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Role Play in Drug Discovery and Development: Biosciences student performance and perspectives when role play experiential learning activities are integrated into learning

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Abstract :

Objectives : Science education should not be viewed as absolute and unchanging. Instead of teaching a multitude of facts that might change tomorrow, there should be an emphasis on supporting learners to develop adaptability and ability to connect prior knowledge with future utility. Experiential learning in the form of role play offers accelerated learning experience and connect students to the real world setting. Role play activities deploy a student-centered approach that empowers students to take learning into their own hands and apply it in an engaging context. This paper describes the design and implementation of role play simulation activities for the module principles of drug discovery and development for Biomedical Science and Biotechnology students in the School of Biosciences at Taylor's University, Malaysia.

Methods : Students were taught about the principles of drug discovery and development; at the end of the semester, a role play experiential activity was introduced. Students' performance between different cohorts was compared before and after the implementation of the role play and qualitative responses using open ended questionnaire were collected. Alongside the questionnaire an evaluation was also completed by the students for the module-based responses.

Results : Student evaluation of the role play experiential activity was positive. Applying knowledge in real life scenarios, interactive, and cooperation as a team emerged as the main themes of biosciences students to the activity. Students indicated that the role play activity helped with the application drug discovery and development concepts and enabled them to collaborate as a team in the activity. In addition, evaluation have shown that it enhances their ability to relate subject matter to real world examples, connecting the relationship of lesson activities to learning objectives and outcomes as well as improving their communication skills. The overall performance results for the module have also improved upon introduction of the activity compared to the last offered semester. Student evaluation of the role play experiential activity was positive. Applying knowledge in real life scenarios, interactive, and cooperation as a team emerged as the main themes of biosciences students to the activity. Students indicated that the role play activity helped with the application drug discovery and development concepts and enabled them to collaborate as a team in the activity. In addition, evaluation have shown that it enhances their ability to relate subject matter to real world examples, connecting the relationship of lesson activities to learning objectives and outcomes as well as improving their communication skills. The overall performance results for the module have also improved upon introduction of the activity compared to the last offered semester.

Conclusion : Students had better performance and expressed favorable responses after the introduction of the role play activity. Role play represents a beneficial tool in terms of understanding and application of complex concepts in the area of drug discovery and development.

Keywords: Role play; drug discovery and development; experiential learning; biosciences

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Introduction

Keeton and Tate (1978) explained that experiential learning prepares learners to be directly in touch with with the realities being studied[1]. It is contrasted with the learners who only reads about, hears about, talks about, or writes about these realities but never comes into contact with them as part of the learning process. The emphasis is on direct sense experience and in-context action as the primary source of learning. Many educational institutions

offer experiential education programs such as internships, field projects and classroom experiential learning exercises to add a direct experience component to their traditional academic studies. John Dewey (1938) emphasizes that there must be a relationship between experience and education[2]. A learning experience does not just happen; it is a planned event with meaning and with experiential learning the meaning is reaffirmed by the learners. Kolb (1984) indicates that there should be a link between the classroom and the future work for which the classroom is supposedly preparing the learner[3]. Hence, there is a need to translate abstract ideas of academia into concrete practical realities. Experiential Classroom-Based Learning in a formal setting which includes teaching methods that involve the students in doing activities and reflecting on what they did. This includes techniques such as role play, case studies, simulations, or any activity that uses real life experiences as its basis of instruction.

The module Principles of Drug Discovery and Development is offered to Biomedical Science and Biotechnology students in the School of Biosciences as one of the elective modules under the minor for Drug Discovery. This module introduces key concepts and processes in discovery and development of new drugs, including issues in social responsibility, national policies, patents and regulatory affairs. Upon completion of this module, students will appreciate the scientific, social and economic motivators behind decisions to discover and develop new drugs. In the drug discovery and development sector, rising costs of drugs and withdrawal of drugs with unexpected side effects remain a big challenge for pharma and biotech companies. Candidate drugs to be used in the clinical setting require rigorous assessment in terms of their safety and efficacy profiles in human clinical trials before being approved by regulatory bodies. In the clinical development phase II trial, a candidate drug was tested on a small number of patients for its efficacy. A major decision will be made at this stage assuming there is clear evidence of benefits from this new candidate drug which will then proceed further to Phase III. The cost of Phase III will depend on the number of patients recruited and the length of the study. It will typically range from $300m to $600m. However, nearly 50 per cent of Phase III trials end in failure of the drug. Hence, pharmaceutical companies must plan and prioritize development of promising drug candidate with a very high chance of success to move beyond Phase II trial and contribute significantly to the company's income. Hence, the use of role play experiential learning activity will concentrate on these issues and primarily focus on the pharmaceutical companies and the pressures on them when developing new medicines.

In the proposed activity, students play the roles of various stakeholders in a pharmaceutical company to discuss on the development of drugs that are involved in the treatment of a particular disease. This role play activity aims to get students involved in making a decision in drug discovery and development that could affect many patients. The activity allows students to appreciate the conflicting expectations (internally from scientists and commercial managers; externally from patients, shareholders and healthcare agencies) in a large pharmaceutical company. It also help students to gain insight into some drug targets that research scientists have recently discovered and learn more about some important diseases. Students would be able to understand more fully the trials that drugs have to undergo before being approved and be aware of the huge costs and timescales involved in drug development.

Method

Module information

This module "PHA60104 Principles of Drug Discovery and Development" introduces the students to the key concepts in drug discovery and development. Topics include an overview of pharmaceutics, target identification and validation, bioassay development, -omics platforms in target identification and pharmacological profiling, animal models, high throughput screening, biopharmaceuticals, clinical development of drugs, patent issues and regulatory requirements for drugs, nutraceuticals and supplements. These concepts are taught in lectures with diagrams illustrating the concepts (**Table 1**. learning outcomes for the Principles of Drug Discovery and Development module).

Table 1 Learning outcomes of the module PHA60104 Principles of Drug Discovery and Development

Discuss the principles and key concepts in drug discovery and development
Describe the use of -omics platforms in identifying and validating drug targets
Compare different bioassays in terms of their mechanisms, detection systems and ease of use
Differentiate biopharmaceuticals and small molecules
Discuss the clinical development, patent issues and regulatory requirements of pharmaceuticals
Demonstrate competency in communication and interpersonal skills through presentation and teamwork

Role play instructions

In this role play activity, students are required to play a scenario called the 'Big Picture in Drug Development'. First, students are briefed on the background information regarding the limitations in the use of statin as the main therapy in lowering cholesterol and controlling heart diseases. Students are randomly grouped together. Then, each student in the group will play the roles of individual stakeholders of a pharmaceutical company, either representing the Chief Executive Officer, Head of Research and Development, Head of Commercial Operations, Chief Financial Officer, Patient advocacy group, or Shareholder/investor and debate on the development of a promising drug candidate "Drug X" (a fictitious drug which is known to raise HDL) whether it should progress from Phase II to Phase III trial. Students are expected to prepare a maximum of 2 pages of power point presentation slides for the role play activity. The Chief Executive Officer will chair the meeting, explaining the agenda and introducing Drug Development Leaders. This will be followed by presentations from each of the Drug Develop-

ment Heads which inform on the case for the drug from their company's pipeline. The panel in the meeting are then invited to raise questions pertaining to the efficacy, safety as well as cost for developing the drug. At the end of question and answer session, the Chief Executive Officer will perform a voting session and move on to the decision of whether to continue developing the drug at a larger confirmatory Phase III trial.

This role play activity represents one of the assessments for the module (assessment rubrics was included in Appendix 1). Instructions pertaining to the activity was incorporated in the module information booklet (document which provides all information of the module offered in the semester) and provided to all students upon commencement of the semester. The role play activity will only take place on week 12, whereby students have full two weeks for preparation of the activity after teaching is completed in week 10. Each group was allocated with a total of 20 minutes for the role play activity.

Evaluation questions

Immediately after the role play, students reflect on their roles and relate how it is linked to the big picture of drug development through a short questionnaire. The questionnaire included one open ended and four closed questions (**Table 2**) that addressed learning outcomes, impact on connecting to real world examples, relationship between learning and assessments, and communication skills. In total, 35 surveys were completed for the 2018 cohort. Content analysis was performed on the survey and recurring themes were observed. For the closed questions, responses were collated and tabulated. In addition, the overall exam results for the 2018 cohort was collected and compared to the last offered semester in 2017 cohort.

Table 2 *Description of the closed questions from the evaluation*

My lecturer related the subject to real world examples
I clearly understood the relationship of the lesson activities, the learning objectives and the learning assessments
The assessments were set according to the module learning outcomes
This module has helped me improve my communication skills

Results and analysis

Thirty-five Bachelor of biomedical science and biotechnology students were invited to complete an open-ended questionnaire upon completion of the role play activity during the module offering semester in Aug 2018; the role play activity was conducted 2 weeks after completion of teaching of the concepts in each semester. For the open-ended questions, three key themes were identified from the students' responses, as outlined in **Table 3**. These themes are described below.

Application of knowledge

The application of knowledge was a strong theme that emerged from the free-text questions in this study. Participants reported that the role play allowed for the application of the principles and concepts to be understood. In addition, some commented that the activity allows them to connect processes in drug discovery for example patent lifespan, regulatory requirements, drug efficacy in the consideration of approving the drug candidates progression to subsequent clinical development phase; students also explained that they now could envisage the drug development concepts to pharma and patients. The role play activity was also described as making principles and concepts "real" as it represents real-life scenarios.

Interactive

Students also commented that the role play activity is interactive, fun and engaging. Instead of solely imparting and discussing the principles and key concepts during lectures and tutorials, the activity creates a lively environment that allow students to "experience" the roles as key stakeholders during the drug development process. More importantly, students felt that it is a fun way of learning.

Cooperate as a team

As the role play involve groups of student role playing key stakeholders in the drug development process, cooperation and teamwork emerged as one of the main themes in the survey. Many students reported that the activity encouraged them to work and learn in groups. Modern learners nowadays want to be challenged and inspired in their learning, they want to collaborate and work with their peers. Through this activity, students are able to improve collaboration and teamwork skills by improving their self-awareness, resource management, and communication skills.

Table 3 Themes emerged from the free text comments

Application of knowledge
Interactive
Cooperate as a team

Regarding the evaluation component, overall, majority of students responded that they agreed or that the statements are extremely evident with all Likert-type scale statements (**Table 4**) regarding the use of role play activity in the module. Students were positive for all the questions, which received over 80% agree/extremely evident responses. The most positive response was from question 1 (72.7% extremely evident); "My lecturer related the subject to real world examples." This was closely followed by question 2 (63.6% extremely evident); "I clearly understood the relationship of the lesson activities, the learning objectives and the learning assessments."

The final exam results for the module was also evaluated. Students performed to a better degree in the current semester compared to the last offered semester. The distribution was shifted to a higher score, in which there are more students obtaining Grade A and B, and the overall

Table 4 Percentage of responses to each question across surveyed participants

	Likert-type scale response per student group expressed in percentage (%)				
	Not evident (1)	Disagree (3)	Neutral (3)	Agree (4)	Extremely evident (5)
My lecturer related the subject to real world examples	0	0	9.1	18.2	72.7
I clearly understood the relationship of the lesson activities, the learning objectives and the learning assessments	0	0	9.1	27.3	63.6
The assessments were set according to the module learning outcomes	0	0	18.2	27.3	54.5
This module has helped me improve my communication skills	9.1	0	0	45.5	45.5

shape of distribution significantly shifted to have a greater proportion of respondents scoring higher and this is illustrated in **Figure 1**.

Figure 1 Distribution of overall results obtained from students taking the module Principles of Drug Discovery and Development in two different semesters (current semester = 2018; last offered semester = 2017).

Discussion

The results of this study demonstrate that, (1) the role play activity improved total test scores and there was a significant change in distribution at the higher category of score distribution, whereby more students performed better in the final exam, and (2) the role play was perceived positively by students as an addition to the conventional teaching within the module, with students reporting that the activity is able to support application of knowledge, being interactive as well as enhancing their cooperation teamwork skills, while (3) it also connects to the learning outcomes of the module as indicated from the closed question survey. Overall, the survey results indicate that the role play was effective as part of learning as it requires students to participate and learn from each other, which validates interactive and cooperation as two of the main themes in the survey.

Based on the themes identified, it is worth noting that students can apply content in a relevant, real world context where they take on a decision-making position that allows them to transcend and think beyond the confines of the classroom setting. They see the relevance of the content for handling real world situations. In this case, they appreciate the considerations involved in a pharmaceutical company for deciding whether a candidate drug achieved the benefits over risks ratio which warrants further testing in the long-term Phase III clinical trial that involved huge investment and patient numbers. Meanwhile, other studies showed that students also choose the vocabulary and coherent expressions to the situations to play[4]. Cooperation in a team emerged as one of the main themes where it can be seen to promote students' creativity through collaborative learning. It is a task-based and group-structured educational approach in which students in groups collaborate with each other for achievements that are advantageous to each member alongside with the educational and proper assistance from lecturer.

In addition, role play was valued by students in the acquisition of communication skills. Kusnierek (2015) defined role play as a "complete range of communication technique which develops language fluency and promotes student interaction during the class, increasing students' motivation, encouraging their learning, but also sharing responsibilities between teacher-student"[5]. Role play allows learners to improve their communication skills such as argumentation, the organization of ideas, group understanding, interpretation and inferring[6]. A study conducted by Yen, Huei, & Kuo (2013) found that instructional course that uses Facebook and Skype as platforms through which students participated in role-playing activities helped them to develop speaking abilities using the learning tools and role-playing tasks[7].

Overall, the role play activity represents an innovative assessment strategy which mapped to all learning outcomes of the module. Students are able to perceive the development of a promising drug candidate from a bigger picture. For example, they can appreciate the pathogenesis mechanisms of the disease which relates to the target identification and validation. Based on the target identified, discovery of hits and leads can be achieved using bioassay system, followed by the use of animal models in pre-clinical validation and subsequent clinical trials studies. Students can also relate the drug discovery and development process to the decision of when to file for the patent and its impact to the rights and protection of the drug candidate and its indication specified in the application. In addition, students are able to link this to the regulatory requirements for clinical trial application and management of the process.

Conclusion

Role play can be applied to biosciences education. Biosciences students had higher test scores and favourable responses to the role play experiential activity being used in drug discovery and development teaching. Biosciences students can relate the lesson activities (role play), the learning objectives and the learning assessments, especially in terms of application of knowledge. Interestingly, after the use of role play there was a significant increase in test scores in the higher categories,

together with a significant change in the distribution of scores, suggesting that there is an increase depth of knowledge by higher percentage of students. Effective role play can be carried out by providing guidelines for adequate preparation, alignment of roles and tasks with level of practice, structured feedback guidelines and acknowledgment of the importance of social interactions for learning.

Conflict of Interest

There is no conflict of interest.

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Appendix 1

PHA60104 Principles of Drug Discovery and Development - Role Play Marking Rubric

Name: _____ Student ID: _____

Criteria	Level of achievement				Score
	Exemplary (80-100%)	Competent (65-79%)	Developing (50-64%)	Non-competent (<50%)	
Preparation (10)	Well prepared with required materials and preparatory work for discussion	Prepared with required materials and preparatory work for discussion	Prepared with some required materials and preparatory work for discussion	Not prepared with required materials and preparatory work for discussion	
Accuracy and believability of role (20)	Point of view, arguments and solutions proposed were realistic and consistent with his/her role	Point of view, arguments and solutions proposed were realistic and have some consistency with his/her role	Point of view, arguments and solutions proposed were realistic but not in consistent with his/her role	Point of view, arguments and solutions proposed were not realistic and not consistent with his/her role	
Clarity of speech (10)	Communicates clearly and precisely. Speech is easy to understand	Communicates clearly and precisely	Communicates with some clarity and understanding	Communicates unclearly	
Question and Answer (10)	Answers do not reflect accurate comprehension of the topic(s).	Answers are occasionally correct and demonstrate an incomplete comprehension of the topic.	Answers are occasionally correct and demonstrate an incomplete comprehension of the topic.	Answers are mostly correct and demonstrate excellent comprehension.	
Total