Using Standardized Patients in Research

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Agenda

- Introduction (Rich Kravitz)
- Pulling It Off (I): Role development, IRB issues and physician recruitment. (Ron Epstein)
- Pulling It Off (II): Hiring, training, and monitoring SPs. (Arthur Brown)
- Pulling It Off (III): A project manager’s perspective. (Carol Franz)
- Questions and Discussion
Why Use SPs in Research?

- Experimental control in naturalistic settings
- Assess physician performance
- Examine stimulus-response relationships
Kinds of Questions SP Studies Can and Cannot Answer

- **Can address**
  - Physician history taking
  - Physician physical examination skills
  - Physician prescribing, consultation, and follow-up
  - Physician communication skills

- **Cannot address**
  - Patient outcomes
  - Patient responses to physician behaviors
  - Physician diagnostic reasoning
A Tale of One Study

- Social Influences on Practice Study ("SIP")
- Collaborative effort
  - UC Davis
  - University of Rochester
  - UC San Francisco
- Main results published in JAMA April 27, 2005
- Lessons learned may help others
Design

- Randomized trial using unannounced SPs
- 152 physicians from 4 physician collectives in 3 cities
  - Sacramento, CA
  - San Francisco, CA
  - Rochester, NY
SP Roles

- **“Louise Parker”**
  - 48 yo divorced Caucasian woman
  - Depressed mood for a month, worse past 2 weeks
  - Low energy, early awakening, no suicidality

- **“Susan Fairly”**
  - 45 yo divorced Caucasian woman
  - Insomnia and low energy
  - No sleep/appetite disturbances and no significant interference with functioning
## Distribution of SP Visits

<table>
<thead>
<tr>
<th></th>
<th>“I saw this ad for Paxil...Do you think it might help?”</th>
<th>“I was watching this program on depression...do you think medication would help me?”</th>
<th>No Request/ Symptoms Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major depression</td>
<td>n=51</td>
<td>n=50</td>
<td>n=48</td>
</tr>
<tr>
<td>Adjustment disorder</td>
<td>n=49</td>
<td>n=49</td>
<td>n=51</td>
</tr>
</tbody>
</table>
## Results: Impact on Prescribing

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Brand specific request (n=51)</th>
<th>General request (n=50)</th>
<th>No request (n=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major depression</td>
<td>53%</td>
<td>76%</td>
<td>31%</td>
</tr>
<tr>
<td>Adjustment disorder</td>
<td>55%</td>
<td>39%</td>
<td>10%</td>
</tr>
</tbody>
</table>

Comparisons within severity level significant $p<.001$
Minimally Acceptable Initial Care for Major Depression

- Antidepressant prescription
- Referral to a mental health provider
- Primary care follow-up within 2 weeks
Percent Receiving Minimally Acceptable Initial Care

P < .001
Results Summary

- Standardized Patients’ requests increased antidepressant prescribing
- Increased prescribing observed in both major depression and adjustment disorder
- General requests *at least as effective* as DTC-driven, brand-specific requests and possibly “safer”
Making unannounced SP research work: role development, IRB issues and physician recruitment

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Rochester Center to Improve Communication in Health Care
Some problems assessing clinical practice

- Physician reports, chart audits and use of vignettes all introduce biases into assessment of clinical practice.
- These biases are more important if the target behavior is emotionally charged or socially desirable.
- Recording real patient encounters requires multiple recordings to sample target behaviors.
- Surveys completed by real patients are biased because patients tend to select and adapt to physician styles and leave physicians they do not like.
Definitions

- Simulated patient = person with or without a disease trained to play a patient role for clinical training
- Standardized patient = … trained to portray role in nearly identical fashion on repeated occasions for assessment purposes
- Unannounced standardized patient = … trained to present in actual clinical settings so that experienced clinicians will not be able to distinguish between SP and a real patient
- Standardized patient-instructor = …SP trained to give educational feedback
History of SPs

- 1960’s: Barrows, van der Vleuten, Swanson
- 1970’s: Short SP skills stations
- 1980’s: Long-station OSCEs, behavioral counseling, patient-instructors
- 1990’s: Unannounced SP research, SP-trainers, validation, post-encounter exercises, Canadian Boards, Macy project
- 2000’s: Web-based SP encounters, NBME
Prior uses of SPs

- Objective Structured Clinical Examination (OSCE)
- Training (classroom, skills lab or real patient care settings)
- Assessment of clinical practice
Using SPs in Teaching

- Basic interviewing skills
- Integrating pathophysiologic knowledge with interactional skills
- Difficult situations (i.e., giving news of an unexpected death, conflict, malingering)
- Situations where students are usually in observer role (informed consent, health care proxy)
- Most physical examination skills -- including genital, breast, prostate
- Behavioral counseling (smoking, weight loss)
Reliability and Validity of SPs

- With training, excellent reliability of role portrayal
- Excellent face validity
- Good correlation with direct observation with real patients
- Tests different attributes than surveys of patients or physicians
- Few studies demonstrate predictive validity
- Content-specificity limits generalizability
Unannounced SP Visits

- Used successfully for assessment of:
  - utilization
  - communication
  - adherence to practice guidelines
  - preventive screening
  - management of chronic disease
  - detection of depression
  - education about domestic violence

- Excellent sound quality with concealed audio recordings
Unannounced SP Visits

- Adaptable to multiple settings -- inpatient, outpatient, ED, home, family
  - Does not require special facilities or on-site ancillary staff
- Strong face validity
  - Assesses performance in real settings
  - Realistic clinical scenarios can be created
  - Can simulate a wide variety of physical findings
  - Low-frequency events (e.g. specific patient requests) can be simulated
Unannounced SP visits

- Excellent data quality
  - Clinical behavior can be observed directly and recorded
  - Excellent sound quality with concealed audio recordings
  - Can assess integration and use of knowledge, physical examination, counseling, decision-making and actions
  - Can compare recorded encounter with medical chart and administrative data
Unannounced SP Visits

- Convenient and available
  - Does not require patient consent
  - Most medical schools have SP programs
- Possibility of immediate or delayed feedback for educational purposes to participants
Using SPs to Assess Clinical Practice

- Minimal study effect = physician performance is similar to real life
- Can tailor cases to study objectives
  - Can adjust the difficulty and number of tasks
- Clinician acceptance is high
Unannounced SP visits: problems

- Does not directly evaluate factual knowledge or clinical judgement
- Case-specificity – performance in one context may not predict performance in another context
- Expense
  - SPs must be paid for waiting time
- Marginal reduction in physician clinical income or performance statistics
Unannounced SP visits: problems

- First visit effect
  - Difficult to simulate continuity or follow-up
- Cannot simulate some physical findings (masses, murmurs, fasiculations)
- Requires cooperation from clinic staff
- Care must be taken not to compromise care of real patients by mistaking identity or delaying care
Developing an SP role

- Start with study objectives
  - Make the purpose of the evaluation consistent with the goals of the study without including extraneous information
Developing an SP role

- Make the case realistic
  - Base cases on real patients, then change data to protect confidentiality – easier to write and lends face validity
  - Don’t make clinical presentations too classic, but make them typical enough so that practice guidelines can apply
Developing an SP role

- **Attention to affect**
  - Include detailed descriptions of affect at baseline and in response to a variety of physician actions (e.g. initially passive, but then anxious when physician proposes a diagnostic test)

- **Responsiveness**
  - Account for numerous physician actions and specify SP responses (e.g., when to ask questions, how much to wince during exam, when to remain silent, etc.)
Developing an SP Role

- Create plausible demographic data
  - Local address, phone, prior physician
  - Insurance ID cards

- Develop monitoring criteria
  - Comprehensive checklist of expected SP behaviors (SP monitoring form)
  - Develop study-specific rating scales of expressed affect (e.g. depression), pain, insistence (if patient requesting something), passivity, etc.
Developing an SP role

- Create detailed disclosure guidelines
  - What should the SP volunteer spontaneously, volunteer with prompting (and how much) and not volunteer at all.

- Plan for the unexpected
  - What to do if physician proposes genital/rectal exam, blood tests in the office, etc.
  - What to do if the physician is called away for an emergency
  - What to do if staff suspect/know you are an SP
Defining and assessing “detection” and “suspicion”

- Passive (let them tell us) or active (send a survey) inquiry
- Timing and medium (e-mail, fax) of detection survey
  - 2 days to 2 months
  - Longer interval → lower apparent “suspicion” or “detection” rate
Defining and assessing “detection” and “suspicion”

- Wording
  - “At any time before the end of the visit did you suspect that the patient was an SP?”
  - When did you suspect?
  - What made you suspect? (staff told me, something about the role portrayal, saw the microphone, etc.)
  - Overall, how realistic was the portrayal (1 – 10)?
  - Did you feel that you acted differently knowing the patient was an SP? How?
Piloting

- For study investigators
- For multidisciplinary advisory board
- In non-participating practices
Creating SP Checklists

- Unambiguous yes/no items for information gathering, physical exam, pt education and counseling
  - SPs can assess both simple and complex tasks
  - focus on interview tasks rather than skills
- Likert scale items for subjective ratings of communication, trust, satisfaction
  - Scales developed for real patients requiring no training
  - Scales developed for SPs that require training and reliability
- Be aware of limitations in SPs ability to rate physician behavior
  - Generally, SPs do not assess clinical reasoning.
Ethics, IRB and Deception

- What to tell potential participating physicians
  - “… a study of the influence of sociodemographic factors on health care…”
  - “… a study of patient influences on quality of care…”
  - “… a study of patient-centered communication and outcomes of health care…”

- BUT….When and how to tell the whole truth?
  - Post-data-collection letter
  - Secondary consent
IRB issues

- Potential harms
  - Confusing a real patient for an SP
  - Harming the SP (never)
  - Psychological harm due to acting in ways that are later regretted (Milgram experiment)
    - Ameliorate through debriefing, normalizing responses and offering further discussion
Recruiting physicians

- Build trust and relationship
  - Engage physician or non-physician recruiters who are respected and trusted
  - Be up front when you cannot disclose study hypotheses
  - Be clear when participants will learn study hypotheses
  - Think about what will make participants want to participate in the next SP study
Recruiting physicians

- Person-to-person recruiting is best
  - Initial contact via e-mail requesting response or fax with follow up within a few days by phone
  - Physicians vary in use of e-mail
  - Letters will have very low response rate

- Pay physicians for their time
  - Lost visit income
  - Time completing surveys

- Pay the staff for their time
  - $75 for the xmas party fund will win lots of friends
Physician recruitment

- Partner with community organizations
  - Insurers willing to share physician lists
  - Insurers willing to issue false ID cards
- Be responsive
  - Anticipate and take seriously potential participants’ questions
  - Minimize participants’ time and effort
  - Thanks go a long way
Keeping physicians involved

- Provide brief periodic updates on the study
- Be responsive to concerns
- Gentle persistence getting physicians to return forms (surveys, detection questionnaires, requests for payment)
- Provide physicians with copies of published papers
- Give local presentations
- Don’t make physicians look stupid or feel tricked (all too easy to do!)
Other issues

- Releasing audio-recordings or personal survey results to physicians
- Timing of revealing the SP’s identity (if ever)
Training SPs

- Take the time to train SP’s well
- Be clear about how you want the SP to portray the clinical situation
  - Think about how the SP presents him/herself as a person as well as the disease that the SP portrays
- The SP trainer will use the checklist for initial training to the role -- usually there are questions.
- The case author should
  - do the final training of the SP -- about 30-60 minutes
  - observe the SP in action -- live or on video
- SPs can be trained to give feedback
Pulling Off an Unannounced Standardized Patient Study: A Project Manager’s Perspective

Goal: Seamless integration of standardized patient into a medical practice with as little impact on the MD or office staff as possible.

I. Organization
   A. Pre-visit
      1. Learn as much as possible about organizational practices (affects study design, enrollment, randomization, SP visits)
      2. Contact and coordinate with:
         - Health systems, insurance plans (enroll SPs as patients in health plans/insurance plans)
         - MDs (enroll, consent)
         - Practice managers (practice specific procedures)
         - SP trainers
      3. Determine whether visits will be audiotaped
         Pro: monitor SP performance; additional data
         Con: extra training; more costly

   B. During data collection period
      1. Scheduling and organizing visits
      2. Smoothing out visits (insurance “fraud”; problem-solving)

   C. Post-visit
      1. Canceling scheduled follow-up appointments/ specialists
      2. Paying/canceling office visit bills
      3. Cancel insurance
      4. Monitor SP performance and provide feedback
      5. Debrief physicians and office staff
      6. Data management
II. Preventing detection of standardized patients

A. SP realism: Helping the SP look like a real patient
   1. Insurance or health plan cards/ co-pays
   2. Keep SP anxiety reduced (minimize unexpected)
      a. Training
         1) Pre-training (already covered)
         2) On-going training/refresher sessions
            a) provide regular feedback
            b) regular meetings to keep informed
         3) Training for logistics:
            a) talking with front desk staff
            b) learning to problem solve (when to go to
               practice manager; staying calm and in role
               when things go wrong)
            c) staying in role in calls, and from car to
               office and back
            d) educating SPs about typical office visit
               behavior and expectations.
      b. Organization
         1) simplify demands on actors
         2) no surprises just before visit
      c. Familiarity with locations
      d. Cancel visits if SP ill or unduly stressed in own life

3. Actors physically consistent with region/role
   a. Self presentation: social class, dress, conversation etc
   b. Personal identifying information (in order to check-in)
      1) social security numbers
      2) contact information
         ▪ cell phone
         ▪ post-office box
         ▪ fake local address
B. Manage physician awareness (or lack thereof)
   1) Delay between enrollment and first visit
   2) Delay between SP visits (not too many unusual patients)
   3) Smooth office visits (no red flags from staff on day of visit)
   4) Well trained, flexible actors

C. Develop good relationships with practice managers

D. Assess detection (Detection fax)
   After visit assessment of whether MD suspected or detected the visit
   (Handout of detection fax)
   1) Provides detection rate for data analysis
   2) Provides valuable feedback for ongoing SP training

III. Maintaining consistency: Need to ensure there is no drift in role
     over time or between actors
   A. Regular meetings between trainers/PIs/and office staff
      (dynamic relationship between scientific goals of study and limits
      of SP performance)
   B. Ongoing training and refresher training
   C. Review of audiotapes and reporting forms
   D. Develop measures and procedures (a priori) for monitoring performance