Generating a Future Vision of Patient Safety: A Pilot Program to Test the Integration of Certified Professional in Patient Safety™ Curriculum into Undergraduate Medical Education

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ABSTRACT: Preventable healthcare-associated harm results in significant morbidity and mortality in the United States, costing nearly 400,000 patient lives annually. The Institute for Healthcare Improvement provides high-quality educational resources tailored for working healthcare professionals. One such resource is the Certified Professional in Patient Safety (CPPS™) review course, which equips professionals with advanced proficiency in 5 core patient safety domains. The CPPS™ certification is the only interprofessional, patient safety science credential recognized worldwide. In 2010, the Lucian Leape Institute at the National Patient Safety Foundation described the critical need for medical students to participate in patient safety solutions as well. However, equivalent patient safety credentialing remains challenging for students in the preclinical and clinical stages of training to obtain. To address this growing dilemma, the Texas College of Osteopathic Medicine (TCOM) piloted the first-of-its-kind CPPS™ course with 10 medical students to test a novel, academic-level approach to patient safety curriculum. Medical students showed large gains in performance on the post-test (83.18% ± 26.12%) compared to the pre-test (46.46% ± 27.18%) (P < .001, η² = .368), representing increased knowledge across all learning domains. On the national certification examination, students had a 90% first-time pass rate, exceeding the current national average of 70% for first-time examinees. In satisfaction surveys, students expressed the value of pilot curriculum for their medical training, the importance of similar Patient Safety Education and CPPS certification for all medical students, their confidence as future healthcare change agents. Content analysis of open response questions revealed 3 key areas of strength and opportunity for guiding future iterations of the course. This pilot generates a future vision of patient safety, equipping students with critical knowledge to systematically improve healthcare quality.

KEYWORDS: Patient safety, education medical undergraduate, education medical graduate, curriculum, credentialing, pilot projects, safety, safety management, United States

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Introduction

Healthcare-associated harm results in significant morbidity and mortality worldwide. A meta-analysis using a trigger tool to analyze medical records estimated that preventable harm may cost more than 400,000 patient lives each year in the United States.1,2 Mortality is only a fraction of the story, as some studies have predicted that the rate of patient harm in the hospital-setting has reached between 25% and 33% of all care.3-6

The Institute for Healthcare Improvement (IHI) provides safety science education tailored for healthcare professionals. One such resource is the Certified Professional in Patient Safety (CPPS™) review course, equipping candidates to sit for the CPPS™ certification exam. This certification attests that professionals have reached advanced proficiency in 5 core domains of patient safety: Culture, Leadership, Patient Safety and Risk Solutions, Measuring and Improving Performance, and Systems Thinking and Design/Human Factors. The CPPS™ certification is the only interprofessional, patient safety science credential recognized worldwide. It has been earned by healthcare professionals spanning diverse backgrounds, representing all 50 U.S. states and 20 countries. Currently, certification requires a combination of education, 3 to 5 years of direct clinical experience and successful completion of the evidence based CPPS™ exam.

For those healthcare professional students in the pre-clinical and clinical phases of medical training in the United States, patient safety credentialing is challenging to obtain. A recent systemic review of patient safety curriculum in undergraduate medical students was decisively sparse, with relatively few studies being published on integrating patient safety education into U.S. medical curriculum.7 The Lucian Leape Institute8 at the National Patient Safety Foundation issued a the Unmed Needs: Teaching Physicians to Provide Safe Care report describing the critical need to ensure that undergraduate medical students are appropriately trained to become part of the patient safety solution. To address this growing dilemma, the Texas College of Osteopathic Medicine (TCOM) pilot program was developed to investigate whether qualified medical students could prepare...
for and achieve CPPSTM certification. This effort was accomplished through collaboration between IHI’s national safety programs office, TCOM, University of North Texas Health Science Center (UNTHSC), and SaferCare Texas to design a custom 6-week course, using a flipped classroom model and the IHI CPPSTM Review Course modules.

Methods

Participant selection

Applications for 10 scholarships were opened for TCOM’s rising second year medical students to participate in the Patient Safety Pilot. To qualify for selection into the course, participants were required to meet the following criteria:

- Active membership in the IHI Open School—Fort Worth Chapter
- Evidence of good academic and disciplinary standing with TCOM and UNTHSC
- Validated experience in a healthcare setting, including time spent in direct clinical exposure, clinical rotations, and residency training.

Pilot structure

The pilot was implemented from June 4 to July 8, 2019, utilizing the IHI Online CPPSTM Review Course materials supplemented by subject matter expert discussions. The course content was divided into 5 in-person learning sessions, each focusing on the 5 safety domains tested on the CPPSTM certification exam (ie, Culture, Leadership, Patient Safety & Risk Solutions, Measuring & Improving Performance, Systems Thinking & Design/Human Factors). Course instruction during these sessions utilized a flipped classroom model, in which students reviewed print, audio, and video material before attending learning sessions. The purpose of sessions was to facilitate active learning and knowledge application by solving case-based scenarios. Before the final session, students completed an online CPPSTM Practice Exam offered by Certification Board for Professionals in Patient Safety (CBPPSTM). The rationale for best answers were discussed during the final session to promote optimal cognitive discernment.

Pre- and post-course assessments

Students completed a 22-item Qualtrics-based assessment before and after the Patient Safety Pilot to evaluate changes in competency across the 5 domains. The questions were formatted similarly to those found in the IHI Online CPPSTM Review Course Comprehension Checks and the online CPPSTM Practice Examination.

Practice examination

During the final week of the course, students completed an online practice examination administered by PSI Testing Services, the official testing partner of CBPPS. Students then brought their results to the final classroom session to discuss the rationale for best answers and promote optimal cognitive discernment.

Course satisfaction survey

Following the Patient Safety Pilot Program, students were asked to complete an online satisfaction survey. This survey consisted of 9 Likert-type items and 3 open-ended questions. Responses on Likert-type items ranged from 1 = “Strongly Disagree” to 5 = “Strongly Agree”.

Core measures

Prior to pilot implementation, an evaluation plan was created considering that TCOM would not have access to IHI’s online CPPSTM Review Course comprehension check results for each student. Four criteria were selected to assess course effectiveness and overall success:

1. Completion of online pre-test assessment on the first day of class
2. Completion of online post-test assessment on the last day of class
3. Completion of a course satisfaction survey and qualitative assessment completed on the last day of class
4. Completion of the CPPSTM certification examination within 2 weeks of the course ending date, scheduled at the convenience of participants at an off-site PSI Testing Center.

Institutional Review Board approval

All data were collected as part of the patient safety pilot course (June 4–July 8, 2019). Prior to data analysis, the North Texas Institutional Review Board rendered our investigation exempt from IRB review under the provisions of 45 CFR 46.104 (d), category (1) and category (4)(ii).

Data analysis

For the pre- and post-test assessments, factorial ANOVA was used to compare changes in overall and domain-specific performance. The dependent variable was Assessment Score measures before and after the pilot implementation. The between-subjects independent variables were Time (ie, score measurement before and after the pilot) and Learning Domain (ie, Culture, Leadership, Patient Safety and Risk Solutions, Measuring and Improving Performance, and Systems Thinking and Design/Human Factors). During analysis, Shapiro-Wilk’s test of normality was performed for all levels of the independent variable. This test was significant for Post-Test Score in the Patient Safety & Risk Solutions Learning Domain. All other values were non-significant, indicating approximate normality of the data set. Levene’s Test for Homogeneity of Variance and
White's Test for Heteroskedasticity were non-significant, indicating maintenance of these assumptions. All measures of central tendency, dispersion, statistical tests and effect size estimates were calculated using IBM SPSS Statistics for Mac (Version 27.0. Armonk, NY: IBM Corp). For statistically significant results ($P < .05$), post-hoc testing was performed using Bonferroni-corrected simple main effects analysis of estimated marginal means. Although not a pre-specified endpoint of this study, additional post-hoc analysis of total time spent testing was assessed using an independent $t$-test. Graphical figures were generated using GraphPad Prism for Mac (Version 9.0. San Diego, CA: GraphPad Software Inc). All bars represent the mean and error bars represent standard deviation (SD).

For the course satisfaction survey, the percentage of positive responses (“Agree” or “Strongly Agree”) were calculated for each item and descriptive statistics were summarized into a frequency table. Open-ended questions were analyzed using conventional content analysis. Following established guidelines, our analysis began with 2 separate researchers independently generating codes, categories, and sub-categories. Researchers then compared and collaborated to establish consensus for definitive data organization. This process has been shown to minimize the bias inherent to subjective analysis and improve validity. Researchers coded the student responses for the presence “1” or absence “0” of each consensus code. Cohen’s kappa was then calculated to ensure statistically significant, substantial-to-perfect agreement between the 2 researchers’ coding of responses.

**Results**

**Medical students significantly improved performance across all learning domains following the Patient Safety Pilot**

Factorial ANOVA revealed a significant main effect of Time on Assessment Scores ($F(1, 34) = 19.79, \ P < .0001, \ \eta^2_p = .368$). Overall, medical students showed considerable performance gains on the post-test ($M = 83.18, SD = 26.12\%$), as compared to the pre-test ($M = 46.46, SD = 27.18\%$) (Figure 1A). The main effect of Learning Domain did not reach statistical significance ($F(4, 34) = 1.17, \ P = .442, \ \eta^2_p = .102$). There was also no significant Time $\times$ Learning Domain interaction effect ($F(4, 34) = 1.17, \ P = .341, \ \eta^2_p = .121$) (Figure 1B). Taken together, these data suggest that improvements in medical student performance were attributable to increased knowledge across all domains, rather than any individually. Additional analysis also revealed that students completed the post-test significantly faster ($M = 596.70, SD = 106.38\mathrm{seconds}$) than the pre-test ($M = 772.00, SD = 117.77\mathrm{seconds}$) [$t(18) = 3.493, \ P = .003, \ d = 1.56$].

**Medical students exceeded the mean passing rate on the CPPS™ Certification examination**

Within 2 weeks following course completion, all medical student participants had completed the certification exam with a first-time pass rate of 90%. This performance exceeds the current 70% average national pass rate for first-time certification exam candidates.

**Medical student feedback demonstrates high course satisfaction, as well as areas for future improvement of the Patient Safety Course**

Medical student satisfaction surveys demonstrated strong satisfaction with the course. Overall, students indicated that all 5 learning domains were important for their training, with percent positive scores ranging 90% to 100%. They further stated that all medical students should complete Patient Safety Education (100%) and become Certified Professionals in Patient Safety (90%). They also confidently indicated that this curriculum prepared them to become healthcare change agents (90%) (Table 1).

Content analysis of open-ended questions gave detailed insight into student experiences (Table 2). During class meetings, students seemed to find significant value in the flipped classroom approach. Discussion of course content and answer rationale, as well as hearing patient stories, helped identify areas for more in-depth self-study and solidify understanding of core content. However, students also asked for a larger bank...
of practice questions with dedicated time for discussion to enhance their ability to answer questions through cognitive discernment.

Students were concerned with their lack of knowledge of key regulatory and accrediting organizations, as well as safety science. They found supplemental articles and a professor-generated index of key terminology to be highly valuable for their learning experience. However, the majority of student feedback in this area recommended additional class time to cover these concepts.

| Domain-specific questions                                                                 | STRONGLY DISAGREE | SOMEWHAT DISAGREE | NEITHER AGREE, NOR AGREE | SOMEWHAT AGREE | STRONGLY AGREE | MEAN SCORE ± SD | PERCENT POSITIVE SCORE (%) |
|----------------------------------------------------------------------------------------|-------------------|-------------------|--------------------------|----------------|---------------|----------------|---------------------------|
| Culture: learning about the impact of organizational change, alongside patient and family involvement, in a culture of safety is an important part of my training. | 0                 | 1                 | 0                        | 4              | 5             | 4.30 ± 0.95     | 90.00                      |
| Leadership: learning how leadership within an organization can advocate successfully for patient safety is an important part of my training. | 0                 | 1                 | 0                        | 3              | 6             | 4.40 ± 0.97     | 90.00                      |
| Patient safety risks & solutions: understanding methods of proactive and reactive risk analysis and the impact of technology on patient safety and best practices, is an important part of my training. | 0                 | 0                 | 1                        | 3              | 6             | 4.50 ± 0.71     | 90.00                      |
| Measuring and improving performance: understanding, interpreting and applying data displays to facilitate decision making is an important part of my training. | 0                 | 0                 | 0                        | 3              | 7             | 4.70 ± 0.48     | 100.00                     |
| System thinking & design and human factors analysis: applying systems theory to improve processes for patient safety is an important part of my training. | 0                 | 1                 | 0                        | 2              | 7             | 4.50 ± 0.97     | 90.00                      |
| Curriculum-specific questions                                                          |                   |                   |                          |                |               |                |                           |
| All medical students should complete patient safety education in the first 2 years of medical school. | 0                 | 0                 | 0                        | 5              | 5             | 4.50 ± 0.50     | 100.00                     |
| All medical students should become a certified professional in patient safety.         | 0                 | 1                 | 0                        | 4              | 5             | 4.40 ± 0.70     | 90.00                      |
| The patient safety course helped me better understand other curriculum that I have completed. | 1                 | 1                 | 1                        | 3              | 4             | 3.80 ± 1.40     | 70.00                      |
| Professional question                                                                  |                   |                   |                          |                |               |                |                           |
| I am confident that I will be able to help change the health care system for the better. | 0                 | 0                 | 1                        | 3              | 6             | 4.50 ± 0.71     | 90.00                      |
Table 2. Areas of strength and opportunity identified on content analysis of course satisfaction survey.

| CATEGORY                        | FEEDBACK AREA      | OPEN CODE                                      | EXAMPLES                                                                                                                                                                                                 |
|---------------------------------|--------------------|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Class meetings                  | Areas of strength  | Class discussions                              | • “The in-depth discussion was helpful to talk about the topics we were less comfortable with,”  
• “I enjoyed discussing the module questions (pre-test questions),”  
|                                 | Hearing real patient stories |                                    | • “I enjoyed . . . the stories that were shared of how patients and their families were impacted by healthcare industry,”                                                                                                    |
|                                 | Content delivery    |                                    | • “The modules went really well and learning worked best when reviewing the slides and then going over questions briefly,”  
• “The instruction was carried out very well and it was clear that the instructors wanted us all to be successful,”  
• “The information was delivered in an excellent manner and was very understandable,”                                                                                                    |
| Areas of opportunity            | Content delivery    |                                    | • “modules have room to improve because a lot of material were not covered in the module,”  
• “I did not enjoy going over the slides [in class] since I did it in my own time,”                                                                                                                  |
|                                 | Practice question quantity |                               | • “A larger bank of practice questions would be helpful if possible,”                                                                                                                        |
|                                 | Time for practice question discussion |                                    | • “. . . more time to talk about the content within the questions that would be helpful to bridge the gap between the content and applying our knowledge.”                                                                                      |
| Background & context for patient safety content | Areas of strength | Defining terminology | • “I think that having the sheet of terms was tremendously useful,”  
|                                 | Supplementary learning materials |                               | • “[Professor] gave us articles and terminology physical copies,”                                                                                                                                 |
| Areas of opportunity            | Defining terminology |                                    | • “[Have] a 30-60min review over basic terminology for the course,”  
• “A module that goes over all of the introductory terms would also be good,”                                                                                                                    |
|                                 | Insufficient background information |                               | • “It would be helpful if we had . . . foundational knowledge of regulation and accreditation in health care,”  
• “A lot of this information seems to build on experience so it would be helpful to talk about experiences or simulate them,”                                                                                   |
| Course management               | Areas of strength  | Class structure & organization               | • “I liked when we switched class to slide format and I enjoyed discussing the module questions (pre-test questions),”  
• “I enjoyed meeting every week to go over the slides of each of the modules,”                                                                                                                             |
|                                 | Flexible scheduling of class meetings |                               | • “The flexibility of the class in covering material and meeting time,”                                                                                                                                 |
|                                 | Areas of opportunity | Inconsistent class meeting schedules | • “Make sure you are able to start the course on time. Changing the times and dates is very hard to plan around,”                                                                                       |
|                                 | Handling of logistics & student issues |                               | • “Less time spent with logistics, and individual issues which could be discussed one-on-on,”                                                                                                           |

The last area of feedback pertained to overall course management. The opinions about class meeting schedules were conflicting, with some appreciating class time flexibility and others citing that inconsistent class time impacted learning. Students also commented that handling logistics of certification exam registration and addressing individual student issues took valuable class time as well.

Discussion
The purpose of this innovative pilot was to investigate whether qualified U.S. undergraduate medical students could prepare for and complete the CPPS™ certification exam in 8 weeks or less. Results revealed that the pilot enhanced participants' knowledge of the 5 patient safety domains covered in the IHI CPPS™ Online Review Course. Additionally, first-time examinee pass rates among course participants exceeded current national averages. This intensive approach to addressing the need for more medical school patient safety curriculum outlined in the aforementioned Unmet Needs report appears to have been successful.8 Employing a flipped classroom model, using a faculty expert in patient safety, and utilizing IHI’s pre-existing materials adequately facilitated knowledge transfer and content assimilation.

To enhance medical students' knowledge and application of patient safety science, we believe the CPPS™ Review Course
should be considered as a new standard in the curriculum of undergraduate medical education. Student-specific feedback should be taken into consideration for future iterations of the Patient Safety course. Students found that the flipped classroom model facilitates learning and emphasizes that face-to-face discussions with patient safety experts were important for shaping understanding. Systematic reviews of the flipped classroom model in higher education consistently find better academic outcomes than traditional lecture-based learning.11–13

Making students responsible for learning background information before class shifts the course instructors’ role to fine-tuning students’ knowledge base and providing expert-level cognitive strategies for problem-solving. This strategy likely underscores how students could become proficient in patient safety curriculum in such a concentrated timeframe.

Interestingly, health care professional students further indicated that the pilot’s 5-week timeframe could be condensed further, offering up to 2 modules per week. Other suggested improvements included integrating more case studies, patient scenarios, and simulation activities. In addition, students felt they lacked foundational background and context in several areas (ie, regulation, accreditation, and terminology) which steepened their learning curve throughout the duration of the course. This discrepancy well illustrates the critical need for patient safety in undergraduate medical education. Of note, this pilot study is limited to a small sample size for data analysis, therefore, generalizability should be met with caution until validation with larger groups can be accomplished.

In conclusion, this study demonstrates the first known successful implementation of the CPPSTM curriculum with medical students at the academic level. This pilot takes the first step in generating a future vision of patient safety education by equipping medical students with critical knowledge to systematically improve healthcare. We also believe this additional certification will equip our graduates with a higher level of mastery of the Accreditation Council for Graduate Medical Education (ACGME) Milestones in the domain of Patient Safety.

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Author Contributions

All authors listed on this manuscript have made substantial contributions to designing experiments, acquiring and analyzing data, generating the final manuscript, and approving the final version for publications. All authors agree to maintain accountability for all aspects of the work, ensuring questions relating to accuracy or integrity of any part of the work are appropriately investigated and resolved.

Data Availability Statement

De-identified data underlying the results presented in this article can be made available to Investigators who provide a methodologically sound proposal and/or evidence of approval for their data use by an independent review committee (learned intermediary). All inquiries should be directed to Lillee.

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REFERENCES

1. de Wet C, Bowie P. The preliminary development and testing of a global trigger tool to detect error and patient harm in primary-care records. Postgrad Med J. 2009;85:176–180.

2. James JT. A new, evidence-based estimate of patient harms associated with hospital care. J Patient Saf. 2013;9:122-128.

3. Levinson DR, General I. Adverse events in hospitals: national incidence among Medicare beneficiaries. Department of Health and Human Services, Office of the Inspector General. Published 2010. Accessed May 8, 2021. https://oig.hhs.gov/oas/reports/oas-06-09-00090.pdf.

4. Landrigan CP, Parry GJ, Bones CB, Hackathorn AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. N Engl J Med. 2010;363:2124-2134.

5. Unbeck M, Schildmeier K, Henriksson P, et al. Is detection of adverse events affected by record review methodology? An evaluation of the “Harvard Medical Practice Study” method and the “Global Trigger Tool”. Patient Saf Surg. 2013;7:10.

6. Card AJ. Patient safety: this is public health. J Healthc Risk Manag. 2014;34:6–12.

7. Nie Y, Li L, Duan Y, et al. Patient safety education for undergraduate medical students: a systematic review. BMC Med Educ. 2011;11:33.

8. Lucian Leape Institute. Unmet needs: teaching physicians to provide safe patient care. Published 2010. Accessed May 8, 2021. http://www.ihi.org/resources/Pages/Publications/Unmet-Needs-Teaching-Physicians-to-Provide-Safe-Patient-Care.aspx.

9. Elo S, Kyngäs H. The qualitative content analysis process. J Adv Nurs. 2008;62:107-115.

10. Bengtsson M. How to plan and perform a qualitative study using content analysis. Nursing Plus Open. 2016;2:8-14.

11. Berthavus V, Bridgman H, Kornhaber R, Cross M. The evidence for ‘flipping out’: a systematic review of the flipped classroom in nursing education. Nurse Educ Today. 2016;38:15-21.

12. Wong TH, Ip EJ, Lopes I, Rajagopalan V. Pharmacy students’ performance and perceptions in a flipped teaching pilot on cardiac arrhythmias. Am J Pharm Educ. 2014;78:185.

13. Chen K-S, Monrouxe L, Lu Y-H, et al. Academic outcomes of flipped classroom learning: a meta-analysis. Med Educ. 2018;52:910-924.