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RESEARCH ARTICLE

Development, implementation and evaluation of an innovative, project-based assignment for final year pharmacy students, relating to novel drug delivery systems

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Abstract

Introduction: Students must efficiently integrate knowledge gained during their training. Application of this knowledge is important when students need to assess novel drug delivery systems (NDDSs). The objective of this study was to explore the impact of a Project-Based Learning (PBL) approach within a fourth-year pharmacy degree as a way of improving the ability of students to become independent researchers and critical thinkers using NDDSs as the subject topic.

Methods: Students chose a NDDS and researched intellectual property, drug pharmacology, design, clinical features, marketing, regulatory and commercial issues. Results were presented in a written report and seminar. Data from student performance in the written and oral components of the assignment and the written questionnaire were collected and analysed.

Results: Students performed well in both the written and oral assessment items, locating relevant information, synthesising a synopsis and presenting the information clearly. Evaluation of individual student responses indicated strong student satisfaction with the new approach across multiple measures. The assignment met its objectives and achieved its learning goals.

Conclusion: The development and implementation of a project-based assignment for final year pharmacy students proved to be highly successful, and a similar approach could be easily implemented by other pharmacy schools.

Keywords: *Australia, Novel Drug Delivery Education, Pharmacy Students*

Introduction

Traditional forms of didactic teaching (DT) such as lectures are educator-centred with an emphasis on content delivery (Johnson & Hayes, 2016). The main disadvantages of DT include the passive transmission of information leading to surface learning and poor student motivation (Meijerman *et al*., 2013). Traditional laboratory-based work often consists of recipe-style exercises which follow precise instructions, providing little opportunity for student ownership or agency (Venville & Dawson, 2012). E-learning resources are an alternative to traditional DT which when used thoughtfully can complement DT. Importantly it provides new opportunities for educators to incorporate innovative teaching pedagogies into their courses.

Inquiry-based learning (IBL) (Anderson, 2002) is a broad pedagogical teaching method which has received widespread support from educators. It provides a structured approach to learning in which students are given a question or problematic scenario to develop solutions to a given problem through a combination of investigation, their own critical thinking and application

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of problem-solving skills (Green & Elliot, 2004). IBL requires guidance from the educator acting as a facilitator, providing structure and support for students as appropriate. Project-Based Learning (PBL) (English & Kitsantas, 2013; Robinson, 2013;), a pedagogy related to IBL, involves students undertaking an assignment or project over an extended time frame. Students are challenged to solve real-world problems or complex questions. To demonstrate the knowledge and skills they have acquired students are often required to present their results in a public forum. IBL and PBL place the student at the centre of the learning with the role of educator shifting toward that of a designer and counsellor of projects, in contrast to DT. PBL has been described as challenging, motivating and enjoyable (Norman & Schmidt, 2000). PBL has previously been successfully used in teaching drug delivery in pharmacy and pharmaceutical based courses. Haworth *et al.*, (1998) determined that PBL was effective in encouraging critical thinking in students and led to a broad knowledge base and long-term retention of information. PBL has also been used to teach second year students about pharmaceutical formulation-based problems (McKenzie & Brown, 2017). Unlike the study presented here where students worked individually, students worked in groups and each group had a dedicated staff member assisting them. The McKenzie and Brown approach was welcomed by most students as well as staff, even though there were initial concerns with a new approach from both groups (McKenzie & Brown, 2017). PBL has also been successfully used to expose pharmacy students to the options of working in a pharmaceutical industry as opposed to a traditional hospital environment (Hussain *et al.*, 2019). These studies show that a PBL approach can be used in quite diverse settings, yet clear benefits in both student learning as well as staff satisfaction are noted when using this approach. In this study the approach was used to teach novel drug delivery systems (NDDSs) at the University of South Australia (UniSA), Australia.

'Dosage Form Design 4' (DFD4) is a one-semester course offered by the School of Pharmacy and Medical Sciences at UniSA. Prerequisite completion of three consecutive Dosage Form Design courses (DFD1, DFD2 and DFD3), aim to provide a solid grounding in hands-on formulation and compounding of various drug dosage forms, including intellectual property and regulatory issues. The DFD courses are designed to equip students with the practical, formulation and research skills required to work in the pharmaceutical industry. DFD4 is designed to be a capstone course to the previous DFD courses through the study of NDDSs, and analysis of the influence of pharmaceutical regulation in industry, hospitals, and community pharmacies.

Given the enormous variation in NDDSs and complexity of pharmaceutical regulation, it can be challenging to teach these skills. In the past, this challenge was addressed through a traditional combination of lectures, practicals, tutorials and workshops. While academically sound and providing vital skills to the students, these traditional teaching methods were unable to fully meet the aims of the course. While the skills being gained were clear to the teaching staff, their importance was not well appreciated by the student population, with negative comments seen in the Student Evaluation of Teaching (SET). Students failed to see the relevance to their careers as pharmacists or pharmaceutical scientists and found the exercises both boring and uninspiring.

In response to this written feedback, an alternative innovative approach was developed with the aim to excite, challenge and motivate the students. The approach had to introduce students to complex concepts in the design, formulation, intellectual property, marketing and regulatory requirements, in as broad a range of NDDSs as possible. This topic being a novel application of PBL for pharmacy and pharmaceutical science students. It also had to lead to an appreciation of the application of the NDDSs to real-world products and clinical situations. Finally, there needed to be an assessment instrument which could assess student abilities in the areas of database searching, critical analysis, report writing, and oral presentation.

The key research objective of this project was to trial a new approach to better deliver the course aims and enhance student motivation; the DFD4 course was taught through a PBL-centred assignment conducted over a semester. This approach was first introduced in 2015 and modified in 2016 following the first round of student feedback, in combination with an on-line practical. The results from the 2016 intervention demonstrated that the modifications had been successful in achieving the desired learning goals. Considering the written student feedback from the SET in 2017, the approach was modified, increasing the assignment assessment weighting and removing the online practical component. The impacts and benefits of the approach are discussed in this manuscript.

Method

Assignment

The assignment was designed to integrate theory and practice from DFD1, DFD2 and DFD3 courses and develop new student knowledge through a self-guided PBL method. Time to work on the assignment was allocated through a series of weekly practical (two hours) and workshop (three hours) sessions throughout the semester. Educational support and advice were provided by lecturers and tutors at four workshops, two practical sessions, an online course forum and email, which addressed individual students' questions. The assignment commenced in week two of a 14-week semester with a written report submitted in week ten. Following submission of the written report, each student was further assessed via an oral presentation to the whole class. The presentation highlighted what the student considered the main points of their report. Students in the audience were encouraged to ask relevant questions as part of the assessment process. Presentations were conducted during weeks 11-13 of the semester.

Table I: Report guidelines provided to the students at the commencement of the semester

1. Review scientific and medical literature and select any one novel drug delivery system for any route of administration or drug. This should not be a conventional dosage form, such as simple tablets or oral liquid. It should have an element of technological innovation, which provides it with a unique pharmacokinetic advantage or other benefits to patients. Examples can include Nicoderm Patch, Glidel, etc. A good way to pick correct product is to ensure that delivery system, controls or amends the drug release in some form.
2. Write a report including the following:
   - i. Name of the novel delivery system selected. If the product is available in multiple countries under different names, select the Australian product.
   - ii. Manufactured or marketed by?
   - iii. Countries where available (maximum 10)
   - iv. Active ingredient(s) and quantity
   - v. Excipients
   - vi. Rationale for novel delivery system, i.e. why
   - vii. Relevant drug(s) characteristics; physical, chemical and biological
   - viii. Technology or design features, i.e. how
   - ix. Advantages offered
   - x. Sales data in various countries (maximum 10 and those listed in point iii)
   - xi. Competition, i.e. options of other delivery systems for the same drug available to a doctor while prescribing
   - xii. Limitations
   - xiii. Pharmacy-related information
   - xiv. References (maximum 25)
   - xv. Intellectual property position,
3. Don't pick a product that your friend(s) has selected. You will, therefore, be able to discuss different products and learn from each other's assignment multiply your learning.
4. Look for the information at reliable sources of information, such as the company website, FDA or TGA website, scientific publications, US or European patent office, etc. Avoid using non-scientific websites and Wikipedia. Contact pharmaceutics staff, Ph.D. students and other experts working in the field for additional information. You can contact the course coordinator who will try to connect you to the right people, as required.
5. The assignment will require you to develop new skills such as searching for patents. You will do that for the first time in some cases, so don't panic and ask for help as required.
6. Make sure to complete the task within limits specified in the template for each section. Do not attempt to change the format. In order to maintain uniform standards, only the reports submitted in the correct format will be accepted.
7. Submit the report to learn online.

*Pharmacy related information means any dispensing or patient information issues, such as not breaking a coated sustained release tablet, transdermal patch to be kept at the site of application for the prescribed number of hours, specific storage

FDA= Food and Drug Administration; TGA= Therapeutic Goods Administration; Learn online is part of the Moodle Learning Management System (LMS) used at UniSA

The assignment required students to review the scientific and medical literature, choose a NDDS for any drug and route of administration and research its clinical, commercial, design and intellectual property issues. The report was written according to prescribed formatting requirements and length restriction to enable uniform assessment across the class and encourage succinct writing. The guidance provided to the students is shown in Table I and the weighting of the assessment for DFD4 in 2016/17 is shown in Table II.

Table II: Assessment weightings used in 2016 and 2017

Assessment	2016	2017
Multiple Choice Test	20%	20%
Assignment		
1. Written report	10%	20%
2. Oral Presentation	5%	10%
3. Online Practical	5%	-
Written Examination	60%	50%

Assignment design

Driving Question: Describe the clinical, commercial, design and Intellectual property of a Novel Drug Delivery System (NDDS) in a concise report for an employer, educational or government body.

Design of study to evaluate teaching effectiveness of the assignment.

The effectiveness of this new teaching approach was assessed via student feedback including a questionnaire and online SET survey. Ethical clearance for this study was obtained from the University of South Australia Human Ethics Committee (application number 200330).

Student Cohort

Students in DFD4 were enrolled in either the Bachelor of Pharmacy (B.Pharm. [Hons]) or Bachelor of Pharmaceutical Science (B.Pharm.Sci.) programme at UniSA. In 2016, 122 students were enrolled, 64.8% were female and 35.2% were male, while in 2017, 134 students were enrolled, 64.9% were female and 35.1% were male.

Questionnaire

The questionnaire (Table III), consisted of a combination of Likert scale (Likert, 1932) based questions, and a free text section for additional comment on the course. Questions 1-9 were divided into two broad themes, the first focused on the assignment (Questions 1-4) while the second theme reflected on the process and administration of the assignment (Questions 5-9).

Table III: Course evaluation questionnaire

Dosage Form Design 4 – Questionnaire on Major Assignment 2017

Circle one of the options (1-9)

1. The Assignment included topics presented in all four dosage form design courses

Strongly agree | Agree | Neutral | Disagree | Strongly disagree

2.The format of the assignment made it an enjoyable experience

Strongly agree | Agree | Neutral | Disagree | Strongly disagree

3.The headings were appropriate for the assignment

Strongly agree | Agree | Neutral | Disagree | Strongly disagree

4.The assignment was relevant to professional and career options

Strongly agree | Agree | Neutral | Disagree | Strongly disagree

5.The weighting of this assignment at 30% of the course was appropriate

Strongly agree | Agree | Neutral | Disagree | Strongly disagree

6.Finding the required information was a good learning experience

Strongly agree | Agree | Neutral | Disagree | Strongly disagree

7.Searching the patents online is a novel way of learning

Strongly agree | Agree | Neutral | Disagree | Strongly disagree

8.The tutors and lecturers provided good support

Strongly agree | Agree | Neutral | Disagree | Strongly disagree

9.This approach allows for flexible learning

Strongly agree | Agree | Neutral | Disagree | Strongly disagree

10.Anything else you would like to add

Results

A total of 131 (97.8%) students completed the assignment in 2017. The categories of NDDSs that were chosen by the students are shown in Table IV. The category descriptions are generic and do not distinguish between different NDDSs within each category. For example, the transdermal patch category includes 14 different NDDSs based upon transdermal technology, varying from nicotine to travel sickness patches. In total, 69 unique NDDSs were selected by the students. As each student independently chose their NDDS to study, some students did choose the same NDDS, however it was noted that each student approached the assignment in their own way and with different points of emphasis to other students. Of the 69 NDDS, 25 (36.2%) of the NDDSs were chosen by two or more students to study.

Table IV: Distribution of student choices for the various novel drug delivery systems (NDDSs)

NDDS Category	% of students choosing the NDDS category (n=134)	% of female students that chose the NDSS category	% of male students that chose the NDSS category
Antibody-drug conjugate injection	1.5	0.7	0.7
Contraceptive implant	10.4	9.7	0.7
Contraceptive ring	6.7	6.0	0.7
Drug Eluting bead	0.7	0.7	0.0
Intranasal spray/ inhaler	4.5	0.0	4.5
Liposomal injection	9.7	4.5	5.2
Microsponges	0.7	0.7	0.0
Modified release injection	20.9	14.9	6.0
Modified release tablet/capsule	7.5	4.5	3.0
Modified release topical (gel/foam)	1.5	0.7	0.7
Protein-bound injection	3.7	3.0	0.7
Stent	2.2	2.2	0.0
Sublingual film	1.5	1.5	0.0
Transdermal	23.9	12.7	11.2
Wafer implant	2.2	1.5	0.7
Did not Submit	2.2	1.5	0.7
Total	**100.0**	**64.9**	**35.1**

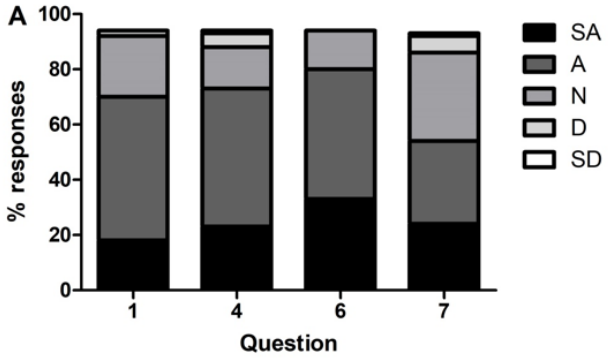
Data analysis

A total of 94 students (70%) completed the written questionnaire. The results are shown in Figure 1A and 1B. The number of responses for each of the five-point Likert ordinal scale that measures student attitude for each question has been calculated as a percentage of the total respondents.

Analysis of written comments

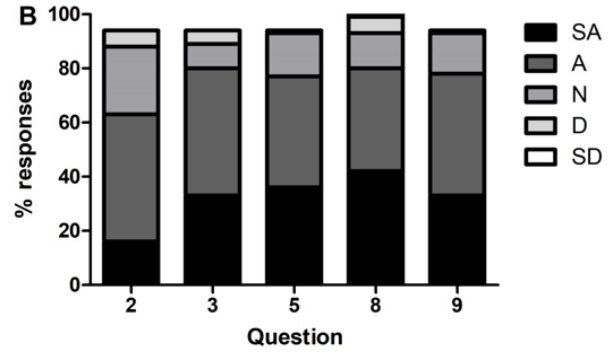
Written comments from the questionnaire were analysed using thematic analysis. Thematic analysis is a process for encoding qualitative information and can be considered a bridge between qualitative and quantitative research (Boyatzis, 1998). It was used in this study to find common themes in content from an open-ended question in the questionnaire. The results were collated and visually represented by a word cloud (Figure 2 and Appendix see Supplementary document for Figure 1). In a word cloud, word usage and frequency are represented, the more frequent the word is used, the larger and bolder in print it is displayed (Cidell, 2010).

Figure 1A: Student responses to content-based questions



Q1 - The assignment included topics presented in all four dosage form design courses'
Q4 - The assignment was relevant to the profession and career options;
Q6 - Finding the required information was a good learning experience;
Q7 - Searching for patents online is a novel way of learning.

Figure 1B: Student responses to the approach used in the study



Q2 - The format of assignment made it an enjoyable experience;
Q3 - The headings were appropriate for the assignment;
Q5 - The weighting for this assessment at 30% of the course was appropriate;
Q8 - The tutors and lecturers provided good support;
Q9- This approach allows for flexible learning.

Figure 2: Thematic analysis of responses to Question 10 of questionnaire using a word cloud

Student Evaluation of Teaching (SET) feedback

Student feedback was collected in 2016 and 2017 via a SET. This approach allowed for changes in the approach to be implemented at the next teaching opportunity. The SET results were collected anonymously via an online survey accessed only by DFD4 students. Core questions, (Table III) were rated on a 5-point Likert scale with 1- Strongly disagree; 2- Disagree; 3- Neutral; 4- Agree; and 5- Strongly Agree. A weighted mean score for each question was calculated from the SET responses with possible values between 100 (strongly agree) and -100 (strongly disagree). In 2016 there were 34 responses to the SET online survey (27.9% response rate), while in 2017 there were 32 responses (23.9% response rate). The response rate varied in 2016 as not all students answered all questions. This feedback was used to identify key themes, which were then used as the basis for future modification to improve the way that the assignment was structured and assessment weightings.

Summary of Questionnaire results

Questions 1, 4, 6 and 7 investigated student perceptions of the course content. The questions covered content from previous DFD courses, whether they considered the course relevant to their training and careers, whether the course adopted a novel approach to learning and if they found the approach provided a good learning experience.

Question 1: The assignment included topics presented in all four dosage form design courses

A total of 19% of students strongly agreed and 55% agreed with the question. This is an important finding, as DFD4 is one of four courses which covers distinct aspects

of pharmacy practice. The main aim is that DFD4 is an integrated and applied course where the previously covered material is applied in a new context. This response indicates that the new approach had been successful in clearly demonstrating the relatedness of information to the student cohort.

Question 4: The assignment was relevant to the profession and career options

A total of 24% of students strongly agreed and 53% agreed with the question. Again, the topics covered in DFD4 are aimed at being directly relevant to those activities required of a practicing pharmacist/ pharmaceutical scientist, particularly those working in industry rather than a clinical setting. The skills developed in this assignment, such as searching for new patent information, are key skills that are not addressed within any other courses within the four-year degree programme.

Question 6: Finding the required information was a good learning experience

A total of 35% of students strongly agreed and 50% agreed with this question. The key benefit here is that students were being asked to locate information in an active process and in a manner not previously used in any of their courses during their studies. These are key workplace skills that are readily transferable to other working scenarios. This was clearly seen as a positive learning experience by the students.

Question 7: Searching for patents online is a novel way of learning

A total of 25% of students strongly agreed and 32% agreed with the question. While still over half the class either strongly agreed/agreed with this question, it is clear there were many neutral responses. This is most likely due to some inherent difficulties experienced by the students in locating the relevant information in the relevant databases as well as familiarity with using such databases. The issues around the location of information as well as strategies to improve on these points are further expanded below in the discussion.

The remaining questions investigated the students' perception of the approach used in the assignment. In particular, the support provided by staff, whether the approach allowed for flexible learning, if the format made for an enjoyable learning experience, if the areas of investigation were appropriate, e.g. marketing and sales information, patent and clinical information, and finally whether the weighting of the assignment from an assessment perspective was appropriate.

Question 2: The format of assignment made it an enjoyable experience

A total of 17% of students strongly agreed while 50% agreed with the question. The format of the assignment involved both data resourcing as well as a presentation of the required information to the class. This approach to teaching was less commonly used in this course, and the variation in teaching method used was valued by the students.

Question 3: The headings were appropriate for the assignment

A total of 35% of students strongly agreed, while 50% agreed with the question. Related to Question 3, clear heading/subheadings were provided to the students to facilitate their journey in locating the relevant information for this assignment. Given the possible complexity of this assignment, it was critical to have clear boundaries for the students. Such guidelines facilitated students' performance as demonstrated by their assessed performance.

Question 5: The weighting for this assessment at 30% of the course was appropriate

A total of 38% of students strongly agreed and 44% agreed with the question. As with all tasks, it is important that the amount of work required to complete the task is given sufficient weighting that the students acknowledge its importance. As a result, a weighting of 30% was given to this new assignment and over two-thirds either strongly agreed or agreed that this was a fair weighting. This weighting also reflects other institutions (McKenzie & Brown, 2017).

Question 8: The tutors and lecturers provided good support

Fourty-five percent of students strongly agreed and 40% agreed with the question. Overwhelmingly, the teaching staff were highly valued by the students in their approach and support provided. This is also clearly seen in the word cloud where "Dr Aldous" is one of the most common terms identified in the comments. This again related to the appreciation by the students of the availability of the teaching staff.

Question 9: This approach allows for flexible learning

A total of 35% of students strongly agreed and 48% agreed with the question. This new assignment allowed the students to choose a NDDS and provided them with control in searching for new information. They were placed in control of their learning and this flexibility was valued by most students. This is in contrast with traditional teaching approaches where the lecturer provides the information and the students can become more passive in their learning.

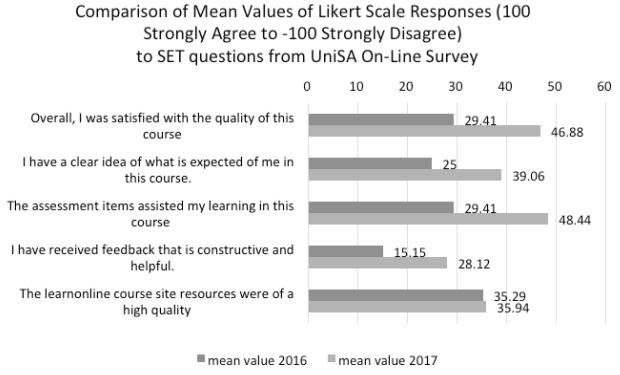
Thematic analysis

An open-ended question was included at the conclusion of the questionnaire. A total of 26 comments were received, and these were analysed via a thematic analysis. Key themes evident in the data were viewed as important in determining the feelings of the participants. The strongest theme was that the students "enjoyed" the new assignment format and the varying challenges they experienced.

Student teaching and course evaluation

Published summaries of SET research generally conclude that the instruments are reliable, especially when utilising class averages (Clayson, 2018). Figure 3 compares the weighted mean value of SET responses to questions on the DFD4 course in 2016 and 2017. In both years response rates averaged between 24-28%. While not all students responded, this response rate is similar to that seen in other courses taught by the authors. Some care needs to be taken in the interpretation of the results given this response rate. The upper limit of the scale is +100, which indicates strong agreement while the lower limit is -100 indicating strong disagreement with the question. All questions except for Question 5, showed the student attitude to the course improved. Question 5, relating to online site resources, was only slightly improved.

Figure 3: Analysis of SET values from UniSA Website.



A *t*-test comparing the weighted means for 2016 and 2017, showed a significant difference in the students' response to the questions in each year (p two-tailed = 0.03, t critical-two tailed = 2.31) and that the difference was positive indicated significantly greater student satisfaction with the course in 2017 than 2016.

Discussion

Based on student feedback through the questionnaire and SET, the assignment met its objectives and achieved its learning goals. Student performance in both the written and oral aspects of the assignment were improved. Since these results are for a single assessment time point, it would be useful to track the impact of this PBL intervention after the students have graduated. Pharmacy graduates in Australia do undertake additional examinations, administered by the Australian Pharmacy Council (APC). However, these results are not freely available to identify any potential benefits to student learning. An alternative option to assess the impact of this approach would be to implement PBL in either second or third year courses and then track the performance of individual students as they progress through their degree. This approach is consistent with similar approaches reported in the literature (McKenzie & Brown, 2017; Hussain *et al.*, 2019).

A questionnaire was used to gather feedback from the students regarding distinct aspects of the PBL approach. In 2016 and 2017, response rates averaged between 24-28%. Low responses rates are a well-known issue with student-based surveys (Ahmad, 2018). Due to the lower response rate some caution should be taken in interpreting the results. With this is mind, in general, there was strong agreement with the outcomes being investigated but less so for Question 7, with the least agreement and satisfaction among the cohort. This question relates to the ease of locating relevant information. The difficulties faced are most likely due to a lack of familiarity in using pharmacy-based databases and searching for the required type of information. This may have also included identifying the best databases to use and then being able to use them effectively to efficiently locate the required information. To address these issues, several approaches have been designed. A list of recommended databases including patent, academic databases, and search engines will be included in all written documentation provided to the students. This information will also be made available on the course homepage with hypertext links so direct access is possible. In addition, a screen capture video will be generated showing step-by-step instructions on how to interrogate Medline and MIMS online databases and collect the required information.

The written feedback was also assessed using a word cloud. This approach highlighted key terms, such as "enjoyed", "difficult" and "interesting". By combining the word cloud with the full text comments, areas of strength and weakness in the approach could be identified. For example, students "enjoyed" the novel approach to teaching, as well as their learning of a new topic, while "difficult" related to their ability to effectively use the required databases and to readily locate the relevant information. This information, as discussed above, has informed changes in the approach that will be implemented in assisting students to use the required databases effectively.

Apart from the questionnaires, another approach that was trialed included focus group sessions. Unfortunately, only one student attended the session run by an independent teaching and learning staff member. One possible reason for the poor attendance may have been the timing of the session. The focus group was held near the end of the semester and it is likely that students were busy preparing for end of semester examinations. In addition, they may have felt intimidated by this approach or that they had already given their feedback through their written comments.

Conclusions

Student feedback obtained via the administered questionnaire and SET feedback relating to the inclusion of an PBL assignment in the DFD4 course was highly positive. The move from a traditional form of assignment allowed the students greater freedom while requiring them to take ownership and responsibility for their own learning. The assignment was highly successful in introducing students to the high technology world of NDDSs. It exposed them to many more NDDS examples than would have been possible with traditional DT methods. It also successfully linked knowledge introduced from previous DFD1, 2 and 3 courses and demonstrated the relevance of this knowledge in applied, practical terms. Being asked to search for information relating to patents, marketing, regulatory and clinical aspects of a student chosen NDDS is an effective approach of applying the knowledge and skills required of a pharmacist/pharmaceutical scientist in a 'real world' industrial, hospital and retail pharmacy setting; skills which are expected and essential for a trained professional (Australian Pharmacy Council, 2020).

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Appendix A

Supplementary Figure 1: Word list of terms used by students and the number of times the term was stated

Number of times (n)	**Words**
22	assignment
10	enjoyed
8	really
5	found
4	choose, difficult, help, interesting, time, topic
3	drug, good, headings, learn, never, overall, patents, references, search, semester
2	< >
1	< >

< > indicates multiple terms which appeared at a low frequency