RESEARCH

Implementation of an Opioid Overdose and Naloxone Distribution Training in a Pharmacist Laboratory Course

Min Kwon, PharmD,a Ashley E. Moody, PharmD,b Jonathan Thigpen, PharmD,b,c Andrea Gauld, PharmDb

a Sinai Hospital, LifeBridge Health, Baltimore, Maryland
b Notre Dame of Maryland University, School of Pharmacy, Baltimore, Maryland
c Editorial Board Member, American Journal of Pharmaceutical Education, Arlington, Virginia

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Objective. To describe the instructional design, implementation, and evaluation of an opioid overdose response program (ORP) and opioid overdose education and naloxone distribution (OEND) training program to third-year pharmacy (P3) students.

Methods. Using the 5-E learning cycle during a three-hour laboratory session, the authors developed an OEND training program. The training began with an engagement exercise encompassing validated pre-Opioid Overdose Knowledge Scale (OOKS) and pre-Opioid Overdose Attitudes Scale (OOSAS) assessments. Directly after, students moved to the exploration phase of the program, which consisted of two stations with placebo naloxone products. There, instructors explained key content related to OEND. Students applied what was learned during the elaboration by completing two cases: using group-based point-by-point counseling as well as a scenario with a simulation patient manikin. The class ended with an evaluation exercise that involved completing post-OOKS and post-OOAS.

Results. Fifty-six students participated in the ORP certification and OEND training. Significant increases in total scores were seen on the pre- and post-assessment. Additionally, significant increases in student confidence in providing overdose response counseling and dispensing naloxone were observed. Students rated all the learning activities as very effective.

Conclusion. Use of the 5-E learning cycle as an educational design method to structure active-learning activities was effective in increasing students’ knowledge and improving their attitudes toward and confidence in providing overdose response.

Keywords: naloxone, opioid, opioid overdose, overdose response program, overdose education and naloxone dispensing

INTRODUCTION

Pharmacists play a vital role in preventing opioid overdose-related deaths by educating patients and providers, increasing access to naloxone, and disseminating information in the community.1-3 Several successful models of community pharmacy-based opioid overdose education and naloxone distribution (OEND) programs have been described in the literature, specifically programs based in Rhode Island and Massachusetts.3 However, barriers to implementation remain, including legal misconceptions about prescribing, dispensing, and use, and the need for education and advocacy at the health care provider level.1,3

An opportunity exists to decrease the gaps in training, increase knowledge, and resolve misconceptions that may pose barriers to pharmacist participation in OEND. One way to address this gap is to incorporate OEND education and training within the pharmacy curriculum. This addition offers schools a unique way to address Standard 3 of Accreditation Council for Pharmacy Education (ACPE) Standards 2016, further expanding students’ ability to demonstrate communication, patient education, and advocacy.4 In addition, training may help schools achieve the Center for Advancement of Pharmacy Education (CAPE) objectives Domain 2.1, by allowing students to practice patient-centered care.5

There are limited studies describing effective implementation and assessment of OEND training with pharmacy students. Monteiro and colleagues focused on increasing student knowledge, skills, and attitudes toward opioid misuse through an interprofessional workshop.6 The forum included a patient panel, a simulated standardized patient encounter, a case discussion session focused on an individual who was misusing opioids, and naloxone
training. Although health professional students from medicine, nursing, pharmacy, social work, and physical therapy were included, pretest and posttest assessments adapted from the Opioid Overdose Knowledge Scale (OOKS) were only administered to medical students from the host institution. The OOKS results demonstrated a significant increase in knowledge. More specific to pharmacy, Schartel and colleagues examined the implementation and assessment of an overdose management and naloxone administration training program for first-year (P1) pharmacy students in a laboratory course using an objective structured clinical examination (OSCE) for assessment. However, only one type of naloxone administration device was assessed. Additionally, students were only taught about naloxone administration, and changes in students’ attitudes toward overdoses were not assessed.7

In October 2015, the Maryland General Assembly passed a law that expanded public access to naloxone. This law allowed anyone access to naloxone, either with a prescription or through a standing order at a community pharmacy, if they first completed training through a certification-based overdose response program (ORP) authorized by the Maryland Department of Health.2

Faculty members at Notre Dame of Maryland University School of Pharmacy recognized a need to implement an ORP certification program for pharmacy students to assess students’ knowledge and attitudes toward opioid overdose and naloxone distribution. We describe the instructional design, implementation, and evaluation of an ORP certification training program for P3 pharmacy students in a required course.

**METHODS**

In February 2017, the pharmacy school applied for and received ORP authorization from the Maryland Department of Health. The course coordinator designed and developed an ORP certificate and OEND training for the third-year (P3) Pharmacist Care Laboratory course, and two faculty members assisted with implementation. The course coordinator designed and developed the OEND program, and two faculty members assisted with implementation. The program consisted of the core curriculum set forth by the Maryland Department of Health, which focused on reducing harm to the patient, recognizing the signs of opioid overdose, using naloxone products properly, and learning the steps to opioid overdose response. We expanded the program to include: naloxone placebo product stations, simulated patient case scenarios, assessment rubrics, content on legal parameters related to pharmacists dispensing naloxone, and completion of the OOKS and Opioid Overdose Attitudes Scale (OOAS). Learning activities were structured using the 5-E learning cycle, an instructional design method.

Fifty-six P3 pharmacy students enrolled in the final module of the six-semester Pharmacist Care Laboratory course sequence were included in the ORP certification and OEND training program. The goal of the Pharmacist Care Laboratory course was to apply information and skills taught throughout the curriculum. Students were assigned to one of three 3-hour sessions, with approximately 18 to 20 students enrolled in each session. All faculty members involved were ORP certified and designated as trainers, meaning they had both observed and taught a previous ORP session. Each laboratory section was led by one faculty member with support from four, fourth-year (P4) pharmacy students on an advanced pharmacy practice experience (APPE). The learning objectives of the ORP were for participants to be able to:

describe harm reduction and epidemiology of opioid overdoses as well as associated statistics in the state of Maryland; identify at-risk patients; recognize signs and symptoms of an overdose; counsel a patient/caregiver on how to respond to an overdose via the proper use of various naloxone products; and understand how to dispense naloxone in accordance with Maryland state law.

To ensure incorporation of active-learning strategies for student engagement, the Pharmacist Care Laboratory course used the 5-E learning cycle as an instructional method to design laboratory activities (Figure 1). The cycle consists of five instructional phases. The first phase is engage and involves an activity that serves to promote curiosity and to elicit students’ prior knowledge. The second phase is explore, and involves an activity that allows students to explore content and construct their own understanding. The third phase is explain, and involves an activity that allows the instructor to facilitate understanding and building of concepts introduced during the prior engagement and exploration activities. The fourth phase is elaborate, and involves completing additional activities that allow students to apply understanding of concepts to broaden their skills. The fifth phase is evaluate, during which faculty members have the opportunity to assess student’s understanding and abilities.9 The activities for the school’s ORP were therefore designed according to the 5-E learning cycle.

The engagement activity for the ORP involved each student completing an OOKS and OOAS during the first 15 minutes. The OOKS and OOAS are validated scales that can be used to evaluate naloxone training. The OOKS is a 45-item questionnaire that assesses the level of knowledge of overdose management in four domains: risk factors for having an opioid overdose; signs of an opioid overdose; actions to be taken in an overdose situation; and
naloxone effects, administration, adverse effects, and aftercare procedures. The OOAS is a 28-item questionnaire aimed to evaluate attitudes towards managing an overdose in three domains: competence, concerns, and readiness. Competence is the student’s self-perceived ability to manage an overdose. Concerns are the student’s apprehensions about dealing with an overdose. Finally, readiness is student’s willingness to intervene in an overdose situation. Completion of the OOKS and OOAS helped engage students while assessing their baseline knowledge and attitudes on the topic. Once the questionnaires were completed, the faculty members used the next 20 minutes to present introductory material consisting of epidemiology of opioid-related deaths in Maryland, the concept of harm reduction, defining an opioid, risk factors, and signs and symptoms of an overdose.

For the exploration activity, students were divided into groups that rotated through two 15-minute naloxone stations focusing on intramuscular (IM) and intranasal (IN) naloxone products. The stations had instructional handouts and four placebo training devices: Evzio (kaleo Inc., Richmond, VA), vial (sterile water to mimic vial) and syringe, Narcan (ADAPT Pharma Inc., Radnor, PA) and Luer-Jet prefilled syringe with atomizer (Wallcur, China). Groups were led by P4 students who each educated approximately five P3 students. The P4 student initiated the activity, described appropriate background information, observed the P3 students’ demonstrations, and guided them as they clarified their understanding. While examining the products, they also completed a fill in the blank naloxone information table. The table guided learners to identify key information related to route of administration, injection sites, treatment dose, supplies needed to administer the dose, storage, expiration, disposal, and administration for each of the products.

Following the exploration activity, students reconvened as a large group for the explanation phase of the 5-E cycle to discuss the key concepts from the exploration table and to learn about responding to an overdose. During this 30-minute portion, the following information was reviewed as a class and discussed: appropriate steps for responding to an overdose, the Maryland Good Samaritan Law, MDH ORP certification specifications and regulations, and pertinent knowledge related to dispensing naloxone, such as price. The P4 students and faculty members also shared real life experiences and strategies for counseling patients on the use of naloxone and overdose response.

The elaboration activity consisted of each student completing two 25-minute case simulations where students had to apply what they learned to a new situation. The first case, a counseling scenario, required the students to counsel a patient on recognizing the signs and symptoms of an overdose, how to respond to an overdose, and how to administer a naloxone product. This simulation was led by one P4 student who coached about five students conducting counseling. At the end of the counseling, the P4 student provided feedback about strategies for improvement. The second simulation involved the use of SimMan, a simulation patient manikin, to allow students the opportunity to apply the five steps of an overdose response. Students were divided into pairs and instructed to read the information provided to them prior to entering the room. The scenario consisted of a man (the manikin) with a history of heroin use lying on the floor, unresponsive. Upon entering the room, students had five minutes to respond appropriately. One P4 student or faculty member observed the students’ performance and provided feedback using a rubric. The rubric was used to assess the students’ ability to: rouse and stimulate the patient, call 911, administer naloxone (Evzio), provide further resuscitation; and provide care for the patient until help arrived.

The class ended with a 15-minute evaluation phase where students were asked to complete a post-training OOKS and OOAS. Performance on the OOKS was calculated using a 10-point scale and averaged into the students’ weekly grade. They also received ORP certification upon completion of the session.

To assess students’ competency and retention of the knowledge they learned during the training session,
naloxone counseling was included as part of the final examination. The final examination included a station where students were given 10 minutes to counsel a standardized patient about the signs and symptoms of opioid overdose, how to respond, and how to administer a randomly assigned naloxone product. A rubric was used to assess student performance and patient’s understanding of the student’s counseling through the use of the teach back method. Students were given advanced notice that the station would be included on the final examination. Sessions were recorded using B-Line Medical-SimCapture (Laerdal Company, Washington, DC), a system for recording in-person simulations. Two faculty members reviewed the videos and used the rubric to assess student performance.

The OOKS, OOAS, and OEND training survey were administered at the beginning and end of class. Students rated their level of confidence in seven areas of practice in the OEND training survey using the following Likert scale: 1 = not at all confident, 2 = not very confident, 3 = somewhat confident, 4 = very confident, and 5 = extremely confident. In addition, students were asked to rank the effectiveness of the varying learning activities and methods used.

Paired t tests were used to assess changes (pretest vs posttest) in student scores for the OOAS, OOKS, and OEND training survey (Tables 1 and 2). Differences were determined significant at $p < .05$. Additional descriptive analyses were performed. All analyses were performed using SPSS, Version 23 IBM Corp, Armonk, NY. This study was approved as exempt research by the Institutional Review Board of Notre Dame of Maryland University.

RESULTS

Fifty-six students completed the laboratory training and received ORP certification. Students scored a mean (SD) of 33.3 (4.4) out of 45 total points on the pre-OOKS. Baseline knowledge subcategory points were lowest in areas of signs of an overdose (mean = 6.5; SD = 1.3) and naloxone effects, administration, and aftercare procedures (mean = 9.7; SD = 2.8). At the end of the laboratory session, a significant increase in knowledge was observed between pretest and post-test OOKS in both total scores and in all four subcategories (risk, signs, action, and use of naloxone); all $p$ values were $< .001$ (Table 1).

Similarly, significant increases in positive attitudes toward opioid overdose management were observed by the end of the training via OOAS. Improvement was seen in students’ self-perceived attitude in competence, concerns, and readiness to manage an opioid overdose (Table 1). Mean total score increased from 93.3 pretest to 120.4 posttest ($p < .001$) out of 140 total points.

Students’ confidence in providing OEND significantly improved in all seven areas by the end of the program (Table 2). Highest mean changes were observed for the following: students’ confidence to dispense naloxone (2.5, $p < .001$), counsel a patient on administration of all forms of naloxone (2.6, $p < .001$), and counsel on how to rouse and stimulate a patient who may have overdosed (3.0, $p < .001$).

Students’ evaluation of the effectiveness of the various learning activities used in the laboratory training session ranged from mean (SD) of 4.4 (0.6) to 4.7 (0.5). The learning activities at stations one and two, where students received hands-on experience on how to use and administer the various naloxone products, received the highest mean scores (4.7, SD = 0.5 and 4.7, SD = 0.5). Use of a PowerPoint slide presentation received the lowest mean (SD) score of 4.4 (0.6).

On the final examination, where students counseled a standardized patient on overdose response and naloxone administration, students scored a mean (SD) of 15.2 (2.0) out of 17 total points. This would convert to a mean (SD) score of 89% (2.0). Student performance in the individual areas in providing counseling on opioid overdose

Table 1. Pharmacy Students’ Opioid Overdose Knowledge and Attitudes Before and After Completing Laboratory Training

| Area         | Responses | Total Possible | Pre-training Mean (SD) | Post-training Mean (SD) | Mean Change (95% CI) | $p$ Value |
|--------------|-----------|----------------|------------------------|-------------------------|----------------------|-----------|
| Total OOKS   | 56        | 45             | 33.3 (4.4)             | 41.9 (1.6)              | 8.6 [7.5, 9.7]       | < .001    |
| Risk         | 56        | 9              | 7.0 (2.0)              | 7.9 (1.2)               | 0.9 [0.4, 1.4]       | < .001    |
| Signs        | 56        | 10             | 6.5 (1.3)              | 8.6 (0.8)               | 2.1 [1.6, 2.5]       | < .001    |
| Action       | 56        | 11             | 10.1 (0.9)             | 11 (0.2)                | 0.9 [0.6, 1.1]       | < .001    |
| Naloxone     | 56        | 15             | 9.7 (2.8)              | 14.5 (0.7)              | 4.8 [4.0, 5.5]       | < .001    |
| Total OOAS   | 47        | 140            | 93.3 (9.8)             | 120.4 (10.3)            | 27.2 [23.7, 30.6]    | < .001    |
| Competence   | 52        | 50             | 23.8 (6.4)             | 41.9 (4.1)              | 18.1 [16.1, 20.1]    | < .001    |
| Concerns     | 54        | 40             | 27.8 (3.7)             | 33.1 (6.5)              | 5.3 [3.6, 7.0]       | < .001    |
| Readiness    | 51        | 45             | 40.9 (5.6)             | 44.6 (4.0)              | 3.6 [2.2, 5.1]       | < .001    |

Abbreviations: OOKS = Opioid Overdose Knowledge Scale, OOAS = Opioid Overdose Attitude Scale
response and naloxone counseling is reported in Table 4. Of the three naloxone products given for the counseling scenario, the lowest mean score was observed for counseling on the administration of intranasal naloxone using an atomizer, mean (SD) of 4.0 (1.1). Evzio was not used during the final examination counseling station because of its automated voice instruction capability.

**DISCUSSION**

As the opioid epidemic continues to worsen in the United States and community access to naloxone has become essential, there is more emphasis on the pharmacists’ role in providing opioid overdose response and naloxone counseling. To the authors’ knowledge, this is the first study capturing pharmacy students’ knowledge and attitude towards managing an opioid overdose at baseline and after ORP certification and OEND training. We described the use of the 5-E learning cycle in the implementation of a certification and training program that focused on opioid overdose response, naloxone administration, and distribution to P3 pharmacy students in a laboratory course. The Pharmacist Care Laboratory course underwent curriculum revision in which inclusion of the ORP certification was planned for the P3 year as students were exposed to the role of opioids in pain management in a prior pharmacotherapy course.

Although there are few studies describing implementation of an ORP and OEND certification program in the pharmacy curriculum, Schartel and colleagues describe implementation and assessment of a naloxone training program for P1 students in an abilities laboratory course. In that study, the focus of assessment was on students’ ability to counsel a standardized patient on intranasal naloxone use in an opioid response during an OSCE. On average 82% and 93% of students either agreed or completely agreed that the OSCE improved their confidence in counseling about management of opioid overdose. Their results were similar to those of our study, with students receiving a mean score of 89% on their final assessment with a standardized patient. The use of simulation helped improve students’ confidence in providing naloxone education and counseling. However, the impact of the training program on students’ ability to respond without use of validated assessments, like OOKS and OOAS, limits interpretation. Furthermore, the impact...
of learning from other activities used in the training program (pre-laboratory questions, lecture, and practice counseling) was not assessed. Monteiro and colleagues describes implementation of an interprofessional workshop focusing on increasing students’ knowledge, skills, and attitudes toward opioid misuse.6 Second-year pharmacy, medical, nursing, and physical therapy students, and first-year social work students were grouped into small interprofessional teams. Each interprofessional team rotated through stations consisting of a patient panel, naloxone training, standardized patient case simulation, and a case study. A pre and post-OOKS was completed by medical students only. Pre-knowledge scores were lowest in the areas of naloxone effect and duration of naloxone effect. While the study did not report the full OOKS assessment, results were comparable to our study in that pharmacy students’ pre-knowledge scores were also lowest in the area of naloxone effects, administration, and aftercare procedures. Furthermore, although students had some instruction on opioids in a pharmacotherapy course prior to entering the ORP certification, the focus was on pain management vs overdose.

Table 3. Pharmacy Students’ Perception of the Effectiveness of Laboratory Activities in Learning About Opioid Overdose and Naloxone Distribution

| Responses | N = 56 | M (SD) |
|-----------|--------|--------|
| PowerPoint Presentation | 51 | 4.4 (0.6) |
| Station 1: hands on experience on how to use/administer differing forms of injectable naloxone | 56 | 4.7 (0.5) |
| Station 2: hands on experience on how to use/administer differing forms of intranasal naloxone | 56 | 4.7 (0.5) |
| Case simulation with simulated patient/family member in which you counseled on signs and symptoms of overdose, how to respond to an overdose, and how to administer a given naloxone product. | 56 | 4.6 (0.5) |
| Case simulation in which you provided overdose response by applying the 5 steps learned to a patient who may have overdosed. | 56 | 4.6 (0.5) |

Students ranked effectiveness of learning activity or method on a Likert scale as follows: 1=not at all effective, 2=not very effective, 3=somewhat effective, 4=very effective, and 5=extremely effective

Table 4. Pharmacy Student Performance on Final Examination Counseling Station with a Standardized Patient on Opioid Overdose Education and Naloxone

| Response | N = 56 | Maximum Points | Mean Points Earned (SD) | Mean % (SD) |
|----------|--------|---------------|------------------------|-------------|
| Total Score | 56 | 17 | 15.2 (2.0) | 89 (2.0) |
| Introduced him/herself and profession | 56 | 1 | 1 (0.00) | 100 (0.0) |
| Verified OEND certification | 56 | 1 | 0.9 (0.3) | 93 (0.3) |
| Inquired about situation regarding use of naloxone | 56 | 1 | 0.9 (0.4) | 86 (0.4) |
| Counseled on signs and symptoms of opioid overdose | 56 | 3 | 2.8 (0.7) | 92 (0.7) |
| Counseled on how to respond to an opioid overdose | 56 | 5 | 4.5 (0.8) | 89 (0.8) |
| Counseled on how to use/administer naloxone product: vial and IM | 15 | 5 | 4.3 (0.8) | 87 (0.8) |
| Counseled on how to use/administer naloxone product: Narcan IN | 16 | 5 | 4.4 (1.0) | 88 (1.0) |
| Counseled on how to use/administer naloxone product: Naloxone Amphastar IN via Atomizer | 25 | 5 | 4.0 (1.1) | 81 (1.1) |
| Had patient/family demonstrate understanding using teach back method | 56 | 1 | 1.0 (0.2) | 95 (0.2) |
By the end of our training, pharmacy students’ scores in all four subcategories significantly increased, thereby meeting the learning objectives for the program. Students’ retention of knowledge over time is also important to capture, but was not formally reassessed using the OOKS during the final examination. However, students’ performance on counseling and educating a patient about overdose response and naloxone use was assessed during the final examination with a standardized patient. Students scored a mean of 89%, in which 96% of students scored at or above the 70% achievement level.

The impact on pharmacists’ self-perceived readiness to act is critical to ensure that pharmacists feel prepared to participate in providing OEND. Based on the pre-OOAS score, students had an overall score of 93.3 out of a possible 140 points. By the end of the certification and training laboratory, students’ total score significantly increased to 120.4, indicating students had an increased positive attitude toward managing an overdose. Although a significant increase was seen in all three subcategories, the largest increase was seen in competence (mean change of 18.1 points). Competence assessment grouped question items on the OOAS self-perceived ability to manage an overdose. These results align with the OEND training survey in which student’s confidence in overdose education and naloxone use also increased significantly in all seven categories. Increases were observed in students’ self-confidence to dispense naloxone, counsel a patient about the signs and symptoms of opioid overdose, and in knowledge of the five steps to providing overdose response. Also, competence scores increased on the OOAS assessment, which indicated students’ willingness to act in providing overdose response.

In our study, intentional use of an instructional learning model laid the foundation for designing and structuring the learning activities. The 5-E learning cycle is an explicit pedagogical principle that carefully provides structured learning sequences of instruction where the student is placed at the center of the learning experience. Although the 5-E instructional cycle is not a novel teaching methodology, its application to a pharmacy curriculum is not well documented in current literature. The 5-E learning cycle was identified as a mode of instructional design for the Pharmacist Care Laboratory course because of its tool-like means, in which the five instructional phases allow for a standardized and structured approach to teaching the skills. Pharmacy student’s perceptions about the effectiveness of the laboratory activities in the ORP certification were generally positive. On a scale of 1 (not at all effective) through 5 (extremely effective), naloxone stations and case simulation received a mean score range of 4.6 to 4.7. The slide presentation component was viewed to be the least effective learning method, receiving a mean score of 4.4.

Use of simulation, placebo naloxone products, and presentation has been described by Monteiro and colleagues and Schartel and colleagues. However, intentional sequencing or structuring of activities to facilitate learning is not well described. Although simulations and placebo naloxone products were used in the aforementioned studies, our simulations focused on counseling a patient about overdose response and administration of all four naloxone products, and a SimMan was used to teach students to perform overdose response.

Based on anecdotal feedback, faculty members realized that local pharmacists and prescribers had misconceptions about the legal and ethical aspects around dispensing naloxone under the new state naloxone accessibility law. Because of this, faculty members intentionally included and addressed information in training sessions related to the following topics: concept of harm reduction, impact of providing naloxone in overdose-related deaths, misconceptions about the impact of making naloxone available, the state Good Samaritan Laws protecting pharmacists, naloxone certification specifications and regulations, and dispensing. It is also important to include ORP certification and OEND training, as legal misconceptions about naloxone and ethical considerations (ie, pharmacist refusing naloxone to certain patients) have been described as barriers to pharmacy-based naloxone distribution in literature.

A limitation of our study is the small sample size of 56 students. Therefore, results may not be generalizable to other pharmacy students and/or other institutions. Although use of a control group could have strengthened the overall evaluation, use of a validated OOKS and OOAS and significant changes in pre- and post-intervention scores can be used as markers to show the effectiveness of the training provided. Also, the original focus of the ORP certification and OEND training was on design, implementation, and achievement of educational outcomes.

Adaptation of the ORP certification and OEND training program by another school is feasible and would only require revision to state laws regarding naloxone dispensing and distribution. Associated costs were limited to copying materials. All placebo naloxone products used in the stations were obtained free from the manufacturers. Atomizers were obtained by faculty members through donations from a local pharmacy. Therefore, naloxone stations would be very easy to replicate. Use of an APPE student to help facilitate stations and counseling would also be feasible and a means to integrate trainers for the program. Although most schools of pharmacy might not have access to SimMan for live simulations, APPE students or standardized patients could also be used as the parameters for the simulation are minimal (nonresponsive).
CONCLUSION

An ORP certification and OEND training were developed using the 5-E learning cycle and implemented in the third-year Pharmacist Care Laboratory course. Significant changes in both knowledge and attitudes were seen post certification and training. Increases in students’ confidence in dispensing naloxone, counseling a patient on the signs and symptoms, and the five steps to overdose response were also observed. Students also met competency in providing counseling on overdose response and naloxone use on a final examination administered weeks later. Finally, students reported that the use of active learning was very effective.

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