REVIEW

# A New Vision of Teaching Clinical Pharmacology and Therapeutics for Undergraduate Medical Students

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Abstract: For many years, clinical pharmacology (CP) has been taught at schools of medicine via traditional methods including classic lectures and experimental sessions. The explosion of scientific knowledge and the availability of many treatment options have necessitated the development of new strategies for pharmacology teaching and learning. Applying information learnt in real-life situations has become more important than finding information that is readily available in many places. The newly implemented reformed curriculum at Umm Al Qura University - Faculty of Medicine (UQUMED) is a student-centred, competency-based curriculum with enhanced integration across the disciplines. Teachers and students have a great responsibility in updating the curriculum. The "Use of Medicine" (UofM) vertical module is part of this reformed curriculum that focuses on key principles, a core list of medications, the vertical and horizontal integration of subjects, the knowledge application to real case situations, enhanced critical thinking and self-learning. It emphasizes rational prescribing, safe medical practice and excellence in teaching CP and therapeutics. The adoption of newer and innovative teaching and assessment methods and the training of faculty/staff can help to refresh CP education. One challenge in CP education is that teachers are shifting from acting as information providers to acting as facilitators so that students become life-long learners. The assessment of our reformed curriculum uses several valid reliable tools to evaluate the achieved skills and competencies. This manuscript describes the transformational changes in CP education at UQU up to the development and implementation of the UofM vertical module as part of the reformed UQUMED curriculum. Continuous updates in CP education are critical for rational, safe, and affordable medication prescribing for better patient care. Keywords: clinical pharmacology, therapeutics, medical education, undergraduates

#### Introduction

Clinical pharmacology (CP) is the discipline that includes all scientific aspects of medication use in the healthcare process. It includes new drug development, drug utilization in therapy of various diseases, adverse drug reactions (ADRs) and drug interactions and the intentional medication misuse among individuals.<sup>1</sup> For centuries, CP has been applied via studying the herbal remedies and their effects on human illness, mostly through trial and error. With progress of research techniques, scientists in the early 1900s, started to combine the physiological studies with the biological effects, leading to the first breakthrough discovery of insulin. Thereafter, CP grew to become an integrative field, influencing the interpretation of medication safety and therapeutic efficacy in human diseases.<sup>2</sup>

Clinical pharmacology has been defined later, in 1970, by a group of specialists, upon request of the WHO to define CP and how it might help in improving medication use. Since then, medication therapy has changed the human health worldwide.<sup>3</sup> Several fatal communicable diseases were cured using antimicrobial agents, and complex surgery is now performed efficiently using recent safe anaesthetics.<sup>1,3</sup> However, despite the great interest in CP teaching, most of the medical educational programmes (both undergraduate and postgraduate) are still not optimal.<sup>4</sup> Medication prescribing is rated by most medical graduates as a very challenging task in their career, for which they are not well trained.<sup>5</sup> Currently, many newly graduated physicians still feel inadequately prepared to undertake the responsibilities of medical prescribing.<sup>6</sup> Thus, it is crucial to improve and update the CP curriculum at medical schools.<sup>7</sup> Many reports have

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indicated that the insufficient training with and knowledge of medication use among prescribing physicians is an essential factor in harmful drug events that may lead to the aggravation of patient illness, poor clinical outcome, and increased costs of health care.<sup>8,9</sup>

Rational medication prescribing is an essential skill for every medical graduate that enable them to prescribe medicines safely and effectively, during their clinical practice without supervision.<sup>10</sup> The newly graduated physicians are not usually required to take on high-risk clinical procedures, but they are frequently expected to use high-risk medications throughout their healthcare practice. In fact, these new physicians are often responsible for most prescription writing in the hospital care of patients.<sup>9</sup> All newly qualified doctors should have a strong foundation in the main principles of rational prescribing, supported by efficient CP education. The main factor in prescriber efficiency in medical practice is education and the ability to deal with continuous changes in medication therapy.<sup>11</sup> Indeed, assistance of other professionals in the healthcare system, such as nurses and pharmacists, and the use of electronic prescribing helps physicians in their practice; besides continuous medical training.<sup>12</sup>

Applying CP appropriately (through modernizing and harmonizing CP medical education) can improve the efficiency of the healthcare system.<sup>6</sup> This can be achieved through encouraging the realistic, cost-effective use of medicines, recognizing ADRs and prescribing errors, de-prescribing ineffective medications and increasing adherence to prescriptions over time, the application of CP has enabled more accurate medication measurements and personalized therapies.<sup>2,13</sup> The objective of this review is to follow and report the evolutionary changes of different aspects of CP education at Umm Al Qura University – Faculty of Medicine (UQUMED) up until the development and implementation of the reformed curriculum. We describe the model used in teaching CP and learning therapeutics in this competency-based reformed curriculum, the educational strategies and the new assessment tools used.

## Reformed Curriculum - How Did We Make It?

#### General Description

The new reformed curriculum at UQUMED, decreases pharmacology hours to less than 100, to be covered over the 5-year period of medical education. The new "Use of Medicine" (UofM) vertical module has case-based scenarios in small group sessions (include 10 to 15 students) and other integrated teaching strategies. It is interesting to note that the UofM module has a clinical component of therapeutics integrated with various topics of horizontal modules, particularly in the later years.

The reformed curriculum includes new issues relating to ethics, clinical problem-solving, prescription writing, professionalism, and communication skills. Workplace-based learning with simulated volunteers and real patients is also included in the teaching of CP in the reformed curriculum. Prescription writing skills are much emphasized to enable future doctors to write correct, legible, and rational prescriptions. Moreover, the UofM vertical module in the reformed curriculum reflects competency-based pharmacology teaching integrated with other subjects in all years starting from the second year.

The UofM module in the UQUMED reformed curriculum is a vertical module with a spiral arrangement and is concerned with the application of pharmacological science in clinical patient care. Spiral arrangement refers to design in which in which there is repeated revisiting of topics, or themes throughout the course but with deepening layers of complexity. Each revisit has added objectives and presents new knowledge or skills relating to the theme or topic.<sup>14,15</sup> However, with the huge expansion in knowledge, it became increasingly challenging to grasp the basic principles of science rather than applications in clinical practice. The recent trend in medical education is to integrate the UofM module in the clinical context, emphasizing the application in healthcare settings. The module is designed to focus on therapeutics to improve the competency of future doctors for safe and effective medication prescribing (Figure 1).

The learning objectives of CP education emphasize on what the learner should be able to do in various learning domains, such as knowledge (cognitive), skills (psychomotor), and professionalism (affective) domains.<sup>16</sup> These objectives address several important therapeutic problems, and this could be used to provide rational clinical applications of the medications. This reformed curriculum is competency-based, addressing well-defined competences for various roles, for example, whether a student is competent to prescribe rationally, inject intramuscularly, etc.<sup>17</sup> Self-learning approach,

| <br>Hajj &<br>Umrah                          | Research &<br>Evidence | Pathological<br>sciences | Anatomy &<br>Imaging | Clinical<br>Skills |  | Use of<br>ledicine                            | Professional<br>Development | Family<br>Health |  |
|--|------------------------|--------------------------|----------------------|--------------------|--|---|-----------------------------|------------------|--|
| Year 2: Fundamentals of clinical science - 1 |                        |                          |                      |                    |  | Basic principles of clinical pharmacology - 1 |                             |                  |  |
|  |                        |                          |                      |                    |  |   |                             |                  |  |
| Year 3: Fundamentals of clinical science - 2 |                        |                          |                      |                    |  | Basic principles of clinical pharmacology - 2 |                             |                  |  |
|  |                        |                          |                      |                    |  |   |                             |                  |  |
| Year 4: Clinical Practise -1                 |                        |                          |                      |                    |  | Integrated clinical care                      |                             |                  |  |
|  |                        |                          |                      |                    |  |   |                             |                  |  |
| Year 5: Clinical Practise -2                 |                        |                          |                      |                    |  | Specific population prescribing               |                             |                  |  |
|  |                        |                          |                      |                    |  |   |                             |                  |  |
| Year 6: Pre-Internship                       |                        |                          |                      |                    |  | Emergency and toxicity management             |                             |                  |  |
|  |                        |                          |                      |                    |  | 7   |                             |                  |  |

Figure I Use of Medicine. A vertical module integrated with the learning activities of other vertical and horizontal modules of the new curriculum.

better critical thinking with integration of subject, and application of basic concepts are preliminary positive effects of the introduction of reformed curriculum in the teaching of UofM module.<sup>18</sup> The typical didactic lectures are made interactive two-way communication using various techniques, such as asking questions, debates, quizzes, and brainstorming in small groups. There is a huge scope for the improved use of audio-visual aids in CP education.<sup>19</sup>

Competency-based education involves various components of professional abilities observable in real-life situations, such as knowledge, skills, values, and attitudes. The core competencies required of a medical graduate are predetermined in the curriculum and are contextual to the environment in which the medical graduate would eventually practice his profession.<sup>20</sup> The six domains of general competency, described for graduates by the UQU Med MBBS program include scientific approach to clinical practice, patient health care, community-directed practice, communication-collaboration, research and scholarship, and professionalism. Three broad outcomes have been specified for the medical graduates, namely, doctor as a scholar and a scientist, doctor as a practitioner, and doctor as a researcher.<sup>21,22</sup> Moreover, the student is motivated for self-directed learning to be "a life-long learner". This implies the adoption of teaching methods that emphasize skills development, and objective assessment methods with inbuilt feedback. So, learning does not stop at the end of the professional year, but progresses into the remaining years, until the student graduates, and until the defined competency is achieved.<sup>23,24</sup>

#### Principles for Application

There were three principles for the effective application of the reformed curriculum learning outcomes:

- Integration—As UofM is often incorporated in different courses throughout the medical curriculum, it was essential that outcomes are consistent with the learning strategies and assessment. The topics of the UofM vertical modules are integrated with their related subjects in all horizontal modules. For example, learning antimicrobial agents and their mechanisms of action (in CP) is integrated with learning of various classes of microorganisms (in microbiology) and the pathogenesis of related disease conditions (in pathology). The same apply with studying neuropharmacology and its integration with related subjects of neurosciences, and so on. Consistency between assessment, teaching strategies and proposed learning outcomes is fundamental for the successful application of learning outcomes.
- Outcome-based—The purpose of introducing UofM learning outcomes is to direct teaching and students' learning, and this was clearly addressing what a graduate of this program can do in the first day of his/her graduation conveyed to medical students and teachers. Core learning principles in UofM included knowledge and understanding about medications, medication prescribing skills and professional approaches to pharmacotherapy. The outcome-based learning of CP provides the graduate with required competencies to deal with the safe evidencebased practice needed for patient care. It emphasizes greater accountability, flexibility, and learner-centred approach to medical training.
- Early clinical exposure—The teaching and learning methodology encourages exposure of medical students to patients (real human contact) as early as the second year of medical college in a clinical perspective that develops

CP learning for rational and practical medication prescribing. It emphasizes solving therapeutic problems and appropriate use of medicines in various clinical settings, dose calculations, patient counselling, and medication consultation in medical practice.

These principles emphasize several important therapeutic problems that might stimulate rational clinical applications of medications. Self-directed learning, critical thinking, and the integration of basic concepts with clinical applications are the preliminary positive effects of the reformed curriculum and the UofM module.

## Domains

The new learning strategy applied via the UofM vertical module in the reformed curriculum at UQUMED aims to improve the rational use of medicinal products by providing medical students with the scientific foundation necessary for the active learning of CP and therapeutic concepts, thus enabling safe and effective use of medicines as a general practitioner. The UofM module consists of three major domains: (1) fundamentals, (2) therapeutics and (3) clinical skills.

Fundamentals include pharmacokinetic, pharmacodynamic, pharmacoeconomic and pharmacogenomic aspects. Therapeutics include the use of medicines in therapy of various disease conditions, such as diabetes mellitus, hypertension, heart failure and bronchial asthma. Clinical skills include the use of medication charts, writing valid medication prescriptions, medication counselling and the use of electronic resources. The models are integrated to accomplish the overall goals of the reformed curriculum in each academic study period. Because this reformed curriculum is competency-based, there are defined competences for various roles in the learning process, such as critical thinking, rational prescribing, parenteral injection, filling in an ADR form and medication consultation. The competencies recommended for an undergraduate student in the UofM module include the ability to:

- Identify the commonly used medication formulations, define their advantages and disadvantages, and select the appropriate one for a given condition.
- Select suitable medications for common diseases and write a correct prescription for a given patient.
- Define commercial and non-commercial sources of medication information and use them to update rational prescribing and respond to pharmaceutical promotion.
- Assess the implications of the misuse of medicines, particularly antimicrobial agents.
- Counsel patients regarding correct medication administration, adherence, and interactions.
- Communicate appropriate medication information to patients to ensure compliance with medication therapy.
- Detect, monitor, and report adverse drug reactions (ADRs).

## Interactive Teaching Methods

In the reformed curriculum, different ISBM strategies were used. These were divided into six learning processes: interactive lectures, case-based learning, problem-based learning, evidence-based medicine, discussion groups and electronic learning.

Ensuring a balance of teaching and learning in small and large groups, practical sessions and self-learning were the main goals. Most prescribing classes are meant to discuss clinical cases and solve therapeutic problems, requiring proper skills and knowledge emphasized in the reformed curriculum design. Case-based learning is another approach to UofM, including writing case reports with arguments relating to therapeutic decisions, reviewing prescribing skills with patients as part of communication skills, evaluating therapeutic trials and medication prescribing workshops. For instance, one of the student workshop topics is writing valid medication prescriptions and the use of medication charts. This is designed to help students correlate clinical signs and symptoms to prescription writing, critically appraise treatment options essential for medication charts or prescriptions, fill in medication charts for inpatients and write ADRs and drug–drug interactions (DDIs).

Medical students are also trained in the use of electronic resources for medication information (such as Lexicomp (embedded in the UpToDate program) and the British National Formulary (BNF)), as computer-supported learning

packages are available. For instance, one of the electronic learning topics (E-Medicine: Online Prescription in KSA) is designed to help students to identify the importance of incorporating technology into patient care, to recognise the role of E-medicine in the KSA healthcare system (now and in the future) and to use common E-medicine applications and websites.

## Academic Year Themes

For each academic year, there is a theme. These themes are integrated with the learning activities of other vertical and horizontal modules of the new curriculum throughout all the academic years of medical studies. The reformed curriculum is designed to provide medical students with basic scientific knowledge and early clinical exposure starting from the second year of medical study. The theme for years 2 and 3 is the "basic principles of clinical pharmacology"; for year 4, it is "integrated clinical care"; for year 5, it is "specific population prescribing"; and for year 6, it is "emergency and toxicity management".

Using the reformed curriculum allowed students to move smoothly through the three steps of learning in their academic study. The first step is to gain a firm understanding of scientific knowledge and the basic language of medication action, as this is essential for excellence in clinical practice. These basic pharmacology principles are incorporated and integrated with the subjects of the horizontal modules of the early academic years. The second step involves the students applying this understanding in a clinical setting during the clinical years to develop rational prescribing and therapeutic problem-solving skills. The third step involves the students developing the attitude needed to evaluate medication therapy regimens and newly emerging medicines and to participate in therapy decisionmaking. This combined approach of basic information and clinical application in the UofM vertical module together with early clinical exposure led to consolidation of the learnt knowledge and skills. The "spiral" arrangement of this UofM vertical module allows revisiting important topics to build upon more thorough and advanced aspects of knowledge in the remaining years of study emphasizing pharmacovigilance and patient safety in the therapeutic process. Drugs targeting the renin-angiotensin-aldosterone system (RAAS) will be used as an example for spiral arrangement application: for year 2 and 3 (fundamentals of clinical science) students, the tutor will focus on mechanisms of action and main clinical indications. In clinical practise years, for year 4 students, the tutor will revisit the drugs targeting RAAS and go deeper by explaining ADRs, DDIs and contradictions, while, year 5 students will learn more about the use of drugs targeting RAAS in special population such as geriatrics and pregnancy. Year 6 (pre-Internship) the tutor will explain the toxicity of drugs targeting RAAS and their use in emergency cases, as shown in Figure 1.

## List of Core Medications

The students often complain about having to learn about a large number of medications and describe pharmacology as a challenging subject. This is the result of putting too much emphasis on theory in the old curriculum and neglecting hands-on experience. In the reformed curriculum, we focus our teaching process on a list of core medications including the most prescribed 100 medications based on the pattern of disease in Saudi Arabia. We created this list from different resources, including the Ministry of Health (MoH), and by asking one of the largest pharmacies in the region, the Al Nahdi private pharmacy and Doctor Soliman Fakeeh Hospital, a private tertiary care hospital, to provide us with the most prescribed medications. Then, with the help of CP experts at the faculty and different curriculum designers representing different disciplines, the final list was created. The medications on the list were chosen to highlight their pharmacological properties emphasizing the main pharmacokinetic, pharmacodynamic and pharmacotherapeutic principles, foe proper use of medicines in management of various diseases.

The massive medication lists are avoided, since specialist prescription of medicines will be applied later after several years when the medical graduates have selected their speciality. The medication lists that should be common to prescribers will then differ according to their speciality, for example, general practitioners, cardiologists, neurologist, rheumatologists, and internists. Postgraduate training in CP will consequently decide the medications that are most prescribed. Furthermore, understanding of the key aspects of CP can enable physicians to take a rational learning approach about the common medications encountered throughout their clinical practice.<sup>25</sup>

For each academic year, there is a core of interest. For years 2 and 3, students are expected to focus on the mechanisms of medication action and identify the appropriate indications. For years 4 and 5, the focus is common ADRs, contraindications and DDIs. For year 6, the focus is emergency medication and antidots. The core medication list is arranged by organ system together with the common clinical conditions in which they are indicated. This highlights the problem-based learning approach, helping in development of deep understanding about CP and enhancing the integration within the system-based curriculum.

#### Assessment

The traditional assessment system is mainly knowledge-based and minimally designed to test attitudes or practical skills. Therefore, the assessment and learning methods should be designed for a higher level of knowledge of CP. The assessment system needs to be reliable, valid, feasible and acceptable, and should have a positive impact on the educational process.

The new competency-based reformed curriculum has an updated assessment system with formative and summative components. To test student achievements of the learning outcomes and to ensure that they are fit to practice, we tried (in the reformed curriculum) to focus on developing a reliable and validated assessment scheme.<sup>26</sup> The assessment is a mix of multiple methods, consist of (1) written exams (include multiple-choice questions and therapeutic case scenarios). (2) Practical skills (include prescription writing and using medication information centres). Moreover, we designed and implemented (3) an objective structured clinical examination (OSCE). Students have the opportunity for continuous formative assessments with the ability to assess themselves during the medical course at consistent intervals. Assurance of quality is applied to ensure the CP learning and evaluations are fit for the purpose of providing graduates with adequate knowledge and practical skills. The appointment of external examiners with CP expertise could help to ensure the achievement of the required standards.<sup>26</sup> Therefore, external examiners from the MoH were invited to participate in the examination.

## Postgraduate Challenges

We believe that education of CP and rational prescribing should be an ongoing process in postgraduate medical training, because of the continuous emergence of new medications and the continuously changing knowledge about the previously established in therapeutic practice.<sup>11</sup> Developing a firm postgraduate training platform is important for continuous updating of physicians with current therapeutic schedules. The progress from undergraduate supervised prescribing should be gradual to the less supervised specialized clinical practice during residency and fellowship years. Programs for specialist education and associated training and evaluations will be essential in establishing the importance of CP principles.<sup>27</sup>

Unfortunately, postgraduate education of CP did not have standardized common curriculum with clearly defined objectives. Recently, postgraduate CP education been shifted to competency-based curricula comprising the acquisition of clinical skills, scientific writing skills, professionalism, communication skills, and training in problem-based medical practice.<sup>28</sup> This continued CP education ensures the alignment between undergraduate and postgraduate learning especially emphasizing pharmacovigilance, appraisal of scientific literature, weighing clinical evidence of therapeutic benefits and economic aspects of medication therapy. These learning principles including safe nonthreatening environment, make learner to become an active contributor, build on existing knowledge, and use relevant content to solve problems and provide constructive feedback.<sup>29</sup>

Continuing medical education (CME) should be arranged for primary care specialists to update their knowledge and practical skills, improving their clinical practice. The development of new prescribing professionals, such as pharmacists and nurses, might offer an additional opportunity for CP education, and support patient care.<sup>30</sup> The main aim of CME is to enable change and improvement of patient management and healthcare practice. It should be arranged depending on the needs of prescribers, based on self-evaluation and frequent review.<sup>31</sup> Identification of these learning needs is the foundation for suggesting and planning of CME and training programs by specialized organizations to enhance life-long self-learning. For tutors to design and deliver high-quality training programmes, they should understand the natural patterns of learners and develop their educational competencies.<sup>31,32</sup>

The main challenge for postgraduate CP education is to arrange for the needed time in the busy shifts and clinical rotation. For instance, this time problem can be resolved at least partially, with the development of web-based learning tools and flexible access to training resources. Also, recognition vis-à-vis the relicensing process required for all doctors

need sufficient time for the CME.<sup>33</sup> Current advances in continuing medical training have embraced Web-based options for delivery and self-evaluation of virtual learning programmes. These opportunities can be a very useful for continued training, while respecting the time-limits of the postgraduate learners. The online learning resources can provide efficient learning activities especially in case-based therapeutic problems that are constantly accessible.<sup>34</sup> The required new competencies may include writing and reviewing appropriate prescriptions, calculating medication dosages, identifying, and avoiding ADRs and medication errors, in addition to prescribing skills in real patient situations. The core competencies reflected here would be those of a clinician, a communicator, and a professional.<sup>35</sup>

Another critical challenge for postgraduate CP education is to offer non-promotional, good-quality training. Pharmaceutical companies play a significant role in providing postgraduate medical education. Clinical pharmacologists should take the opportunity to participate in organization and delivery of non-promotional educational programmes in partnership with pharmacotherapeutic specialists.<sup>36</sup>

#### Limitations

The teaching methods used in the CP module of the UQUMED reformed curriculum include interactive lectures, tutorials, problem-based learning, E-learning and other innovative methods. These innovative methods require the proper infrastructure, finances, teaching skills and staff (IT, administration, and teaching staff). However, applicability is limited. In response, we have presented steps and principles that might guide the change process and enhance the current good practice.

Furthermore, there were no patient outcome measures. However, in the future, we plan to measure how this new integrated teaching of basic and clinical sciences can affect patient understanding of medication therapy, counselling, and adherence.

#### Conclusion

The current approach to learning CP is quite different from yesterday's traditional way of teaching. The UofM vertical module is an integral part of the new reformed curriculum at UQUMED. It is a competency-based, student-centred module that focuses on key principles, the application of knowledge, critical thinking, enhanced integration, and life-long self-learning. The UofM module consists of three major domains: (1) fundamentals, (2) therapeutics and (3) clinical skills. It depends on innovative methods of CP education, including interactive lectures, case-based sessions, group discussions, and problem-based learning. New assessment tools are implemented to allow for continuous shaping of the learning process and the achievement of the required competencies. This enhances the ability of medical graduates in terms of rational, safe prescribing, decision-making and improved patient care.

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