

Considerations for Training Front-Line Staff and Clinicians on Pragmatic Clinical Trial Procedures

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Introduction

The purpose of this guidance is to help pragmatic clinical trial (PCT) teams plan training for study procedures that involve front-line clinicians and staff.

PCTs answer questions that are designed to improve practice and policy. They take place in settings where everyday care happens, such as community clinics, hospitals, and health systems. Their conduct therefore requires engaging partnerships at multiple levels, including with patients, practitioners, health systems, and communities.

PCTs typically involve front-line clinical or operational personnel in study procedures. Just as with other study team members, these staff require training related to the research. However, training front-line clinicians and staff in PCT procedures differs from training in typical research procedures in four important ways:

1. **Audience:** The people receiving the training are not research staff but rather clinicians and clinical and operational staff at the PCT sites (e.g., community clinics, hospitals, healthcare systems).
2. **Content:** Training content is focused on intervention procedures that may become part of regular care delivery—*care delivery tasks*. Therefore, new care processes and workflow are the central focus. As such, one objective of training is likely to be to build and maintain engagement with clinicians and staff over time. Another is to teach and reinforce any *study-specific tasks* such as tracking procedures that would not otherwise happen. Research-specific procedures such as administering informed consent may be included as well depending on the specifics of the study, but there is less emphasis on this than in traditional trials. Several existing resources provide excellent information on integrating research-specific procedures into practice settings, for example a report on Practice-Based Research Network (PBRN) Research Good Practices available through the North American Primary Care Research Group:
<http://www.napcrg.org/Portals/51/Documents/PBRN%20Conf%20Handouts/PRGP%202014-09-29.pdf>.
3. **Structure:** Training around PCTs conducted as part of routine care and operations typically occurs via the healthcare delivery organization's existing training structures in those clinical settings.
4. **Change over time:** Because change over time is typical in healthcare delivery settings, training programs should be designed to be adaptive and ongoing. Training and engagement efforts by the research team will occur at the launch of the trial to teach clinicians and staff new procedures but also will need to continue over time. Some activities that the research team should anticipate include:
 - Orienting new leaders who join the health system. Systems that face high leadership and staff turnover present unique challenges to prioritizing a research project in the face of competing administrative priorities.
 - Updating study procedures and reference materials to accommodate any related changes in the health system. For example, a research study that is testing an

electronic clinical decision support tool in a health system that decides to revise its electronic health record will need to update the study workflows and training accordingly.

This document presents seven considerations for PCT training programs that were developed by drawing on trial-specific experience in the [NIH Health Care Systems Research Collaboratory](#). The NIH Collaboratory supports PCT Demonstration Projects that address questions of major public health importance and engage healthcare delivery systems in research partnerships. These projects help to establish best practices and strengthen the national capacity for conducting pragmatic clinical research.

Considerations for PCT training design

1. How does the training approach relate to implementation complexity?

Needs and approaches for training of front-line clinicians and staff are closely linked to study design and will vary depending on the specifics of a trial. PCTs have varying levels of complexity. Some fit very smoothly into day-to-day operations and can be called **passive interventions**. These require close initial planning with the staff implementing the change but are unlikely to require more than limited additional training on an ongoing basis. At the other end of the spectrum of change management are **active interventions** that involve ongoing system-wide changes. These require training staff in new clinical and operational procedures and are likely to require substantial training and reinforcement over time. An example of each follows.

- [LIRE](#) is an example of a passive intervention. It is testing adding epidemiologic benchmarks to imaging reports produced by the electronic health record. Implementing this change required significant up-front planning with IT and outreach to leadership and clinicians who will see the intervention. However, only limited ongoing training is required.
- [PPACT](#) is an example of an active intervention. It is establishing new care team structures to treat patients with chronic pain. This study requires ongoing training about the intervention approach and new roles. Some of the skills involved in the intervention, such as working with patients to increase their active involvement in their own care, are advanced skills for participating clinicians. Thus, the research study is supporting advanced training in new clinical skills. The use of such skills and rationale for the changes has to be reintroduced with the addition of new staff, clinicians, and leaders who may not be familiar with the innovative configuration of the care team and must be reinforced over time.

2. What input is needed from care delivery organizations?

As with any aspect of PCT procedures, local input on the training approach is essential. It is important to coordinate with care delivery organizations up front and have a structure for doing so over time. It is helpful to identify a champion at each organization who can help advise and troubleshoot before and throughout the study. The research team can work with the local champion to seek input on the following:

- **Standard training structures and materials:** Training efforts will likely overlap with ongoing training efforts in the healthcare system. Ideally, one can align trial-specific training with these efforts and make use of existing training structures, materials, and terminologies. However, it is important to understand the extent to which intervention skills and procedures differ from standard processes in a healthcare system.
- **Who needs to be trained:** For example, the receptionist may need to be trained to provide a study information sheet or medical assistants may be tasked with asking patients if they are interested in participating as part of rooming procedures.
- **Who is the ideal trainer:** Who the trainer is can affect study credibility. For example, a well-respected leader in the organization may generate more buy-in than an unknown researcher.
- **Parallel training efforts that overlap with the research:** The training approach may need to factor in procedures and associated training to fit with parallel initiatives occurring in the health system.
- **How procedures are working:** Once the study begins, the study team should encourage input from the champion about how the study procedures are working. For example, the champion may learn from front-line staff that the study tracking procedures are too burdensome and have suggestions for how to refine the process.

3. What are the potential Human Resources considerations?

Planning for training often goes hand-in-hand with broader staffing and associated human resources considerations.

- Work closely with the clinic manager to understand existing staff roles and responsibilities. *In active intervention PCTs*, a new position may need to be created if staff will be responsible for both clinical care and study activities. For example, the [ICD-Pieces™](#) trial created a new position. The staff member is based in and employed by the clinic and performs both clinical and study work. It may also be appropriate to “re-design” an existing position, which would fit the needs of the study and limit the study’s effect on the clinic environment. For example, the [TSOS](#) study redesigned nurses’ roles to include seeing patients outside of the hospital. Organizational standards will influence the extent to which study-related responsibilities can be added to an existing position’s duties. Be sure to include Union representatives in planning for represented positions.
- Developing a clear scope of work for personnel will help in determining the best hiring procedures, contracting mechanisms, and training plans. Splitting the scope of work into study tasks, care delivery tasks, and hybrid tasks will clarify the expected responsibility and time commitment of front-line personnel for training and carrying out study tasks. Documenting these decisions in a memorandum of understanding can help ensure the study team and delivery system managers agree on responsibilities.
- Turnover will occur during the project and should be anticipated during planning for training. Training new staff and engaging leaders when a study is already underway may

require a different approach than training at the start of the study. When developing a study training plan, create specific training for each study phase (e.g., start-up, recruitment, data collection).

- “Job aid” documents that explain specific steps for each role help both to prepare for turnover and serve as a reference.

4. *What topics should the training cover?*

The training should address new procedures, including care or workflow changes. *In active interventions* that involve ongoing system-wide changes, the training needs around new skills or processes may be substantial. Training should also address any tracking needed for the study. Examples of tracking may include the number of patients a study sheet was given to or the number of patients who underwent the study procedure.

If the trial is testing new procedures with patients, clinical staff should receive training in how to explain the change to patients. Depending on the study specifics, clinical staff may be trained to explain changes to all patients, know how to answer patient questions, or direct patient questions to the research team. For example, a study that is testing longer versus shorter procedure duration should anticipate patient questions about why they are receiving a different procedure duration than some other patients or why the amount of time has changed from the last time the patient had the procedure.

The training should provide context for the study, including why the study may benefit patients and why the research needs to be done. This helps build investment in the research.

Some studies involve clinical staff administering informed consent for research procedures, in which case they need to be trained in human subjects protection, good clinical practices, or other research-specific content. More commonly in PCTs, research-specific procedures such as informed consent or data analyses are conducted by distinct research personnel.

Training should also reinforce content and provide updates and opportunities for trainees to ask questions or suggest improvements over time.

5. *How widely should front-line staff be made aware of the intervention, especially those in the control group?*

As noted above, pragmatic trial training is closely related to study design. A randomization plan that results in differential procedures at the provider level can be very difficult to operationalize. For example, it can be difficult to blind control groups from study procedures, especially if patients or providers cross over. Project staff in a medical practice that have been randomized to what they

perceive as an exciting or interesting new intervention may be more enthusiastic and motivated in their efforts to recruit individual patients than are staff who are assigned to the “usual care” control group.¹

If the study question and design provide good reason for limiting awareness of differences between arms, there are several approaches to balancing transparency about the trial procedures and the details of the intervention group. If this type of communication is necessary, one could consider the following:

- Customizing communication according to study arm. This might involve developing a “big picture message” to one group but allow for more detailed information to be shared in communications going directly to intervention groups.
- Using IT to restrict access to details to users in certain facilities.
- Providing only a big picture explanation of what the trial is studying (e.g., all patients will receive one of two counseling approaches).
- Conducting patient recruitment prior to training participating sites in what arm they have been randomized to.

However, expect that contamination will occur—it does in almost all cases. The best way to address this is to keep track of what happens via study monitoring so that the study analysis can take it into account.

6. What training should be provided via routine structures versus trial-specific structures?

Ideally, PCT procedures should be integrated into routine healthcare operations so that if the intervention is sustained, it is already part of standard work. However, to make research participation easier on the site, the research team may need to deliver trial-specific trainings in coordination with management. As noted in Consideration #2 above, local input on the approach that will work best in a particular health system is important.

A train-the-trainer approach is often advisable so that a leader or champion can implement training using normal meetings and communication mechanisms. Keep in mind that there may be more than one trainer; for example, the medical director might train clinicians, while the practice manager might train operational staff. Provide detailed study information, such as a binder or project website, to trainers so they have the information they need to teach others about the study.

An example of how a study could integrate their efforts into routine structures without undue burden is the **PROVEN** study, which included funding to hire part-time nurse educators for each site’s staff to focus on training and oversight using a train-the-trainer model. As noted earlier, clinicians employed by the partners will have greater credibility. The research staff are available to support the trainers and to track and reinforce training over time.

¹ Pladevall M, Simpkins J, Donner A, et al. Designing CRTs: An Introductory Toolkit (Updated 1/2015). 2014. Available at: <https://www.nihcollaboratory.org/Products/Forms/DispForm.aspx?ID=84>

7. How does training overlap with fidelity monitoring?

Worksheets or procedures to track what the clinical team is doing can serve the dual purpose of reinforcing training and allowing the study team to monitor how the intervention is being delivered. The overlap also allows study teams to identify patterns of non-compliance across teams or individuals. If a particular study procedure is routinely missed, or not done well, this will highlight a need for revised training or may indicate that the procedure may not be feasible in a real-world setting. In such cases, the local champion is critical to help the research team understand the root cause and identify possible solutions, for example, adaptations to the intervention to make it better align with healthcare system procedures or a training refresher.

For example, the [ABATE Infection](#) study uses antiseptic bathing for all patients and nasal ointments for patients harboring methicillin-resistant *Staphylococcus aureus* (MRSA) to reduce antibiotic-resistant bacteria and hospital-associated infections. In this study, unit managers track both use of the bathing and nasal products as well as adherence to the process by which the products should be applied. Tracking of product use occurs through computer-generated reports that allow unit managers to assess usage down to the patient level as well as report summary-level compliance to study coordinators. Product use is assessed daily until >85% compliance is reliably achieved, then usage is checked once weekly. Assessment of proper application is based upon quarterly staff skills assessments which consist of a one-page checklist and short-answer questions that are completed during direct observation of staff members assisting with bathing. In addition, quarterly patient assessments are performed using a 10-question survey asking about patient perception, the thoroughness of bathing, and whether certain steps were performed. These tools allow the investigators to assess usage and process without being physically present at each site.

Summary

Training front-line clinicians and healthcare staff in PCTs requires close coordination with partner healthcare systems and care delivery settings. The project team needs to identify relevant users, target content and structure to the users, and develop mechanisms to reinforce new skills and procedures. Plan to maintain training over time in order to reinforce content and orient new staff and clinicians. Interventions that involve more change to standard work will require more training. A checklist to help organize training development can be found below.

Checklist for PCT training design

Item	Considered/Completed
Determine implementation complexity	
Coordinate with delivery organizations	
<ul style="list-style-type: none"> Identify local contact/champion 	
<ul style="list-style-type: none"> Check if standard training structures and materials are available 	
<ul style="list-style-type: none"> Determine who needs to be trained 	
<ul style="list-style-type: none"> Determine if staff or clinician in the organization is able to conduct study training 	
<ul style="list-style-type: none"> Review parallel training efforts or programs planned by the care organization that may overlap with study training plans 	
Human Resources	
<ul style="list-style-type: none"> Review existing staff roles with Clinic Manager and discuss study-specific roles or tasks 	
<ul style="list-style-type: none"> Create scope of work for staff performing study tasks 	
<ul style="list-style-type: none"> Discuss potential contracting or hiring requirements with care delivery organizations' Human Resources departments 	
Training topics	
<ul style="list-style-type: none"> Define new procedures and changes to existing clinic workflow 	
<ul style="list-style-type: none"> Review communications to be given to patients and suggestions for staff if patients have questions about the trial communications or procedures 	
<ul style="list-style-type: none"> Determine if staff roles require training on human subjects protection 	
Control and intervention arm(s)	
<ul style="list-style-type: none"> Develop specific training procedures for different study arms as relevant 	
<ul style="list-style-type: none"> Track training activities (study analyses may need this) 	
Training structure	
<ul style="list-style-type: none"> Consider how standard training structures might correspond/not correspond with study training 	
<ul style="list-style-type: none"> Will a train-the-trainer approach work? 	
Fidelity monitoring	
<ul style="list-style-type: none"> Consider how tools needed to track study procedures might also be used to indicate need for retraining 	
<ul style="list-style-type: none"> Encourage input from staff about tools to make tracking easier for them and update over time 	

Appendix A: Resource Materials

National Institute of Dental and Craniofacial Research. Toolkit for Clinical Researchers. *Clinical Care vs. Research Slides*. 2012. Available at: http://www.nidcr.nih.gov/research/toolkit/Documents/Clinical_Care_vs_Research_Slides_approved_v10_20120322.pptx. Accessed July 23, 2015.

This 5-slide presentation gives a high-level overview, in lay terms, of the similarities and differences between research and clinical care.

D'Avolio L, Ferguson R, Goryachev S, et al. Implementation of the Department of Veterans Affairs' first point-of-care clinical trial. *J Am Med Inform Assoc* 2012;19(e1):e170-6.

The article describes the pilot of the point-of-care clinical trial (POCCT). Page e174 includes a workflow diagram showing how clinicians and the study team work together in recruitment and management.