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## Ethnography, Fidelity, and the Evidence that Anthropology Adds: Supplementing the Fidelity Process in a Clinical Trial of Supported Employment

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*This discussion considers the role and findings of ethnographic research within a clinical trial of supported employment for veterans with spinal cord injury. Contributing to qualitative evaluation research and to debates over anthropological evidence vis-à-vis clinical trials, we demonstrate how enactors of a randomized controlled trial can simultaneously attend to both the trial's evidentiary and procedural requirements and to the lived experiences and needs of patients and clinicians. Three major findings are described: (1) contextual information essential to fidelity efforts within the trial; (2) the role of human interrelationships and idiosyncratic networks in the trial's success; and (3) a mapping of the power and authority structures relevant to the staff's ability to perform the protocol. We emphasize strengths of anthropological ethnography in clinical trials that include the provision of complementary, qualitative data, the capture of otherwise unmeasured parts of the trial, and the realization of important information for the translation of the clinical findings into new settings. [randomized controlled trial, spinal cord injury, ethnography]*

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Mythological, ritualized and culturally embedded aspects of all healing systems, biomedicine included, can in themselves possess great healing potential. Orthodox medicine can be blind to such aspects of its own praxis in its claim to scientific legitimacy, and these elements are not studied in the [randomized controlled trial].

—Barry (2006:2649)

We try to give [the staff] updates on the progress of the study as well as share successes and talk about the challenges and how we want to meet those challenges for the next plan. . . . In the last meeting . . . we set it up so that the front line people, the site coordinators and the VR counselors—were presenting information from their perspective on what recruitment strategies were working at their site. And the VR counselor presented success stories, which was very energizing, motivating, and led to a lot of discussion of things.

—Clinician explaining team culture and information sharing within the RCT

The randomized controlled trial (RCT) is considered Western medicine's most rigorous scientific test of a clinical treatment. The RCT tests an experimental intervention against a control treatment, usually focused on a single specific outcome.<sup>1</sup> Randomization is achieved through strict adherence to statistical methods, standardized sampling procedures, and defining the dependent variables and controlling for independent variables in the sampling process (Matthews 2000). Control is achieved through strategies like standardized diagnostic methods, fixed-dose medication administration, use of detailed treatment manuals, and rigorous clinician training and certification procedures. But for all its highly structured and faithfully attended protocols, the RCT is but one hammer in a very expensive toolbox.

As part of the discussions surrounding evidence-based medicine, RCTs have been critiqued for the limited degree to which such highly controlled results can be generalized to the larger population of people in need of treatment (Lambert 2006; Mykhalovskiy and Weir 2004). And RCTs often do not "provide the information necessary for clinicians to tailor treatment strategies to the social and cultural needs of their individual patients, who live in a wide variety of circumstances" (Hohmann and Shear 2002:201). We present data that reveal how the distinctive benefits of an RCT—even the most regulated, clinic-based efficacy trials—can be expanded through strategic application of anthropological constructs and ethnographic methods.

Anthropologists have contributed much to research in clinical settings (Hunter et al. 2008) and to clinical trials (Cabassa et al. 2008; Fisher 2006a, 2006b), but their gaze has rarely been directed unambiguously at the RCT itself, its distinct language, its native perspectives, and its priorities. Leadership in this work comes from a fairly small group of anthropological scholars (e.g., Adams 2005; Barry 2006; Landsman 2006). This article reports an ethnographic study of a clinical trial that treated the clinical processes and context—rather than patient experiences—as the main focus of research. We join the critique of the "rhetorics of evidence in biomedicine" (Barry 2006) to reveal how enactors, here of an RCT, can simultaneously attend to both the trial's evidentiary and procedural requirements but also to the lived experiences

and needs of patients and clinicians. We therefore illuminate the specific dimensions of ethnography that provide new information to trial assessments and reconsider and expand the relevant evidence in an evidence-based medicine. And we challenge a common assumption that the RCT is necessarily a sterile and context-free outcome of rigorous scientific method.

The RCT discussed here was not the iconic drug trial in which individual variation is all but erased from the line of questioning. Instead, this RCT tested a new method of person-centered rehabilitation for spinal cord-injured veterans. It is a contextually sensitive treatment directed at achieving the outcome of post-care employment: a model that envisions a broader view of life quality and rehabilitation than traditional medical approaches. Combining qualitative data with this expanded approach to rehabilitation from spinal cord injury, this trial offers a model for more widely applied research in clinical intervention trials, redefining current standards for not only rehabilitation outcomes but also evidence.

We identify several advantages of qualitative and ethnographic assessment within clinical trials. First, we examine the process behind the trial's ultimate results: that is, a broader and more detailed view of the trial in its context so that the specifics of negotiated and "contingent" performance (Adams et al. 2005) reemerge and the non-focal variables are not erased. Second, we catalogue the human interrelationships and idiosyncratic networks that prove important to the trial's outcome. This type of work is not only context driven and locally specific, but requires the ethnographer to discover the social dynamics and processes that undergird but are often invisible to the traditional clinical trial. Third, we map vital power and authority structures that were determinate of key services and features of the trial. By fulfilling these three critical engagements, the ethnographic data make the ultimate translation of clinical trial results into real-life social hierarchies and the limited resources of patient life-worlds more likely.

### Background and Definitions: Two Histories of Exclusion

We begin with a review of key background, definitions, and intersections of, on the one hand, RCTs' strict rules of evidence and scientific inquiry and, on the other, the contested notions of rehabilitation and its goal of returning patients to a societally sanctioned and defined standard of function or health. That the forms of scientific and medical research are under constant revision is obvious. Even as the RCT remains valorized as the gold standard in research, ethnographic methodologies have been embraced by clinical trial researchers in certain ways. Nevertheless, a wide gulf remains between the methodologies and rules for an RCT and the inherent variability that anthropological ethnography presumes. By using ethnography to illustrate how this rehabilitation RCT challenges old notions of post-injury quality of life, we hope to expose and address two convergent histories of exclusion: one regarding domains accessible only by ethnography and the second rehabilitation care.

What, then, is an RCT? Its proponents argue that an RCT is "a true experiment whereby study participants are assigned by chance, following a pretest, to at least two conditions: An experimental treatment or intervention, and a control intervention sued for purposes of comparison on outcomes" (Solomon et al. 2009:5).

Evidence from randomized controlled clinical trials is widely accepted as “the only sound basis for assessing the efficacy of new medical treatments” (Matthews 2000). An RCT typically involves large sample sizes, has complicated and long documentation requirements,<sup>2</sup> and places a priority on the standardization of treatment delivered.

Citing the demanding nature of these characteristics, researchers regularly exclude certain categories of data uniquely accessible through ethnographic methods such as nuances of communication, information sharing, and hierarchy that reflect undocumented power structures profoundly relevant to intervention outcomes; the narrated experiences of participants, clinical staff, or investigators; and subjective impressions and opinions not captured in written instruments. In particular, participant observation, “which requires flexibility as well as a refusal of *a priori* etic categories, fits very poorly in this context” (Sobo 2009:70–71). In medical anthropology, sample sizes are usually small, methods are both embedded and unfolding, and findings are not easily replicated or validated. Anthropologists value context and culture over things like control and randomization, so it is difficult for them to fully recognize the Western/industrial world cultural assumptions of trial protocols. Adams et al. expose several cross-cultural challenges to “the very idea of a clinical trial” (2005:269).

More recently, however, standard ethnographic techniques such as semi-structured interviewing, participant (and non-participatory) observation, and other qualitative methods have been used in clinical studies with growing frequency (Fisher and Kalbaugh 2011; Joseph and Dohan 2009; Swanson and Ward 1995). Ethnography in clinical settings is typically narrower than in traditional anthropology; that is, long-term immersion and participant observation are impossible or rejected in the clinic, and a rich dataset available from social context is thrown away or never seen (Abel and Sankar 1995; Sobo 2009). But these and more recent studies reveal that social process and contextual factors can be incorporated into study designs for very specific treatments (e.g., Hohmann and Shear 2002; Ware et al. 1999).

Our ethnographic research design was based on an ecological, or context-rich, perspective (Perkins et al. 2005), using individual and group interviews plus participant observation in both the clinic and in veterans’ lives (though only data on staff narratives are discussed here).<sup>3</sup> Anthropologists were able to participate in all clinical interactions for the trial as well as staff meetings and regular office activities related to the project. Our participant status was also aided by the treatment of the lead anthropologist as a member of the trial’s principal investigative team. Other anthropologists do engage in RCT work, but their subjects are typically the same patients that the trial is designed to treat. In our case, this broad access was granted so that the trial itself—the broader context in which clinical practices were designed, implemented, and evaluated, and the structures that sustained and limited the focal subject of the study—could be evaluated.<sup>4</sup> Our trial therefore presents a promising break in the history of exclusion from evidence that ethnography has experienced.

The second history of exclusion intersecting the clinical trial is that of rehabilitation. In medicine, rehabilitation is a broad concept, referring to a variety of care that aims to restore patients to *health or normal life* (Oxford Online Dictionary; emphasis added). Of course, the notion of health or normal life is contingent and contentious. Within the confines of an RCT, the definition of health has traditionally

been exceedingly narrow, and normalcy was defined almost exclusively by reference to unitary standards and norms inferred through central tendency statistics rather than by its social standards. Here is the crux of our problem and the reason an RCT of a rehabilitation intervention is a good model for redressing this exclusionary bias.

Rehabilitation as a medical specialty expanded greatly after World War II, in response to the demand to care for returning soldiers with amputations, spinal cord injuries (SCIs), and other physical limitations (Gritzer and Arluke 1989). By the 1950s and 1960s, advocates for the rights of persons with disabilities shifted the focus to deinstitutionalization and independent living supports and opportunities (Fleischer and Zames 2011). Helping injured soldiers and other disabled persons return to work was an important focus of pioneers such as Howard A. Rusk, Mary Switzer, and others (H. Rusk 1977; H. A. Rusk 1977; Verville 2009). Over time, the importance of employment to the individual and society grew, and governmental entities, particularly the individual states, assumed the largest roles in vocational rehabilitation (VR).

A national disability rights movement gathered momentum after the signing of the Rehabilitation Act in 1973, and further amendments were added in 1978. Persons with disabilities partnered with rehabilitation professionals in many instances to promote health care access for persons with disabilities and, more centrally, to fight segregation and discrimination against persons with disabilities. In short, the social history of rehabilitation has emerged as a praxis that is highly sensitive to context and to social and behavioral activities of value for individuals undergoing rehabilitation, including work.

A notable diversity of worldviews exists among VR professionals. Advocates of VR argue that disabled persons live in a “catch-22” situation related to work: Lack of money for housing or personal care may force a disabled person into a Medicaid-funded nursing home, which makes employment-seeking difficult. Paid employment, they argue, would allow the disabled person the resources to live independently (Hershey N.d.). But others critique this employment focus as inappropriate for all patient groups and biased in favor of market-centric rather than person-centered values (see, e.g., [www.disabledveterans.org](http://www.disabledveterans.org)).

Complications confront the ideals of rehabilitation that does not share a single definition of what health or a normal life may mean. Of major concern to the principal investigators of this RCT was the narrow view of rehabilitation for persons with SCI focused on unemployment after SCI and its direct connection to lower quality of life and life satisfaction (Chapin and Kewman 2001; De Vivo et al. 1999). Yet common approaches to rehabilitation excise employment support from the rest of rehabilitation medicine and are then of such limited intensity or depth as to be of little use for patients with complex needs. The effect of these structural decisions was, in our view, to (re)produce further reduction in quality of life, completeness of health, and avenues to normalcy.

Aware of these concerns, in designing the SCI-Vocational Integration Program (SCI-VIP) described below, the clinical researchers planned to not only take a committed and engaged view toward helping veterans with SCI who wanted to return to work, but also to redefine the scope of possibilities that rehabilitation could include. And they would do this while adhering to rigorous standards of measurement, fidelity to an evidence-based model, and accuracy of reporting befitting the

Table 1. Principles of Individual Placement & Support (IPS)/Supported Employment (adapted from Becker and Drake 2003:22)

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1	Rehabilitation is considered an integral component of treatment, rather than a separate service;
2	The goal of IPS is competitive employment in integrated work settings, rather than prevocational, sheltered, or segregated work experiences;
3	People with spinal cord injury can obtain and succeed in competitive jobs directly, without preemployment training;
4	Vocational assessment is continuous and based in competitive work experiences, rather than in artificial or sheltered settings;
5	Follow-along supports continue for a time that fits the individual, rather than terminating at a set point after starting a job;
6	Job finding, disclosure, and job supports are based on clients' preferences and choices, rather than on providers' judgments;
7	Services are provided in the community, rather than in treatment or rehabilitation settings;
8	A multidisciplinary team approach, rather than parallel interventions in separate agencies or systems, promotes the integration of vocational, clinical, and support services.

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nomenclature RCT. This particular intervention is already laudably context sensitive in that the patient's life context and evolving needs are taken as a whole. That they accomplished this within an RCT format is noteworthy and may offer model directions for future anthropological work.

### Research Design and Methods

The SCI-VIP tested a treatment model that emphasized social interactions both between clinicians and between clinicians and patients. The model is termed "supported employment," and it calls for both a political and a spatial integration of the VR counselor—a role traditionally outside the clinical team—directly into the space of clinical negotiations (Becker and Drake 2003; Bond et al. 2008a; Bond et al. 2008b). This is different from conventional VR in an important way. While conventional VR involves intensive assessment, case management, and sometimes therapy, these services typically occur outside the Veterans Healthcare Administration SCI centers, with either the Veterans Benefits Administration Vocational-Rehabilitation and Employment office or with state-contracted VR providers. Supported employment, on the other hand, integrates the VR counselor more fully into the clinical team and provides more holistic and continuous support to the client (Becker et al. 2006; Bond et al. 2008a; Bond et al. 2008b). These priorities are outlined in the core principles of the supported employment model of care (see Table 1).

Participants were veterans with SCI between the ages of 18 and 65 years who received medical and/or rehabilitation health care services at the site. Only veterans who were not employed or employed but not at a substantial income level were eligible. Veterans were randomly assigned to either the SCI-VIP or the standard care condition. Veterans in the standard care condition were free to use whatever vocational services were available at their Veterans Affairs Medical Center,

including referrals to outside agencies (e.g., state VR). Detailed protocols were prepared for each activity, including treatment, reporting of activities to the principal investigators (PIs), communication within clinical teams, and the like (Ottomanelli et al. 2012).

### Ethnographic Methods

Anthropological methods sought to capture a greater diversity and depth of data on program outcomes and to describe both staff and veterans' experiences of the trial. The PI's foresight in measuring social and interpersonal processes, plus the fact that the supported employment model they were testing was already a context-sensitive intervention, differentiated this RCT from most others. Standard ethnographic methods involved semi-structured and open-ended interviews with staff and participants, observations within provider-participant encounters, and participant observation in clinical and service activities within the SCI unit.

Observations of 28 Veterans Affairs Medical Center staff and/or SCI-VIP staff members were conducted. Formal audiotaped interviews were conducted with all six of the local SCI-VIP staff. Interview questionnaires focused on the program schedule and staff roles and responsibilities; perceptions of success and failure in the research project; details of supervision, training, and employee evaluations; significant experiences in the research program; and topics emerging from staff meetings or current cases. Interview narratives were transcribed verbatim, then coded and analyzed using Atlas.ti software to identify recurrent themes, categories, and expressions. Coding was performed to identify key and recurrent concepts. Two independent coders marked transcripts, followed by discussion and reconciliation of the two lists. Discrepancies were resolved through consensus, producing a two-level hierarchy of 22 final codes, each containing at least five references in at least three different informant interviews.

### Research Findings

Three major ethnographic findings from coded, narrative data were as follows: (1) it was important yet difficult to implement the model precisely as designed; (2) a shared culture among the trial's staff had to be cultivated for the model to be successfully implemented; and (3) a locally authoritative champion for the treatment model was essential to implementation.

#### *Fidelity-Driven Research and Integrated Care*

The term "fidelity" refers to whether an intervention was conducted consistently and completely according to the procedures specified in the project protocol. Clinical trials that adopt the fidelity approach rigorously monitor, coach, and supervise the services performed to ensure ideal adherence to the intervention model (Bond et al. 2008a; Bond et al. 2008b). Values associated with the fidelity approach are the replicability of data and the reliability with which researchers can attest that the model, as designed, was indeed what occurred during research. This characteristic of the SCI-VIP trial—a measured dedication to the principles behind the intervention—is

important because fidelity to the treatment model is one of the requisite features of scientific rigor in an RCT.<sup>5</sup>

*The Intensive Effort of Home Visits.* To demonstrate fidelity to all of the principles of the supported employment model involves rapid engagement, zero exclusion, and ongoing support (see Table 1), making the VR counselor's job exceptionally intensive. In the traditional model, clients came to the VR counselor; it is rarely the other way around. In the supported employment model, VR involves numerous home visits and intensive support. One VR counselor, for example, had a client who lived at the maximum-allowed distance for the trial's catchment area (100 miles). The drives to see him were long, and the patient's reluctance to visit with the VR counselor (even at his own home) was exacerbated by his drug use. In the traditional VR model, this man may never have received support for employment, because those supports were only available in a professional office. But the trial's VR counselor wouldn't relent:

I had a guy in Fort Worth, who had an obvious drug problem and didn't want anyone in his house. He hated company. He admitted to me he signed on [to the SCI-VIP] just to get the fifty dollars [research stipend] every month. So I continued to go out there, you know. Then he started to get angry, because he didn't really want me to visit . . . but I continued to go out anyway. Just kept going, kept going, kept trying to talk to this guy. And he and I started to get along pretty well.

Through persistence and a flexible approach to goal-setting, the VR counselor established rapport and was able to help this client land two job interviews, a much better result than traditional methods of VR might have achieved. Below, the VR counselor reflects on the difficulty of achieving the same outcome (i.e., paid employment) with clients who start in such different states of readiness:

That's difficult, trying to find people at that right place. And spinal cord cases are delicate, and some people take a long time. You know, I've had cases that didn't get a job until that twelfth month. I have people who have never found a job. You know, to think it's going to be just a blanket fix, you know, it's not going to happen.

Identifying good targets and then providing job leads or setting up interviews for participants was not enough to reach a positive employment outcome. The VR counselor had to discover participants' interests, maximize their capabilities through mechanical, technical, and clinical supports, and then discover possible sources for work where the participant might apply. She was simultaneously a support counselor for the patient and administrative assistant for setting up (and sometimes driving the veteran to) job interviews.

But even these efforts were not enough, considering the tremendous personal transformations that these veterans were experiencing (Smith-Morris et al. 2013). No small aspect of the VR counselor's task was to help veterans develop new ideas



about productivity and work in their post-injury capacities. One VR counselor reported having to do a significant amount of motivational work with her clients: “You have to find that caveat, that one carrot that they will grasp on to and say, ‘Wow!’ Because, I don’t want to oversimplify things, but when you present them with the right option, they will do it.”

The supported employment model demands more of the VR counselor than is typical for non-supported employment settings. But by offering more to the client in terms of support, the veteran’s sustained employment becomes more likely.

*Clinical Integration of the VR Counselor.* What is still unclear was *how* the VR counselor accomplished so much more than her non-supported employment counterparts. A portion of her success was attributable to a smaller caseload. However, as the ethnographers learned through duplicating the VR counselor’s driving and home/employer-visit schedule, the time savings of the smaller caseload were quickly and completely overshadowed by travel time to homes and communities within a 100-mile radius of the office.

More important to the VR counselor’s success was clinical integration, the first of the eight principles listed in Table 1. As an integral member of the existing interdisciplinary SCI treatment team, the VR counselor gained access to the treatment team’s resources, including clinical professionals and knowledge central to SCI rehabilitation. Persons with SCI have more frequent medical complications, such as urinary tract infections, skin issues, or depression. The VR counselor could communicate directly with the veteran’s physician, facilitate medical care when necessary, and offer input to treatment planning that connected the healing process to a return to work. The VR counselor also conducts job finding and utilizes techniques that may include job carving, job coaching, and follow-along with employers that must be informed by a veteran’s medical status. These are all listed in the principles of supported employment and so were the focus of the RCT itself.

*What Ethnography Adds.* What, then, did ethnography uncover that the RCT outcomes did not already capture? The medical ethnography was designed without reference to any specific elements of the model or even to the model itself, but rather as an open-ended exploration of salient issues and concerns of the informants. The structures and protocols of the program were important to understand. But it was the topic of integrated care that rose most frequently and naturally within staff discourse. As staff talked about the supported employment principles, and the challenges of meeting these guidelines, integration of care was mentioned far more often than any other as critical to their success. Here is how a non-researcher clinician spoke about the inclusion of the VR counselor in the Inter-Disciplinary Team (IDT) meetings:

[In the IDT meetings], we talk about cases—things that have happened with their medical [condition], things that have happened with people and how that has interfered or helped. Or maybe good things, like so-and-so had a medical issue that came up and [the VR counselor] rapidly referred him to me and we took care of it and avoided a problem. . . . [The VR counselor]

came to our IDT meeting [to tell us about this problem] and those are things that help.

This clinician is describing the novel feature of the SCI-VIP program; namely, the VR counselor's regular access to the inpatient clinical team—the same team of clinicians who cared for each client when she or he first received their SCI. Research staff members had this to say:

When the [inpatient] staff meeting occurs, we try to give an update on [SCI-VIP] enrollment. . . . We try to kind of keep it in the forefront of [the clinical staff's] minds.

We've been trying to kind of translate the success stories back to the team, so that they can see kind of the fruits of their labor in terms of what actually is happening; and try to facilitate some of that mutual learning process between the vocational clinician and the SCI clinician that didn't previously have any exposure to what voc rehab meant. So, you know, the vocational clinician maybe doesn't know what an OT [occupational therapist] does and so we've been sort of trying to cultivate this cross, the integration.

Cultivating communication and mutual support between VR and the other disciplines on the clinical team is a key part of integration of care, and is named by multiple types of staff as key to success of the supported employment model. By educating the clinical team on the principles and methods of the supported employment model, the trial expanded the normal purview of that team well beyond the clinic and into the communities and work settings of their patients. Likewise, clinical integration of the VR counselor promoted her greater knowledge of and sensitivity to the medical needs of veterans, yielding greater success in her own work.

The staff narratives above reveal that fidelity to the first principle of supported employment (i.e., integration) was often more important to the overall success of the program than any other. And although fidelity monitoring might capture the number and type of services provided or contacts made by the VR counselor, it could not capture or characterize what made the relationships work or the interactions successful. Thus, ethnographic findings complement the clinical trial outcomes for a more robust description of the model of care.

### *Teaching and Celebration*

The process of biannual fidelity monitoring reviews could be psychologically painful for those whose work was undergoing scrutiny. Identification of errors or gaps in records is meticulous and preparations for these site visits can be intense and worrisome. However, in their larger context, these reviews became a teachable moment and an opportunity for reviewers/coaches to offer support in this difficult work while promoting the program throughout the site.

The six-month [fidelity] eval., that's very useful. It's like a day and a half, and it's done at all the sites. . . . That includes, you know, opening sessions, and then meeting with different people, and then a closing session. . . . They

get information from the progress notes, but they also get information from the team. Like, say they talk to the team about [the VR counselor], how much is she coming to the [inpatient] team meetings, how well is integration working.

The biannual reviews were part of the clinical research protocol, but the political support and in-depth supervision and training that these reviews promoted were not. The fostering of a shared ethos around supported employment and its notions of integration and exceptional effort by VR counselors was a major undertaking. These biannual reviews, combined with many other smaller events and meetings at each individual site, provided the mechanisms through which a shared culture could be built among the diverse staff involved in the RCT.

Annual conferences of research staff from all sites included (again) training about the supported employment model for the staff and enjoyable trips out of the office, but also an enthusiastic session of awards and recognition for many of the project VR counselors and site coordinators. The positive and enduring effects of these celebrations could be heard in staff narratives many months later, as in this doctor's comments:

We have had annual meetings, and at the annual meeting we try to give people updates on the progress of the study as well as share successes and talk about the challenges and how we want to meet those challenges for the next plan. . . . [We] also focus on a little bit of skill building because we do bring in . . . our coach [on] the evidenced based principles. In the last meeting, which I think people enjoyed the most—and by enjoy, they say they got the most out of it—we set it up so that the front line people, the site coordinators and the VR counselors—were presenting information from their perspective on what recruitment strategies were working at their site. . . . And the VR counselor presented success stories, which was very energizing, motivating, and led to a lot of discussion of things.

The centrality of this culture-building to the overall success of the trial should not be underestimated, although it is not recorded as part of the trial's outcomes. Even so, to replicate this trial's success, future programmers will need to take seriously the need for a system of shared values and mechanisms of support for advancing these new ideas. Here again is the VR counselor:

You know, so you have to be all over the place. Be out there. With this program being so brand new and the whole notion of SCI and work, I think my first year was spent just doing a lot of marketing face to face, getting to know people, getting your name out there, getting the program's name out there, you know? Because people had to get used to the idea of people in wheel chairs going back to work, doing work outside of the computer, and just work outside of going to some kind of workshop. I mean real world work. So people have to kind of grasp that concept. I can say this though, now people are more friendly to the idea. I don't meet as much opposition about it.

Arguably, the mechanisms and processes through which RCT staff developed a shared focus—the culture behind the RCT—is pivotal to the success of any RCT. But these are precisely the aspects of care that are made invisible in outcome-based studies. Trial protocol demands that the model of care itself, not the variable context in which the model is implemented, is the factor of interest. Yet no matter how carefully we measure and count the interventions, time spent, and minutes invested, it somehow fails to convey the character of “the concept” and whether people are “friendly to the idea.”

### *Local Champions*

Finally, the genuine and wholehearted advocacy for the supported employment model by specific clinically influential staff could not be ignored and was a major theme in staff narratives. Our SCI-VIP site (recall we only operated at one of several nationwide sites of the clinical trial) had several advocates, each of whom might have been considered a local champion of its cause. A local-cause champion is a person of influence within a setting who can convince or lead others to join the cause. For the SCI-VIP, the most important champion would have been a physician on the SCI clinical team. For reasons of confidentiality, we will not reveal the professional role identity of these speakers, but a diversity of voices on the topic concur that a champion must be both knowledgeable and influential within the hierarchy of a given setting.

You get that local cheerleader in leadership. A cheerleader is not somebody who just loves the program. A cheerleader would be someone who talks it up all the time. . . . They talk up the program at staff meetings. They tell everybody, you know, show some caring. You motivate employees, you know, to be involved. You motivate them to do their best for the veterans.

When the program is running effectively, veterans tend to be referred to the program by their clinicians, and not solely recruited to the program by project staff. Here, a non-SCI-VIP staff person states:

Well, all of us have people that are enrolled in this. All of the clinicians have people that are enrolled. But yeah, so each of us, all of us have referred people. I feel like that's been a part of my role, is to make sure that things are clinically relevant and that the medical problems that might interfere with people's participation [in the SCI-VIP] are looked at and the appropriate people get into the study or don't get into the study, from a medical perspective.

Clinicians work with veterans regularly but may never have addressed work-related questions or treatment needs. When the topic of work is made relevant early in treatment, the likelihood of a return to work is not only increased but moved forward in time (Ottomanelli et al. 2012). Two veterans describe their introduction to the idea this way:

They have pamphlets and, at the outpatient desk, and they, the doctor asked me to participate in it. So after about two or three years of them asking me I finally decided to go ahead and try to participate in it and see what it was like.

I believe it was [my outpatient doctor] mentioned it to me while I was in for an appointment and told me about and I was interested in going back to work anyway, so it was like perfect timing.

Another clinician, reflecting on the experience at another site for the SCI-VIP, summarized:

In [another site], their performance kind of waxed and waned in terms of recruitment. And I think, I'm not sure how much the PI had the time to be a champion. And initially, I think most of the referrals were coming through the PI himself, when you can't get enough referrals through one person. It has to be through the team. So it was actually after that meeting in '08, where we did the success stories, where [he] made some comment about, "Oh, okay, I finally get it. We're not just kind of picking and choosing the people who we think are going to do well at voc rehab. We're offering it to everybody." So yeah, it's kind of like, it's important for the clinical champion not to necessarily be a screener as it is like, "Let's open this gate really well, let everybody through and . . . see how far they can go!"

Champions are the charismatic and influential leaders who draw attention to the program so that the scientific and evidence-based ideas develop some local enthusiasm and meaning. Further, they are authoritative members of the clinical team whose support for the otherwise burdensome change to normal operations is essential to short- and long-term integration of employment services in the clinical setting. The fact that these champions speak as existing insiders to clinical medicine gives the VR counselor not only a social and political support but a vehicle by which to enter the otherwise closed clinical realm. However, these champions must also be willing to use the administrative influence they have to support the myriad needs for implementing such a complex and novel new strategy. In short, no matter how great the quantifiable or scientific success of a program, it must be shared and spread through human relationships and power networks.

## Discussion—The Benefits and Challenges of Ethnography in Clinical Trials

One needs charts and soundings to navigate fraught channels, but only the seasoned river pilot has the lived-in wisdom to find the way safely through channels.

—Charon and Wyer (2008)

Ethnography gets behind the curtain of protocol and models, to describe what makes the RCT work. Ethnographic data on the SCI-VIP pointed to three main factors in staff culture and practice. These were, first, the personal forbearance of VR counselors and the client-by-client adjustments necessary to achieve the high

standards of the model's core principles. Second, there was in this trial, as is likely in many RCTs, an enormous investment in creating a shared vision of the trial's goals, a sense of community across the staff in multiple sites, and intentional efforts to foster throughout all levels of staff a high level of capacity, skill, and motivation. And third, locally influential clinicians had to invest in the treatment model and champion its cause in the surrounding political and professional contexts, for the trial to succeed. These themes represent a substantial body of evidence relevant to the trial's success, yet it is routinely excluded from the clinical literature.

How is it that the gold standard for scientific research would regularly ignore so much relevant information? Critiques of the RCT and of the evidence-based medicine movement have been steady over the past two decades.<sup>6</sup> Adams assesses the changing context of Tibetan practice under an increasingly biomedical marketplace (Adams 2002, 2005; Adams et al. 2005). The state enjoys the privilege of defining what is and what is not valid and safe medical practices, criminalizing certain traditional Tibetan practices for not conforming to dominant standards and definitions of care. That the RCT fails to consider patient views and narratives, ignores modalities that are less easily manipulated into standardized metrics (e.g., for physical therapy, see Landsman [2006]; for homeopathy, see Barry [2006]), or produces overly formulaic guidelines that do not translate well into individual patient care are among the major critiques of RCT (and evidence-based medicine) by social scientists (Lambert 2006). These scholars lament the over-valuation of the RCT as a tool for measuring what works, and the large and growing "audit culture" within biomedicine where notions of evidence, efficacy, and cost-effectiveness predominate (Barry 2006).<sup>7</sup>

Anthropological research suffers some of the same politico-scientific marginalization that Tibetan and homeopathic traditions have undergone. Our forms of evidence are typically excluded from dominant biomedical discourse and are relegated a standard far lower than gold in the hierarchy of scientific achievement (Landsman 2006; Mulligan 2010). Yet, to challenge biomedical and scientific suppression of knowledge is to take up a double-edged sword. Although we push the socio-cultural dimensions of health into a conversation that seems endlessly downward looking—microscopically and pharmaceutically focused—we are also professionally and humanistically compelled to seek the most effective healing options for our informants in their lived contexts. To succeed in arguments over what constitutes meaningful evidence, medical anthropologists must offer both theoretical and methodological remedies to this problem of effectiveness.

Toward this end, we consider and engage with the RCT more closely.<sup>8</sup> First, the RCT can take multiple forms (Schulz et al. 2010; Stolberg et al. 2004; Wells 1999). Efficacy trials examine whether treatments (e.g., talismans or pills) improve certain outcomes under controlled and isolating conditions. These types of studies are important for understanding biological, chemical, and physiological events, but are very limited in value for understanding homeopathy or faith healing. Effectiveness trials, on the other hand, evaluate treatments on health outcomes in conditions closer to normal care, including community settings. Effectiveness studies attempt to determine the feasibility of bringing a treatment to a population in need, and therefore sample representative patients. Effectiveness studies can also evaluate longer-term clinical and morbidity outcomes than efficacy trials. Broader

still are long-term ethnographic studies, which have the greatest ability to map the complexity and interrelatedness of variables in human life but which also seek out causal and explanatory patterns either intra- or inter-culturally, if not also over time.

Neither efficacy nor effectiveness trials deal as well or as fully with context as anthropological studies. We are sensitive to the admonitions of other scholars that RCTs, even effectiveness trials, can fail to holistically address the reality of clinical practice and of patients' lives. This stance can, thereby, put itself at odds with patient-centered care. We suggest that anthropological methods can improve both effectiveness and even efficacy trials in important ways.

The RCT we have presented was a hybrid of efficacy and effectiveness research that produced clinically significant results. However, it simultaneously produced several compelling ethnographic findings that offer insight into the forces shaping delivery of these programs in community settings. This RCT was distinctive in two ways:

1. The PIs envisioned the need for qualitative and anthropological perspectives early and then built these into the trial, addressing some of the gaps that should concern social scientists about what is touted as a gold standard of scientific research.
2. The treatment model we tested was a community-based intervention based on personalized methods and integration of the VR counselor into the larger clinical team. Given that the VR counselor was *simultaneously* providing community-based services while also serving as an integrated member of the clinical team, this model shows further hybridity of clinic- and community-based roles.

So, contrary to the stage-model required by the U.S. Food and Drug Administration for trials of a drug (U.S. FDA 2012) that requires careful determination of drug effects well before a drug can be tested on humans, clinical trials of service models should be hybridized at an earlier phase, as this supported employment trial was. The highly decontextualized and sterile form of RCT must *not* be considered the gold standard for these subjects and strategies.

Certain typical trial protocols were more useful than may have been expected at the onset of the research. Fidelity monitoring, in particular the quantitative test executed periodically during an RCT to ensure records and treatment conform to the model's principles, helped reveal the relative importance of integration to the rest of the model's principles and to the trial's overall success in this site. As discussed above, the principle of integration helped ensure a high degree of VR counselor flexibility and creativity in her work. And there was broad agreement among staff that integration was the most important aspect of the model. This strength is largely attributable to the supported employment model being tested, but some credit should also be given to the fidelity-monitoring process for capturing its relative importance among all of the model's principles.

Ethnography of these protocols identified key structural supports that made care more successful, easier, or more efficient. For example, the relative importance of integrated care to the overall success of the intervention emerged through grounded analysis of this narrative theme and through two independent codings of narratives.

That other principles did not emerge in the same way does not suggest they were unimportant to the trial, but does suggest that the first principle of integrated care is a fundamental or first concern for a successful intervention. The combination of careful qualitative analysis, in tandem with rigorous fidelity monitoring (of a highly context-sensitive model), helps make a good model for future social scientific research of and employing the RCT format.

The two other major ethnographic themes were less collaborative with the RCT process, but offered proof of the narrow view that most RCTs take to outcome evidence. The educational and celebration events aimed at ensuring our trial was successful were not an explicit part of the intervention model nor part of the evidence recognized by the gold standard CONSORT guidelines for reporting on RCTs (see Note 3 and Schulz et al. 2010). These celebratory and training/supervisory events produced information (well known to the staff) that would normally be considered background to the trial or part of the procedures manuals of a clinical intervention, rather than part of its published findings. Ethnographic analysis of these events revealed that these events had a major impact on staff's ability and resources to enact the protocols. Local project champions likewise were not an explicit part of the trial's protocol, yet they ensured locally authoritative support for the VR counselor's integration as well as needed training and professional development along the way. These events create the needed common culture and mobilize social capital for the trial.

In sum, ethnographic data fill gaps of knowledge that traditional RCTs have created. These research methodologies, when embedded within clinical trials, help redefine and decolonize notions of evidence. Through these hybrid RCTs, evidence is expanded to include not just CONSORT guidelines and statistically significant outcomes, but better information about "essential methodological factors" (Devereaux et al. 2002:381) that would allow "clinicians to tailor treatment strategies to the social and cultural needs of their patients" (Hohmann and Shear 2002:201).

## Conclusion

There were limitations and challenges to this anthropological ethnography. It was limited both in its duration—it did not span the entire course of the trial—and in its depth—only part-time ethnographic study was conducted, and in only one of the three clinical trial sites. In the future, it would be important to address these weaknesses through long-term investigation of the intervention at all sites, ideally from its conceptualization through its conclusion. However, the access ethnographic staff had to both clinical and home sites was quite good. Further, because of this trial's design, which included home and community settings, there was a diversity of settings for which ethnographic methods are well suited. The findings described here are being used to improve the design and reach of a subsequent iteration of this trial, specifically for long-term placement of and follow-up with participants in the supported employment program.

Ethnographic data offer critical evidence about outcomes and about performance of treatment models that expand the impact of an RCT. The complementarity of ethnographic methods to clinical trials, particularly to fidelity-driven research



models, is an opportunity to impact what evidence counts. A supplemental team of anthropological researchers can offer substantially different and relevant data on both the model being tested and on any RCT process and context. This model helps pave a new direction in the field of qualitative evaluation research, but also encourages more clinical and trial-based applications of medical anthropology.

## Notes

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1. A distinction is made between efficacy trials, typically conducted in tightly controlled clinical or laboratory settings, and effectiveness trials, for which some of the controls are relaxed to achieve samples that are more representative of the community in which the intervention is likely to be delivered (Solomon et al. 2009; Stolberg et al. 2004). This distinction is blurred for this discussion of our RCT because it had elements of both types of trial.

2. The CONSORT Guidelines include a 25-item checklist of information to include when reporting an RCT such as: methods for randomization, allocation, and blinding; details on participant flow, recruitment, outcomes and estimation; and discussion of limitations, generalizability, and interpretations (Schulz et al. 2010).

3. Savage summarizes and defines ethnography as it is typically applied in clinical settings as the “study [of] phenomena in their everyday context . . . in an attempt to secure an in-depth understanding” (Savage 2006:284). Our methodology might further be described as a “naturalist ethnography” (Skeggs 2001) to present our data “in a way that conveys a sense of ‘being there’, or indicates the nature of the relationship/s between the research and the researched” (Savage 2006:385). Finally, it is also an applied ethnography, since its focus on the clinical trial is a “narrow field of inquiry” and targets more specific research questions than the traditional descriptive study might address (Savage 2000:388).

4. As previously stated, this article discusses only one portion of the ethnography, namely the study of the trial’s design and implementation. Intensive ethnography was also conducted among patients to expand the trial’s findings for veteran patients and their outcomes, though those results are reported elsewhere. It is important to note that there would have been interactions between the availability of these data to staff *during* the trial and their subsequent motivation, and sense of accomplishment (or failure). This point is taken up in the ethnographic findings section.

5. Fidelity to the supported employment model was measured in a number of ways. Biannually, the program records of SCI-VIP as well as participant medical records are reviewed to assess the degree to which the program (documented in these notes) adheres to the principles of evidence-based supported employment described by Bond (2008a; 2008b). During site visits, consultant trainers gather data on program fidelity through semi-structured interviews with consumers, employers, clinicians, program managers, health care team members, administrative management and leadership; chart reviews; and observation of team meetings. A fidelity scale for supported employment that has been widely used and

is consistently linked with employment outcomes among programs that serve persons with mental illness was also used in SCI-VIP (Becker et al. 2001; Bond et al. 2008b).

6. A very useful review of this literature begins with Mykhalovskiy and Weir's 2004 publication, followed by a special issue of *Social Science & Medicine* in 2006 on social science perspectives on evidence-based health care. Adams's work in this field (specifically for Tibet (2002; Adams et al. 2005), is particularly compelling, as is Timmerman and Almeling's broader review and discussion of standardization and objectification in modern medicine (2009).

7. Barry suggests three main problems with the audit culture's reliance on RCTs: (1) a preponderance of gaps in the evidence base, owing to the very narrow gaze of each controlled trial; (2) the failure of RCT evidence to address the reality of clinical practice; and (3) conflicts of evidence-oriented medicine "with other accepted healthcare policies, such as patient-centred medicine, characterized by increasing involvement of patients in decision-making about healthcare" (Barry 2006:2649–2650). She does not, however, address the distinction between efficacy trials and effectiveness trials (see Note 1). Her argument is best aimed at the more highly controlled efficacy trials. In fact, effectiveness trials have come into practice to address some of the concerns that Barry raises.

8. We acknowledge that this stance, and our contribution to the debate over evidence-based medicine (EBM), may prove part of an "assimilationist response" of biomedicine to the criticisms of EBM. Lambert's 2006 discussion of these criticisms, and biomedicine's strategic responses to them, is exceptionally good. But if, following the model our research offers, more RCT scientists work to incorporate ethnographic data and holistic perspectives into the very models they are testing, then the sanctity of research evidence may well be broken and expanded.

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