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Using a Standardized Patient Walkthrough to Improve Implementation of Clinical Trials

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Abstract

This report describes a standardized patient (SP) walkthrough to facilitate implementation of a clinical trial within the National Drug Abuse Treatment Clinical Trials Network (CTN). SPs are actors trained to portray a set of symptoms consistently across interactions with multiple clinicians. The Oregon/Hawaii node of the CTN employed one SP to pilot participant screening processes in a study of the combined effects of buprenorphine-naloxone (Suboxone®) and standard medical management for people dependent on prescription opioid analgesics. The SP mimicked an individual seeking treatment and “walked” through study intake processes. Findings such as study staffs’ inadequacy in describing issues of patient confidentiality and problems explaining the Health Insurance Portability and Accountability Act led to modifications to the clinical implementation of the study. Research coordinators and staff found use of an SP to be highly effective. The Node is now making routine use of SPs in the implementation of CTN protocols.

1. Introduction

Standardize patients also known as “simulated” patients (Barrows, 1987) are actors trained to portray a set of symptoms consistently across clinical interactions (Colliver & Swartz, 1997; Swartz & Colliver, 1996). Most typically, standardized patients are used for clinician (physician, nurse, dentist, etc.) training. Standardized patients adopt specific client roles and simulate patient behaviors, allowing for multiple clinicians to observe and treat particular patient symptoms at critical learning points. Educators can observe and evaluate clinician skills.

At least 80 percent of medical schools in the United States utilize standardized patients for training and evaluation purposes (Brownell, Stillman & Wang, 1994; Rosenberg, 1997). Standardized patients assist in evaluating and teaching dentists (Hazelkorn & Robins, 1996), nurses (Marchiondo & Kipp, 1987), physician assistants, pharmacists, and others (Madden, Quick, Ross-Degnan, & Kafle, 1997). In 1993 Canada implemented standardized patients in the Canadian National Medical Licensing Examination (Colliver & Swartz, 1997). Beginning

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in 2004, the National Board of Medical Examiners required a standardized patient exam as part of the United States Medical Licensing Examination for physicians in the United States. Medical students rated standardized patients as more helpful than real patients or videotapes (Dillon, Boulet, Hawkins, & Swanson, 2004; Eagles, Calder, Nicoll, & Walker, 2001).

A small but growing literature exists on the use of standardized patients to portray people with alcohol and drug disorders (see Christison & Haviland, 2003; Eagles et al., 2001; Matthews, et al., 2002; Roche, Stubbs, Sanson-Fisher, & Saunders, 1997; Wagner, Lentz & Heslop, 2002; Walsh, Sanson-Fisher, Low, & Roche, 1999; Walsh, Roche, Sanson-Fisher, & Saunders, 2001). Standardized patients portrayed alcohol as well as marijuana abusing individuals in order to evaluate interviewing skills of substance abuse clinicians (Baer et al., 2004; Rosengren, Baer, Hartzler, Dunn, & Wells, 2005). Murphy, Scott and Mandel (1995) used standardized patients to assess nursing students' ability to obtain substance abuse histories. However, there has been limited work using standardized patients with substance abuse treatment practitioners. Recent work suggests that actors can be trained to portray convincingly people with substance abuse problems for counselors (Fussell, Lewy, & McFarland, 2009).

Standardized patients have advantages over "real" patients for training. Because standardized patients portray the same set of symptoms across clinical interactions, clinicians and treatment processes can be compared on consistent dimensions of interest (e.g., clinician affect, flow of intake processes, diagnostic capabilities). If asked to portray the same symptoms repeatedly, real patients, quite understandably may struggle with consistency, thereby decreasing reliability of comparisons between multiple treatment environments or clinicians.

Additionally, real patients' emotional connections to their own problems may interfere with their abilities to remain "detached" enough from the treatment environment to observe their surroundings critically. A key component to fielding clinical problems involves exposure to the delivery of negative news or difficult conversations. For example, in order to test the efficacy of intake processes in substance abuse treatment it may be important to test turning a client away in order to identify problems with exit strategies. Delivering such news (even if it is as part of a mock intake) with real patients risks introducing risk for relapse and upsetting or exacerbating their problems. Finally, and particularly important for roles involving substance abuse and/or mental health conditions, using standardized patients alleviates problems with client confidentiality.

This report describes a standardized patient walkthrough to facilitate implementation of a clinical trial within the National Drug Abuse Treatment Clinical Trials Network. The Clinical Trials Network is a national organization conducting randomized studies of substance abuse services within community-based treatment organizations. A standardized patient was used to prepare study staff to work with real study participants in the Prescription Opiate Addiction Treatment Study (POATS). The protocol tests the efficacy of adding individual drug counseling to the prescription of Suboxone® (buprenorphine/naloxone), along with standard medical management to improve treatment outcome for people dependent on prescription opioid analgesics.

2. Methods

The goal of the standardized patient walkthrough was to identify potential problems with protocol participant screening and intake prior to "going live" with real participants. The walkthrough process included an actor, equipped with appropriate symptomatology, participating in the protocol screening and intake steps while "in role." A member of the research administration team was present to observe and take field notes documenting the walkthrough. The standardized patient was instructed to stay in role throughout the screening process. Importantly, the member of the research administration team did not interact with the

standardized patient other than for debriefing. After each section of the screening visit was complete, the standardized patient would come “out of character” and debrief with the research team. The walkthrough took place in a substance abuse treatment agency located in a relatively rural, blue collar timber community three hours south of Portland, Oregon.

2.2 The Standardized Patient Role

The standardized patient was given background information and was trained to portray the specific conditions of the individuals who would be involved in the protocols in order to understand the complexities that the participant may be experiencing. Training of the standardized patient and authenticity of the standardized patient's portrayal are described elsewhere (Fussell, Lewy, & McFarland, 2009).

“Ted Franks” was a 30 year old unemployed construction worker. Two years previous to the date of the walk-through he injured his back in a construction accident, when a heavy beam landed on him. He underwent surgery to correct a herniated disk. He was prescribed Vicodin and Percocet for pain but the doctor “cut him off.” At the time of the walkthrough, Ted reports using eight to nine 20 mg doses of OxyContin a day without a prescription. The standardized patient script included physical dependence on opioids (using at least 20 days per month) the need for medical assistance for opioid withdrawal, a desire for detoxification, and good general and psychiatric health.

3. Results

The standardized patient called the treatment program to complete a phone screening procedure. An appointment was scheduled for all intake/screening processes that would take place for “real” participants. See Table 1 for examples of walk-through screening content.

The standardized patient met with the research assistants to complete the procedures that were required during the screening visit. These procedures included consenting for the protocol, determining eligibility by completing the inclusion/exclusion criteria forms, completing locator forms and baseline data assessments. The assessments included both research assistant administered interviews and self-administered surveys. The standardized patient then met with the medical staff for the clinical assessment and walked through the lab procedures. Additionally, the standardized patient met with the protocol counselors to complete the intervention. Only the screening visits were piloted.

3.1. Narrative Account of the Walkthrough

“Ted Franks” was waiting in the reception area. Ted looked disheveled (his hair was unruly; he looked as if he had not showered; and he had not shaved in a few days). He was wearing a flannel shirt, work boots and jeans that appeared to be dirty. Ted appeared to be uncomfortable in the chair and was moving around and ‘grunting’ a bit. The site coordinator came out to the reception area asking Ted if he was ready to begin. Ted stood gingerly and followed the site coordinator into an office. The research assistant introduced herself and Ted sat in a chair on the other side of her desk. Ted seemed uncomfortable, was breathing heavily and appeared to be in pain, symptoms consistent with his back injury and opioid dependence. The site coordinator stayed in the room and sat at a chair next to the desk. The research assistant told Ted that they would need to review the pre-screening form. It was not clear what the research assistant was doing, so Ted responded in a somewhat confused fashion.

After completing the form, the standardized patient came out of character and told the research assistant that she needed to be more conversational with the questions. It appeared too much

like she was reading. He suggested that she refer back to things that he has already said, thus making him feel like she was paying attention to his responses.

3.1.1. Informed consent—The research assistant said that they needed to review the informed consent form. "Ted" read the consent silently. He and the research assistant went through each section of the form and completed the informed consent form quiz together. Ted appeared to have difficulty understanding the study flow. He asked for clarification of the word "opioid" and the purpose of the audio-recording. He was concerned about "mandatory reporting," and asked for clarification of the medication description. Ted asked many questions about the Health Insurance Portability and Accountability Act (HIPAA). The research assistant and research coordinator attempted to answer Ted's questions. It was clear, however, that more training was necessary so that the research staff were comfortable with each facet of the informed consent form.

When the standardized patient came out of character for the debriefing, he suggested that that study staff develop a flow chart for participants so they could better understand the study flow. He made seven additional suggestions to improve the consent process: 1) too much repetition in the consent form; 2) provide a bulleted abstract of the consent in which each key point is associated with a page number within the actual consent so that the patient can obtain the key point and then access it in the larger document; 3) provide an overview of the consent; 4) attempt to build rapport before the consent process begins; 5) talk more about the cards that the participants are asked to carry with them in case of emergency (wallet cards); 6) explain in layman's terms the definition and benefits of a wallet card; 7) summarize long sections of the consent form rather than reading the entire section (patients have the opportunity to read each word).

3.1.2. Assessment—Once the informed consent debriefing concluded, "Ted" resumed his uncomfortable posture and acted restless. Frequent scratching and moaning reflected his uncomfortable physical state and he adjusted his posture to release the pain from his back. At times Ted stood to relieve the pain in his back. The research assistant began the assessment process. She gave Ted papers to review and complete while she asked questions. These forms took about two hours to complete – longer than projected.

The standardized patient came out of role for debriefing. The assessment debriefing session led to additional suggestions for protocol modifications and enhancements. It was obvious that the patient needed a clipboard to write on. The standardized patient felt that the room was very sterile and not comfortable; it looked like a doctor's office and should be more personalized. He expressed concern that people outside of the room could hear his responses and suggested soft background music so that people outside the room would not hear the entire conversation. He suggested that the research assistant sit next to participants while they complete forms. This change would create a more personable environment and reduce the "hierarchical" feel that came from the research assistant sitting behind the desk. In addition, because some of the forms were read and answered silently by the participants whereas others were completed verbally, the standardized patient suggested that all the forms could be read and answered aloud. This approach would provide more of a 'team' effort and would help maintain overall rapport and involvement. He requested a list of screening activities so study participants could 'check off' items as they are completed and track how many more activities remain. The introduction to the Addiction Severity Index should note that some questions are repetitive and may be frustrating. The research assistant should keep notes and be able to remind participants of their earlier responses. The standardized patient expressed surprise at the personal nature of the Risk Behavior Scale. He suggested that the research assistant introduce the survey by saying that the questions are very personal and responses will be kept confidential. Finally, he observed

that the research assistant and research coordinator had repetitive responses, such as “uh huh” and seemed like they were acting as robots and not invested in the process.

3.1.3. Physician interview—The research assistant led “Ted” to the office where he would meet with the physician. Ted spent about 30 minutes with the physician behind closed doors. Ted talked about his back injury, the surgery and his use of prescription pills, both prescribed and not prescribed. Batteries fell out of the tape recorder and the physician expressed frustration and did not record the session as required. The physician failed to complete the case report forms. The site coordinator indicated that she needed to train the physicians on how to complete the forms.

After the session, the standardized patient came out of role and indicated that he did not like being left in the room alone (maybe the research assistant could stay with him). There was nothing to do while he waited. He inquired about whether the study could make reading material available to participants. The standardized patient also indicated that the physician was very personable and seemed informed about the study.

3.1.4. Counselor interview—The extended medical management counselor entered the room, introduced himself and led “Ted” into his office and shut the door. After about 45 minutes Ted and the counselor came out of the room.

The debriefing comments observed that it was uncomfortable to sit silently while the counselor reviewed Ted's paperwork. The protocol should build in time for the counselor to review a participant's paperwork prior to seeing the participant. The counselor should be prepared for the study participants to request suggestions for obtaining non-study related comfort medications (such as sleeping aids) and/or other medications. The counselor needs to be reminded to turn the tape recorder on (and needs training on how to use the recorders). The counselor should emphasize that the homework assignments are not just “busy work” and explain their value. Overall, the extended medical management counselor established rapport quickly.

Table 2 summarizes results of the walkthrough procedures. Note that not every item noted during debriefing resulted in changes to participant screening processes. Decisions on which items to modify were based on combined perspectives of study staff and the standardized patient.

4. Discussion

Standardized patient methods were applied to a walkthrough of participant screening and intake procedures in a clinical trial. Debriefing with the standardized patient and study team identified five categories of implementation issues: 1) scheduling / organizing, 2) consent, 3) case report forms, 4) protocol flow, and 5) participant comfort.

The standardized patient noted complexities in scheduling. Accommodating a participant's schedule includes coordinating numerous research and medical staff schedules. To assist in alleviating problems associated with coordinating multiple schedules, the standardized patient suggested early morning and late evening appointments.

The consent form was pilot tested to see whether it “made sense” to a participant. Due to the length and complexity of the consent form, the standardized patient recommended that a summary sheet be developed to highlight the important aspects of the study and to clarify expectations. The standardized patient expressed substantial concerns over the staff's ability to address participant concerns and / or respond adequately to questions about confidentiality,

the Health Insurance Portability and Accountability Act (HIPAA), and mandatory reporting. Importantly, as an SP he was able both to detect the need for additional research assistant training in this area and to report on his level of discomfort as a participant. This recommendation resulted in increased training for staff on these critical issues directly relevant to participant comfort and safety.

Research staff members were able to practice data collection in “real time.” Completing case report forms with a participant took much longer than expected. Process reorganization including the order of activities was recommended in order to address this lengthy task. Practicing data collection also highlighted the need to build in additional time for appointment scheduling in order to combat fatigue and avoid jeopardizing the participant’s physical and mental health.

The standardized patient found the organization of study activities awkward. For example, the location of activities was not always clear (i.e., where to go when and how to get there). The standardized patient noted that individuals experiencing drug withdrawal may have limited ability to access various study locations and may have trouble following directions. Materials for a given step in the intake process were sometimes incomplete and the staff lacked group coordination in some instances, which could elicit frustration from a participant. To address these problems, the standardized patient recommended confirming that all documents were easily accessible and had clear explanations and directions. Furthermore, a calendar of study events would ease the process of date recall for the patients. Without the calendar it was difficult to track timing of specific study events. Additional standardized patient recommended changes to the study process included moving the computer so that it was not located between the staff and the participant during questioning, and asking the participant to complete the locator form (which includes contact and other information so that the research assistant can reach the participant) at the beginning of the session when the concept of confidentiality is discussed. For individuals possibly undergoing withdrawal, these issues (in particular identifying directions to and location of activities and discussing personal activities that may be illegal) can become uncomfortable and frustrating thereby increasing their adverse physical and mental reactions to the environment and experience.

Finally, the standardized patient also emphasized the importance of providing rooms that would be perceived as comfortable and welcoming. The standardized patient noted that the research setting was uncomfortable. In particular, bright lighting can prove problematic for individuals in withdrawal or who may have attention difficulties. Standardized patient suggestions included reducing the lighting, which would also make the room less “sterile,” providing comfortable chairs, and providing “lap desks” or trays so the participants can complete paperwork more comfortably. The latter is essential when dealing with a population prone to chronic pain.

Although some issues in the screening process identified by the standardized patient may appear small (e.g., more flexible scheduling options), the implications for real patient retention are notable and move beyond the clinical trials. The standardized patient’s detections of possible patient concerns with the consent form, confidentiality, the Health Insurance Portability and Accountability Act (HIPAA), and mandatory reporting are clear examples of the importance walkthroughs hold for clinical trial protocols. Study staff must be prepared to answer these questions confidently and clearly.

Walkthroughs are widely applied in initiatives such as the Network for the Improvement of Addictions Treatment (NIATx) (Ford et al., 2007) to address process improvement needs in substance abuse treatment admissions walkthrough results. Typically, treatment program personnel conduct these walkthroughs to identify and improve problem areas such as wait-

times or retention. Whether using a standardized patient or treatment program personnel, the attraction of walkthroughs is similar – namely, the ability to understand research or treatment program practices from the perspective of the patient. Adopting this lens offers a unique opportunity to address organizational and procedural issues that would otherwise go undetected. The addition of a standardized patient to walkthroughs both "standardizes" the process and removes confounding factors associated with performing a real life role in any given walk-through environment.

Importantly, the standardized patient helped research staff prepare for real study participants. The research staff felt that it was an extremely efficient use of their time and that the learning experience was invaluable. The experiences and outcomes were also taken to the Clinical Trials Network Steering Committee where they were received with enthusiasm for the innovative approach at training research staff and implementing a complex clinical trial within existing infrastructures. Many other Clinical Trials Network nodes inquired about implementing such standardized patient exercises locally and how the Clinical Trials Network can support such activities. Due to this valuable experience, it has been decided to use standardized patients to pilot test all future clinical trials in the Oregon/Hawaii Node.

4.1. Limitations

The walk-through results from this application of standardized patient technology are specific to one research protocol and the use of one standardized patient. Potential problems related to quality of care in participant intake will vary for other Clinical Trials Network protocols. The Node, however, has now used the SP to help study staff implementation in four protocols. Further, standardized patients are individuals who, in or out of role, carry their own perceptual lenses and therefore, may highlight varied concerns in conducting walkthroughs of clinical processes. Standardized patients require script development, training and compensation. These factors, while not prohibitive, do affect the feasibility of using standardized patients for walkthrough purposes.

4.2. Conclusion

This report summarizes the use of a standardized patient to conduct walkthroughs of participant screening protocols being implemented in the National Institute on Drug Abuse Clinical Trials Network. The purpose of the walkthroughs was to identify potential problems with the patient screening processes prior to implementation of the protocol with real patients. The narrative account of the walkthrough process, as well as categorical summaries of identified problems and associate solutions illustrates the utility of this technology for future clinical trials. The standardized patient provided rich and detailed examinations of study processes from a participant's perspective. Consequences of this work included additional use of standardized patients within the Clinical Trials Network.

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Table 1

Examples of Screening Visit Content

Screening Visit	Screening Visit Content
Screening visit 1	Consent, locator, demographics, medical & smoking history, depression & anxiety scales, pregnancy / birth control, prior & current medications, study eligibility, psychological & behavioral scales (e.g., thoughts on abstinence, suicidal / homicidal intent), Clinical Withdrawal Scale, Brief Pain Inventory, Addiction Severity Index
Screening visit 2	Vital signs, CIDI [*] modules E & K, Fagerstrom ^{**} for nicotine dependence, Beck Depression Inventory, SF-36, physical exam, urinalysis, Risk Behavior Survey, session with counselor

^{*} CIDI – Composite International Diagnostic Interview

^{**} Fagerstrom test for nicotine dependence

Table 2

Summary of Process Changes by Category

Implementation categories	Process changes
Scheduling/organizing	Allowed for more flexibility in scheduling (early morning/late evenings); Ensured study staff review and prepare study materials ahead of seeing participants; Provided training on study related equipment
Consent	Developed a summary sheet and overview of the consent highlighting the important aspects of the study; Provided additional staff training on issues related to confidentiality, HIPAA & mandatory reporting; Prepared staff to effectively “talk” about the contents of the consent form
Case report forms	Prepared for longer visits than originally planned; Provided a list of activities so the participant can “check off” things as they are completed; Prepared participant for the personal nature of some questions
Protocol flow	Provided a calendar for recall; Changed positioning of computer so that it was not located between the staff and participant; Improved timing of the completion of the locator form
Participant comfort	Reduced lighting and made the room less “sterile”; Provided more comfortable chairs; Provided “lap desks” or trays so participants can complete the case report forms in comfort & with ease; Provided “white noise” to reduce others hearing the participant responses; When able, reduced physical barriers by sitting next to participant; Provided reading material in doctor office