Preface

As physicians' clinical skills cannot be measured solely by written examination, a National objective structured clinical examination (OSCE) has been considered necessary as a part of medical licensure examination. By the end of 2008, about 20 medical centers/ hospitals in Taiwan announced that OSCE has been a regular clinical examination for their trainees. However, there is little consensus about how to implement a high-stake, large scale OSCE.

The Medical Council of Canada (MCC) has administered an OSCE for the license to practice medicine since 1992. The high stake, large scale OSCE is to test physicians' skills of history taking, physical examination, and communication. The examination results with psychometric evidence indicate that a full-scale national administration of an OSCE model for licensure is feasible in Canada.

Professor, Sydney Marla Smee is currently the Manager of MCCQE Part II, Evaluation Bureau Medical Council of Canada (1990-Present). She is an internationally recognized expert in implementing a high stake OSCE. The workshop in Taiwan lead by Dr. Smee is to facilitate the establishment of a Taiwanese model of high stake OSCE.

Contents

Day1 Agenda

High- Stakes OSCE (I): Administrative Issues and Related Topics

Date: January 7, 2010 (Thursday)
Place: 臺北醫學大學 醫學綜合大樓前棟 4 樓-**誠樸廳**
台北市信義區 110 吳興街 250 號
Instructor: Dr. Sydney M. Smee
Instructor Assistant: Dr. Charity T.C. Tsai

Time	Activity	Moderator
08:30-08:45	**Registration**	
08:45-09:00	**Opening Remarks** Minister Chaur-Shin Yung **楊朝祥部長** President Wen-Ta Chiu **邱文達校長** Director Chong-Liang Shi **石崇良處長**	Prof. Chi-Wan Lai **賴其萬教授**
09:00-09:30	**Presentation:** Update on Plans for a Taiwan OSCE	
09:30-10:30	**Presentation:** High Stakes Multi-site OSCE: Key Processes and Design Issues	
10:30-10:45	**Break**	
10:45-12:00	**Group Activity:** Five Groups- Create an OSCE Design	
12:00-13:00	**LUNCH**	
13:00-14:30	**Group Activity:** Group Reports & Discussion	
14:30-14:45	**Break**	
14:45-15:15	**Group Activity:** Large Group Exercise- Examination Day Scheduling	
15:15-16:15	**Group Activity:** Five Groups- Required Resources - Human and Other	
16:15-17:00	**Group Activity:** Group Reports	
17:00	Adjourn	

Day2 Agenda

High- Stakes OSCE (I): Administrative Issues and Related Topics

Date: January 8, 2010 (Friday)
Place: 臺北醫學大學 醫學綜合大樓前棟 4 樓-**誠樸廳**
台北市信義區 110 吳興街 250 號
Instructor: Dr. Sydney M. Smee
Instructor Assistant: Dr. Charity T.C. Tsai

Time	Activity
08:30-09:00	**Check-in:** Questions/Answers
09:00-10:30	**Presentation & Exercise:** Costing the OSCE
10:30-10:45	**Break**
10:45-11:15	**Presentation:** Training Issues- Examiners, SPs and Staff
11:15-12:00	**Presentation:** Production Timeline-Critical Milestones
12:00-13:00	**LUNCH**
13:00-14:30	**Presentation:** Hot Topics: Examiner Qualifications, Incidents, Re-scores and Appeals
14:30-14:45	**Break**
14:45-17:00	**Wrap-Up - Next Steps**
17:00	**Closing Remarks 閉幕致詞** Vice Dean Keh-Min Liu **劉克明副院長**

Speaker's Curriculum Vitae

Dr. Sydney M. Smee

Higher Education

2007 *Doctor of Philosophy*
University of Ottawa
Major: Education
Minor: Measurement and Evaluation

1994 *Master of Education*
Ontario Institute of Studies in Education
University of Toronto
Major: Adult Education

1982 *Bachelor of Arts*
McMaster University
Major: Political Science

Professional Positions

1990-Present ***Manager, MCCQE Part II***
Evaluation Bureau, Medical Council of Canada

1987 - 1990 ***Coordinator, Volunteer Services***
Casey House Hospice, Toronto

1986-1988 ***Consultant, Standardized Patient Program Development***
University of Massachusetts, University of Toronto, McMaster University

1984 - 1985 ***Coordinator, Patient Instructor Program***
University of Massachusetts Medical School, Worcester, MA

Editorial Activities

Ad Hoc Reviewer:

Advances in Health Sciences: 2001, 2007

Medical Education: 2001 – 2002, 2005, 2009.

Publications

Boulet, J.R., Smee, S.M., Dillon, G.F., and Gimpel, J.R. (2009).The use of standardized patient assessments for certification and licensure decisions. Simulation in Health Care 4:1 Spring.

Smee, SM. (2008). High Stakes OSCE scoring: Station-specific rating scales versus checklists. Paper presented at the 13th Ottawa Conference on Medical Education: Melbourne, Australia.

Smee, SM. (2008). Impact of judgmental weights for OSCE checklist items on station pass marks. Paper presented at the 13th Ottawa Conference on Medical Education: Melbourne, Australia.

Boursicot, KA, Smee, SM, & Paterson, J. (2008). Ten years of monitoring test security in graduation level OSCEs. Paper presented at the 13th Ottawa Conference on Medical Education: Melbourne, Australia.

Wood, TJ & Smee, S. (2008). Does editing an OSCE station after an examination improve its performance on subsequent examinations? Paper presented at the 2008 annual meeting of the Association of Medical Educators of Europe (AMEE): Prague, Czech Republic.

Wood, TJ, Smee, SM, Bartman, I, & Blackmore, DE. (2008) Do two different processes for limiting false positive errors add to the quality of the pass/fail decision on a high stakes examination? Paper presented to the annual meeting on Research in Medical Education (RIME): San Antonio, USA.

Tamblyn, R, Abrahamowicz, M, Dauphinee, D, Wenghofer, E, Jacques, A, Klass, D, Smee, S, Blackmore, D, Winslade, N, Girard, N, Du Berger, R, Bartman, I, Buckeridge, D, & Hanley, J. (2007). Physician Scores on a National Clinical Skills Examination as Predictors of Complaints to Medical Regulatory Authorities. Journal of the American Medical Association, 298, 993-1001.

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Birtwhistle, R, Blackmore, DE, Smee, SM, & Wood, T. (2002). Does specialty play a role when physicians are used as examiners in a nationally administered OSCE? Paper presented at the 9th Ottawa International Conference on Medical Education Capetown, South Africa.

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Smee, SM & Blackmore, DE. (2002). Setting standards for an objective structured clinical examination: The borderline group method gains ground on Angoff. Medical Education, 35, 1009-1010.

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Proceedings of the Eighth International Ottawa Conference - Evolving Assessment: Protecting the Human Dimension (pp. 92-98). Philadelphia: National Board of Medical Examiners.

Dauphinee, WD, Blackmore, DE, Smee, SM, Rothman, AI, Des Marchais, J, & Reznick, RK. (2000). Adaptive testing: A report on the results and myths arising from the use of a sequenced OSCE for national licensure. In D. E. Melnick (Ed.), Proceedings of the Eighth Ottawa International Conference - Evolving Assessment: Protecting the Human Dimension (pp. 241-246). Philadelphia: National Board of Medical Examiners.

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Dauphinee, WD, Blackmore, DE, Smee, SM, Rothman, AI, & Reznick, RK. (1997). Optimizing the input of physician examiners in setting standards for a large scale OSCE: Experience with Part II of the Qualifying Examination of the Medical Council of Canada. In A. J. J. A. Scherpbier, C. P. M. van der Vleuten, J. J. Rethans, & A. F. W. van der Steeg (Eds.), Advances in Medical Education: Proceedings of the Seventh Ottawa International Conference on Medical Education (pp. 656-658). Dordrecht: Kluwer Academic Publishers.

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Medical Education (pp. 458-461). Dordrecht: Kluwer Academic Publishers.

Smee, SM. & Sumawong, V. (1997). Advancing the use of standardized patients: A workshop for the consortium of Thai medical schools. In AJJA. Scherpbier, CPM van der Vleuten, JJ Rethans, & AFW van der Steeg (Eds.), Advances in Medical Education (pp. 714-716). Dordrecht: Kluwer Academic Publishers.

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Smee, SM. (1994). Medical Education Clinic: Using SPs for teaching and evaluation. Adult Education Quarterly, 6, 9-10.

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Instructor Assistant's Curriculum Vitae

Charity TC Tsai, MD, PhD

China Medical University
University of Calgary, MSc in Medical Education
University of Calgary, PhD in Medical Education
Present Academic and Administrative appointment:
Director, Department of Pediatrics, Taipei Medical University WanFang Hospital
Vice Director, Faculty of Medicine, Taipei Medical University
Vice Director, Education and Research, Taipei Medical University WanFang Hospital

Publication (in recent 5 years)

1. Tsuen-Chiuan Tsai, Using children as standardized patients for assessing clinical competence in pediatrics. Arch Dis Child 89 (12): 1117-1120, Dec. 2004
2. Tsuen-Chiuan Tsai, M.D., Peter H. Harasym, Ph.D., Cheri Nijssen-Jordan, and Greg Powell, Learning gains derived from a high fidelity simulation in emergency department J Formos Med Assoc 105 (1):94-98, 2006
3. JD Tsai, FU Huang, CC Lin, TC Tsai, HC Lee, and JC Sheu. Intermittent hydronephrosis secondary to ureteropelvic junction obstruction: clinical and imaging features. Pediatrics. 2006 Jan;117(1):139-46.
4. Tsai TC, Harasym PH. Challenges of pediatric residency education in Taiwan. Acta Pediatrica Sinica. 47(1):3-6, 2006
5. Tsuen-Chiuan Tsai . Psychosocial effects on caregivers for children in Taiwan on chronic peritoneal dialysis. Kidney Int. 2006 Dec;70(11):1983-7
6. Tsuen-Chiuan Tsai . University of Washington 家醫科及臨床技能中心參訪. J Med Education. Jan. 10(1): 86-88, 2006
7. Tsuen-Chiuan Tsai,[1] Pei-Jung Chang,[2] Shin-Yuan Fang, [2] Chyi-Her Lin[3.] A Mannequin-based Simulation on Teaching Emergent Crisis Care. J Med Education, 10(2): 115-125, 2006
8. Sheu JC, Koh CC, Chang PY, Wang NL, Tsai JD, Tsai TC. Ureteropelvic junction obstruction in children: 10 years' experience in one institution. Pediatr Surg Int. 2006 Jun;22(6):519-23
9. Tsai YC, Tsai TC, Tsaf JD, Huang FY, Lin CC, Sheu JC. Clinical analysis of chronic peritoneal dialysis related peritonitis in children. Pediatr Neonatol. 2006 Mar-Apr;47(2):72-6
10. Tsuen-Chiuan Tsai, Chyi-Her Lin, Chung-Lin Chen, Co-Chi Chao, Taung-Lieh

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12. Tsai TC. Resistance to educational change: management and communication. Pediatr Neonatol.48:3-6, 2007
13. Tsai TC, Lin CH, Harasym PH, Violato C. Students' perception on medical professionalism: the psychometric perspective. Med Teach. 2007 Mar;29(2-3):128-34.
14. Peter H. Harasym, Tsuen-Chiuan Tsai, and Payman Hemmati. Current trends in developing medical students' critical thinking abilities. Kaohsiung J Med Sci July 2008. 24 (7) 341-354
15. Tsuen-Chiuan Tsai. The Use of Medical Cognition in Medical Curriculum Reform in Taiwan. Pediatr Neonatol 2008;49(3):53−57
16. 蔡淳娟、邱文達、王先震、連吉時、粟發滿、郭雲鼎、徐明義.The use of portfolio in internship clinical education. J of Med Edu 12(1): 8-19.2008.
17. Lee MD, Lin CC, Huang FY, Tsai TC, Huang CT, Tsai JD. Screening young children with a first febrile urinary tract infection for high-grade vesicoureteral reflux with renal ultrasound scanning and technetium-99m-labeled dimercaptosuccinic acid scanning. J Pediatr. 2009 Jun;154(6):797-802.
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19. Tsuen-Chiuan Tsai, Peter H. Harasym, Sylvain Coderre, Kevin McLaughlin, & Tyrone Donnon. Assessing ethical problem solving by reasoning rather than decision making. Med Edu 2009: 43: 1188–1197
20. Ju-Chuan Yen,Tsuen-Chiuan Tsai, Min-Huei Hsu, Kung-Jiang Chang, Du-Jian Tsai, Wei-Hua Lee. The attitudes toward disclosure of medical errors: the perspectives of Taiwanese with different occupational backgrounds. Submit to The American Journal of Bioethics (UAJB-2009-0218) 2009/04/14
21. Tsuen-Chiuan Tsai, Peter H. Harasym. An Ethical Reasoning Model: Contributions to Medical Education. (Submitted to Med Educ in 2009/09)
22. 蔡淳娟,林其和,劉克明. 台灣各界對醫學系學制變革可行性的看法. 投稿醫學教育雜誌. 2009/09

Moderator's Curriculum Vitae

Professor Chao Hsiang Yang (楊朝祥部長)

Present Positions

Minister, Ministry of Examinations

Professor Wen-Ta Chiu (邱文達校長)

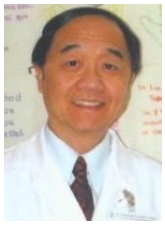
Present Positions

Professor and President, Taipei Medical University

Professor Chong-Liang Shi (石崇良處長)

Present Positions

Director of Medical Affairs, Department of Health



Professor Chi-Wan Lai (賴其萬教授)

Present Positions

Executive Secretary, Medical Education Committee, Ministry of Education

CEO, Taiwan Medical Accreditation Council

Professor Keh-Min Liu (劉克明副院長)

Present Positions

Professor and Vice-Dean, Collage of Medicine, Kaohsiung Medical University

Presented at Taipei Medical University, WanFang Hospital by the Taiwan Association of Medical Education, January 2010

High Stakes Multi-site OSCE: Key Processes and Design Issues

Sydney M Smee, Ph. D.
Manager, MCCQE Part II
Evaluation Bureau, Medical Council of Canada

Presented at Taipei Medical University, WanFang Hospital by the Taiwan Association of Medical Education, January 2010

My Background

- Standardized Patient at McMaster University with Dr. Howard Barrows and Gayle Gliva-McConvey
- Coordinator for Patient Instructor Program at University of Massachusetts for Dr. Paula Stillman
- Did other things….
- Standardized Patient Training Coordinator for the pilot project for the Medical Council of Canada's new Qualifying Examination Part II in 1992
- Now – Manager for the MCCQE Part II
- Keep this in mind - I am strongly influenced by long time commitment to standardized patients and OSCEs

What is the Part II?

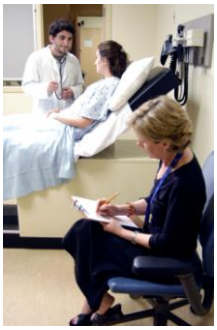
- (Part I assesses knowledge and clinical decision-making at end of medical school – computer testing / MCQs)
- Part II is an OSCE that assesses clinical skills after 12 months of post-graduate clinical training
- Multi-site, administered twice per day
- Timed circuit of 12 stations
- Patient-based
- Physician-scored
- Prerequisite for licensure in Canada since 1993

Why do we have the Part II?

- Requested by the Medical Licensing Authorities because they were facing:
  - Increasing number of complaints, often based on a physician's communication skills.
  - Need to be publicly accountable; e.g., reports that not all trainees were being assessed in a clinical setting.
  - Obligation to audit the training of all medical graduates seeking licensure in Canada.

Content of Part II

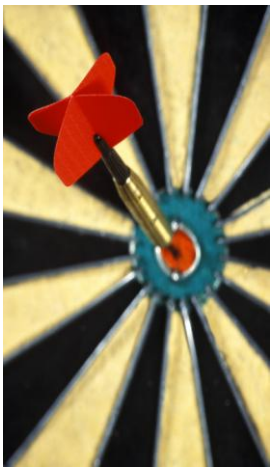
- Multidisciplinary, patient-based cases
  - Some have a written component based *directly* on the patient problem
- Common or acute presenting problems
  - Some problems include legal and ethical issues
- Assesses skills:
  - History taking
  - Physical examination skills
  - Counseling / patient education skills
  - Patient management ability



Part II - Fall 2009

- 12 case OSCE with 2 pilot cases
  - 5+5 minute couplets (patient + written components)
  - 10 minute case (sometimes there was an oral component)
- OSCE was run twice per day
- 16 university-based sites (at teaching hospitals)
- 2,644 test takers assessed in two days
- Most common site model ran two tracks and administered the OSCE twice in one day – assessed 128 test takers -
  - 44 clinic rooms - 50 to 60 standardized patients
  - 44 physician examiners - 16 to 20 staff people

Goals for Workshop



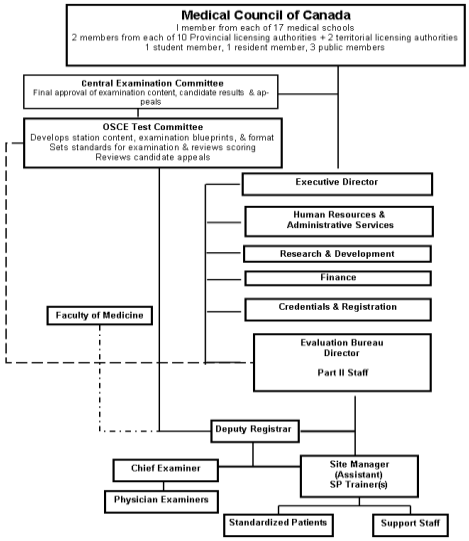
- Provide overview of OSCE processes
- Set specifications for an OSCE
- Identify critical tasks and timelines
- Estimate costs
- Review training needs
- Discuss "hot topics"
- Specify next steps in the process

Six OSCE Processes for Multi-site Model

- Initiation
  - Governance
  - Terms of Reference
  - Design and scope
- Content Development
  - Create
  - Edit and Format
  - Approve
- Site Development
  - Determine specifications
  - Recruit key staff
  - Provide training
- Production (pre-OSCE)
  - Establish supply needs
  - Create and produce materials
  - Ship
- Processing (post-OSCE)
  - Receive
  - Enter scores
  - Analyze data
- Registration and Reporting
  - Eligibility criteria
  - Document requirements
  - Results and appeals

Initiation

MCC Part II Governance Model



Part II Terms of Reference:

- Collaborative agreement
  - Schools provide office space, clinic space (for OSCE days), equipment, and name the Chief Examiner
  - MCC provides funds, OSCE materials, training and supervision
- Design & Scope
  - Part II has changed over time
  - Two days / 20 stations / 5 sites
  - One day / sequenced / 12 sites
  - One day / 14 stations / 15 sites
  - One day / 12 stations / 16 sites
  - Two days/ 12 stations / 17 sites
- This workshop:
  - Design and define an OSCE…

Content Development

- MCC content is created centrally
  - Multidisciplinary committee with members balanced across
    - Medical specialty
    - Language (French – English)
    - Geography
    - Gender
  - Members are active clinicians with faculty appointments
  - All have a keen interest in medical education
  - Faculty from the medical schools work with the committee to create and review cases
- MCC staff provide support:
  - Plan meetings
  - Psychometric and logistical advice
  - Edit, format and produce OSCE materials
- More on case writing at the next workshop….

Site Development
(It's all about the people.)

- Determine site specifications
  - Clinic Room requirements
  - Large rooms for orientation
  - Office space, furniture and computers, telephones, etc.
  - Exam day staffing needs
  - Parking and catering
- Recruit key site staff
  - Site Manager
  - Chief Examiner
  - SP Trainer
- Provide training and supervision
  - Job descriptions
  - Manuals
  - Central meetings
  - Telephone support
  - Site visits
  - Exam day supervision
  - SP training materials
    - Case materials
    - Videos
    - Internet resources
    - Diagrams
    - Training for Trainers

Production

- Establish supply needs
  - Signage, props, registration materials, incident reporting
  - Exam sheets
  - Orientation materials for site staff, examiners, and test takers
    - Print, video, other? (e.g., booklets and lab values)
  - Identify security challenges and solutions
- Create and produce exam materials
  - What software?
  - How are you collecting score data?
  - What about other data? Feedback from examiners?
- Ship the materials to the site(s)
  - Shipment deadline is a major milestone

Processing

- Receive (after the examination)
  - Verify return of materials is complete
- Enter scores
  - What process depends on software used
  - Ensure format of data allows for quality assurance and for score reporting
- Analyze data
  - Item analysis of cases
  - Reliability of OSCE
  - Review of examiners and exam day reports
  - Review of results

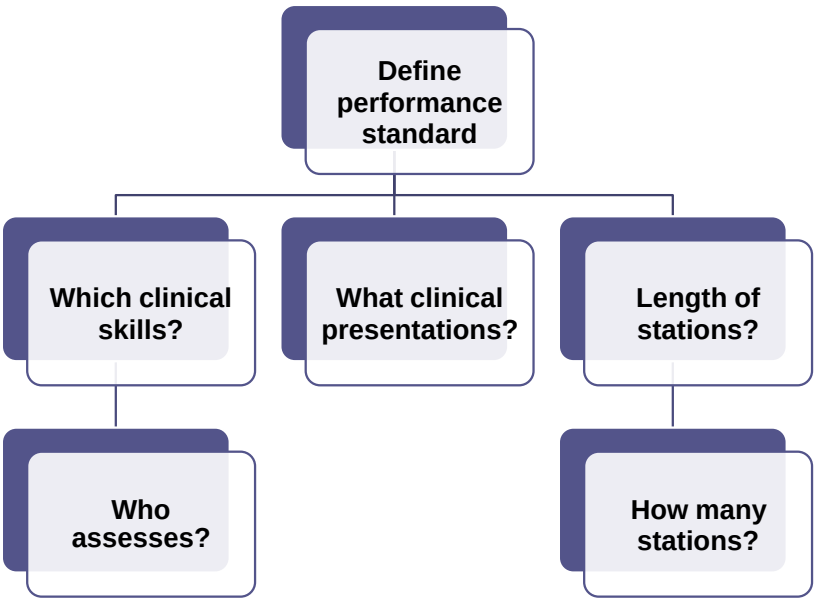
Presented at Taipei Medical University, WanFang Hospital by the Taiwan Association of Medical Education, January 2010

Registration and Reporting

- Eligibility criteria
  - What are the criteria and how will this be communicated to test takers?
- Document requirements
  - How will you verify eligibility?
- Results
  - Who has access to the results?
  - How will they be reported?
- Appeals
  - Define conflict of interest and other reasons for appeals
  - Determine process for appeals
    - Consider different levels; e.g., rescores and feedback calls

Defining an OSCE

....Making many decisions



Define a standard –

MCCQE Part II:

Acceptably competent to enter independent medical practice in Canada

Blueprint criteria = Validity

Body Systems	Clinical Tasks				
	History Taking	Physical Exam	Procedural	Patient Education	??
Cardiac					
Respiratory		X			
Gastrointestinal					
Reproductive	X			X	
??					

Define the criteria for selecting cases for each test form

MCCQE Part II Blueprint Criteria

Patient problems are common or critical; each case is linked to the MCC Objectives

DOMAIN	Counseling/Education	**2**
	History	**4** (or 5)
	Management / Acute Care	**2**
	Physical exam	**4** (or 3)
	Combined History / Physical	(2 – if possible)
	Patient Interaction Rating scales are integrated within most stations	
DISCIPLINE	Medicine	**3**
	Ob/Gyn	**2**
	Pediatrics	**2**
	Psychiatry	**2**
	Surgery	**3**
NOTE	Review problems to ensure balance across body systems CLEO content must comprise a minimum of 10% of overall content. CLEO is integrated into cases with oral questions and patient interaction rating scale items	
HISTORY of USE	No more than 3 stations with high exposure (as a guide) New cases in each blueprint (no specific numbers assigned)	
Item Total Score Correlation	Minimum: 0.20 (AS A GUIDE)	
GENDER	as balanced as possible	
AGE GROUPS	Elderly / Adult / Adolescent / Young children One or more cases representing each age group	

Clinical Skills and Presentations

- Some things are more “OSCE-able” than others
- Some cases cost more to administer
  - Multi-patient cases and manikins may be a challenge
- Large-scale, multi-site OSCE have some limitations
  - Must have the same resources at all sites
- Focus on skills and content best assessed by OSCE
  - Content that can be assessed more cost effectively in other formats (like multiple choice examinations) should not be included in an OSCE

Long versus short cases / Reliability

- Long cases (>12 minute cases)
  - Assess complete encounters (e.g., Hx + Physical)
  - Fewer cases and examiners per test taker
  - Long testing time required to achieve reliable scores
  - Can assess performance on more complex problems
- Short cases (5 -12 minute cases)
  - Assess samples of performance
    - Suggests assessment of clinical judgment
  - More cases and more examiners per test taker increases reliability
- Mix of long and short cases
  - More complex OSCE design (but still do-able)

What is your preference for an OSCE?

1. Fewer longer cases
2. More shorter cases
3. Mix of short and long cases

What do you think the minimum number of cases is for a valid OSCE?

1. Six
2. Eight
3. Ten
4. Twelve
5. Fourteen
6. Sixteen
7. Eighteen

Which of the following do you think should be assessed in an OSCE?

1. History taking
2. Physical examination skills
3. Patient education ability
4. Managing acute problems
5. Managing non-acute problems
6. Responses to ethical issues
7. Interpretation of investigations
8. Procedural skills
9. Written tasks (e.g., admission orders)
10. Other

Group Task for After Break

- Five Groups – One Reporter for each group
- Start designing an OSCE for assessing ….
- Specify the clinical skills you want assessed
  - Define the range of clinical presentations by discipline and/or body system (or other criteria)
  - Determine how many patient cases
  - Specify the time limit for cases
- Group reports after lunch…

Group Reports

Exam Day Scheduling

- To cost an OSCE you need a design and an exam day schedule (to start)
- Large portion of the costs are people
  - Need to specify what is expected of the people
- Once you cost a design, you will likely revise it…

Exam Day Schedule

	Activity	Time	Chief Examiner	Manager	SP Trainer	Timers	Hall Staff	Group Leaders	Caterers
	Set-up site	6:00							
	Register SPs /Staff	6:15							
	Register / Orient Examiners	6:30							
	Register / Orient AM Test takers	6:45							
	Move people to stations	7:00							
1	Start OSCE	7:15							
	Break in OSCE?	7:30							
2	End OSCE	7:45							
	Lunch Break?	8:00							
	Register / Orient PM Test takers	8:15							
3	Start OSCE	8:30							
	Break in OSCE?	8:45							
4	End OSCE	9:00							
	Clean-up Site	9:15							
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Tasks

- Central Tasks
  - Communicate with stakeholders: Test takers, medical faculties, ??
  - Establish registration processes
  - Create and produce OSCE materials
  - Develop protocols for training everyone
  - Visit sites
  - Run central meetings
  - Process results
  - Report results
- Site Tasks
  - Plan layout of OSCE stations at the site
  - Book clinics and orientation rooms
  - Recruit SPs and examiners
  - Train SPs
  - Recruit staff- train them too
  - Plan out the OSCE day in great detail
  - Run the OSCE
  - Ship everything back

Production Timeline - Milestones

10. Report Results ← 9. Complete QA on Scores ← 8.Exam Day ← 7. Ship to site(s) ← 6. Print mark sheets

5. Training meetings ← 4. Recruit staff at exam site ← 3. Letter of Agreement with site ← 2. Finalize case content ← 1. Finalize OSCE design

Work backwards……
Production processes overlap with site development processes…..
Note: List does not address registration milestones.

1. Finalize OSCE design → 2. Finalize case content

3. Agreement with sites → 4. Recruit site personnel → 5. Training meetings

3. Letter of Agreement signed
   - Funds forwarded
   - Chief Examiner appointed
4. Recruit site personnel
   - Manager and SP Trainer
   - Examiners and Standardized Patients
   - Site staff for timing, registration etc.
5. Training meetings
   - Centrally – site team(s) and core staff
   - Not too early and not too late
   - Balance input from sites with central control….

6. Print mark sheets → 7. Ship to site → 8. Exam Day

6. Print mark sheets
   - Significant deadline – no more changes without pain
   - Production takes careful, detailed planning
   - Attend to security issues/ inventory tracking etc.
7. Ship to sites
   - Central control is "gone" – it's in the hands of the site team
   - Increasing focus on support
8. Exam day
   - Oversight
   - Incident reporting
   - What can go wrong, will go wrong – be prepared to learn

9. Complete QA on Scores → 10. Report Results

9. Complete quality assurance on scores
   - Verify the scores are accurately recorded
   - Assess how the cases performed (item analysis)
   - Assess how the examiners performed (any hawks or doves?)
   - Assess how the OSCE performed (reliability)
   - Take into account exam day incident reports
10. Report results
   - Who gets what?
   - Scores? Pass/Fail?
   - Feedback?

Required Resources

Central Resources

- Staff Positions
  - How many?
  - What qualifications?
- Case Writers
  - How many?
  - How many meetings?
- Office(s)
  - Existing or new?
- Equipment and software
  - Existing or new?

Site Resources

- Staff positions
  - How many?
  - What qualifications?
- Office(s)
  - New or existing?
- SP training room(s)
- Equipment and software
  - Existing or new?
- Challenges?
  - What else do you need to know?

Five Groups – Tasks to be assigned

- Group 1:
- Group 2:
- Group 3:
- Group 4:
- Group 5:

Group Reports

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Day Two: What does the OSCE cost?

A large group experiment with an Excel workbook

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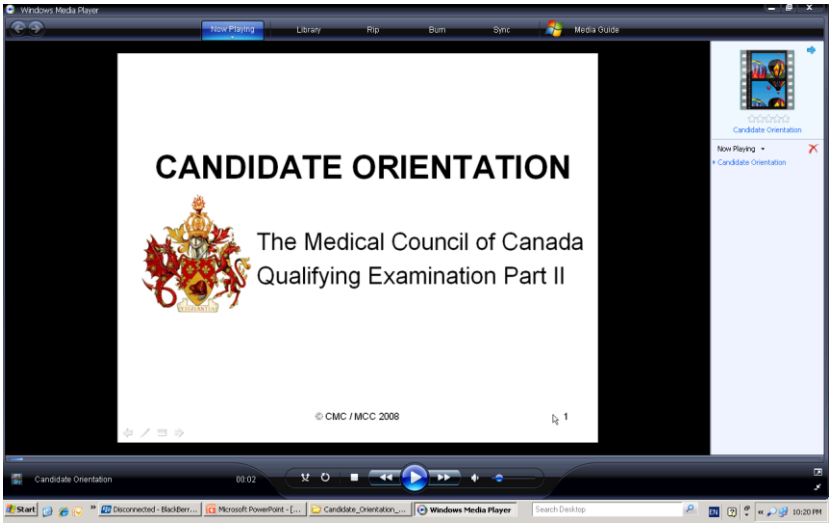
Training Issues

- Chief Examiners & Managers
  - Critical roles in preparing for the OSCE at the site level
  - At the beginning, these people can help create protocols and forms to ensure the OSCE is standardized
  - Benefit of multi-site OSCE is working with others, receiving training
  - Cost of multi-site OSCE is loss of local autonomy
- Examiners
  - Orient to the OSCE
  - Training may be delivered locally by site staff OR centrally via web-based technology
  - When and how to orient examiners is a compromise between the ideal and practical
  - Local support and direction to site-specific issues is always needed



Training Issues

- Standardized Patients
  - Longer cases require more training
  - More complex cases require more training (e.g., psychiatric affect, multiple physical symptoms)
  - Good training involves practicing with someone acting as a candidate and getting feedback
  - Training should happen close to the OSCE
- Exam Day Staff
  - Need to understand the OSCE and why its important
  - Need to know their specific tasks (e.g. timing, collecting mark sheets, directing people)
  - Need to know what to do when something goes wrong (and something always does)
  - Training based on centrally developed materials and given locally leads to fair testing

Hot Topics

- Examiner qualifications
- Incidents
- Re-scores and Appeals

Examiner Qualifications

- Formal MCC Criteria:
  - Must have the Licentiate of the Medical Council of Canada (LMCC).
  - Should be 3 years post-LMCC.
  - Should have at least 3 years in independent practice.
  - Cannot be residents or fellows. Examiners must hold an unrestricted license and currently be practicing medicine.
  - Should have the ability and stamina for the task (e.g., hearing loss is a serious handicap).
  - May be community physicians.
- Informally, Chief Examiners interview any examiners who are not known

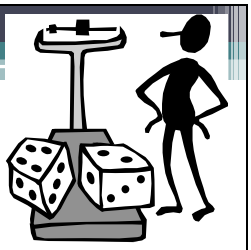
Incident Reports – What can go wrong?

- Conflicts of interest
- Examiner errors
- Candidate is inappropriate
- Timing errors
- Illness (SPs, test takers, examiners)
- Missing materials
- Missing SP
- Missing examiner
- Flooding toilet, fire alarms, parades, strikes…

What can be done?

- With a pass/fail examination the incidents that are most critical are those that impact test takers who are borderline failures
  - Is incident significant?
  - Delete the station?
  - Invalidate the examination?
    - MCC will not assume a pass standing

Re-scores and Appeals: Risk Management



- Have policies and procedures in place for answering post-OSCE questions and complaints
  - Follow-up to selected letters and incident reports
  - Providing feedback in exam reports or by request
  - Rescores to verify results
  - Appeal process for complaints
    - Process for low level issues, more formal for serious issues

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Next steps?

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The Use of Standardized Patient Assessments for Certification and Licensure Decisions

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Although standardized patients have been employed for formative assessment for over 40 years, their use in high-stakes medical licensure examinations has been a relatively recent phenomenon. As part of the medical licensure process in the United States and Canada, the clinical skills of medical students, medical school graduates, and residents are evaluated in a simulated clinical environment. All of the evaluations attempt to provide the public with some assurance that the person who achieves a passing score has the knowledge and/or requisite skills to provide safe and effective medical services. Although the various standardized patient-based licensure examinations differ somewhat in terms of purpose, content, and scope, they share many commonalities. More important, given the extensive research that was conducted to support these testing initiatives, combined with their success in promoting educational activities and in identifying individuals with clinical skills deficiencies, they provide a framework for validating new simulation modalities and extending simulation-based assessment into other areas.
(*Sim Healthcare* 4:35–42, 2009)

Key Words: Licensure, Certification, Simulation, Standardized patient, Simulated patient, OSCE

There are many types of simulations that are currently being used to assess healthcare professionals.[1–4] In both Canada and the United States (US), many of these simulation modalities, including multiple choice questions, part-task trainers, and computer-based case simulations, have been used as part of the examination process used to certify and license physicians.[1,5,6] These simulation-based examinations, which can vary somewhat in terms of purpose and focus, all attempt to provide the public with some assurance that the person who achieves a passing score has the knowledge and/or requisite skills to provide safe and effective medical services, either independently or under supervision. Here, as with any simulation-based assessment, the structure, content, fidelity, and difficulty of the modeled exercises, combined with the scores, will determine what inferences one can make about the individual test taker.

From a simulation perspective, the use of standardized patients (SPs) for certification and licensure decisions has been a relatively recent phenomenon.[7] Historically, SP-based assessments were implemented as part of formative evaluation activities.[8–10] Individuals were trained to portray specific patient conditions, allowing medical students to practice their clinical skills and receive immediate feedback concerning strengths and weaknesses. In the 1980s, with an increased emphasis on evaluating what medical trainees could do, as opposed to what they knew, various organizations started research programs aimed at determining how assessments employing SPs could be structured to make valid skills-based proficiency decisions. Over the next two decades, the end result of these research activities was the implementation of a number of high-stakes assessments all aimed at measuring abilities in key clinical skills domains. Although these research efforts required extensive resources, they were successful in identifying the specific conditions and structures that are needed to produce defensible scores and decisions for multistation, performance-based, simulation activities.[11–17]

The introduction of SP-based certification and licensure examinations in medicine was a monumental achievement. Although other high-stakes simulation-based assessments have been developed and used in other professions, the logistical, economical, and psychometric challenges associated with national multistation clinical skills assessments were staggering.[18,19] Organizations that built these assessments all had to address concerns regarding test content (eg, types of scenarios to model), test administration models (eg, fixed versus temporary sites; number, timing and sequencing stations), measurement rubrics (eg, holistic or analytic), eligibility requirements, scoring models (eg, compensatory or conjunctive), and the establishment of defensible standards, just to name a few. Nevertheless, even with these hurdles, and despite numerous objections concerning the need to measure

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clinical skills as part of certification/licensure process,[20] each of these organizations was able to produce a high-quality simulation-based assessment that was appropriate for their particular needs. In doing so, many lessons were learned, the most important being that simulation-based summative assessment of clinical skills was viable, even with large examinee populations, differing testing purposes, and varying examination administration protocols.

PURPOSE

The purpose of this article was to describe and contrast the Clinical Skills Assessment (CSA) programs that are employed in Canada and the US as part of the certification and licensure process for physicians. These assessments include the Medical Council of Canada (MCC) Qualifying Examination Part II (MCCQE Part II),[21] the United States Medical Licensing Examination (USMLE) Step 2 Clinical Skills (USMLE Step 2 CS),[22] and the National Board of Osteopathic Medical Examiners (NBOME) Comprehensive Osteopathic Medical Licensing Examination Level 2-Performance Evaluation (COMLEX-USA Level 2-PE).[23] To better understand the USMLE Step 2 CS, a brief overview of the Educational Commission for Foreign Medical Graduates (ECFMG) CSA is also provided.[24] The CSA was used to assess the clinical skills of international medical graduates (IMGs) before the introduction of USMLE Step 2 CS. Following this overview, a brief synthesis of the similarities and differences in the assessments and assessment programs is provided. With these distinctions in mind, and knowing the success and scope of the individual testing programs, it is possible to envision where summative simulation-based assessment activities could be enhanced, applied in other areas, and used for the evaluation of nonphysician healthcare professionals.

ASSESSMENT OF CLINICAL SKILLS

In general terms, clinical skills refer to information gathering and communication skills, applied during the patient encounter, that help to establish an accurate diagnosis and support high-quality treatment. Within the medical education and practice community, these skills have long been recognized as essential to patient care. Several organizations, including those responsible for the accreditation of undergraduate and graduate medical education (GME) programs, have included clinical skills among the competencies deemed important to the education and assessment of practicing physicians.[25–27] As a result, it is not surprising that considerable efforts have been made to develop, and subsequently defend, testing methods than can be used to reliably and validly measure these skills.

STANDARDIZED PATIENTS

SPs, often referred to as simulated patients or programmed patients, are people who have been trained to accurately portray the role of a patient with a specific medical condition or conditions. The term "standardized" refers to the fact that the person is specifically trained to model the "real" patient's condition, including symptoms and emotional states, and to do so consistently over time. Examinees who interview the same SP with the same presenting complaint will receive, on questioning, the same patient history. The physical findings relevant to the case, either real or simulated, need to be stable and, for a given modeled scenario, they must not vary from one SP to another.

LARGE-SCALE SP EXAMINATIONS

Medical Council of Canada Qualifying Examination Part II

Since 1912, the MCC has been setting an examination that is a prerequisite for medical licensure in Canada; the Licentiate of the MCC is granted to those who successfully complete it. In 1992, the MCC added the Qualifying Examination Part II (MCCQE Part II) to the assessment sequence. Initially the MCCQE Part II was a 20-station Objective Structured Clinical Examination (OSCE).[7,28] Although the use of OSCEs is now commonplace throughout the world, implementing a national summative, performance-based, assessment based on a series of SP encounters was, at the time, unprecedented. The impetus for implementing the MCCQE Part II came largely from the licensing authorities. In the late 1980s, because of the number and nature of related complaints that they received each year, members of these authorities began calling for an assessment of clinical and communication skills. The existing paper-and-pencil test of medical knowledge and problem solving (MCC Qualifying Examination Part I—MCCQE Part I) was not sufficient to address the emergent belief that candidates for medical licensure should be assessed more broadly.

To qualify for the MCCQE Part II, candidates must have completed successfully 12 months of postgraduate clinical training and passed the MCCQE Part I, currently a computer-adaptive test of knowledge and clinical decision-making. The number of candidates who qualify for the MCCQE Part II continues to grow. In 1992, 401 candidates took the examination. In 2007, 3481 candidates completed this assessment, a more than eightfold increase.

As the measurement qualities of the MCCQE Part II became better understood, the number of stations was reduced from 20 to 14, and is now set at 12. This reduction in station length could be attributed to evolving test development processes, allowing for a more efficient and appropriate targeting of test content to examinee ability. Each station is based on a clinical problem presented by a SP; scoring is completed by physicians who observe from within the room. Checklists and rating scales are used to generate the station scores. At this time, the MCCQE Part II is comprised of eight 10-minute encounters with a SP and six couplet stations that include a 5-minute encounter with a SP followed by a 5-minute written component (Two of the stations in the assessment, including one of the couplets, are used for pilot testing purposes). Four domains are assessed based on common presenting problems: history-taking skills, physical examination skills, patient management, and doctor-patient interactions. Patient safety issues and professionalism are also evaluated.

Each scored station, while potentially measuring slightly different skill sets, counts equally in terms of generating a total score. Although station scores are compensatory, mean-

ing poor performance in one station may be compensated by superior performance in another, the overall pass/fail decision is based on a conjunctive standard; candidates must pass both by total score (the sum of their station scores) and by the number of stations passed.

Results from the MCCQE Part II are reported as a standard score (mean = 500, standard deviation = 100). The examination is criterion-referenced, with the individual station pass marks set using the borderline group method.[29] Candidates receive a bar graph indicating their performance in each of four domains relative to the mean score for their testing cohort. The four domains are data gathering (from history taking and physical examination tasks), patient interaction (from rating scale items across stations), problem-solving and decision-making (based on certain stations; eg, acute care of trauma and the written work from the couplet stations), and legal, ethical, and organizational issues (which comprises a minimum of 10% of the total score). More extensive feedback is provided to those candidates who are unsuccessful; specifically, they are told which stations they failed and are provided with a more extensive description of the four domains.

To balance accessibility and costs, a multisite, fixed test form model with two administrations per year is employed. In the spring, one test form is administered twice over 1 day at 10 university sites across Canada. At most sites, the examination runs in two or more parallel tracks. In the fall, there are two test forms, one for each of 2 days of testing, and the examination runs at 16 sites. In spring, over 500 SPs are trained to simulate the patient problems. Twice that many are recruited for the fall. Ensuring that the SPs present their problems consistently and with sufficient fidelity for valid testing is critical. Each site has its own trainers who recruit and prepare the SPs according to the protocols developed centrally. Training videos, meetings with MCC staff, consultation with supervising physicians, along with telephone support are all part of a process aimed at ensuring the SPs are ready for the examination.

Like all large-scale testing programs, there have been some administrative challenges. Developing feasible, psychometrically sound cases (simulated scenarios) is an ongoing task and takes considerable time and effort. Because the MCCQE Part II is a national examination, the scoring instruments and the supporting materials for SP training are developed centrally by a multidisciplinary test committee. Cases range from those requiring relatively little simulation (eg, history of diarrhea) to those where the SP must accurately simulate specific patient presentations (eg, shortness of breath, decreased consciousness, pain, anxiety).

The MCC is continuously assessing different aspects of the MCCQE Part II. Numerous research studies suggest that both valid and reliable competency decisions are being made.[30–32] Most recently, the predictive validity of the MCCQE Part II was investigated by looking at the relationship between MCCQE Part I and Part II scores and complaint records from two licensing jurisdictions.[33] The authors concluded that poor performance on the MCCQE Part II patient-physician communication component and the clinical decision-making component from the MCCQE Part I were predictors for complaints.

Educational Commission for Foreign Medical Graduates Clinical Skills Assessment

Based on several years of extensive research and consultation with the MCC, the ECFMG CSA was instituted in July 1998.[34,35] This 11 station clinical skills examination was developed to evaluate whether graduates of international medical schools (IMGs) possessed the skills necessary to enter supervised GME programs in the US. Successful completion of this examination became one of the required elements for ECFMG certification. Initially, the assessment was offered at one fixed site in Philadelphia, Pennsylvania. In 2002, in collaboration with the National Board of Medical Examiners, a second testing site was constructed in Atlanta, Georgia. Between 1998 and 2004, 43,624 IMGs were tested (37,930 first-time takers) in a total of 372,674 simulated clinical encounters. During this time, numerous studies were published, several providing evidence to support the validity of the assessment scores.[36–38] Of particular note, research was conducted to show that SP and physician evaluations of clinical skills were comparable.[39] In 2004, administration of the ECFMG CSA ceased. Instead, IMGs were required to take and pass USMLE Step 2 CS (described below), a similar simulation-based assessment that was developed to measure the clinical skills of American allopathic medical students and graduates. The USMLE Step 2 CS examination is part of the USMLE sequence (There are three "Steps" to the USMLE. Step 1 is intended to assess whether the examinee understands and can apply important concepts of the sciences basic to the practice of medicine. Step 2 focuses on the examinee's knowledge, skills, and understanding of clinical science essential for provision of patient care "under supervision"—typically the point that medical school graduates begin their postgraduate education and experience. Step 3 is intended to assess whether the examinee can apply medical knowledge and understanding of biomedical and clinical science essential for the unsupervised, independent practice of medicine.) To qualify for a medical license to practice in the US, graduates of MD-granting schools in the US and graduates of medical schools located outside the US must take and pass all components of USMLE.

United States Medical Licensing Examination Step 2 Clinical Skills

From the time that introduction of the USMLE program was first proposed in the late 1980s, it was the intent of the National Board of Medical Examiners and the Federation of State Medical Boards (the organizations that sponsor USMLE) to include clinical skills among the areas assessed as part of the examination program supporting the US medical licensing system. After many years of development, this goal became a reality in June 2004 when USMLE Step 2 CS was administered for the first time.[40] At this point, the previously existing Step 2 examination, a 1-day, computer-based multiple choice questionnaire test, was renamed the Step 2 Clinical Knowledge examination. The introduction of Step 2 CS in the USMLE sequence was informed by the research of many organizations interested in the assessment of these important

skills and by the operational experiences of organizations that brought this type of format to the arena of large-scale, high-stakes assessment, in particular, the MCC and the ECFMG.[41–43]

The USMLE Step 2 CS examination, which is delivered at each of five regional testing centers (Atlanta, Chicago, Houston, Los Angeles, and Philadelphia), requires test takers to move through a series of 12 simulated encounters (stations), interacting with SPs, individuals who are trained to portray real patients. Examinees are given up to 15 minutes to interact with each SP. During that time they are expected to take a history and to perform a physical examination that is focused on the chief complaint of the patient and on the information that is revealed during the encounter. After the simulated encounter, examinees are given 10 minutes to write a patient note that summarizes and synthesizes their findings, including possible diagnoses. The mix of cases seen by any one examinee is guided by a group of content experts who are charged with overall design and development of Step 2. Based on a test blueprint established by this committee, each test form contains a blend of patient presentations that would not be uncommon for clinical practice in the US. This same committee is involved in the process used to establish passing standards.[44,45] Because the Step 2 CS examination is offered daily across five sites, a variable test form administration model is used. The test form (mix of clinical presentations and SP characteristics) for any given administration, at any site, is individually constructed to meet blueprint specifications. Efforts are made to minimize case and SP exposure for previously failing examinees who are repeating the assessment.

USMLE Step 2 CS examinees are required to pass three subcomponents: the integrated clinical encounter, which includes demonstration of skills in history taking, physical examination, and documentation; communication and interpersonal skills, which includes skills in information gathering/sharing and establishing rapport; and spoken English proficiency, which requires clear communication with the patient. With the exception of the postencounter notes, which are scored by a group of physicians who are specially trained to the specifics of the case, all scoring is done by the SPs who are extensively trained and monitored in their use of a series of checklists and rating scales that were specifically designed for gathering reliable and valid measures of these components. To pass the USMLE Step 2 CS, an examinee must pass all of the three subcomponents (integrated clinical encounter, communication and interpersonal skills, and spoken English proficiency) in a single administration. Failing examinees are provided with feedback outlining relative strengths and weaknesses in the various clinical skills components that are measured.

The USMLE Step 2 CS program has been fully operational for almost 4 years, delivering, scoring, and reporting results year round. More than 120,000 examinations have been administered, representing more than 1.4 million examinee-SP encounters. Because of the complexities of an overall system that handles, at any one time, thousands of examinees, hundreds of SPs, and multiple testing centers, there are substantial quality assurance measures in place[46] and, as a result, for the most part, the examination process has been completed with relatively few problems. Similar to the other USMLE examinations, significant efforts are dedicated to all phases of testing, including content development and validation, examinee scheduling, administration, scoring, equating, standard setting, and score reporting.

Despite the technical and administrative challenges, the implementation of the USMLE Step 2 CS program has been successful. USMLE Step 2 CS identifies examinees with deficiencies in important practice skills who might not otherwise have been identified based on the other examinations in the USMLE sequence.[47] In this way, the examination has made a significant contribution to the medical licensing process in the US and, at the same time, has called special attention, within the education and practice community, to the role of clinical skills in patient care activities. In a recent study that was based on interviews of 25 leaders of medical school CSA programs, respondents noted that the new national examination validated the importance of clinical skills for medical students.[48] Also, of particular note, numerous schools have changed the objectives, content, and emphasis of their preclinical curriculum in response to the implementation of the Step 2 CS.[49]

Comprehensive Osteopathic Medical Licensing Examination Level 2-Performance Evaluation

In 1994, the NBOME started the process of developing a SP-based clinical skills examination for osteopathic physician licensure. After considerable research and several feasibility and pilot studies, the COMLEX-USA Level 2-PE was launched in 2004.[50] Similar to both the MCC and the USMLE, this new assessment complemented the other examinations that are part of the licensure process for osteopathic physicians (COMLEX-USA or Comprehensive Osteopathic Medical Licensing Examination is a series of three osteopathic medical licensing examinations administered by the NBOME. The examinations include Level 1, Level 2-CE, Level 2-PE, and Level 3. COMLEX-USA is the most common pathway by which osteopathic physicians (DOs) apply for licensure, and is accepted in all 50 states and numerous international jurisdictions.) The COMLEX-USA Level 2-PE, which is usually taken in the 4th year of osteopathic medical school, tests the clinical skills of graduating students of osteopathic medical schools in the US. As of 2008, the accreditation body for osteopathic medical schools in the US (Commission on Osteopathic College Accreditation of the American Osteopathic Association) requires that all students pass COMLEX-USA Level 2-PE before graduation, and examinees are not eligible to take the COMLEX-USA Level 3 examination, the final examination in the COMLEX-USA series, unless they have passed COMLEX-USA Level 2-PE. Through the end of the 2007 calendar year, there have been a total of 992 COMLEX-USA Level 2-PE test administrations, involving more than 11,800 examinees.

Based on the COMLEX-USA Level 2-PE assessment design, examinees encounter 12 SPs in a simulated ambulatory clinical medical environment. The assessment takes 7 hours and is administered at a single fixed site (NBOME National Center for Clinical Skills Testing) located in the Philadelphia,

Pennsylvania area. For each of the 12 simulated encounters, examinees have 14 minutes to evaluate and treat the SP based on the clinical presentation. Following the 14-minute encounter, the examinee has an additional 9 minutes to complete a written patient note. Content design for the examination, including test form specifications, was informed by analysis of national practitioner databanks and expert consensus.[51] The mix of cases for a given test form is balanced with respect to acute, chronic, and health promotion/disease prevention presentations. To enhance content validity, the mix of SPs is governed by specifications related to patient characteristics, including gender and age. The COMLEX-USA Level 2 PE is administered almost every day, and sometimes both in the morning and in the evening. Consequently, a variable test form administration model is employed.

The COMLEX-USA Level 2-PE assesses skills in four clinical skill areas: doctor-patient communication, interpersonal skills, and professionalism; data gathering, which includes medical history-taking and physical examination; documentation and synthesis of clinical findings (including treatment); and osteopathic principles and osteopathic manipulative treatment (OMT). Doctor-patient communication, interpersonal skills, and professionalism are evaluated by the SPs using behaviorally anchored holistic scales. Data gathering proficiency is derived from case-specific checklist items, documented by the SPs following the clinical encounter. Written notes are evaluated by physician examiners located throughout the US using a holistic rubric. Unique to COMLEX-USA Level 2-PE, osteopathic principles and OMT are evaluated by physician examiners via a distributed video review system. Here, the physician examiners, also located across the US, access assigned clinical encounters through a secure web link and then provide structured performance ratings.

The four skill area scores, summarized over the encounters, are combined into two domains. The Humanistic domain summary score is based solely on the SP ratings of doctor-patient communication, interpersonal skills and professionalism. The Biomedical/Biomechanical domain summary score is a weighted composite of an examinee's data gathering, written patient notes, and OMT scores. For both domains, the generation of a summary score, over encounters, is compensatory, meaning that an examinee can compensate for poor performance in one station with excellent performance in another. However, across the two domains, COMLEX-USA Level 2-PE uses a conjunctive scoring model; examinees must achieve passing scores in both domains to receive a passing score for the examination. Examinations standards were initially set in 2004–2005 and, based on widely accepted testing protocols, updated in 2007. Only candidates who fail the examination are given specific feedback on their skills performance in the two domains and four skills areas.

To ensure that decisions based on the COMLEX-USA Level 2-PE examination scores are fair, an extensive quality assurance program has been implemented. In addition to pilot testing cases prior live usage, double scoring a large percentage of the encounters, investigating the relationships among scores, and regularly checking physician and SP rater stringencies, the performances of failing candidates are systematically reviewed to ensure that the decisions are accurate and can be defended.

The introduction of COMLEX-USA Level 2-PE, although logistically challenging, helps to fulfill the public and licensing authority mandate for enhanced patient safety through the documentation of the clinical skills proficiency of graduates from osteopathic medical schools. As a consequence, it has effectively highlighted the importance of clinical skills training as part of the osteopathic medical school curriculum.[52–54] Moreover, there has been an associated increase in the use of simulation throughout the medical school curriculum. Based on a survey of the deans of the 23 fully accredited Colleges of Osteopathic Medicine and branch campuses, Gimpel et al.[55] concluded that the use of SPs and mechanical simulators at colleges of osteopathic medicine increased substantially from 2001 to 2005.

DISCUSSION

The clinical skills examinations described above (MCCQE Part II, USMLE Step 2 CS, NBOME COMLEX-USA Level 2-PE) share many commonalities. They all use a multistation format where candidates rotate through series of clinical encounters, alternating between patient interviews and some form of postencounter exercise. Here, the development and choice of clinical encounters (stations, cases) is governed by detailed test specifications. Multiple stations are used in an effort to broadly sample the practice domain and to ensure that the scores, and associated pass/fail decisions, are reliable. All of the examinations model typical patient settings and doctor-patient interactions. This high-fidelity simulated environment provides the means to measure fundamental clinical skills, including history taking, physical examination, doctor-patient communication, and interpretation of clinical data. In measuring these skills, some combination of rating scales and checklists is used to produce examinee scores. Given the high-stakes nature of these examinations (access to the medical profession), significant resources are allotted to development and validation of the simulated clinical scenarios. For all three examinations, unscored pilot stations are incorporated into live examinations before their active use in making decisions about clinical skills proficiencies. In this way, data can be gathered to establish the fidelity of the simulation, the appropriateness of the clinical content, and the ability of the resultant scores, both ratings and checklists, to discriminate between those who possess the skills and those who do not. Finally, and likely most important, they all employ highly structured training and quality assurance protocols, both for the SPs and physician evaluators. This helps to ensure that valid inferences (ie, pass/fail decisions) can be made from the available scores and ratings.

Although the assessments share a common structure, there are some important differences that, taken collectively, serve to broaden the potential assessment domain and provide potential test administration frameworks that could be useful to other health professions that wish to evaluate clinical skills. First, the USMLE Step 2 CS and NBOME COMLEX-USA Level 2-PE run at fixed sites, whereas the MCCQE Part II operates periodically on weekends at actual clinics

across Canada. Although choice of variable or fixed sites is dependent on candidate volume, political considerations, and economics, quality exams can be offered under either administrative model as long as steps are taken to ensure proper standardization and security. Second, because of the almost daily administration of the COMLEX-USA Level 2-PE and USMLE Step 2 CS exams, test forms are continuously changed and are rarely repeated. For the MCCQE Part II administrations, which take place at the same time across different sites, a fixed form model is appropriate (The actual examination does not take place at exactly the same time across Canadian sites. Examinees at sites in later time zones are sequestered so that examination information cannot be shared.) Third, unlike the MCCQE Part II, which is usually taken in the second year of residency, the US-based examinations (COMLEX-USA Level 2-PE, USMLE Step 2 CS, former ECFMG CSA) are targeted at individuals who are just entering GME programs. As a result, the content of the MCCQE Part II is somewhat more challenging, requiring more advanced management and clinical decision making abilities. Fourth, because of differences in the practice characteristics of allopathic and osteopathic medicine, the clinical content modeled in the various assessments is not identical. For example, on the COMLEX-USA Level 2-PE there are proportionally more encounters involving SPs with musculoskeletal complaints. Moreover, unlike any of the other assessments, the evaluation of osteopathic principles and OMT is a fundamental part of this examination.[56] Given the differing purposes of these assessments, it is not surprising that they diverge somewhat in terms of focus. Modeling clinical encounters that are important to the profession, combined with tailoring the examinations to the expected performance level of examinee, provides a basis for establishing the content and construct validity of the assessments. A similar strategy could easily be used for non SP-based simulation activities, including those employing mannequins or part-task trainers.

Although the skills that are measured in these performance-based assessments are similar, the measurement protocols vary. For both the USMLE Step 2 CS and COMLEX-USA Level 2-PE, a score equating strategy is employed.[42] Because the examination content, and associated SPs, can vary considerably from day to day, it is important to account for potential differences in the difficulty of the test forms administered. Unlike the other assessments, the MCCQE Part II employs physician examiners who sit in the room while the clinical interview takes place. These physicians are trained to score the encounters and also to make summary, holistic, judgments of the adequacy of the performance. These summary measures are then used, in combination with assessment scores, to derive performance standards.[29] In contrast, for both the COMLEX-USA Level 2-PE and USMLE Step 2 CS, where SPs complete history taking and physical examination checklists, separate standard setting exercises are conducted periodically. Interestingly, while all three assessments employ some form of assessment of doctor-patient communication skills, there are no common rubrics or training protocols. For both the COMLEX-USA Level 2-PE and USMLE Step 2 CS, the SPs provide ratings of interpersonal and communication skills; for the MCCQE Part II, the physician in the room evaluates these traits. Finally, although employed somewhat differently, all of the examinations have both compensatory and conjunctive scoring elements. Test-level scores are generated by averaging performance in specific domains over the series of modeled encounters. For the COMLEX-USA Level 2-PE and USMLE Step 2 CS, a candidate's pass fail status is determined by summary performance in multiple areas. For the MCC Part II examination, candidates must also demonstrate an acceptable level of performance across a minimum number of stations.

Overall, based on a fairly limited usage of mock-up settings and simulation modalities, the three SP-based examinations are successful in fulfilling their assessment goals. For the most part, the restricted use of simulation modalities can be attributed to the fundamental purposes of the assessments, the logistics and economics of large scale assessment, technological limitations, and psychometric issues pertaining to scoring. Nevertheless, going forward, one can envision the adoption of other simulation strategies to broaden the assessment domain. For example, if logistical and psychometric issues could be effectively addressed, incorporating paired SP-Part task trainer stations could be an effective way to measure procedural skills and clinical decision making.[57–59] Likewise, although stations involving one SP and one examinee are efficient, at least from a testing perspective, the measurement of communication skills in this context is restricted to the doctor (examinee) and the patient. To evaluate teamwork, and certain facets of professionalism and ethical behavior, it would be appropriate to include other simulated healthcare workers and even standardized family members.[60–63] The MCC has already integrated some stations of this nature into their clinical skills examination; for example, working with a nurse to care for a trauma patient in an acute care setting and advising another healthcare professional over the telephone. Finally, even though some physical findings can be simulated by SPs quite well, many cannot (eg, trauma, breathing difficulties). As a result, for an OSCE that only includes SP-based encounters, it can be difficult to fully evaluate physical examination skills. Here, provided financial and logistical concerns can be addressed, electromechanical mannequins could be employed in some stations.[64]

Although the incorporation SP-based performance assessments as part of licensure and certification has spurred substantial research, there remain several important areas where further investigations are warranted. With respect to scoring, the available checklist and rating scales used for SP-based assessments, although appropriate for measuring basic clinical skills including history taking and physical examination, may not yield valid and reliable measures when employed for acute care situations, especially those modeled with electromechanical mannequins or even part-task trainers. Here, other constructs (eg, timing, sequencing, accuracy) will need to be incorporated within the measurement framework. In terms of content sampling, additional research focusing on the choice and structure of the various forms of simulation exercises is needed. Knowing which types of simulated scenarios provide for the best assessment conditions, and most valid and reliable scores, is essential if one seeks

meaningful and generalizable measures of ability. Likewise, if new ability measures are constructed, additional psychometric work will be needed to delimit the score, or scores, that separate those who are proficient from those who are not. Finally, and arguably most important, there is still relatively little published research that shows that performance in the simulated environment translates to real-world patient care. Designing and completing outcome studies that provide support for the validity of the performance measures derived from simulation-based assessments is paramount.

Conducting large scale, high-stakes performance assessments for medical licensure has been extremely successful. Although the MCC, USMLE and NBOME clinical skills exams have somewhat different purposes, administration models, and scoring protocols, they are all effective in providing a fair and equitable assessment of the clinical skills of their test populations. All three assessments are supported by a substantial number of research studies aimed at establishing the validity and generalizability of the test scores. As medical simulation further expands into other areas (eg, specialty board certification, selection of residents, continuing medical education, maintenance of certification), the processes used to develop and administer these examinations, with some modification, can be used as a model for assessment design and delivery. Should simulation-based assessment be adopted more broadly, especially for high-stakes competency decisions, one ought to expect a fairly large consequential educational impact, including an enhanced curricular emphasis on any particular skills that are evaluated as part of new assessment strategies. As other health provider groups seek to evaluate their trainees and make defensible competency decisions, the lessons learned in developing high-stakes, SP-based assessments in medicine will certainly prove to be quite valuable.

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A Comparison of Physician Examiners and Trained Assessors in a High-Stakes OSCE Setting

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Abstract

Background
The Medical Council of Canada (MCC) administers an objective structured clinical examination for licensure. Traditionally, physician examiners (PE) have evaluated these examinees. Recruitment of physicians is becoming more difficult. Determining if alternate scorers can be used is of increasing importance.

Method
In 2003, the MCC ran a study using trained assessors (TA) simultaneously with PEs. Four examination centers and three history-taking stations were selected. Health care workers were recruited as the TAs.

Results
A 3 × 2 × 4 mixed analyses of variance indicated no significant difference between scorers ($F_{1,462}$ = .01, p = .94). There were significant interaction effects, which were, localized to site 1/station 3, site 3/station 2, and site 4/station1. Pass/fail decisions would have misclassified 14.4–25.01% of examinees.

Conclusion
Trained assessors may be a valid alternative to PE for completing checklists in history-taking stations, but their role in completing global ratings is not supported by this study.

Acad Med. 2005;80(10 suppl):S59–S62.

Background

The objective structured clinical examination (OSCE) is widely used to evaluate medical students, select foreign medical graduates for training, and for medical licensure. The OSCE has proven to be a reliable and valid assessment of clinical skills.[1] One area of controversy is who should be observing and rating the encounters. In the Medical Council of Canada Qualifying Examination Part II (MCCQE Part II) physician examiners are used as raters and standard setters, whereas in the Educational Commission for Foreign Medical Graduates (ECFMG) examination standardized patients (SP) are used. One argument for the use of physician examiners is that experienced physicians are essential to judge the ability level of examinees for making high-stakes decisions. However, with higher clinical demands on physician's time and difficulty recruiting physician examiners, the use of nonphysicians is an attractive alternative.

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Although there are studies that support the use of SPs,[2–4] several have identified concerns with their use as examiners. Rothman and Cusimano,[5,6] in two separate studies of the Ontario International Medical Graduate Program OSCE, found poor consistency between physician examiners and SPs in their ratings of interviewing skills and little agreement between them in identifying potentially problematic examinees regarding English proficiency.

One challenge for SPs is that they are commonly scoring by recall. One study that explicitly examined this issue compared physician examiners to SPs in five history-taking stations. Martin and colleagues[7] compared physician examiners, SP observers, and SPs completing checklists from recall. Their findings suggest physicians should be used to rate examinees whenever practical. SP observers were considered better than the SPs who rated from recall.

One source of alternate scorers is medical students, and Van der Vleuten et al.[2] demonstrated that trained medical students were almost as good as trained faculty. One interpretation of this study is that individuals with some medical knowledge may be superior to lay persons. Medical students are not appropriate for use in high-stakes examinations where they will be eventual test-takers.

In Canada, the MCCQE Part II is a requirement for medical licensure. The examination is run twice per year and each administration requires between 400 and 900 physicians. Securing sufficient numbers of physician examiners is becoming more challenging. We therefore wanted to determine if nonphysicians are a viable alternative. We chose individuals with a medically related background, as the literature suggested they might perform better. Physicians and nonphysician raters were compared on checklist scores and global rating scales in a high stake OSCE.

Method

The MCCQE Part II is a 12-station OSCE consisting of seven ten-minute patient encounters and five couplets. The couplets are five-minute patient encounters paired with five-minute written exercises. The patient problems of each station are derived from one of the five major disciplines of medicine

(medicine, obstetrics and gynecology, pediatrics, psychiatry, and surgery). The study was based on the fall 2003 administration and data was collected at four of 15 sites. Only English sites were selected to exclude variance due to language. Sites were chosen from different regions to provide a broader sample of data.

Three five-minute history-taking stations were selected for this study. Two of the cases were from the domain of obstetrics and gynecology and the third was a pediatrics case. The objectives tested were vaginal bleeding, pelvic pain, and eliciting a history regarding a crying and fussing child. There were 24 to 30 checklist items for each of the stations. One station also contained a rating scale item for "questioning skills" and another for "rapport with person."

Scoring procedures have been described elsewhere.[8] In essence, for each station, examiners complete a checklist measuring the observed performance of the examinees' clinical skills and subsequently completed a global rating. The global rating scale is a six-point scale ranging from "inferior" to "excellent," with the two middle categories described as "borderline unsatisfactory" and "borderline satisfactory." Cut-scores for each station were established by the modified borderline group method. With this method, each station cut-score was the mean of the case scores for individuals rated as "borderline."[9] The physician examiner score and cut-score were considered the "gold standard."

Thirty-three nonphysicians were recruited to be trained assessors. They were trained to score one of the three history-taking stations selected for this study. Most (27/33) of the trained assessors had a medical background such as nursing, pharmacy, physiotherapy, occupational therapy, paramedics, or psychology. The other six had no medical background but had been SPs in previous examinations. The training involved a two-hour general training session in which trained assessors were provided with a self-study booklet and then participated in one hour of "dry runs" of their patient problem. This step involved watching four to eight SPs portray the case and completing a checklist along with a physician examiner. Each trained assessor scored only one case.

Each of the 33 trained assessors was paired with two physician examiners, one in the morning session and one in the afternoon session. Each pair viewed the encounter in real time and scored up to 32 examinees. They completed the same checklist and global rating scale but were not allowed to discuss results at any time. Each trained assessor scored up to 64 candidates and a total of 466 examinees completed all three stations.

The data were analyzed using SPSS 13.0 (SPSS Inc., Chicago, IL) to calculate correlations between examiner types and to conduct a $3 \times 2 \times 4$ repeated-measures analysis of variance. For this latter analysis, the three stations and examiner types (trained assessor versus physician examiner) were treated as within subject variables and the examination site (1–4) was treated as the between subject variable.

Results

The main effect for examiner was not significant ($F_{1,462} = .01$, $p = .94$). The mean scores and standard deviations are shown in Table 1. However, the interaction between station and examiner was significant ($F_{2,924} = 17.46$, $p < .001$), as was the three-way interaction among station, examiner, and site ($F_{6,924} = 7.50$ $p < .001$). As shown in Table 2, which displays the means and standard deviations by site for stations and examiners, the significant three-way interaction likely occurred because there was a difference between the scorers at some sites and stations that did not occur at other sites and stations. This observation was confirmed by running post hoc comparisons for each pair of trained assessor and physician examiners as a function of site and station. Table 2 displays the resulting level of significance and effect size measure for these comparisons. To protect against an inflation of the family-wise error rate, a significance level of .02 was used for these comparisons. As shown in the table, there was a significant difference in mean scores between trained assessors and physician examiners at site 1/station 3, site 3/station 2, and site 4/station 1 that did not occur elsewhere.

Despite these differences in mean scores, the correlations between scores assigned by the examiners were relatively high. As shown in Table 2, the correlation between examiner scores range from .49 to .92 indicating a relatively high level of agreement between examiners for each site and station. The high correlation and similar mean scores between pairs of examiners suggest that there were few differences between trained assessors and physician examiners, other than some isolated differences due to the interaction of site and station. In the full examination, all three stations were psychometrically sound with means and standard deviations well within expected norms. Item total score correlations were station 1 = .347, station 2 = .421, and station 3 = .359.

Table 1 displays the cut scores for each station as determined by the global ratings of the trained assessors and physician examiners. Although the cut scores for each station appeared to be similar, the agreement in terms of pass/fail decisions was not high. Examinees were classified in opposing pass/fail categories as follows: station 1, 67/466(14.4%); station 2, 78/466

Table 1

Means, Standard Deviations, and Cut-Scores by Examiner-Type across Stations (*n* = 466)

Station	PE Mean %	PE SD %	PE Cut-score %	TA Mean %	TA SD%	TA Cut-score %
1	60.8	10.0	54.8	60.3	10.5	54.8
2	57.7	11.0	51.6	55.9	10.5	49.2
3	60.3	11.6	49.4	62.2	11.7	53.9

PE = physician examiner; TA = trained assessor.

Table 2

Means, Standard Deviations, by Examiner-Type across Stations and Geographical Sites

Site	Station	N	PE Mean %	PE SD %	TA Mean %	TA SD %	ES Mean %	sig	*r* Standard Deviation %
1	1	118	62.0	11.6	62.0	11.1	.00	.93	.92
	2	118	58.6	11.5	58.1	12.4	.03	.40	.90
	3	118	57.7	10.8	63.7	11.6	.56	.00	.60
2	1	127	58.2	10.8	58.8	10.9	.06	.10	.93
	2	127	56.3	11.0	56.5	10.0	.02	.78	.69
	3	127	58.2	11.8	59.9	12.1	.14	.09	.58
3	1	160	61.4	10.6	60.5	9.8	.08	.12	.75
	2	160	59.2	10.3	53.7	9.3	.53	.00	.77
	3	160	61.9	12.1	61.5	11.7	.03	.64	.49
4	1	61	62.4	8.5	59.6	9.9	.32	.01	.73
	2	61	55.2	10.8	56.1	9.7	.09	.38	.66
	3	61	65.1	8.7	65.4	9.9	.03	.74	.72

PE = physician examiner; TA = trained assessor; ES = effect size of the comparison between the mean scores for the PE and TA; sig = level of significance of the comparison of mean scores for PE and TA.

(16.74%); station 3, 117/466 (25.01%). Physician examiners failed more examinees in every station compared to the trained assessors (136 versus 103 in station 1, 127 versus 109 in station 2, and 174 versus 99 in station 3).

Discussion

The purpose of this study was to determine if a nonphysician trained to score examinees on a particular case could produce ratings similar to that of a physician. In this study there was very good agreement between the physician examiner and trained assessor checklist scores for history-taking stations that were administered as part of a high-stakes OSCE. There was poor agreement, however, on pass/fail decisions. Up to 25% of candidates were misclassified by the trained assessors. This study confirms the findings of previous research suggesting that trained observers are a viable alternative for scoring checklists. The findings also raise the same concern identified by other studies regarding the ability of nonphysicians to complete global rating scales.

The finding that nonphysicians may have difficulty making judgments regarding the appropriateness of certain lines of questioning should not be surprising. A physician examiner may interpret a certain line of questioning favorably, for example recognizing a candidate who is ruling in or out disease, which the nonphysician would not have the medical knowledge to credit. For the Ontario International Medical Graduate OSCE, Rothman and Cusimano[5,6] reported good consistency between physician examiner and SP ratings of English proficiency, but less agreement in their ratings of interviewing skills and little agreement in identifying problematic candidates. For similar reasons, Colliver et al.[10] recommended caution in the interpretation of scores obtained from a case checklist completed by multiple SPs, especially if scores would be used for pass/fail decisions.

This study differed from some of the other studies because it was based on real-time simultaneous observations by the physician examiner and trained assessor pairs. The qualitative loss that may be associated with viewing videotaped encounters was avoided. A second difference lies in the approach to the recruitment and training of the trained assessors. The trained assessors were required to have a university-level degree and a professional background that would support their role as an examiner in a clinical skills examination. In addition they received three or more hours of training related to medical history taking and the case they would be observing. This is less than the 15 hours given to SPs who score the ECFMG examination,[3] but these SPs are trained to portray a case as well as to score it. Newble and colleagues[11] studied the effect of training in physician examiners. They concluded that training for physicians was not effective and that selection of inherently consistent raters was the critical factor. Van Der Vleuten et al.[2] reported similar results and concluded that training was least effective and least needed for medical faculty. However, they also noted that with only two hours of training, laypersons approached the accuracy of untrained faculty.

Conclusions

In conclusion, the study demonstrated that trained nonphysician assessors may be a valid alternative to physician examiners for scoring checklists in a high-stakes OSCE. As a preliminary study, this is encouraging. The next step is to develop a better understanding of the interaction effect that occurred at two of the four sites.

The ability of trained assessors to make valid global judgments that contribute to pass/fail decisions was not supported by the present study. This challenge to the standard setting methodology will need to be addressed before trained assessors

are incorporated in this high-stakes OSCE.

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Physician Scores on a National Clinical Skills Examination as Predictors of Complaints to Medical Regulatory Authorities

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Physician Scores on a National Clinical Skills Examination as Predictors of Complaints to Medical Regulatory Authorities

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Context Poor patient-physician communication increases the risk of patient complaints and malpractice claims. To address this problem, licensure assessment has been reformed in Canada and the United States, including a national standardized assessment of patient-physician communication and clinical history taking and examination skills.

Objective To assess whether patient-physician communication examination scores in the clinical skills examination predicted future complaints in medical practice.

Design, Setting, and Participants Cohort study of all 3424 physicians taking the Medical Council of Canada clinical skills examination between 1993 and 1996 who were licensed to practice in Ontario and/or Quebec. Participants were followed up until 2005, including the first 2 to 12 years of practice.

Main Outcome Measure Patient complaints against study physicians that were filed with medical regulatory authorities in Ontario or Quebec and retained after investigation. Multivariate Poisson regression was used to estimate the relationship between complaint rate and scores on the clinical skills examination and traditional written examination. Scores are based on a standardized mean (SD) of 500 (100).

Results Overall, 1116 complaints were filed for 3424 physicians, and 696 complaints were retained after investigation. Of the physicians, 17.1% had at least 1 retained complaint, of which 81.9% were for communication or quality-of-care problems. Patient-physician communication scores for study physicians ranged from 31 to 723 (mean [SD], 510.9 [91.1]). A 2-SD decrease in communication score was associated with 1.17 more retained complaints per 100 physicians per year (relative risk [RR], 1.38; 95% confidence interval [CI], 1.18-1.61) and 1.20 more communication complaints per 100 practice-years (RR, 1.43; 95% CI, 1.15-1.77). After adjusting for the predictive ability of the clinical decision-making score in the traditional written examination, the patient-physician communication score in the clinical skills examination remained significantly predictive of retained complaints (likelihood ratio test, $P<.001$), with scores in the bottom quartile explaining an additional 9.2% (95% CI, 4.7%-13.1%) of complaints.

Conclusion Scores achieved in patient-physician communication and clinical decision making on a national licensing examination predicted complaints to medical regulatory authorities.

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DECADES OF RESEARCH HAVE confirmed that poor skills in patient communication are associated with lower levels of patient satisfaction, higher rates of complaints, an increased risk of malpractice claims, and poorer health outcomes.[1-16] Medical schools have responded by incorporating training in patient communication and clinical skills into the curriculum. However, these skills were not systematically evaluated, nor was a minimum level of proficiency required for medical licensure.[17] To address this problem, licensure reforms were undertaken in North America.[18] The Medical Council of Canada (MCC) (1993),[19] the Educational Commission for Foreign Medical Graduates (1998),[20] and most recently the United States Medical Licensing Examination (USMLE) (2004)[21] have all introduced a clinical skills examination (CSE)—a nationally standardized assessment of patient-physician communication, clinical history taking, and examination skills—as a requirement for licensure. All US and Canadian medical

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school graduates must now pass a multiple-case standardized patient assessment, where patient and physician examiners observe and grade clinical and communication skills to predict a candidate's competence to practice.

While mandatory assessment of clinical and communication skills is supported by the general public,[22] concerns have been raised about the cost of the examination and the lack of evidence that a 1-day assessment could predict future practice, particularly as it relates to deficiencies in patient-physician communication.[23-27]

Since instituting its CSE for all Canadian physicians, the MCC has tested more than 25 000 medical graduates using an examination format similar to the USMLE Step 2 clinical skills examination.[19] We investigated the ability of CSEs to predict future complaints in medical practice. We tested the hypothesis that lower scores in patient-physician communication would be associated with a higher rate of patients' complaints about quality of care and communication. We also assessed whether the use of clinical examination scores improved the prediction of complaints beyond results from the traditional written examination.

METHODS

Context

In Canada and the United States, medical regulatory authorities (state medical boards and provincial colleges of physicians and surgeons) use a common framework to govern how physicians are trained, accepted into practice, regulated, disciplined, and removed from practice.[28-32] A principal obligation of state and provincial medical regulatory authorities in both countries is to address and resolve public complaints against physicians. In accordance with a common set of principles and procedures, all complaints that are received in writing are investigated. A triage system is used to collect information from the patient and physician for each complaint, weed out frivolous or vexatious actions, and undertake informal steps to attain early resolution of minor issues. When these informal steps are either unsuccessful or deemed inappropriate, the complaint is managed by a more formal committee or panel process that determines further action. Most complaints are resolved through a graded series of regulatory actions, typically education, cautions, and warnings. For the most serious complaints, and for all complaints involving issues of sexual misconduct, formal disciplinary hearings of a quasi-judicial nature are convened. These hearings can result in a variety of sanctions up to loss of license. When a patient complaint about a physician is made directly to a hospital, the hospital in most state and provincial jurisdictions is required to report problems of professional misconduct to the medical regulatory authority.

Design and Population

The cohorts of physicians who took the MCC clinical skills examination between 1993 and 1996 and were licensed to practice in Ontario and/or Quebec were identified. Nearly two-thirds of the Canadian population and approximately 50% of all physicians reside in these 2 provinces. All complaints filed against these physicians with the medical regulatory authority in either province were retrieved between the date of licensure and March 2005. The MCC identified the 6677 physicians taking the examination during this period and provided the first and last name, sex, medical school, and year of graduation of each candidate to the medical regulatory authority in Ontario and Quebec. These 5 nominal fields were used to link to the registry of licensed physicians in each province. Physicians who matched on all fields were retained. Partial matches were manually inspected and adjudicated. Specialty, postgraduate training location and dates, and license year were obtained from the provincial medical regulatory files as well as from the national training registry of all physicians completing postgraduate medical training in Canada. Of the 6677 physicians, 8.6% could not be linked to Ontario/Quebec medical regulatory files or the national postgraduate training registry. Compared with linked physicians, unlinked physicians were more likely to be older (>45 years, 44.2% vs 11.4%; χ^2 $P<.001$), men (73.6% vs 57.4%; χ^2 $P<.001$), have trained outside Canada (83.4% vs 12.7%; χ^2 $P<.001$), have not yet passed the CSE (15.7% vs 1.8%; χ^2 $P<.001$), and have lower traditional written examination scores (495.4 vs 524.7; *t* test $P<.001$) and CSE scores (436.8 vs 517.8; *t* test $P<.001$).

Physician identity and confidential information were protected by replacing all nominal data with an MCC-generated study number, which was used to link demographic, score, and complaint files for each study physician. The McGill Faculty of Medicine institutional review board provided ethical approval. The provincial privacy commission, the Ontario and Quebec medical regulatory authorities, and MCC approved and oversaw data access, linkage, and anonymization procedures.

Measurement of Complaints

Provincial medical regulatory authorities collect standardized information for each written complaint against a physician. This information includes the names of the patients and physicians involved, and a description of the problem, circumstances, medical interventions, outcome, and the location of the incident. The investigation process includes a review of the letter with the complainant, the physician response, the patient's medical records, information from the hospital if applicable (eg, for surgical complications), and information from witnesses. All evidence is reviewed by physician investigators (Quebec) or a complaints committee (Ontario) who determine the legitimacy of the complaint, the type and seriousness of problem, and the recommended approach for resolution and subsequent action. Complaints are classified by investigators into 1 of 55 (Quebec) or 57 (Ontario) mutually exclu-

sive categories (eg, complication due to medical or surgical error, breach of confidentiality, incomplete medical reports), along with the outcome (retained or not) and the action (warning, counseling/training, license withdrawal, suspension, or restriction).

All complaints recorded for study physicians were retrieved by medical regulatory personnel. Data included the physician study number, date of filing and closure, the classification of problem type, and the outcome (retention decision and action taken). Complaint classification codes from the respective regulatory authorities were grouped into 6 categories based on comparable groupings used by the Ontario and Quebec regulatory authorities: communication and attitude; quality of care; professionalism; office-related problem; physician health-related behavior problem (eg, mental illness); and other (eg, false advertising). Assignment of complaint classification codes was independently verified by medical regulatory investigators who arbitrated disagreements on final assignment.

The primary outcome was the complaint rate: the number of complaints retained as valid by the medical regulatory authority after investigation per year of practice time. Because judgment about the validity of a complaint may vary between provincial regulatory authorities, we conducted a sensitivity analysis including all complaints to assess whether our findings were influenced by retention decisions. The subset of retained complaints that were related to problems in communication and quality of care were assessed as secondary outcomes, as these problems should be more strongly associated with the competencies being assessed by the examination.

The complaint rate for each physician was calculated using as the denominator years in practice, defined as the number of years between the final year of postgraduate training exit date and the end of follow-up (March 2005). To assess the validity of using exit date from postgraduate training as the starting date for practice time, we retrieved for 1161 Quebec physicians a count of the number of years in which the physician billed for patient services to the provincial insurance agency. In comparison with actual billing data between 1993 and 2003, our approach modestly overestimates the number of practice-years (mean [SD] from billing, 4.2 [2.4] years; from training exit year estimate, 4.9 [2.2] years). However, there was very good agreement between the 2 methods (intraclass correlation, 0.67; 95% confidence interval [CI], 0.54-0.75) and no relationship between practice-years and communication score (Pearson $r=-0.06$). Thus, potential errors in measurement of practice-years should not confound the association between complaints and communication score.

Medical Council of Canada Examinations

Traditional Written Examination. This examination tests an individual's competence to enter postgraduate training. It is generally taken at the end of medical school and must be passed to be eligible for licensure. Medical knowledge is assessed using approximately 450 multiple-choice questions to assess knowledge in medicine, surgery, obstetrics-gynecology, psychiatry, pediatrics, and preventive medicine.[33] Clinical decision making is assessed using key feature problems.[34] Examinees are asked to respond to critical aspects of diagnosis or management in 36 to 40 clinical problems using write-in or menu-selection response formats.[34] Unlike multiple-choice questions, key feature questions focus exclusively on the components of a case where physicians are required to make critical decisions where errors could have an effect on patient outcome. Grading is based on the relative quality of the response, rather than a single correct answer, and errors of both omission and commission are considered in scoring. The score is calculated as the weighted sum of the multiple-choice (weight=0.75) and clinical decision-making skills components (weight=0.25), where the weights reflect the amount of testing time devoted to each component. A criterion-based passing score is established by a modified Nedelsky method,[33,34] and scores for first-time takers are standardized to a mean (SD) of 500 (100). For the study population, the Cronbach α estimate of the reliability of the written examination varied from 0.90 to 0.92 for the multiple-choice component, and from 0.60 to 0.69 for the clinical decision-making component in different administrations.

Clinical Skills Examination. This examination tests competence in data collection (history, physical examination), patient communication, and problem solving (diagnosis and management) through a 20-case objective structured clinical examination, and can be taken after 1 year of postgraduate training.[19] Most physicians take the examination in the second postgraduate year or the first half of the third postgraduate year (93% of physicians taking the examination between 1993 and 1996). Data collection is assessed in a 5- or 10-minute interaction with a standardized patient, by trained physician observers using case-specific checklists.[19] Patient-centered communication is assessed in 3 to 4 cases, selected to represent situations where communication is required for effective management (eg, discuss refusal of treatment for a terminal illness, counsel an adolescent about birth control). Examples of patient-physician communication that would receive a low score include condescending, offensive, or judgmental behaviors, or ignoring patient responses during the encounter. Problem solving is assessed by postencounter written responses to short-answer questions on diagnosis, investigation, interpretation of test results, and management. Responses are scored by physician examiners using an answer key. The passing score for the overall examination is established using criterion-referenced methods,[19,33-35] and scores for first-time takers are standardized to a mean (SD) of 500 (100). For the study population, the Cronbach α estimate of

the reliability of the CSE scores ranged from 0.25 to 0.50 for communication, 0.59 to 0.75 for data acquisition, and 0.41 to 0.67 for problem solving in different administrations.

Covariates

Physician characteristics that may be associated with communication ability or complaint rate were measured as potential confounders and effect modifiers.[6,10] They included information on the sex of the physician, international medical graduate status, and specialty, which were retrieved from the MCC master file, postgraduate training registry, and the medical regulatory authorities. Practice province also was considered a potential confounder because differences may exist in health service delivery and the management of complaints between jurisdictions.

Statistical Analysis

Correlations between examination scores were estimated by Pearson product-moment correlation coefficients. Score reliability was assessed using a weighted Cronbach α, where weights were based on the number of candidates taking the examination in each administration. Disattenuated correlations also were calculated to determine the expected correlation if both scores were measured with perfect reliability, using the formula[36]

$$r_{xy}\ \text{Disattenuated} = \frac{r_{xy}}{\sqrt{\text{Reliability}_x \times \text{Reliability}_y}}$$

The relationship between the CSE scores and complaint rate was assessed using multivariate Poisson regression (SAS version 9.1, SAS Institute, Cary, North Carolina), adjusting for physician sex, specialty, country of training (Canada or international), and province. A 2-sided test with a *P* value of .05 was used to assess statistical significance. Number of complaints was the dependent variable, and number of years in practice was used to measure person-time for each physician. The predictive ability of each examination score was assessed in a separate model that adjusted for sex, specialty, international medical graduate status, and practice province, using continuous scores as well as score quartiles. To determine if the relationship between examination scores and complaints was modified by characteristics that may be associated with communication scores, including practice jurisdiction, physician sex, and foreign training, we assessed interactions between the examination score and these characteristics and used the likelihood ratio test to determine if the interaction terms improved the model fit.

Licensing examinations aim to assess a required level of proficiency, and thus minimum thresholds of communication ability may exist, below which the complaint rate is high and above which the rate is lower and relatively uniform. To assess whether a linear association provided an appropriate representation of the association between examination score and the complaint rate, we tested the multivariate Poisson models for nonlinearity using generalized additive models (GAM) nonparametric extension of Poisson regression.[37] The adjusted effect of examination score was estimated using smoothing splines with 4 *df* and the statistical significance of the nonlinear effect was tested by nonparametric χ^2 test. All models were estimated separately for primary and secondary outcomes.

To determine if including the CSE communication score improved the prediction of complaints beyond the traditional written examination results, we first estimated the independent relationship between scores achieved in the traditional written examination and complaint rate. The CSE communication score was then added to the model that included the traditional written examination score, and improvement in the prediction of complaints was assessed by the likelihood ratio test. The explanatory power of the CSE communication score in predicting complaints was estimated by the population attributable fraction, the proportion of all complaints that were explained by physicians in the bottom communication score quartile,[38] after adjustment for existing predictors.

Power was estimated using the approach proposed by Signorini[39] for Poisson regression. Based on a type I error of 5%, a baseline complaint rate of 3.1% in the study population, and 3424 physicians followed up for a mean 6.5 years, the study had a power of 95% to detect a relative rate difference of 12% per 2-SD decrease in score.

RESULTS

Among 6677 physicians taking the CSE between 1993 and 1996, 3424 (51.3%) were licensed to practice in Ontario and/or Quebec. At the time of the examination, 71.6% of study physicians were 25 to 30 years of age, 55.5% were men, and 12.3% were international medical graduates. Following the examination, 84% completed postgraduate training in primary care or medical subspecialties, and two-thirds entered practice in Ontario (TABLE 1). The mean score of the study population for both the clinical skills and traditional written examinations was approximately one-quarter of an SD above 500. However, the range was considerable—approximately 7 SDs for the CSE and 5 SDs for the traditional written examination. Overall, 230 physicians (6.7%) failed the CSE on the first attempt, and 52 of these physicians never passed the CSE but were licensed to practice during the transition to the new licensure requirements.

Correlations between the clinical skills and traditional written examinations overall scores and subscores varied between $r=0.10$ and $r=0.40$ (TABLE 2). The communication score had the lowest correlation with the traditional written examination scores and with other scores on the CSE. Even when corrected for unreliability, the correlation between the communication and traditional written examination scores was low (disattenuated $r=0.23$). Communication ability previously has been shown to be a domain independent from more cognitive abilities that are assessed in traditional written examinations.[40]

Overall, 1116 complaints were filed in a total of 22 585 practice-years (4.9

complaints per 100 practice-years) (TABLE 3). The mean (SD) follow-up time per physician was 6.5 (2.4) years, corresponding to the first 2 to 12 years in practice. Of the 3424 physicians, 21.5% had at least 1 complaint filed, and 17.1% had complaint(s) retained in their file after investigation. The majority (81.9%) of retained complaints were for attitude/communication and quality-of-care problems. Communication problems in management and inappropriate treatment/follow-up were the most common causes of quality-of-care complaints. Among the 696 retained complaints, none led to an immediate loss of license, 71 (10.2%) led to recommendations for additional counseling/training or discipline, and the remainder led to verbal and written warnings.

Lower CSE communication scores were associated with a higher rate of retained complaints, particularly in the lowest quartile of these scores (TABLE 4). The 853 physicians in the bottom communication score quartile had 236 retained complaints filed in their combined total of 5542 practice-years. This yielded an overall rate of 4.26 complaints per 100 practice-years compared with 2.51 per 100 practice-years for physicians in the top communication score quartile (Table 4). In multivariate models that adjusted for other physician characteristics, significantly higher complaint rates also were found for male vs female physicians, surgeons and primary care physicians vs medical subspecialists, and physicians practicing in Ontario vs those practicing in Quebec (Table 4). Even after adjustment for these characteristics, physicians in the lowest communication score quartile had an excess complaint rate of 1.75 per 100 practice-years compared with physicians in the top score quartile (adjusted relative risk [RR], 1.52; 95% CI, 1.30-1.78), and an excess complaint rate of 2.15 per 100 practice-years compared with the upper 3 quartiles (adjusted RR, 1.43; 95% CI, 1.22-1.68). The population attributable fraction indicated that 10.0% (95% CI, 6.0%-13.9%) of all retained complaints were explained by physicians in the bottom communication score quartile.

There was no evidence of significant nonlinearity ($P=.25$ for the GAM nonparametric test). According to the lin-

Table 1. Characteristics of the 3424 Physicians Taking the National Postgraduate Clinical Skills Examination Between 1993 and 1996 Who Were Licensed to Practice in Ontario and/or Quebec, Canada[a]

Physician Characteristics	No. (%)
Sex	
Female	1525 (44.5)
Male	1899 (55.5)
Age at the clinical skills examination, y	
<25	159 (4.6)
25-30	2451 (71.6)
>30	814 (23.8)
Mean (SD)	28.9 (4.7)
Undergraduate medical education	
Quebec/Ontario medical school	2655 (77.5)
Other Canadian medical school	349 (10.2)
International medical graduate	420 (12.3)
Postgraduate specialty program	
Family/general medicine	1393 (40.7)
Medical specialty	1481 (43.3)
Surgical specialty	550 (16.1)
Practice location	
Ontario	2263 (66.1)
Quebec	1009 (29.5)
Both provinces	152 (4.4)
Licensing examination performance[b]	**Mean (SD) [Range]**
Clinical skills examination	
Overall score	525.1 (79.9) [50-749]
Communication subscore	510.9 (91.1) [31-723]
Data acquisition subscore	508.8 (90.7) [19-875]
Problem-solving subscore	541.6 (98.5) [170-864]
Traditional written examination	
Overall score	526.5 (77.6) [338-787]
Multiple-choice questions subscore	524.4 (82.7) [278-793]
Clinical decision-making subscore	525.0 (75.8) [221-739]

[a] Percentages may not total 100% due to rounding.
[b] Scores standardized with a mean (SD) of 500 (100) for all first-time takers from Canadian medical schools in a given examination administration.

Table 2. Correlation Between Overall Scores and Subscores on the Medical Council of Canada Traditional Written and Clinical Skills Examinations[a]

	Traditional Written Examination[b]		
Clinical Skills Examination	Overall Score	Multiple-Choice Questions	Clinical Decision-Making Skills
Overall score	0.40	0.36	0.33
Communication	0.14	0.10	0.17
Data acquisition	0.23	0.21	0.16
Problem-solving	0.38	0.36	0.30

[a] For the traditional written examination scores, weighted Cronbach α in different examination administrations was overall score, 0.92; multiple-choice questions, 0.91; and clinical decision making, 0.64. For clinical skills examination scores, weighted Cronbach α was overall score, 0.77; communication, 0.41; data acquisition, 0.66; and problem solving, 0.54. Weights were based on the number of candidates taking the examination in each administration.[36] Disattenuated correlations (r)[30] between the scores for the traditional written examination and clinical skills examination were overall score, 0.47 and communication, 0.23; between the traditional written examination clinical decision-making score and the clinical skills examination score: overall score, 0.47 and communication, 0.43.
[b] Pearson product-moment correlation coefficients. All correlations were statistically significant ($P<.001$).

ear model, a 2-SD decrease in communication score was associated with a relative 38% increase in the complaint rate (1.17 more complaints per 100 practice-years) (Table 4). The relationship between communication scores and complaint rate was significantly stronger in Quebec (RR, 1.84; 95% CI, 1.51-2.24) compared with Ontario (RR, 1.34;

Table 3. Frequency of Complaints by Type, Status, and Number of Physicians Among 3424 Physicians Followed Up for the First 2 to 12 Years of Practice and 22 585 Combined Practice-Years in Ontario and Quebec, Canada

	Proportion of Physicians With Complaints (N = 3424)[b]				Complaint Rate by Type (N = 22 585 Practice-Years)			
					All Complaints		Retained Complaints	
	≥1 Complaint		≥1 Retained Complaint					
Type of Complaint[a]	No.	% (95% CI)	No.	% (95% CI)	No.	Rate/100 Practice-Years (95% CI)	No.	Rate/100 Practice-Years (95% CI)
Attitude/communication	422	12.3 (11.1-13.4)	307	9.0 (8.0-10.0)	548	2.4 (2.2-2.6)	367	1.6 (1.4-1.8)
Communication problem in management of care[c]	356	10.4 (9.4-11.4)	239	7.0 (6.1-7.8)	357	1.6 (1.4-1.8)	240	1.1 (1.0-1.3)
Rude, abusive conduct to patients[c]	94	2.7 (2.2-3.2)	57	1.7 (1.3-2.1)	94	0.4 (0.3-0.5)	57	0.3 (0.2-0.4)
Quality of care	289	8.4 (7.5-9.3)	161	4.7 (4.0-5.4)	385	1.7 (1.5-1.9)	203	0.9 (0.8-1.0)
Inappropriate treatment/follow-up[c]	138	4.0 (3.3-4.7)	81	2.4 (1.9-2.9)	138	0.6 (0.5-0.7)	81	0.4 (0.3-0.5)
Inadequate assessment[c]	54	1.6 (1.2-2.0)	32	0.9 (0.5-1.2)	54	0.2 (0.2-0.3)	32	0.1 (0.1-0.2)
Professionalism	72	2.1 (1.6-2.6)	42	1.2 (0.8-1.6)	79	0.4 (0.3-0.5)	45	0.2 (0.2-0.3)
Office-related	37	1.1 (0.7-1.4)	28	0.8 (0.5-1.1)	39	0.2 (0.2-0.3)	30	0.1 (0.1-0.2)
Physician health problem	5	0.2 (0.1-0.3)	4	0.1 (0-0.2)	8	0.1 (0-0.1)	6	0.03 (0.01-0.07)
Other	50	1.5 (1.1-1.9)	42	1.2 (0.8-1.6)	57	0.3 (0.2-0.4)	45	0.2 (0.2-0.3)
Total	735	21.5 (20.1-22.9)	584	17.1 (15.8-18.4)	1116	4.9 (4.6-5.8)	696	3.1 (2.9-3.3)

Abbreviation: CI, confidence interval.
[a] Examples of professionalism included conflict of interest and advertising. Examples of office-related included inadequate records and office staff problems. Examples of physician health problems included mental health and alcohol-related behavior problems. Other complaints included those that were classified in multiple categories.
[b] 118 Physicians had 2 or more retained complaints. The distribution of the 191 retained complaints against these physicians was similar to the distribution of all 696 retained complaints: communication, 86 (45%); quality of care, 68 (35.6%); professionalism, 24 (12.5%); office-related, 10 (5.2%); physician health problem, 1 (0.5%); and other, 2 (1.0%).
[c] The most prevalent subcategories of complaints within each category.

Table 4. Medical Council of Canada Clinical Skills Examination Communication Score and the Rate of Retained Complaints

	Population		Retained Complaint Rate		Relative Rate of Complaints Adjusted for Physician Characteristic[a]	
	No. of Physicians	Combined No. of Practice-Years	No.	Rate/100 Practice-Years (95% CI)	Relative Rate (95% CI)	*P* Value
Communication score, by quartile[b]						
1	853	5542	236	4.26 (3.75-4.84)	1.52 (1.30-1.78)	<.001
2	847	5444	159	2.92 (2.50-3.41)	1.13 (0.96-1.32)	.29
3	867	5672	152	2.68 (2.29-3.14)	1.06 (0.90-1.24)	.63
4	857	5929	149	2.51 (2.14-2.95)	1 [Reference]	
By continuous score (per 2-SD decline in score)					1.38 (1.18-1.61)	<.001
Physician sex						
Female	1525	10 281	211	2.05 (1.79-2.35)	1 [Reference]	
Male	1899	12 305	485	3.94 (3.60-4.31)	1.64 (1.39-1.94)	<.001
Medical school						
Canadian	3004	19 615	580	2.96 (2.73-3.21)	1 [Reference]	
International	420	2970	116	3.91 (3.26-4.70)	1.11 (0.93-1.34)	.25
Specialty						
Medical specialty	1481	8162	163	2.00 (1.72-2.33)	1 [Reference]	
Family medicine or GP	1393	11 633	394	3.39 (3.07-3.74)	1.79 (1.49-2.16)	<.001
Surgical specialty	550	2790	139	4.98 (4.22-5.88)	2.43 (1.93-3.04)	<.001
Province of practice						
Ontario	2263	15 086	553	3.67 (3.38-3.99)	1 [Reference]	
Quebec	1009	6486	107	1.65 (1.37-1.99)	0.49 (0.40-0.61)	<.001
Both provinces	152	1014	36	3.55 (2.56-4.92)	1.00 (0.71-1.40)	.99

Abbreviations: CI, confidence interval; GP, general practice.
[a] Estimated by multivariate Poisson regression, adjusting for physician sex, specialty, country of training (Canada or international), and province.
[b] Cutoffs for the quartiles were first quartile, <457; second quartile, 457-518; third quartile, 519-575; fourth quartile, >575.

95% CI, 1.25-1.49). Physician sex and international medical graduate status were not significant modifiers of the communication score effect. Sensitivity analysis incorporating all complaints (retained and not retained) showed the same significant increase in the relative rate of complaints with declining communication score (6.55 per 100 practice-years in the lowest quartile compared with 4.78, 4.46, and 4.05 in the third, second, and upper quartile, respectively); however, the risk was smaller for all complaints (RR, 1.30; 95% CI, 1.22-1.39).

Among the CSE scores, only the communication score was significantly associated with complaint rates (TABLE 5). The CSE data acquisition and problem-solving scores had no relationship to complaint rate, including quality-of-care complaints. The CSE communication score was most strongly associated with the risk of communication complaints. The traditional written examination also was significantly associated with complaint rate, with the strongest association being for the clinical decision-making (CDM) score. The association between multiple-choice scores and complaint rate was significant for overall retained complaints but not significant for communication or quality-of-care complaints. Statistically significant nonlinearity was found in the relationship between CDM scores and overall complaint rate ($P = .02$, for 3 *df* GAM test). The complaint rate increased with declining CDM scores between 600 and 450, with no systematic effect beyond this score range.

The CSE communication score, when added to a model that included traditional written examination CDM score, significantly improved the prediction of overall retained complaints and communication complaints, but not complaints about quality of care (Table 5). After adjustment for the traditional written examination CDM score, an additional 9.2% (95% CI, 4.7%-13.1%) of retained complaints and 11.2% (95% CI, 5.8%-16.9%) of communication complaints were explained by physicians in the bottom communication score quartile.

COMMENT

In a longitudinal study of physicians who took the MCC clinical skills examination and entered practice in Ontario and/or Quebec, scores obtained in patient-physician communication were statistically significant predictors of future complaints to medical regulatory authorities. The credibility of the association was strengthened by evidence of a linear relationship between complaint rates and communication scores, a slightly stronger association when the outcome was limited to communication complaints, consistency of the direction and statistical significance of the association in Ontario and Quebec, and the persistence of the association after adjustment for physician sex, specialty, international medical graduation status, and time in practice.

We observed a complaint rate of 0.0491 per physician. This rate is within the range of US state medical boards, where the mean complaint rate for all licensed physicians (including those with no complaints) varied from 0.02 per physician in Wisconsin to 0.20 per physician in Alabama between 2001 and 2003.[41] Similar to others, we found that communication problems were the most common reason for complaints[42]: 49.1% of complaints in our study compared with 55% of com-

Table 5. Scores on the Medical Council of Canada Qualifying Examinations and the Rate of Retained Complaints: Overall and by Type of Complaint

	Relative Rate of Retained Complaints by Examination Score After Adjustment for Physician Characteristics[a]					
	Any Retained Complaint		Communication Complaint		Quality-of-Care Complaint	
Examination Scores	Relative Rate (95% CI)	*P* Value	Relative Rate (95% CI)	*P* Value	Relative Rate (95% CI)	*P* Value
Clinical skills examination						
Overall score	1.19 (1.00-1.42)	.05	1.28 (1.00-1.64)	.05	1.06 (0.76-1.48)	.74
Communication score	1.38 (1.18-1.62)	<.001	1.43 (1.15-1.77)	.001	1.38 (1.03-1.86)	.03
Data acquisition score	0.98 (0.83-1.16)	.85	0.97 (0.78-1.22)	.82	1.00 (0.74-1.35)	.92
Problem-solving score	1.02 (0.88-1.19)	.76	1.13 (0.92-1.41)	.25	1.01 (0.76-1.33)	.97
Traditional written examination						
Overall score	1.39 (1.14-1.70)	.001	1.34 (1.01-1.76)	.04	1.54 (1.06-2.22)	.02
Multiple-choice score	1.25 (1.03-1.50)	.02	1.22 (0.94-1.57)	.14	1.29 (0.92-1.80)	.14
Clinical decision-making score	1.51 (1.25-1.84)	<.001	1.47 (1.13-1.92)	.004	1.77 (1.25-2.56)	.002
Clinical skills examination communication score, adjusted for clinical decision-making score[b]	1.32 (1.13-1.71)	<.001	1.37 (1.10-1.71)	.005	1.30 (0.97-1.75)	.09

Abbreviation: CI, confidence interval.

[a] Estimated by multivariate Poisson regression, adjusting for physician sex, specialty, country of training (Canada, international), and province, using the examination score as a continuous variable. Results presented as the change in relative rate per 2-SD decrease in score. A separate model was used to estimate the association of each score with retained complaints, adjusting for all of the same physician characteristics.

[b] Estimated by multivariate Poisson regression. Model includes communication score, clinical decision-making subscore of traditional written examination, physician sex, specialty, country of training (Canada, international), and province. Improvement in the fit of the model with clinical decision-making score alone and communication plus clinical decision-making score was assessed by likelihood ratio test.

plaints to 1 US state medical board between 1989 and 2000[43] and 74.7% in an investigation of hospital complaints between 2001 and 2003.[6]

Our results provide some feedback for medical educators and licensing authorities. Our study supports the predictive validity of providing a standardized assessment of communication skills prior to entry into practice. Almost 1 in every 5 physicians had a retained complaint filed with the provincial medical regulatory authorities in the first 2 to 12 years of practice. The risk of complaints was significantly greater among physicians in the lowest quartile of communication scores. This result suggests that direct observation and assessment of patient communication skills may be useful in identifying trainees who are more likely to experience difficulties in practice. Assessment of communication could play a role at different stages in training—to select candidates for medical school admission[44] or to identify trainees who may benefit from more intensive communication skill training, as these skills can be improved with training.[45]

In addition, our results suggest that a minimum passing standard should be established for communication on the CSE, as has been done in the US Step 2 Clinical Skills Examination.[21] To do so, the number of cases in which communication is assessed would need to be increased from the 3 to 4 cases to approximately 10 to 14 to obtain a sufficiently reliable score to make pass-fail decisions.[46] The MCC has already increased the number of cases in which communication is assessed to meet this reliability threshold.

Complaints were mainly associated with 2 subscores—clinical decision making and communication. Clinical decision-making assessment was specifically designed to select problems and test aspects of the decision-making process where physicians were more likely to make errors that would have an effect on patient outcome.[34] This approach to the selection of test material may explain why this component of the examination was predictive of complaints, while the data collection and problem-solving components of the CSE were not. The key features approach to clinical decision-making assessment was first instituted by the MCC in 1992, and to our knowledge this is the first evaluation of its ability to predict future practice outcomes.[47] It may be useful to increase the use of key feature problems in traditional written assessment, as this format appears to be more predictive of quality-of-care complaints than ordinary multiple-choice questions. Selecting case and test elements for the national CSE on the same basis as key feature written problems also may be beneficial. The discriminating ability of data acquisition and problem-solving assessment on the CSE may be improved by selecting aspects of data collection that are critical for a given clinical problem, and where physicians tend to make errors.

Our study had several limitations. The poor-to-moderate reliability of the communication score component of the examination likely led to an underestimation of the strength of the relationship between communication and complaints.[48] The use of practice-years as a denominator for estimating the rate of complaints would not take into account differences between physicians in the frequency of patient contact, the type of patients, and the procedures performed, all of which may be associated with the risk of complaints. However, it seems unlikely that physicians with lower scores in communication would systematically seek out work activities and patient populations that are more likely to generate complaints.[13] On the other hand, higher rates of complaints that we found for surgeons, family physicians, and male physicians, even after adjustment for lower scores in communication, may be related to higher practice volume or differences in work activities or practice populations. As higher complaint and malpractice claim rates also have been found for these physician subgroups in other studies,[1,10] a better understanding of the contributing factors would be important. Finally, we did not have information on language of greatest proficiency for the physician or language in which the test was taken, and could not include these factors in the analyses.

In summary, we found that communication and clinical decision-making ability were important predictors of future complaints to regulatory authorities. Current examinations could be modified to test these attributes more efficiently and at earlier points in the training process. Future research should examine whether remediation of communication problems can reduce complaints, and whether other indicators of the quality of practice could be assessed by a clinical skills examination.

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High-stakes OSCE International Workshop 高標準 OSCE 國際工作坊*(I)*

時間:99 年 1 月 7 日(星期五)~8 日(星期六) 8:30-17:00

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時間:99 年 1 月 7 日(星期五)~8 日(星期六) 8:30-17:00

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時間:99 年 1 月 7 日(星期五)~8 日(星期六) 8:30-17:00

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High-stakes OSCE International Workshop 高標準 OSCE 國際工作坊*(I)*

時間:99 年 1 月 7 日(星期五)~8 日(星期六) 8:30-17:00

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