Research Article

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Evaluating Pharmacy Students' Perceptions with Outcome-Based Learning in Toxicology Testing

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Abstract: This research highlights inaugural exploration of student perceptions of outcome-based learning at Rangsit University, College of Pharmacy. The study focuses on PHA 552 Toxicology Testing, a novel lecture course in the industrial pharmacy curriculum that offers one credit to fifth-year students. Currently, the curriculum is content-centric, but a shift toward outcome-based learning is anticipated. The course serves as a pilot for innovative educational methods, employing a constructivist alignment strategy. This approach used intended learning outcomes to guide the creation of relevant assessments and teaching activities based on the ADDIE model. The objective was to devise teaching strategies using the ADDIE framework and assess student reactions to outcome-based learning in this context. In this study, an online questionnaire served as the primary instrument for collecting pharmacy students' perspectives on outcome-based learning in this course. The assessment of the effectiveness of the learning approach was determined through a descriptive analysis of the average scores for each survey question. From a total of 78 students, feedback from 76 students revealed that the ADDIE model successfully guided the comprehensive analysis, design, development, implementation, and evaluation of learning activities, all of which were aligned with set outcomes. The activities were thoughtfully designed using a backward design, ensuring alignment with these outcomes. Students responded positively to the course process, teaching methods, and evaluation, particularly in term of appreciation for the formative assessments and the clarity of the evaluation methods. However, course timing was a noted concern. Overall, the application of ADDIE model in creating the PHA 552 course was effective, with most students indicating high satisfaction with the outcome-based approach.

Keywords: ADDIE, Instructional design, Outcome-based learning, Student perceptions, Toxicology testing

INTRODUCTION

In today higher education environment, there is a clear shift toward outcome-based learning. This educational approach prioritizes achieving predefined learning outcomes for students. It promotes a student-centered learning environment, carefully detailing the expected attributes and outcomes of learning, which are measurable and assessable. Therefore, teaching tends to favor engaging students in active learning rather than relying purely on lectures, providing opportunities for learning through practical engagement (1).

Instructional design is conceived as a structured process intentionally formulated to construct supportive and facilitative learning experiences that prioritize students' optimal learning efficiency and promote the retention of information in long-term memory. It encompasses the thoughtful planning of performance objectives or learning outcomes, the selection of effective instructional strategies, and the choosing and creating of pertinent materials and media, followed by evaluation methods. This systematized process reliably shapes educational and training programs, adhering to various design approaches. Notably, the ADDIE model stands out among instructional design methods segmenting the design process into five interconnected, nonlinear cyclic modes—analysis, design, development, implementation, and evaluation—thereby ensuring the development of a comprehensive and adaptable learning strategy (2).

Analysis phase: Begins with identifying instructional goals by analyzing learner needs, the learning environment, and existing knowledge and skills. This stage sets the foundation for designing an effective course by understanding the challenges and opportunities within the educational process (2).

Design phase: Focuses on creating a structured blueprint for the course, including defining clear learning objectives, selecting appropriate teaching methods and teaching materials and determining assessment strategies to align with intended outcomes (2).

Development phase: Translates the design blueprint into actual educational materials, involving the creation or selection of media, development of guides for instructors and students, and formative testing to validate instructional content (2).

Implementation phase: Entails the practical application of the course materials and strategies, preparing both instructors and learners for the educational activities, and integrating resources into the learning environment for effective instruction (2).

Evaluation phase: The evaluation phase requires a thorough examination of the instructional strategy, probing its effectiveness and identifying opportunities for enhancement. Incorporating both formative and summative evaluations, feedback is used not only for post-implementation adjustments but also as a continuous guide throughout the instructional process. This phase should appear throughout the entire process of constructing instructional strategies. Feedback gathered is used for immediate improvements and guiding future instructional decisions, ensuring continuous enhancement of the learning experience (2).

In the drug registration process, nonclinical toxicology testing is vital to confirm the safety of the new pharmaceutical item as it adheres to the ASEAN Common Technical Dossier (ACTD) and Thailand Food and Drug Administration guidelines. This critical step involves extensive evaluations, including examining single-dose toxicity, repeat-dose toxicity, reproductive and developmental toxicity, genotoxicity, carcinogenicity, local tolerance, antigenicity, immunotoxicity, dependence, studies on metabolites and studies on impurities (3, 4). The College of Pharmacy at Rangsit University has introduced a new lecture subject, PHA 552 Toxicology Testing, to the industrial pharmacy curriculum, allocating 1 credit for fifth-year industrial pharmacy students. This subject which focuses on toxicology testing in nonclinical studies, is crucial for regulatory pharmacists. Regulatory pharmacists should possess the ability to understand, select, analyze, and research toxicology testing information in databases. The course is delivered by various instructors from the pharmacology department, with each of whom specializes in topics in which they have expertise. The content of each topic is not necessarily interconnected; thus, the teaching strategy is of paramount importance and should encourage students to understand and apply the knowledge from every topic to achieve the desired learning outcomes. Consequently, this study aimed to design teaching strategies based on the ADDIE model and to evaluate student's perceptions of outcome-based learning in this course.

METHODS

Study design and setting

This research was conducted from August-November 2023 and used a quantitative descriptive design. The participants were pharmacy students majoring in pharmaceutical science who registered PHA 552 Toxicology Testing in the first semester of the academic year 2023 at the College of Pharmacy, Rangsit University. The study protocol was approved by the ethics committee of RSU Ethics Review Board (RSU-ERB) of Rangsit University, Thailand (reference DPE. No. RSUERB2023-008).

Subjects

There were 78 students who met the inclusion criteria. The sample size was calculated by Taro Yamane's formula with a confidence level of 95%. The course was offered to students in the fifth year of the professional program.

Intervention

The course was thoughtfully designed using the ADDIE approach, a prevalent instructional design framework favored by various instructional designers and educational content developers. Encompassing five critical phases—Analysis, Design, Development, Implementation, and Evaluation—the ADDIE model provides a comprehensive approach to course development. Aligning with outcome-based learning, its structure matches our teaching methods with desired learning outcomes. This one-credit lecture is scheduled to occur every Tuesday from 3:00 to 5:00 p.m., extending over a period of seven weeks.

Data collection and analysis

An online questionnaire was used as the research instrument. The questionnaire was anonymous, and confidentiality was guaranteed by the researcher. It included 4 main parts. The first part included a question for admission year. The second part included 20 questions and were answered on a as 5-point Likert scale. The participants were asked about their degree of opinion about outcome-based learning in this course divided into 3 parts: the opinion about the teaching process, instructional steps, and assessment opinion about teaching quality and content, and opinion about the case discussion section. The third part was a question 5-point Likert scale for overall satisfaction. Additionally, the last part was an open question for any suggestion from students.

For the second part, the items were rated on a 5-point Likert scale ranging from Strongly Disagreed (1) to Strongly Agree (5). For each question, the average score was used to assess the effectiveness of outcome-based learning as perceived by the students. The scores for the effectiveness of the teaching process, instructional steps, and assessment were divided into ineffective (less than 30), average (30-39) and effective (more than 40). For the effectiveness of the teaching quality and the content, the scores were divided into ineffective (less than 9), average (9-11) and effective (more than 12). For the effectiveness of the case discussion section, the scores were divided into ineffective (less than 21), average (21-27) and effective (more than 28). The data were analyzed using descriptive analysis and are displayed as the mean, standard deviation and percentage.

Before the questionnaire was distributed to the students, a validity review was performed by experts in the learning field utilizing the index of item objective congruence (IOC) for evaluation. IOC values, derived from the experts' assessments, spanned between 0.67 and 1.00, aligning with accepted criteria. Additionally, the questionnaire's reliability was scrutinized through a pilot study conducted among 30 pharmacy students who attended classes in the academic year 2022. With a Cronbach's alpha coefficient of 0.97, the instrument demonstrated reliable attributes and was deemed suitable for data collection.

RESULTS

The outcome-based course based on the ADDIE model.

Analysis phase

The students enrolled in this course were majoring in Pharmaceutical Science. Upon graduation, these students will possess the competencies needed to assume roles as pharmacists within various sectors, including the pharmaceutical industry, pharmaceutical research, or regulatory affairs. This course is a requisite subject within the curriculum, as the knowledge and skills imparted are essential for pharmacists specializing in regulatory affairs. The students completed the prerequisite course, Pharmacology for Pharmacy Laboratory and Toxicology, before enrolling in this area.

Concerning its content, this course encompasses various toxicology testing methods in nonclinical studies, which provide the safety information necessary for new drug registration as per the ASEAN Common Technical Dossier (ACTD). The course is facilitated by several instructors from the pharmacology department, each of whom imparts knowledge on topics where they possess expertise. Given that the content of each topic is not inherently interconnected, the implementation of effective teaching strategies becomes pivotal. These strategies should serve to promote student understanding and application of knowledge across all topics presented.

The course instructors used a backward design to identify the essential knowledge, skills, and attitudes needed for student pharmacists, focusing specifically on toxicology testing in nonclinical studies, particularly within the context of the regulatory pharmacist's role. The course learning outcomes (CLOs) included the following:

CLO1 Describes the principles and foundational theories of toxicology testing in nonclinical studies.

CLO2 Describes the mechanism of toxicology used in toxicology testing in nonclinical studies.

CLO3 Describes the study design, interpret the results, and conclude the findings from toxicology testing in nonclinical studies.

CLO4 Search and selection of toxicology testing data required for the registration of new drug formulas in Thailand.

Design phase

During the analysis phase, the course coordinators and instructors defined the learning objectives, instructional strategies, and testing strategies. The requisite summative assessments for this course were also identified, with the details of the summative assessment in relation to the CLOs presented in Table 1. Subsequent to the selection of summative assessments, the instructors identified formative assessments, learning experiences, and instruction.

Table 1. The mapping of the summative assessment and CLOs.

CLOs	Summative assessment	Detail of assessment
CLO1	Paper examination	Paper examination in midterm and final exam
CLO2	Paper examination	Paper examination in midterm and final exam
CLO3	Paper examination	Paper examination in midterm and final exam
	Case discussion	Searching, selection, and discussion on toxicology testing data in nonclinical studies of FDA-approved drugs
CLO4	Case discussion	Searching, selection, and discussion on toxicology testing data in nonclinical studies of FDA-approved drugs
	Practice examination	Assessment searching skill of toxicology testing data in FDA website

Given the intricacy of the content and the involvement of multiple instructors, meticulous course design became pivotal to facilitating student success in achieving the course learning outcomes. A case discussion activity was chosen to enhance students' understanding and application of knowledge to real data from the FDA website. This activity also integrated skill development in data searching. Students learned how to locate toxicology testing data for FDA-approved drugs using a searching manual provided by the course coordinators, which they could then apply to relevant cases. The case discussion activity commenced with student division into groups, each receiving a case and accompanying questions two weeks prior. During the class session, groups responded to the case questions, followed by instructor feedback to foster reflective learning and knowledge consolidation.

The formative assessment within this course was embedded in both lecture classes and case discussion sessions. In lecture classes, the nature of the formative assessment could vary according to the instructional style of the respective instructors. Some instructors opted for discussions centered on toxicology testing data, while others employed question-and-answer sessions. For case discussions, instructors evaluated student performance utilizing a rubric score, which was also applied in the summative assessment. During these discussions, instructors provided feedback and offered recommendations for future improvements. Both scores and feedback were subsequently relayed to the students, ensuring that they were cognizant of their strengths and areas necessitating improvement, thereby facilitating ongoing enhancement of their performance.

Development phase

In alignment with established learning objectives and identified needs, course coordinators devised and developed instructional materials for this course, including materials for case discussion sessions and practice examinations. Materials for the case discussion were composed of toxicology testing data sourced from the FDA website and distinct questions designated for each group to foster discussion. Notably, the questions varied between groups. This approach enabled students to apply their knowledge to toxicology testing and data retrieval from the FDA website, with data for each case discussion pertaining to different drugs. Despite the variability in information across cases, the principles employed in the discussions remained consistent. Additionally, course coordinators formulated instructions for the presentations and a rubric for assessing student performance. All the materials for case discussions, along with instructions and assessment rubrics, were subjected to validation by the instructors prior to implementation.

The instructors meticulously developed learning materials and content for each topic related to toxicology testing in nonclinical studies and assessments for paper examinations. Additionally, course coordinators comprehensively briefed all the instructors on the teaching strategies and provided information about the case discussions. This information served as a guide for preparing learning materials, ensuring that instructors understood how students would apply knowledge to cases. All the learning materials were uploaded to Microsoft Teams, which enabled them to interact with the content conveniently.

Implementation phase

In preparation, instructors received materials for case discussion, instructional guides, and rubric scores 2-3 weeks in advance from the course coordinators. To enhance participant engagement, the coordinators introduced students to the course's learning activities during the initial session and monitored student learning throughout the course. Lectures were delivered by the instructors as per the scheduled timeline. Regarding the case discussion activity within the course, the first session was designed as a formative assessment, while the second session was designed as a summative assessment. In both

sessions, student performance was assessed using a rubric score, and instructors provided feedback to students to facilitate the enhancement of their subsequent performance.

Evaluation phase

The evaluation phase, instrumental in diagnosing and assessing each preceding stage—analysis, design, development, and implementation—should permeate the entire course process, enabling timely adjustments based on evaluation outcomes. Throughout this course, coordinators maintained communication with instructors and learners via Microsoft Teams, ensuring receptivity to ongoing opinions and suggestions throughout the analysis, design, development, and implementation phases. This feedback mechanism empowered coordinators to adjust and improve in response to both positive and negative feedback across each phase. Furthermore, coordinators perpetually engaged with learners to gauge their perspectives and emotions toward learning tasks and activities, employing interviews and other methods. Upon the completion of the implementation phase, students undertook summative assessments to quantify the learning results. The students' perceptions were subsequently assessed in this study.

Students' Perceptions of Outcome-based Learning in This Course

General Information

The data were collected from a group of 76 students, surpassing the required sample size calculated using Taro Yamane's method for a 95% confidence level. Comprehensive information about the students is detailed in Table 2.

Table 2. General information of the students (n = 76)

Admission Year	Number (Percentage)
2018	17 (22.37)
2019	59 (77.63)
Total	76 (100)

The process, teaching methods, and evaluation

Table 3 outlines a detailed breakdown of student feedback regarding the process, teaching methods, and evaluation. The data in Table 3 reveal that students predominantly had favorable views on the process, teaching techniques, and evaluation methods used in this outcome-based course. The highest average rating (4.59) was awarded for the instructor's facilitation of student inquiries, encouragement of opinion sharing, and attentiveness to student feedback, highlighting a significant preference for interactive teaching and

Table 3. Student responses to the process, teaching methods, and evaluation.

Survey Items	Mean	SD
The explanation of the teaching process plan is clear.	4.46	0.64
The objectives of course are clear.	4.38	0.69
The teaching format allows learners to acquire knowledge according to the learning objectives.	4.39	0.67
The teacher uses questions or supportive activities to stimulate students to analyze or critique.	4.45	0.66
The teacher provides opportunities for students to ask questions, express opinions, and listens to the students' feedback.	4.59	0.57
The information technology used in teaching is appropriate.	4.53	0.64
The learning environment promotes learning.	4.24	0.73
Students are satisfied with the teaching process of the course.	4.29	0.65
There is a learning process that provides opportunities for students to learn by themselves.	4.50	0.68
There are clear and appropriate methods of assessment and evaluation.	4.58	0.62

acknowledgment of student input. Positive assessments were also noted for the clarity and suitability of the evaluation methods. However, the aspect with the lowest average score (4.24) pertained to the learning environment's effectiveness in promoting learning.

The quality and content of the instructions

Table 4 displays student feedback on the quality and substance of the instructional content. Generally, the responses were favorable. A notable average score of 4.51 emphasized the students' perception that the knowledge and skills gained are valuable for their future prospects. This implies that the course content is both high quality and relevant for students' future endeavors. On the other hand, the aspect receiving the lowest score (4.30) was related to the appropriateness of the content volume provided per hour of instruction.

Table 4. Student responses to the quality and content of instruction.

Survey Items	Mean	SD
The acquired knowledge, the thinking process, and the skills obtained from the study are of high quality.	4.39	0.59
The acquired knowledge and skills are beneficial for the future.	4.51	0.66
The amount of content per teaching hour is appropriate.	4.30	0.80

Case discussion activities

Table 5 details the students' reactions to the case discussion activities. The most highly rated aspect was the enhancement of student learning through instructor feedback, with the highest score indicating that such feedback significantly contributes to their learning process. Students also perceived that these activities greatly aided in their learning and comprehension, as reflected by a score of 4.47. The aspect with the lowest rating concerned the time allocated for the case discussion activities. Other factors such as the structure of the activity, the preparation time before the activity, and instructional methods, received scores ranging from 4.32 to 4.38, indicating overall positive student feedback on the case discussion activities.

The effectiveness of outcome-based learning and overall satisfaction

Table 6 illustrates student perceptions regarding the efficacy of outcome-based learning. The results indicate that a majority of the students (over 80%) considered key components to be effective: the teaching process, instructional methodology, and assessment; the overall quality of teaching and the content; and the case discussion activities. Furthermore, Figure 1 reveals that 55% (42 students) and 36% (27 students) of the participants were very satisfied and satisfied, respectively, with this course, reflecting an average satisfaction score of 4.42±0.79.

Table 5. Student responses to case discussion activities.

Survey Items	Mean	SD
The instruction documentation of the case discussion is clear.	4.36	0.65
The preactivity duration to prepare the case discussion is appropriate.	4.32	0.68
The duration for the case discussion activity is appropriate.	4.29	0.67
The format of activity is appropriate.	4.34	0.70
The activities enhance students' learning and understanding.	4.47	0.72
Receiving feedback from the instructor enhances students' learning.	4.53	0.62
The activities allow students to be motivated to learn from their group members.	4.38	0.73

Table 6. The effectiveness of outcome-based learning as perceived by the students.

	The teaching process, instructional steps, and assessment		The teaching quality and the content		Case discussion activities	
	n	%	n	%	n	%
Ineffective	1	1.32	0	0.00	0	0.00
Average	7	9.21	10	13.16	12	15.79
Effective	68	89.47	66	86.84	64	84.21
Total	76	100	76	100	76	100

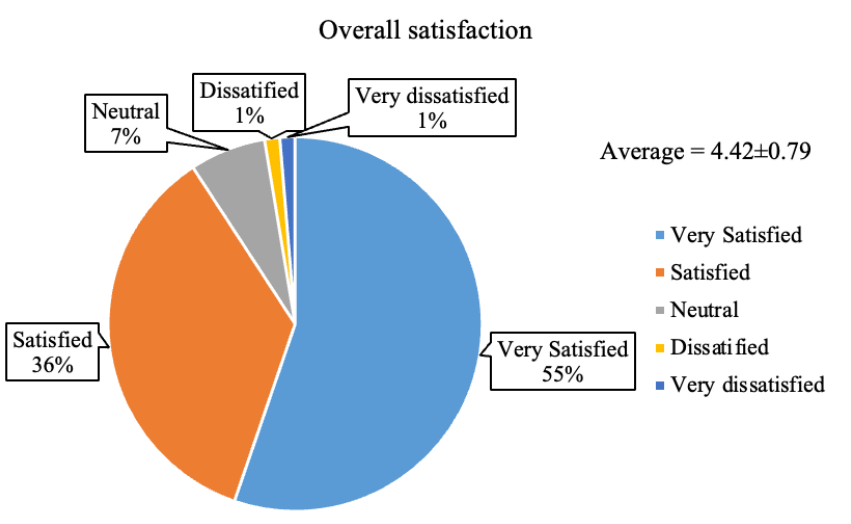

Figure 1. The percentage of students who responded to the overall satisfaction of this course.

Student Feedback

Feedback from the students was gathered and is summarized in Table 7, which shows predominantly positive responses. Nonetheless, there were concerns raised by some students, notably regarding the course's scheduling. They expressed that having this course as the last subject of the day led to feelings of fatigue.

DISCUSSION

This study represents the first formal assessment of student perceptions regarding outcome-based learning at the College of Pharmacy at Rangsit University. At present, the curriculum is predominantly content-based. However, a transition to outcome-based learning is planned for future programs. This necessitates the development of new educational approaches, especially for this newly introduced course. In response, we designed innovative learning activities that strictly adhered to the principles of outcome-based learning. These activities are intended to integrate seamlessly with the evolving pedagogical landscape of the college.

This course was designed using a constructivist alignment approach, which utilized intended learning outcomes to inform the development of pertinent outcome-based assessment methods and teaching-learning activities. The ADDIE model, a widely recognized instructional design method evidenced by multiple studies (2, 5, 6), served as the foundational framework. The application of the ADDIE model ensured a meticulous process of analysis, design, development, implementation, and evaluation of learning activities, all aimed at achieving the defined learning outcomes.

In structuring the course, the instructors employed a backward design strategy. This approach commenced with identifying the essential knowledge, skills, and attitudes critical for student pharmacists, with a specific emphasis

on toxicology testing in nonclinical studies, a key area within the regulatory pharmacist's role. The assessments, both formative and summative, along with the learning experiences, were closely aligned with the course's learning outcomes. All the educational materials were developed to correspond with the established learning objectives and the identified educational needs of the students.

Following thorough analysis and design phases, the course's learning tasks were implemented seamlessly, facilitating effective knowledge construction and enabling students to achieve the learning outcomes. The evaluation phase was an integral, continuous component throughout the course, allowing for timely adjustments based on evaluation feedback. This ensured that the learning activities could be executed successfully and efficiently.

In this course, student perceptions of the process, teaching methods, and evaluation were highly positive. They expressed strong agreement with the teacher's encouragement of student interaction, characterized by opportunities to ask questions, share opinions, and the respond to student feedback. This approach forms a key component of the formative assessment in lecture classes. The nature of this assessment varied according to each instructor's teaching style. For instance, some educators facilitated discussions based on examples from toxicology testing data, whereas others implemented question-and-answer formats.

Additionally, the students acknowledged the clarity and appropriateness of the assessment and evaluation methods. This reflects a fundamental benefit of outcome-based learning, which is its emphasis on clear learning objectives. Such clarity helps students understand the expectations set for them. Furthermore, the alignment of assessments with these outcomes ensures more objective and transparent criteria for student evaluation, as supported by various studies (7-10).

In case of discussion activities, the students also agreed unanimously that receiving feedback from the instructor significantly enhanced their learning experience. This feedback was viewed positively, aligning with multiple studies that affirm the role of formative assessments in enhancing students' understanding of the subject matter (7, 11). Moreover, the course was recognized for its utility; students strongly concurred that the knowledge and skills acquired were beneficial for their future careers. This indicates a deep appreciation of the course's relevance and the practical application of the learned skills and knowledge in future professional contexts.

Despite generally positive feedback, students expressed a lower level of agreement about the effectiveness of the learning environment in promoting learning and were less satisfied with the teaching process of the course. This could be due to the diversity and inconsistency of teaching styles, which are the result of having multiple lecturers. Another factor contributing to this sentiment is course scheduling. Positioned as the last subject of the day, following three other lecture subjects, students often experience fatigue. This is further supported by student feedback on the adequacy of the content amount per teaching hour and the duration of case discussion activities. This feedback highlights a significant challenge in outcome-based learning: its resource intensity. The development and implementation of outcome-based learning demand considerable resources, including time, training, and materials (9). The course timing emerges as a critical factor that significantly impacts students' perceptions and performance in an outcome-based course. This is primarily because outcome-based learning requires more active engagement and energy than traditional lectures. Students specifically noted course timing (3–5 pm) as a factor contributing to decreased attention levels. Based on this feedback, there is a clear need for scheduling adjustments in the forthcoming academic year to enhance the effectiveness of the learning experience and better align with the students' needs and preferences.

Regarding overall satisfaction with outcome-based education teaching methods, most students were highly to extremely satisfied. However, a portion of the students expressed less satisfaction, suggesting that while outcome-based learning

methods are effective for most students, they may not resonate equally with all students. This variation in satisfaction levels aligns with the perceived effectiveness of outcome-based learning as reported by the students. Some students perceived the outcome-based learning approach to be less effective, which may be attributed to their first-time experience with this method in the course. This initial exposure could have influenced their views, as it required them to adjust from a familiar content-based learning model to a new outcome-based framework.

Notwithstanding these variances, the predominant sentiment among students was favorable for the efficacy of outcome-based learning. Such positive perceptions and acknowledgment of outcome-based learning's effectiveness are vital considerations for its integration into the curriculum. This outcome aligns with findings from other research, indicating that students provide positive feedback on activities and assessments within outcome-based learning courses (11, 12). Students' attitudes toward outcome-based learning are pivotal for the success of transitioning to this approach. Their attitudes directly influence their knowledge, beliefs, readiness, and acceptance of this novel educational methodology (10). Therefore, understanding and addressing these diverse student perspectives is crucial for the effective implementation and success of outcome-based learning in the educational framework.

This research has two limitations. First, the study did not include a control group for comparison. Second, it does not track students' performance after the course concludes.

CONCLUSION

The results suggest that the application of the ADDIE model in the development of the PHA 552 toxicology testing course has been effective. This model facilitated a comprehensive process encompassing the analysis, design, development, implementation, and evaluation of the course's learning activities, all of which were strategically aligned with the intended learning outcomes. The course structure was meticulously crafted using a backward design approach, ensuring that each activity directly contributed to these outcomes. Student feedback further corroborates the success of this method; the majority of students reported high to very high levels of satisfaction with the outcome-based learning approach implemented in this course.

CONFLICTS OF INTEREST

None.

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