Development of a Practical Examination Utilizing Standardized Participants for Disease State Management Credentialing

Eric F. Schneider, Stephanie Gardner and Jill T. Johnson

College of Pharmacy, University of Arkansas for Medical Sciences, 4301 West Markham, Slot 530, Little Rock AR 72205-7122

Pharmacists are developing practices in which they take responsibility for managing patients' disease states. A mechanism to assess problem solving and patient communication skills for the purpose of credentialing is needed. Drawing from the experience of medical education, utilizing standardized participants is an ideal method for such assessment. The University of Arkansas has developed four practical examinations for credentialing pharmacists in disease state management (DSM). These examinations utilize actors trained to portray patients or physicians in a variety of scenarios pertinent to a pharmacist's DSM practice. The pharmacist is evaluated on his/her ability to assess a clinical situation, develop a solution, and communicate a response. To date, 114 pharmacists have been tested in anticoagulation, asthma, diabetes mellitus, and dyslipidemia with an overall pass rate of 89.5 percent. Standardized patient use may prove to be the most effective method of evaluating pharmacists' practical skills for the purpose of DSM credentialing.

With the approval of a Health Care Financing Administration (HCFA) waiver in May of 1998, the State of Mississippi launched the practice of pharmacy into a new arena(1). The HCFA waiver provides an avenue for reimbursement of clinical activities performed by qualified pharmacists in the areas of diabetes mellitus, asthma, dyslipidemia, and anticoagulation. Thus, the goal of payment for patient care services has been met. However, with the approval of the waiver, the Mississippi State Board of Pharmacy was given the task of assuring pharmacists are qualified to provide these services(2).

Following the lead of Mississippi, many States have begun the process of integrating patient management services into the practice of pharmacy. In July of 1999, the newly amended Arkansas Pharmacy Practice Act charged the Arkansas State Board of Pharmacy with the task of developing regulations for the credentialing of pharmacists for disease state management (DSM) practices(3). The result was a two part credentialing process consisting of a standardized pencil-and-paper examination developed by the National Association of Boards of Pharmacy (NABP) as well as an examination of practical skills.

Under the authority of the Arkansas State Board of Pharmacy, the University of Arkansas for Medical Sciences (UAMS) College of Pharmacy was asked to develop and administer DSM practical examinations for pharmacists licensed in Arkansas. The purpose of this manuscript is to outline the methods adopted for practical examinations by the UAMS College of Pharmacy. The examinations utilize standardized participants and are designed to evaluate the competencies set forth by the NABP in specific areas of disease state management. Competencies selected for testing by practical examination are those deemed difficult to assess using a written examination. These competencies are available from NABP. To date, examinations have been developed and

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administered in the areas of anticoagulation, asthma, diabetes mellitus, and dyslipidemia.

HISTORY OF THE STANDARDIZED PARTICIPANT

A standardized patient is "a simulated or real patient who has been taught to present a problem so accurately that the simulation cannot be detected by a skilled clinician(4). Standardized patients are used in the education of medical students in objective structured clinical examinations (OSCEs). Developed in the 1970's, the OSCE format assesses specifically defined clinical skills(5). In an OSCE examination, students are presented with a short clinical scenario containing directions about the encounter. The student then enters an examination room and performs the task outlined on the direction sheet. A faculty grader observes the student. Performance is based on a predefined checklist and may be assessed by both the faculty grader and standardized participant. The student receives feedback from the faculty grader and then moves to the next station(6). The use of standardized patients in medical education has progressed to the point that they will become a required component in Step two of the United States Medical Licensure Examination for physicians within the next three years(5).

The UAMS College of Pharmacy has used the Pharmaceutical Care Encounters Program (PCEP) to evaluate clinical skills of traditional Doctor of Pharmacy students since 1996. The PCEP is based on the OSCE used by the College of Medicine; however, the PCEP utilizes standardized participants (SP). In contrast to a standardized patient, a standardized participant may be a patient, physician, nurse, or other healthcare professional. In the PCEP, the student is allowed a nine-minute preparation period prior to entering the room with the SP. The student then has nine minutes to complete the encounter. Like the OSCE, the student is evaluated with a pre-defined checklist of objectives for each station(7).

METHODS

DSM Practical Examination Structure

The DSM examinations utilize actors to serve as standardized participants. Each examination consists of three standardized participant encounters. The standardized participant is typically a "patient"; however, the actor may be portraying a physician or other healthcare professional. Most encounters are face-to-face, but telephone encounters are occasionally utilized. The examination is conducted at the UAMS clinical skills center. The clinical skills center consists of a control room, 10 examination rooms, and 10 preparation stations. Each examination room is equipped to allow a grader to observe and hear the entire encounter from the control room. The observer can also provide feedback via intercom in a specific examination room without leaving the control room. Additionally, all encounters can be videotaped from within the control room. A sample patient encounter is outlined in the Appendix.

Examination Procedure

Once the examinee enters the clinical skills center, he/she is directed to a preparation station. At that time, the "Instructions to the Pharmacist" are available. The pharmacist has 15 minutes to prepare for the encounter. Appropriate reference materials are provided at each station. Because the intent is to test patient assessment, communication, and clinical skills rather than disease state knowledge per se, the examinee is also allowed to bring his/her own references. If the SP is a patient, his/her pharmaceutical care "chart" may also be available in the preparatory station.

After the 15-minute preparation period, the examinee is instructed to enter the patient room. A faculty grader observes and scores the encounter from the control room. The examinee has 15 minutes to complete the encounter. Scoring is accomplished using a standardized checklist with each item graded on a pass/fail basis. All encounters are videotaped for review in the event of a contested examination. When the 15-minute time period in the examination room is complete, the examinee proceeds to the next preparation station.

After completion of the third and final station, the examinee moves to a note writing station. He/she is given 30 minutes to write a note documenting one of the three encounters, as selected by the faculty. The note is to be written in the subjective, objective, assessment, and plan ("SOAP") format.

Station materials (case content, checklists, directions to the SP, and directions to the pharmacist) were validated via review by a panel of clinical practitioners. This method is identical to that used in the UAMS PCEP program and has been described in greater detail elsewhere(7).

Examination Grading

The general grading scheme is identical for all four examinations. Each of the three stations comprises 25 percent of the score. The other 25 percent is divided equally between the candidate's written and oral communication skills. While the individual checklist items are in a pass/fail format, some checklist items are weighted differently than others. The individual cases had multiple actors playing the role of SP as well as different graders.

RESULTS

One practical examination has been administered in Arkansas for each of the disease states. A total of 114 candidates have been examined (21 in anticoagulation, 29 in asthma, 36 in diabetes mellitus, and 28 in dyslipidemia). The overall the pass rate was 89.5 percent. The pass rates on the individual examinations are as follows: anticoagulation 100 percent, asthma 75.9 percent, diabetes mellitus 91.7 percent, and dyslipidemia 92.9 percent.

Areas of Concern

Several areas of concern regarding the use of SP's as part of a credentialing process have been identified. These include maintaining examination validity when multiple actors and/or graders are utilized for the same station, validation of checklists, maintaining examination security when stations are used more than once in different testing situations, and setting the passing score for a given examination.

Up to three actors were utilized for any given station in the DSM practical examination. The concern that not every candidate is exposed to the same SP has been evaluated in the OSCE literature. Data from 2,072 medical students from eight medical schools were tested over a two-year period using the same cases and different standardized patients(8). The authors found that measurement error due to multiple standardized patients on inter-case reliability fell within an acceptable range, implying that quality control can be maintained even when multiple standardized patients are utilized over an extended period of time(8).

The issue of interrater reliability has been addressed by Monaghan and colleagues in conjunction with the UAMS

PCEP program(7). Each of the ten testing stations was evaluated by a panel of six faculty graders. Interrater reliability was calculated individually for each station. Good to excellent agreement between raters occurred, with interrater reliability ranging from 0.8-0.94(7).

Performance criteria (checklists) were derived from the objectives and standards developed by the National Association of Boards of Pharmacy. These standards of care were agreed upon by a panel of experts from across the country. The final case material was then validated by review of a clinical practitioner panel. This method is similar to other published methods of validation of performance criteria(7,9).

Confidentiality is a concern because the time and costs associated with developing new stations require that scenarios be reused over multiple exam administrations. All examinees are required to sign a confidentiality agreement prior to entering the testing area. This agreement states that they will not divulge any examination content. Violations of examination confidentiality are reported to the State Board of Pharmacy and may lead to forfeiture of the DSM credential. The issue of testing station security has been addressed for OSCE examinations of medical students. Niehaus and colleagues evaluated 15 stations administered three or four times a year(10). The authors found three of the stations had a linear trend in scoring, one with decreasing and two with increasing scores. They concluded that there was no evidence that repeated use of stations within an academic year compromised the reliability of test scores.

While a unified passing standard was arbitrarily agreed upon for all four DSM examinations, other models of determining the pass/fail cutoff have been described for examinations using SPs. Morrison and colleagues present a method for using a modification of the Angoff procedure to set the passing standard for an OSCE examination(11). In this procedure, a group of judges use their professional judgment to predict how a minimally competent candidate would score on each item of the examination. The sum of a given judge's expected score represents that judge's assessment of the passing score associated with minimal competence. The overall passing score for the examination is determined by using the mean of the scores from a group of judges. Ideally, the group of expert judges consists both of academic and non-academic practitioners. The DSM practical examinations will likely utilize this format for determining the passing standard in the future.

DISCUSSION

As Boards of Pharmacy are charged with the task of credentialing pharmacists to offer disease state management practices, methods of adequately assessing patient care skills must be developed. In addition to verifying that the pharmacist has the appropriate knowledge base, the boards of pharmacy must also certify that the pharmacist has the patient assessment and communication skills necessary to adequately manage a patient's disease state. A practical examination utilizing standardized participants was developed by faculty at the University of Arkansas for Medical Sciences College of Pharmacy to assess such skills.

While relatively new to pharmacy, examinations using actors to portray patients have been used extensively in medical education/licensure. Such examinations have been shown to be reliable in assessing clinical and communication skills among examinees even when cases are used repeatedly, different actors portray the patients, and different faculty graders are utilized for evaluation.

References

(1) NABP**.** "Mississippi makes pharmacy history," National Association of Boards of Pharmacy Newsletter, 27(6), 86(1998).

(2) NABP. "NABP answers questions on DSM exams/credentialing," *National Association of Boards of Pharmacy Newsletter,* **27**(6), 126, 137(1998).

(3) Isreal, S.F., "Three new pharmacy laws you need to know about: Pharmacy practice act revisions," *Arkansas Pharmacists Association Legislative News* (1999).

(4) Ferrell, B.G., "Clinical performance assessment using standardized patients: A primer," *Fam. Med*., **27**, 14-19(1995).

(5) Wallace P., "Following the threads of an innovation: The history of standardized patients in medical education," *Caduceus,* **13**(2), 5-28(1997).

(6) Heard, J.K., Allen, R., Tank, P.W., Cason, G. J., Cantrell, M. and Wheeler, R. P., "Assessing clinical skills of medical students," *J. AR Med. Soc*., **93**(4), 175-179(1996).

(7) Monaghan, M. S., Vanderbush, R. E., Gardner, S. F., Grady, A. R. and McKay, A.B., "Standardized patients: An ability-based assessment for the evaluation of clinical skills in traditional and nontraditional education," *Am. J. Pharm. Educ*., **61**, 337-344(1997).

(8) Colliver, J.A., Swartz, M.H. and Robbs, R.S., "The effect of using multiple standardized patients on the inter-case reliability of a large-scale standardized patient examination administered over an extended testing period," *Acad. Med*., **73**(10), S81-S83(1998).

(9) Fielding, D.W., Page, G. G., Schulzer, M., Moody, K., Dyer, S., O'Byrne, C. and Rogers, T., "Developing an objective structured clinical examination for performance evaluation in pharmacy," *Am. J. Pharm. Educ*., **57**(suppl), 101S-102S(1993).

(10) Niehaus, A. H., DaRosa, D.A., Markwell, S.J. and Folse, R., "Is test security a concern when OSCE stations are repeated across clerkship rotations?" *Acad. Med*., **71**(3)**,** 287-289(1996).

(11) Morrison, H., McNally, H., Wylie, C, McFaul, P. and Thompson, W.. "The passing score in the objective structured clinical examination," *Med. Educ*., **30**, 345-348(1996).

APPENDIX. SAMPLE DSM EXAMINATION STATION

Task: Insulin Pattern Management—identifying Somogyi effect.
Designed for: Disease State Management
Station requirements: Standardized patient, copies of the blood glucose diary, a therapeutics reference textbook
Activities and time required: Preparation for encounter: 15 minutes, Standardized encounter: 15 minutes

Instructions for the Standardized Patient

CASE SYNOPSIS: You are Robert Johnson, a 26-year-old patient with type 1 diabetes. You are visiting this pharmacist because he/she runs a diabetes clinic in his/her pharmacy and your physician, Dr. Stevens, referred you for disease state management. The pharmacist has been helping you adjust your insulin dose to get your blood glucose concentrations under better control.

WHY YOU ARE SEEING THE PHARMACIST TODAY? Follow-up visit for diabetes management. You bring with you a blood sugar diary.

HOW YOU WILL APPEAR DURING ENCOUNTER? Well-educated, cooperative, motivated to get your diabetes under better control so you don't get any additional complications

CURRENT MEDICAL HISTORY: You have had diabetes for 21 years, with poor control for much of that time. Because of your poor control, you have developed complications of diabetes. You have hypertension, for which you take the ACE inhibitor medication enalapril, or Vasotec®, 10 mg twice a day. You also have gastroparesis (a condition where the contents of your stomach do not empty as quickly as they should, causing a feeling of fullness, bloating, and nausea. Occasionally it causes vomiting). You take cisapride, or Propulsid®, 10 mg four times a day (before meals and at bedtime) for

your gastroparesis. You currently take regular insulin 30 minutes before each meal and NPH insulin at bedtime.

You have noticed that your morning fasting blood glucose levels are high and have tried to get them down by increasing your bedtime NPH insulin dose.

OTHER QUESTIONS THE PHARMACIST MIGHT ASK: Have you had nightmares or night sweats recently (these are signs of nighttime low blood sugar)? Respond that you have not. Have you checked a 2AM or 3AM blood glucose level? You should respond that you did last night, but forgot to write it down. It was 42. If the pharmacist doesn't ask if you checked a 2AM or 3 AM blood sugar, he/she may tell you this is necessary before making a decision about changing your insulin dose. If he/she makes this statement, tell him/her that you did last night and forgot to write it down. It was 42.

Instructions for the Pharmacist

You are a pharmacist who runs a diabetes clinic in your pharmacy. Today, you are seeing Mr. Johnson. You have been working with him on self-management of his diabetes and he brings his blood glucose diary with him (see Table). Over the past few months, he has been on an intensive control regimen.

Checklist

1. Pharmacist introduces self and shakes hands with patient
2. Pharmacist recognizes morning hyperglycemia on the glucose diary
3. Pharmacist recognizes lunchtime hyperglycemia on the glucose diary
4. Pharmacist knows that a 3AM blood glucose is necessary to differentiate the cause of morning fasting hyperglycemia
5. Pharmacist recognizes that the low 3 AM blood sugar is a result of the Somogyi effect
6. Pharmacist instructs the patient to decrease his bedtime NPH dose to 16-17 units
7. Pharmacist explains Somogyi effect to the patient
8. Pharmacist instructs the patient not to increase his breakfast insulin dose until his morning fasting is under good control
9. Pharmacist asks the patient if he has any questions

Self Blood Glucose Monitoring Diary for Robert Johnson

	Breakfast			Lunch			Supper			Bedtime			Other		
Date	Time	Glucose	Insulin Dose	Time	Glucose	Insulin Dose	Time	Glucose	Insulin Dose	Time	Glucose	Insulin Dose	Time	Glucose	Insulin Dose
	8:00 AM	199	16 R	11:45 AM	147	16 R	5:45 PM	90	16 R	10:15 PM	85	18N			
	7:45 AM	190	16R	11:30 AM	138	16R	6:00 PM	85	16R	11:00 PM	86	19N			
	8:10 AM	195	16 R	11:50 AM	142	16 R	5:30 PM	93	16 R	11:15 PM	89	19N			
Today	8:05 AM	190	16 R	11:30 AM	145	16 R									