INSTRUCTIONAL DESIGN AND ASSESSMENT

Using Collaborative Drug Therapy Agreements to Train Student Pharmacists to Provide Clinical Patient Care Services

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Objective. To assess the impact of a new course designed to train student pharmacists to provide clinical patient care services delivered through collaborative drug practice agreements.

Design. An intensive two-credit, one-week course with a combined self-study and interactive pedagogical approach was developed. Content from the online Washington State Pharmacy Association Clinical Community Pharmacist training program was integrated with a live, eight-hour seminar.

Assessment. Student-pharmacist learning, effectiveness of content presented, and perceived value of the material were evaluated. Scores on quizzes, a knowledge assessment, a patient-case examination, pre- and post-seminar surveys, and voluntary student certification rate were collected and analyzed. Of 132 student pharmacists enrolled in the course, 121 students met competency on their first attempt at completing the knowledge assessment and 126 students met competency on their first attempt at completing the practical examination. A pre- and post-training survey found that student pharmacists were significantly more comfortable performing and recommending implementation of services after completing the course.

Conclusions. Training student pharmacists who are competent and comfortable providing clinical patient care services can improve access to care and reduce the impact of the impending physician shortage.

Keywords: collaborative drug therapy agreement, collaborative pharmacy practice agreement, community pharmacy, education, student pharmacist

INTRODUCTION

The American Association of Medical Colleges predicts that by 2025 our nation will have a shortage of 90,000 physicians, including 31,000 primary care providers.1 The impact of this shortage is likely to be most pronounced in underserved populations. In the state of Washington, many patients, particularly in rural and underserved areas, lack full access to health care services. In Washington, 27 out of 37 counties are classified as medically underserved areas by the Health Resources and Services Administration because of “too few primary care providers, high infant mortality, high poverty or a high elderly population.” 2,3

Providers in other health care disciplines are looking for ways to reduce the impact of this projected physician shortage. Increasing primary care and specialized physician residency slots and using nurse practitioners (NPs) and physician assistants (PAs) to their fullest extent as providers are two current trends in addressing the physician shortage.4,5 The latter solution becomes complex because the legal scope of practice is regulated by each state and those regulations may not align with the professional competencies of NPs and PAs.6 The same is true for pharmacists and the practice of pharmacy. The average American lives within five miles of the nearest community pharmacy, making pharmacists and the care they provide highly accessible.7 A collaborative approach is necessary to increase patient access to care.

State pharmacy boards and commissions regulate the practice of pharmacy at the state level, resulting in variation across the country as to the use of collaborative drug therapy agreements (CDTA) also called collaborative practice agreements (CPA). While many states have CDTAs or CPAs there is wide variation in how they can be used. Some states place restrictions on the conditions pharmacists can treat, the medications they can prescribe, and additional training they must have.8 In Washington, the Pharmacy Practice Act has allowed all pharmacists to
prescribe medication under CDTAs since 1979.9 There is no limitation on the population or disease states they are allowed to treat outlined in the agreements. In the past several years, many states’ pharmacy practice acts have been modified to match the evolving role of pharmacists as members of integrated health care teams. In California, Montana, New Mexico, and North Carolina an advanced practice pharmacy designation is awarded to qualified pharmacists that authorizes them to prescribe, monitor, manage, and dispense medications.10 While expanding patient access to care is a complex and difficult issue to solve, pharmacists are in an integral position to provide expanded care to patients.11 In 2012, the Food and Drug Administration (FDA) considered creating a behind-the-counter or pharmacist class of drugs to provide treatment for patients who have untreated or undertreated medical issues and difficulty accessing care.12 Creating a pharmacist class of drugs would address the need to provide treatment in three ways: increasing access to care for minor ailments and conditions, decreasing costs to both patients and the health care system, and decreasing burden on physicians so they can focus on seriously ill or medically complex patients.13-15 The opposition highlighted concerns about the quality of care, access to needed therapy, and the adequacy of pharmacist training to provide this care.15 With these concerns in mind, the FDA decided not to comment on the creation of a pharmacist class of drugs.

Following the lack of action by the FDA, a pharmacist in Washington collaborated with a local health care provider to develop and implement collaborative drug therapy agreements (CDTAs) aimed to provide treatment for patients with minor ailments and conditions in a community pharmacy. The Washington State Pharmacy Association (WSPA), other community pharmacists, Washington State University, and the University of Washington built upon this model by developing training to support other pharmacists who were interested in expanding the clinical services provided in community pharmacies. The workgroup developed educational modules that were bundled into a 20-hour continuing education certificate program, the WSPA Clinical Community Pharmacist Training program (WSPA CCP), which was launched in 2015.16 The workgroup chose these disease states because they were identified by local pharmacists as being undertreated in the community and because the workgroup received feedback from local physicians that these medical conditions had differential diagnoses that could be determined with minimally invasive or complex procedures. While pharmacists are not required to complete any additional education to create and practice under a CDTA in Washington, the creators believed that having additional education about the identification and treatment of these disease states would endow pharmacists with additional confidence in performing these services as well as provide evidence of knowledge that can be shared with a physician to encourage the creation of the CDTAs.

The modules were developed using the Joint Commission for Pharmacy Practitioners (JCPP) Pharmacist Patient Care Process, to provide a foundation of training to support consistent, measurable, predictable, and scalable implementation of the included pharmacists’ services.17 Disease state modules provided in the Clinical Community Pharmacist Training program are listed in Table 1.16 The “Fundamentals” module includes information regarding development of a business and marketing plan, documentation, and practical points. All of the clinical modules are based on current practice guidelines and include specific learning objectives, a review of the disease state, differential diagnosis including when to treat and when to refer, pharmacologic treatment options, medication counseling information, patient follow-up recommendations, a patient screening tool, and references to practice guidelines.16

Faculty members at Washington State University integrated the WSPA CCP modules into a new two-credit-hour course, Point of Care and Clinical Services. This new course was created during curriculum revision as a required course in the second professional year (P2). The goal of this course was to provide an educational experience focused on specific clinical services that can be provided in a community pharmacy setting and to develop the knowledge and skill set needed to provide innovative clinical services.

Table 1. Clinical Community Pharmacist Modules16

| Module Title            |
|-------------------------|
| Fundamentals            |
| Allergic Rhinitis       |
| Anaphylaxisa            |
| Bites                   |
| Bronchospasm           |
| Burns                   |
| Contraceptivesa         |
| Fluoride                |
| Headache                |
| Insulin refill          |
| Shingles                |
| Stinging Insects        |
| Swimmer’s Ear           |
| Urinary Tract Infection |
| Vaginal Yeast Infection |

*Indicates modules that were optional for the Point-of-Care and Clinical Services Course
patient care services delivered under CDTAs. This course builds upon the content included in a traditional self-care course through the addition of legend medications that can only be prescribed by pharmacists under CDTAs. It provides an additional level of instruction to educate student pharmacists about how CDTAs can increase the type and diversity of clinical services provided in a community pharmacy and increase patients’ access to care. The course developers believe that both point-of-care testing and pharmacist-provided patient care services will continue to evolve in pharmacy practice and this course can be updated to meet the needs of pharmacy student education in this area.

A portion of this course includes integration of the self-study online WSPA CCP modules with a five seminar aimed at increasing student pharmacist confidence with the clinical skills needed to provide these advanced services. We hypothesized that the addition of the live seminar would increase student pharmacists’ comfort in performing and interest in implementing the services included in the WSPA CCP training.

The vision of the Washington State University College of Pharmacy is to be a leader in advancing, promoting, and protecting human health. Our faculty believes incorporating this training as a required course meets this vision by developing student pharmacists who are focused on increasing patient access to care. This course was also designed to meet ACPE standards 2016. Specifically, ACPE Standard 2.1 (Patient Centered Care) was addressed by preparing students to put the patient at the center of all therapeutic decisions. Standard 2.4 (Population-Based Care) was integrated by using clinical practice guidelines and evidence-based practices when providing care, and Standard 3.3 (Patient Advocacy) was met as students were encouraged to provide care for patients who lack needed access to services for acute care. Much of the content of the P1 self-care course focused on differentiating between when self-care is appropriate and when a referral is necessary, as well as patient physical assessment, which includes blood pressure, temperature, head-to-toe examination, and glucose and cholesterol finger-stick testing. This new course further differentiates the referrals from the P1 course into those who can be treated through initiation of prescription therapy when necessary. This course built upon student pharmacist knowledge regarding self-care and nonprescription medications, subjects that are taught during the spring semester of the first professional year (P1). Much of the content of the P1 self-care course focused on differentiating between when self-care is appropriate and when a referral is necessary, as well as patient physical assessment, which includes blood pressure, temperature, head-to-toe examination, and glucose and cholesterol finger-stick testing. This new course further differentiates the referrals from the P1 course into those who can be treated through initiation of prescription medication by the pharmacist using a CDTA.

As part of the WSPA CCP module independent study, students were required to complete 12 hours of immunization independent study (AphA immunization certification requirement) and 15 hours of WSPA CCP module independent study. The team of instructors consisted of five faculty members, one adjunct faculty member, one resident, and a community partner who delivered immunization training. Point of Care and Clinical Services complements the Communication and Applied Patient Care (APc) series, which focuses on developing clinical decision-making and patient-care skills and is delivered longitudinally across the didactic curriculum. A combined self-study and interactive pedagogical approach was used to deliver the content in three phases: independent study and self-assessment, live skills-training seminar, and summative assessment of student learning.

During summer break, student pharmacists were required to independently complete 10 modules from the WSPA CCP. Each module provided background education about a minor ailment or condition as well as how to identify and treat the condition using a CDTA. The WSPA CCP modules were chosen for inclusion in this course because they provided education about services that could realistically be provided in a community pharmacy setting using CDTAs to initiate prescription therapy when necessary. This course built upon student pharmacist knowledge regarding self-care and nonprescription medications, subjects that are taught during the spring semester of the first professional year (P1). Much of the content of the P1 self-care course focused on differentiating between when self-care is appropriate and when a referral is necessary, as well as patient physical assessment, which includes blood pressure, temperature, head-to-toe examination, and glucose and cholesterol finger-stick testing. This new course further differentiates the referrals from the P1 course into those who can be treated through initiation of prescription medication by the pharmacist using a CDTA.

As part of the WSPA CCP module independent study, students were required to complete a formative quiz following each content area. Quizzes were to be completed individually online using the Blackboard Learning Management System. Participation was required but no minimum competency level was needed and the quizzes were formative. The student scores were used by the course instructors to identify gaps in student
knowledge so that emphasis could be placed on these areas during the live seminar. Using the quizzes as a formative but required component of the course also ensured that students engaged with the material prior to the live skills seminar.

After completion of the modules, students attended the faculty-led, eight-hour live interactive skills seminar. The live course was delivered to 132 second-year student pharmacists. During the seminar, students were provided with additional material that built on the information included in the self-study modules. Students applied their knowledge and honed patient evaluation and care skills as they worked through patient cases and practiced implementing the protocols. Patient questionnaire and pharmacist assessment forms included in the WSPA CCP training modules were used as templates to create a scenario realistic of that which would occur with a patient in a community pharmacy setting. The agenda for the day was split up by disease state. Students were given a patient scenario and used the OLDCART (onset, location, duration, characteristics, aggravating factors, relieving factors, treatment already tried) method to ask clarifying questions to determine if the patient should be referred or if they qualified to be cared for using the CDTA. A completed patient questionnaire and blank pharmacist assessment form then were given to the students to complete and make their recommendation for care. Throughout the day several patient cases were discussed for each condition where the pharmacist would either make a clinical assessment and initiate therapy, or make a referral. The developers of the course believed it was important to include referral cases to ensure students fully understood the importance of understanding condition complexity and the referral criteria delineated in each CDTA. Multiple active-learning strategies including cooperative cases, individual cases, role-playing, peer formative assessment, and application activities were employed during the live seminar. Learning objectives for the live skills seminar are included in Table 2.

Table 2. Point-of-Care and Clinical Services Course Learning Objectives

| Learning objectives for the online independent modules |
|-------------------------------------------------------|
| List referral criteria                                 |
| Recognize common prescription, non-prescription, and non-pharmacotherapy treatment options (dose/directions) |
| Identify potential differential diagnoses              |
| Apply current guidelines to create treatment recommendations |

| Learning objectives for the live skills seminar |
|-------------------------------------------------|
| Develop a care plan for patients who present with any of the covered conditions |
| Determine which patients require referral        |
| Select appropriate medication options based on patient presentation and severity of symptoms |
| Conduct patient/provider follow-up and complete required documentation |

The goals of this course included increasing student comfort and interest in implementing the included services. To assess student pharmacist comfort, a pre-post survey model was used. A pre-seminar survey of student comfort level regarding the services included in the training was completed by student pharmacists after completion of the self-study modules and quizzes but prior to attending the live seminar. A post-seminar survey was conducted to assess changes in student comfort levels following completion of the live skills seminar. Both surveys were conducted using the survey tool in Blackboard LMS. Data were examined and stored in Microsoft Excel and then exported to SPSS, version 23 (IBM SPSS Statistics 23, Armonk, NY). The Mann-Whitney U test was used to determine p values. This project was given exempt status by the WSU Institutional Review Board.

Following completion of the live seminar, students were required to demonstrate competency by achieving a minimum competency score of 80% on both an electronic knowledge assessment and a patient case practical examination. The knowledge assessment included 18 multiple-choice questions and was delivered electronically via ExamSoft (ExamSoft Worldwide, Inc., Dallas, TX). The questions, ranked as knowledge or application level in Bloom’s taxonomy, required students to demonstrate knowledge of minor ailments and conditions content or correctly apply that knowledge to short patient vignettes. Assessment questions were designed to be the same level of difficulty as the formative quiz and mapped to the learning objectives for the clinical modules.

The patient case practical examination required students to directly apply their clinical patient care skills. Students were given two sheets of paper, each with a written patient case on it that included the chief complaint, history of present illness, past medical history, allergies, medication history, and a result of the physical assessment which would be undertaken following the protocol in the WSPA CCP modules. Each case also included the
blank corresponding clinical community pharmacist patient evaluation sheet for the student to complete. Students used the patient evaluation sheet to determine whether the patient met criteria for treatment and then selected the appropriate treatment or referral. Students were also provided space to write a short justification of the treatment choice.

Student performance data from the multiple-choice Knowledge Assessment and Patient Case Practical Examination are useful in determining student knowledge but insufficient to gauge student interest in the material. The number of students choosing to pay for the optional certification was tracked to provide insight into the value students placed on the training and likelihood that they would implement or use these clinical services in future practice. The WSPA provides a certificate to pharmacists who have completed the online training. Student pharmacists were required to attend and participate in the WSPA CCP online training for the course; however, they were given the option to pay for the certificate after course completion. The certificate costs $75 for WSPA student-members and $95 for nonmembers, rates discounted from the full pharmacist price of $375 for WSPA members and $575 for nonmembers. In order to become certified, a minimum competency score of 75% was required on each module quiz; however, for the course, the quizzes were formative. Once the course was completed, students were given the opportunity to resubmit answers for the module quizzes if needed to reach the 75% competency.

Student pharmacists were also given the option to complete five additional modules to add to their list of skills on the WSPA CCP training certificate. These modules included initiation of fluoride therapy and refill protocols for anaphylaxis, contraception, bronchospasm, and insulin. Completion of these modules had no impact on students’ course grades. These modules were omitted from the required course material due to the coverage of this content in other courses and the time limitations of this one-week course. The number of students who elected to complete these optional modules was also tracked. These modules and associated assessments, like the originally required modules, were completed in Blackboard LMS.

**EVALUATION AND ASSESSMENT**

Several methods were used to evaluate the effectiveness of the course with the goals of evaluating student pharmacists’ learning, perceived value of the material, interest in becoming certified, and the effectiveness of the self-study modules and the live seminar. In addition to the formative quizzes, knowledge assessment, and patient-case practical examination, other methods of evaluation included student pre- and post-seminar surveys, and student certification.

The mean and standard deviation scores on the formative quizzes ranged from 66%±21% to 84%±19% (Table 3). Students were required to take the quizzes, but there was no required minimum competency score. Two students did not complete one of the required quizzes, and one student did not complete several of the required quizzes. The latter student was required to complete a make-up assignment.

Of the 132 student pharmacists taking the knowledge assessment, 121 students met 80% competency on the first attempt. Ten students met competency on the remediation examination given one week after the initial examination. Both the initial knowledge assessment and the remediation examination were written to cover the same learning objectives and had the same difficulty level. The one student who did not pass the remediation examination was required to complete a special project during the fall semester to meet the requirements of the course.

Of the 132 student pharmacists taking the patient case practical examination, 126 students met competency on the first attempt. To meet competency, students had to successfully evaluate and decide to treat or refer two

| Topic                  | Students Participating, No. | Score, % Mean (SD) | Assessment Questions, No. |
|------------------------|----------------------------|--------------------|---------------------------|
| Fundamentals           | 132                        | 81 (18)            | 5                         |
| Allergic Rhinitis      | 132                        | 74 (21)            | 5                         |
| Bites                  | 132                        | 78 (20)            | 9                         |
| Burns                  | 132                        | 77 (18)            | 7                         |
| Headache               | 129                        | 82 (17)            | 6                         |
| Shingles               | 132                        | 79 (17)            | 7                         |
| Stinging Insects       | 131                        | 66 (21)            | 5                         |
| Swimmer’s Ear          | 131                        | 68 (21)            | 6                         |
| Urinary Tract Infection| 131                        | 66 (22)            | 5                         |
| Vaginal Yeast Infection| 131                        | 84 (19)            | 5                         |
randomly selected patient cases. Four cases were written and used for the initial assessment. All six of the students who did not reach competency during the initial assessment each correctly completed one of their two patient cases but did not correctly evaluate and treat/refer their second case. For remediation, each student was given an additional patient case developed for the remediation examination. All six students met competency on the remediation case.

Of 132 student pharmacists, 127 (96.2%) completed the pre-seminar survey and 126 (95.5%) completed the post-seminar survey (Table 4). Questions 1, 2 and 4 all were significantly different from the pre- to post-survey while question 3 showed no difference. In question 1, I am comfortable providing the services included in the Clinical Community Pharmacist Training, the significant difference occurred because of all the students moving from the “neither agree or disagree” category to the “agree” category. For question 2, I am comfortable recommending implementation of these services in a community pharmacy, the difference occurred because of the students moving from “agree” and “neither agree or disagree” in the pre-test to “strongly agree” in the post-test. There were no differences found in question 3, if I owned a community pharmacy I would implement these services. In question 4, I am comfortable with knowing when to treat and when to refer patients for the services included, the difference was from the students moving from “neither agree or disagree” to “strongly agree,” pre- to post-survey, respectively. Student responses to questions 1, 2, and 4 all were significantly different between the pre- and post-seminar surveys, while responses to question 3 showed no significant change. Mean responses to question 1, “I am comfortable providing the services included in the Clinical Community Pharmacist Training,” changed from neither agree or disagree on the pre-seminar survey to agree on the post-seminar survey. Mean student responses on question 2, “I am comfortable recommending implementation of these services in a community pharmacy” changed from agree and neither agree or disagree on the pre-seminar survey to strongly agree on the post-seminar survey. Finally, mean student responses on question 4, “I am comfortable with knowing when to treat and when to refer patients for the services included,” changed from neither agree or disagree on the pre-seminar survey to strongly agree on the post-seminar survey.

Of the 132 students enrolled in the class, 114 students (86.4%) chose to pay to receive the WSPA CCP training certificate. Approximately 67% of the students completed one or more of the five additional modules to add to their list of skills on the certificate (Table 5).

**DISCUSSION**

This innovative training module design enhanced student confidence to deliver patient care services in a community setting. By providing this training to future pharmacists, we are preparing practitioners who are passionate about expanding the role of the community pharmacist to include treatment of minor ailments and conditions, increasing patient access to care, improving patient quality of life, and reducing the burden to the health care system. The researchers believe that the high number of students choosing to pay for the optional certificate illustrates the value students place in this training.

The live seminar training session has already expanded beyond student use in Washington. An ongoing funded research project is using the WSPA CCP modules as well as the eight-hour live training session with five community pharmacy chains throughout Washington. Pharmacists involved in the study go through the training with the live session facilitated by a WSU COP faculty member prior to implementation of services. The three-year study aims are to evaluate the feasibility and sustainability of the community pharmacy-provided patient care services.

| Survey Questiona | Strongly Agree | Agree | Neither Agree or Disagree | Disagree | Strongly Disagree | p-value |
|------------------|----------------|-------|---------------------------|---------|------------------|---------|
| I am comfortable providing the services included in the Clinical Community Pharmacist Training | Pre 22 | 75 | 24 | 5 | 0 | .019 |
| | Post 25 | 94 | 6 | 0 | 0 | |
| I am comfortable recommending implementation of these services in a community pharmacy | Pre 26 | 70 | 24 | 5 | 0 | .012 |
| | Post 46 | 63 | 14 | 4 | 0 | |
| If I owned a community pharmacy I would implement these services | Pre 66 | 51 | 7 | 2 | 0 | .68 |
| | Post 65 | 43 | 15 | 2 | 0 | |
| I am comfortable with knowing when to treat and when to refer patients for the services included | Pre 20 | 78 | 21 | 6 | 1 | .01 |
| | Post 34 | 79 | 12 | 1 | 0 | |

aPre-seminar survey: 127/132 students (96.2%); Post-seminar survey: 126/132 students (95.5%)
Table 5. Completion Rates for Optional Washington State Pharmacy Association Clinical Community Pharmacist Modules\textsuperscript{a}\textsuperscript{b} (N=132)

| Module Title   | Students Completing Module, No. |
|----------------|---------------------------------|
| Anaphylaxis    | 91                              |
| Bronchospasm   | 90                              |
| Contraceptives | 89                              |
| Insulin refill | 89                              |
| Fluoride       | 87                              |

\textsuperscript{a}One hundred thirty-two students completed the course. The table shows the number of students who completed each optional module. Some students completed more than one of the optional modules.

Pharmacists are often underutilized in community settings, partly because of a lack of recognition by payers to bill health insurance, as reported by the National Governors Association.\textsuperscript{15} The barrier of pharmacists credentialing and privileging has been overcome with recent legislation in Washington that requires that by 2017 private health insurers include pharmacist decision-making that complies with individual state regulations regarding CDTAs and pharmacist-provided advanced patient care services. The online module content is updated by the WSPA to follow current practice guidelines, which allows for increased sustainability of the program by users.

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This innovative approach could easily be implemented within other colleges and schools of pharmacy. The WSPA CCP training modules are available online to both association members and nonmembers, with discounted rates for student pharmacists. Programs can select to include a live training session to hone skills, or can solely use the online modules. The live training session can be customized through development of patient cases and pharmacist decision-making that complies with individual state regulations regarding CDTAs and pharmacist-provided advanced patient care services. The online module content is updated by the WSPA to follow current practice guidelines, which allows for increased sustainability of the program by users.

Future modifications are being considered by faculty members at the WSU College of Pharmacy. For research purposes, a survey was not conducted prior to students beginning the online modules and the pre-seminar and post-seminar surveys were not pretested. This information would strengthen the results as each step in the education process could be compared in a before/after fashion. Additional content on financial considerations such as reimbursement and insurance adjudication is being considered as well. Finally, consideration is being given to changing the patient case practical examination to an objective structured clinical examination (OSCE) to create a more authentic scenario for assessment and the addition of more information regarding the creation of a CDTA, including how to find a physician.

Another limitation of this research is the newness of this course. Without previous data points or comparators from other universities we only have one data point. Future course data will be useful in comparing year-to-year results. The student pharmacists who received the training will not graduate until 2018. Ideally, with newly graduated pharmacists adding clinical services into their practices, future student pharmacists will be able to participate in IPPEs and APPEs at community practice sites where these services already exist, adding further to the expansion of knowledge and practice in this area.

SUMMARY

An innovative content and delivery approach was successful in developing a course designed to increase the knowledge base and comfort level of student pharmacists to provide needed direct patient care services in a community pharmacy setting. The results of the surveys showed an increase in student pharmacists’ comfort level with providing these services, recommending that services be implemented, implementing the services themselves if they owned a pharmacy, and in understanding when to treat or refer after completion of the live seminar.

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