

Understanding The Role Of Pharmacology And Toxicology In The Research, Development, And Innovation Process By Analyzing The Drug Development Process

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Abstract

To encourage students to integrate the knowledge of the various subjects of the course that form the basis of the preclinical and clinical research, the Sargodha Medical college has implemented a new methodological strategy and an educational action centred on the subject of pharmacology and toxicology in R + D + I as part of the Degree Course in Pharmacy. Consequently, we decided that part of the teaching strategy would be based on: 1) reworking the content that students had received in other subjects or had been taught in the same semester and placing it in the pharmaceutical industry environment; 2) presenting the content of its own and not previously seen by the world of drug toxicological development, and 3) developing a battery of activities to be carried out as a group focused on the R & D & I process of an sp.

Building on the subject's pedagogical blueprint, these exercises should help students learn and practice the stated goals. In light of the survey's findings, we feel confident that our efforts to enhance students' knowledge of pharmacology and toxicology related to drug development in the modern pharmaceutical industry have been successful.

Keywords: proficiency, guided practice, independent study, and group effort

INTRODUCTION:

Undergraduate and graduate course requirements have shifted due to establishment of the European Higher Education Area. Some changes in the content have resulted from the curricula's remodelling and adaptation to the CFU, but the teaching-learning process as a whole has also undergone significant transformations; it is now more dynamic, more participatory, and takes into account the transversality knowledge that can be contained in the different subjects and subjects of the same teaching (Chang, 2020).

Educators in today's universities strive to help students develop their learning strategies. As educators, we are increasingly expected to go beyond passively imparting information and actively engage students in learning. Furthermore, it is essential to consider how the subject is combined with other related topics, issues on which our contents are based, or, on the other hand, the knowledge that the student must acquire by addressing the subject we teach and that it will be essential to overcome or learn in the context of other issues (Brandão & García, 2020).

Moreover, the educational mission must align with the student's future career once he leaves the classroom and begins addressing the labour market demands in his field. In light of this, it is becoming increasingly clear that the design of the contents of the various subjects must account not only for the specific contents specific to them but also for their interrelation with the knowledge of other issues of the same degree, the so-called transversal skills that can reach the entirety of the learning process, and the work environment that the future graduate will find upon completion of their studies (Gómez et al.).

Competencies such as critical and self-critical thinking, analysis; synthesis; global perspectives and practical application of knowledge; teamwork (e.g., the ability to collaborate with others and make a meaningful contribution to a joint project); the ability to seek and integrate new knowledge and attitudes; the ability to seek or use and integrate information; and the ability to express oneself orally all contribute to the definition of transversal competences at the Sargodha Medical college. Genuine masters have always had this challenge in mind (Ghanim et al., 2021).

So the innovative aspect is not so much in the goal as in the method used to achieve it. To a large extent, we have neglected to ask whether or not students are actually learning subject-specific skills, instead focusing on issues such as how classes are organized, when they are held, and how their performance is assessed. The main difference is that we need to think more about how it is learned, which can be used as a benchmark in lesson preparation and evaluation (Dmitrichenkova et al., 2020).

The project

The incorporation of Pharmacology and Toxicology in R + D + I (from now on FTIDi) into the degree in Pharmacy necessitated a new methodological strategy and didactic action that aimed to cultivate some of the transversal skills of the Sargodha Medical college and that students integrate the knowledge of different subjects of the degree that form the basis of preclinical and clinical development of a drug. To pass the FTIDi course, students must demonstrate mastery of the skills and knowledge outlined by the course's preparation and teaching staff (Yang et al., 2019).

Two of the UB's transversal competencies were incorporated into the course's lesson plan. The researcher developed one's analytical, synthesis, global perspective, practical application of learned material, and decision-making and flexibility-enhancing skills. Capacity to explore, use, and integrate information; fluency in Catalan, Spanish, and a third language; and the ability to understand and express oneself orally and in writing in all three languages.

In terms of the degree's required skillset, they included the following:

Determining the effectiveness and safety of pharmaceuticals is a valuable skill. Capability to recognize and create drugs, treatments, and other products and raw materials of health interest for human and animal usage. Toxicity assessment skills, including designing and implementing relevant tests and analyses. Acquiring expertise in the scientific method and legislation management, information sources, bibliography, and procedures (Arana Alcazar et al.).

These abilities and knowledge were unavoidably the focus of the field within which the Degree in Pharmacy Study Plan was designed. They were characterized during the planning process by the subject's descriptors. These descriptions ensured that students understood how new medications are chosen and developed in response to medical and market needs (Castillo López, 2021).

The protection of the pharmaceutical industry's intellectual property, norms for regulation, and legal framework for new pharmaceuticals.

- The pharmacologist's and toxicologist's place in pharmaceutical research's basic principles and structure and the creation of novel medications.
- Pharmacological targets, therapeutic interest, and the targeted population subset as criteria for selecting and prioritizing novel compounds.

Technology for rapid and extensive testing of samples

- The importance of preclinical studies in pharmacology, toxicology, and drug safety while developing novel therapeutics.

I am researching organs, tissues, and animal models to predict novel compounds' pharmacokinetics, toxicity, and efficacy.

- Computational modelling to foretell human safety and effectiveness; protein structure and ligand interaction prediction.
- The importance of pharmacological and toxicological evidence in approving a novel medicine for human use.
- Clinical trial design includes randomization, endpoint selection, GCP guidelines, adverse effect monitoring, risk/benefit analysis, and data interpretation.

Construction and design of the material (2.1)

Subject and the activities that should be included in the same teaching plan.

The evaluation of the FTIDi's programming compared to the other subjects of the Degree Course in Pharmacy revealed that some of the FTIDi's programmed contents had already been partially and independently produced in other required and elective subjects. The overlapping of issues is not new within university instruction and does not in and of itself affect the improvement of the student's learning and academic performance; nonetheless, if recognized, it should be redirected to improve the achievement of the knowledge and skills of the degrees (HERNANDEZ & VEGA, 2018).

Because of this, we decided that an essential part of our strategy for teaching would involve 1) re-elaborating these contents and setting them in the context of pharmaco-toxicological research in the pharmaceutical industry, 2) presenting contents that had not been seen before in the world of toxicological, pharmacological development, and 3) developing an entire battery of activities that the student must develop, focused on the research, development, and innovation process of an sp. Two innovation groups, the Section of Pharmacology and the Toxicology Unit, worked together to implement the subject.

Outline the course's pedagogical goals

Therefore, the primary goal of the 2021-started didactic project for introducing FTIDi in the 2021-2022 school year was to develop and implement a set of exercises that would allow students to put their newfound knowledge into practice. Molecular design, through their entry into human clinical practice, pharmacology, toxicology, biotechnology, and drug design, all play crucial roles in the research and innovation process underlying the creation of novel molecules with pharmacological activity. The team of educators decided that using a novel medicine in pharmacotherapeutics as the unifying concept for all lessons was the best course of action (Perales et al., 2018).

As such, the following steps have been developed:

1. settle on medication to serve as the central "leitmotif" of all efforts.
2. Include a new subtopic on pharmacological alternatives to the pathology or pathologies for which the medicine was approved within the context of the overall program.

The third step is to create a re-profiling activity tailored to the student's pharmaceutical aim. To choose new compounds with pharmacological action, it is necessary to conduct research into the pharmacological and toxicological information sources already available. Fifth, compile all available scientific literature on the drug of choice and use that to inspire your sixth activity, which should simulate the various phases of drug development. Students must complete these tasks in groups and present them orally to their classmates.

Creating a Strategy for Getting Things Done

All the theoretical, practical, and temporary programming was provided to the students on the first day of class, and each member of the teaching group was responsible for a particular set of activities and accompanying theoretical sessions. Below, we've outlined what has to be done to accomplish this. The first step in creating the FTIDi material is to compile a dossier outlining the project's specifications.

Each member of the teaching group was aware of the time they were to participate, the tasks assigned, and the delivery date of all the information to implement the topic at the right time, all thanks to the prepared form that allowed for the organization of a Gantt chart to identify the tasks to be carried out, and the temporary space to do it.

The document has been parsed, and the following details have emerged:

The timeline for implementation is 2021–2022.

- First semester of their fifth year.
- 6 CFU, or 3 for each subfield of study.

Appoint a coordinator for each department.

Define theoretical courses.

The first step is identifying the potential substance driving your immediate job activities.

- Read detailed material and attend presentations on direct activities to prepare for seminars.
- Outline what will be done during the assessment.
- Determine how much each assignment/test will count toward your final grade.

Phase 2: Primary Drug Selection

This stage aimed to select the medication that would serve as the impetus for all subsequent endeavours and plan out those endeavours in detail, including any necessary lectures, following activities, direct work, instructor follow-up, and evaluation.

Dabigatran, a direct thrombin inhibitor anticoagulant, was the medication of choice. Dabigatran is the first medicine to meet the characteristics to be a significant drug of activity because of its innovative mechanism of action, adverse effects, and specific indications, even if it has been years since we found commercialized anticoagulant treatments. Studies on its pharmacological target, therapeutic and safety profile, and pharmacodynamic, pharmacokinetic, and toxicological features have been substantial because of its well-understood pharmacological mode of action.

Analysis:

Face-to-face and hands-on experiments were separated into sub-categories for the

Pharmacological and toxicological analysis of dabigatran.

a) Arranging a conceptual discussion of dabigatran's pharmacology and therapeutic application. Indications for the use of the medication were also discussed during this meeting. Dabigatran's development was aimed at a specific population, and this session's primary focus was to identify that population, the pharmacological target, the therapeutic interest, and the descriptions that best describe it (Lopes et al., 2018).

b) Conduct independent pharmacological and toxicological research to equip students to participate in all course-related activities on the selected substance. This exercise will provide the student with skills to serve him well in his future professional endeavours of discovering and developing new pharmaceuticals. These skills include the ability to identify, select, and use databases that are commonly employed in this industry. This is not an entirely original assignment, as a similar but broader term on toxicology was created during the previous semester.

c) Modeling the target protein's folding and folding dynamics to obtain a re-profiling of the original molecule will allow for face-to-face and direct activity design. The learning outcome of this exercise is for the learner to be able to use protein visualization software independently. To achieve this goal, two labs have been set up where students can work on an assigned exercise under the watchful eye of their instructor while utilizing their personal laptop computers or other comparable devices. This task necessitates access to the primary protein database and applying bioinformatics techniques to identify protein-drug interactions (Urgoiti González, 2020).

After the workshops are created and the students have gained sufficient competence with the software, they are given independent work concerning dabigatran's drug target (thrombin) and the interactions between the medication and its target. The student is tasked with deciding whether or not it is feasible to reevaluate this medicine for usage beyond that already established. The learner must take a macro and micro perspective on the issue. This task is graded based on submitting an individual project to the instructor by the conclusion of the semester.

d) The criteria above will examine the future candidate once the target (thrombin) and a molecule have been identified.

Organizing Group Tutored Activities

The following schedule calls for six activities, one for each of the six class periods:

The assembly of task forces. This activity takes place during the first two weeks of the course, and it is free and open to all students via a Wiki on the relevant Virtual Campus.

- Setting a time for group members to submit their written reports orally.
- Providing the student with a copy of the script for a work-related activity. This script and supporting materials for the activity's creation are available via the relevant Virtual Campus. A 10- to 15-day window precedes the in-class presentation for the various deliveries.

• Each group will also be graded on their in-class presentation and on a test covering material covered while working on three of the six tasks planned for the tutoring sessions (table 1).

Resources for helping students create their lessons and assignments

Each of the eight activities (2 per student) has its blog to support student work and encourage collaborative participation. A blog is an online forum where students and teachers can connect and interact, facilitating the activation of various learning processes. The blog's user's anonymity must be protected, which will encourage its use as a communication channel between the instructor and the class (Aranda, 2021).

This blog aims to achieve the following:

- To portray the dynamic between a professor and a pupil.
- Instruct students to open up to one another.
- Ask questions that your instructor or fellow students can help you answer.

To prevent any unwelcome interference, the blog was built in a way that makes it invisible in a standard Google search. Under no circumstances can a student use their original profile without first changing it to protect their anonymity. This blog has as many categories as actions in the topic, giving each step its "own" place here.

Evaluation:

Subject evaluation final grades are calculated using the weights shown in table 1.

Table 1: the continuous and single assessment modes assign different percentages to the various subject-specific assessment activities.		
Exercise	Continuous assessment weighting	Single assessment weighting
Information search activity	5%	5%
Profiling activity	15%	15%
Directed activities	15%	-
Group presentation	15%	-
Exam	50%	80%

Academic success and student happiness

During the first semester of the 2021-2022 school year, the topic was developed without incident in the ninth semester of the Degree Course in Pharmacy. After the two scheduled calls during the course had concluded, the following results were calculated as the subject's final grade, considering the type of assessment and the weighting of the various activities as indicated in Table 1. Degree-related courses are introduced this year (Ramos Alonso et al., 2019).

One student (one per cent) did not submit a presentation.

- Eleven students (12%) scored an A+.
- Of note, 38 students account for 39% of the total.
- 35 out of 80 students (43%) gave the green light.

- No one in the class is nervous.

Figure 1 shows the percentage distribution of both the initial call and final results. Seven students (7.1%) did not pass the first call, and thirteen (16.0%) did not attend. Four of the suspended students did not participate in any required activities, and one was visiting from another country and attending school there temporarily (Erasmus program).

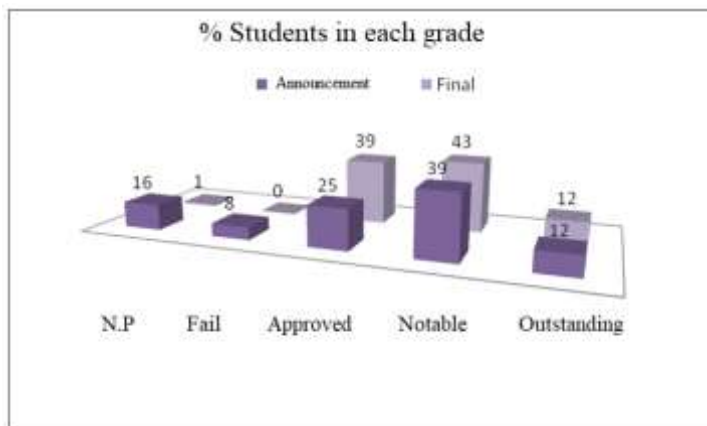


Figure 1 shows the percentage of students who passed the Pharmacology and Toxicology in R&D&i course on their first try compared to those who did not.

Only 26 students out of 88 who registered for the class agreed to take even one exam. We found that students who opt for continuous assessment have a lower dropout rate (4.8 per cent in constant valuation compared to 15.4 per cent in single valuation) and a higher pass rate (16.1 per cent in continuous valuation compared to 3.8 per cent in single valuation) than those who opt for single assessment. To determine whether or not the goals set by the faculty were met and to make any required revisions for the upcoming academic year, a survey was administered at the end of each semester. 2022-2013. Fifty-three per cent (47/90) of the class participated in the survey (Ruiz Pacco, 2018).

These factors were considered in the survey:

Concerning the preparation, execution, and assessment of the matter

For this survey section, all four cardinalities (Strongly Disagree, Disagree, Agree, and Strongly Agree) were on the table.

- The course's goals, syllabus, and evaluation rubric were detailed at the semester's outset.
- Eighty-two per cent of the student body agrees or strongly agrees with this statement.
- The progression of the topic has been well-planned (including seminars, workshops, and activities).
- Over eighty-five per cent of pupils are on board.
- The final product met all the subject-matter requirements that had been set. Over eighty-one per cent of students would either agree or strongly agree.
- The theoretical classes have generated concepts not covered in any other courses.
- There was the most discordant tone here (38%).
- Evaluation methods used for steps 3-8 are satisfactory.
- More than two-thirds of the class is on board with this view.
- The relative importance of the various components of the total grade is reasonable. Eighty-one per cent of students give the statement a positive response, either agreeing or strongly agreeing.

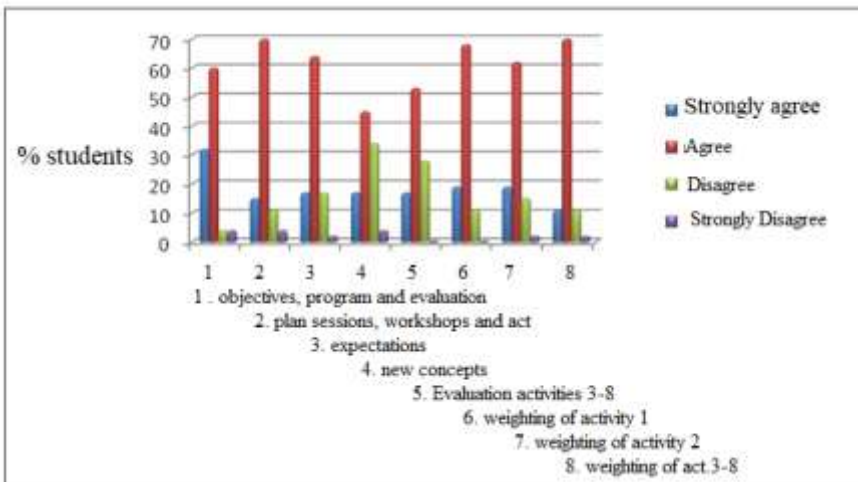


Figure 2: Research, Development, and Innovation Multiple-Choice Test Results on the Evolution of the Pharmacology and Toxicology Topic

Concerning the subject-matter blog,

We asked respondents to rate the blog's usefulness in this poll section. There were 372 unique visitors (students) who viewed the blog, and their activity may be broken out as follows:

- 11 comments and 165 pageviews for ACTIVITY 2
- 3rd ACTIVITY: 5 comments, 37 pageviews
- In ACTIVITY 5, 5 people commented, and 46 pages were read.
- The results for ACTIVITY 6 are as follows: 4 comments and 57 pageviews
- Five words and sixty-seven pageviews make up ACTIVITY 7.

In addition, 798 viewers were located outside of the United States. Figure 3 shows the results of the blog survey. Forty per cent of students report not utilizing it, primarily due to a lack of necessity. Only 2% of people could not log in, and only 4% chose not to use it because they did not want their opinions made public. Almost nine in ten pupils (88%) who utilized it agreed it was helpful.

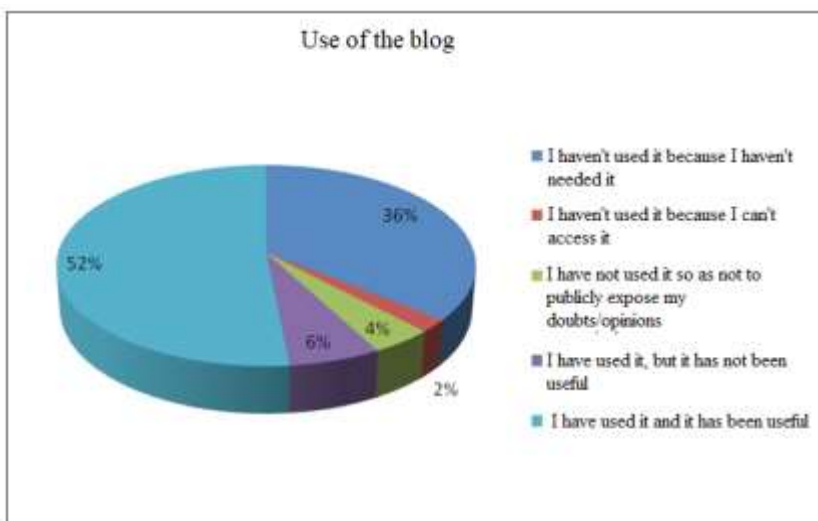


Figure 3: Student feedback on the blog's accessibility for activity-related queries

Regarding how much time you spend on each activity, including preparation and execution.

Generally speaking, the number of times students report spending on activity readiness matches our original estimate. Regarding the presentation activities, students taking either the continuous or the single assessment spend an average of 2.5 hours on activity 1 and 8.5 hours on activity 2, which is more complex. On average, they spend 3.5 hours on steps three through eight.

It took them noticeably more time to prepare for the activity they had to give, and they made that fact clear (Fig. 4). Notably, they spent a great deal of time on activity 7 (some students spent 25 or more hours on it), prompting us to reconsider and simplify this task for future classes.

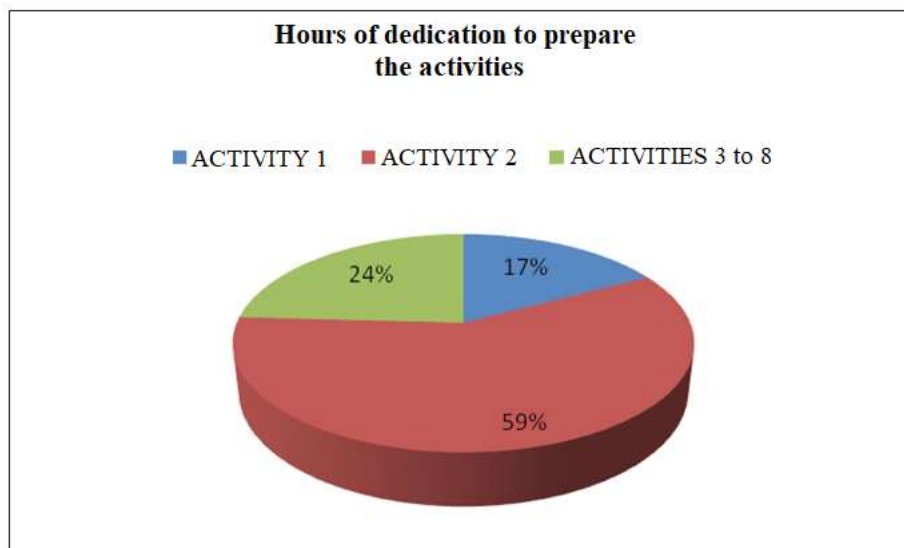


Figure 4 shows the typical amount of time a student spends on preparatory work and processing for required one-on-one and small- to large-sized group assignments (1–8).

Open discussion of the topic

Free-form responses from students were overwhelmingly positive, using language like "useful," "well structured," "interesting," and "important" to describe the issue. They add that while the course does propose some of the same content as other courses in the degree, it does so from a different perspective, one that is more grounded in practice and relevant to the realities of the pharmaceutical sector. They also gave high marks for the workshops led by professionals in the pharmaceutical business (Pérez Jimeno et al., 2019).

Some tasks have been too taxing, and they feel like the workload has been unevenly distributed. In general, the poll findings suggest that we should proceed with the proposed approach, making any required revisions to minimize overlap and standardize the time spent on each step.

CONCLUSION:

Compared to the traditional strategy of merely transmitting knowledge, the work done to implement the subject of Pharmacology and Toxicology in R + D + I as part of the Study Plan of the Degree Course in Pharmacy at the Sargodha Medical college has resulted in the development of a teaching process-learning in which different actors (teachers and students) can be defined with different and differentiated roles. To begin, faculty members were tasked with considering the subject's goals in light of the VERIFICATION memories of the Study Plan and the broader context provided by the content covered in other courses—issues of the Degree Course in Pharmacy. Students are encouraged to take charge of their education by building on prior knowledge (Aquino-Canchari et al., 2020).

Combining what he already knows with the new material allows him to learn more about it and apply what he has learned practically rather than just regurgitating facts. Students learn independently with a teacher's help by incorporating reasoning and reflective organization into the classroom setting. Teachers can devote more time and energy to their work at the university level using these resources. Without a doubt, this tactic represents for the faculty a more serious commitment to teaching, which undoubtedly favours a better knowledge of the students in terms of desires and aspirations so that the process can be adapted to the specific needs of each student.

Teachers could reflect on the subject's contents and activities and make modifications, thanks to student feedback gathered in the first year of implementation via an opinion questionnaire. In contrast, the subject's educators conferred with their peers in adjacent fields to share resources and prevent topic overlap.

We want to draw attention to the following new features implemented during the 2022-2023 school year:

a) Regarding the material presented: - Enhance the pharmacology material by elaborating on safety pharmacology.

Please rewrite any sections that make use of animal testing.

Introduce a series of talks given by professionals from the pharmaceutical business and academic institutions.

b) Regarding the actions: - Simplify the procedures for those that took too long.

c) Evaluating the Group Presentation: Use two criteria to rate the group's performance. The first is the presentation as a whole (worth 10%), while the second is the individual contributions of each student (worth 5%). Finally, we can conclude that we are optimistic about the success of the imposed target, which is to enhance students' learning and develop their specialized and transversal abilities in the areas of Pharmacology and Toxicology relevant to modern drug development.

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