
 **2011 Web Seminar Series**

Standardized Patient Walkthroughs Findings and Trends


Presented on May 18, 2011 by: Holly Fussell, PhD
Lynn Kunkel, MS, CCRP

Produced by Liz Buttrey, NIDA CTN CCC Training Office
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Training Outline 

1. Understand the history of using Standardized Patient Walkthroughs (SP)
2. Understand the current methodology and unique contribution of SP technology to the CTN
3. Generalized SP observations and recommendations
4. Understanding how SP walkthroughs can improve comprehensive SOPs by testing them in practice


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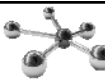


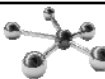
Standardized Patient The History





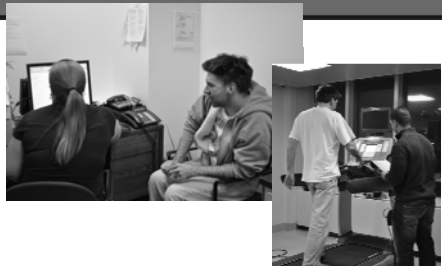
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<h2>Standardized Patients (SPs)</h2>	
<ul style="list-style-type: none"> ■ Actors trained to portray patients with a set of medical symptoms <ul style="list-style-type: none"> ➢ Used in 80% of US medical schools ➢ Assist evaluating and teaching ➢ US National Board of Medical Examiners (NBME) requires an SP examination for Medical Physician Licensing ■ Authenticity tested during a previous NIDA Ro3 study <ul style="list-style-type: none"> ➢ Rated as highly authentic for stimulant & opioid roles 	
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<h2>SPs in the CTN</h2>	
<ul style="list-style-type: none"> ■ The SPs is a training tool for CTN studies <ul style="list-style-type: none"> ➢ Actors trained to portray typical, eligible study participants ➢ Actor enters as a potential study participant completing study screening, consenting, and baseline data collection to rehearse study procedure 	
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<h2>Why SPs in the CTN</h2>	
<ul style="list-style-type: none"> ■ Helps to refine the unique skills of each research staff member ■ Enhancing training and site preparedness ■ Very realistic representation of expected research experiences ■ Identify procedural strengths and weaknesses ■ Increased confidence in implementing study procedures 	
6	


	<h2>Studies - walkthroughs </h2>
	<ul style="list-style-type: none">■ Prior to CTN wide, within local node only:<ul style="list-style-type: none">➢ CTN-0027 START➢ CTN-0029 Adult ADHD➢ CTN-0030 POATS➢ Project Aware➢ CTN-0044-A-1➢ CTN-0044 Web Delivery■ CTN wide<ul style="list-style-type: none">➢ CTN-0031 STAGE-12 (most sites)➢ CTN-0032 RAPID HIV (most sites)➢ CTN-0037 STRIDE (all sites)➢ CTN-0046 SCAST (all sites)➢ CTN-0047 SMART ED (all sites)

	
<h2>Methodology and Contributions</h2>	
	


	<h2>Setting up an SP Walkthrough </h2>
	<ul style="list-style-type: none">■ Preparation process<ul style="list-style-type: none">➢ SP facilitator conducts calls with key site personnel to gain information needed➢ SP is customized to achieve realistic participant representation➢ 15 hours spent rehearsing and developing focused research protocol portrayal

<h2>SP Walkthroughs</h2> 	
<p>ARE:</p> <ul style="list-style-type: none">■ A mechanism to enhance CTN protocol training by "walking through" screening, intake, baseline and occasionally intervention procedures prior to randomization of real participants■ An opportunity for real time feedback during practice sessions	<p>ARE NOT:</p> <ul style="list-style-type: none">■ Monitoring test or an individual evaluation■ A way to compare individuals' performances


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<h2>SP facilitator</h2> 	
<ul style="list-style-type: none">■ Benefits of having SP facilitator observe<ul style="list-style-type: none">➢ Impartial➢ Can advocate for sites	


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<h2>The day of the walkthroughs</h2> 	
<ul style="list-style-type: none">■ SP facilitator(s) meet with the CTP staff to<ul style="list-style-type: none">➢ Finalize details➢ Address questions and concerns➢ Opportunity to review procedures➢ Notes, findings, and reporting parameters	

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<h2 style="margin: 0;">The Walkthrough Begins</h2>	
<ul style="list-style-type: none"> ■ SP enters "in role" <ul style="list-style-type: none"> ➢ Approach is customized to reflect authentic research environment ➢ Research staff approaches as outlined in research procedures <ul style="list-style-type: none"> ▪ Screening ▪ Baseline data collection ▪ Randomization ▪ Study interventions (sometimes) 	
<small>13</small>	


	
<h2 style="margin: 0;">Review & Feedback</h2>	
<ul style="list-style-type: none"> ■ Occurs during natural breaks in the flow of the protocol (<i>following consenting</i>) ■ Research staff, SP and Facilitator <ul style="list-style-type: none"> ➢ A review of the experience ➢ Share and Discuss <ul style="list-style-type: none"> ▪ Strengths/Weaknesses ▪ Recommendations 	
<small>14</small>	


	
<h2 style="margin: 0;">Exit Interview</h2>	
<ul style="list-style-type: none"> ■ What is your overall impression of this SP experience? ■ What went well? ■ What needs more attention? ■ Was this experience valuable? ■ Value that differs from national training ■ SP Authenticity ■ Was feedback helpful 	
<small>15</small>	


	Site Feedback 
	<ul style="list-style-type: none">■ More realistic than role plays■ Builds Research Staff confidence■ Identifies areas that need improvement
	<small>16</small>

	Summary Report 
	<ul style="list-style-type: none">■ Summary report to lead team<ul style="list-style-type: none">➢ Developed after all site walkthroughs are completed➢ Generalized findings➢ Use walkthrough notes to debrief and create report➢ Overall strengths and weaknesses identified➢ Recommendations to address
	<small>17</small>

Observations and Recommendations	
	
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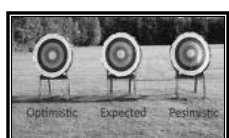
	
<h3>Three Types of Findings</h3>	
<ul style="list-style-type: none"> ■ Individual performance <ul style="list-style-type: none"> ➢ Strengths / weaknesses identified ■ Standardized Operating Procedures <ul style="list-style-type: none"> ➢ Processes that work and don't work ■ What can future lead nodes learn <ul style="list-style-type: none"> ➢ What are the 3 things that can improve implementation 	
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<h3>Key Findings</h3>	
<ul style="list-style-type: none"> ■ Consent ■ Time estimates ■ CRF completion 	
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<h3>Key Findings</h3>	
<ul style="list-style-type: none"> ■ Consent form <ul style="list-style-type: none"> ➢ Thorough training on how to consent <ul style="list-style-type: none"> ▪ Maintaining participant attention <ul style="list-style-type: none"> ○ Deconstruct for participant ▪ Highlight and distinguish key points. ▪ Summarize sections to extract critical details ▪ Highlighted notes to help RA emphasis importance ▪ Visual aids ▪ Use simple words as much as possible. Make eye contact to make sure study participants are tracking. ▪ Use positive wording (e.g. screening is to see if the "study is a good fit for you" rather than whether the person is a good fit for the study). 	
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Key Findings


- **Time estimates**
 - Often vastly underestimated
 - Leads to staff frustration
 - Emphasis on going quicker rather than on quality
 - Impacts patient flow estimations
 - Communicate to educate

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Key Findings

- **CRF completion**
 - Address variability
 - Recognize and reduce confusion
 - Explain what CRF question is collecting
 - Explain how to collect the data
 - Sometimes questions are tricky
 - Prepare staff for participant being resistant to give data



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More Information on SP Walkthroughs

- **Standardized Patients as Participants in Clinical Trials Protocol Implementation.**
 - Fussell, Holly E.; Kunkel, Lynn E.; Shannon-Lewy, Colleen; McFarland, Bentson H. Poster presented at the NIDA Blending Conference, "Blending Addiction Science & Practice: Bridges to the Future," Seattle, WA, October 16-17, 2006.
- **Using Standardized Patients to Pilot Screening Visits in Clinical Trials.**
 - Kunkel, Lynn E.; Fussell, Holly E.; Shannon-Lewy, Colleen; McFarland, Bentson H. Poster presented at the Society for Clinical Trials Annual Meeting, Montreal, Canada, May 20-23, 2007.
- **Using a Standardized Patient Walk-Through to Improve Implementation of Clinical Trials.**
 - Fussell, Holly E.; Kunkel, Lynn E.; Lewy, Colleen S.; McFarland, Bentson H.; McCarty, Dennis. *Journal of Substance Abuse Treatment* 2008;35(4):470-475. [doi: 10.1016/j.jst.2008.03.001].
- **Training Clinical Trial Staff to Implement a Rapid HIV Protocol: The "Role" of a Standardized Patient".**
 - Kunkel, L.E., & Fussell, H.E. (2009). Poster presented at the 18th Annual Society of Clinical Research Associates, Memphis, Tennessee.
- **Responses to Standardized Patient Walkthroughs of a Clinical Trial Assessing Treatment for Stimulant Abuse.**
 - Holly E. Fussell, Ph.D., Lynn E. Kunkel, MS, CCRP, Colleen Lewy, Ph.D., Dennis McCarty, Ph.D. Poster presented at 2009 conference of the Western Psychological Association, Portland Oregon.


To learn more about SP walkthroughs see
the CTN dissemination Library
<http://ctndisseminationlibrary.org>

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Questions or Comments?



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Upcoming Webinars

■ Strategies to Improve Treatment Adherence in CTN Research Protocols	June 1
■ Relapse Prevention	July 20
■ Certificate of Confidentiality (CoC)	Aug 10
■ Integrated Treatment of Co-Occurring Disorders	Sept 14
■ Informed Consent	Oct 12
■ A New Look at Manual of Procedure (MOP) Development	Dec 7

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<https://livelink.nida.nih.gov>
