

# Experience with Objective Structured Clinical Examinations as a Participant Evaluation Instrument in Disease Management Certificate Programs

Joli D. Cervený<sup>1</sup>, Rebecca Knapp, Mario DelSignore and Deborah Stier Carson

*College of Pharmacy, Medical University of South Carolina, Charleston SC 29425*

Nanette C. Bultemeier

*College of Pharmacy, Oregon State University, Portland OR*

This paper describes the South Carolina Diabetes Management Certificate Program, the comprehensive approach to participant evaluation, and presents an analysis of participant evaluation instruments. The four-month certificate programs have been offered since 1996. Successful completion of the certificate program is determined by written examination and clinical evaluation. The clinical evaluation is comprised of a case presentation, portfolio, and objective structured clinical examinations (OSCEs). Participant OSCE performance for the 1996-1998 cohorts was compared to performance on other clinical evaluation instruments. Results indicated low correlation between the three clinical evaluations and between the written examination and the overall clinical evaluation, suggesting the necessity of multiple evaluation instruments. Although time and resource intensive, OSCEs offer a unique addition to traditional evaluation. This data suggests a comprehensive approach to participant evaluation is necessary because of the high level of responsibility and care expected of pharmacists completing certificate programs.

## INTRODUCTION

Certificate programs are gaining momentum as a mechanism for pharmacists to upgrade their clinical skills and knowledge base so that they can remain viable health care providers. Colleges of pharmacy, state and national pharmacy organizations, and pharmaceutical industry have been developing certificate programs to meet this demand. In 1997, 38 certificate courses were offered by 20 different colleges and schools of pharmacy.<sup>2</sup>

Not surprisingly, the content of these programs varies significantly, as do the participant evaluation standards. In a move toward consensus on the critical elements and indicators of quality of certificate programs, the American Association of Colleges of Pharmacy (AACCP) and the American Council on Pharmaceutical Education (ACPE) held the second Invitational Conference on Certificate Programs in Pharmacy in 1998(1). Participant evaluation was addressed with three broad statements. The evaluation of participants in certificate programs should:

- be required of the participants and should be a part of the initial planning. Evaluation should include both didactic and experiential components.
- be congruent with outcome expectations. For example, if skill development is an outcome expectation, the participant evaluation should include demonstration of skill acquisition.
- consider a predetermined passing level based upon the stated level of performance expectation. Also, evaluation should provide feedback to participants on their performance.

The participant evaluation indicators may be used to support the development of standards and provide benchmarks for a process of quality assurance(1).

The certificate programs in South Carolina use a comprehensive approach to participant assessment, and may serve as a model for evaluation instruments used in other certificate programs. The Colleges of Pharmacy in South Carolina, the Medical University of South Carolina (MUSC) and the University of South Carolina, have provided disease management certificate programs since 1996. These certificate programs are the result of collaborative efforts from faculty at both Colleges of Pharmacy, the MUSC College of Medicine, and experts in the field from the professions of pharmacy, nursing, and allied sciences. The overall goals and an overview of the curriculum of the certificate programs are listed in Tables I and II, respectively.

In addition to a written examination which assesses knowledge, the South Carolina certificate programs use three clinical evaluation tools: portfolios, case presentations, and objective structured clinical examinations (OSCEs). The OSCE is an innovative component of certificate program participant evaluation. It features a brief encounter structure, during which the focus is typically on evaluating a single clinical

<sup>1</sup> Corresponding author address: Medical University of South Carolina, P.O. Box 250554, Charleston SC 29425.

<sup>2</sup> Supernaw, R.B., "Reflections on developments: where do we go from here?" The American Association of Colleges of Pharmacy Interim Meeting, March 3, 1997, Washington DC.

**Table I. Overall goals of the South Carolina Disease Management certificate programs**

1.	Enhance the knowledge base and clinical skills of participants in the preventative aspects and therapeutic management of specific disease states;
2.	Provide a framework for interactive and interdisciplinary exercises in a team approach to disease management;
3.	Reinforce and enhance communication skills of participants in order to more effectively provide patient education and drug information to other health care providers;
4.	Explore methods of establishing clinical pharmacy activities and services, particularly in the community setting; and
5.	Provide a method by which participants who successfully complete the program may apply the experience toward academic credit in a PharmD program.

skill(2-4). The OSCE is widely used in medical education, as this evaluation method allows direct and reliable assessment of clinical performances on a large scale(5). The OSCE, or similar clinical skill evaluation methods using standardized patients (SPs), are beginning to be recognized by pharmacy educators and licensing agencies as an important means of assessing clinical competence when interacting with patients and health care providers(6-9). This article describes the South Carolina Certificate Program participant evaluation process and assesses three years' experience with the Diabetes Management Certificate Program OSCEs.

**METHODS**

**Diabetes Management Program.** The first program in a series of disease management modules was Diabetes Management. It was first offered in Fall 1996 and was offered subsequently in 1997 and 1998.

MUSC College of Pharmacy has allotted 1.5 full-time equivalents (FTEs) toward administration of the program and preceptorship. Preceptors, faculty, and standardized patients are paid through dual employment or with an honorarium. The cost of the program is primarily incurred by the participants (\$800-\$1,000) and pharmaceutical company support. Support from the Diabetes Initiative of South Carolina, a legislatively funded program whose purpose is to educate health care professionals in the management of diabetes, was highly instrumental in the development and success of the Diabetes Management program(10).

**Evaluation of Participant Performance.** The evaluation process is both formative and summative and is comprised of two components, a didactic portion and a clinical evaluation. The didactic portion is a case-based multiple-choice exam. The clinical evaluation includes a portfolio, a case presentation, and

**Table II. Overview of certificate program curriculum**

- Program curriculum was developed based on input from faculty and a survey of community pharmacists.
- Ten to 15 hours of reading is assigned prior to the first classroom session.
- During two weekends, 30-35 hours of didactic and workshop sessions are conducted. The two weekends are purposefully separated by four to five weeks so that participants have a chance to return to their practices, identify patients, contact primary care providers, and begin developing pharmacotherapy plans before they return to class.
- Participants are expected to commit 80 to 100 hours of experiential effort in their own practice. They are under the guidance of a regionally based clinical preceptor.
- Small groups of participants who are regionally matched with a preceptor are encouraged to form weekly work-study groups to stimulate discussion regarding patient care and practice management.
- The programs are approved for 80 to 85 C.E.U.s and 4.0 hours of academic credit.
- A certificate of completion is awarded for each module successfully completed.

OSCEs. The portfolio is weighted the heaviest of the clinical evaluation instruments. (See footnote a, Table III) A minimum score of 70 percent must be achieved on the didactic portion in order for the participant to advance to the clinical evaluation. The participant must then achieve at least 70 percent on the clinical evaluation to complete the certificate program.

The written examination is a 200 question multiple-choice open-book test that occurs approximately two months into the program after the second didactic weekend. The written examination is a summative evaluation of knowledge base. The written exam covers areas such as standards of care, assessment of medical records, and knowledge of therapeutics, disease presentation, and complications.

The clinical evaluation instruments-portfolios, case presentations, and OSCEs-evaluate communication skills, as well as the ability to make clinical assessments and apply knowledge on a patient-specific basis. At the first didactic weekend, participants are instructed to compile a portfolio of patient cases that are encountered during the program. Participants must track three or more patients for at least three months. They must gain access to the medical record, suggest pharmacotherapy and non-pharmacotherapy recommendations, provide plans for follow-up, discuss the plan with the physician, and document outcomes. The portfolio is used to evaluate the participants' documentation skills and their ability to formulate a therapeutic plan and track clinical outcomes. The portfolio is due at the end of the four-month program. For most participants, this is the last component submitted.

**Table III. Participant performance on all evaluation instruments, 1996-1998**

	OSCE	Portfolio	Case presentation	Clinical grade <sup>a</sup>	Written exam
No. participants <sup>b</sup>	89	74	53	73	91
Mean	78.68	85.97	87.34	84.48	88.84
Range	58-96	68-100	75-98	75-95	65-98
SD	8.33	6.68	5.19	5.35	6.07

<sup>a</sup> Calculation of clinical grade: 1996: OSCE 25 percent, Portfolio 50 percent, Case Presentation 25 percent; 1997: OSCE 35 percent, Portfolio 65 percent; 1998: OSCE 30 percent, Portfolio 50 percent, Case Presentation 20 percent.

<sup>b</sup> 91 participants completed the written exam. 73 participants completed the written examination and all components of the clinical evaluation. The case presentation evaluation instrument was not administered in 1997.

SD - Standard Deviation

**Table IV. Participant performance on OSCE stations, 1996-1998**

Year (number participants)	Statistics	Mix and inject insulin	Meter instruction	Call physician	SOAP note	Insulin dosing	Screening	Foot care	Pharmaco- therapy work-up
1996 (41)	Mean	8.37	8.78	8.64	8.15	5.40	NA	8.56	7.16
	Range	4.5-10.0	1.3-10.0	6.4-10.0	3.3-10.0	0-10.0		7.0-10.0	1.9-9.5
	SD	1.17	1.64	0.90	1.60	2.93		0.88	1.80
1997 (22)	Mean	8.50	9.66	7.12	6.84	8.30	8.27	7.70	8.18
	Range	6.4-10.0	8.1-10.0	4.5-10.0	4.0-10.0	2.5-10.0	2.0-10.0	4.0-10.0	5.5-10.0
	SD	1.09	0.57	1.44	1.67	2.33	2.20	1.56	1.36
1998 (26)	Mean	8.35	9.71	6.91	7.03	6.73	7.69	7.60	6.62
	Range	4.5-10.0	7.5-10.0	2.1-10.0	2.5-10.6	0.0-10.0	4.0-10.0	5.0-10.0	2.0-10.0
	SD	1.38	0.66	2.18	2.63	2.64	1.81	1.24	2.07
1996-98 (89)	Mean	8.40	9.27	7.75	7.50	6.51	7.96	8.07	7.26
	Range	4.5-10.0	1.3-10.0	2.1-10.0	2.5-10.6	0.0-10.0	2.0-10.0	4-10.0	1.9-10.0
	SD	1.21	1.28	2.70	2.70	2.93	2.00	1.26	1.86

SD - Standard Deviation

NA - Not Applicable

Case presentations are used to assess communication of the plan to providers. Participants present a patient in SOAP (Subjective / Objective /Assessment / Plan) format to their preceptor. Participants are evaluated for presentation content and appropriateness of interventions. Preceptors provide feedback to participants following the presentation.

OSCEs serve as both a formative evaluation process and as part of the summative evaluation. They are designed to assess clinical competence when interacting with patients and health care providers. OSCEs occur two or three weeks after the written exam so that participants can meet with preceptors to review areas of uncertainty on the written exam and to prepare practical skills. The OSCEs require the participant to be present on campus for one half-day.

**Description of Diabetes Management OSCE.** The participant rotates through nine stations that are set up with patient-related scenarios. The stations are prepared with all of the items needed to complete the task. The SPs are instructed to portray patients or health care professionals in a standardized and consistent manner during the staged encounters. Participants interact with the SPs as if they were performing a real encounter. Pharmacy residents, faculty, and the program coordinator's family were recruited to portray the SPs in the Diabetes Management OSCEs.

The stations are designed to assess the participant's performance of a task based on pre-determined goals and objectives. Encounters are developed from actual life experiences and incorporate skills deemed essential by the faculty. Examples include educating a patient on insulin injections and the self-monitoring of blood glucose, interpreting laboratory data, recognizing and interpreting clinical signs, taking histories, and providing drug information and suggestions to health care professionals.

Participants rotate through stations at twenty-minute intervals. Fifteen minutes are allotted to complete the station. Evaluators are present during the encounters to assess the participant's performance. Checklists are used to provide consistency in evaluating. The station evaluator is allotted five minutes to provide immediate feedback and instruction to the participant.

#### Comparing OSCE and Other Evaluation Methods.

The analysis of participants' performance throughout the evaluation processes was performed for several reasons. Univariate

descriptive statistics including means, standard deviations, and frequency distributions were determined for each evaluation instrument for all participants, as well as for each OSCE station for each year of the program. Mean participant scores for each OSCE station were analyzed to determine relative areas of high, mid-range, and low performance. This information will be used to refine the program curriculum and to focus future continuing education of participants who have completed the Diabetes Management Certificate Program. Comparison of mean performance across time was carried out using a one way analysis of variance (ANOVA). If ANOVA results indicated significant difference across years, Tukey's multiple comparison procedure was used to make pairwise comparisons between years. The ANOVA procedure was carried out separately for each OSCE station. This information was used to determine the presence of year-to-year consistency in performance measurement.

Because the use of multiple evaluation instruments, and especially the OSCE, requires significant time and financial commitment, we sought to determine whether participant performance on any one of the evaluation instruments predicted performance on another. This finding would suggest that one or more of the evaluation instruments could be eliminated without losing the strength of a multiple instrument evaluation approach. However, we believed that the OSCEs measure clinical skills that can not be evaluated by other means. The magnitude of the association between scores on the OSCE and the written exam, case presentation, and portfolio was addressed by performing simple linear regression and calculating Pearson product moment correlation between OSCE and each of the other instruments. Results are reported as both correlation coefficients and as percent of variation in one instrument explained by another instrument (*e.g.*,  $r^2$ ). These analyses were carried out for all years combined and separately in each observation year. In addition, the association between written exam and clinical grade was determined.

## RESULTS

Data for 73 participants who completed the Diabetes Management certificate program in 1996, 1997, and 1998 were available. Data pertinent to 1996-1998 OSCE performance were available for 89 participants.

**Table V. Comparison of OSCE and other performance tools, 1996-1998<sup>a</sup>**

Year	Statistic <sup>a</sup>	OSCE versus portfolio	OSCE versus case presentation	OSCE versus written exam	Written exam versus clinical grade
1996	r <sup>2</sup> P	0.1941 0.007	0.0359 0.268	0.0815 0.078	0.0908 0.083
1997	r <sup>2</sup> P	0.0640 0.256	NA	0.1611 0.064	0.4931 <0.001
1998	r <sup>2</sup> P	0.2471 0.050	0.0071 0.748	0.2011 0.022	0.2702 0.039
1996-98	r <sup>2</sup> P	0.1221 0.002	0.0158 0.370	0.1623 <0.001	0.1446 0.001

<sup>a</sup> P value, and r<sup>2</sup> are from linear regression analysis.

NA - No data available

**OSCE Station Performance.** Descriptive statistics including means, ranges, and standard deviations from the univariate analysis for each evaluation instrument and for each OSCE station are summarized in Tables III and IV, respectively. Relatively high levels of performance are evident for teaching patients to mix and inject insulin and for instructing patients on using a glucose meter. Mid-range levels of performance are found for the foot care and diabetes screening stations. Performance levels are lower for the SOAP note, pharmacotherapy workup, call to physician, and insulin dosing stations. No statistically significant pattern in year-to-year participant performance emerged in the comparison of means using ANOVA for each OSCE station.

**Associations between OSCE Scores and Performance on Other Evaluations.** The results of simple linear regression as summarized in Table V indicate a statistically significant linear relationship between OSCE and portfolio ( $P=0.002$ ), OSCE and written exam ( $P<0.001$ ), and written exam and clinical grade ( $P=0.001$ ). The linear relationship between OSCE and portfolio is significant for 1996 ( $P=0.007$ ) and 1998 ( $P=0.05$ ). The OSCE and written exam linear relationship is statistically significant for 1998 ( $P=0.022$ ) and marginally significant for 1996 ( $P=0.078$ ) and 1997 ( $P=0.064$ ). The linear relationship between the written exam and clinical grade is significant for 1996 ( $P=0.083$ ), 1997 ( $P<0.001$ ), and 1998 ( $P=0.039$ ).

Although there is a statistically significant linear relationship between OSCE and portfolio, OSCE and written exam, and written exam and clinical grade, the magnitude of each association, and hence the predictive value, as given by the coefficients of determination (r<sup>2</sup> values) of 12.21, 16.23 and 14.46 percent respectively is very weak. The r<sup>2</sup> values of 12.21, 16.23 and 14.46 percent indicate that approximately 12 percent of the variation in portfolio is explained by OSCE, approximately 16 percent of the variation in written exam is explained by OSCE, and approximately 14 percent of the variation in written exam is explained by clinical grade.

## DISCUSSION

A sophisticated skill set is required to provide disease management services. These skills range from disease and therapeutic knowledge to communication and documentation abilities to physical assessment. All of these areas are addressed in the curriculum of the South Carolina Diabetes Management certificate program. The performance measured with the evaluation

instruments is congruent with the complex set of expected outcomes. Because the certificate program is one of the credentialing mechanisms for pharmacist reimbursement in South Carolina, and because of patient care liabilities and the need to uphold program reputation, comprehensive participant evaluation is important.

The rationale for multiple evaluation instruments to assess participant performance is that each instrument will measure a different dimension of performance. Our data implies this to be true for the written examination, OSCE, portfolio, and case presentation, and is in agreement with previously published findings(11). Participant performance on the OSCE is not indicative of performance on the portfolio and the case presentations, and vice versa. Performance on the written examination was not predictive of performance on the overall clinical evaluation. These findings suggest multiple evaluation instruments, including the OSCE, are necessary to comprehensively assess certificate program participants.

**Pros and Cons of Incorporating OSCEs into Participant Evaluation.** The use of OSCEs has several major advantages over other assessment strategies(12). Each participant encounters a variety of clinical scenarios since all nine OSCE stations can be done in one half-day. Specific challenges, such as those that may be encountered by the practicing pharmacist, can be incorporated into the scenarios. Each participant encounters the same stations, controlling the case mix included in the examination. In contrast, the portfolio and case presentations do not allow direct comparisons of the participants' abilities. For OSCEs, objective performance criteria are developed in the form of a checklist and marked as the participant works through the scenario. As such, OSCEs provide systematic assessment of clinical skills, much like a written examination permits for assessment of knowledge.

The OSCE encounters are similar to written clinical simulations, but have the additional advantage of human interaction. Because the intent of participant evaluation is to determine the individual's ability to competently provide patient care, observing the participant doing just that—providing patient care—is insightful. Staged encounters are carried out because it is not practical for preceptors to directly observe the participants' interactions with the real patients that they are asked to follow in their own practice setting and because control of the case mix would be lost. Additionally, OSCEs may assess skills other than the recollection of facts, allowing stu-

dents to generate original, spontaneous responses rather than selecting responses from a given list or formulating a response on paper. OSCEs allow the student to integrate pharmacotherapeutic knowledge, problem solving skills, and communication and interpersonal skills into each exercise. In addition, OSCEs permit participants to learn from potentially dangerous mistakes prior to an actual patient encounter.

The OSCE is a valuable instrument of formative feedback. Because the OSCE encounter occurs "live" as opposed to being videotaped, evaluators can provide immediate feedback to participants. Skill performance and information delivery can be analyzed by evaluators, and corrections and instructive tips can be given while the encounter is fresh in the participant's mind. In addition, the clinical preceptors use the results of the OSCEs to tailor the learning experience of the participants by addressing areas of deficiency. We believe both participants and faculty gain insight from the OSCEs regarding the definition and identification of specific learning needs. Faculty members responsible for developing and administering OSCEs may derive clearer and more meaningful descriptions of the focus for future Diabetes Management programs.

While the OSCE can determine whether the participant is capable of carrying out a particular skill, it does not determine whether the participant will use that skill with an appropriate problem(5). In this respect, case presentations and portfolios are useful for evaluating the appropriateness of the application of clinical skills and interventions.

Most of the criticism against OSCEs has centered around their high cost. Development and implementation of OSCEs requires substantial effort and resources. Initial reports, primarily from medical literature, on OSCE costs have provided very disparate data, ranging from a low of \$11 per participant, to a high of \$1,200 per participant. We estimate the cost per participant for the Diabetes Management OSCE to be about \$80 - \$100. Several factors contribute to this huge variability, including the format of individual OSCEs (number of stations, number of standardized patients, number of evaluators), institutional differences in administrative and faculty costs, available educational resources, the purpose of the examination ("high stakes" versus "low stakes"), and other "hidden" administrative costs. Low-cost reports are often limited in their expense reporting process.(13).

**Limitations.** Although there are a number of psychometric issues that merit attention relative to OSCEs, including validity and reliability analyses, this assessment of the Diabetes Management OSCE primarily explores the issue of practicality(11). The OSCE has been extensively studied as an evaluation method in undergraduate and postgraduate medical training, and the validity and reliability of OSCEs have been successfully demonstrated(14). The Diabetes Management OSCE is a relatively "low stakes" evaluation, since the OSCE is one of three clinical evaluation instruments that is factored into the clinical grade. If participant performance is unacceptably poor on an OSCE station, formative feedback is given immediately to the participant. If overall OSCE performance is unacceptably poor, the participant is given the opportunity to repeat the entire OSCE sequence.

## CONCLUSION

The South Carolina Disease Management certificate program approach to the evaluation of participants reflects all of the critical elements defined by the AACP/ACPE conference for participant evaluation. The participant evaluation instruments used in the South Carolina certificate programs include both didactic and experiential participant evaluation, as well as clinical performance evaluation. The approach includes both formative and summative evaluation of the participant's achievement. The outcome expectations—enhancement of knowledge base and clinical and communication skills—are assessed through the multi-instrument evaluation process and the passing level is predetermined. Feedback is provided formally in the case presentation and OSCE evaluation components and informally throughout the learning and evaluation process.

Although time and resource intensive, using the OSCE in addition to more traditional evaluation instruments measures ability-based outcomes probably not otherwise measured. We believe a comprehensive approach to certificate program participant assessment, such as employed by the South Carolina certificate programs, is necessary because of the high level of responsibility and care that is expected of pharmacists completing certificate programs.

*Am. J. Pharm. Educ.*, **63**, 377-381(1999); received 5/14/99, accepted 7/19/99.

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