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How Turning a QI Project into “Research” Almost Sank a Great Program

BY LUCY M. CANDIB

Two years ago I had a great idea. I was able to put two disparate thoughts together in the same sector of my brain. One thought was that the low-income patients of my health center needed a place to exercise at no cost. The other was that the local YWCA, where I had been exercising for twenty years, offered institutional memberships to local agencies, like day care centers, which used these memberships as a staff benefit or incentive. My idea was to purchase institutional memberships for our patients as a new intervention that we could offer in the management of chronic disease. Institutional memberships cost the same as a membership for a family of four, but they allow any four members of an agency to use the cards whenever the facility is open. When a staff member comes from an agency to exercise, she swaps some form of identification for one of the assigned magnetic cards and then has use of all the exercise areas—pool, gym, strength room, aerobics classes, and so on. I checked with the membership coordinator about whether she would be open to offering YWCA institutional memberships to our patients, and she was happy to say, “Yes, why not?” The local community mental health center had recently made a similar arrangement for their patients.

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I immediately sent out a flurry of emails to every doctor and nurse practitioner at the health center. I also contacted residents who had graduated from our program and former faculty, asking them to send me money or checks written to the YWCA to buy these memberships. Each would cost \$875, or only \$850 if we paid the total up front. Within two weeks I had raised \$1,700. I also wanted to be sure that health center employees would benefit from the project, so I decided to raise money for a staff membership as well. One former graduate called me and asked, “How much money do you need, Luce?” I told him I needed \$850 for a staff membership, and he said, “Hey, I blow that much at the track every week! No problem.” The check was in the mail.

So we started out with two institutional memberships for patients (eight cards) and one for staff (four cards). I had to work through the grants and contracts officer to get everything signed, but the deal was done. I emailed all the providers that they could start referring patients to the YWCA. All they had to do was give the patient a little blue Family Health Center registration card that, up till that point, had no real function. The plan was that each patient would go down to the YWCA and get an orientation, during which he or she would make an appointment for a one-on-one introduction to the strength training room. Patients could attend any aerobics class, and those who wanted to swim could get the pool schedule and start immediately.

This process was like scattering bird seed in a public park. Pretty soon the pigeons were landing around me and crowding each other out. I had multiple phone calls from the YWCA, providers, and patients, sometimes all in the same day. We needed more cards. They needed more Spanish-speaking interpreters. The first version of our medical clearance form was inadequate. Patients missed appointments for the strength room orientation. Some people tried to use the room without the introduction. Some people brought their friends without a card. Some not yet sixteen years old—the cut-off for the strength room—tried to get in with a fake ID. At the end of the first month the YWCA sent me the original sign-in list of all the patients who had attended, but since the signatures were illegible, I had no way to decipher who had gone. We decided that patients should sign in with their medical record number, which was, after all, on the little blue card. At the end of the second month we had to buy an additional membership because when all the cards were in use, patients were having to wait to get in. We had more than eight patients wanting to exercise at the same time! By now, usable data was flowing in: hundreds of names and chart numbers of the patients who had exercised each day of the month. I began keeping track of the names myself, a task that initially took only a few hours a month.

The medical clearance form was more complicated. The fitness instructors wanted a lot of medical informa-

tion available to them on some kind of form, but I didn't want to create a new barrier for providers by requiring them to complete a complicated referral form. Together with the fitness staff and our own sports medicine physician, we devised a one-page form that covered medical problems, medications, goals of exercise, and current and past exercise activities. It also stated what kinds of exercise, and at what level of intensity, the provider recommended. The provider and the patient both had to sign the form.

Within six months I had a lot of data. When the exercise list was cross-matched to the patient registration data at the office, I was able to identify patients with diabetes who had started to exercise. One patient with diabetes lowered his Hb_{A1c} from 13 percent to 6.9 percent—a terrific improvement in an indicator that we watch closely. Others made less spectacular but still clinically important reductions. I was very excited about the results and quickly broadcast the great news to providers. They referred more patients. The YWCA hired more bilingual staff. The availability of free exercise gave our providers a concrete intervention they could offer to patients willing to make lifestyle changes. The influx of people of color into the YWCA fulfilled one of the goals of their mission statement: to eliminate racism. We had a win-win situation for patients, providers, and both institutions.

The close of our first year brought some wonderful news. One of our state Medicaid programs, encouraged by patient interest in the program, offered to fund two memberships. A colleague began an affiliated formal research project that studied group exercise visits for Latino patients with diabetes, with the grant for this research paying for another membership. Additionally, the health center's Board of Directors decided to make staff access to the YWCA a standing employee benefit—in essence establishing a lasting commitment to providing a staff membership. My individual fundraising efforts were over. I corralled health-center volunteers to continue entering names in the database, a task that was now taking eight hours a month of my personal time. We had over six thousand exercise visits in the first year.



I had not conceived of this project as research. I thought I was building a community link between the health center where I had worked for thirty years and my exercise home, the YWCA, where I had comfortable relationships with nu-

merous people. I was not asking anyone to do anything experimental. I had no control group. I applied for no grants to get the project going. I had no formal, predesignated primary and secondary endpoints, expected sample sizes, nor a strategy for randomization. But I certainly was interested in what would happen as a result of this straightforward intervention, and I hoped that the project would enable our patients to exercise. I had started a little ball rolling that would eventually turn into a boulder.

In October of 2004 I presented the first six months of results at the CDC Women and Diabetes conference in Savannah, Georgia.¹ Amidst many programs aimed at low-income

people with diabetes, only one other place in the country (a YWCA in Alaska) was doing anything similar. I was on to something. Then, somewhere along the line, someone asked if I had IRB approval. IRB approval? Well, no, that hadn't occurred to me. I had started a program, and I was evaluating it on our own terms at the health center. It was a kind of quality improvement project—could we make open access to exercise available to our multiethnic, low-income patients? I wasn't recruiting people into an experiment; I was making a service accessible to them. My questions, insofar as I had questions at the outset, were more like: Could the two agencies collaborate over the long term? And, “if

you build it, will they come?”

We did have to follow some rules. Patients signed a paper authorizing us to release their medical information on the exercise clearance form to the YWCA. But it never crossed my mind to check with the local medical school IRB before keeping track of our patients' exercise activity—that did not seem to be research.

Our health center is a free-standing, nonprofit entity independent of the local medical school, even though we teach medical students and train family practice residents at the health center. I am also on the faculty. Still, we have our own internal equivalent of an IRB, the Program and Policies Committee of the Board of Directors. (By law, 51 percent of the board members of a federally funded community health center must be consumers—that is, patients at the health center.) This committee must approve all programs in the center. They were well aware of the YWCA exercise project from board reports from the medical director, from the plan to make staff access an employee benefit, and from the growing collaboration with the YWCA. The P and P Committee approved my work, and the data collection was well within the

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quality improvement work of measuring and evaluating our progress in encouraging self-management for chronic disease. I was, I thought, working within the community partnership section of the chronic care model. No IRB for me.

I understand that the point of the IRB review is to protect patients from unethical practices and unintentional abuses. I fully support the need for patients to be fully informed about any risks from entering a research project. I had in fact gone through the IRB process for a research investigation eight years earlier. That time, I intended to offer an experimental intervention for chronic pain and study the results. However, I found the process so frustrating that I finally gave a seminar on my frustration at a national meeting.² Along with the well-known challenges of doing research in a community health center,³ I had faced the problem of working with IRB-mandated consent forms. The project almost died when I had to administer an eight-page, legally-worded human subjects form in English or Spanish to the fifty-odd adults with chronic pain. These patients had to sign a form that they could not understand—it was designed for, written by, and directed to lawyers, not patients. The last thing I wanted to do was place another barrier between patients and exercise. This time, I sought help from experienced investigators, some with close contacts with the IRB.

Experts differed about whether our program needed IRB approval. Some said, “No, it is truly a quality improvement project, with no intervention.” For instance, the chronic disease projects promoted by the Institute for Healthcare Improvement did not seek IRB approval and were not designed as research projects.⁴ Others said, “Oh, yes, you do. If you are going to publish this information, medical journals will insist that you have IRB approval.” The quality assurance expert in the department said I had to do it—but that it wouldn’t be too bad. She would help. I argued it up and down. I sighed and kicked and screamed. We applied for IRB approval.

Well-meaning people helped me with the IRB process and did much of the paperwork. The leadership in my department wanted to support me and promote the project. Still, this homemade follow-up project did not fit easily into the form developed for experimental design required by the medical school IRB. The IRB asked questions about when “the study” would end and how many “subjects” would be included. I was not enrolling a specified number of patients; rather, those who were interested were enrolling themselves. Since we planned to continue following our patients’ exercise activities, I thought it would be “ongoing”; we had no plans to stop tracking the exercise events, any more than we planned to stop keeping track of lots of other things—visits, no-show rate, and disease management registries. Nevertheless, in their first response to me, the IRB pushed: “Please provide an expected time period; ‘ongoing’ is not acceptable.” But the line that galled me the most was this:

Page 1, #3.b: It is stated that this program began in March 2004 and had immediate success. What is the difference between what had been ongoing and what is being implemented? Please provide more background information. Why is this now research?⁵

My point exactly! I am doing just what I was doing and need IRB approval. There *is* no difference between “what had been ongoing and what is being implemented.” We seemed to be going in circles. If the IRB doesn’t think this qualifies as “research,” then why can’t we consider this surveillance? And, therefore, why do I need IRB approval?

Six months of negotiations and disparaging comments. “There are sections missing from the table.” “The protocol for data collection is not well defined.” You didn’t specify this person’s role. Your HIPAA form is not compliant. You did not specify this or that. We asked for a waiver for having patients sign a consent form about the project on the grounds that it would be unduly burdensome. (The harried provider has only fifteen minutes with the often complex patient. The provider is already completing an exercise form with the patient and having him or her sign that. Why yet another form?) Ultimately, the IRB agreed to let us get verbal consent from patients for the project as long as we explained and handed them an IRB approved fact sheet, but every patient would still have to sign a HIPAA form allowing us to look at their personal health information—even though following their health data was already a part of their chronic health care.

Okay, two forms, the YWCA form and the HIPAA form. I could swallow that. But then it got worse:

It would not be unreasonable or burdensome for the PI to obtain consents, especially since subjects will be asked to sign a permission slip to have their medical information released to the YWCA. . . . Please identify who will be obtaining consent and collecting data . . . All key personnel (direct subject contact, or access to confidential information about the subjects) who are involved in this research study, are required to successfully complete the Human Subjects Educational Training located at <http://www. . . .edu/subjects/human>.⁶

In other words, only people who have taken the online, three-plus hour human subjects educational training test (and passed it) can explain the project, hand out the fact sheet, and administer the HIPAA form to the patients. As best I can tell, among some thirty-five providers, only five physicians have taken this test, as well as the nurse and two educators involved in diabetes management. Now, in order to keep track of the results, we would have to go back and explain the project and try to get forms signed by all those already exercising (about one thousand people at present), and going forward we would have to get signatures when referring patients to exercise. None of the three nurses or four medical assistants on my team (one of three teams at the health center) had ever been involved in

research. The few who had already passed the human subjects test are already far too busy. Asking these few to give out the fact sheet and administer the HIPAA form to potential exercisers is, in actuality, “unreasonable” and “burdensome.” As in other settings, such obstacles will deter providers from referring patients.⁷ The quality-improvement-to-research transition was proving the point: health centers are good at QI and should do more of it; but research is very hard to do in a community health center.⁸

Quality assurance people wonder, “Why isn’t quality improvement work published more often?” After I sent this story to the department’s quality improvement expert, she gave me a copy of Davidoff and Batalden’s paper on publication guidelines for quality improvement. I found that they had already written about my problem—that quality improvement projects are now being considered research.

To complicate matters, since quality improvement in medicine virtually always involves human participants, quality improvement work that is published is now frequently considered to be a form of human subject research. Framed in those terms, virtually all quality improvement immediately becomes subject to the regulatory mechanisms that govern clinical research—most importantly, protection of human subjects through ethics committee or Institutional Review Board (IRB) review.⁹

These authors see that under the “Common Rule” governing the conduct of federally funded research in the United States, QI projects are having to go through the IRB process even though the Common Rule itself acknowledges that an intervention designed to enhance the well-being of individuals or groups is “a procedure applied in practice” and does not need to be considered as research.¹⁰ Davidoff and Batalden go on to recognize that the IRB process can be an impediment to quality improvement:

Most IRBs are overburdened, understaffed, and underfunded; formal IRB review is generally slow and cumbersome; IRB judgments are often inconsistent; and most IRBs have little familiarity with the nature and methodologies of quality improvement. Requiring all quality improvement efforts to undergo such review could therefore have the paradoxical and damaging result of actually discouraging improvements in care.¹¹

Although I was happy with the thirteen thousand patient exercise visits we had by now achieved, I was certainly discouraged about finding a way to keep track of the outcome and to let others know about it. I was ready to let it all drop multiple times in the IRB process. The only thing that kept me going was seeing my patients on the treadmill, in the pool, in the locker room, beaming about their access to exercise and glowing with better health.¹² The stories of the changes for these patients will have to wait for a paper on narratives and QI.¹³ No doubt that will require an amendment to the IRB application.

The IRB finally gave the project their blessing, with the above requirements. The only concession from the IRB was that patients would not have to sign a specific consent form for the project. Patients must sign the clearance form to release their data to the YWCA and will receive a fact sheet about the project. A person who has passed the human subjects educational training will explain the project and administer the HIPAA form. I am collaborating with my colleagues to find ways to get these forms signed. We will try to get patients to sign the form in groups; we will try to help the medical assistants take the three-hour test with coaching from a medical student and volunteers. I will need a lot of help to make this project

work—help from people from outside the health center who are not struggling with the urgencies of patient care.

Many people have already helped with this project and its mundane hassles. Someone ran around making three copies of the IRB proposal and got them all signed by all the “investigators” and collaborators and then the department chair before submission. Others heard me out as I railed against the circus nature of the hoops we were jumping through. Others met patiently with me over Vietnamese noodle soup to smooth out the rough spots in getting open access to exercise for a thousand low-income people. Others still—primarily the staff at the Y—carefully managed the daily pressures of orienting our non-English-speaking patients and checking them in when they came for exercise. I was not alone in making it work, but the decision to look at the impact of the project on patients was mine. Still, I am a family doctor, not a formal researcher or experimental scientist. I like to come up with good ideas and get things done. We already know exercise is good for people; we don’t need to prove it—we just need to make it happen. My frustration with this whole process will make me think twice about turning my next good

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idea into a project. Too bad that if I want to evaluate it or write about it, it will have to be called “research.”

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2. L. M. Candib, “Clinical Trials and Tribulations: Learning from My Mistakes in Research” (Seminar at the STFM Annual Spring Conference, Orlando, Fl., May 4, 2000).

3. S.C. Lemon et al., “Challenges to Research in Urban Community Health Centers,” *American Journal of Public Health* 96 (2006): 626-28; R.A. Fried, *Research in Community Health Centers* (Washington, D.C.: National Association of Community Health Centers, 1998).

4. Institute for Healthcare Improvement, home page, <http://www.ihp.org/ihp>.

5. IRB Administrator, expedited review Docket #H-11874 (electronic communication to Lucy M. Candib, Worcester, Mass., Dec. 22, 2005).

6. Ibid.

7. S.M. Anderson and M.V. Bloom, “The Effect of Institutional Review Board (IRB) Requirements on Levels of Clinician Participation in a Research Study,” poster presentation at the Society of Teachers of Family Medicine Annual Meeting, San Francisco, Calif., April 26-29, 2006.

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9. F. Davidoff and P. Batalden, “Toward Stronger Evidence on Quality Improvement—Draft Publication Guidelines: The Beginning of a Consensus Project,” *Quality and Safety in Health Care* 14, no. 5 (2005): 319-25.

10. Ibid.

11. Ibid.

12. L.M. Candib, “When the Doctor Takes Off Her Clothes: Reflections on Being Seen by Patients in the Exercise Setting,” *Families, Systems, and Health* 17 (1999): 349-63.

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Unscientific Ethics: *Science and Selective Ethics*

BY DAVID BENATAR

Biological, medical, and other scientists have a much greater interest in ethics than they once did. Many scientists speak of the importance of conducting science in an ethical way and for ethical purposes. They commonly proclaim that science should not advance unfettered by moral constraints and without ethical evaluation. Accordingly, scientific journals and books are increasingly interested in including articles providing ethical analysis of scientific matters. All things considered, this development is welcome, not only because attention to ethical issues is important, but also because the trend feeds itself—it causes more and more people to become interested in and give attention to ethical issues.

The problem with trends is that they are often not very reflective. They are not created by vast numbers of independently minded people coincidentally having the same idea. Instead, they emerge as increasing numbers of people emulate others. When the trend is greater attention to ethics, the danger is that the interest will not always be genuine. In other words, when all those around one are professing the importance of ethics, there is (often unconscious) pressure on one to offer similar professions, whether one has a deep commitment to the idea or not. As a result many people will pay mere lip

David Benatar, “Unscientific Ethics: Science and Selective Ethics,” *Hastings Center Report* 37, no. 1 (2007): 30-32.

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