

# Advances in Pharmaceutical Education: An Experience with the Development and Implementation of an Objective Structured Clinical Examination (OSCE) in an Undergraduate Pharmacy Program

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## Abstract

The objective of this paper is to describe how a hybrid-OSCE was developed and applied to an undergraduate clinical pharmacy course as a pilot for assessing clinical competence in a Malaysian university; to present some of the instruments utilized for the conduct and assessment of the examination; and to evaluate the performance of the students in the OSCE. A seven-station OSCE (five live and two rest stations) was designed and implemented to accomplish the learning objectives of the clinical pharmacy course(s) as enshrined in our bachelor of pharmacy curriculum. The key processes involved in designing and implementing the OSCE include: development of a blueprint which served as a guideline; development and face-validation of the seven stations in accordance with the blueprint; design of dichotomous performance checklist/assessment instruments for individual stations; feasibility/pilot testing and rehearsals at OSCE stations; and conduct of the final examination. The broad competencies tested in the OSCE included patient counselling and communication, identification and resolution of drug-related problems (DRPs) using evidence-based approach, and literature evaluation/drug information provision. The students scored the highest marks in insulin delivery devices counselling station (mean  $\pm$  SD=17.6 $\pm$ 3.1), followed by DRPs identification/resolution and warfarin counselling stations with mean  $\pm$  SD of 17.36 $\pm$ 2.7 and 16.9 $\pm$ 2.2, respectively. Examinees also scored the least in the drug information station (mean  $\pm$  SD=15.55 $\pm$ 3.8). There were statistically significant differences between students' performances at the individual OSCE stations ( $F=3.698$ ;  $p=0.012$ ). The study revealed that undergraduate pharmacy students were better in performing patient counselling and identification/resolution of DRPs than in the drug information task. The design and implementation of the OSCE among fourth-year BPharm students was technically feasible and a great success.

**Keywords:** *Advances, clinical competence, OSCE, pharmaceutical education*

## Introduction

The growth of pharmacy as a clinical profession and the corresponding need to restructure pharmaceutical education would require significant review of pharmacy curricula and competency assessment methods (Monaghan *et al.*, 1995; Commission, 1993; Brandt, 2000; Bruce *et al.*, 2006). OSCE, an acronym for **O**bjective **S**tructured **C**linical **E**xamination is now one of the tools used to evaluate the clinical competency of pharmaceutical undergraduate students (Rutter, 2002; Corbo *et al.*, 2006; Pierre *et al.*, 2004; Carraccio and

Englander, 2000). It is also the standard of practice in high-stake settings such as licensure and certification examinations in some parts of the world (Austin *et al.*, 2003; Fielding *et al.*, 1997; Monaghan *et al.*, 2000; Cervený *et al.*, 1999).

The traditional clinical examinations through viva, long case, and short case have all been faulted and disputed to be highly biased and lack strong correlation amongst different evaluators. Hence, OSCE has been rated as the most reliable and valid tool of assessing clinical competency (Austin *et al.*, 2003; Woodburn and Sutcliffe, 1996; Carpenter, 1995).

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OSCE was first described by Harden *et al.*, (1975), designed to assess the clinical skills and competence of final year medical students. Although OSCE was originally a UK invention, by the 1990s medical schools across the world have increasingly adopted the idea (Rushforth, 2007). It has now been widely described in the medical literature and adopted by the medical and nursing profession (Ross *et al.*, 1988; Alimier 2003). OSCEs have been reported to be used in Malaysian Colleges of Medicine curricula (Tan and Rokiah, 2005). The global paradigm shift toward pharmaceutical care practice dictates the need for such changes in pharmaceutical education even in countries where clinical pharmacy and pharmaceutical care are still at infancy.

An OSCE is comprised of a series of stations through which all candidates rotate on a timed basis (Austin *et al.*, 2003). In each station, the candidate is faced with a simulated task or problem; the candidate is required to perform specific functions to complete the task or address the problem (Austin *et al.*, 2003). This method of assessment provides information difficult to obtain through traditional pencil-and-paper tests (Stowe and Gardner, 2005). In fact, as a performance-based assessment method, OSCE measures cognitive learning, mastery of essential practice skills, and the ability to communicate effectively through problem-solving skills.

The contents of the present manuscript and its companion (Awaisu *et al.*, 2007) are guided by an innate desire to share our experience in totality with pharmaceutical educators from all over the globe, first because this is our maiden experience. Secondly, no other pharmacy schools from Malaysia, to the best of our knowledge, have reported a similar experience.

Here we report our experience with the development and conduct of the examination in a narrative way.

## Description of a course and design of an assessment method

### Synopsis of the *Clinical Pharmacy III* Course

The *Clinical Pharmacy III* course (PHM 4213) at the International Islamic University Malaysia (IIUM) is offered in each semester II to fourth-year Bachelor of Pharmacy students who have fulfilled its prerequisites (i.e. *Clinical Pharmacy I*). It is a three credit-hour faculty-required (core) course with a total of 40 contact hours: 22 contact hours (22 × 1 hour) for didactic lectures; 13 contact hours (10 × 4 hour) for hospital attachments; and 5 contact hours (5 × 1 hour) for tutorials. The amount of workload in PHM 4213 stands at about eight percent of the total workload (credit hours required) in the fourth year syllabus. Its instructional strategies include didactic lectures, hospital ward attachments (clerkships), and tutorials.

The course was designed to provide understanding on the various factors that determine the choice of drugs for individual patients. It is aimed to expose the students to practical aspects of pharmacy with regards to patient care and drug therapy in the ward. Students were given the opportunity to put into practice their knowledge in clinical pharmacy and therapeutics. They also had the opportunity to observe and

participate in ward rounds with other caregivers. Emphasis was placed on the role of pharmacists in patient care. Students were also expected to understand the clinical pharmacokinetic aspects of certain drugs and their relationship to the patient's treatment.

The key learning outcomes of the course include integration of the concepts of pharmaceutical care, pharmacotherapeutics and clinical pharmacokinetics in the identification and resolution of drug-related problems and the application of evidence-based approach. The course assessment methods include clerkship (i.e. clinical attachment) rating, long and short essays (via examination) and the OSCE. All the forty-two final year B.Pharm students who registered for the *Clinical Pharmacy III* course in the second semester of 2005/06 academic session were examined via OSCE in addition to the other assessment methods.

### Overview of the OSCE

A seven-station OSCE was designed and implemented to achieve the objectives and learning outcomes of the *Clinical Pharmacy III* course as outlined above. The examination covered areas that we felt were pertinent to contemporary pharmacy practice and in tandem with the clinical pharmacy courses requirements and expected learning outcomes. Faculty members were the assessors and simulated health professionals for the OSCE. The examination was performed in two concurrent sessions for two groups of students (21 for each). A session typically comprised of seven stations in which two stations were provided for rest. Students were asked to complete their tasks within 15 minutes at each station and were assessed through a structured and standardized marking scheme. The design was adapted to mimic our local circumstances.

### Processes for OSCE Development

The following key developmental stages were followed in the design of OSCE:

- Blueprint construction;
- Workstations development meeting with faculty and other stakeholders;
- Development of OSCE workstations components (assessment instruments, instructions to candidates, instructions to simulated patients);
- Patient's recruitment/approval;
- Development of final examination materials by examination coordinators (including instruction to examiners for each station);
- Stations and assessment tools review meetings with all OSCE stakeholders;
- OSCE feasibility testing;
- Meeting of all stakeholders on the conduct of the examination;
- Students' briefing sessions.

### Blueprint development

A group of two faculty members involved with teaching of the *Clinical Pharmacy III* course were assigned to develop a blueprint delineating competencies to be assessed and how they were to be assessed. The blueprint was to serve as a guideline for designing and running an OSCE in the faculty for the pioneering examination and the future. It clearly spelt

out the fundamentals of the examination, including proposed workstations and their development, assignment of responsibilities, examination venue, financial requirements, ethical considerations and so on. Cases were determined by extraction from the *Clinical Pharmacy III* modules, as described above. Further workup was completed by thorough review of the literature on how OSCEs for both undergraduate and licensure examinations were conducted in other parts of the world (Austin *et al.*, 2003; Fielding *et al.*, 1997; Newble and Reed, 1997; Newble *et al.*, 1994). One landmark document reviewed was developed at the University of Sheffield, encompassing UK and Australian experiences (Newble and Reed, 1997). Although it was meant for developing an OSCE in medical settings, it was found to be valuable for the amalgamated blueprint. The primer guidelines developed provided a conceptual framework and building blocks for the development and implementation of the OSCE during the 2005/06 academic session and hopefully a guide for the future.

#### OSCE Station development

The first meeting with faculty members and other stakeholders was convened to develop the cases in

consonance with the blueprint. The emphasis was that the workstations/cases should be designed to achieve the course objectives and expected learning outcomes. The authenticities of the cases outlined in the blueprint were verified by course instructors and the ideas were modified and expanded. This effort was reinforced by a more thorough literature review to explore the experiences of others, especially from Canada and North America (Rutter, 2002; Corbo *et al.*, 2006; Austin *et al.*, 2003; Fielding *et al.*, 1997; Cervený *et al.*, 1999; Newble and Reed, 1997; Newble *et al.*, 1994). However, contents of respective stations and their assessment tools were further face-validated by the departmental Chair (a clinical pharmacist and associate professor), the course coordinator (a clinical pharmacist and lecturer), and one external reviewer (a physician and professor of clinical pharmacology) through a review and consensus. All three had extensive experience with how OSCEs are run in pharmacy and medical colleges. The purpose of the face-validation was to ensure that the tasks at the stations were meant to measure the clinical skills and competence of the students and the appropriateness of the discrete items used for scoring the performances of the examinees.

Table I: Summary of the OSCE Stations

Station	Description of Competency	Task/Objectives	Evaluator	Participants/Actors
Station 1	Patient Counselling on Oral Anticoagulant Therapy	Assessment of student's ability to counsel a patient on long-term warfarin therapy.	Faculty member	RP: Male, mid 50's on warfarin.
Station 2	Counselling and Education on Asthma Inhaler Devices and Smoking Cessation	Evaluation of student's ability to educate patient on the rationale of treatment and proper use of inhaler devices and advice on smoking cessation.	Faculty member	RP: Female, mid 40's smoker on MDI for asthma, now prescribed a beclomethasone inhaler in addition.
Station 3	<b>REST STATION</b>	-	-	-
Station 4	Drug-Related Problems Identification and Resolution	Assessment of the student's ability to identify DRPs using a standard taxonomy and give evidence-based recommendations for a pharmacist's care plan to resolve and/or prevent the problem.	Faculty member	SP: Male CVD patient with comorbidities.
Station 5	Counselling on the Use of Insulin Delivery Devices	Evaluation of the student's skills and competence on insulin (Novopen <sup>®</sup> ) preparation and administration techniques.	Faculty member	SP: Female, mid 40's newly prescribed Novopen-3 <sup>®</sup> .
Station 6	<b>REST STATION</b>	-	-	-
Station 7	Drug Information Inquiry from a Health Professional	Evaluation of the student's ability to select and evaluate appropriate literature and respond to drug information inquiry in a timely manner.	Faculty member	Another faculty member (acting as a physician) making enquiry about the superiority, availability and use of a new inhalational insulin product (Exubera <sup>®</sup> ).

DRPs = drug-related problems; RP = real patient; SP = standardized patient or patient actor; CVD = cardiovascular disease; MDI = metered dose inhaler.

The broad competencies tested in the objective structured clinical examination (OSCE) included patient counselling and communication, identification and resolution of drug-related problems (DRPs) using an evidence-based approach, and literature evaluation/drug information provision. The clinical situation in which these were tested include cardiovascular disease(s) with co-morbidities (for DRPs competency); anticoagulation, diabetes and respiratory clinics (for counselling and education competencies); and enquiries on drug information from other healthcare professionals (for literature evaluation and drug information competency). A summary of the workstations is found in Table I. Detailed samples on how the workstations were developed are available from the authors upon request. The validated contents of the workstations were sent back electronically (through OSCE coordinators) to all stakeholders with the sole purpose of getting feedback. Feedback was received and final versions of the stations were developed and documented.

#### *Development of OSCE stations components*

Another meeting was summoned and standardized assessment instruments (structured marking schemes) were developed based on the tasks assigned at individual stations. Instructions to candidates and to simulated patients/actors were also designed during this meeting. The marking schemes were prepared in the form of dichotomous checklists for all the competencies. The checklists items were individualized to each station. These were again face-validated later by the external reviewer, course coordinator, and departmental Chair. One of the fundamental innovations is the design of the checklists for the drug-related problems and drug information stations, which we could not find elsewhere. Samples of these materials are also available on request.

#### *Patient recruitment/approval*

Since the conduct of the OSCE involved human subjects, existing ethical principles were complied with. The Blueprint and other written protocols were approved by the University Ethics Committee. Patients and actors were recruited in collaboration with physicians from a local hospital (a centre utilized for teaching). Real patients with the related disease states were randomly selected from the hospital electronic medical records. Outpatients that attended specialists' clinics for review were included, depending on the tasks. Critically-ill patients were excluded from participation in the OSCE. Preference for selection was given to real and simulated patients who had previous experience with similar examinations. Patients recruited into the OSCE were given thorough explanation on the purpose of the OSCE and were required to sign an informed consent form which was prepared in Malay language (Bahasa Malaysia) on a voluntary basis. The recruited patients and patient actors underwent two briefing/training sessions and rehearsal to ensure the practicability of the examination.

#### *Compilation of final examination materials by OSCE coordinators.*

All required examination materials and assessment tools were reviewed, prepared and compiled by the two coordinators and one faculty professor. Instructions to examiners for each station were also designed. Two review meetings of OSCE stakeholders were convened and all examination materials

were thoroughly scrutinized for accuracy and consistency. A final meeting on the conduct of the OSCE was held three days prior to the examination to assess and verify the degree of preparedness for the real examination. The examination was pilot-tested to ensure feasibility on the same day after the final meeting, using a few members of faculty staff, authors of stations, coordinator, and few medical students.

#### *Students' Briefing Sessions*

Two briefing sessions were conducted. The first on "What is OSCE and How it Works" with audiovisual demonstration on how OSCEs were conducted in other schools and how our OSCE was to be conducted. In this, all necessary details on the nature of the examination and what was expected of a student were given by the course coordinator. The second briefing was convened two days prior to the examination in which students were briefed on the general rules of conduct of the examination as well as order of proceedings.

#### **Implementation and Procedure for the OSCE**

The examination was conducted in two concurrent sessions for two groups consisting of 21 students each, randomly assigned to Clinical Skills Laboratory or Pharmacy Practice Departmental Rooms. A session comprised of seven stations including two stations provided for rest. Twelve faculty members were the evaluators and health professionals (actors) during the examination. Structured and standardized marking schemes were used by the evaluators for all the five active stations, where students were allowed 15 minutes at each to complete the assigned tasks. There were three rotations for the 21 students in the Clinical Skills Laboratory (seven students per rotation). The same pattern applied to the students examined at the Pharmacy Practice Departmental Rooms (seven students for the first, second and third runs). For the two-session examination (consecutive sessions), the estimated time per run was 140 minutes (2 hrs 20 mins) and 420 minutes (7 hrs 0 min) for the entire examination (including allowance for movements and logistics). Another 1-hour provision was made for lunch break after the second rotation. In order to review the processes of setting and conducting the OSCE and to increase fairness and objectivity, most of the activities were videotaped and surveys of the students' opinions were conducted. The videotapes could be used for checking the consistencies of the examiners, errors committed during evaluation and how to improve in the future. They could also be used as educational materials for teaching and learning. The five active-station OSCE contributed a total of 20 marks in the end of the course examination. The individual station's checklists that contained maximum obtainable points of 24 were scaled-down (reduced proportionally) to maximum obtainable points of 20 after the examination.

#### **Evaluation**

An OSCE was successfully developed and applied to test the clinical competencies of fourth-year students. The objective was to ensure that the OSCE contained appropriate and adequate samples of the competences that were meant to be assessed, yet only five active stations were used in the pilot.

Performance grading by holistic method showed that all the students successfully passed the examination. The overall performance in the OSCE was appreciable with 16.8 out of 20 marks as the class average. The minimum and maximum marks obtained were 13.4/20 and 19.8/20 respectively.

Individual OSCE station scores with mean  $\pm$  SD, maximum, and minimum marks obtained by the students are summarized in Table 2. The students scored the highest marks in insulin delivery devices counselling station (mean  $\pm$  SD=17.6 $\pm$ 3.1), followed by DRPs identification/resolution and warfarin counselling stations with mean  $\pm$  SD of 17.36 $\pm$ 2.7 and 16.9 $\pm$ 2.2, respectively. Examinees also scored the least in the drug information station (mean  $\pm$  SD=15.55 $\pm$ 3.8). Inferential statistical analysis was also performed using repeated measures ANOVA to see variations on how the students performed at the stations. Statistically significant differences were found between students' performances/abilities at the individual stations (Greenhouse – Geisser correction formula revealed  $F=3.698$ ;  $p=0.012$ ). Subsequent pair-wise  $t$ -test showed that the students performed significantly lower in the examination at the Drug Information Station than at Insulin Counselling Station ( $t=2.94$ ,  $p=0.005$ ), DRPs Station ( $t=2.64$ ,  $p=0.012$ ), and Warfarin Counselling Station ( $t=2.10$ ,  $p=0.042$ ).

Furthermore, a questionnaire survey was conducted to obtain students' feedback on the new assessment tool. Students generally accepted this method of assessment as the most appealing and rated it better than other traditional methods of assessment from the perspective of degree of learning. In addition, an overwhelming proportion of the students admitted that the OSCE provided a useful and practical learning experience and majority found it to be helpful in highlighting areas of weaknesses in their clinical competencies. One fundamental finding is that, about half of the students raised concerns that personality/ethnicity/gender

as well as inter-patient and inter-assessor's variability were potential sources of bias which could affect their scores. Detailed findings on the validity and reliability of the designed and implemented OSCE through the survey are available in a companion article (Awaisu *et. al.*, 2007).

## Discussion

The Kulliyyah (Faculty) of Pharmacy at the International Islamic University Malaysia (IIUM) strives to train graduates that would be competitive and able to deliver direct and effective patient care as envisioned by the profession. Thus, the Faculty has taken the pioneering role during 2005/06 academic session to experiment the effectiveness of this type of examination on their final year students. This innovation is also a means to strengthen the confidence of our students as they go into a competitive world of professional practice.

This change comes at a time when the profession of pharmacy is undergoing transformation towards more clinically-oriented roles. It is worthwhile to note that, even in Malaysia where pharmacists are still in the era of disputes over "dispensing rights and its separation," the profession has metamorphosed from a profession chiefly concerned with the bulk preparation and distribution of drug products to one centred on ensuring that optimal drug therapy outcomes in patients are achieved. Hence, pharmacy training and education should in parallel be focused towards inculcating problem-solving skills. By this, we would surely respond to the paradigm shift in pharmacy education and practice around the globe.

Although this method of assessment provides information difficult to obtain through traditional pencil-and-paper tests, it requires considerable financial resources and faculty time (Stowe and Gardner, 2005). In fact, OSCE has not been used

Table II: Students' Performance at Individual OSCE Stations

Station Number	Task at the Station	Mean Score $\pm$ SD	Max. Score	Min. Score	$p$ -value <sup>a</sup>
1	Counselling on warfarin	16.90 $\pm$ 2.2	20	14	0.012
2	Counselling on asthma devices	16.60 $\pm$ 3.1	20	9	
3	Rest Station	-	-	-	
4	DRPs identification and resolution	17.36 $\pm$ 2.7	20	10	
5	Counselling on insulin delivery devices	17.60 $\pm$ 3.1	20	9	
6	Rest Station	-	-	-	
7	Drug information provision	15.55 $\pm$ 3.8	20	6	

<sup>a</sup>Repeated Measures ANOVA was used to examine the effect of task at OSCE station on students' performance. There were statistically significant differences between students' performances at the individual stations ( $F$ -value=3.698;  $p=0.012$ ).  $p < 0.05$  was considered significant.

extensively in pharmacy education due to high costs and difficulties associated with developing and implementing this vital assessment method (Fielding *et al.*, 1997; Carpenter, 1995). In our own case, the seven station examination for 42 students ran in two concurrent sessions consumed about 420 minutes on the average for each session. This occurred regardless of logistics and an hour break. The OSCE was highly time and resource consuming such as six stakeholders meetings and provision of food for examiners, supportive staff, invigilators, and patients. Incentives and reimbursements were also provided to patient participants.

We hypothesized that different clinical competencies or tasks at OSCE stations may have profound effects on the examinees' performance. Based on the students' performances at the individual stations, it was clear that the final year pharmacy students were better at counselling patients on, for example, insulin delivery devices, identification of DRPs and using evidence-based approaches for their resolution, as well as patient counselling on warfarin therapy compared to counselling patients on asthma devices and drug information provision. Therefore, there were obvious variations in the students' abilities depending on the types of tasks they were prompted with. This finding has important implications for the students' preparedness for effective delivery of pharmaceutical care, especially as it relates to problem-solving skills and literature evaluation. Perhaps it has highlighted areas of weaknesses in students' knowledge and skills. More emphasis should therefore be placed on drug information and literature evaluation competencies, since students performed poorly in these activities. However, the inter-evaluator variability could have eluded some realities and might have significantly affected the outcomes.

One of the cardinal strengths of the OSCE was the use of both simulated and real patients which was influenced by the individual station's objectives as well as availability of resources. Secondly, a drug-related problems (DRPs) station was designed with tasks that mimic the real-life components of the pharmaceutical care process, that is: identification, prevention and resolution of DRPs based on an evidence-based approach. Nevertheless, it is worthwhile to note that the small sample size (few number of stations) used in the examination might have undermined the reliability of the examination. Previous studies have indicated that 10 to 40 stations are necessary to acquire satisfactory inter-station reliability (Swanson *et al.*, 1987). Therefore, there is a reasonable doubt as to the reliability of the examination. This was further complicated by having two concurrent sessions, making inter-assessor variability an additional confounder of reliability. However, since this exercise was considered a "pilot testing", we would have to embrace the challenges of seeking for a more valid and reliable OSCE development in the future. One solution to this logistic dilemma is to increase competencies to be tested. Some proposed competencies for the future include adverse drug reaction (ADR) causality assessment, pharmacokinetics/therapeutic drug monitoring (testing students' ability to run assays and dosing regimen design) as well as education/counselling in other clinical situations such as HIV/TB patients.

## Conclusion

The design and implementation of the OSCE as a pilot-testing in a Faculty of Pharmacy was a success according to our objectives. However, it was a highly time and resource consuming evaluation method, yet this new trend in pharmaceutical education and curriculum reform could serve as a role model for other colleges of pharmacy to emulate. It is also our hope and belief that this effort would serve as a morale booster for our students to deliver effective pharmaceutical care in their professional life. The study revealed that undergraduate pharmacy students were excellent in performing patient counselling and identification/resolution of DRPs, but not in drug information competency. "*Necessity – is the mother of all inventions; as experience – is the best teacher*".

## Authors' contributions

Both AA and MHNM coordinated the design and conduct of the OSCE; conceptualized the idea of reporting this experience; and initial report writing. AA expanded and redrafted the initial report and MHNM edited its final version. Both authors have read and approved the contents of the final version of the manuscript.

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