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NONPRESCRIPTION MEDICATIONS AND SELF-CARE

Constructing a Self-care Curriculum

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The purpose of this paper is to describe the unique challenges presented by a dynamic marketplace when designing a self-care curriculum. As manufacturers seek to satisfy consumer demand and increase market product shares, rapid changes occur with brand name extensions and prescription to nonprescription switches. The US Food and Drug Administration's continuous process of approving ingredients (monographs) add to this changing environment. Thus, developing learning outcomes beyond drug knowledge becomes critical. Learning outcomes must also address the multifaceted nature of self-care, including the development of skills in patient assessment (triage) and education. Determining which content areas to be covered can be difficult when consumer demand and marketplace changes are considered. For example, consumer use of dietary and herbal supplements forces pharmacists to have some basic knowledge of safety and efficacy regarding these products. Ultimately, given the dynamic, multifaceted nature of self-care, developing life-long learning skills/attitudes in students may be the most important outcome necessary for a self-care curriculum.

Keywords: self-care, prescription drugs, nonprescriptions drugs, line extensions, curriculum design

INTRODUCTION

Designing a self-care curriculum for pharmacy students presents faculty members with unique challenges beyond those of teaching the usual drug-related knowledge, eg, mechanism of action, contraindications, adverse effects, dosing, dosage forms. There are more than 300,000 self-care products and devices in a $34 billion market.[1] More than 700 of these products were medications available only by prescription 30 years ago.[2] Effective self-care learning outcomes require an understanding of the vagaries of rapid change in this market.

Both the prescription drug and self-care markets are dynamic. Prescription drug market changes include brand to generic conversions; new drug approvals; and frequent changes in practice guidelines that stem from new clinical research including challenges to previous therapeutic approaches. Self-care market issues include former medications switched to self-care status (prescription to nonprescription); the ability of manufacturers to change active ingredients without prior notification of pharmacists or physicians; and the constant quest by manufacturers to maintain market share through brand name extensions (referred to as "line extensions"). Frequently, changes also occur within the context of Food and Drug Administration (FDA) proposed rulemaking and final rules or monographs, and when new evidence of safety concerns arise, changes to those rules occur yet again. The result is that course content taught in the previous semester may no longer be valid this semester. Keeping curriculums up to date is a challenge to all faculty members; however, it is especially true of self-care curriculum design. Colleges and schools of pharmacy must ensure that students develop skills necessary for life-long learning to manage the changing environments of both prescription and self-care drugs and products. Similarities exist regarding curriculum design for prescription and self-care medications. However, self-care presents some unique challenges. Prescription to nonprescription switches are one component that illustrates this changing area of pharmacy practice and the multifaceted skills the pharmacist must demonstrate when working in the self-care field.

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MULTIFACETED COMPONENTS

Prescription to Nonprescription Drug Switches

Since 1975, the FDA has approved 89 ingredients or dosages as new nonprescription drugs or transfers from prescription to nonprescription status.[3] In addition, the FDA is considering the switch of orlistat (a lipase inhibitor) to nonprescription status.[4] At present, manufacturers are considering a variety of other prescription to

nonprescription switches, including cholesterol reducers (approved for self-care in Great Britain), asthma and allergy treatments, oral antifungals, and more. Many of these drugs once studied under the purview of pharmacology and therapeutics courses have now been shifted to the growing volume of products being studied in self-care courses. Thus, as more content is shifted from other course work into the realm of self-care, covering an ever-increasing number of drugs and content areas in the curriculum becomes a more complicated and daunting task for faculty members.

The FDA approves prescription to nonprescription switches only after reviewing available evidence to support or deny the switch to self-care status. Volumes of data and testimony on safety concerns are sorted by designated FDA oversight committees who then issue a report recommending for or against the move to self-care status. The FDA approves a switch only after confirming that the switch fulfills a patient need (eg, increased access) and most importantly, that consumers can safely self-medicate by following the labeling/instructions on the product. However, consumers are often confused, misread, or are unable to read product labeling, or simply do not read the label at all.[5]

In particular, prescription to nonprescription switches are one area where the patient would benefit from a pharmacist who is knowledgeable about the drug and who possesses excellent patient assessment and counseling skills. The critical need for appropriate triage and patient counseling become apparent when a patient selects a product that has been switched from prescription status to self-care status and uses it incorrectly.

Patient assessment and counseling for prescription medications is different. A health care practitioner licensed to prescribe medications has already assessed those patients. These patients then need to interact with another learned intermediary (the pharmacist) before obtaining the medication. The pharmacist's role becomes one of ensuring that the patient derives the most benefit from the drug while minimizing risks of adverse events and/or drug interactions.

Unfortunately, when a prescription drug is switched to nonprescription status, consumers interpret this as meaning no professional advice or oversight is needed. Often when patients use self-care products, they have bypassed the physician and have self-diagnosed their symptoms. This is evidenced by patients frequently starting a conversation with the pharmacist that begins by asking, ''What do you have for a cold/heartburn/itching, etc?'' In such cases, the pharmacist must be able to properly assess the patient's symptoms and pertinent medical/drug history and verify or disagree with the patient's original idea of what his/her symptoms signify. This basic assessment or triage, which includes knowing which questions to ask, may lead the pharmacist to recommend emergency care, a physician visit, a nonprescription drug or other self-care product, or no treatment at all. Thus, basic patient assessment skills are a critical component of the self-care curriculum.

Knowing how to ask patient assessment questions is as important as knowing what to ask. Through practice, students must learn to use open-ended questions, followed by more focused questions. Listening to what the patient says along with what is not directly stated is another skill that generally takes practice. Further, cultural competence and health literacy are also needed to provide proper self-care triage and counseling. Hence, the decision to include patient assessment and counseling skills within or in conjunction with a self-care course must be made and demonstrates the multifaceted nature of self-care. Many colleges and schools of pharmacy have separate patient assessment and counseling courses or teach these skills within a practicum or laboratory skills course. When taught as separate skills courses or practice laboratories, the best ways to reinforce these skills cohesively must be considered. Reinforcement between courses prevents students from putting these components (eg, drug knowledge, patient counseling and assessment) into separate learning ''silos.'' Care must be taken to ensure the student is provided with multiple opportunities to practice combining the knowledge and skills necessary for patient care using self-care medications. Thus, self-care instructors need and should work with faculty members who teach other skills-based courses and with the early or advanced pharmacy practice experience (APPE) coordinator to develop specific objectives and opportunities for combining these multiple disciplines.

Switching Product Ingredients and Line-Extensions

Self-care curriculum design must stay current in a field where change is dynamic and occurs at a bewildering pace as manufacturers vie for product market share and attempt to keep up with consumer demands. Brand name or line-extensions is one area that is particularly problematic for one trying to keep up to date. Line-extension examples include using the original product name with small labeling variations such as ''New and Improved'' for a product that has changed part of its formulation, or adding a qualifier onto the name such as Dramamine Non-Drowsy and using a completely different drug from the original. Products such as these may not contain the original ingredient(s) that pharmacists and patients connect with the name. Thus, unexpected adverse effects and drug and disease interactions can occur. The new formula

or ingredient may have different age restrictions on dosing or different dosage recommendations such as once a day instead of 3 times a day or 5 mL instead of 30 mL.

The FDA has been reviewing self-care products since the 1968 Drug Efficacy Study Implementation (DESI) was created to incorporate the recommendations of the National Academy of Sciences investigation of effectiveness of drugs marketed from 1938-1962. An offshoot of the DESI was the initiation of the *OTC Drug Review* in 1972. This review was started as a means to enhance the safety, effectiveness, and appropriate labeling of drugs sold without a prescription. FDA final rules regarding self-care drugs are often slow in coming but often trigger changes in product ingredient prior to release of the final guidelines. An example was the lengthy cycle of FDA review, panel reports, proposed rules, and final rules for antidiarrheal products, which took 28 years to complete.[6–8]

The antidiarrheal product Kaopectate is a good example of the potential for drug or disease interactions or adverse events that can occur when multiple formulation changes are made based on FDA rulings. This product has undergone 3 formulation changes since its originally marketed formula containing pectin and kaolin. The first change was to substitute attapulgite (considered safe in children) when the *OTC Drug Review* found the kaolin and pectin combination of questionable effectiveness. The subsequent formula was later changed again due to FDA rulings on attapulgite. The last change substituted bismuth subsalicylate as the active ingredient. Due to the FDA's Final Rule on the lack of safety and efficacy of attapulgite, the product was changed without notice to contain an ingredient considered contraindicated in children because of its salicylate content. Because older bottles were not recalled, both formulations existed on shelves at the same time and labeling appeared quite similar. Many pharmacists were unaware of this change until the Institute for Safe Medicine Practices issued a warning report.[9] Unfortunately, there are no laws requiring manufacturers to alert and forewarn pharmacists, physicians, or patients/consumers regarding these changes in ingredients if the FDA has previously approved the ingredient.

The ink was barely dry on the new state laws that placed pseudoephedrine HCl in a restricted controlled category (C-V), when several manufacturers changed the active ingredient in their products to phenylephrine, which cannot be synthesized into methamphetamine. Regardless of whether this change reduced illicit use of pseudoephedrine, such ingredient changes without brand name changes further complicate the design and teaching of self-care courses. To ensure that students do not mistakenly connect brand names with particular ingredients or recommend products that are no longer appropriate, self-care course curriculums should include information about both previous and current formulations of nonprescription drugs. Also, students should be aware that additional ingredient changes are possible without notification to pharmacists or consumers. Students should know and abide by the laws pertaining to distribution and use of self-care products; thus, legal issues should also be included in a self-care curriculum.

The course instructor must determine which content areas must be included, which content areas would be nice to include if time permits, and which topics are unnecessary to cover given the time constraints of the course. The Nonprescription Medicines Academy's paper (Zierler-Brown et al) published with this Supplement provides some suggestions and rationales for topics that should be covered. When designing a self-care course or curriculum, an interesting exercise for the instructor is to list all the possible topics that could be included. Topics pertaining to self-care knowledge and skills range from cough/cold/allergy medications, to nutritional and dietary/herbal supplements, to home testing devices, to more controversial yet contemporary areas such as micronutrients, probiotics, traditional Chinese medicine, regional folk remedies, and homeopathy. Regardless of whether faculty members consider some of the more controversial topics as quackery, patients are using many of these products with increasing frequency. Thus, pharmacy students must be knowledgeable about them and know the limitations of these products. These products can interact with a patient's medical problems and prescribed medications; thus, at a minimum, pharmacists should understand the evidence for benefits and risks associated with such products. Therefore, an argument can be made for including even controversial topics in a self-care curriculum so that the students are in a position to educate patients regarding the safety of such products or devices.

If the faculty members make the decision to include only limited instruction on dietary and herbal supplements, the question becomes which ones out of the thousands that are available will be selected? Although the National Association of Boards of Pharmacy, creator of the North American Pharmacist Licensure Examination (NAPLEX), has stated that the examination will cover dietary/herbal supplements, it has given no guidance as to which of the thousands of products are of paramount importance.[10] Nor are there any guidelines elsewhere within pharmacy colleges' accrediting agency, the Accreditation Council for Pharmacy Education.[11] It seems logical that because that portion of the NAPLEX examination which tests on prescription drugs focuses

on the "top 200 drugs," the dietary/herbal supplement component would focus on those products most purchased by consumers, eg, echinacea, glucosamine, fish oils. The rapidly changing marketplace again plays a role. Some supplements or herbals have risen in importance, while others have fallen from prominence. For example, information about glucosamine has changed from anecdotal evidence of effectiveness to NIH-funded study results suggesting possible benefit in moderate osteoarthritis.[12] Just a few years ago, St. John's wort ranked second on a list of most frequently purchased dietary supplements. By 2002, it had dropped to sixth due to increased knowledge of drug or disease interactions involving liver metabolism, and its usefulness was limited to the treatment of mild depression.[13] The decision of which supplements/herbals should be studied becomes even more complicated when we consider the products that are listed as carcinogenic, banned in other countries but available in the United States, or listed as likely hazardous. Just as pharmacists should have a working knowledge of drug interactions associated with drugs such as warfarin (accessible only with physician oversight), pharmacists should also have a working knowledge of these dangerous products that are available without a prescription.

In the end, faculty members are left with an overwhelming list of possible content areas, all arguably important. This listing must be considered in addition to the skills of patient assessment, patient counseling, health literacy, and cultural competence, and designed in such a way as to fit into an average 3 credit-hour course (prior to APPEs).[14] As a side note, although the "average" number of credit hours assigned to didactic coverage of self-care is 3, (about 3% of the professional curriculum prior to APPEs), that should in no way imply that amount of time is adequate to cover even the bare minimum of recommended topics. Faculty members responsible for designing a self-care course or curriculum may find it useful to provide the list of topics suggested above and elsewhere in this Supplement (Zierler-Brown et al) to their college or school educational policy committees (eg, curriculum committees) as a resource when decisions about credit hours will be discussed. This may provide more background and understanding by the whole committee regarding the multifaceted nature, diverse topic requirements, and need for development of life-long learning skills necessary for inclusion in self-care curriculum design. It may also enhance the ability to map course outcomes and demonstrate where these individual components of knowledge and skills are divided within the curriculum and where practice opportunities are currently available or should be added.

DEVELOPING APPROPRIATE SELF-CARE LEARNING OUTCOMES

The constant dilemma of having too much content to cover and insufficient time to do so is not restricted to self-care courses. Whether it is necessary to delete subject matter due to decreasing credit-hour allotment or due to the desire to teach some topics in more depth using active-learning techniques, most faculty members find it difficult to delete content. The field of self-care has an overwhelming amount of changing content combined with a variety of skill development that may need innovative and creative ways to manage. Because of frequency of use by patients, some of these topics (and all of the triage skills) fall into the "should be included" category. The remainder of the material that could be covered can be considered as important but optional. To address this, the instructor must return to the beginning step in curriculum design: asking what is the desired learning outcome. If the learning outcome necessitates memorizing hundreds of facts about thousands of ever-changing products and devices and accomplishing this within a 3 credit-hour course, then the outcome will always remain impossible to achieve within any curriculum. The material learned today in the classroom may be obsolete tomorrow.

An achievable outcome must then be considered in light of this environment of change. In addition to certain "must have" drug knowledge, using an outcome designed around principles and skills, eg, demonstrating life-long learning, is achievable. Other achievable learning outcomes to consider are the ability of the student to:

- conduct appropriate self-care triage of the patient through proper questioning and assessment within the context of the cultural and health literacy domain of the patient;
- make an appropriate patient-specific recommendation and provide necessary patient-specific counseling and follow-up monitoring if the patient's complaint is categorized as self-treatable (eg, seasonal allergies);
- access appropriate self-care information resources, analyze the information provided, and answer questions within the knowledge context of the person who asks them (patient or health-care practitioner).

This last outcome is one way to document or assess life-long learning skills. Another way to achieve this is to assign a chapter from the course textbook for students to study on their own and then test them on the material. Providing students with an opportunity to research and report on a topic not able to be covered in depth, such as

less common dietary/herbal supplements, would also allow students to demonstrate life-long learning skills as well as their ability to provide appropriate recommendations, patient counseling, and follow-up monitoring.

Reinforcing self-care material during the APPE year is vitally important. The APPE year should provide opportunities for students to practice their self-care triage and communication skills and continued knowledge development in self-care. Students should be encouraged to include in their APPE portfolios evidence of achieving self-care triage and communication skills, plus their reflections on the concepts learned and those being developed.

These are just a few of the ways that outcomes can be achieved given an overwhelming amount of changing and multifaceted material. Mapping these outcomes across the entire 4 years of the professional curriculum (including APPEs) is critical to ensure that missing content or skill development areas are identified and addressed, and to ensure reinforcement of material taught earlier in the curriculum. Using active versus passive learning, creating exercises that enable students to practice and develop these skills, designing useful grading rubrics, and using multiple methods of assessment are the remaining pieces of the self-care curriculum design process.

SUMMARY

Designing a self-care curriculum requires taking many diverse and multifaceted factors into consideration. These factors include but are not limited to, the dynamic nature of the self-care marketplace: prescription to nonprescription drug switches, manufacturers' ability to change ingredients, product line-extensions, and FDA final monographs and rules. The myriad of topics that could be included in a self-care curriculum range from traditional content areas to regional folk therapies, complementary medicines, and homeopathy. Skill development in patient assessment and counseling should also be included/addressed. Starting with the desired learning outcomes helps to bring into focus which content areas should be covered and how the outcomes can be assessed. Ultimately, because of the constant and often unannounced changes that take place within the nonprescription drug and product industry, life-long learning skills/abilities may be the most important outcome of a self-care curriculum.

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