGregory School of Pharmacy, Palm Beach Atlantic University, West Palm Beach, Florida

^fCollege of Pharmacy, Sullivan University, Louisville, Kentucky

^gBouvé College of Health Sciences, School of Pharmacy Northeastern University, Boston, Massachusetts

^hSchool of Pharmacy, Southern Illinois University Edwardsville, Edwardsville, Illinois

Submitted June 7, 2013; accepted August 22, 2013; published March 12, 2014.

During the past 15 years, the curriculum content for nonprescription medication and self-care therapeutics has expanded significantly. Self-care courses ranging from stand-alone, required courses to therapeutic content and skills laboratories, have evolved in colleges and schools of pharmacy to accommodate rapid changes related to nonprescription medications and to meet the needs of students. The design of and content delivery methods used in self-care courses vary among institutions. Teaching innovations such as team-based learning, role playing/vignettes, videos, and social media, as well as interdisciplinary learning have enhanced delivery of this content. Given that faculty members train future pharmacists, they should be familiar with the new paradigms of Nonprescription Safe Use Regulatory Expansion (NSURE) Initiative, nonprescription medications for chronic diseases, and the growing trends of health and wellness in advancing patient-care initiatives. This paper reviews the significant changes that may be impacting self-care curriculums in the United States.

Keywords: self-care, nonprescription medications, pharmacy education

INTRODUCTION

In 2012, the Nonprescription Medicines Academy (NMA) and the Self-Care Institute (SCI) celebrated their 15 and 10 year anniversaries, respectively. These anniversaries have encouraged reflection on the vast changes in self-care education, the growing role of nonprescription medicine in health care, and the value of faculty development programming to support faculty members who teach self-care in the pharmacy curriculum. During the past 15 years, the curriculum content for nonprescription medication and self-care therapeutics has expanded significantly. New nonprescription products, formulation

modifications, safety concerns, and regulatory changes are impacting the evolving responsibilities of the pharmacist in self-care. With these changes, self-care courses also transform to include innovative teaching strategies as pharmacy students needs in this area become greater. This paper reviews the significant changes that may be impacting self-care curriculums in the United States.

MILESTONES IN SELF-CARE OVER THE PAST 15 YEARS

The nonprescription medication marketplace has grown extensively over the last 15 years. There are now more than 300,000 nonprescription medication products in 80 therapeutic classes marketed in the United States.¹ This number has increased twofold since 2001 when just more than 100,000 nonprescription medication products were on the market.² A contributing factor to this increase is the recent rise in prescription medications now being available in nonprescription formulation (prescription to

Corresponding Author: Katherine Kelly Orr, Department of Pharmacy Practice, The University of Rhode Island, Kingston, RI 02881. Tel: 401-874-5522. E-mail: KellyO@uri.edu

*This article was prepared on behalf of the Nonprescriptions Medicine Academy Steering Committee by Emily M. Ambizas, PharmD, Karen M.S. Bastianelli, PharmD, Stefanie P. Ferreri, PharmD, Seena L. Haines, PharmD, Misty M. Stutz, PharmD, Jenny A. VanAmburgh, PharmD, and Miranda Wilhelm

nonprescription switches), allowing medications that once required a prescription to be purchased without one.

During this timeframe, more than 35 products have come to the market either directly as a nonprescription medication or as a prescription to nonprescription switch. Table 1 highlights major changes to the nonprescription market during this timeframe.^{3,4} In 2002, loratadine (Claritin) became the first second-generation antihistamine

available without a prescription. This prescription to nonprescription switch revolutionized the treatment of seasonal and perennial allergies by providing the first non-sedating antihistamine option. It also changed managed-care pharmacy, as many pharmacy-benefit managers removed second-generation antihistamines from their formularies, forcing patients to use nonprescription medications as an initial therapeutic approach.

Table 1. Approvals for Prescription Medications to be Available as Nonprescription Medications, 1997-2013

Year	No. of New Approvals for Prescription to Nonprescription Switches	Ingredients	Product Examples (Manufacturers)
1997	6	cromolyn sodium, tioconazole, loperamide/simethicone, triclosan, ketoconazole, minoxidil	Nasalcrom (McNeil Consumer), Vagistat-1 (Bristol-Meyers Squibb), others, Imodium Advanced (McNeil Consumer), Total (Colgate – Palmolive), Nizoral (Johnson & Johnson), Rogaine Extra Strength for Men (Johnson & Johnson)
1998	1	miconazole nitrate	Monistat 3 (Advanced Care Products)
1999	3	terbinafine hydrochloride, cimetidine suspension, naproxen sodium/pseudoephedrine	Lamisil AT (Novartis), Tagamet HB 200 (GlaxoSmithKline), Aleve Cold & Sinus (Bayer Consumer Care)
2000	2	docosanol, famotidine/calcium carbonate/magnesium hydroxide	Abreva Cream (Avanir Pharmaceuticals), Pepcid Complete (J&J/Merck)
2001	1	butenafine hydrochloride	Lotrimin Ultra (Schering-Plough)
2002	5	ibuprofen/pseudoephedrine suspension, guaifenesin extended-release tablet, nicotine polacrilex troche/lozenge, loratadine, loratadine/pseudoephedrine	Children’s Advil Cold (Wyeth), Mucinex (Adams Respiratory Therapeutics), Commit (GlaxoSmithKline), Claritin (Schering-Plough), Claritin-D (Schering-Plough)
2003	1	omeprazole magnesium	Prilosec OTC (Procter & Gamble)
2004	2	guaifenesin/dextromethorphan, guaifenesin/pseudoephedrine	Mucinex DM (Adams Respiratory Therapeutics), Mucinex D (Adams Respiratory Therapeutics)
2005	1	diphenhydramine citrate or hydrochloride/ibuprofen	Advil PM (Wyeth)
2006	4	ecamsule (sunscreen), levonorgestrel, polyethylene glycol 3350, ketotifen	Anthelios SX (L’Oreal), Plan B (Duramed), MiraLAX (Schering-Plough), Zaditor (Novartis)
2007	3	orlistat, cetirizine/pseudoephedrine, cetirizine	alli (GlaxoSmithKline), Zyrtec-D (McNeil), Zyrtec (McNeil)
2008	0		
2009	3	lansoprazole, levonorgestrel, omeprazole/sodium bicarbonate	Prevacid 24 HR (Novartis), Plan B One Step (Schering-Plough), Zegerid OTC (Schering-Plough)
2010	1	ibuprofen/phenylephrine	Advil Congestion Relief (Pfizer)
2011	2	fexofenadine, fexofenadine/pseudoephedrine	Allegra (Chattem), Allegra-D (Chattem)
2012	0		
2013	2	oxybutynin transdermal system, triamcinolone acetone	Oxytrol for Women (Merck), Nasacort Allergy 24 HR (Sanofi)

In 2003, omeprazole (Prilosec OTC) became the first proton-pump inhibitor (PPI) available without a prescription. This prescription to nonprescription switch transformed the treatment of frequent heartburn by providing patients an option beyond antacids and H₂-antagonists. It also allowed pharmacy-benefit managers to implement step-therapy in their formularies, requiring patients to first use nonprescription omeprazole before trying prescription PPIs.

In 2006, levonorgestrel (Plan B) became the first dual-labeled product, ie, available as both a prescription and nonprescription, depending on patient age. Emergency contraception available without a prescription provides thousands of women increased access, which will be further increased now that the age limit has been lifted.⁵ In 2007, orlistat (alli) became the first nonprescription weight-loss medication to receive approval by the Food and Drug Administration (FDA). This prescription to nonprescription switch capitalized on the growing health and wellness trend, providing patients a weight-loss option that, when combined with diet and physical activity, is safer than stimulant products. This movement has expanded further to include chronic conditions with the recent 2013 switch of oxybutynin patch to treat overactive bladder and triamcinolone acetonide for nasal allergy symptoms.^{6,7}

During the past 15 years, dozens of safety concerns have been raised and regulations have been instituted in the nonprescription medicine area. In 2005, the Combat Methamphetamine Epidemic Act was passed. This federal statute placed restrictions on pseudoephedrine sales and access and implemented reporting requirements.⁷ States have passed additional laws regarding restrictions to pseudoephedrine. Another regulatory issue occurred a year later with the passage of the Dietary Supplement and Nonprescription Drug Consumer Protection Act. This act required manufacturers, packers, distributors, and retailers to record and report adverse events.⁸ Regulations requiring current Good Manufacturing Practices for dietary supplements became law in 2006. This ruling ensures the quality of supplements by setting guidelines related to the manufacturing, labeling, and holding of these products; however, it does not provide additional safety, effectiveness, and dissolution evidence that is greatly needed.⁹ In 2007, the FDA rejected the prescription to nonprescription switch of a statin for the third time.¹⁰ Pediatric cough and cold products were recalled, relabeled, and are still being investigated for appropriateness in children 2-11 years old.¹¹ Acetaminophen labeling and formulations for infants, children, and adults have also undergone changes to ensure safe usage.¹² Historically, prescription to nonprescription changes have involved

medications that treat acute problems (symptoms lasting less than 2 weeks). However, the most recent switches of 2013 are now dealing with more chronic issues and could increase the potential for further concerns in the future.

Significant changes in growing therapeutic categories as well as regulatory and safety concerns have impacted content delivered in self-care curricula. Both the SCI and NMA have been at the forefront of providing the most up-to-date information regarding these products to assist self-care faculty members with the integration of this information into both classroom and experiential teaching. The NMA Facebook page has been a resource highlighting these updates in nonprescription news, and editorial board members from SCI provide chapter updates through the American Pharmacists Association's Handbook of Nonprescription Drugs.^{13,14}

SELF-CARE EDUCATION

During this 15-year time period, there also have been great strides in self-care within pharmacy education. The blueprint for the North American Pharmacists Licensure Examination (NAPLEX) was revised in 2005 to recognize the importance of nonprescription medicines, eliminating any distinction of importance between prescription and nonprescription medicines.^{15,16} The *Journal* published a Nonprescription Medicines and Self-Care theme issue in 2006, which featured several articles reinforcing the importance of self-care instruction. Part of this supplement identifies the pharmacist as the "only health professional who receives in-depth formal education and skill development in nonprescription drug therapy."¹⁷ Shortly after this publication, the 2007 Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree stated that education relating to nonprescription medicines and self-care should be incorporated throughout the pharmacy curriculum, including introductory and advanced pharmacy practice experiences (IPPEs and APPEs). Guidance regarding the incorporation of self-care and nonprescription medicines into the pharmacy curriculum can be found in Appendix B, C, and D of the accreditation standards.¹⁸ Establishment of the American Association of Colleges of Pharmacy Self-Care Therapeutics/Nonprescription Medicines Special Interest Group (SIG) soon followed, providing another opportunity for self-care faculty to network, learn, and promote the scholarship of self-care education.¹⁹ Practicing pharmacists are also enhancing their self-care knowledge through continuing education opportunities such as the National Alliance of State Pharmacy Associations partnership with NMA to conduct Student Pharmacists Self-Care Championships, which are held nationwide at annual state pharmacy

conventions.²⁰ These events are often led by local self-care faculty members as student teams compete in an event similar to a quiz bowl, during which they answer questions developed by NMA faculty members and which may involve continuing education credit.

Self-care instruction is incorporated into the pharmacy curriculum in many ways. Some colleges and schools require it to be a standalone course, while others offer it as an elective. Still others may integrate the curriculum within existing therapeutics courses, simulation laboratories, or in IPPEs and APPEs.²¹ Various methods have been used to assist with self-care instruction in the classroom. Although lecture is still the most common mode of delivery, active-learning strategies appear to be a growing trend.²²⁻²⁴ Use of active-learning strategies in the classroom to support and develop a student's ability to critically think and problem solve has been well established. There are several active-learning strategies that could be incorporated into the self-care curriculum from think-pair-share, one-minute reflection, or the muddiest point exercises; to more complex activities, such as role-playing, problem-based learning, case-based learning, and team-based learning. Additionally, there are technology-based active-learning activities, such as audience-response systems, videos, and social media, that can be incorporated to engage students in their learning. Several strategies discussed herein have been incorporated into NMA and SCI programming to assist and encourage faculty members to use various methods to enhance the delivery of self-care instruction. Faculty members are regularly invited to present poster/platform presentations and roundtable discussions to share their innovations in teaching.^{25,26} Faculty resources, including complex cases, assessment questions, grading tools, syllabi, active-learning techniques and strategies are available on the NMA website. The SCI also makes available resources from the annual meetings and editors continually provide updates through the APhA Library and Pharmacy Today articles.

Two key learning components in the self-care curriculum are effective communication and patient assessment. The pharmacist must be able to effectively and efficiently ask the patient pertinent questions to determine the problem, the most bothersome symptoms, other medical conditions, and medications being used. Role-playing and vignettes are strategies that can be used to teach these skills. Scenarios can be created and the students can then act out what they would do for the patient. The faculty member can assess and evaluate the students not only on the process used (ie, communication skills and critical thinking) but also on their nonprescription medication knowledge. Role-playing activities wherein students engage in patient consultations also can be used to develop

social emotional competences.²⁷ There is a growing body of evidence to support the use of this type of active learning in the classroom to meet the educational needs of future pharmacists and ensure they develop necessary skills.²⁸⁻³⁵

Team-based learning (TBL) is a type of collaborative learning that shifts the focus of classroom time from a lecture format to the application of key concepts. This type of learning is sometimes called the "flipped classroom" because it requires students to acquire the initial content through readings, online presentations, or other resources prior to class. At the beginning of class, students are assessed on the preclass requirements by means of a Readiness Assurance Technique (RAT). Both individual assessments (I-RAT) and group assessments (G-RAT) are completed at the beginning of class. Having both RATs holds the students accountable for being prepared for class. Following the completion of both RATs, the remainder of the class is spent on application-type activities, such as case discussions, ethical dilemmas, and pro/con discussions. Use of TBL is emerging in the development and delivery of self-care therapeutics.³⁶⁻³⁹

Pharmacy school curricula have expanded to incorporate YouTube projects and Facebook campaigns in self-care and public health courses. This strategy is intended to expand the skills and abilities of pharmacy students in reaching the community at large with succinct self-care messages. The purpose of these messages is to stress the safe use of nonprescription medications and to promote the role of pharmacists in assisting and educating patients regarding self-care products.⁴⁰ Example projects, course outcomes, and evidence of student impact have been presented at NMA, enabling other colleges and schools of pharmacy to consider adopting a similar approach in their courses. The use of YouTube for patient education is an area in which further research is needed to determine the impact that videos have on patients' understanding of their medications, improving adherence, and reducing medication errors and adverse events. Social media content could be considered as labeling and advertisement of these products, which is under the jurisdiction of the FDA.⁴¹ FDA guidance and regulations regarding social media messaging will be an important statement for colleges and schools of pharmacy that are using media as an instructional tool to review and integrate into their curricula.⁴²

THE FUTURE OF SELF-CARE Nonprescription Safe Use Regulatory Expansion (NSURE) Initiative

In 2012, the FDA announced it was looking at ways to approve the use of prescription medications by making them available as nonprescription through conditions of

safe use. Under the FDA's NSURE Initiative, the "conditions of safe use" could include pharmacist interventions or innovative technologies. Manufacturers can submit an application to the FDA for review and consideration. The FDA states that this paradigm could address the public health problem of under-treatment of common conditions.^{43,44} Other FDA considerations for this paradigm include: allowing some medication products that require an initial prescription to be available for refills without a prescription, with a condition of safe use for that purpose and permitting some drug products to be available by prescription and without a prescription simultaneously, with conditions of safe use.

This potential new paradigm is important to pharmacists, as it would serve as an opportunity for them to communicate and collaborate with the medical community to improve team-based care; reconnect and refer into the healthcare system those patients who may have undertreated chronic conditions or may need expanded access to life-saving rescue medications; and leverage patients' access to pharmacists to safely increase the availability of certain medications, as pursued by manufacturers for non-prescription approval as developed within this initiative.⁴⁵

Although the FDA is considering the NSURE Initiative, not all healthcare professions support this action. In June 2012, the American Medical Association House of Delegates adopted resolution 235, which was in opposition to the FDA's Rx to OTC Paradigm Shift.⁴⁶ The steering committee and editorial boards for NMA and SCI have incorporated regulatory issues such as NSURE into their programming when relevant so that self-care faculty members can share it with students in the classroom and with practicing pharmacists at the state level.

Health and Wellness Initiatives

As more Americans have become increasingly aware of their health, there is a growing trend toward disease prevention and maintaining healthy lifestyles. Although pharmacists have traditionally been available to offer advice and education on disease states, they are equally capable of offering advice and education on how to prevent disease through healthy lifestyles and information on nutritional supplementation, such as dietary supplements.

Over the past 3 to 4 years, most pharmacy retailers are encouraging pharmacists to offer wellness services to their patients.⁴⁷⁻⁵⁰ These include blood pressure and cholesterol screenings, blood glucose testing, risk assessments for chronic obstructive pulmonary disease and diabetes, immunizations, and weight-loss management. Some pharmacies even offer organic foods and fresh produce while nutrition experts educate patients on the benefits of healthy, nutritious foods.

Many insurance companies and employers are offering incentives for members to participate in wellness initiatives. The majority of services are offered free of charge to patients. Most of the financial benefits seen in pharmacies stem from increased sales of wellness products. Billing for pharmacy services not linked to a product, including wellness services, has traditionally been a challenge for pharmacists because they are not able to bill for cognitive services under their own National Provider Identification number but must collaborate with another provider or insurance company to gain reimbursement for services.

As Americans take control of their health through wellness initiatives, the pharmacist's role becomes increasingly more important in the overall well-being of our patients. SCI and NMA continue to play a key role in providing self-care educators resources for preparing the next generation of pharmacists. Just as self-care has become more preventative, SCI and NMA have followed this trend, consistently incorporating topics related to health, wellness, and disease prevention and expanding on nonpharmacological measures, appropriate use of dietary supplements, and the growing role of home-based health-monitoring devices. Although current legislation does not allow for full reimbursement of services, we anticipate that future healthcare reform will give pharmacists the opportunity to be engaged in health and wellness initiatives.

CONCLUSION

Self-care has evolved and will continue to grow as patients become more empowered and medications that once were available only by prescription become more readily available without a prescription. Pharmacists have a vital role in triaging and assisting patients in the selection of the most appropriate treatment option. As self-care continues to expand, it is imperative that pharmacy colleges and schools meet the challenges of educating future pharmacists to effectively assist patients in this area. Although changes have been made in self-care curricula, there is a great need for outcomes research to evaluate how well this challenge is being met.

ACKNOWLEDGMENT

The authors recognize Schwanda Flowers, PharmD, University of Arkansas for Medical Sciences College of Pharmacy, for her assistance with preparation of this manuscript.

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