"Democratizing" Clinical Research?
Efficiency and Inclusiveness in an Electronic Primary Care Research Network

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Brenda L. Hudson

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Carol Berkenkotter, Ph.D., Adviser

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Abstract

This dissertation is a critical ethnography and rhetorical study of the development of an electronic network designed to advance medical research and improve health. Specifically, this study focuses on the network's social and technological affordances of efficiency and inclusiveness to connect communities of primary care physicians and clinical researchers to both expand participation in and expedite the research process. By examining the network's technical elements aligned with its social context, the assumptions that influence the choice of technologies, and the network's subsequent design, Brenda L. Hudson explores the network's hierarchical structure and potential democratizing capabilities in clinical research.

Through field notes, interviews, and textual analysis, Hudson provides a micro-level examination of the electronic network's development and technical affordances during the program's three-year funded contract. An ethnographic narrative describes how the group functions as a "community of practice" to create a network linking primary care practices with clinical research. Further, Hudson provides a macro-level examination that draws on critical theories of technology and explores to what extent the network might serve as a "democratic" technology through its involvement of previously unprivileged populations in clinical research—primary care providers and patients.

Results indicate that assumptions of efficiency and inclusiveness in clinical research—and specifically in the network's technical affordances—provide potential benefits to patients' health by widening the pool of researchers and participants and streamlining the recruitment process. However, manifest in this electronic network, these assumptions also pose potential risks and ethical challenges surrounding private health information and "therapeutic misconception," whereby a research participant believes that enrolling in a research study will provide direct therapeutic benefit. Further results indicate that although the development team has done much to assure a "democratic" development of use of technology by operating as a "community of practice," there exist unintentional asymmetrical hierarchies of who controls and uses the network, favoring primary care providers and practices that already exist in clinical research.

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Chapter One:
Introduction

This study examines the development of an electronic network geared to advance medical research and improve health. Specifically, this study focuses on the network's social and technological affordances of efficiency and inclusiveness to connect communities of primary care physicians and clinical researchers to both expand participation in and expedite the research process. By examining the network's technical elements alongside its social context, and the assumptions that influence the choice of technologies and the network's subsequent design, I aim to uncover the network's hierarchical structure and democratizing capabilities in clinical research.

In this chapter, I first provide background and context for the study, including a brief introduction to clinical research (in short, patient-oriented research), the National Institutes of Health's (NIH) initiative to further involve primary care in the nation's research enterprise, and the NIH-funded electronic Primary Care Research Network (ePCRN) project, the subject of my study. Next, I introduce the focus and theoretical framework of my study, explanation of the study's significance, and description of each chapter.

Background and Context

> *Clinical research is a vital component of progress toward improving America's health. But while clinical research helps insure that new treatments are safe and effective, it is a* ***lengthy*** *and sometimes* ***inefficient*** *process. The current system of clinical research must be* ***re-engineered*** *if it is to respond to these changing scientific and health care needs. Meeting*

> *these demands will require **new** and more **efficient** approaches to discovery and clinical validation of research results.*
> NIH: Re-engineering the Clinical Research Enterprise, 2005 (emphasis mine)

In medical research, basic science discoveries in the laboratory are transformed into drugs, treatments, or prevention methods to improve human health. Ideally, translation of discovery to clinical application would occur quickly and efficiently, with relevance across the nation's population. Yet, it is estimated that only 14% of research findings make their way into everyday clinical practice, and those that do typically take 17 years (Balas & Boren, 2000). In addition, a "disconnect" exists between research and clinical practice as most research is conducted in academic medical centers, which accommodate less than 1% of Americans visiting physicians, with the following consequences: "research may not translate expeditiously to everyday practice, and clinical problems encountered in everyday practice are often underinvesitgated" (Tierney et al., 2007, p. 243).

National Institutes of Health (NIH) and the Roadmap Initiative

These challenges have been recognized by the National Institutes of Health (NIH), the nation's main funding agency for medical research, which in September 2003 announced a major initiative to accelerate medical research progress.[1] In an effort to meet the health needs of the twenty-first century, the NIH Roadmap for Medical Research was launched to "transform the nation's medical research capabilities and speed the

[1] Part of the U.S. Department of Health and Human Services, the NIH annually invests over $28 billion in medical research: "More than 83% of the NIH's funding is awarded through almost 50,000 competitive grants to more than 325,000 researchers at over 3,000 universities, medical schools, and other research institutions in every state and around the world" (NIH, 2007).

movement of research discoveries from the bench to the bedside" (NIH, 2005). Underlying this initiative is the assumption that public health will directly benefit by *accelerating* the pace of discovery and *translating* that knowledge into new prevention strategies, new diagnostics, and new treatments. To achieve this, the NIH identified three areas of focus: improving understanding of biology, fostering interdisciplinary research teams, and reshaping clinical research. These three areas address overlapping concerns with a common goal in transforming medical research; however, my study focuses on "Re-engineering the Clinical Research Enterprise," the NIH's aim to reshape clinical research by "adopting a systematic infrastructure that will better serve the evolving field of scientific discovery" (NIH, 2009a).

Coinciding with the NIH Roadmap launch, the authors of a 2003 report in the *Journal of the American Medical Association* highlight the importance of overhauling the nation's research infrastructure to benefit public health: "Without mechanisms and infrastructure to accomplish this transition [from basic science to the public] in a systematic and coherent way, the sum of the data and information produced by the basic science enterprise will not result in tangible public benefit" (Sung et al., 2003, p. 1279). This same article identifies "information systems" as a key means to help address the "crisis" in clinical research (ibid.).

It is important to note that implicit in the NIH Roadmap initiative are two aims: *efficiency*—accelerating the process of conducting research and making those findings known to other researchers, practitioners, and the public—and *inclusiveness*—allowing for more clinically relevant research and broadening the study-participant population to

more closely represent the nation's diverse patient population. Toward the goals of obtaining efficiency and inclusiveness in clinical research, in 2004 the Roadmap initiative funded development of a new electronic network to link researchers with primary care providers who, although not typically involved in clinical research, see most of the nation's patients.

electronic Primary Care Research Network (ePCRN)

The electronic Primary Care Research Network (ePCRN), based at the University of Minnesota, was funded so that researchers and primary care physicians may more easily and systematically collaborate—widening the pool of available study participants while streamlining the research process and reducing the amount of time it takes to translate new findings into primary care practices, and thus, to the public.

The ePCRN's principal investigator is a primary care physician and researcher with experience leading clinical trials based in primary care clinics. From this vantage point, he had identified a need for an electronic network to better coordinate and expedite clinical research that draws on the expertise and perspective of primary care providers. With a team of clinical and information technology experts, he submitted a proposal for an NIH Roadmap contract in 2004, outlining "the development of an electronic infrastructure that facilitates the recruitment of subjects and the performance of RCTs [randomized controlled trials] in primary care practices anywhere in the United States, and that promotes the rapid integration of new research findings into primary care" (Peterson, 2004, p. 3).

The stated objectives for the three-year project are:

- To provide a Web portal[2] that will enable primary care practices anywhere in the United States to link with researchers in academic centers or NIH to facilitate recruitment, entry, and follow-up of multidisciplinary randomized controlled trials.

- To establish a clinic-based registry[3] in primary care using distributed database technology[4] that interfaces with the Web portal solution in order to enhance the process of clinical trials recruitment and the translation of research findings into practice.

- To port a combined solution to open-source Internet2 components[5] that will allow additional functionality including real-time opportunistic identification of subjects by primary care clinics, enhanced communication, additional decision support for providers, enhanced security, and warehousing of trial data[6] (ibid., p. 3).

These objectives were developed to address the existing challenges to greater participation of primary care providers and patients in clinical research. These challenges, noted in the ePCRN proposal, include a lack of or difficulty in: identifying and inviting potential subjects in a standardized way across multiple study sites; prompting trial information when eligible patients arrive at a primary care office; delivering complex interventions in a standard way across multiple sites; tracking subjects as they change address or change practice during the trial follow-up; ensuring privacy, confidentiality, and human subjects protection issues; and, providing cost-effective research training and

[2] A Web-portal is a Web site that acts as an entry point to other Web sites or pages. See also Appendix A.
[3] A clinic-based registry is a list of all the patients in a physician's practice who share some characteristic, such as a certain condition or medication regimen. See also Appendix A.
[4] Distributed database technology refers to a database in which portions of the database are stored on different computers within a network, but which is managed centrally. See also Appendix A.
[5] Open-source refers to computer software for which the source code is freely available. Internet2 provides advanced, high-speed, high-capacity networking applications among its consortium members in academia, industry, and government. See also Appendix A.
[6] Data warehousing refers to the means to retrieve and analyze data from various databases. See also Appendix A.

monitoring across a large geographic area (Peterson, 2004).

In addition to accelerating the conduct of research, there also is a need for expediting "translation" of research into practice. For instance, the principal investigator notes in the proposal: "The rapid expansion of knowledge and an explosion of medical literature strain the ability of clinicians to keep up with the latest recommendations. …. As more information becomes available at a faster pace, greater reliance is needed on evidence-based data to inform practice. In addition, isolation of primary care from participatory research appears to further aggravate the delay between the discovery of new research findings and the adoption of those findings into practice" (ibid., p. 5).

The ePCRN proposal outlines how an electronic network can address these challenges by electronically networking 6,500 physicians to perform research in more than 2,700 primary care practices in the United States. Using Internet2 and access grid[7] technologies, the ePCRN development team aims to aid recruitment of study participants and support primary care providers in conducting clinical trials within their practices—leading, it is hoped, to more rapid integration of new research findings into the primary care setting and to the public.

Specifically, by virtue of its electronic infrastructure, the ePCRN is designed to allow primary care providers and their patients to participate in clinical research to a greater extent than before. Primary care physicians will be notified electronically of clinical trials in which their patients may be eligible (for instance, individual patient

[7] Internet2 technology provides advanced, high-speed, high-capacity networking applications among its consortium members in academia, industry, and government. Access grid technology allows groups at different physical locations to interactively collaborate using high-quality audio, multiple video streams, and digital presentation resources. See also Appendix A.

records may be flagged when specific criteria are met). The physician may then discuss with the patient the possibility of participating in the study, and if the patient is willing, the physician will administer the study protocol as outlined via the network's technological infrastructure. In essence, the primary care physician becomes a co-investigator of the study, with the potential for many physicians and their patients to participate nationwide. De-identified data is then sent to the principal investigator(s) and once completed, study results are directly communicated to the participating physicians, as well as being more broadly published in journals. Primary care physicians also may contribute to the research enterprise by collaborating with academic centers on clinical issues that are relevant to their practices and patients.

Importantly, the ePCRN team[8] recognizes that, although this project is based on technology, key aspects of its success depend on building relationships among researchers, physicians, and patients / potential participants. "Although the proposal is heavily invested in the development of cutting edge technology, *the technologic issues are perhaps among the least likely to cause significant challenges*" (Peterson, 2004, p. 29, emphasis mine). For instance, the principal investigator cites "maintaining interest among the participants" and "local resources in the clinics" as potential issues. While primary care providers may be interested to perform research, conducting studies may have "unintentional but substantial burdens on the local clinical research team. .... Busy practitioners are showered with competing demands, and it is important that their work be accompanied by perceived value" (ibid.).

[8] See Appendix B for list of ePCRN team members and their roles.

The ePCRN model attempts to overcome these challenges by combining new technology in collaboration with the expertise and relationships of practice-based research networks (PBRNs), which have a history and vested interest in combining research and primary care. PBRNs represent groups of primary care physicians in multiple practice sites (both academic and community-based) who work with each other and research investigators to study health care issues of mutual interest (Fagnan et al., 2007).[9] Common topics of research in PBRNs include prevention, diabetes, cardiovascular risk factors, and mental health (Tierney et al., 2007). In addition, the ePCRN also collaborates with the Federation of Practice-Based Research Networks (FPBRN), the single national organization representing primary care PBRNs in the United States, comprising 58 network members and affiliates (American Academy of Family Physicians, 2010). FPBRN membership includes all disciplines of primary care research, including the national networks from the American Academy of Family Physicians, the American College of Physicians/ American Society of Internal Medicine, the American Academy of Pediatrics, and the American College of Nurse Practitioners. FPBRN members have an estimated accessible population of 16 million individuals (ibid.).[10]

The proposal describes the notable role practice-based research network members

[9] Populations within the primary care community and relevant funding agencies in the United States government have recognized the potential benefits of tapping into primary care settings. In 1999, the Agency for Healthcare Research and Quality (AHRQ) was designated by Congress to "serve as the principal source of funding for primary care research in the Department of Health and Human Services" (AHRQ, n.d.). Under this remit, the AHRQ funds practice-based research networks, which have grown from a reported 28 in 1994 to 111 in 2004. AHRQ currently provides infrastructure support for over 50 regional and national PBRNs (AHRQ, 2006).

[10] For a comprehensive history of the FPBRN and PBRNs, see Green & Hickner (2006).

across the nation serve in the ePCRN's development and testing of the network. First, the principal investigator is well known in these circles, as director of the Minnesota Academy of Family Physicians Research Network and as previous chair of the FPBRN. In addition, directors of 10 PBRNs serve on the ePCRN board. Through their involvement, the ePCRN team hopes to develop the electronic network in ways that are relevant to clinics and their patients, and build relationships to implement clinical trials through PBRNs and their member clinics.

Prior to the ePCRN, practice-based research networks have been involved in attempts to advance collaborative research among primary care practitioners and clinical researchers (Green & Hickner, 2006). However, the ePCRN, backed by NIH Roadmap funding, lends greater legitimacy and technological infrastructure to the movement. The network's potential, realized partially through new technology, is viewed optimistically by the development team. For instance, the ePCRN's abstract states:

> The role of emerging Internet2 / grid technologies is to provide *seamless* and *scalable* access … to enable the *sharing*, scheduling and *aggregation* of a wide variety of geographically distributed … resources and present them as a *single, unified resource*—a virtual laboratory or organization—accessible from the desktop via a Web portal. . . . . Such a network would have the potential to deliver a *quantum difference* to clinical primary care research due to *comprehensive coverage* and *increased accuracy* of monitoring, resulting in clear benefits to society at large. . . . The principal aim of this study is to *enable* the development of an electronic infrastructure that *facilitates* the conduct of RCTs [randomized controlled trials] in primary care, and *promotes* the *translation* of research findings into practice (Peterson, 2004, p. 5-6, emphasis mine).

The abstract directly addresses the issues of efficiency and inclusiveness. Use of language, including "seamless," "enable," "comprehensive," "increased accuracy," and "promotes," all point to potential benefits of using an electronic network to bridge

primary care practice and clinical research. The argument is made that the network's technological abilities will provide these benefits to researchers, physicians, and society.

Such optimism of technology's potential (on the part of the NIH in funding the network and the development team, as seen above) is not surprising. Increasingly, technology is used in many fields to improve performance (e.g., multinational organizations including the banking and publishing industries, as well as educational institutions). The Internet's infrastructure and its characteristics of speed, reach, anonymity, and interactivity (Gurak, 2001) have been shown to facilitate communication, for instance by breaking down hierarchical barriers (Kiesler, Siegel, & McGuire, 1984). Indeed, such effects translate to medical settings. For instance, studies have examined how Internet technology affects clinical trials (e.g., Marks, Conlon, & Ruburg, 2001, discuss how an electronic network can enhance recruitment opportunities, including within primary care sites); how technology can be utilized to improve patient care (Brennan & Strombom, 1998, report that computer-based applications need to be built to support clinicians in "integrating patient preferences with scientific knowledge, clinical guidelines, and the realities of contemporary health care"); and how electronic networks can aid in providing tailored care in primary care (Nagykaldi & Mold, 2007) and psychiatric (Rosenheck & Dennis, 2001) settings.

Yet, technology itself does not guarantee improved performance (e.g., Ash, 1997; Berwick, 2003): technology is optimized by its human users within their social contexts. In the case of the ePCRN, it is not enough that a sophisticated network has been built, designed to streamline and expand the conduct of clinical research. An equally important

part of the equation is how the network may be used within social contexts—that is, by primary care physicians and academic researchers, each group with its own social and professional milieu. As such, development of the network must take into account the concerns each group may have and the ways in which the users will interact via this online community. I discuss how my study addresses these issues, through theoretical perspective and methodology, later in this and subsequent chapters.

Clinical Research and Ethical Considerations

The next sections provide additional context on clinical research, including ethical concerns. First, I provide background on what constitutes clinical research, followed by a brief examination of ethical concerns regarding participant recruitment and informed consent, relevant to the NIH and ePCRN initiative to advance clinical research through efficiency and inclusiveness.

Definition of Clinical Research

According to the National Institutes of Health, clinical research is "research that either directly involves a particular person or group of people or uses materials from humans, such as their behavior or samples of their tissue, that can be linked to a particular living person" (NIH National Institute of Child Health and Human Development, 2009). This includes studies of mechanisms of human disease, of therapies or interventions for disease, of studies to develop new technology related to disease, and clinical trials. In addition, clinical research includes epidemiological and behavioral studies that examine

the distribution of disease, factors affecting health, and how people make health-related decisions; and outcomes and health services research that focus on identifying the most effective and efficient interventions, treatments, and services.

Clinical Trials

Clinical trials, while comprising only one aspect of clinical research, are deemed by the NIH as "the linchpin of the nation's biomedical research enterprise" (NIH, 2005), and is the most relevant type of clinical research for my examination of the ePCRN. Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. The NIH defines a clinical trial as a "biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices)" (NIH Office of Extramural Research, 2010).

There are different types of clinical trials depending on the aim of the research. They include:

- **Treatment trials** test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.
- **Prevention trials** look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning. Better approaches may include medicines, vaccines, or lifestyle changes, among other things.
- **Diagnostic trials** determine better tests or procedures for diagnosing a particular disease or condition.
- **Screening trials** test the best way to detect certain diseases or health conditions.
- **Quality of life trials** (or supportive care trials) explore and measure ways to improve the comfort and quality of life of people with a chronic illness. (NIH, n.d.).

In addition, clinical trials of a drug, treatment, device or intervention are conducted in "phases," depending on the research purpose and what questions the research is designed to answer. These four phases are:

- **Phase I.** Testing in a small group of people (e.g., 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects).
- **Phase II.** Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety.
- **Phase III.** Study to determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use.
- **Phase IV.** Studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use. (NIH Office of Extramural Research, 2010).

The ePCRN project is geared to support any of the different types of clinical trials mentioned above, along any of the phases. For instance, the network potentially could help identify a small number of participants at a single clinic for a Phase I study testing a new treatment, to a Phase IV study involving large number of participants across multiple sites to test a screening method.

Concepts and Steps in Conducting Clinical Research and Clinical Trials

In many cases, a clinical trial aims to determine whether a new product or therapy is better in some way than an existing product or therapy. To help make this comparison, some studies use *placebos*, "an inactive product that resembles the test product, but without its treatment value" (NIH, n.d.).

Another concept used in clinical trials is *randomization*, whereby two or more alternative treatments are assigned to participants by chance rather than by choice. The results of these treatments are compared at certain points during the trial to determine which treatment is superior.

Finally, clinical trials are often *blind* or *masked* to prevent potential bias from influencing the results. In single-blind studies, the participants do not know which treatment they are receiving. In double-blind studies, members of the research team are not told which participants are receiving which medications; only the pharmacist knows.

The ePCRN is designed to support research using *placebos*, *randomization*, and *blind* methodology. In addition, the network helps recruit and screen potential study participants, enroll participants, support providers administering informed consent, and conduct and monitor the study through automatic electronic notification to primary care providers of eligible patients, access to study-specific informed consent documents and other study information, and tracking systems to monitor study progress. Specifically, the ePCRN aims to increase efficiency and inclusiveness in these areas. My research examines how the ePCRN was developed to meet these needs, and more broadly, as a technical system situated in a specific cultural context of primary care and clinical research.

Clinical Research Ethics Guidelines and Regulation

Achieving efficiency and inclusiveness in clinical research do not come without ethical considerations. Ethics guidelines and regulations have been established to protect

human participants and to ensure safe and ethical conduct of research, but a specific examination of ethical concerns surrounding participant recruitment and informed consent are of particular relevance to my examination of the ePCRN, which I cover in the next sections of this chapter.

Serving the goals of improved prevention, diagnosis, and treatment of diseases, clinical trials are designed to be ethical, balancing risk against potential benefit to participants and society, with regulatory oversight to ensure such consideration takes place. For instance, the Nuremberg code (1947) identified voluntary *informed consent* as a fundamental condition for ethical research; potential benefits of the study must be important enough to justify any risk to the participant and must be unattainable by other means; qualified persons must conduct the research; the study must be terminated whenever the investigator deems that continuation of the study would result in death or permanent harm to the subject; and the subject must also be allowed to terminate their participation if and when they wish. Subsequently, the National Research Act of 1974 required "a formal written consent for experimentation on human subjects and the establishment of institutional review boards (IRBs) to evaluate proposed experiments" (Guerrini, 2003, p. 141). Further, in 1979 the Belmont Report identified three principles for research on human subjects: respect for persons (requiring fully informed consent of the participant), beneficence (maximizing benefits and minimizing harm to participants), and justice (a fair distribution of benefits and burdens of research), (National Commission for the Protection of Human Subjects of Behavioral Research, 1979).

Participant Recruitment

Recruiting participants into clinical trials in an ethical yet efficient manner is a major concern to researchers. In a 2000 report "Recruiting Human Subjects," the Department of Health and Human Services (DHSS) states that "[t]he critical challenge is to ensure essential human-subject protections without unnecessarily slowing the pace of research and discovery" (p. 3). The report identifies four main strategies that sponsors and investigators use to recruit human subjects in an efficient and timely fashion:

- Sponsors offer financial and other incentives to investigators to boost enrollment.
- Investigators target their own patients as potential subjects.
- Investigators seek additional subjects from other sources such as physician referrals and disease registries.
- Sponsors and investigators advertise and promote their studies (ibid., p. 2).

According to the report, some of the issues involved with these strategies include disclosing financial arrangements between sponsors and investigators, possible breach of confidentiality in searching medical records for potential subjects, determining whether physicians should receive fees for referring patients as potential subjects, and the appropriateness of offering bonuses to investigators for recruiting subjects. These are issues that researchers and IRBs grapple with daily, and ones that ePCRN researchers and primary care physicians would face. For instance, how would confidentiality of patients be insured under the ePCRN model's patient recruitment? Would researchers, either based at academic institutes or at drug companies, be able to offer incentives for physician referrals of patients, and if so, how would that relationship be transparent?

Informed Consent

The 2000 DHHS report "Recruiting Human Subjects" states that IRB officials and others involved in clinical research identified "the erosion of informed consent" as a major concern with current recruitment practices. "The most fundamental concern is that the consent process may be undermined when, under pressure to recruit quickly, for example, investigators misrepresent the true nature of the research or when patients are influenced to participate in research due to their trust in their doctor" (ibid., p. 2). The report goes on to identify reasons for this concern, which "particularly impact human-subject recruitment" (ibid., p. 12). First, there is increased pressure for quick turnaround times of research findings into practice. This is due to higher drug development costs and increasing industry investment in research and development. Secondly, an intensified search for human subjects is occurring as more drugs are in development and more subjects are needed for each trial due to trials' increasing complexities. Thirdly, there is a quest for more efficient research sites, with commercial research shifting to private settings and the growth of private-practice investigators. Again, these are potential concerns for research conducted under the ePCRN model, particularly when potential research participants are recruited by their physicians, possibly blurring the lines between research and treatment, known as "therapeutic misconception" (Appelbaum, Roth, Lidz, Benson, & Winslade, 1987).[11]

[11] Therapeutic misconception arises when a research participant believes that enrolling in a research study will provide direct therapeutic benefit. Therapeutic medicine, or patient care, is designed to provide benefit to the individual patient. However, the primary purpose of clinical research is to generate new knowledge. Therapeutic misconception is addressed in Chapter 4.

While these issues highlight complexities from a researcher's point of view, it also is important to examine informed consent from a participant's perspective. In a review on informed consent, James Flory & Ezekiel Emanuel (2004) note, "ethically valid informed consent demands more than just disclosure. Research participants should also *understand* the essential disclosed information" (p. 1593, emphasis mine). This is sometimes difficult to achieve as evidenced in a variety of studies documenting participants' lack of comprehension in clinical settings (e.g., Bergler, J.H., Pennington, A.C., Metcalfe, M., & Freis, E.D., 1980, found that nearly all hypertensive patients entering a specific clinical trial believed that participating in the trial would provide them the best care; Daugherty, C.K., Banik, D.M., Janish, L., & Ratain, M.J., 2000, found that nearly all subjects in a Phase I cancer trial stated they understood all or most of the information presented to them as part of the informed consent process, yet subsequent questioning uncovered that less than one-third of the subjects knew the research purpose of a Phase I trial and 40% stated that no alternatives were discussed, despite signing a consent form stating the opposite).

Various methods have been used to improve the process of informed consent in terms of patient comprehension, such as use of multimedia and enhanced consent forms. However, after a systematic review of informed consent in clinical trials, Flory & Emanuel's study concludes that "[h]aving a study team member or a neutral educator spend more time talking one-on-one to study participants appears to be the most effective available way of improving research participants' understanding" (2004, p. 1593).

The ePCRN model may be particularly susceptible to potential therapeutic misconception. Patients being approached by their primary care provider for research purposes, as opposed to clinical care, may not fully understand how research differs from therapeutic care. Typically, patients see their primary care provider for individual treatment (i.e., therapeutic care). The aim of therapeutic care is to benefit that particular patient. The primary purpose of research, however, is to generate new knowledge, which may or may not directly benefit the participant. Being approached for research by one's primary care provider may blur the lines in the mind of the patient/participant of the primary care provider's role as physician vs. researcher. To insure that therapeutic misconception does not occur in the ePCRN model, particular care must be taken during the informed consent process. These issues are addressed further in Chapter 4.

Risk Versus Benefit

A set of federal regulations governing federally funded human subject research, known as the "Code of Federal Regulations for the Protection of Human Subjects" (or 45 CFR 46) stipulates that risks of clinical research be reasonable in relation to anticipated benefits (U.S. Department of Health & Human Services, 2005). The balance between risk and benefit must be examined by an IRB prior to research approval and before subject recruitment. Potential risks to participants could be physical, psychological, social, economic, and legal (Prentice & Gordon, 2001). In addition, special consideration must be given to protect vulnerable individuals, for instance those who are mentally or

terminally ill or living in poverty, where their fully informed and voluntary participation may be more susceptible to coercion or exploitation.

Analyzing the risk / benefit ratio is rarely straightforward, according to the National Bioethics Advisory Commission's 2001 report "Ethical and Policy Issues in Research Involving Human Participants." Based on their findings, the NBAC devised a procedure for assessing the balance between risk and potential benefits, known as "research equipoise" or "the state in which genuine uncertainty exists regarding which intervention—experimental or control (including placebos)—is better" (NBAC, 2001, p. 78). In such a case, a judgment of research equipoise "relies on a comparison of the risks and potential benefits of the proposed study interventions with those of accepted practice" (ibid.). This comparison relies on an approximate equality between risks and benefits of the study and control interventions. For instance, an experimental invention may be riskier to participants than accepted practice; however, it may be acceptable if it also offers the prospect of "greater direct benefit" to the participant and if the relation between risks and benefits "falls within a range of equivalency to accepted practice" (ibid.).

In examining the benefit side of the equation, however, Churchill & colleagues (2003) interviewed nearly 60 IRBs and state that "[a] major goal in the evaluation of human subjects research should be to bring consideration of potential benefits to the same level of maturity that consideration of risks of harm has attained." They argue that a reasonable analysis cannot be made without "clear and consistent benchmarks for assessing potential *benefits*" and that "providing reliable standards and common tools for

assessment [of benefits] is particularly timely" as increasing numbers of patients enroll in clinical trials (ibid., emphasis mine). For instance, they call for greater specificity in describing potential benefits. In addition, benefits both to individuals and society should be considered, they argue.

Looking broadly at issues of recruitment, informed consent, and risk/benefit analysis, the DHHS makes the following recommendations: "provide IRBs with direction regarding oversight of recruitment practices, clarifying that IRBs have the authority to review recruitment practices; facilitate the development of guidelines for all parties on appropriate recruiting practices; and ensure that IRBs and investigators are adequately educated about human-subject protections" (U. S. DHHS, 2000, p. 4). Clearly, ensuring ethical standards are met in biomedical research is an ongoing endeavor involving IRBs, researchers, institutions, and the public.

Categories of Participants and Reasons for Participation

It also is important to understand who participates in clinical research and why. For this analysis I rely on two sources: a case study that examined participants' experiences in two medical research projects in the 1970s, identifying five categories of research participants (Gray, 1975); and, results from the 1995 Subject Interview Study (SIS), part of the Final Report of the Advisory Committee on Human Radiation Experiments (1996), an intensive inquiry "into the history of government-sponsored human radiation experiments and intentional environmental releases of radiation that occurred between 1944 and 1974."

The five "subject types" identified by Bradford Gray serve as a useful starting point. From his sociological study of two clinical research projects, Gray categorized the following types of research participants: unaware subjects; unwilling subjects; indifferent subjects; benefiting subjects; and, committed subjects (see Figure 1).

Figure 1. Five "Subject Types" (Gray, 1975)

Unaware Subjects

In one of the studies he examined, where pregnant women were offered an experimental drug to induce labor, 20 women (or 39%) of those interviewed "were not aware that research was involved in their inductions until after the drug infusion had begun, although all had signed consent forms" (Gray, 1975, p. 129). This is a telling example of the need for informed consent that is *understood* by the participant. Gray then offered characteristics of unaware subjects: "the more dissimilar the subject was from the physicians she saw, the more likely she was to be unaware of the research" (ibid.). Perhaps not surprisingly, factors included education and race, and also whether she had a private physician.

Unwilling Subjects

Although unwilling participants knew research was occurring, they felt "constrained to participate" (ibid., p. 140). In their interviews with Gray, four women (or

8%) stated that they would have preferred not to be in the study, but felt they could not refuse. Gray discovered that three participants in this category were private patients and "it was partly their relationship with their private physician that constrained them in this particular situation" (ibid.). This touches on issues of doctor-patient relationships, particularly when the doctor is also the researcher.

Benefiting Subjects

These subjects, according to Gray, participated knowingly and voluntarily, primarily because they believed participating would benefit them. Of the 51 women in the labor-induction study, 22 (or 43%) were classified as benefiting subjects, the largest group in the study. The perceived benefit most often was cited as convenience. "Perhaps the most frequently made comment from the labor-induction subjects concerned their overwhelming impatience with being pregnant and their readiness to deliver" (ibid., p. 155). Gray notes that most of the benefiting subjects had known about the research before they were admitted to the hospital, which may have aided in their decision-making process.

Indifferent Subjects

Gray explains this category as those who "expressed no interest in the research and gave only one reason for participating—that it was what the doctors wanted" (ibid., p. 162). Only three women (or 6%) were labeled indifferent subjects. These women did not learn of the research until being admitted to the hospital, again indicating the

importance “for the extent of awareness of the research and for the degree to which the subject was able to make a free decision” (ibid., p. 164).

Committed Subjects

“Committed subjects agreed primarily because they wanted to help the researchers or make a contribution to medical progress. They may have had additional reasons for agreeing, but they gave this as the most important reason” (ibid., p. 165). Only 2 of the 51 women (4%) fit into this category. Although the subjects mentioned their belief in risk was minimal, the desire to help other people was their primary motive. Both women had previous knowledge of clinical research.

Subject Interview Study

The Subject Interview Study (SIS) provides further detail into some of these categories (Advisory Committee on Human Radiation Experiments, 1996). Although patients reported a range of reasons for participating in research, the primary reported reason was to obtain benefits, either through the experimental treatment or closer medical attention they believed they would receive through research.

Thirty-one percent of patients believed they had little or no choice in participation, often meaning they believed they had no medical alternatives. According to one participant’s response: “My doctor told me if I do not take the drug, in a couple of months I . . . [will] . . . die. So, I had no choice. Who wants to die? Nobody” (ibid.). Another participant initially declined to participate, but when his condition

worsened, agreed. In this way, there appears to be more patient control in whether to participate, despite their perceived "last chance," than noted in Gray's unwilling subjects, who felt they were not in a position to decline because of their doctor-patient relationship.

Yet results from the SIS also noted that doctors' recommendations were one of the most influential factors in deciding whether to participate. A theme of trust emerged, whether of a specific physician, medical professionals in general, or the overall research enterprise. Responses such as, "Oh, I love that man. He has kept me alive and I obey him and I do what he tells me to do. . . ." and "They know what they're doing. They wouldn't have you to do this if they didn't know what they were doing . . . ." along with "I do not feel like the drug would be on the market if it were going to harm me," indicate this trust (ibid.).

Altruism also played a role in deciding to participate, similar to Gray's committed subjects. "This desire to help others took many forms, including helping others who had the same medical condition, advancing medical science more broadly, and contributing to society" (ibid.). For those facing a life-threatening illness, some participants reported a greater sense of self-worth and a chance to contribute to society.

Non-participants and Reasons for Non-participation

The SIS also interviewed patients who declined to participate. Ten percent (or 191) of the 1,882 patients interviewed reported that "at some point they had made a decision not to participate in research" (ibid.). Of these 191 patients, 112 had never

participated in research, while 79 previously had been involved in research. This suggests that some patients had discriminated between research in which they were and were not willing to participate. The study found that those who declined ranged in age from 21 to 83, with a median of 56; 53% per male, 47% female; were predominantly white (69% white, 27% African-American, the remainder being of other ethnicities). There were also wide educational backgrounds, from less than the eighth grade to those with professional degrees.

Reasons given for not participating including: wanting to know what treatment they were getting (64%); wanting to make their own medical decisions with their doctors, not by researchers (56%); believing that the research study was not the best way for them to get better (45%); and the seeing the research study as being inconvenient (43%).

Recently, there has been a drive to broaden the population of research participants (Trauth, Musa, Siminoff, Jewell, & Ricci, 2000; NIH, 2008b). Research studies have examined willingness to participate among patients, survivors, and those at-risk of certain diseases, such as HIV/AIDS. However, less work has been done to examine the general public's attitudes toward participation. In a survey of 489 persons that asked if they would be willing to take part in a medical research study focusing on a new treatment for a specific disease that was of concern to them, Trauth et al. (2000) found that 25% stated they would not be willing and 29% stated they were undecided. Yet under certain circumstances, such as experience with cancer, over half who said they were undecided, later stated they would be willing to participate. "The determinants of being undecided in contrast to not willing include: having at least a college degree, having a favorable or

neutral attitude toward the use of humans in medical research and, believing that the well-being of participants is the primary concern of researchers" (ibid.). As a result, they recommend it may be possible to increase participation by targeting recruitment efforts not only toward the willing but also toward those who are undecided.

Yet, for some, participation has not been a matter of choice. As recently as the early 1990s, patient care was being modeled on research typically conducted on white males—research that did not always account for some very real and significant differences of gender and race (NIH Office of Research on Women's Health, 2009).

For instance, cardiovascular disease is the leading cause of death in women and particularly prevalent in African Americans. But until about 20 years ago, women and men were treated for heart disease in the same way, despite the fact women's symptoms and outcomes were often different than men's. As a result, women's heart disease was often misdiagnosed, undiagnosed, or under treated. At this time, researchers at the University of Minnesota also discovered that African-American men responded to heart failure medicine differently than white men. When it became clear that assumptions for treatment did not apply across patient groups, women's activist groups led the charge for clinical research to address gender and race (Hudson, 2005). In 1993, the NIH set up the Revitalization Act to include women and minorities in research (NIH Office of Research on Women's Health, 2009).

A recent study examined the sociocultural barriers African Americans have faced in relation to clinical research participation (Shavers, Lynch, & Burmeister, 2002). They found that African Americans and whites differ in their willingness to participate in

medical research, due to a "lower level of trust of medical research among African Americans" (ibid., p. 248). For instance, African Americans in the study were less willing to participate if they "attribute high importance to the race of the doctor when seeking routine medical care, believed that minorities bear most of the risks of medical research, and if their knowledge of the Tuskegee study[12] resulted in less trust in medical researchers" (ibid.). Shavers and colleagues suggest that researchers need to build trusting relationships with minority communities. This can be done, they suggest, by acknowledging previous unethical research behavior, discuss specific ways in which study participants will be protected, in addition to explaining the need for participation of minorities in research studies.

Understanding the motives for participation (or nonparticipation) in clinical research will be important as the ePCRN model is implemented in primary care clinics. For instance, as one of the goals of this network is to include populations typically not involved in clinical research it would be helpful for researchers to understand what hurdles exist and what might motivate patients to participate. In addition, the ePCRN model may raise new issues in participant motivation (or lack thereof), depending on the degree to which the technology is visible in the research process and individuals' attitudes toward automated, networked communication and data exchange.

Summary of Ethical Concerns in Clinical Research

[12] In the Tuskegee Syphilis experiment, conducted in Alabama from 1932 to 1972, treatment was withheld from nearly 400 black men in the late stages of syphilis, who were not told of their condition or of their status as experimental subjects (see McNeill, 1993).

Biomedical research offers the promise and hope of better treatments and possible cures for disease as well as prevention, and clinical trials play a major part in those discoveries. The involvement of human participants requires vigilant ethical oversight into research purposes, methods, and conduct. Although ethics regulations are in place through legislation and the establishment of IRBs, ensuring ethical behavior is rarely straightforward, even with the best of intentions.

The recent interest in efficient and quick study turnaround further highlights the need for ethical recruitment of participants. Consent may not be truly informed by participants who may feel "rushed" through the procedure. They also may not understand all the risks and/or benefits of the study. Ensuring ethical recruitment is in large part a responsibility of the researcher and the IRB overseeing the study.

Individuals have various reasons for participating in research. Some view research as a means that will directly benefit them, others may have altruistic motives. Still others may not be aware they are part of a research study, mostly as a result of communication breakdown between researcher and participant, or may participate because they believe that is what their doctor wishes. In order to ensure individuals participate in research voluntarily and fully informed, researchers and potential participants need to have clear communication, not only of the research details, but also of the research process—for instance, making sure the individual understands he or she has the right to refuse participation.

In addition, there has been a concerted effort to be more inclusive in research participation since the NIH's 1993 mandate to include more women and minorities in

clinical research and the NIH Roadmap for Medical Research. Electronic infrastructures, such as the ePCRN, may assist in broadening the pool of potential participants. However, historical barriers must be overcome before women, African Americans, and other ethnic and racial minorities more readily consider participation.

These are concerns that the ePCRN team face as they develop their network to accelerate and expand clinical research to the primary care patient population. The aims of efficiency and inclusiveness must be balanced with ethical conduct of research and treatment of participants. Promisingly, many of these issues are being navigated in practice-based research networks, which like the ePCRN, aim to conduct clinical research that is relevant to everyday clinical practice.

The Focus of my Study

My dissertation is a critical ethnography and rhetorical study of the electronic Primary Care Research Network (ePCRN). In particular, my study examines the interface between technology and its use as a communications tool within social contexts to connect disparate communities (i.e., practicing primary care physicians, and clinical researchers based at large academic health centers) to facilitate clinical research and improve health. Through examination of the network's development at the University of Minnesota during its three-year NIH-funded contract (2004-2007), I explore how the network is designed to meet the NIH's aim of efficiency (accelerating the process of conducting research and making those findings known to other researchers, practitioners, and the public) and inclusiveness (allowing for more clinically relevant research and

broadening the study-participant population to more closely represent the nation's diverse patient population). My aim is to understand how development of this electronic network takes into account both technology's potential and issues of human use so that researchers and primary care physicians may more easily and systematically collaborate in clinical research. In this study, I address the following research questions:

1. How does the NIH Roadmap's expectations of efficiency and inclusiveness affect the ePCRN's development with potential implications for clinical research?

2. During the developmental stage, to what extent does the ePCRN function as a "community of practice"?

3. What values are laden in the ePCRN's technology and in the social/cultural context of its use, and how do these values influence the ePCRN's potential to function as a "democratic" technology?

4. To what extent are unintended/unanticipated consequences likely to occur during the ePCRN project?

The ePCRN project was led by a principal investigator at the University of Minnesota Medical School's Department of Family Medicine and Community Health. The team (given pseudonyms for the purpose of my dissertation) included members with expertise in clinical practice, research, and/or information technology from the University of Minnesota and the University of Birmingham, England, as well as directors from practice-based research networks across the United States (see Appendix B). Once the project received NIH funding, the team began weekly meetings, using access grid technology[13] whereby members located in different physical locations connected via

[13] See Appendix A.

high-speed networking over the Internet, providing meetings with high quality audio and real-time video interaction capabilities. These meetings were coordinated from a conference room in the Department of Family Medicine and Community Health. University of Minnesota servers, physically based at the University, housed the ePCRN's infrastructure, and logistics of securing access to the network during the development and testing phase of the NIH contract was handled by the ePCRN team at the University of Minnesota. Reports to the NIH were compiled by the team, led by the principal investigator.

I was fortunate to gain access to this project from its inception, initially through my position at the University's Office of Communications and then as a graduate student in the University's Department of Rhetoric.[14] In October 2004, just after the project received NIH funding, I was assigned to write a feature story on the ePCRN and was immediately intrigued by its potential as a communications tool to link primary care physicians and academic researchers. In spring 2005, I began to follow the project more closely as part of a graduate course in ethnography. The pilot study I conducted as part of my coursework served as the starting point for this study (see Appendix C).

Theoretical Framework: Rhetorical and Critical Theoretical Analyses of Internet Technologies and "Communities of Practice"

In order to examine the effects of the ePCRN to foster clinical research in a primary care setting—beyond a merely technical point of view—my research is informed by a theoretical framework consisting of rhetorical and critical theoretical analyses of the

[14] The Department of Rhetoric changed to the Department of Writing Studies in the College of Liberal Arts in 2007.

technological affordances of Internet capabilities and use. First, I examine concepts of Internet speed and reach (Gurak, 2001) and community ethos of online communities (e.g., Doheny-Farina, 1996) to provide a background of research focusing on both the technological and social aspects of electronic networks. This informs a micro-level examination of the electronic network development team's intentions and actions, using communities of practice theory, where "community of practice" is defined as "a system of relationships between people, activities, and the world" (Lave & Wenger, 1991, p. 98). From there, I conduct a macro, technological system-wide critique employing critical theories of technology (Feenberg, 1995; 1999; 2002; 2008b; Pacey, 1983). Examining the ePCRN through these multiple lenses (see Figure 2) provides a necessarily rounded understanding of the network's technological and social aspects.

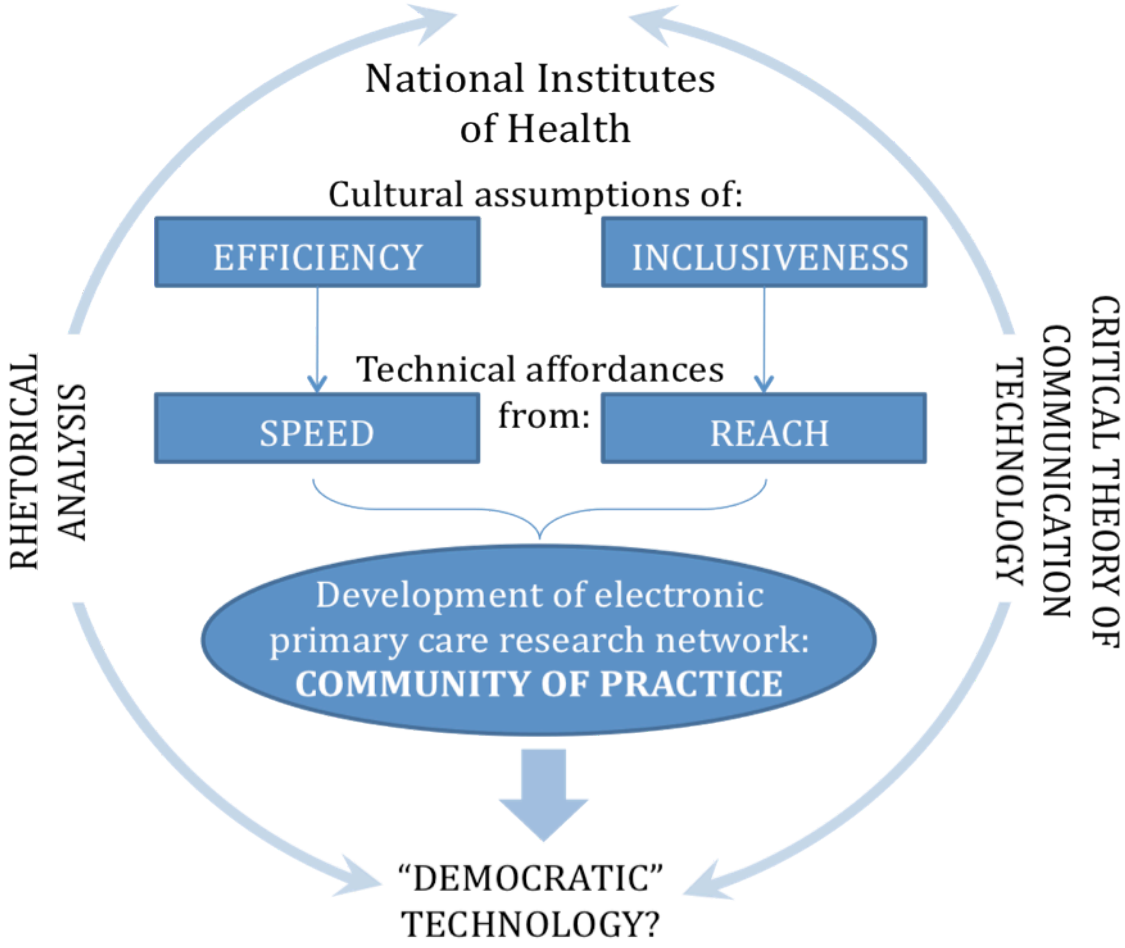

Figure 2. Theoretical Framework Schema

Central to my study is the assertion that computer-based technologies are not socially neutrally (e.g., Zuboff, 1988), but further, that they are embedded with values and social purposes in their *design* as well as their *use* (Feenberg, 2002, 2008b; Pacey, 1983). Critical theories of technology, including Feenberg's instrumentalization[15] theory

[15] With a basis in philosophy, instrumentalists claim theories are "nothing more than instruments;" that is, theories are neither true not false, "but only more or less adequate given a particular problem" (Caldwell, 1980, p. 367). Instrumentalism is often contrasted with realism. While "realists claim that theories and theoretical terms should make real references, instrumentalists deny it" (ibid.). Feenberg's

and Pacey's "technology-practice" model, provide a theoretical framework to examine biases inherent in technology, as well as ways in which technology may become more "democratic," which I examine in the context of ePCRN's development and its potential use. I also employ Gibson's theory of affordances (1977, 1986), which marries technological infrastructure (or "environment") with usage. These theories argue that a full examination of the technological infrastructure cannot be divorced from its relation to the user, also a central tenet of my research.

Gurak's concepts of cyberliteracy and the Internet's speed and reach (2001) also provide an important framework for examining social and organizational aspects of technology. Cyberliteracy, where we understand the "relationship between our communication technologies and ourselves, our communities, and our cultures" (p. 16), clearly places technological operation within the frame of its impact on our world. Developers of the ePCRN promise greater technological speed and reach for clinical research in primary care clinics, yet human issues of use when implemented in clinics cannot be ignored.

Examining the ePCRN as an online community (Doheny-Farina, 1996) and "community of practice" (Lave & Wenger, 1991) also provides greater understanding of how technology can affect how people interact, with whom they interact, and what they interact about. Specifically, I analyze the ePCRN's development against a "community of practice" framework whereby team members are given agency to negotiate the network's meaning and practice within their social context (i.e., primary care clinics and research

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instrumentalization theory, however, bridges substantivist claims in philosophy of technology, which views technology in abstract and unhistorical terms, and constructivist claims in social studies of technology, with its perspective of social and historical contexts. I discuss this further in Chapter 2.

institutes). I examine how team members "mutually engage" across a wide range of expertise (e.g., clinical, technical, practice-based research networks) toward a goal (or "joint enterprise") of efficiency and inclusiveness in research by developing tools (or "shared repertoire") comprising a Web-based portal, patient registry, and Internet2 technology.[16]

Chapter 2 provides a more comprehensive literature review pertaining to these areas and a discussion of their convergence in relation to the ePCRN and potential future research in networked communications.

Explanation of the Study's Significance

Potential implications from this research are important. The ePCRN represents a potentially important juncture in how clinical research is conducted and by whom, as researchers and primary care physicians collaborate in new ways. With the ePCRN's development, cultural and institutional assumptions are being played out as those involved in the network's development attempt to meet the NIH Roadmap's objectives of efficiency and inclusiveness through technology in a population not typically involved in clinical research. What I aim to do in this study is to examine to what extent an electronic research network might serve as a "democratic" technology—specifically, whether the ePCRN model is able to privilege excluded values (conducting research in primary care settings) and the publics that articulate them (researchers, primary care providers, patients), by granting actors who lack financial, cultural, or political capital access to the

[16] See Appendix A for detailed descriptions and definitions of these concepts.

design process (those primary care providers not typically involved in research and their patients). To reach these conclusions, I also examine the implications of the network's technical affordances to achieve efficiency and inclusiveness.

In addition, one of the purposes of this dissertation is to the test the method employed to answer my research questions. Specifically, my research begins with a thorough examination of the assumptions and affordances behind a technology, followed by how the group made decisions in developing the technology, and then an analysis merging the affordances, the aims, and the dynamics used to determine the technology's role within its social context. I believe the multi-theoretical lens in which I examine the ePCRN is a strength of my research, and that it is necessary I set out to test this approach as a contribution of my research.

Finally, while this examination is bound by the development period of the network, it will provide a baseline study should the network be implemented in primary care clinics. Examining the development and implementation of this new network may provide important insight into technological and social roles in clinical research, specifically in how and to what extent it may shape patient care. More generally, this study's findings may have relevance for other electronic networks focused on bridging disparate communities toward a common aim, particularly in how to overcome asymmetrical hierarchies of those who design and use networked, technological systems. I address these and other implications in greater detail in Chapter 7.

Outline of the Dissertation

This study continues with Chapter 2, a literature review of rhetorical and critical theoretical perspectives of Internet technologies and online communities, "communities of practice" (CoP), and instrumentalization and "technology-practice" theories.

Chapter 3 details the methodology and methods used in this study: a qualitative critical ethnographic and rhetorical study of an electronic network's development, with data collection methods based on semi-structured interviews with ePCRN team members and observation of weekly meetings at various points over the ePCRN's three-year development phase. In addition, I analyzed a variety of ePCRN documentation, including the ePCRN's NIH proposal, quarterly reports, activity reports, and meeting minutes to answer my research questions.

Chapter 4 examines potential for and implications of the NIH Roadmap initiative's aim for efficiency (speed) and inclusiveness (reach) in clinical research. In this chapter I argue that potential benefits of efficiency and inclusiveness (e.g., widening the pool of researchers and participants and streamlining the recruitment process) must be balanced against potential risks, particularly in areas of participant recruitment, informed consent, data collection and management, and communication. In addition, I discuss how the eCPRN team must address the benefit/risk trade-off at the earliest stages of the network's development and throughout its eventual implementation and use.

Chapter 5 examines the ePCRN as a community of practice. My analysis outlines how the team functioned as a community of practice, evidenced through the three characteristics of a CoP. In the ePCRN project, this included: the project and team's "joint enterprise" (its overall aim) to facilitate clinical research in primary care settings;

its “shared repertoire” (shared resources in a shared practice) comprising the project’s stated objectives of a Web portal, patient registry, and Internet2 capabilities; and, its “mutual engagement” in which members are engaged in a common negotiated activity. I conclude that functioning as a community of practice benefits the project; however, it will be important to see whether the community of practice model is viable in the project’s intended social context of primary care clinics (beyond the scope of my current research).

Chapter 6 analyzes values and formal biases of communication technology in the ePCRN's project using critical theories of technology. In this chapter, I argue that although the team has done much to assure a “democratic” development and use of technology, assumptions of expediency and inclusiveness in the ePCRN have led to some level of unintentional asymmetrical hierarchies of who controls and uses the network. Finally, Chapter 7 provides a discussion of implications and conclusions, including future research directions.

Chapter Two:
Literature Review

A Sociotechnical Examination of Communication Technology

In the previous chapter, I outlined the NIH's Roadmap initiative and its aim to transform clinical research. In particular the initiative focuses on conducting research with greater efficiency and moving research results more quickly to clinical settings. This is recognition that previous models no longer meet 21st century needs and new models of research conduct, collaboration, and communication are needed to help advance science. By virtue of its electronic network, the ePCRN has potential to address the NIH aims of increased efficiency and inclusiveness by electronically linking researchers in multiple sites and across disciplines, disseminating information more quickly and widely, and including community needs in the research process. However, the functions of an electronic network cannot be examined through the lens of technology alone. It is necessary to examine both the ePCRN project's technical and social aspects in a critical theory of communication technology. Before I can do this, however, I first examine the Internet's characteristics of speed and reach and the ethos of online communities.

Internet Studies: The Road to Speed and Reach

Rhetorical implications of electronic networks have been examined since Licklider & Taylor's seminal 1968 article on the computer as a communication device, which predicted the social features of the Internet. This study placed technology within the framework of the human, recognizing that an effective model for interactive

communication must be fluid and dynamic as well as "a common medium that can be contributed and experimented with by all" (p. 22), a key technological and social feature of the Internet, and one with implications for this study.

Subsequent works further examined the social and organizational implications of electronic communication. Hiltz & Turoff (1993) provided the first major study to document social and workplace aspects of the Internet, covering issues such as social and psychological differences in online vs. face-to-face communication, anonymity, and workplace hierarchy. Kiesler, Siegel, & McGuire (1984) followed by examining the social and language-based features of online communication and were among the first to note changes in organizational communication within digital environments, including centralization of control and flattened hierarchy due to universal access within the organization—elements on which the ePCRN aims to capitalize, to facilitate clinical research amongst primary care physicians who previously have not had easy access to the clinical research enterprise.

As electronic communication grew beyond its government and academic roots and became more widely available in organizations and homes, it became clear that technological capabilities were changing social and workplace behaviors. Sproull & Keisler (1986) examined online communication from a social/psychological perspective, which confirmed Hiltz & Turoff's previous work on the effects of removing social cues from communicative exchange. They concluded that electronic mail "does not simply speed up the exchange of information but also *leads to the exchange of new information as well*" (ibid., emphasis mine): that is, information would not have been conveyed

through any other medium, since social cues would have prohibited it. For instance, one respondent reported receiving a conference report via email that s/he would not have otherwise had access to; others were solicited for "ideas about a new product" and "suggestions for new ways to use a particularly piece of software," activities they would not have been involved in non-electronically (p. 1509). Zuboff (1988) provided an important critique of this new technology, stating that computer-based technologies are not socially neutral, that technology can both impose and produce new patterns of information and social relations.

These implications are examined in the context of the ePCRN and its use, building on the theory of affordances (Gibson, 1977; 1986), leading in turn to the Internet's rhetorical functions of speed and reach (Gurak, 2001). The theory of affordances marries technological infrastructure (or "environment") with usage. In this sense, users of technology are influenced not only by the technology itself but by possibilities for action (affordances)—a full examination of the technological infrastructure cannot be divorced from its relation to the user. Although the term "affordance" originally described those actions that are physically possible, the term later included actions of which the actor is cognizant[17]—a point relevant in Laura Gurak's call for "cyberliteracy" (2001).

Cyberliteracy is not merely a matter of mastering a set of skills, but of understanding the "relationship between our communication technologies and ourselves,

[17] Affordance theory attempts to explain how perception informs meanings of objects. James Gibson's theory assumed objects and events have inherent meaning. Gibson defined "affordance" as "a specific combination of the properties of its substance and its surfaces taken with reference to an animal" (1977, p. 67). I use affordance theory in my research to examine how the form of the technology informs its use and vice versa. See also Chapter 4.

our communities, and our cultures" (p. 16). This approach clearly places technological operation within the frame of its impact on our world. Also in this work, Gurak outlines four qualities of Internet communication: speed, reach, anonymity, and interactivity. Two of these qualities—speed and reach—form the basis of my examination of the ePCRN's technological capabilities, both in terms of goals and operation. I will use this conceptual framework to examine both affordances and constraints of speed and reach in the ePCRN's realization—an important area of investigation, as these technologies are not without social and organizational implications.

In regards to my study, the goals of speed and reach are certainly represented in the language used by the NIH—and in the case of the ePCRN abstract, by primary care physicians as well. By "re-engineering" the clinical research enterprise, the NIH explicitly aims to become more efficient. Implied in "re-engineering" is utilizing technology. By embracing technology, as seen through funding the ePCRN, the NIH is making a value judgment toward efficiency. Katz (1992) warns of the culture of efficiency in technical writing that hides or supersedes ethical considerations. As outlined later in this chapter, critical theory of technology highlights similar concerns of technology's "hidden" agendas and affordances, calling for a critical analysis of technological systems and their implications in use (see Critical Approaches to Communication Technology section later in this chapter). Although the NIH does not turn a blind eye to the need for safety and ethical consideration in conducting clinical research through a new medium (the ePCRN), language in the Roadmap initiative certainly privileges speed and transformation.

The ePCRN itself also operates under the assumptions of the value of speed and reach. As seen earlier (Chapter 1) in the language of its abstract, it focuses on the benefits of technology, which it states as "facilitating" and "seamless," and able to "promote" translation of research findings into clinical practice for the benefit of patients. Not surprisingly, throughout the ePCRN's proposal, language of technological benefits is placed within the setting of the primary care practice; the proposal discusses how primary care benefits clinical research, which comes back to benefiting primary care again. For instance: "The development of such a platform [the ePCRN itself] would provide the ability to perform large national collaborative studies throughout the U.S., improve efficiency, reduce costs for individual trials, provide easier access for data retrieval and analysis, and involve primary care in recruitment, performance, and translation of findings into practice" (Peterson, 2004, p. 6). Here we see the same type of language: "efficiency," "easier access," "reduce costs," and "translation."

However, the proposal also addresses concerns faced by primary care physicians in relation to clinical research (such as how to identify potential participants, privacy, confidentiality, and human subjects protection issues, tracking participants' progress, etc.). By giving voice to these concerns, while at the same time promoting the network as a means of efficiency and inclusiveness, we see the primary care setting already negotiating both worlds. A comprehensive examination of speed and reach is required to move beyond assumptions and determine both affordances and constraints of this network and is covered in Chapter 4.

Community Ethos of Online Communities

Online communities provide another lens through which to examine the social and organizational aspects of the ePCRN. Howard Rheingold, a pioneer in Internet research, defined online communities as "cultural aggregations that emerge when enough people bump into each other often enough in cyberspace" (Rheingold, 1994, p. 57). While no singular definition of online community exists, generally the following are core characteristics of online communities:

- Members have a shared goal, interest, need, or activity that provides the primary reason for belonging to the community.
- Members engage in repeated, active participation and there are often intense interactions, strong emotional ties and shared activities occurring between participants.
- Members have access to shared resources and there are policies for determining access to those resources.
- Reciprocity of information, support and services between members is important.
- There is a shared context of social conventions, language, and protocols. (Preece & Maloney-Krichmar, 2003, p. 597, citing Whittaker, Issacs, & O'Day, 1997, p. 137)

Clearly, the ePCRN is being developed to function as an online community. But what are the implications? Online communities' ability to enhance or diminish our lives is greatly debated. Early research focused on comparisons of online with face-to-face communication, and findings seemed encouraging for online communication, including communicating independent of time or location (Rheingold, 1994), exhibiting more confident, less inhibited behavior (Turkle, 1995) and having less hierarchical

communications in the work place (Sproull & Kiesler, 1991). In the meantime, people "meeting" in a virtual or online space for any number of purposes (e.g., to chat, seek information, shop, to work, or find support) has become a fairly common occurrence (e.g., Lenhart, Purcell, Smith, & Zickuhr, 2010).

On the other hand, Stephen Doheny-Farina, in *The Wired Neighborhood* (1996), expresses concern that online communities may be detrimental to local communities (i.e., geographic communities, such as a town). He states that: "we do not need electronic neighborhoods; we need geophysical neighborhoods, in all their integrity. The revolution that must be joined is not one that removes us from place but one that somehow reintegrates the elements of our dissolving placed communities" (p. xi).

This sense that online communities have potential to "remove" members socially as well as allow people to come together in previously unattainable ways illustrates the complex sense of and reaction to this technology's capabilities. Indeed, although Doheny-Farina cautions about potentially alienating features of online communities, he does not recommend that we the "shun" the Internet but "steer" it through civic networking: "limited, focused, carefully applied efforts that attempt not to move us into cyberspace but to use communication technologies to help *reintegrate people within their placed communities*" (p. xiii, emphasis mine). Later, he adds: "Given the inevitability of the net, the most fruitful path is to participate in it in ways that benefit our localities" (p. 123).

This seems to match the aim of the NIH Roadmap and the ePCRN as it moves to make clinical research more relevant for patients and the benefits of improved treatment

and prevention more readily available. Yet, the ePCRN, as a successfully functioning online community, must exhibit and promote necessary characteristics for participants to feel vested and safe in its use. In addition, examination of the ePCRN needs to move beyond the more generalized studies of online communities (e.g., Wellman & Guila, 1999; Pew Internet & American Life Project, 2001), to focus on a specific type of online community. To this end, I employ the concept of "communities of practice" (Lave & Wenger, 1991; Wenger, 1998b) to examine the dynamics of the ePCRN as an online community designed to advance clinical research in primary care, coupled with a critical theory of communication technology to examine assumptions behind the network's technology on a system-wide level.

Communities of Practice

"Communities of practice" have their roots in constructivism (Knowles, Holton, & Swanson, 1998; Oliver & Herrington, 2000; Palloff & Pratt, 1999; Persichitte, 2000; Squire & Johnson, 2000), whose main principle shifts control from instructors to learners. Constructivism involves concepts such as learning environments that replicate a realistic problem situation; the social interdependence including group activities, collaboration, and teamwork; shared goals between learners and instructors; and cognitive tools that aid in organizing knowledge (Johnson, 2001).

Originally developed by Lave & Wenger (1991), the concept of "communities of practice" was first outlined in an ethnographic study of situated learning in the context of apprenticeships, which the authors were studying in terms of learning theory. Observing

five different apprenticeships, the researchers describe how work, responsibility, and knowledge are distributed among practitioners within their communities. As indicated by its subtitle—"legitimate peripheral participation"—this work describes how individuals over time can move from the periphery of a socially organized activity to become a fully functioning member of that community.

A community of practice is defined as "a system of relationships between people, activities, and the world; developing with time, and in relation to other tangential and overlapping communities of practice" (Lave & Wenger, 1991, p. 98). Communities of practice constitute groups of people with a shared area of interest "for something they do" and a passion to "learn how to do it better" as the members "interact regularly" (Wenger, 2006). In terms of learning potential, although a community of practice acts as "a living curriculum for the apprentice," its activity is "dynamic and involves learning on the part of everyone" (ibid., pp. 3-4).

Necessary components of a CoP include domain (or a shared area of interest), community, and practice—the combination of which constitutes a CoP. Members are committed to that domain, where a "shared competence … distinguishes members from other people," (ibid.). "Community" in CoPs refers to members who pursue interest in the domain, who "engage in joint activities and discussions, help each other, and share information" (ibid.). Members in this type of community build *learning relationships* with each other, interacting and learning together. Finally, members of CoPs are engaged in "practice;" they are practitioners who "develop a shared repertoire of resources: experiences, tools, ways of addressing recurring problems" (ibid.). For Wenger,

"community" and "practice" are essential components of a social theory of learning, where social participation is a process of learning and knowing. In communities of practice, members learn by both doing and belonging. The two are inextricably linked.

Wenger's theory focuses on the social interactive dimensions of situated learning. He purports that *how* people interact and *who* interacts are at least as important as *what* they interact about. Specifically, meaning is negotiated through participation and reification, which Wenger defines as the process of giving form to experience by producing objects. "Any community of practice produces abstractions, tools, symbols, stories, terms, and concepts that reify something of that practice in a congealed form" (Wenger, 1998b, p. 59).

Importantly for the members and the communities they serve, CoPs help foster an environment where knowledge is created, shared, and used in practical ways to improve effectiveness, efficiency, and innovation (Lesser & Everest, 2001). As such, CoPs fulfill a number of functions: exchange and interpretation of information on best practices, tips, or feedback; retain knowledge in dynamic, "living" ways, as opposed to static manuals or databases; steward competencies to keep up to date with new developments; and provide homes for identities, organized around what matters to the members (Wenger, 1998a, p.6).

CoPs: Mutual Engagement, Joint Enterprise, and Shared Repertoire

In forming a coherent community, a CoP defines itself along three dimensions: *joint enterprise*, what it is about; *mutual engagement,* how it functions; and *shared repertoire*, what capability it has produced (Wenger, 1998a, p. 2; see Figure 3).

Figure 3. Community of Practice Model

Mutual Engagement

Mutual engagement means that CoP members are engaged in a common negotiated activity. "Activity" is key here; how members "practice," by doing what they do together and by defining what they do through negotiated interactions, helps cohere them as a community. "Practice does not exist in the abstract. It exists because people are engaged in actions whose meanings they negotiate with one another" (Wenger, 1998b, p. 73).

Communities of practice must therefore *enable engagement* (ibid.). That is, for members to be engaged in a community's practice, they must be "included in what matters" (ibid.). This can include overt negotiations such as coming to an agreement over necessary tasks at a meeting where members' views are voiced and considered, to an understanding of and participation in more nuanced information, such as the importance of a particular type of atmosphere at work. "What it takes for a community of practice to cohere enough to function can be very subtle and delicate," requiring "community maintenance" which can be "much less visible than more instrumental aspects of the practice" (Wenger, 1998b, p. 74).

In addition, Wenger argues that mutual engagement requires *diversity* of membership. The contribution and knowledge of others, with differing expertise, is crucial for a CoP's development. Members tend to find their own place and identity, which become further integrated and defined as the CoP engages in activities as negotiated through its members. Mutual engagement "draws on what we do and what we know, as well as on our ability to connect meaningfully to what we don't do and what we don't know—that is, to the contributions and knowledge of others" (ibid., p. 76).

Communities of practice also foster *mutual relationships*, comprising clusters of interpersonal relationships that "arise out of engagement in practice and not out of an idealized view of what a community should be like" (Wenger, 1998b, p. 76). For instance, peaceful coexistence among members is not guaranteed. In fact, instances of disagreement and tension are likely. It is important to remember, however, that despite

potential disagreements, challenges, and competition, these are all forms of participation, crucial to mutual engagement.

Joint Enterprise

A community of practice's joint enterprise concerns its common goal, to which members draw on their diverse expertise and perspectives to continually negotiate the development of practice toward this identified shared goal. This process of continual negotiation works to keep a community of practice functioning together (Wenger, 1998b, pp. 77-78):

1.) It is the result of a collective process of negotiation that reflects the full complexity of mutual engagement.

2.) It is defined by the participants in the very process of pursuing it. It is their negotiated response to their situation and thus belongs to them in a profound sense, in spite of all the forces and influences that are beyond their control.

3.) It is not just a stated goal, but creates among participants relations of mutual accountability that become an integral part of the practice.

Several elements are crucial here. First, that it is a *negotiated enterprise* (ibid.). Each member has a stake in the enterprise and how it is realized. "The enterprise is joint not in that everybody believes the same thing or agrees with everything, but in that it is communally negotiated" (ibid., p. 78).

Second, it is an *indigenous enterprise* (ibid., p. 79). While CoPs exist and develop within larger historical, social, cultural, or institutional contexts and are subject to influences outside members' control, the enterprise is "never fully determined by an outside mandate, by a prescription, or by any individual participant" (ibid., p. 80). Rather,

it is negotiated by the members' response to their situations, however externally constrained. "It is their response to their conditions, and therefore *their* enterprise" (ibid., p. 79).

Finally, negotiating a joint enterprise leads to a sense of *mutual accountability* as members determine what is central to the CoP's mission, what is important and why, and what needs to be accomplished and what doesn't. "This communal regime of mutual accountability plays a central role in defining the circumstances under which, as a community and as individuals, members feel concerned or unconcerned by what they are doing and what is happening to them and around them, and under which they attempt, neglect, or refuse to make sense of events and to seek new meanings" (ibid., p. 81). This is a process, not a singular point of agreement, where members continually negotiate what is accountable to the enterprise.

Shared Repertoire

As a community of practice engages in negotiating its enterprise and developing ways of working together, a pool of resources, or shared repertoire, is created. "The repertoire of a community includes routines, words, tools, ways of doing things, stories, gestures, symbols, genres, actions, or concepts that the community has produced or adopted in the course of its existence, and which have become part of its practice" (ibid., p. 83). These serve as shared points of reference. From the shared repertoire, members are able to further negotiate the enterprise.

Stages of Development

In addition to having these characteristics, communities of practice also move through various stages of development "characterized by different levels of interaction among the members and different kinds of activities" (Wenger, 1998a, p. 2). Beginning with ePCRN's origins in practice-based research networks, I examine the ePCRN's development along Wenger's five stages (see Figure 4).

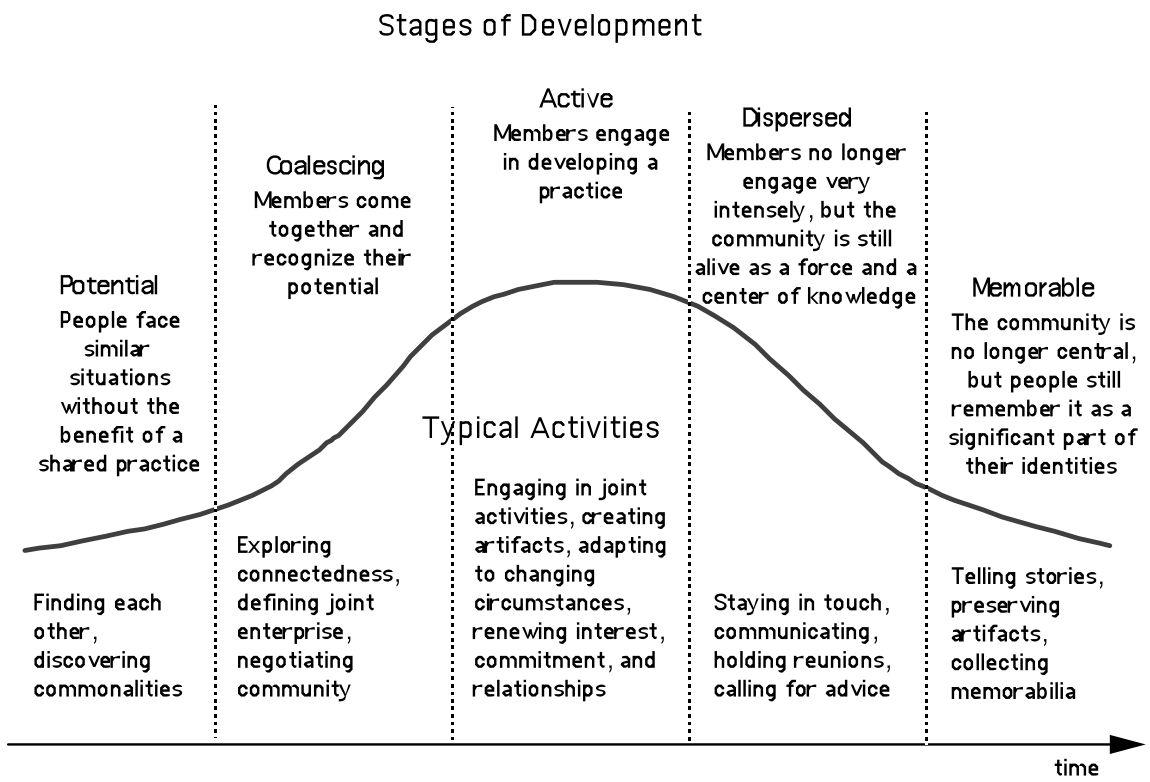
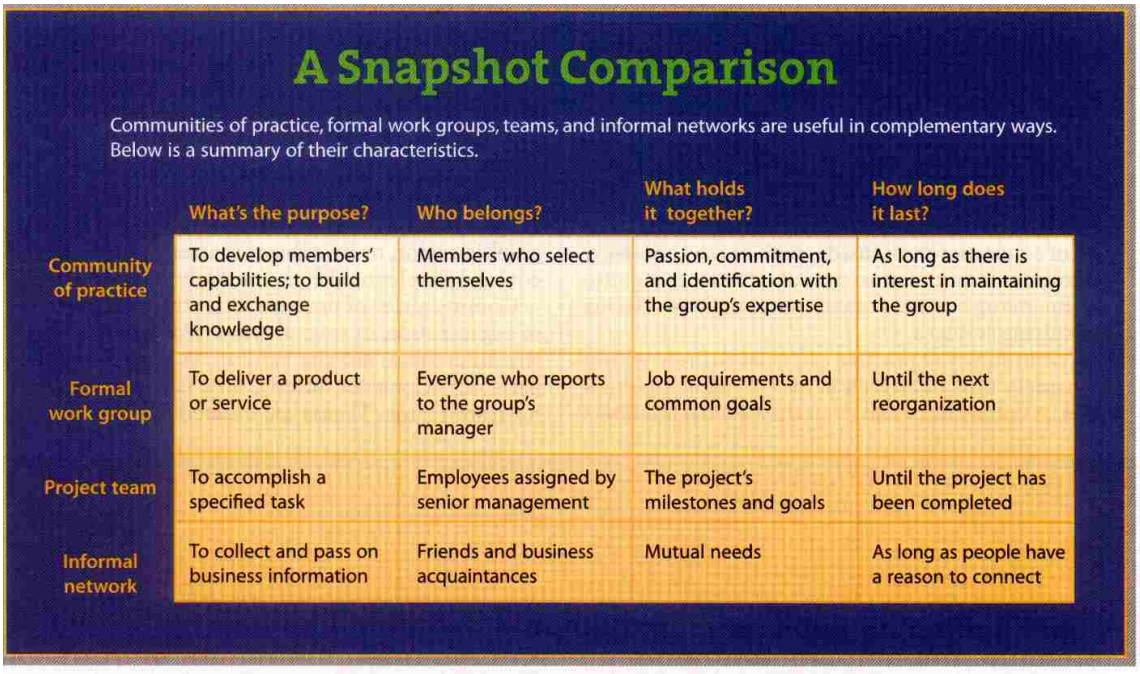


Figure 4: CoP Stages of Development (Wenger, 1998a, p. 3)

Types of communities

Wenger is explicit in differentiating communities of practice with other types of communities or groups. These entities have differing purposes, members, cohesion, and durations (see Figure 5). For instance, whereas a business or functional unit may be based on an institutional aim, a community of practice "defines itself in the doing, as members development among themselves their own understanding of what their practice in about," resulting in more flexible boundaries for participants and their participation (Wenger, 1998a, p. 4).



A Snapshot Comparison

Communities of practice, formal work groups, teams, and informal networks are useful in complementary ways. Below is a summary of their characteristics.

	What's the purpose?	Who belongs?	What holds it together?	How long does it last?
Community of practice	To develop members' capabilities; to build and exchange knowledge	Members who select themselves	Passion, commitment, and identification with the group's expertise	As long as there is interest in maintaining the group
Formal work group	To deliver a product or service	Everyone who reports to the group's manager	Job requirements and common goals	Until the next reorganization
Project team	To accomplish a specified task	Employees assigned by senior management	The project's milestones and goals	Until the project has been completed
Informal network	To collect and pass on business information	Friends and business acquaintances	Mutual needs	As long as people have a reason to connect

Figure 5: "Communities" comparison chart (Wenger & Snyder, 2000, p. 142)

Electronic technologies add another level of distinction in communities of practice. Although initially used to explain more traditional face-to-face interactions, communities of practice were quickly co-opted to examine "virtual" communities in an

electronic setting (Johnson, 2001; McLure Wasko & Faraj, 2000; Dube, Bourhis, & Jacob, 2005; Daniel, Schwier, & McCalla, 2003). Yet, Wenger is quick to point out that online communities of practice differ from "garden-variety online communities":

> Every group that shares interest on a Website is called a community today, but communities of practice are a specific kind of community. They are focused on a domain of knowledge and over time accumulate expertise in this domain. They develop their shared practice by interacting around problems, solutions, and insights, and building a common store of knowledge (Wenger, 2001, pg. 1).

Certainly, the ePCRN fits this characterization, with its shared practice of primary care healthcare, its interaction around problems, solutions, and insights in context of conducting clinical research, and building a common store of knowledge in creating and disseminating evidence-based medicine (i.e., medicine that is based on clinical research findings). This is addressed further in Chapter 5.

Communities of practice have also been examined in the context of health and health research (McDonald & Viehbeck, 2007; Rosenheck, 2001; Parboosingh, 2002). For instance, CoPs were found to "perform several roles that ultimately facilitate the conduct, implementation, and use of research to improve health promotion practice and accountability" by connecting those who might not otherwise interact, such as researchers and practitioners with specialized expertise (McDonald & Viehbeck, 2007, p. 143). Importantly, CoPs were found to "provide a shared context to communicate and share information and experience" (ibid.). Further, the authors recommend that for a CoP to be successful in facilitating both [clinical] research and practice, "each CoP should include a

combination of research *producers* and research *users*" (ibid.) The dual role of producer and user is examined in my analysis of the ePCRN.

Critical Approaches to Communication Technology

As seen, technology's effect on a community is oftentimes viewed in largely optimistic or pessimistic terms. One critical theorist notes: "While technocrats hail the power of the computer to render social life transparent and controllable, humanists foresee the domination of man by the machine" (Feenberg, 2002, p. 117). Specifically, the Frankfurt school of critical theorists (e.g., Theodor Adorno, Max Horkheimer, Herbert Marcuse, Jürgen Habermas) and others (e.g, Martin Heidegger, Jacques Ellul) have been criticized by postmodernists and constructivists for being "anti-technological and/or at odds with (human experiences of) concrete technological practices" (Radder, 2008, p. 1). These theories seem to either praise technology's modernizing features as moving toward efficiency and progress, or lament its dominating effect on Western civilization.[18]

Rather than viewing technology as primarily driven by its "technical" aspects, critical theorists tend to examine technology within its larger social and cultural contexts (e.g., Pacey, 1983; Feenberg, 2002). Such critical theorists ascribe technology with social and cultural values, which may be hidden behind the more obvious "technical" features of a technological system. For instance, Pacey (1983) provides the example of the snowmobile, whose use in the 1960s expanded beyond leisure pursuits in North America

[18] A comprehensive examination of the Frankfurt school is beyond the scope of this study; for a more detailed narrative, however, see Chapter 1 in Feenberg's *Questioning Technology* (1999).

to hunting by Eskimos and reindeer herding in Swedish Lapland. On the face of it, the snowmobile's technology may seem "culturally, morally, and politically neutral" providing "tools independent of local value-systems which can be used impartially to support quite different kinds of lifestyles" (p. 2). Yet, implications of its use are quite different in different cultures. As a sporting vehicle used on trips between well-equipped tourist centers, its use has different maintenance and service issues than as a vehicle used by Eskimos to pull heavy loads across remote landscapes. Pacey argues that technology may at first seem culturally neutral "[i]f we look at the construction of a basic machine and its working principles. … But if we look at the web of human activities surrounding the machine, which include its practical uses, its role as a status symbol, the supply of fuel and spare parts, the organized tourist trails, and the skills of its owners, the answer is clearly no" (p. 3). It is therefore important to understand how technologies are embedded in social structures or systems.

Technologies are created among choices, and as a result "the real issue is not technology or progress *per se* but the variety of possible technologies and paths of progress among which we must choose" (Feenberg, 2002, p. v). This variety of possibilities, made through choices comprising both technical and social aspects, can have both potentially democratizing and oppressive influences on society (e.g., Pacey, 1983; Winner, 1986; Bijker & Law, 1992; Feenberg, 2002, 2008b). That is, technology systems' effects on community are neither inherently positive nor negative. To critically understand these implications, it is necessary to examine how decisions are made in the

design and use of technology, determining the biases behind decisions that have led to asymmetrical hierarchies of who controls and uses these technologies and systems.

Critical theories of technology (including social studies of technology and philosophy of technology) provide a rich literature to examine these issues. Key among these theorists are Andrew Feenberg, Arnold Pacey, Langdon Winner, Wiebe Bijker, and David F. Noble. My research aim in using critical theory is to understand the social and cultural values behind the technology of the electronic Primary Care Research Network, and how those values may affect decisions of its design and use with resulting asymmetrical hierarchies and/or democratic potential. With this aim in mind, I have identified four main concepts, for which commonalities exist among the above-mentioned critical theorists of technology. The concepts are the *non-neutrality of technology*; *social, cultural, and organizational aspects of technology*; *participatory design of technology*; and the *"democratic" potential of technology*.

These concepts have robust literatures of their own, beyond the scope of my current research. For instance, there is a strong European tradition in democratizing technology and participatory design, where researchers explore user participation in the design and introduction of computer-based systems, particularly as it relates to distribution of power in the workplace (Kensing & Blomberg, 1998).[19] These researchers

[19] Early work in Europe includes Nygaard (1979), who looked at ways workers and shop stewards in trade unions could strengthen their position at the bargaining table in response to new technologies thought to serve only the interests of management. In North America, Braverman (1974), Noble (1977), and Winner (1977) found that computer-based systems tended to increase managerial control. Other more recent research to examine technology's potential "democratic" effects on society includes Mansell, 2010; Della Porta & Tarrow, 2004; Feenberg, 2002, 2008b; and Poster, 1997.

argue that technological artifacts result from factors other than merely "technical" ones—factors that include political, social, cultural, and organizational considerations.

The next sections examine the literature of *non-neutrality of technology*; *social, cultural, and organizational aspects of technology*; *participatory design of technology*; and *democratic potential of technology*, which inform my research. I draw on the perspectives of the theorists mentioned above, among others, but for the most part I employ Feenberg's instrumentalization theory[20] and Pacey's "technology-practice" model[21] as a theoretical and practical basis to examine the cultural, organizational, and technical aspects of the electronic Primary Care Research Network and the resulting asymmetrical hierarchies and/or democratic potential (see Chapter 6).

Non-Neutrality of Technology

Central to the argument that technology is not neutral is that social, cultural, and organizational values shape how technology is developed and how it is used. These values may be "hidden" behind technical aspects (Pacey, 1983), or not given much thought until a technological breakdown occurs (Bijker & Law, 1992). Researchers warn of the consequences of ignoring or disregarding the values behind technology, whereby

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[20] Instrumentalization theory takes elements from philosophy of technology, in which substantivists view technology in "abstract" and "unhistorical" terms, and constructivism's social studies of technology (Feenberg, 2005, p. 49). It encompasses both the "distinctive operations that define a technical relation to the world," and the "social dimensions" affecting those technical relations (Radder, 2008, p. 1); that is, the abstract technical elements (e.g., database technology itself) and the social context surrounding and influencing a system's technical elements (e.g., how the database is used in practice).

[21] The "technology-practice" model focuses on the *process* of technological activity, broadening examination of a "restricted," technical meaning of technology (e.g., skill, technique, tools, machines) to include cultural (goals, values, ethical codes) and organizational (economic and industry activity, users and consumers) aspects of technology.

society is unable to understand and influence the technologies affecting people's lives and work (Brinkman 1971; Winner 1977; Mander 1978; Harding 1980; Pacey 1983, Winner 1986; Wajcman 1991; Postman 1992).

Others view technology as "ambivalent"—that is, that technology itself is neither inherently neutral nor a means to an end but "suspended between different possibilities" (Feenberg, 2002, p. 15). This view also contends that technical systems are embedded with values and social purposes, and further, that technical features are "insufficient by themselves" to determine a technical system's design (Feenberg, 1995, p. 4). In other words, "technology is not destiny" (Cohen, 1994, p. 576). As a result, any examination of technical systems, such as the ePCRN, must include the social, cultural, and institutional contexts, as well as the technical principles involved (see Social, Cultural, and Organizational Aspects of Technology section later in this chapter).

In this way, technology is also "underdetermined," whereby certain technologies succeed at the expense of other possible technologies, due to social, cultural, and other non-technical factors. Existing technical devices inevitably leave in their wake alternative designs. These alternative designs may never be realized, or perhaps will be merely forgotten. Underdetermination shows that "technical considerations alone cannot explain why we are living with this particular survivor of the process of elimination rather than that one" (Feenberg, 2009, p. 80). Oftentimes, historical or cultural factors determine a device's design, "not technical superiority in some absolute sense" (ibid.).

What ultimately determines the success of one technological alternative over another (or others) is the "fit" between the technology and the needs and views of those

who are able to influence the design process (Feenberg, 1995, p. 3). Improvements in one area, such as increasing efficiency in workload, "are sometimes accompanied by less desirable developments elsewhere," such as deskilling the labor force (Pacey, 1983, p. 14). Depending on the aims of those influencing the design process and how the technology is used, technological systems have the potential to, at one end of the spectrum, maintain existing hierarchies of power, while at the other end, to transform and democratize (see Participatory Design and Democratic Potential of Technology section later in this chapter).

Non-neutrality of technology is also seen in the concept of *formal bias* (Feenberg, 2008b). Formal bias purports the process of developing technologies today is neither "disinterested" nor "objective" but one of "ordinary politics" in which competing interests vie for influence over technical design "just as they have always fought for influence over legislation" (ibid., p. 14). Advocates of differing interests, whose livelihood or wealth may rest on controlling technical designs, will "argue more or less rationally" for their perspective (ibid.).[22]

Competing interests in how technology is developed can lead to formal bias, when a "relatively neutral system" such as a technical device "produces effects of inequality through its relation to its context" (Feenberg, 2008a, p. 122). Such a situation will favor a particular social group, and in the case of technology, produce an asymmetrical hierarchy of power with the favored group(s) influencing design and

[22] Pinch & Bijker (1987) also note that new technological systems form out of negotiation and struggle among relevant social groups.

control of technically mediated activities and "disempower[ing] subordinates relative to those at the top of organizational hierarchies" (ibid.).

Formal bias can represent "values embodied in the nature or design of a theoretical system" (constitutive) or "values realized through contextualizations" (implementation) (Feenberg, 2008b, p. 10). An example of constitutive bias is sidewalk design that does not allow equal access for the handicapped. An example of implementation bias is the digital divide: "it strengthens the rich at the expense of the poor, but only because the artefacts are distributed in a specific context of wealth and poverty, not because computers are inherently hostile to the poor. In fact, they can be a means of social advancement once the poor get hold of them" (ibid., p. 11). This distinction is evidenced in the ePCRN as I examine how formal bias exists on a constitutive level for efficiency and inclusiveness (see Chapter 6).

Another means to evaluate values behind technology is the concept of *technical codes*, defined as "the rule under which technologies are realized in a social context with biases reflecting the unequal distribution of social power" (Feenberg, 2005, p. 47). Technical codes represent underlying assumptions or values that become manifest in the technology itself (through the technological design and use). These assumptions or values can be explicit (for instance, articulated in the technology's specifications or regulations), but often are implicit in culture, training, and design. The invisibility of such established codes (e.g., everyday devices already accepted in our culture, such as the car or the telephone) is called "black boxing" because what is "inside" the technology is no longer questioned (Feenberg, 1995, p. 5).

Technical codes further show how technology systems are produced beyond consideration of mere technical capabilities, but also out of social and cultural factors. As the ePCRN is build on Internet technologies, an examination of the World Wide Web and Internet technical codes is useful (Flanagin, Farinola, & Metzger, 2000).[23] Flanagin et al. find that examining a technology's form and design via technical codes reveals much about the social and cultural environment in which the technology exists, particularly the "typically unnoticed aspect of technologies" and the "cultural and social priorities" behind the choices made in developing these technologies, which provide insight into the technology's future development (p. 413). Specifically, this study focuses on technical design, user data and usage patterns, and formal and informal policy, to reveal the Internet's technical code of "inclusiveness," "sharing of diverse information," "flexible capabilities," and policies that support "decentralized control, free market economics, and freedom of speech" (2000, p. 421). (See Table 1.)

Table 1: Technical Code of Internet/WWW

Design features	• Inclusiveness • Free flow of information
User data and usage patterns	• Sharing of diverse information • Flexible capabilities accommodating a variety of uses
Policies	• Decentralized control

[23] Other researchers concur with the principle of examining a technology's form and design to learn more about their social and cultural contexts. Cultural critic Neil Postman, in his book *Technopoly* (1992), asserts the importance of understanding technology's design in order to determine its effect on society particularly because a new technology does not confine itself to a "limited sphere of human activity"; instead, a significant technology change can generate "total change" within a society (p. 18). In addition, Langdon Winner (1986) writes that technical design can have political consequences, citing the design of New York City overpasses, which restricted public transport bus access (and thus, access of low-income people) around city parkways. Internet researcher Barry Wellman (2002) similarly shows that the Internet's design influences social phenomena such as how social relationships are formed and maintained and how power is structured in organizations.

	• Free market economics • Freedom of speech

The authors provide the following rationale for choosing the elements of design, user data and usage patterns, and policies to examine technical code. First, they identify *design* as "the most evident aspect of technological form" (ibid., p. 413). This includes the technology's "physical form" (e.g., its hardware), the "procedures" that define its use (e.g., software, rules of conduct), and specific features and capabilities, comprising how a technology "looks as well as how it works" (ibid., p. 414).[24] Second, *user data and usage patterns* provide information on demographics, behaviors, and decisions to describe how users "actively appropriate" the choices behind the technology (ibid.). Lastly, *policies* serve to formally and informally "establish, codify, and guide appropriate behavior" (ibid.). These areas are not mutually exclusive, and in fact they interact in complex ways. However, examined separately they illustrate specific aspects of the Internet's technical code. Table 2 outlines the components examined under each category. The following section outlines the study's findings in greater detail, which will be used in my examination of the ePCRN's technical code in Chapter 6.

Table 2. Categories of Inquiry: Technical Code of the Internet/WWW

Internet design	• Physical connectivity • Data communality • Interactivity • Ease of use
Demographic data and usage patterns	• Demographics • Information • Entertainment and social aspects • Commercialization

[24] See Willinger & Doyle (2005) for a comprehensive survey of Internet design and evolution.

Internet policy	• Control • Protected groups • Copyright

Design Features

In examining the Internet/WWW's design features, the authors turned to physical connectivity; data communality; interactivity; and, ease of use. For physical connectivity, they found that the Internet has gained a "critical mass" of users and has become widely accessible, although by no means universally accessible, within the United States (Flanagin et al., 2000, p. 414).[25] They attribute this to declining costs of computer hardware, the relative affordability of Internet service from providers, and increasing public access to computing. Data communality includes the Internet's ability to quickly and widely share data between remote sites, (e.g., databases of information are available 24 hour a day, 7 days a week for any number of purposes—to check airline schedules, to pay bills, to search library catalogs). In addition, the Internet's programming language of HTML (hypertext mark-up language) allows users to navigate Web pages and sites quickly and easily, ensuring its interactivity. The feature of its programming language allows users to engage with information in a non-linear fashion, and as a result, gives them agency to easily choose among the many "paths" of available information. Finally, the Internet's ease of use is evidenced in its intercompatibility where "information is transferred easily and quickly [from content servers] to receiving computers," and the

[25] Much research has been conducted on the "digital divide" that exists between those with effective access to digital technology and those with limited or no access. For example, a 2010 Pew Internet study found differences in Internet access based on household income (60% Internet use in households with less than $35,000/year compared to 94% with $75,000/year) and educational attainment (39% Internet use of those with less than high school education compared to 94% with college graduates).

development of sophisticated search engines and browsers enable users to easily search and obtain relevant content (ibid., p. 416).

The Internet's technical code is informed by these design characteristics "because the form of a technology reflects decisions about its intended use" (ibid., emphasis mine). This is a relevant point for the ePCRN's technical code: examining the network's design characteristics provides important information about the decisions surrounding its intended use in clinical settings (see Chapter 6).

Regarding the Internet/WWW's technical code, Flanagin et al. identified features of general inclusiveness and a free flow of information," indicated by increased physical connectivity and greater data communality, as well as ease of use and increased interactivity (ibid., p. 416). Its interactive design also supported users who both provided information as well as consumed information, a characteristic "relatively novel among communications media capable of reaching large numbers of people" (ibid.). This, too, is a relevant characteristic of the ePCRN, which aims to support users that contribute to the knowledge base of the network through research, as well as "consume" knowledge through dissemination of research results.

The authors summarize the Internet/WWW's technical code, as it relates to its design features, as "simultaneously a complex technical achievement as well as a relatively easy-to-use tool for communication and information sharing" (p. 416). They also state the Internet's complexity does not hinder use, but encourages inclusiveness and free flow of information, "fundamental aspects of its technical code, and fundamental aspects of the culture that created it" (ibid.).

User Data and Usage Patterns

Social and cultural values built into the Internet may also be uncovered by examining who uses the Internet and how they have chosen to use it (see also Weiser, 2001; Katz & Rice, 2002). To do so, the authors considered *demographics*, *usage*, and *commercialization trends*. The study cited increased numbers of Internet users from 1997 to 2000, when the study was published. Since then, Internet users have increased.[26] In addition, the Internet is used as a "mass medium that is relied upon for widescale information delivery" and has been found to be "the most often used source for gathering information," compared to other media and interpersonal sources (Flanagin et al., 2000, p. 417). As well as being used to gather information, the Internet is increasingly used for entertainment and social activities. Due to advancing interconnectivity capabilities, as a social technology the Internet provides a forum for cultivating interpersonal relationships. In fact, since this study was published, social media applications such as Facebook have seen growing popularity—from 8% of online American adults using social networks sites in 2005 to 46% in 2009 (Pew Internet Study, 2009a). Finally, the Internet also is increasingly used for commercial purposes, such as online sales of goods and services, a "resounding testament to the Internet's flexibility" (Flanagin et al., 2000, p. 418). These user and usage characteristics provide important information about the Internet's technical code of "diversity, flexibility, and decentralization" (ibid.).

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[26] According to a 2009 Pew Internet study, the percentage of adult Internet users from increased from 46% in 2000 to 79% in 2009; from 5% with broadband at home in 2000 to 63% in 2009; and from 0% connecting to Internet wirelessly in 2000 to 56% in 2009.

Policies

The formal and informal policies surrounding Internet design and usage, through issues of *control*, *protected groups*, and *copyright*, also reflect its technical code (ibid., p. 419).[27] Control occurs through formal methods of law and policy statements and informal methods of local policy and "interpersonal and social normative pressures," and includes policies on Internet commerce, privacy, and use of blocking software, which restricts access to particular types of content, such as pornography (ibid.). Policies designed to protect certain groups, such as children, aim to balance the Internet's freedom of information with a need to regulate potentially harmful material or practices. Finally, copyright law, created to protect an author's intellectual property against unauthorized use, has been extended to include electronic work; however, the lines of authorship in a "virtual" setting can be "blurred" as "a computer creates information using digital code which can be combined and recombined in many different ways and by many different individuals" (ibid., p. 420). Despite these efforts to control information, protect children, and enforce copyright, the Internet maintains characteristics of "freedom of information" and "decentralized mechanisms of control" through self-regulation and "market-driven control (ibid., p. 421).

Summary of Internet/WWW Technical Code

[27] See Sarikakis (2004) for further discussion of Internet policies and their implications.

The Internet/WWW is a result of various choices made by designers, users, policy makers, and others (ibid.). Examining the technical code reveals values of "equality," "freedom of information," and "empowerment" achieved via the Internet's technical capabilities that allow users to easily interact with others from a wide range of backgrounds and locations (ibid., p. 423). However, the authors also identify a number of constraints—due to issues of cost, physical access, and necessary skills and training—which may impede the Internet's characteristic "freedoms," specifically to "limit the range of users rather than inhibiting the scope of use by those who do enjoy access" (ibid., p. 422). The issue of constraints is particularly relevant for the ePCRN, to determine whether these factors affect access to the network and/or the range of activities offered by the network (see Chapter 6). These issues are seen in the social, cultural, and organizational aspects of technology.

Social, Cultural, and Organizational Aspects of Technology

Bijker & Law (1992) ask the fundamental question: how are technologies shaped? They argue that technologies are often "hidden," that oftentimes people don't think about how a certain technology works until it doesn't. While a technology is shaped one way, it's likely there are many other ways it could have been shaped. To truly understand technology and its effect on society, it is necessary to "think simultaneously about the social and the technological" (ibid., p. 4). *This is a central tenet in my research: that social and other non-technical factors influence technological design and its usage, with implications for individuals and society as a whole.*

To examine this concept more closely, I draw on critical theories of technology, focusing on instrumentalization theory (Feenberg, 2008b) and "technology-practice" model (Pacey, 1983). These perspectives provide a philosophical basis and a grounded, practical framework in which to understand the social and cultural values behind the technology of the electronic Primary Care Research Network, and how those values may affect decisions of its design and use with resulting asymmetrical hierarchies and/or democratic potential.

Both instrumentalization theory and "technology-practice" model outline various "levels" or "aspects" in which a technological system exists. These levels / aspects broaden the technology's "technical" aspect to include social, cultural, and organizational features. Moving beyond the mere "technical" aspects is necessary to understand the values and biases potentially "hidden" among or within the actual technology itself. This section outlines the important features of the social, cultural, and organizational aspects of technology.

The "technology practice" model includes cultural, organizational, and technical aspects to provide a more comprehensive view of technology, beyond the more "restricted" meaning of technology that comprises tools, machines, skills, and products (Pacey, 1983; see Figure 6). This is a key point because by considering technology only in the restricted sense, "cultural values and organizational factors are regarded as external" to technology. Only by viewing "technology" in the more general sense (i.e., with its cultural and organizational aspects), can its full meaning and impact be understood.

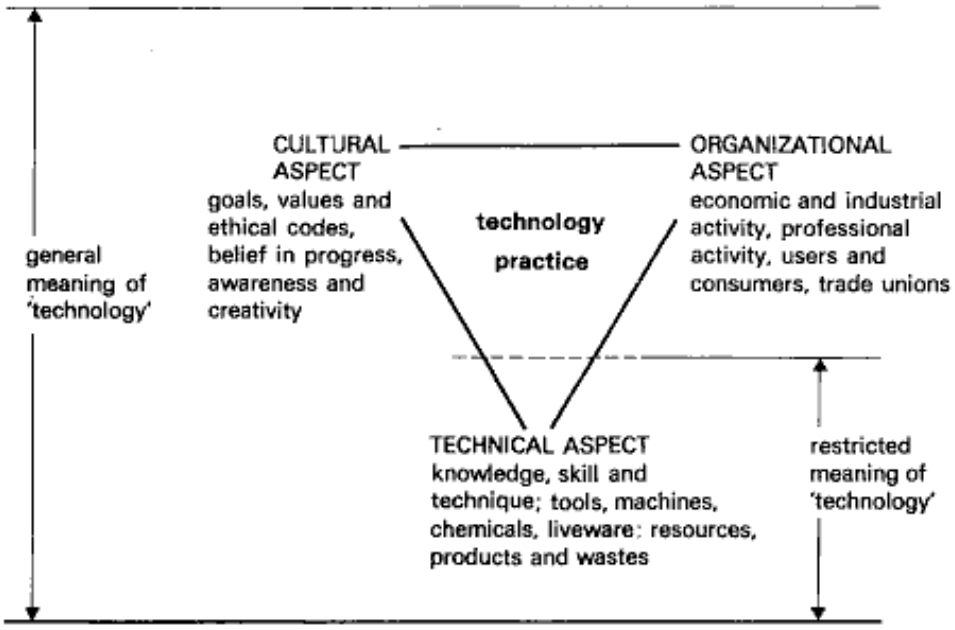

Figure 6. "Technology" and "Technology Practice" (Pacey, 1983, p. 6)

The concept of "practice," coupled with cultural and organizational aspects, indicates "human activity" and "imprecise values" in technology, rather than merely "comprising machines, techniques, and crisply precise knowledge" (ibid., p. 4). "Technology practice" is defined as "the application of scientific and other knowledge to practical tasks by ordered systems that involve people and organizations, living things, and machines" (Pacey, 1983, p. 6). In the ePCRN, "practice" is an important component for the network, technically, culturally, and organizationally, and certainly allows for examination of the network beyond its mere "technical" components. This is further examined in Chapter 6.

The technical, cultural, and organizational aspects of the "technology practice" model are also seen in instrumentalization theory. Similarly, instrumentalization theory analyzes technology beyond the "technical" to include "the level of our original functional relation to reality and the level of design and implementation" (Feenberg,

2005, p. 50).[28] Primary instrumentalization is the "functional constitution" between technical objects and subjects, while secondary instrumentalization focuses on technology's "realization" (1999, p. 202). In primary instrumentalization, technologies are "decontextualized," or reduced "to their useful properties" (2005, p. 50). This involves "de-worlding," taking technical objects out of their contexts, and simplifying technology's elements to arrive at the "affordances[29] with which all technology begins" (2008b, p. 15). Next, in secondary instrumentalization, technology is "integrated" with other technical systems and devices against social constraints, which further informs the technology's design and use (ibid.). In other words, the primary level breaks down and simplifies technology for incorporation into a particular device, network, or system. The secondary level integrates them in a social environment (ibid.).

These concepts illustrate that both affordances and social constraints coexist beyond a purely functional capacity of technology. Primary and secondary instrumentalization marries a functional perspective of technology with one of social meaning: "To reduce an automobile to its function as a means of transportation is reasonable from the standpoint of an automotive or highway engineer but is not true to life as it is lived by drivers and passengers" (2008a, p. 121). Technology fits alongside its social environment in the following way:

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[28] Hans Radder (2008) proposes a similar approach to Feenberg's primary and secondary instrumentalizations in the aim to "make explicit what is and what is not required in developing and using technologies" (p. 64). For similarities and differences of the two theories, see Radder (2008).

[29] Affordance theory was developed by ecological psychologist James J. Gibson (1986): "The affordances of the environment are what it *offers* the animal, what it *provides* or *furnishes*, either for good or ill" (p. 127). An affordance suggests particular behaviors: we perceive objects in relation to the possibilities they offer us. For instance, a knife's affordance follows its physical form but our perception focuses on its use. With one sharp edge, its affordance is for cutting; two sharp edges afford a stabbing ability.

> In technical fields a function is the designated purpose of a bundle of affordances orchestrated in a feature. When technical workers are told what function their work must serve, they look around for materials with affordances that can be combined and bent to this purpose. The secondary instrumentalization intervenes in the realization of the function in features. The affordances must be cast in a form acceptable to eventual users situated in a definite social context (2008b, p. 22).

An example of this distinction can be seen in the refrigerator, where engineers work on a primary level using "basic components such as electric circuits and motors, insulation, gases of a special type, and so on, combined in complex ways to generate and store cold" (ibid.). At this level, social context is barely present. These basic components tell one aspect of the story, but it does not afford a complete picture of the refrigerator as technology. For this, the secondary instrumentalization is required. Social factors such as "the likely needs of a standard family" (e.g., how many members in a typical household, whether they shop daily or weekly) must be taken into account to determine the refrigerator's appropriate size. In this way, society influences the artifact's technical design. Again, in terms of the ePCRN, the technical elements used in constructing the network (e.g., the Internet infrastructure, software, hardware) consists of its primary instrumentalization; the social context of clinical practice and research will also affect aspects of the network's design and use, which constitutes its secondary instrumentalization.

Another way to consider primary and secondary instrumentalization is by the terms "function" and "lifeworld"[30] (Feenberg, 2008b, p. 21). Those who are in a position

[30] The concept of "lifeworld" was introduced by social scientists / philosophers Alfred Schutz & Thomas Luckmann (1973) as "man's fundamental and paramount reality," the everyday life that a person "takes for

to directly influence and create technical artifacts operate "in a world of functions," focusing on the affordances and initial design of a technology to meet its intended function. The "lifeworld," however, constitutes the "everyday objects, activities, and communicative engagements of the population at large" (ibid.). The lifeworld imposes its social context on technical devices and systems, and in turn, these same devices and systems "disclose meanings that structure the lifeworld" (ibid.). In this way, primary and secondary instrumentalizations are "inextricably imbricated in practice" (ibid.); that is, they overlap each other.

As the explanation of function and lifeworld indicate, it is important to note that the primary and secondary levels do not exist independently of each other: "the device does not pre-exist the social determinations of its design" (Feenberg, 2008b, p. 15). However, primary and secondary levels are separated for analytical purposes. By breaking down a technological device or system to its elemental parts and then examining its social context, it is easier to see how each aspect influences the other, otherwise obscured or seemingly invisible when encountered holistically, as a "finished device" within a "social background" (ibid., p. 16). Any formal bias and other influences in the technology itself and/or in its application in the social world can then be determined.

By examining the ePCRN project using concepts, I determine that the network's development is at a primary instrumentalization level, although elements of secondary instrumentalization are also at work. In addition, the ePCRN's technical components (e.g., its Web portal) also are informed by cultural and organizational aspects, as outlined

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granted in the attitude of common sense" (p. 3). In my analysis, I use the terms "lifeworld" and "social context" interchangeably.

in a "technology practice" model. These aspects are found in the context of clinical research and primary care and include the research and clinical ethical codes, and clinics' organizational resources such as staffing ability to conduct research duties. I discuss these points further in Chapter 6.

Participatory Design and "Democratic" Potential of Technology

Both participatory design and democratizing technology involve users and laypersons responding to technology in ways that meet their needs and which break down asymmetrical hierarchies of power. My study mainly draws on instrumentalization theory's definition of democratic rationalization of technology (Feenberg, 2002), the call for more "user" and "layperson" collaboration with "experts" in designing technology (Pacey, 1983; Feenberg, 2002), and the need for "new professionals" with a broad interdisciplinary approach to designing technology and solving problems (Pacey, 1983).

Democratic rationalization is defined as "user interventions that challenge harmful consequences, undemocratic power structures, and barriers to communication rooted in technology," emphasizing "the public implications and consequences of user agency for technical design" (Bakardjieva & Feenberg, 2002, p. 186). Under democratic rationalization, democratizing technology "is about privileging … excluded values and the publics that articulate them" (Feenberg, 2002, p. 22) which is achieved by "granting actors who lack financial, cultural, or political capital access to the design process [of the

technical system(s)]" (Feenberg, 1995, p. 7). The result is a system that meets a "broader range" of needs than originally intended (Feenberg, 2008b, p. 25).[31]

While most technologies are created with a "specific social purpose in mind," many may also have "an influence which nobody expected or intended" (Pacey, 1983, p. 25). Modern technologies are built from collections of "parts," whose initial purpose(s) may veer off their original track to serve very different purposes in a wide variety of contexts (Feenberg, 2002). Gaps between existing technologies and new purposes can occur as a result of tensions between design and "lifeworld" contexts, where the status quo of design no longer fits the needs or purpose of users or current situations. For instance, participants of a technical network may become cognizant that the existing technical arrangements no longer benefit their interests. If these participants are able to "reconfigure the technical systems to take into account a broader range of human needs and capacities," new technologies may be established, changing a technology's design and/or use (Feenberg, 2002, p. 20).

One approach toward democratizing technology involves engaging users and laypersons, along with experts such as engineers or project managers, in the planning, design, and policy-making processes of technology, which typically has been of exclusive professional concern. In participatory design, "experts" and "lay actors" collaboratively influence, change, or reinvent technology to create a product to meet their

[31] Other researchers also note how users can divert technology in ways other than the initial purpose(s). The Internet, for example, was originally designed for military research, but was appropriated by its users for more widespread communication purposes (Rheingold, 1993). For other examples, see Turkle, 1984; Contractor & Seibold, 1993; Contractor & Eisenberg, 1990.

needs.[32] Spheres of "users" and "experts" working together on technology have potential for "innovative dialogue" that may more adequately solve problems while addressing users' needs (Pacey, 1983). In contrast, "halfway technology" results when professionals work in a "self-sufficient way within the expert sphere," without collaborating with users (ibid., p. 51). For example, such "halfway technology" might be equipment that is "over-elaborate and costly" or developed in "professional tunnel vision" where the technology matches the focus of the expert's sphere despite other, more appropriate options (ibid.). To avoid professional tunnel vision, participatory design theory proposes that experts broaden their approach through interdisciplinary teamwork. Through collaboration among "user" and "expert" spheres and adopting an interdisciplinary dialogue, a "new professional" emerges (ibid., p. 149). This new professional is "a new type of engineer who is oriented more toward maintenance (and nurturing) than development (and creation of novelty) and who can take a broad interdisciplinary approach to problems" (Baum, 1984, p. 1015).

An example of participatory design occurred in the 1980s and late 1990s when patients with AIDS confronted the clinical research establishment in order to obtain access to experimental drugs outside of the research protocol (Feenberg, 1995). Clinical researchers ("experts") adhered to research regulations that stipulated experimental drugs were not yet approved for treatment of AIDS. However, many AIDS patients involved in the research of these drugs ("laypersons" or "users") wanted to receive the drugs, rather than the placebo used to measure against the experimental drugs' safety and

[32] Stirling (2008) also examines the roles of "expert analysis" versus "participatory deliberation" in technology.

effectiveness. At that point, many AIDS patients believed they had a fatal illness and that they had a right to access to drugs, even if their safety and effectiveness were not yet clinically ascertained. The AIDS patients viewed these experiments as "inhumanly restrictive" and confronted the clinical researchers' scientific ethos (Feenberg, 2008b, p. 25). In other words, they challenged the technical code of the standard research protocol that requires a placebo group, and "out of confrontation of users and technical systems emerged a distinctive hybrid that served a broader range of human needs than was originally envisaged" (ibid.).

Regarding the ePCRN, my study closely examines the network's potential as a "democratic" technology through its intended participatory inclusion of primary care providers and their patients in the clinical research setting. For instance, the ePCRN team is responsible for adapting technology to increase access to clinical research and to facilitate the process of conducting and communicating the results of research—that is, to break down the "undemocratic power structures" of the clinical research enterprise that did not typically include primary care settings and to remove "barriers to communication" so that primary care practitioners and academic researchers may more easily recruit patients, conduct research, and disseminate research results. In Chapter 6, I examine to what extent the ePCRN realizes "democratic rationalization" through such a model of "participatory design" among the principal investigator, the ePCRN team, and potential users of the network.

Chapter Three:
Methodology and Methods

Introduction

This chapter describes the methodology and methods for this study, which examines the social dynamics of the ePCRN group during the project's development and how the network's technological affordances, hierarchies, and biases may affect the development and use of an electronic network geared to advance medical research and improve health. This chapter outlines the emergent research design of this study, evolving from a pilot ethnographic study employing grounded theory to a critical ethnography. This study's theoretical and methodological development is discussed in context of a reflexive research process during which ethnographic research methods (e.g., field observations, field notes, interviews, and document analysis) were used to collect, code, and interpret data. The result is a critical ethnography with a shift in methodological focus from 1.) a micro-level examination of the electronic network development team's intentions and actions, using "communities of practice" theory (Lave & Wenger, 1991; Wenger, 1998b), to 2.) a macro, technological system-wide critique employing a critical theory of technology framework (Feenberg, 1995; 1999; 2002; 2008b; Pacey, 1983).

In addition, this chapter includes a description of the research site, along with my evolving role as a participant/observer in the network's development, and an analysis of potential problems of method and ethical considerations when conducting ethnographic research. I also include a section on the methods used in the pilot project and current

research. First, however, I discuss my rationale for choosing this methodology for my study, followed by an overview of qualitative, ethnographic methodology.

Rationale for Ethnographic Methodology and Overview

It could be said that I chose an ethnographic methodology before choosing my research topic, site, and focus. First, my background in journalism and writing initially drew me to ethnography. The methods associated with ethnography—observing, interviewing, and writing narratives—were familiar to me, prompting me to enroll in an ethnographic methods course (RHET 8012) during the first year of my graduate studies in rhetoric. As mentioned in Chapter 1, the pilot study I conducted as part of this class led to my current research.

Before deciding on a research project for RHET 8012, however, I knew that the methodology must fit the research. I therefore considered John W. Creswell's (2003) framework elements for research design: *knowledge claims*, *strategies of inquiry*, and *methods*. Specifically, Creswell provides three key questions in designing a research project (p. 5):

1. What knowledge claims are being made by the researcher (including a theoretical perspective)?
2. What strategies of inquiry will inform the procedures?
3. What methods of data collection and analysis will be used?

Although the course dictated that I employ an ethnographic methodology, I deliberately returned to an analysis of these three questions to ensure that the research I chose to

undertake in this class would be supported by an ethnographic approach. In the following paragraphs I outline my framework analysis as it pertained to my early research. (See subsequent section on research design for discussion of the pilot study's evolution to a critical ethnography.)

"Knowledge claims" cover how researchers "make claims about what is knowledge (ontology), how we know it (epistemology), what values go into it (axiology), how we write about it (rhetoric), and the processes for studying it (methodology)" (Creswell, 2003, p.6). Generally, my knowledge claims fall under social constructivism with assumptions that meaning is found subjectively by understanding one's surroundings and experiences; that our historical and social perspective shape how we make sense of the world and our experiences; and that these meanings are varied and complex (ibid.). As a researcher, I am interested in the process of interaction among individuals and focus on the social contexts in which people interact to interpret meaning. In addition, I believe my interpretation cannot help but be influenced by my own background and experiences.

As opposed to the more philosophical level of knowledge claims, strategies of inquiry are more applied, providing "specific direction for procedures in a research design" (ibid., p. 13). Creswell categorizes strategies of inquiry associated with quantitative, qualitative, and mixed methods approaches. Not surprisingly, with my background in journalism (e.g., interviewing, observing, and writing) and a social constructivist bent, I found myself drawn to a qualitative approach to research. At this point, I began to consider potential research sites and questions for an ethnographic

study. At the time, I worked in the communications office at the University of Minnesota's Academic Health Center and had learned that a primary care researcher had secured a National Institutes of Health (NIH) contract to develop an electronic research network. I had interviewed him about this project as part of my job and was interested to follow its development for RHET 8012.

This project was funded by the NIH as a new way to engage primary care researchers in clinical research through electronic networks (see Chapter 1). My research interests were to track the decisions surrounding issues of communication, intervention, privacy, confidentiality, and human subjects' protection in developing the electronic Primary Care Research Network (ePCRN). As such, I believed that a qualitative approach would be appropriate to address my research questions. As stated by Creswell, qualitative research is "exploratory and is useful when the researcher does not know the important variables to examine. This type of approach may be needed because the topic is new, the topic has never been addressed with a certain sample or group of people, or existing theories do not apply with the particular sample or group under study" (ibid., p. 22). I was interested to discover the issues faced by the development team as they occurred, rather than start with any preconceived hypotheses, particularly as development of this network was in its early phase and the aim of connecting primary care physicians with potential research projects via an electronic network was relatively new. Using a qualitative approach provided me with an emergent way to explore these issues, as opposed to my taking a quantitative approach which typically requires the researcher to identify of

experimental variables as part of the research design as the purpose of the quantitative approach is to analyze causal relationships, rather than processes.

The strategies of inquiry I used in my qualitative study included ethnography, grounded theory, and case study. First, in the pilot study I employed a case-study approach to examine the ePCRN as a specific case, using an ethnographic method. I then used grounded theory (Glaser & Strauss, 1967) to obtain a general theory of process, grounded in the experiences and views of the ePCRN participants (see Research Design section for more information on use of grounded theory in my study). Second, I used multiple sources of data collection during my pilot ethnography, comparing my data to identify emerging categories and inform my developing theory. And, as discussed later in this chapter, my current research used the pilot study findings as a springboard to move beyond the pilot ethnography to writing a critical theory case study bounded within the ePCRN three-year development project.

Finally, using Creswell's framework for research design, I considered the specific methods of data collection and analysis for the pilot study. In choosing one's methods, Creswell suggests organizing the possibilities "by their degree of predetermined nature, their use of closed-ended versus open-ended questioning, and their focus for numeric versus non-numeric data analysis" (2003, p. 17). In considering the research site and the stage of the ePCRN project, I determined that I would need to employ an emergent design methods model[33] from which I would develop themes using open-ended questions during interviews and data from field observations, along with a textual analysis of data

[33] By emergent design, I mean the process where one's data collection results inform subsequent data collection and research design decisions.

and documentation. In particular, in the pilot study I was interested in the following research questions:

- What special concerns arise from the new technology being employed for the ePCRN, in terms of ethical patient care?
- How do concerns such as patient confidentiality and privacy, which are handled via well-established regulations in traditional clinical trial protocols, translate into the new model of ePCRNs?
- What are the overriding concerns, articulated during the decision-making processes, who articulates them, and what are the dynamics of discussion / debate?

To my mind, such research questions required methods that were descriptive rather than prescriptive, allowed for open-ended questioning and had a narrative, as opposed to numeric, focus for data analysis. (A full discussion of research methods used in the pilot and current study is covered later in this chapter.)

Despite my thorough analysis of the framework for my pilot study's research design, I had a remaining doubt about employing a qualitative, ethnographic methodology to this research. The field of clinical research, rooted firmly in the scientific method, has a positivist/postpositivist tendency that focuses on quantitative, empirical science. Although my research focuses on the communicative, process-oriented aspects of a developing clinical research network and qualitative research is not unheard of in clinical research (e.g., case histories), I was concerned my approach would not be taken seriously by the clinical researchers embedded in the ePCRN project and others in clinical research, who may be more interested in developing a quantitative approach to evaluating the ePCRN. I was thus interested to note a whole chapter on conducting qualitative clinical research in Norman K. Denzin & Yvonna S. Lincoln's *Strategies of*

Qualitative Inquiry (2003). In that chapter, authors William L. Miller & Benjamin F. Crabtree note that in addition to the more traditional experimental and survey research methodologies used in clinical research, other methodologies including field or qualitative research can be equally or even more relevant, depending on the research questions involved. "Our guiding premise is that the questions emerging from clinical experience frame conversations and determine research. … The clinical research space needs to be open to all of these possible sources and types of knowledge" (Miller & Crabtree, 2003, p. 400). The authors then lay out three goals for including qualitative research in clinical research settings (p. 401):

> (a) *creating a space* for research that is open and celebrates qualitative and multiparadigmatic approaches to the clinical world,
>
> (b) *providing the tools and translations* necessary for the discovery and interpretation of the clinical stories and knowledge within this space, and
>
> (c) identifying and describing the means for *telling the stories* and sharing the knowledge.

To create a space for qualitative research, Miller & Crabtree suggest a strategy of "entering biomedicine" (ibid., p. 402). Working within the biomedical paradigm, qualitative researchers using this strategy must understand the cultural context of biomedicine (or clinical research, in the instance of my research) "while clearly articulating a model that highlights the clinical implications of qualitative clinical research" (ibid.). In this regard, I had the advantage of five years' experience working with clinical researchers to educate the public on research results, including stem cell and cancer research. I thus understood and was able to navigate the clinical research setting, as well as articulate benefits of conducting qualitative research to provide research results

the ePCRN team may not otherwise have obtained (i.e., answers to the research questions regarding processes posed in my pilot study, as mentioned above, as opposed to quantitative findings). In this way, I was able to conduct a qualitative research study while retaining a clinical research focus (i.e., on the goals and setting of the clinical researchers involved in the ePCRN project). Because I was able to bridge clinical research and social science realms, my approach was accepted by the ePCRN team.

In providing tools and translation for bringing qualitative research methods into clinical research settings, Miller & Crabtree advocate an understanding of the similarities of the qualitative research process and the clinical process, particularly in primary health care (in which the ePCRN project sits). For instance, a tool called "relationship-centered clinical method" (RCCM) is used in primary care, whereby four separate processes are conducted sequentially but iteratively: exploring, understanding, finding common ground, and self-reflection (ibid.). RCCM's processes "correspond directly to the four processes of qualitative research: gathering, analysis, interpretation, and reflexivity" (ibid., p. 413). "If we use qualitative research language to describe the clinical process, the parallels and the translation of qualitative jargon become clearer" (ibid.). In the case of the ePCRN, I was able to talk about my research design and aims in a way that the primary care research team instinctively understood as relevant to their project.

Finally, Miller & Crabtree offer strategies to "tell convincing stories" of qualitative research for a clinical research audience. This includes telling a *methodologically* convincing story that answers the question: How was the research designed and done?; a *rhetorically* convincing story that answers: How believable is this

text?; and a *clinically* convincing story that answers: Does this study make clinical sense? (ibid., p.422-424). I have kept these points in mind while conducting my research, analyzing the data, and writing my ethnographic narrative.

Armed with my methodology and research design plan, and with a clear understanding of the clinical research world I was entering, I gained acceptance and access to the research team and site involved in the ePCRN's development through the University's Institutional Review Board. Once I had formalized my research topic and focus and gained access, I began examining the foundational ethnographic work and qualitative research that would inform my research.

Qualitative research has a rich and varied history across human disciplines including sociology, anthropology, education, history, business, medicine, and communications, as a way to study human group life and to understand the "other" (Denzin & Lincoln, 2003). Crossing disciplines, fields, and subject matters, qualitative research is "a situated activity that locates the observer in the world. It consists of a set of interpretive, material practices that make the world visible" (ibid., p. 4). Its approach is interpretive and naturalistic, meaning that qualitative researchers "study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them" (ibid., p. 5). Using a variety of empirical materials such as case study, observation, interviews, and textual analysis to describe people's lives, experiences, and meanings, the qualitative researcher aims to better understand the subject matter through multiple interpretive means. Denzin & Lincoln reference Levi-Strauss's term "bricoleur" as a "Jack of all trades or a kind of professional do-it-yourself

person" (Levi-Strauss, 1966, p. 17) to describe the qualitative researcher. That is, the qualitative researcher may take on multiple roles and methodological practices to assemble his/her research, much like a filmmaker assembles images to tell a story. As Denzin and Lincoln state: "The interpretive bricoleur produces a *bricolage*—that is, a pieced-together set of representations that are fitted to the specifics of a complex situation" (2003, p. 5).

Assumptions and Practices of Qualitative Research

According to many qualitative researchers, reality is socially constructed. As such, they also carry a relationship between themselves and what they are studying. They examine how social experience is created and given meaning. This approach contrasts with quantitative research methodologies, which "emphasize the measurement and analysis of causal relationships between variables, not processes. Proponents of such studies claim that their work is done from within a value-free framework" (ibid., p. 13).

In addition, qualitative research is emergent rather than prefigured, employing largely inductive reasoning (Creswell, 2003). The process is also iterative, moving back and forth from data collection and analysis to re-examining the problem and research questions and back. This process simultaneously occurs with the collection, analysis, and writing up data. This was certainly the case in my research, as discussed later in this chapter.

My research of the network's social and technical processes is informed by the contextualized ethnographic methodology promulgated by cultural anthropologist

Clifford Geertz and historian James Clifford. The narrative "thick description" proposed by Geertz (1973, p. 3)[34] is designed to capture not only human behavior itself, but its situatedness (or its context), so as to render its meaning useful to those outside the circle of those whose behavior is being studied. The result is a written narrative derived from the researcher's study of an "intact cultural group in a natural setting over a prolonged period of time" using primarily observational data (Creswell, 2003, p. 14). A characteristic of qualitative research, the research process of an ethnographic study can evolve in response to the context of the experiences and observations made during the research, and as such, supports an emergent design. The next sections address how these characteristics of ethnography were critical to my research, allowing for a shift in methodological focus from a micro-level grounded theory to a systems-based critical theory.

Research Design

According to Denzin & Lincoln (2003), a research design "describes a flexible set of guidelines that connect theoretical paradigms first to strategies of inquiry and second to methods for collecting empirical material" (p. 36). As mentioned above, my research employs a qualitative ethnographic methodology, originally using grounded theory, but evolving to a critical theory methodology.

[34] Further, Geertz states that ethnographic writing is "really our own constructions of other people's constructions of what they and their compatriots are up to" (1973, p. 9). Presenting their interpretations through thick description helps ensure that readers are able to determine the credibility of the author's work (i.e. of their "constructions," point of view, and analyses).

To answer my research questions about process, I required a methodology that would allow me to discover themes and change direction of my research as necessary, depending on the experience of the ePCRN development group. My research, beginning with the pilot study, required that I study the ePCRN group on a micro-level, learning about their decision-making processes and the social and technical issues they encountered while developing an electronic network to bring together primary care physicians with university researchers in new ways.

At this early stage, I employed grounded theory ethnography to draw out a theory of interaction "grounded" in the views of participants of the study (Creswell, 2003, p. 14). By using inductive analysis of field notes and interviews as part of my research design, I derived categories, themes, and patterns from the group's interaction I observed at meetings and in interviews (see section on data collection and research methods later in this chapter and Appendix C for further detail). These analytical categories provided necessary grounding in the ePCRN's project, and the issues uncovered in the pilot study provided important direction in my proposed dissertation research. Much of the content of the meetings and interviews I observed at this time focused on the development and implementation of an electronic network in primary care clinics to link primary care providers and academic researchers for clinical research purposes.

During the pilot study, I identified some key themes with the development of the network (see Table 3 and Appendix C). From issues such as project complexity, team member roles, and code-switching (i.e., an individual's ability to navigate between two areas of expertise), I focused on the processes involved in how the ePCRN project was

developed and how the team members interacted to achieve their goals during the project's three-year funded period.

Table 3: Pilot Study Themes

Metaphors	Types of metaphors used for the technology and its application included physical characteristics, cognitive and creative writing metaphors, and behavioral metaphors.
Complexity	Complexity mentioned in general and of certain components, the project's timeframe, members' roles within the project, the project's evolution, and of *not* having an electronic network.
ePCRN evolution	How the ePCRN evolved from previous, single clinical projects, to the vision outlined in the ePCRN proposal, to changes required when the IT team began to build the network.
UK involvement	How the UK team contributed a technological knowledge base with their existing electronic network and how the UK and the US teams developed a collaborative relationship.
Roles	Two teams within the project: information technology and clinical.
Code-switching	An individual's ability to navigate between two separate areas of expertise, evidenced mainly by the principal investigator (across clinical and IT areas).

Using Lave & Wenger's "communities of practice" theoretical framework, I conducted a micro-level analysis of the group interactions, drawing on what Geertz (1983) terms "local knowledge"[35] as the team worked to build a network using the processes of *joint enterprise*, *mutual engagement,* and a *shared repertoire* (see Chapter 2 for more information about communities of practice theory; see Chapter 5 for analysis of the ePCRN in context of communities of practice).

[35] Geertz asserts that "local knowledge" is formed and based on one's immediate experiences, that to understand how things work, we draw on those direct experiences.

However, early in this stage of my research, I realized that a more strategic level of analysis was required to explain the ambiguities of the ePCRN project. I needed to expand my research beyond a micro-level view of the development team to a more macro-level systems-based perspective. To examine the ePCRN more broadly as a technical system situated in a specific cultural context of primary care and clinical research, I began to search for a theoretical framework with a broader lens than Lave & Wenger's communities of practice. I discovered that critical theories of technology (Pacey, 1983; Feenberg, 2008b) afforded a way to examine the values tacitly embedded in the ePCRN project and to identify any formal biases inherent in the technology by employing a critical theory methodology.

More specifically, I identify my research as a critical ethnographic case study. First, I discuss what is meant by critical ethnography. Sociologist Jim Thomas sees critical ethnography as "embedded within conventional ethnography" (1993, p. 3). Conventional and critical ethnography share several fundamental characteristics, including "reliance on qualitative interpretation of data, core rules of ethnographic methods and analysis . . . and a preference for developing 'grounded theory'" (ibid.). Distinguishing characteristics include critical ethnography as a reflective process that goes beyond merely describing "what is" to "what could be" by "challenging research, policy, and other forms of human activity" (ibid., p. 4). Thomas gives critical ethnography a political purpose, one in which knowledge is used for social change, whereby "voice" is given to groups previously silenced by "unnecessary social domination" (ibid., p. 5). "Constraints that give some groups or individuals unfair

advantage to the disadvantage of others, or social elements that automatically exclude some people from full participation in (and the benefits of) the resources commonly available to those more privileged (e.g., health care, education, or employment) are considered unnecessary. *Unnecessary social domination* exists when constraints are built into cultural and social life in ways that promote such inequality" (ibid.). In this respect, my research is a critical ethnography of an electronic research network that aims to expedite and expand inclusion of clinical research. The very aims of the ePCRN project attempt to address asymmetrical participation in clinical research, where research in the primary care setting is marginalized and benefits of clinical research take too long to reach those patients targeted to help. It seems to me that both the current research situation and the project that aims to address those shortcomings carry assumptions that need to be critically examined, and thus my research evolved from a conventional form of ethnography to a critical ethnography methodology when I applied a critical theory of technology analysis to my data (for more detail, see Chapters 2 and 6).

Second, referring to my research as a case study, I use Robert E. Stake's guidance that case study "is not a methodological choice but a choice of what is to be studied" (in Denzin & Lincoln, 2003, p. 134). For my research, the case in question is the ePCRN, *bounded* within its three-year NIH funding period. Similarly, as my research design is emergent, the focus of my research as a case study has also evolved. Initially, I identified the pilot study as an *intrinsic case study*, defined by Strake as intrinsic if "it is undertaken because, first and last, the researcher wants better understanding of this particular case" (ibid., p. 136). This was certainly true initially, as I wanted to understand the processes

involved in developing an electronic network for primary care research. Later, when adding a critical theory element, my focus expanded to more of an *instrumental case study*, "to provide insight into an issue or to redraw a generalization" (ibid., p. 137). By examining the ePCRN's development through a critical theory of technology lens, I aimed to broaden the research's relevance beyond the ePCRN itself to a larger examination of technical systems in a clinical research context.

The Research Site and Researcher's Role

My research occurred at the University of Minnesota, mainly within the Medical School's Department of Family Medicine and Community Health on the Minneapolis campus, where the principal investigator of the ePCRN is a faculty member. Key members of the ePCRN team include representatives from the principal investigator's department, the University's information technology office, and a research team based in Birmingham, England. Others involved, to a lesser extent, included a software vendor and a group of practice-based research network directors from across the nation. Weekly meetings were held in a large (approximately 25' x 10') conference room in the Department of Family Medicine and Community Health. The typical set-up was as follows: A long table is set up in the middle of the room, able to seat about 14 people. Keith,[36] the lead investigator, sits at the head of the table, facing the wall on which the visual projection from the access grid[37] (when used) is projected. The rest of the team is

[36] I have used pseudonyms for all network team members.

[37] Access grid technology allows groups at different physical locations to interactively collaborate using high-quality audio, multiple video streams, and digital presentation resources. See also Appendix A.

flanked around the table. Jerry, the senior informatics manager, usually sits at Keith's left hand side. The clinical support team—Penny, Tom, and Christy (who have all worked together with Keith on previous projects)—tend to sit on Keith's right. The technical team in attendance, which usually consists of Sean, Matt, Martin, Andrew, and sometimes Jonathan and Nate, are usually seated further down the table, on either side. When the access grid is in use, Sean and Matt sit together at the far end of the table with the computer running the system. From the computer, they make adjustments to the audio levels and monitor the connection. When Steve attends he usually sits on either side next to Keith. Steve's expertise is mainly technical, but at a more conceptual level than the rest of the technical team.

The Birmingham team and other off-site members (representatives from the technical company Syntech,[38] for example) have access to the weekly meetings either by conference call (initially) or later, by the access grid node. When the grid node is used, their images are projected onto the wall in front of Keith (the team from Birmingham has several camera angles they can transmit to us), so it looks like they're sitting at the end of the conference table. Likewise, an image from our location is transmitted to them. In this fashion, the weekly meetings are conducted. Later, a sub-group consisting of technical members convenes weekly, using the same technology when necessary. The bulk of my field notes are gathered from this setting. I also conducted interviews with key members at the University of Minnesota, typically at their respective offices. In addition to the

[38] Pseudonym used.

observation of the weekly meetings and interviews, I also examined documents prepared by the ePCRN team (see Table 4).

Table 4: Data Sources: Field Notes, Interviews, and Project Documentation

Field notes	all-group meetings	infrastructure meetings	clinical implementation meetings		
Interviews	principal investigator	technical team members	clinical team members		
Documentation	ePCRN proposal	quarterly reports to NIH	ePCRN meeting minutes	ePCRN activity reports	various supporting documents

My role as researcher, particularly during the pilot study when the majority of my field data was collected, was that of participant observer. As a method, Kathleen M. Dewalt & Billie R. Dewalt call participant observation "a way to collect data in naturalistic settings by ethnographers who observe and/or take part in the common and uncommon activities of the people being studied" (2002, p. 2). In my case, I worked in the University's clinical research environment and was familiar with the ePCRN team on a professional basis, and so was not entirely considered an "outside" researcher. This was evidenced in the fact that at times they asked for my communications advice on the ePCRN project. However, based on James Spradley's (1970) continuum of researcher participation (from pure participation, also known as "going native," to nonparticipation, where the researcher does not interact with those being studied), for most of the research period my role fell in the middle of the spectrum (i.e., moderate participation). Moderate participation is characterized by the researcher being "present at the scene of the action, is identifiable as a researcher, but does not actively participate, or only occasionally

interacts, with people in it" (Dewalt & Dewalt, 2002, p. 20). Although I felt able to fairly successfully navigate the balance between participation and observation as a researcher, I was constantly conscious of the tension between these two poles. On the one hand, I had access to the researchers through my job at the University, where I interacted with them on other communication needs outside the ePCRN project. I understood their aims and their language as primary care researchers. In these ways, I was an "insider." On the other hand, I tried to maintain some distance, operating more as a passive observer.

At points throughout my research, I would question how my perspective as a researcher was being influenced by my professional relationship with the team. For instance, I was cognizant that it could be uncomfortable to present any negative findings in my research. This felt particularly acute during the pilot study and the early stages of the subsequent research. However, I eventually arrived at a feeling of appropriate distance when I began employing a critical theory of technology framework to the ePCRN project, moving beyond the micro-level examination of the team's interaction on the network's development. Partly this was due to the fact that I began to focus more on examining the textual dimensions of the project, for example, the initial project proposal and the team's quarterly reports to the NIH, as opposed to transcripts of interviews and field notes of meetings I attended. In the end, I realize it is not possible for an ethnographer to be completely neutral or detached and that my presence may have affected some of what took place in the field. Yet these are not necessarily negative aspects of ethnography. For instance, effects of the ethnographer's participation on how members may talk and behave "should not be seen as 'contaminating' what is observed

and learned. Rather, these effects are the very source of that learning and observation" (Clarke, 1975, p. 99, as quoted in Emerson, Fretz, & Shaw, 1995, p. 3).[39]

Data Collection and Research Methods

My research is characterized by an emergent, reflexive, interpretative process in which I navigated back and forth across research methods to inform my theoretical framework and analysis. I now examine the research methods employed and the cyclical process involved in arriving at my research findings.

Specifically, my research involved: 1.) observations of weekly meetings with the ePCRN development team, including sub-meetings with the technical members; 2.) audio-taped interviews with the principal investigator and key technical and clinical team members; and 3.) collection of documentation supporting the ePCRN development project (i.e., proposal, quarterly reports to the NIH, meeting minutes, activity reports). Table 1 outlines this study's data sources.

Beginning in February 2005, I began attending the ePCRN's weekly meetings to observe and take notes. Initially conducted by conference call with the University of Birmingham in England, eventually the meetings were held using an access grid, a

[39] Issues of the researcher's role in ethnographic studies in workplace settings are addressed by Doheny-Farina (1993). In addition, there is a robust literature on ethnographic studies in workplace settings within the field of rhetoric and scientific and technical communication. While beyond the scope of my study, I provide a few examples regarding workplace transformation: Odell & Goswami (1982) examines writing adults do as a regular part of their daily work; Barley (1996) examines the role of technicians to understand the changing nature of work in a post-industrial economy; Vallas (2003) looks at social and organizational conditions that affect workplace transformation in four manufacturing plants; Henry (2000) analyzes 83 workplace writing ethnographies that "problematize" the local cultures in a variety of organizations by academic researchers in rhetoric and composition; and Peckham (1997) reports on the introduction of email in a particular company within the framework of that company's ethos.

multicasting application where the UK team was projected in real-time on site in Minnesota and vice versa (see section on research site, above). At the end of March, the weekly meeting was divided into two sub-meetings: one regarding infrastructure issues and one focusing on clinical implementation.

These weekly meetings constitute the bulk of my field research. During these meetings, which were usually attended by 8 to 12 people, I took fieldnotes on the behaviors and activities of the group members, using Robert M. Emerson, Rachel I. Fretz, & Linda L. Shaw's *Writing Ethnographic Fieldnotes* (1995) as my guide. My fieldnote descriptions were not "facts" of what happened, but interpretations of activities or "inscriptions of social life and social disclosure" (ibid., p. 8). In this interpretative process the researcher decides what is to be noted and what is not noted (and consequently what is written down and what is not), which has implications: "The ethnographer 'inscribes' social discourse; *[s]he writes it down*. In so doing, [s]he turns it from a passing event, which exists only in its own moment of occurrence, into an account, which exists in its inscription and can be reconsulted" (ibid., pp. 8-9, quoting Geertz, 1973, p. 19).

For the most part, I would write down what I saw and heard, and where appropriate, note parenthetically any reactions/thoughts I may have had. My fieldnote transcription method used what Emerson et al. term "participating to write" (1995, p. 18); that is, writing as an observer throughout the meeting so as to record as much information as possible. In particular, I tried to focus on the content of the discussions, as well as the group dynamics, such as who held the floor or how individuals reacted to technical problems. This work was challenging, not only due to the number of participants

involved, but because the meetings sometimes would be conducted via three different media: face-to-face, conference call, and access grid node. After each meeting, I would write up my fieldnotes as soon as possible.

I usually arrived early for these meetings and had an opportunity to informally chat with members, sometimes about the status of or their feelings about the ePCRN project, but often times our conversation was unrelated to the project or my research. Regardless, I would not start taking notes until the meeting formally convened. If something of particular note was expressed during the pre-meeting phase, I would note that when able. As our seating was in relatively close proximity to each other, I benefited from being able to use shorthand when I wanted to note something potentially sensitive. As I did not consistently use shorthand, I am not sure it was even noticed by the others; it was certainly never brought up or questioned. Because all members of the group took notes during the meeting, I do not believe my note taking was viewed as distracting to the members.

In addition to the weekly meetings, I interviewed key members of the team, which I audio-recorded and then transcribed. To bolster my experience in interviewing as a journalist / communicator and specifically for guidance in conducting interviews for academic purposes, I consulted Irving Seidman's *Interviewing as Qualitative Research* (1998). I agree with Seidman's viewpoint that stories are "a way of knowing" (ibid., p. 1) that we can use interviewing to understand people's experiences from their point of view. That is, I did not use interviewing to obtain answers to questions or to test hypotheses, but to "see how their individual experience interacts with powerful social and

organizational forces that pervade the context in which they live and work" (ibid., p. 112), to learn about the interconnections among the ePCRN group, and to understand their intentions and meanings in context of the ePCRN project. Interviewing key members proved useful at gaining insight into their world as researchers and primary care providers, and how they worked together on their shared goal of developing an electronic research network.

I used primarily open-ended questions during semi-structured face-to-face interviews, intruding on the responses as little as possible. Generally, I asked for details of each interviewee's experience and reflection on the meaning of their experiences relative to the ePCRN project. Although there were several questions I asked of each person (such as "what is your role in the project" and "what are some of the project's challenges"), I did not have a standard list of questions. This seemed necessary, since the team members had such differing roles in the project, depending on whether they were clinical or technical members. In hindsight, it may have been interesting to stick to a set of questions and compare their responses.

During the interviews, I placed high importance on listening, "the most important skill in interviewing" (Seidman, 1998, p. 63). Specifically, Seidman provides guidance on three levels of listening: to what the participant is saying; to the participant's "inner voice" (as opposed to his/her public voice); and remaining aware of the process as well as the substance of what is being said (e.g., nonverbal cues, the time, the participant's energy level), (ibid., p. 63-64). I audio-taped the interviews, which typically lasted about one hour each, and then transcribed them. Methods used to analyze and interpret the

interviews are discussed later in this section. As well as attending the weekly meetings and conducting interviews, I also recorded an informal meeting between several clinical and technical members and then transcribed the interaction using discourse analysis notation which focused on concepts of content, rather than form or structure (Wood & Kroger, 2000).

Finally, I collected documentation developed by the ePCRN team, including the initial project proposal, minutes of the weekly meetings, quarterly progress reports, activity reports, and other various communications. The next paragraphs outline how I analyzed the data from my observations, interviews, and documentation.

My process for analyzing my data includes the following cyclical steps: close readings, questioning the content, open coding, initial memos, focused coding, and reflections. As a first step, I closely and repeatedly read the content of my fieldnotes, interviews, and documents, questioning what I was reading for potential meaning and significance using Emerson et al.'s (1995, p. 146) suggested line of questioning:

- What are the people doing? What are they trying to accomplish?
- How, exactly, do they do this? What specific means and/or strategies do they use?
- How do members talk about, characterize, and understand what is going on?
- What assumptions are they making?
- What do I see going on here? What did I learn from these notes?
- Why did I include them?

In early April 2005, I began coding my fieldnotes and interview transcripts, first using an open coding technique (Emerson et al., 1995). In this phase, I did not use pre-established categories when reading my fieldnotes or interview transcripts. Instead, I

examined my fieldnotes and transcripts "with an eye toward identifying events described in the notes that could themselves become the basis of categorization" (ibid., p. 152). In addition, I did not avoid categories that did not fit with my initial focus, in case my focus was to change as I progressed with my notes. Instead, I examined small segments of my fieldnotes and transcripts by noting words and phrase "that identify and name specific analytic dimensions and categories" (ibid., p.150-151).

In an iterative process, I went back over the open coding in search of themes. It was quickly apparent that more themes emerged than I would be able to deal with in my research, and therefore, I would need to identify central themes. This was determined in several ways. First, I included themes to which a substantial amount of data referred to, suggesting "recurrent or underlying patterns of activities" (ibid., p. 157). Second, I included topics that seemed to be particularly important to the ePCRN members, for example, issues relating to members' roles and the project's complexity. Once I had identified my core themes, I conducted a more detailed focused coding, involving a more line-by-line analysis of my notes and interview transcripts, "building up and elaborating analytically interesting themes both by connecting data that initially may not have appeared to go together and by delineating subthemes and subtopics that distinguish differences and variations within the broader topic" (ibid., p. 160). In this way, I was able to uncover themes in my fieldnotes concerning the technical aspects of the ePCRN's development (e.g., connectivity; audio and/or visual quality; delays). From this data, I selected six categories for further investigation: metaphors; complexity; evolution of the ePCRN; the UK's involvement; roles; and code-switching, or moving between different

areas of expertise (see Table 3, earlier in this chapter; for further information on findings from the pilot study, see Appendix C).

These categories led to a period of reflection on my findings and my decision to focus on the relationships of the ePCRN team members in their work toward creating an electronic network for primary care research. It was from this jumping off position that I came across communities of practice theory, and a re-examination of my pilot study findings indicated that the ePCRN group may have been functioning as what Lave & Wenger (1991) call a "community of practice." In a reflexive, iterative fashion, I switched focus to a micro-level examination of the group's activities in context of communities of practice. In a process similar to that employed during the pilot study, I revisited my data by conducting close readings, open and focused coding, interspersed with questioning and reflecting on the data and findings. In particular, I looked for evidence of the group acting as a community of practice, in terms of their relationships, their goals, and the content of the network.

Similarly, in a cyclical process, once analyzing my data for communities of practice, I realized I needed to broaden my examination to include a critical theory of technology perspective (see previous section of this chapter). Again, an analysis of data similar to that described above was conducted, focused on examining aspects of critical theory of technology, including formal bias, technical codes, and hierarchies.

Writing an Ethnographic Narrative

My research findings are produced in an ethnographic narrative that is richly descriptive of the setting, the participants, their experiences and intentions, and more broadly, the social context in which they operate, gained through fieldwork, interviews, and documentation review. I employed this type of "thick description" (Geertz, 1973) to provide readers of my research the necessary context in which to understand the network as well as my perspectives and subsequent decisions in my analyses. Again, it is important to note that the results of this research are interpretative. As an ethnographer, I selected certain incidents and events, giving them priority over other incidents and events, and thus constructed meaning as articulated in this account.

My narrative does not adhere to a strictly chronological accounting of the ePCRN project throughout its three-year funded period. Rather, it begins with a macro view of the National Institutes of Health framework for advancing clinical research through the NIH Roadmap initiative and the ePCRN's role within this initiative (Chapter 4). My narrative then switches its lens to a micro-level analysis of the ePCRN members' activities and intentions in building an electronic network to advance health and how the team operated as a "community of practice" (Chapter 5). Lastly, my narrative broadens again to a macro-level examination of technical systems in a clinical research context (Chapter 6).

Methodological Limitations and Ethical Considerations

Finally, I believe it is important to outline some methodological limitations of ethnography, including ethnographer bias and issues of reliability and validity, and my

perspective on addressing these in my research. First, because this methodology is interpretative, it is not possible for a researcher to be completely objective. Indeed, ethnographer bias has been reported in the field since the pioneering work of Raoul Naroll (1962, 1970). For instance, his and others' work suggest that "the length of time that a person spends engaged in participant observation does make a very large difference in the kind of findings that may be reported" (Dewalt & Dewalt, 2002, p, 80). Because we all possess biases and particular predispositions, Dewalt & Dewalt propose that "[o]ur reporting, however, should attempt to make these biases as explicit as possible so that others may use these in judging our work" (ibid., p. 81).

As noted earlier, I believe my research cannot help but be influenced by my own experiences and backgrounds—that on a certain level I am not able to separate myself from the data. Hopefully, by acknowledging this constraint and outlining my relevant experiences and background as they pertain to the research, I provide necessary transparency. Also, in response to potential ethnographer bias, I continually challenged my position and role as researcher, and questioned my analyses, as an iterative research process throughout my research.

In addition, the researcher's presence has potential to bias the participants. For instance, in interviewing as Seidman notes,"[a]lthough the interviewer can strive to have the meaning being made in the interview as much a function of the participant's reconstruction and reflection as possible, the interviewer must nevertheless recognize that the meaning is, to some degree, a function of the participant's interaction with the interviewer" (Seidman, 1998, p. 16).

While objectivity as an absolute truth is not attainable, researchers should strive toward "closeness to an accurate description and understanding of observable phenomena" (Dewalt & Dewalt, 2002, p. 94). One potential way to address issues of potential bias is to triangulate data and methodology. By examining the evidence from different data sources (triangulation), a researcher can build justification for themes and their findings. As opposed to a means of attaining complete objectivity, the use of multiple methods or triangulation "reflects an attempt to secure an in-depth understanding of the phenomenon in question . . . . a strategy that adds rigor, breadth, complexity, richness, and depth to any inquiry" (Flick, 1998, p. 230-231).

In summary, to address potential limitations, I strived to be as transparent as possible of any influences and predispositions I may have in the regards to the ePCRN project and its members. I also employed multiple methods as a means of ensuring in-depth analysis of the project. In turn, I believe my multi-method and multi-theoretical perspective became a strength of my research. This approach allowed me to examine the assumptions and affordances behind the ePCRN technology, followed by how the group made decisions in developing the technology, and then providing an analysis that merged the affordances, aims, and dynamics used to determine the technology's role within its social context.

Chapter Four:
Promoting Efficiency (Speed) and Inclusiveness (Reach) in Clinical Research

Aims of efficiency and inclusiveness in clinical research are at the heart of the National Institutes of Health Roadmap initiative and the electronic Primary Care Research Network (ePCRN) proposal, submitted in response to the NIH initiative.[40] Both the Roadmap and ePCRN project attempt to promote efficiencies in the conduct of research studies and implementation of their findings into clinics as patient care, and to expand the pool of research participants as well as the scope and focus of clinical research to be more inclusive and representative of the nation's overall population. In addition, both the Roadmap and ePCRN project identify technology as a means to achieve these aims. This chapter examines the assumptions and technical affordances surrounding efficiency and inclusiveness in clinical research. First, I provide evidence of the NIH Roadmap initiative's claims for efficiency and inclusiveness, followed by the ePCRN's response to this call. Next, the ePCRN's technical affordances, based on Internet technology, are examined against Gurak's framework of speed and reach (2001). Finally, I address the potential implications of greater efficiency and inclusiveness in clinical research via the ePCRN, including potential limitations and ethical concerns.

The Case for Efficiency and Inclusiveness

[40] See Chapter 1 for more information on the NIH Roadmap and history of the ePCRN.

As introduced in Chapter 1, the aim of *efficiency* concerns accelerating the process of conducting research and making those findings known to other researchers, practitioners, and the public, while *inclusiveness* pertains to advancing more clinically relevant research and broadening the study-participant population to more closely represent the nation's diverse patient population. In the case of the NIH, the aims of efficiency and inclusiveness span the entire clinical research enterprise—from advancing understanding of biological systems, to forming multidisciplinary research teams, and overhauling the nation's research infrastructure. The ePCRN, however, targets the research infrastructure and uses technology (i.e., an electronic network) to achieve these aims. This section provides examples of how efficiency and inclusiveness are promoted via the Roadmap initiative and ePCRN project.

The NIH Roadmap initiative was introduced in a 2003 *Science* article by then-NIH director Elias Zerhouni. He writes that the initiative must "ensure both *efficient* and effective discovery" and that its priorities be "essential to *accelerate progress* across the spectrum of the institute missions" (p. 63, emphasis mine). In these passages, Zerhouni expresses an overall aim of efficiency. Later in the article, he outlines a specific arm of the initiative, Re-engineering the Clinical Research Enterprise. For this area of the initiative, the NIH director articulates a desire for *both* efficiency and inclusiveness, as seen in this excerpt:

> [E]xciting basic science discoveries demand that clinical research continue and *even expand*, while striving to *improve efficiency* and better inform basic science. … Clinical research needs to develop *new partnerships* among organized patient communities, community-based physicians, and academic researchers. In the past, all research for a clinical trial could be conducted in one academic center; that is unlikely to be true in the future.

> In these initiatives, NIH will promote creation of *better integrated networks* of academic centers that work jointly on clinical trials and include community-based physicians who care for large groups of well-characterized patients. Implementing this vision will require *new ways* to organize how clinical research information is recorded, new standards for clinical research protocols, *modern information technology* … (Zerhouni, 2003, p. 64, emphasis mine).

While efficiency is referenced explicitly, the call for inclusiveness is subtler. For instance, "new partnerships" and "better integrated networks" include linking primary care providers and their patients in research. In addition, technology's role is mentioned as a potential way to address these needs through NIH Roadmap-funded programs:

> These pilot programs will begin to develop an *informatics infrastructure* that will *link current and emerging clinical research information systems* so that data and resources can be shared within and across clinical research networks, across studies and across institutions, *reducing duplication* and *avoiding unnecessary overlap* between trials. We expect [these networks] to help *streamline* clinical research and to *accelerate the pace* of discovery and application of clinical findings (ibid., pp. 64 & 72, emphasis mine).

As seen, Zerhouni refers to efficiency and inclusiveness in this excerpt's language. Linking information systems is a way to achieve inclusiveness across research sites and studies. He mentions efficiencies through "reduced duplication" and "avoiding unnecessary overlap," followed by an overall aim that networks will "streamline" research and "accelerate" discovery and application of findings (see Table 5).

Table 5. Efficiency and Inclusiveness in NIH Roadmap Initiative

Efficiency	**Inclusiveness**
Improve efficiency	*expand*
link … to share data and resources	*new partnerships*
reducing duplication	*better integrated networks*
Avoiding unnecessary overlap	*link … information systems*
streamline	
accelerate	

The NIH Web site provides further information on how the Roadmap initiative aims to increase efficiencies and expand inclusiveness in clinical research. Here, I examine the area of the initiative under which the ePCRN was funded, Re-engineering the Clinical Research Enterprise. I also provide a summary of the ePCRN's response to the issues raised in the Roadmap initiative (see also Table 6, below).

First, the NIH states how a "re-engineered" enterprise would work. This includes an "infrastructure" to facilitate the translation of laboratory-based discoveries to the clinic and a "robust force of clinical investigators" to conduct research in "larger numbers of patients far sooner than currently possible" through "networks" equipped with "tools to facilitate collaboration and information sharing" (NIH, 2009b).

In response, the ePCRN's proposal attempts to address these issues through the development of an electronic network to link researchers with primary care physicians who, although not typically involved in clinical research, see most of the nation's patients. The basic premise of the ePCRN is that an electronic infrastructure will help researchers and primary care physicians more easily and systematically collaborate—widening the pool of available study participants while streamlining the research process and reducing the amount of time it takes to translate new findings into primary care practices, and thus, to the public. For example, as stated in the ePCRN proposal, new partnerships among primary care providers and researchers "should *enhance* the ability of investigators to conduct research, as well as *facilitate* delivery to clinicians of better tools to provide care" (Peterson, 2004, p. 3, emphasis mine). Specifically, the principal

investigator makes the case in the proposal that emerging technologies can help achieve the Roadmap's vision:

> Introduction of *open-source technology* using very *high speed* backbone networking allows *greater functionality, security, and communication*, and permits the *integration* of primary physicians and their practice populations into the clinical research enterprise, and substantially *enhances the potential for the performance of RCTs* [randomized controlled trials] (Peterson, 2004, p. 3, emphasis mine).

Table 6. NIH Roadmap / ePCRN Response to Efficiency and Inclusiveness

NIH Roadmap	ePCRN response
infrastructure	high-speed electronic network via Internet2
robust force of clinical investigators	new partnerships with primary care providers
larger number of patients	tapping into primary care patient population
conduct research far sooner	enhance ability of investigators to conduct research (e.g., targeted patient recruitment)
tools to facilitate collaboration and information sharing	electronic network's applications (e.g., patient registries, targeted communication of studies and research findings)

Overall, the NIH Roadmap views technology as a means to both increase efficiency and inclusiveness:

> By *enhancing the efficiency* of clinical research networks through informatics and other technologies, researchers will be better able to *broaden the scope* of their research. *Reduced duplication* of studies will leave *more time and funds to address additional research questions*. (NIH, 2009a, emphasis mine).

According to the NIH, a new, networked clinical research infrastructure would allow increased "scope of research activities" and "participation," as well as improved "communication and cooperation" of researchers and studies (ibid.). The ePCRN proposal states the network would:

> provide the ability to perform large national *collaborative studies* throughout the United States, *improve efficiency*, *reduce costs* for individual trials, provide *easier access* for data retrieval and analysis, and

> *involve primary care* in recruitment, performance, and translation of findings into practice (Peterson, 2004, p. 3, emphasis mine).

It is clear that both efficiency and inclusiveness in clinical research are valued aims, as seen from the examples in then-NIH director Zerhouni's *Science* article, the NIH Roadmap Web pages, and the ePCRN proposal. Based on the purposes stated in these sources, it would seem that efficiency and inclusiveness are inherently beneficial for clinical research in general, as well as for future patients, who stand to gain from research findings drawn from a more representative population and efficiently implemented as patient care. In addition, it seems to make sense that an electronic network, with technical affordances of speed and reach, would be well suited to help attain these goals. To fully determine the potential effects of efficiency and inclusiveness via technology on the clinical research enterprise, however, we must further examine the technical affordances of speed and reach, including both the potentially beneficial and more risky implications.

Technical Affordances From Speed and Reach

The term "affordance" was defined by psychologist James J. Gibson (1977, 1986) as something that an environment offers a person. He wanted to understand how perception informs an animal's meanings of environmental objects, and thus its interaction with those objects. Gibson's theory purports a "direct-perception view," that objects have inherent meaning and these meanings are detected by the animal "without mental calculation" (Jones, 2003, p. 107). Gibson (1986) describes affordances of the environment as "what it *offers* the animal, what it *provides* or *furnishes*, either for good

or ill. … [Affordance] implies the complementarity of the animal and its environment" (p. 127). He goes on to discuss how objects have properties or qualities, such as color, texture, and size and that traditionally psychologists "assume that objects are *composed* of their qualities" (ibid., p. 134). However, Gibson breaks with this assumption, stating instead that "what we perceive when we look at objects are their affordances, not their qualities" (ibid.). That is, an object's affordance is what we really pay attention to—what it can do for us, rather than its composition of individual "qualities."

This has relevance for my examination of the electronic network's technology and its affordances. Technology is comprised of properties or qualities (such as the software language used in computer applications), which are often overlooked by the user who engages in the technology's "affordances"—what the technology can "offer" the user. In the case of technology and my examination of the ePCRN, I use affordance to mean the possibilities for what a particular technology (i.e., the ePCRN) can offer someone who interacts with that technology. Affordances marry technological infrastructure with its use, whereby users of technology are influenced not only by the technology itself and what its objective "features" offer (e.g., database functionality), but by possibilities for action (e.g., how the user *actually uses* the database function).

In a seminal exploration of Internet technology, Gurak (2001) identifies "action terms" of *speed*, *reach*, *anonymity*, and *interactivity*: the "functional units by which most Internet communication takes place" (p. 29). Further, she cites *speed* and *reach* as "two of the most obvious yet significant features of online communication" (ibid.). Today, the Internet's characteristics of speed and reach are almost taken for granted. With the stroke

of a key, mass amounts of information in multiple formats (e.g., text, sound, video) can be sent to innumerable recipients across the globe, reaching them within moments. Gurak argues that these affordances inform certain online behaviors and qualities of communication, such as easy replication of information and global reach. In addition, the Internet has informed our sense of "community." Because the Internet's reach allows people with common interests to form communities without geographic constrictions, "virtual" communities spring up where members don't necessarily have to meet face-to-face. In fact, these are the qualities the ePCRN project aims to create by linking researchers and primary care clinics across the United States, and providing efficient ways to communicate and share data.

As seen in the previous section of this chapter, the ePCRN proposal articulates features of speed and reach, focusing on technology's *benefits* with language such as "facilitating," "seamless," and ability to "promote" translation of research findings into clinical practice for the benefit of patients. However, the proposal also addresses *concerns* faced by primary care physicians in relation to clinical research (such as how to identify potential participants, privacy, confidentiality, and human subjects protection issues, tracking participants' progress, etc.). By giving voice to these concerns, while at the same time promoting the network as a means of efficiency and inclusiveness, the ePCRN members have to negotiate two worlds: the affordances of speed and reach are inextricably linked to both potential benefits and constraints of the ePCRN's technology. In this next section, I examine implications of the ePCRN's focus on efficiency (speed) and inclusiveness (reach), specifically regarding issues of *participant recruitment*,

informed consent, *data collection and management*, *communication*, and *privacy and security*—issues identified in the NIH Roadmap, the ePCRN proposal, and elsewhere (e.g., Sung et al., 2003; Paul, Seib, & Prescott, 2005) as relevant to "re-engineering" the clinical research enterprise.[41]

Implications of Efficiency (Speed) and Inclusiveness (Reach)

Coinciding with the inception of the NIH Roadmap initiative, the *Journal of the American Medical Association* published a landmark article (Sung et al., 2003) that identified four "central challenges" facing the nation's clinical research enterprise: enhancing public participation in clinical research, developing information systems, an adequately trained workforce, and funding. The first two challenges directly relate to inclusiveness (public participation) and efficiency (information systems). In this section, I examine the issues identified by Sung et al., and reference the strategies outlined by the principal investigator in the ePCRN proposal to meet these challenges. In addition, I draw on the work of Paul, Seib, & Prescott (2005), which examines the potential advantages and disadvantages of Internet technology in clinical research settings.

In their study "Central Challenges Facing the National Clinical Research Enterprise," Sung et al. (2003) found that clinical researchers faced hurdles of "high costs, slow results, lack of funding, regulatory burdens, fragmented infrastructure, incompatible databases, and a shortage of qualified investigators and willing participants" (p. 1278), which they then grouped under the four central challenges mentioned above. In

[41] Chapter 6 also addresses issues of affordances, in context of instrumentalization and "technology-practice" theories, interpretative frameworks that informs my analysis of the ePCRN's potential as a "democratic" technology.

examining public participation and information systems, inclusiveness and efficiency are seen to potentially affect issues of *participant recruitment*, *informed consent*, *data collection and management*, *communication*, and *privacy and security*. Table 7 provides a summary of these findings. In the next sections, I will examine these affordances and limitations in the ePCRN model.

Table 7. Affordances and Limitations of ePCRN Model

	Affordances	**Limitations**
Patient recruitment	• increase number and diverse representation of study participants • use of "participatory research" model • targeted recruitment	• privacy and security issues
Informed consent	• potential for ongoing dialogue	• risk of therapeutic misconception
Data collection and management	• centralization of study information • coordination of multi-site studies • efficient data searches and data management	• privacy and security issues
Communication	• ability to link primary care providers and researchers • notification and follow-up of studies • dissemination of findings • live audio/visual link via access grid	• privacy and security isssues • availability of Internet2 technology in clinics

Participant Recruitment: The Promise of the ePCRN

Clinical researchers need research participants. In fact, this is an ever-increasing need as the number of clinical studies also increases (Sung et al., 2003). However, recruiting participants can be a lengthy, difficult, and resource-intensive process. For instance, recruitment has been shown to comprise "up to 50% of one total cycle time for

a typical clinical trial," amounting to three years of the development cycle of a typical drug (Marks & Power, 2002, p. 106). In addition, eligible patients are often unaware that they can participate in research studies (Sung et al., 2003).

It is important to note that enhancing public participation in clinical research involves more than just upping the *numbers* of research participants. The pool of research participants must also be more *representative* of the nation's population. A more representative clinical research population also requires involvement of those who have been historically under-represented in clinical research, such as women, children, and some ethnic groups (Sung et al., 2003). Yet, as mentioned in Chapter 1, there can be a cultural mistrust of clinical research, which must be addressed by researchers if adequate representation across age, sex, and culturally diverse groups is to be obtained. It may be that involving patients' primary care provider in the research process would also help involve previously under-represented populations in research. Presumably, patients tend to have more of an existing relationship with their care provider than is likely with an academic researcher. In this way, being approached to participate in research by one's care provider may mean the patient would be more willing to participate. Having care providers approach patients regarding research brings up the issue of potential therapeutic misconception, however, which must also be addressed (see section "Informed Consent," below).

In addition, in general, participants have expressed an interest in being more involved in the research process, such as identifying research questions, ethical review, and implementation of results (ibid.). As Sung et al. report, "The effective recruitment of

sufficient number of clinical study participants may ultimately hinge on the willingness and ability of the scientific community to actively engage study participants in every stage of research, implementing a community-based 'participatory research' model" (pp. 1280-1281).

The ePCRN proposal aims to address these concerns in several ways. First, regarding inclusiveness, the premise of the network is to link researchers with primary care providers and patients. As previously mentioned, primary care providers are not typically involved in research, but they see the majority of the nation's patients (Tierney et al., 2007). This population represents a large, previously untapped research participant pool. In addition to increased numbers, involving primary care settings in research also expands the diversity of potential research participants, as primary care patients are more representative of the demographics of the nation's population than those who are seen at academic health centers, where research typically occurs.

In addition, the ePCRN may represent a more community-based "participatory research" model, cited by Sung et al. as a way to promote public participation in research. By engaging primary care providers and their patients in the clinical research process, the ePCRN is geared to focus on research questions that are relevant to the health needs and concerns to these providers and patients. As indicated by Sung et al., if research studies address issues of genuine concern to patients, they may be more willing to participate.

In terms of efficiency, the ePCRN proposes a "targeted" recruitment function, whereby primary care providers will be notified electronically of clinical trials for which their patients may be eligible (for instance, individual patient records may be "flagged"

when specific criteria are met). This function could streamline the participant recruitment process, obviating the need for a manual search of patients' medical records to determine eligibility.

Despite the potential promise for increased inclusiveness and efficiency in participant recruitment, however, issues of privacy and security must be addressed (see relevant section, below). In addition, care must be taken so that patients as potential research participants fully understand the research process, and how that differs from therapeutic care. I cover this concern in the next section, informed consent.

Informed Consent

Informed consent is the process whereby the potential participant learns more about the study including potential risks and benefits, in order to determine whether to participate. This process usually begins as a dialogue between the researcher and the potential participant (or in the case of the ePCRN, between the primary care provider and the patient). By signing a consent form, the participant indicates that s/he understands the risks and benefits and agrees to participate. However, the "length and depth" of the forms have increased such that they "often are unread by research participants, and they may be so intimidating as to discourage participation" (Sung et al., 2003, p. 1281). The 2003 study recommends a "more accessible" participant consent process, necessitating an open, ongoing relationship between research team members and the participant.

The ePCRN does not specifically address this challenge, although the proposal mentions that once a potential participant is identified as eligible for a particular study,

his/her provider may then discuss with the patient the possibility of participating in the study. The primary care provider is the link between the potential participant and the research team; even if the potential participant eventually interacts directly with the researcher, it is the primary care provider who serves as the initial point of contact for the study. However, the process of informed consent can be complex and further complicated when the roles of provider and researcher are "blurred" in the patient/participant's eye. This confusion of roles is known as "therapeutic misconception."[42]

Therapeutic misconception occurs when a research participant believes that enrolling in a research study will provide direct therapeutic benefit (Appelbaum, Roth, Lidz, Benson, & Winslade, 1987). This, however, is not necessarily the case as therapeutic medicine and research have different goals: while therapeutic medicine focuses on providing benefit to the individual patient, the goal of clinical research is to generate new knowledge to help future patients (Brody, n.d.). As Appelbaum et al. (1987) explain: "To maintain a therapeutic misconception is to deny the possibility that there may be major *disadvantages* to participating in clinical research that stem from the nature of the research process itself" (p. 20, emphasis mine). Unfortunately, therapeutic misconception is not uncommon among research participants. In a 2002 follow-up study, Appelbaum found that "as many as 70% of subjects in a wide variety of clinical research studies may suffer from a therapeutic misconception" (p. 23).

The informed consent process is designed to ensure that potential participants understand all aspects of the research study. To help avoid the possibility of therapeutic

[42] See Chapter 1 for a more detailed discussion on other ethical considerations of informed consent.

misconception, Brody suggests that informed consent "should start with a clear orientation of ***what sort of setting*** one is in" as the potential participant "who thinks he is getting individualized therapy when in fact he is being treated according to a research protocol cannot give informed consent." He goes on to state that "blurring the distinction between research and therapy risks undermining the entire process of informed consent" (ibid.).

In the case of the ePCRN, therapeutic misconception may be particularly risky. Patients may not initially appreciate the distinction between therapeutic care and research, particularly if information about the research comes from the patient's primary care provider, whose role with the patient has been therapeutic, not experimental. In addition, the patient should not feel obliged to participate in research in any way. In particular, patients should know that their care would not be adversely affected should they decline participation. The role of the physician/researcher in the case of the ePCRN will be crucial in avoiding potential therapeutic misconception. Of course, this risk exists in current settings, and is not specific to the ePCRN. Guidelines on avoiding therapeutic misconception will be relevant for the ePCRN. For instance, Appelbaum et al. suggest that a "trained, neutral educator" could aid potential participants' decision-making (1987, p. 24).

Data Collection and Management

Internet technology, such as used in the ePCRN model, provides centralization of study information and coordination of multiple, multi-site clinical trials. The increased

use of electronic medical records and database technology allows for easier data searches and data management (Paul, Seib, & Prescott, 2005). Sung et al. (2003) also recognize that information systems have an important role to play for "new efficiencies" in clinical research, such as streamlining data entry and data coordination across functions (e.g., clinical trial forms, adverse event forms).

Efficiencies in data collection and management are highlighted in the ePCRN proposal. For instance, the ePCRN's proposed patient registry, comprising data from primary care practices across the nation, represents a large, heterogeneous and complex dataset. Use of Internet2 technology, organized under the developed Web portal, facilitates the collection and management of this comprehensive, complex data. The network's technology provides high-capacity storage for data and flexibility in data collection, including collection of large files, which would be accessible to researchers involved in the ePCRN.

This technology allows for increased inclusiveness and efficiency through quicker, more comprehensive collection, analysis, and management of wide-ranging data. Through networked databases and sources, researchers should be able to access a greater range of data, more quickly than ever. Again, however, concerns of privacy and security must be addressed against affordances of inclusiveness and efficiency (see relevant section below).

Communication

Improved communication amongst research teams and care providers, and with the public, including potential participants, is needed to transform the clinical research enterprise (e.g., Zerhouni, 2003; Sung et al., 2003; Paul, Seib, & Prescott, 2005). For instance, conducting complex, multi-site research studies requires coordinated, timely communication across a range of functions—from research concept, protocol development, recruitment, informed consent, data collection, analysis, publication, to dissemination of results. Specifically, Paul, Seib, & Prescott suggest study Web sites can be used to provide information to potential participants, study subjects, and investigators to include contact information and detailed information about the trial. Internet technology can also support communication needs amongst researchers during the conduct of studies, such as centralizing data handling for patient registration, randomization, and data collection. Sung et al. suggest developing effective and efficient ways to "communicate accurate and comprehensive information about the process of findings of clinical research to consumers, policymakers, and the media" (pp. 1281-1282).

The ePCRN proposal includes two main strategies for improving communication amongst researchers, care providers, and the public: a centralized Web portal[43] and access grid technology[44]. The Web portal provides an infrastructure and functions to link primary care practices with researchers in academic centers. Specific activities include recruitment, entry, and follow-up of multidisciplinary randomized controlled trials. These functions require large amounts of information to quickly travel back and forth across

[43] In this case, the entry point to the ePCRN Web site. See Appendix A.
[44] Access grid allows for advanced videoconferencing across multiple sites with large displays and multiple simultaneous camera feeds. See Appendix A.

multiple sites and recipients. In addition, targeted communication amongst researchers, care providers, and patient/participants include information about available studies and dissemination of relevant research results.

Communication via access grid technology was primarily intended for discussions among the ePCRN development team, academic researchers, and other potential primary care collaborators. Despite initial glitches in the use of this technology in the ePCRN planning phase[45], this type of multiple-site videoconferencing provided useful interaction capabilities among the various participants of the ePCRN team, located throughout the United States and Birmingham, England. In addition to providing audio and visual access of participants at each site, the access grid also allowed viewing of Web-based sources, particularly useful when the ePCRN team was discussing the portal development. In this case, the entire team was able to see screen captures, as well as review functions in real time. This capability allowed for immediate feedback from members and helped speed the pace of development.

The access grid was also intended for use beyond the development team's initial purpose of building the network. The proposal outlined its use for training purposes. "Substantial training of primary care personnel is an essential aspect to a successful practice-based trial—but the cost of transportation and training of personnel can be challenging" (Peterson, 2004, p. 16). The ePCRN team envisions the access grid as an "alternative to expensive, time-consuming travel budgets for large [research studies] with potentially hundreds of participating sites" (ibid.).

[45] See Appendix C.

Through the Web portal and access grid technology, the ePCRN model aims to increase efficiency and inclusiveness in communication capabilities for clinical research. While the technology affords this capability, there may be limiting factors of whether intended sites can support Internet2 technology, or whether appropriate human resources are available to complete the tasks afforded by the technology. In addition, as with the other areas mentioned in this section, the affordances of efficiency and inclusiveness must be matched against the need for appropriate privacy and security.

Privacy and Security

Issues of privacy and security in clinical research in general, and for the ePCRN in particular, cut across all the areas mentioned above. When the Internet is used for sensitive information exchange, security and privacy issues must be addressed. In clinical research, patients and researchers need to be confident that data transmitted via electronic forms and email are secure. Database servers must also be protected against unauthorized users and uses. According to Paul, Seib, & Prescott (2005), "a secure Internet clinical trial system should ensure confidentiality (information is only disclosed to users authorized to access it), integrity (information is only entered or modified by users authorized to do so), and availability (information and other resources can be accessed only by authorized users)" (Security Issues section, para. 1).

Across the research process, researcher access to patient data must conform to regulatory guidelines of appropriate access and use. The ePCRN proposes various ways to ensure privacy and confidentiality of personal health information, including firewalls,

encryption of information, restricted access to data, and de-identified personal information. For instance, a secure server controls access using a username, password, four-digit identification and a six-digit code that changes every 60 seconds. While these technical safeguards may be in place, it is crucial that primary care providers and their patients feel secure in the network's privacy and security capabilities. For instance, is it possible for hackers to break into the system to access private health information? Also, what strategies are in place against possible user violation of security measures? If care providers and their patients are not convinced that the network protects against these issues, they may be reluctant to participate, thwarting the network's technical affordances of efficiency and inclusiveness.

Summary

Overall, the ePCRN's technical affordances of inclusiveness and efficiency have potential to widen the pool of researchers and participants and streamline the recruitment process; provide centralized study information and data collection and management; and improve communication amongst research teams and care providers, and with the public. This matches with the NIH's desire for an infrastructure to facilitate the translation of laboratory-based discoveries to the clinic and a robust force of clinical investigators to conduct research in larger numbers of patients far sooner than currently possible through networks equipped with tools to facilitate collaboration and information sharing.

Yet, limitations and potential disadvantages exist. Throughout the areas of participant recruitment, informed consent, data collection and management, and

communication, it is important to maintain a balance of inclusiveness and efficiency with appropriate levels of privacy, security, and consideration of patient rights. While the NIH values *accelerating* the research process, it does not aim to achieve this at the expense of ethical conduct of research. Care must be taken by researchers and primary care providers to ensure potential participants understand the research process—particularly the different aims of clinical research and clinical care and its relevance to the patients' care—to avoid therapeutic misconception. Researchers and care providers must also clearly explain any possible risks and benefits to patients of their involvement in a clinical research study. In addition, real and perceived security threats must be addressed to ensure private health information is kept safe, that data is de-identified, and that only authorized users have access to authorized information for appropriate purposes. The ePCRN project outlines various measures to ensure privacy and security, critical components to the network. However, it may nevertheless be challenging to assure potential participants and their care providers that an electronic network such as the ePCRN *does* provide the necessary privacy and security safeguards. As Paul, Seib, & Prescott (2005) state: "It is difficult to convince the average person of the efficiency of the abstract security measures used in Internet trials (firewalls, encrypted transmissions, password protection) compared with the conventional security measures used in traditional trials (locked file drawers)" (Disadvantages section, para. 1). In addition, the security and privacy measures built into the ePCRN model must be followed *in practice* by those using the network. For instance, the key fob is used to authenticate an authorized user; however, if the owner of the fob gives the device to a colleague and asks that he log

in for her, that would represent a breach of security, despite the appropriate security measures in the model's *design*.

Aiming for efficiency and inclusiveness in clinical research may at first glance appear entirely beneficial. Streamlining the research process potentially saves time and money; involving a wider, more representative study population should result in more relevant research findings; accelerating the pace of research achieves faster results and implementation as patient care. Further, it would seem that technology could help us achieve these goals. However, is it important to step back from focusing solely on technical affordances to include the ethical considerations and potential limitations of an initiative that privileges newness, speed, and transformation of the clinical research enterprise.

The next chapter examines how the ePCRN begins to implement its vision for efficiency and inclusiveness. Using a community of practice framework, I examine how the team faces issues of realizing the network's potential affordances of efficiency and inclusiveness against some of the ethical and technical challenges mentioned here.

Chapter Five:
Toward Democratizing Clinical Research:
Functioning as a Community of Practice (CoP)

This chapter examines the ePCRN in context of its development as a "community of practice" (Lave & Wenger, 1991; Wenger, 1998b) during its three-year NIH-funded contract and its potential to function as a CoP in clinical settings. Specifically, I examine the ePCRN against the three characteristics of successful CoPs (joint enterprise, mutual engagement, and shared repertoire; see Chapter 2), drawing on evidence from the ePCRN's initial proposal to the NIH, field notes from weekly meetings, interviews with members of the development team, meeting minutes, and quarterly/annual reports. From my analysis, I propose that to operationalize the project's aim of greater inclusiveness and efficiency in clinical research, in a sense to "democratize" clinical research, the ePCRN team has taken on characteristics of a Community of Practice (CoP). This analysis has implications for the future of clinical research in primary care settings and other health-related networks, which I discuss in Chapter 7.

ePCRN as a Community of Practice

My analysis shows that the ePCRN development team possessed the essential elements of a CoP, and consequently, that they functioned as a community of practice during the project's three-year funded period. Following my pilot project, I conducted a close re-reading of my field notes, interviews, and quarterly reports to the NIH for indications of joint enterprise, mutual engagement, and shared repertoire. My schema

under which I organized the three dimensions of CoP within the eCPRN framework is seen in Figure 7.

Figure 7. Electronic Network as a "Community of Practice"

The ePCRN's *joint enterprise* (or, what the ePCRN/CoP is about) constitutes the projects's overall aim. As stated in the NIH proposal, its aim is to "enable the development of an electronic infrastructure that facilitates the recruitment of subjects and the performance of randomized controlled trials in primary care practices anywhere in the

United States, and that promotes the rapid integration of new research findings into primary care" (Peterson, 2004, p. 3). In general terms, facilitating clinical research in primary care settings is the project's shared domain of interest. It is the reason each and every team member is at the table, and the guiding principle of the ePCRN's work.

To obtain the ePCRN's overall aim (i.e., its joint enterprise), the ePCRN proposal identifies three objectives[46]:

- a Web-portal that will enable primary care practices anywhere in the United States to link with researchers in academic centers or NIH to facilitate recruitment, entry, and follow-up of multidisciplinary randomized controlled trials
- a clinic-based registry in primary care using distributed database technology that interfaces with the Web portal solution in order to enhance the process of clinical trials recruitment and the translation of research findings into practice
- a combined solution to open-source Internet2 (grid) components that will allow additional functionality including real-time opportunistic identification of subjects by primary care clinics, enhanced communication, additional decision support for providers, enhanced security, and warehousing of trial data emphasizing provenance and ontology of data (Peterson, 2004, p. 3).

From a community of practice perspective, these objectives represent the ePCRN's *shared repertoire*—that is, shared resources in a shared practice. The ePCRN team hopes that the Web portal, the registry, and the grid components will be available resources for the wider ePCRN community (beyond the development team, who are working to make this happen). These resources represent the tools that will become part of the ePCRN's practice as it is implemented in clinical settings. In other words, they will be the tangible results of the ePCRN project.

[46] For definitions of terms used in the objectives, see Appendix A.

Interestingly, both the ePCRN's joint enterprise and shared repertoire were identified and created by the ePCRN's principal investigator prior to the project's funding and thus, formal inception of the ePCRN team. As a key aspect of communities of practice is the communal engagement and negotiation of a CoP's activities and meaning, I was at first concerned that the prescriptive nature of its joint enterprise and shared repertoire, as articulated by the principal investigator in the NIH proposal, would negate the ePCRN as a community of practice. However, as will be shown later in this chapter, there is evidence of communal negotiation in what these ideas mean and how the group shaped its practice to meet these goals.

This leads to the third dimension of communities of practice—*mutual engagement*. The team's diverse composition and the way they negotiated and interacted with each other toward the immediate aim of creating the ePCRN's shared repertoire, and ultimately its joint enterprise, clearly exhibited elements of mutual engagement as identified by Wenger (e.g., 1998b). Because these aspects can be seen in the weekly meetings and in descriptions gained during my interviews with team members, it comprises the bulk of my research findings. This is not accidental, as I believe the majority of communal negotiation of meaning and practice in the ePCRN took place in the team's mutual engagement activities as they worked to implement the project's already-articulated shared repertoire and joint enterprise.[47]

[47] The majority of my analysis focuses on how the team responded to the project's first objective, developing a Web portal for the following reasons: first, the team was mainly working on objective one when I was conducting my pilot ethnographic study, and as a result, most of my research data concerns this aspect of their project; second, I believe objective one provides a fair representational context of the project in terms of how the team was operating as a community of practice. The team's composition would not significantly change based on the objectives, nor would one expect the dynamic manner in which they had

ePCRN's Joint Enterprise: Negotiating the Overall Aim

As mentioned, the ePCRN's joint enterprise—its overall aim to facilitate clinical research in primary care settings—was identified by the principal investigator and articulated in the proposal to the NIH prior to the group's formation. It is important to note that this was not a single person's goal, but occurred within a historical and institutional context. First, the NIH's Roadmap initiative outlined strategic areas to improve clinical research, one of them being "Re-engineering the Clinical Research Enterprise." The principal investigator responded to the NIH's initiative, which identified the need to better link research and primary care. The ePCRN's aim also came from an institutional context as the principal investigator was already involved in practice-based research networks, which had a history of facilitating clinical research in primary care practices (see Background section, Chapter 1). So, while it is true the principal investigator authored the ePCRN's joint enterprise prior to forming the ePCRN team, the project's identified joint enterprise was not conceived in isolation: key players, including those in the NIH and practice-based research networks who were interested in achieving greater efficiency and inclusiveness in clinical research, already had a hand in negotiating what the ePCRN's joint enterprise should be. As such, "buy-in" to the project already existed among these key players once the application was funded and the ePCRN team formalized.

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to negotiate meaning and practice. As a result, I believe focusing on their work regarding the Web portal provides both relevant and important findings.

To further examine the ePCRN's joint enterprise, I outline in the following paragraphs: 1.) how "negotiations" for the project's joint enterprise occurred prior to NIH funding of the ePCRN; and, 2.) how the project comprised an "indigenous enterprise," whose meaning was continually negotiated primarily by its members rather than by any external mandate, such as the NIH Roadmap.

Negotiating the Joint Enterprise

Here I examine evidence of how the ePCRN's joint enterprise was formed (negotiated) prior to the project's funding and how members shaped its mission within the historical and institutional contexts of the NIH, primary care practices, and the academic-based clinical research enterprise. First, it is important to note that the ePCRN arose out of an existing desire by primary care providers and academic researchers to see more clinical research in primary care settings, an aim also recognized and supported by the NIH. In an early interview, the principal investigator acknowledged a general consensus for this aim within professional communities such as the Federation of Practice-Based Research Networks (see Background section, Chapter 1, for further information on FPBRNs) and primary care providers in clinics, which served as the impetus behind the ePCRN's NIH application.

> Keith (project PI): *So it was really starting from that idea that we really wanted to respond to the need of these doctors to be able to do research and do data collection from their practice. How could we connect them better to do research? Of course the other piece was that we really wanted to look at improving practice. One of the things that doctors in the community are most interested in is how they can improve their care delivery.*

Here, the principal investigator refers to the articulated (negotiated) needs of members of practice-based research networks to improve the ability to connect primary care with research and to improve care delivery to patients. It was from this context that the idea to submit an NIH proposal to develop an electronic network for this purpose was born. However, this idea did not exist in a vacuum of primary care physicians and researchers, as it was also supported by the NIH Roadmap initiative. In this way, we see the ePCRN joint enterprise being negotiated by key players within the primary care and academic research fields, even prior to the principal investigator drafting the NIH proposal.

Primary care providers and academic researchers shared a desire and willingness to collaborate, providing support at least in principle for embarking on the ePCRN project. However, researchers and primary care practitioners have differing aims: researchers focus on answering their research questions while primary care practitioners focus on providing care for their patients. These differing aims stood in the way of primary care providers and researchers collaborating, as explained by the principal investigator:

> Keith: *[P]rimary care [practitioners are] so busy in the trenches taking care of people. They like the idea of research, but often don't have the time to do research. [If they did participate in a research study] it rarely actually affected their practice because a single clinical study rarely does. And it always took time [and] it was often associated with a cost. .... so we wanted to reinvent that system.*

So, while a spirit of joint enterprise existed to improve the links between primary care providers and researchers, some logistical and monetary obstacles prevented it from

occurring in practice. In this way, the ePCRN represented a working plan to address the contextual obstacles that mere goodwill and willingness to collaborate could not previously overcome. Building an electronic network that could achieve this was an enormous undertaking, as articulated by virtually every member of the ePCRN team. Yet, many people across a wide range of expertise, both technical and clinical, saw its value. From a clinical perspective, the principal investigator explained why connecting research and primary care practices was so important:

> Keith: *I often think that primary care practice without a basis or without a connection to research becomes obsolete, but research at the same time that doesn't have a connection to practice becomes arcane.*

When asked to explain further, he gave an example of a small rural practice. Practitioners want to provide the best possible care for their patients and to "deliver care that's modern." To do so they need to stay on top of current research. In addition, they may also want to become involved in research, "whether that's giving them the ability to have a patient with a new disease sign up for an NIH clinical trial [or] providing an experimental medicine that may not be FDA [Food & Drug Administration] approved yet, but may have promise in a certain disease." If a small rural practice, without a connection to a large academic research setting, can't keep up with modern research it can become "obsolete."

> Keith: *At the same time we do have research that begins to isolate itself from practice. And as research does that, then research begins to investigate what it feels is important and it's very easy for that to drift into an interesting question that becomes less and less relevant to a practitioner. We can spend a great deal of money investigating questions that are not very relevant. And I think sometimes we begin to fall into that trap. By having a close connection with our providers,*

I think that they [the primary care providers] provide a wake up call [to researchers].

Importantly, the principal investigator was well aware of both the spirit of joint enterprise for improved clinical research in primary care practices, but also the obstacles for its implementation. Here, he explains how an informal conversation with a colleague in the Federation of Practice-Based Research Networks led to other connections and the idea to respond to one of the NIH Roadmap RFAs (Request for Applications). These conversations were the beginning of negotiations for the ePCRN's joint enterprise.

> Keith: [*T]he previous director of the national network here … got me pretty interested* [in the RFA]. *So … I decided I would take a look and try to make a go of it. Now, as things happened, another director from Wisconsin, was in contact, [who was] the chair of the international federation [who introduced him to the team in England also working to connect primary care with research]. And he passed that on to me just because he thought I might be interested in it. Boy, it just all came together … We pulled together by that time, 10 directors from 10 of the networks across the country. The official collaboration was between Birmingham [England], myself, the University of Minnesota, the Federation of Practice Based Research Networks, which brought us the 10 directors … and the University of California.*

Similarly, Christy, one of the clinical team members, describes how she saw the beginnings of the ePCRN and the need to engage others (to develop joint enterprise) in such a project:

> Christy: *[I]f you're going to redesign how clinical research is done … primary care providers needed to be involved and … not just this small element* [of academic researchers]. .... *And there needed to be something at the clinic level if you're going to get the clinics to buy into this … because not all of them have this penchant for being involved in research, but you know, they'd like to, but they just don't have the time. So part of it is making it easier to be involved.*

So, although the overall aim of the ePCRN, to facilitate clinical research in primary care settings, was identified and articulated by the principal investigator in the proposal to the NIH, it was done within the context of a larger community of primary care providers interested in research, and then with ePCRN collaborators once the decision was made to apply for NIH funding and work began on drafting the proposal. That is, networks of physicians and researchers and other collaborators had a hand in negotiating the ePCRN's joint enterprise from the beginning. The principal investigator authored the project's joint enterprise in the proposal, but it grew out of negotiated exchanges leading up to the proposal's submission.

Indigenous Enterprise

The ePCRN's joint enterprise was an "indigenous enterprise," shaped but never wholly determined by "an outside mandate, by a prescription, or by any individual participant" (Wenger, 1998b, p. 79). Of course the ePCRN proposal was written in light of stipulations outlined in the NIH's RFA, which could be said to be a type of "mandate." However, the specific objectives and strategies articulated by the ePCRN team in the proposal were subsequently negotiated by the members themselves. The NIH may have provided external guidelines on what would or would not be funded, but the team had latitude to interpret exactly how they would meet those guidelines. As Wenger states: "Even when a community of practice arises in response to some outside mandate, the practice evolves into the community's own response to that mandate" (ibid., p. 80).

More evidence that the ePCRN's joint enterprise is not exclusively driven by outside forces or by one prominent participant (i.e., the principal investigator), is in what I call the project's "sub-joint enterprises." By this, I refer to the ways different groups within the ePCRN begin to negotiate their own joint enterprises, not in competition with the overall joint enterprise identified in the proposal, but as ways to support it.

For instance, in my interview with several members of the technology team, they identified various goals within their remit to support the ePCRN project. These goals, or sub-joint enterprises, are not at odds with the overall goal, but ways the team can specifically connect to the overall joint enterprise. In addition, the technology team would have more scope to negotiate their own sub-joint enterprises, in this way perhaps acting as their own community of practice. When asked about the overall project and their individual roles, one of the members explains:

> Martin: *let me preface that there's probably I guess individually many different goals. I mean if you wanted the short answer from a systems administrator, it's to make sure that all these systems talk to each other and provide whatever use [the principal investigator] and the ePCRN project desire. I guess beyond that, it sounds as if, I don't even, I guess I don't feel confident enough to tell you exactly what the ePCRN project is other than I guess knowing connectivity-wise what [the PI] has for a goal, which is clinics enter data and data [are] to be gathered and to be used by researchers.*

At this early stage in the project, the ePCRN team was beginning to negotiate exactly what was needed to connect primary care practices and researchers. Although the technical team may have understood the broad aim, it seems from this excerpt that they approached the project in manageable "enterprises" (i.e., providing connectivity for data), which would support the overall joint enterprise. So, while the entire team was operating

under a joint enterprise of facilitating clinical research in primary care practices, at this stage the technical team was focusing on specific joint enterprises based on their individual roles in the project. How this plays out in practice is covered in my findings under "mutual engagement," later in this chapter.

Finally, in a telling example of how the project's joint enterprise is negotiated among team members, the informatics manager explains how he approaches the project using a "story" metaphor. Specifically, he is responding to my question asking how the team decides what equipment and functionality is required, particularly since some details, including timelines, were already prescribed in the proposal:

> Jerry: *It* [the project] *is strongly storylined. I'm not sure that the actual script, the dialogue, and the script is written, but clearly the storyline is very strongly developed. And there is an expectation of completion of critical steps by certain times based on best estimates. And I anticipate that there are many difficulties in getting things started up and that's probably going to make things show up later than the expected times. …. It's strongly storylined though.*

He then goes on to describe how well he thinks the weekly meetings go. When asked to elaborate, he continues his story metaphor.

> Jerry: [The role of the meetings] *has divided the larger problems into manageable sizes, assign them to people who are very interested in coming back in the next week and reporting that they've made progress. …. And the architecture, which drives these smaller steps, the meetings themselves are smaller steps, and they're well driven by the map laid out by the* [NIH] *contract. So in a sense, I look at the contract as an overall story. Chapters are written sort of in terms on a quarterly basis. But the paragraphs and sentences are done in the meetings if you will. So, it's very clear how we're supposed to write the next paragraph and when you need to write it by.*

In this way, he sees the project's joint enterprise (its "overall story"), which was articulated in the NIH proposal (the subsequently funded "contract"), as "scripted" but negotiable in the way it is achieved (i.e., what happens in the meetings and the work that comes out of these meetings). Later in this chapter, I provide more detail on how this occurs in practice, and how the members' varied expertise and perspective influence negotiation in deciding what is crucial to the enterprise and how to achieve this.

ePCRN's Shared Repertoire: Objectives for Joint Enterprise

Like the ePCRN's joint enterprise, the project's shared repertoire was also formally articulated in the proposal. Supporting the overall aim (or the joint enterprise), the project's shared repertoire comprises the ePCRN's three objectives:[48]

- the Web portal
- patient registries, and
- grid technology.

Also like the joint enterprise, the ePCRN's shared repertoire was derived from negotiations with others interested in bridging clinical research and primary care, and was not the result of one person's perspective or authority (i.e., the principal investigator). For instance, the principal investigator is well connected in practice-based research networks and has led clinical research projects in primary care settings (e.g., Peterson, 2002). Through interactions in the field and with his own research, he learned from others and first-hand what elements were necessary to better conduct research in primary care

[48] See also Appendix A for definitions of technical terms.

settings. For instance, in our interview, he explains the need for an electronic patient registry (objective two), which allows practitioners to easily identify patients with particular diseases or conditions for targeted treatment and automated clinical reminders. He identified this need through his own work and through colleagues at practice-based research networks:

> Keith: *Diabetes is a good example. [Providers] usually underestimate the number of diabetes patient they have by almost 50%. …. So what the registry does is allow you to identify those people. And set up reminder letters for those people to come in to see the doctor or a reminder letter to the doctor … about what the patient needs at a given time. Diabetes is a good example because it's a disease of details. There are many different things that need to be checked when a person with diabetes comes in. And if a physician has to page through a chart, it takes a long time to find all of those details in the chart. … What this allows us to do is to list all those things in the front page, so a doc can walk up and say, oh yeah, that's what I need. …*

So, the ePCRN's shared repertoire (the objectives identified in the proposal) was negotiated in ways similar to the negotiation of the joint enterprise—through listening to the perspectives and needs of others interested in advancing clinical research in primary care.

In addition, throughout the ePCRN project, members work to develop these "tools" that will be used by the larger ePCRN community once the network is implemented into clinics. Although members in the ePCRN development team have little scope to re-negotiate the three objectives themselves, as these objectives form the backbone of what the ePCRN project promises to deliver as a funded NIH contract, the ways in which the team will achieve these objectives are wide open for interpretation. In

fact, this aspect of the project constitutes the bulk of their work and as such, the bulk of my analysis, which is covered in the next section, "mutual engagement."

ePCRN's Mutual Engagement: Negotiating Meaning and Practice to Achieve Joint Enterprise

Mutual engagement, the process whereby members engage in a common negotiated activity, requires three elements: *enabling engagement, diversity of membership,* and *mutual relationships* (Wenger, 1998b). (See Figure 8.)

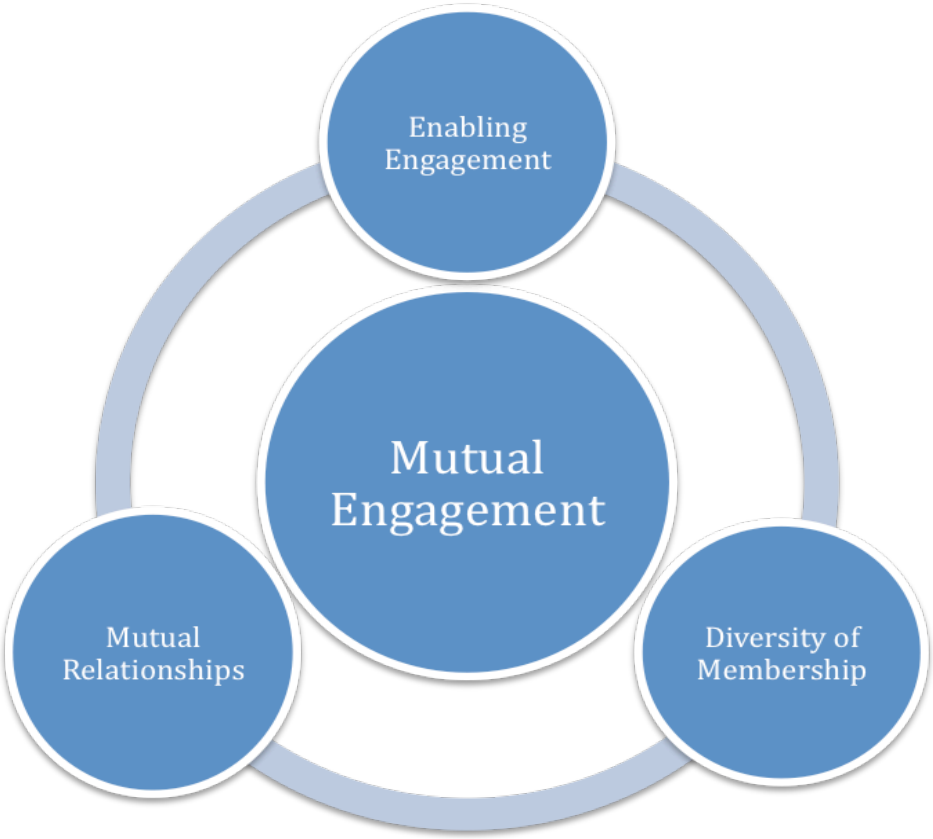


Figure 8. Elements of Mutual Engagement

I saw evidence of all three elements, particularly enabling engagement, in the ePCRN project as they worked to realize the shared repertoire and, ultimately, its joint enterprise. Table 8 provides a sampling of activities in which the ePCRN team exhibited mutual engagement. Most of these items are covered in greater detail under the section "enabling engagement," below. The majority of these instances occurred while the ePCRN team was working on the Web portal (objective one and the focus of my research).

Table 8. Examples of ePCRN Mutual Engagement

Activity	Key players	Documented in
Determining software licensing needs	Technical team, UK team, clinical team, PI	Field notes, meeting minutes
Renegotiation of approval process for equipment	Technical team	Interviews, field notes
Discovery that UK infrastructure not sufficient for ePCRN use	Technical team, UK team, PI	Interviews, field notes, meeting minutes, quarterly report
"Community maintenance" among team members	PI, informatics manager	Interviews, field notes
Development of first RCT, including IRB requirements	Clinical team and PBRN directors	Field notes, meeting minutes, quarterly reports
Training of PBRN directors for first RCT	Clinical team, PBRN directors	Field notes, meeting minutes, quarterly reports
Conduct of "connectivity demo" to demonstrate usability of portal	Clinical and technical teams, PBRN directors	Field notes, meeting minutes, quarterly reports
Evaluating new clinical trials for RCT #2	Clinical team, PBRN directors	Field notes, meeting minutes, quarterly reports
Training of 250 primary care physicians in human subjects protection and in use of the ePCRN portal	Clinical and technical teams, PBRN directors, primary care physicians	Meeting minutes, quarterly reports

Enabling Engagement

The role of principal investigator is leader of the project, so it perhaps not surprising that the PI also functions as the group's "engagement enabler." While he has

ultimate authority in running the project and in making decisions, he relies heavily on his diverse team for knowledge and advice, which requires an environment of open participation among team members. Although a number of team members previously worked together and therefore came to the table with existing relationships involving primary care and clinical research projects, the newly formed ePCRN team comprised a much broader range of expertise for a project of much wider scope. How was a culture of enabling engagement achieved? Partly, it was developed from an existing culture of engagement where the principal investigator recruited people with varying expertise and relied on their abilities and perspectives, as described by one of the clinical team members:

> Christy: *I've worked with [the PI] on a variety of other grants since 1997 and we always … kind of built things from the ground up. …. [B]ecause I think more of knowing how to get things done in the clinic side of things, that's why I was asked to be 20% time on ePCRN to kind of know how things really get done. [laughs] And getting the lab and the billing systems and all to hook in to the system. And what really works in the clinic side of things.*

She also explained her involvement with the informatics experts, and the need to work together:

> *[The informatics manager and I] have to collaborate closely because … we don't have dual roles, but we need to be able to pass things back and forth. "I can't do this, can you follow up on it" or vice versa. Matt is the programmer. Matt and I have worked together for the last 3 years, so we'll kind of mesh. You know, he knows the SQL programming, I know the clinic side and … I test what he does [laughs]….*

While talking about a culture of cooperation and mutual respect is one thing, what happens to mutual engagement when conflict or problems arise? How does a sense of engagement remain intact during and after instances of conflict to help inform decisions?

Wenger (1998b) says that for a community of practice to function with a sense of cohesiveness, "community maintenance" is required. In the ePCRN project, two people serve this function for the most part: the principal investigator and the informatics manager.

First, I examine the principal investigator's role as he invites input from the various experts around the table and navigates opposing opinions to reach decisions while retaining a sense of community and coherence. Here, he looks to his technical team members for advice on software licenses required for the portal, specifically how many licenses are needed and when they can be obtained. As indicated by the lengthy excerpt from my field notes, the principal investigator (Keith) asks a number of people to weigh in, and it takes some time to understand the differing opinions before the PI makes the final decision. It begins with a question of how many licenses they will need to purchase.

> *Jerry* [informatics manager] *wants to confirm about Microsoft licensing. … Martin wonders if they need 100 MS Office licenses or 100 MS Access licenses. "This will depend on how we want end-users to access applications," he says. Keith says he's not sure and asks England team what they do. They bought the Office suite, designed so clinics and university could use.*

At this point, there is some question as to whether they can wait to purchase the licenses, once they know more about what use they will need out of them.

> *Keith says "hard to know what RCTs [randomized clinical trials] will look like. Could they decide and order what might be needed to get them through the first three years? "Can we make a decision on this today? Can we decide to wait?" he asks. Martin says can make this decision as we get users. He suggests if we have 20 users now, we can buy 20 licenses now and build as we add users. Keith says "I like that idea."*

The decision seems to be made; however, Keith notices that one of the informatics experts expressed concern in committing to a particular system.

> *Keith asks England if they using [particular software] right now. England confirms they do but don't always use it. "Researchers use it, but clinics don't." Martin says "we have to decide how functional we want it to be for the users". .... Keith suggests buy a set of [one kind of] license. Use it until the summer. If not being used, will throw them away and buy [the other], basically spending between $500 and $1,000 for a "pilot". Believes US will use system more than England does. The decision has been made.*

In this extended discussion, the principal investigator ensures that the relevant technical members have input into the issue of software licenses. The decision they make will have implications for how the network is built, and as a result, there is discussion among the technical and clinical team members as to the required functionality of the network and which software provides the best solution. Although the ultimate decision lies with Keith, he calls on his team of experts to voice their opinions and articulate what they would decide and why. This discussion took up a significant part of the meeting but in the end they came to a mutually agreeable decision, despite members' initial opposing opinions. In this way, Keith supports engagement among the members in the project's activities, allowing for differences of opinions, but maintaining the group's sense of community.

Another way that the principal investigator attempts to foster a cohesive community is by ensuring that all items on the meeting agendas are addressed and members have a chance to voice their opinions, while keeping the group to task and maintaining a balance of member contributions. For instance, he will often open the floor

for discussion on a particular agenda item, listen to the viewpoints and ask questions, sum up the issues at hand, and suggest final decisions for mutual agreement.

In the following example, the technical team works to resolve an unanticipated problem with securing some of the required equipment. First, the IT department is surprised by this project's lengthy and complex approval process for purchasing equipment. They quickly become concerned that this process would result in substantial delays to the project's deadlines, in addition to being professionally demoralizing compared to how they usually conduct business. In terms of "enabling engagement," the team talks about how they took it upon themselves to creatively circumvent the official process to build a "rack" (a necessary storage solution) for the equipment.

> Andrew: *Well, I guess in terms of contracts and getting things purchased, I don't think we've made as much progress by now as I would have thought we would. …. I mean still, there's three or four big pieces out there that the NIH hasn't approved, that they've actually been sitting on for well over a week. …. Normally my job would have been done by now, but this is much worse. This is probably the most, most complicated and [unintelligible] thing I've ever been involved in.*
>
> Nate: *For not a lot of dollars. We buy millions of dollars of equipment and software a year and this has only been …. Fifty thousand*
>
> [Andrew: *couple hundred thousand all together maybe I can do million dollar ones a lot easier than this so...laughs*]
>
> Nate: *One thing we identified in terms of not getting a contract signed or approved from the NIH, we have servers, you need to put them in a rack, otherwise you spread them all around the studio. We needed a rack for the project. Well that still hasn't, the rack still has not been ordered. Of course the servers are here, and they need to be set up so about two weeks ago, we figured this is just is not going to get done through the normal channels, because nothing else is getting done in a normal amount of time that one would expect, so our department just went out and bought a rack and so we're going to …*

Martin: *a rack, a switch, and a keyboard monitor …*

Nate: *yeah, so we went out and invested …..*

Martin: *we got it in about four days.*

Nate: *four or five thousand dollars just to get, just to help them. So, when finally the ePCRN rack comes in we'll just make a swap at that point. But that was one of the things we decided would be in the best interest for the project because we knew we weren't going to get the rack in time.*

Importantly, if this team was not sanctioned to fulfill their duties as they saw fit, that is, if they weren't "enabled" to "engage," they would not have been able to employ their skills in getting around this delay, and other subsequent challenges they faced in their tasks. Equally important for the morale of the team, the principal investigator later acknowledges their ability to break through delays, in one of the weekly meetings, as recorded in my fieldnotes:

Martin begins to talk about installation of rack; Keith: "I'm just going to jump in here" and then thanks Nate for sorting out rack [he commandeered one of their own because there was a delay in getting a purchase order approved for one]. Keith went on to say that the NIH is now in a position to approve quotes quicker.

Beyond the scope of several pieces of equipment, a major issue in the ePCRN's early days was to what extent could the ePCRN use the University of Birmingham's infrastructure model (i.e., the servers and software). The UK team already had a system for networking primary care and researchers, and this model was referenced in the NIH proposal. Since a working model already existed, the ePCRN team thought that much of the UK's system could be directly used or modeled, reducing the amount of development time for the ePCRN project.

Once the proposal was accepted and funded by the NIH, a formal ePCRN team was constituted (see next section on diversity of membership) and the technical team members were brought in on the details of the proposal, including the intention to model the ePCRN on the UK's system. Early on, the technical team was aware of potential issues, particularly after several of the technical team members visited the site in England. These issues were recounted in my interview with the technical team, and serve as an example of how the ePCRN project fostered a sense of "enabling engagement," as they were able to articulate their concerns and offer potential solutions.

> Nate: *The UK group wanted to partner with the University of Minnesota in terms of sharing infrastructure, and our thoughts, we were rather skeptical about doing that from day one and after we actually visited Birmingham and saw what they had, we recommended to [the PI] that we should build our own infrastructure and be completely separate from the UK group. So, given that, our role really changed and we got way more involved in the project and spent a lot more time on it. But I think the end result will be much better for the ePCRN project as a whole.*

In the same interview, another technical team member concurs, followed by Nate's further comments about the system:

> Martin: *The project over there [England] is not run by a central computing department so I think some of the things, some of the knowledge that we bring to the table is not even really being utilized over there so we saw deficiencies in the initial grant the way it was written, … so we basically had to rewrite that grant and put in all the different components that we … wanted involved.*

> Nate: *We learned that the UK group was behind in a number of releases of software, they hadn't paid maintenance on some software, so we saw that there was great risk in the project. So given that, all of us were involved in it all spent a lot more time because we felt it was needed at that point. We didn't want to let things go too much longer. So, then, we got the equipment all specced out, orders were basically placed and now my role again is kind of waning.*

As a result of perceived shortcomings with the UK model, the technical team increased their involvement in the ePCRN project and effected change in how the ePCRN would be configured, an example of enabling engagement. Meanwhile, the senior informatics manager, who at the time of our interview was newly employed with the project, regarded the UK's role from a more conceptual aspect. Interestingly, his view seems to bridge that of the technical team (explored above) and that of the principal investigator (to follow). We will see further evidence of his "bridging" role across technical and clinical aspects of the project in the following section on diversity of membership. Here, however, he explains his perception of the UK's involvement:

> Jerry: *They* [the UK collaborators] *are … the testers of a very mature beta test. They have a system that is serving participating researchers, and it sounds like fairly well. So they have provided proof of concept and I think they've done a lot of the grunt work that we won't have to do. I think we still have a lot of grunt work to do, but we don't have to do that grunt work. So that's what they bring. And they bring in an international opportunity*.

Later, we will see how the informatics manager must walk the line between what the clinical team members want and require from the network and what the technical team believes is feasible within the constraints of the project (i.e., timelines, budgets). Enabled engagement must exist within the technical and clinical teams, but must also exist across the two teams. The principal investigator must also provide such a bridging role, and which we see here in regards to the UK's partnership. When asked in an interview about the UK's involvement, the PI articulated both the positive and limiting aspects of their collaboration. The excerpt here, although lengthy, shows his commitment

to the collaboration and to the UK's inclusion in many aspects of the ePCRN's development.

> Keith: [*O]ur co-investigators in England, you know, they're wonderfully bright. It's great to work with them. But the National Health Service is limited by a real limitation of resources. And sometimes when we go over that's a bit of a slap in the face…*
>
> BH: *To them?*
>
> Keith: *To us! I mean it's a, it's startling how much they can do with so little.*
>
> BH: *Oh, I see. Okay.*
>
> Keith: *When we walk in, we walked into their information system, and … they have a great connection, … an electronic connection to virtually all the clinics in the UK already. So we thought we were going to walk into a very sophisticated system and we were surprised because it is a bit cobbled together. It's underfunded. It doesn't have the resources that it needed. They'd be running important pieces of information that we would have thrown away. In fact, the computers that we are getting rid of were more modern than their most modern computers. One of the things we thought about doing was shipping our own computers over there. [laughs] So, they do wonderful things and they have done. But there's a sense that as we move forward we have the ability to step … beyond them [in terms of resources and potential]. And so that's why you hear comments like, well, we're learning from them, but in learning from them, we're probably going to leap frog in a sense and have a system that will have more capabilities than their system has.*
>
> BH: *[I]n the NIH contract, was it stipulated that the collaboration with Birmingham would be for you to … see what their system is like and … help build this system, … or was it more that you were going to have a similar system and eventually hook up together?*
>
> Keith: *Well, they have the RCT [randomized controlled trial] piece and we have the translation piece, and we were going to marry them. And have both of them at both sites. That's what drove both of the grants [Birmingham's grant in the UK and the ePCRN grant to the NIH] because they were bringing in our translation piece and we were bringing in their RCT piece. So both systems are stronger when we work together. And then what we were going to do now is to copy these on both sides of the ocean*

and then work together as we move forward. And move forward in putting it onto Internet 2, making it open source, and allowing the world to use it. ….

BH: *And by the translation piece, do you mean taking the clinical trials and … updating practice, is that what you mean by translation?*

Keith: *That's all the translation. You see, the clinical trials are, is a pretty easy technology. They [the UK team] have a nice technology. The translation is a different thing completely because instead of pulling information from the primary care practice, you know, the researcher potentially wants to go out and not affect practice, but just measure it and pull the information away. And the translation person wants to do the opposite, he wants to go out and affect everybody's, and he wants to affect everybody in the clinic and take information he has and disseminate it to everybody in the clinic. And so that because the idea is that it's information flow in different directions. And so it makes the electronics completely different.*

It is interesting to note how the technical team members describe how they evaluated the UK's system against the aims of the ePCRN and how discussions occurred with the UK team on problems of security, which led to a revision of how the UK partnership would play out in terms of disaster recovery plans (how to ensure recovery or continued function of the technology infrastructure in event of a natural or human-based disaster). The team discusses what they found during their UK visit:

Jonathan: *[I]f we're going to be relying on them for our disaster recovery we need to know that what their server environment is like, how they have their server set up, what's their data center like, what's their power, what's their network, all the various environmental… We visited with them and they do not have their servers in a server room. It's quite literally a closet that they have in their office building. Just a 5x5 office, or a closet. It's behind a locked door, so that was good, but it was, when they first set it up, we learned they didn't have air conditioning into the room, it was running off the building air conditioning, which means at the end of every day, air conditioning would turn off in the building and the servers would tend to overheat.*

Nate: *no backup power.*

Jonathan: *No backup power … So we asked if they'd consider moving [the equipment] into a data center … and to be frank the data center was not quite at the level we hoped it would be. … So we were not very comfortable coming back with using UK, using Birmingham as a back up site if we had a problem, the confidence just wasn't there that we would be able to provide the same kind of reliability that we provide. … So we communicated that with [the PI]. ….*

BH: *and how did he then take that? Did [the PI] then talk to the UK people about that? Or was your team involved in that communication and if so, how did that go?*

Nate: *Yeah, there was a conference call about that. They [the PI and another clinical leader on the project] came at it at from a security point of view, as having patient data actually in a foreign country [England] and that pretty much killed it right there. I don't think anyone really thought of that beforehand, because when you're a disaster recovery site, it implies you either have your data there, or can very easily port it over there and having patient information, even if it doesn't have your social security number or any identifier, getting that, having that in a foreign country wouldn't pass muster in too many places around here. I think that helped kill it as much as anything, as a security site.*

Martin: *And I think I guess to tie that up, the really, the decision point as far as whether that could actually happen, we relied a lot on [the hardware/software company] expertise to say that the infrastructure for them to be a fail over for our [server farm] in and of itself, literally the secure elements, … would have to be tightly integrated which means dual administration purposes and you know, working I guess you know side by side, literally, elbow to elbow with that administrator when we've got six hours difference and we work completely different time schedule and it just, [we] just did not see that working very well. And … in the end I think it just became too much. And again, I think primarily it was the data issue, we just couldn't have that database there, but in an infrastructure world I think it was just too much to manage as well. …*

In this instance, technical team members are able to tap into not only their expertise in assessing the UK's system, but of the software/hardware company as well. Their assessment took place following a site visit to the UK where they talked to the UK

team members about their goals for the system as well as the system's technical aspects. The technical team then discussed their findings with the principal investigator, who then engaged the UK team on how best to proceed. Throughout this process, members as individuals and as groups were empowered to inform decisions to the best of their expertise, and with the ePCRN's joint enterprise in mind.

Of course issues beyond technical ones also require team members be "included in what matters." For instance, the clinical team members work with directors of practice-based research networks who have agreed to help test the network on issues of study design and Institutional Review Board (IRB) requirements. First, the field notes describe a meeting held by conference call with the core clinical team based at the University of Minnesota with at least six directors of practice-based research networks. [The access grid technology was not used, so none of the participants had visual access to each other, unless they were in the same room.] In this meeting, they discuss the upcoming "test trial" of the network, and particularly whether they will require IRB approval from all study sites:

> *They are discussing the design trial project and IRB approval when I arrive. Discussing whether IRB is required at this stage since they are only using mock data to test the functionality of the system. …*
>
> *[One of the directors] asks how long it will take for initial log in (for the test protocol). Keith says about 20 minutes. Director says, "10 would be better. Aren't we just testing connectivity?" Keith says they will have a few things to test. … We just want to see how many errors are made, he says. Director confirms, "so it's a validation exercise too."*
>
> *Penny says not only to check whether connected but also able to enter data properly. Director asks if this is a type of study (with the participants / investigators serving as subjects). "Isn't this a study requiring IRB approval?" he asks.*

Keith says getting IRB approval "will really throw a spanner in the works." Steve says can collect data for internal system evaluation. Penny says will talk to IRB regarding regulations, for publication. "At a minimum you will be able to do that," she says. Director (the same one?) says may be that only U of M needs IRB approval, because the data is coming to them. Another director: set it up as a system evaluation where we're not evaluating the participants (the investigators). ….

Penny asks people to go around, person to person, to report whether local IRB approval is needed [this is done with about half saying they would like their own institution's IRB approval]. Penny says concerned if we keep pushing back RCT, will be behind schedule. Keith says he wants to push on. Penny says she'll contact the IRB and ask how they fall on this.

The next week, when the ePCRN group reconvenes (without the practice-based research networks' directors), they re-engage on the IRB issue:

Penny moves on to IRB. Says they need to get a letter in to IRB, to put them on notice that we'll have this going. Need a human subjects approval number. We will need to get human subjects approval for first RCT [which is Phase II – confusing terminology in identifying their research]. … Phase II will need IRB approval (not Phase I), in case doing any kind of analysis, even though using mock data. The clinicians in this case would be considered participants. MN will get expedited IRB. (Phase II is considered the first RCT, Phase I is a registration activity.)

The background work that the clinical team has done on IRB requirements was then relayed to the participating directors of practice-based research networks the following week. For purposes of clarity, the three phases of the RCT have been renamed as follows:

- Phase I: ePCRN registration
- Phase II: simple RCT
- Phase III: real patient RCT.

Keith asks if directors understand the process [of the proposed trials]. Buffalo director has question about IRB sign off. Need to do two-hour tutorial and have IRB sign off from MN? Penny says excellent question, reviews the three-stage process for those who weren't on call last time. Mentions arrived at 3 steps from input that directors gave and said how

helpful that was. "MN will go through our IRB for simple RCT." Penny suggests directors give their IRBs a heads up for eventual need but not necessary, locally, before key fobs [a security access "key"] go out since MN IRB will be approved. Keith says two different levels for registration. Directors have fobs and independent researchers will have fobs. Buffalo asks if they are limited to 25 in our network. Thinks he will have more interested. Penny says that's wonderful. Go for more than 25 and see how it goes [may have drop-out as process continues]. Keith says they have a limit to the number of fobs due to cost.

In the exchange noted above, there is evidence that the directors directly influenced design of the study protocol to test the ePCRN's Web portal (see italics above). In addition, the directors are "selling" the network to their constituents, primary care physicians in their practice-based networks, and there is evidence the directors have buy-in for the ePCRN's joint enterprise:

Someone asks [the director of the practice-based research network in Buffalo] how they've been recruiting, how they've had such an interest already. Buffalo responds that he says it helps them with their work and research and tells them "what we need from you right now." Be part of national studies through electronic connectivity. Mentions the NIH roadmap. Down the line, patient registries. Academics think this is good idea, especially the registries he says. The clinicians, it's the techie people who want to be involved in the latest technology for research and patient improvement, they're very excited. "In two minutes, one researcher said, 'I'm sold,'" he said. Emphasized electronic connectivity, and ability to be connected nationwide.

The excerpts provide examples of technical and clinical team members' involvement in "enabling engagement." Also noted is that several members straddle both teams, bridging both technical and clinical perspectives. This aspect represents a significant feature of mutual engagement in the ePCRN, as a means to maintain a cohesive community while at the same time allowing for a diverse membership, another crucial element of mutual engagement in communities of practice.

Diversity of Membership

The ePCRN membership comprises a wide range of expertise in various fields (see Figure 9).

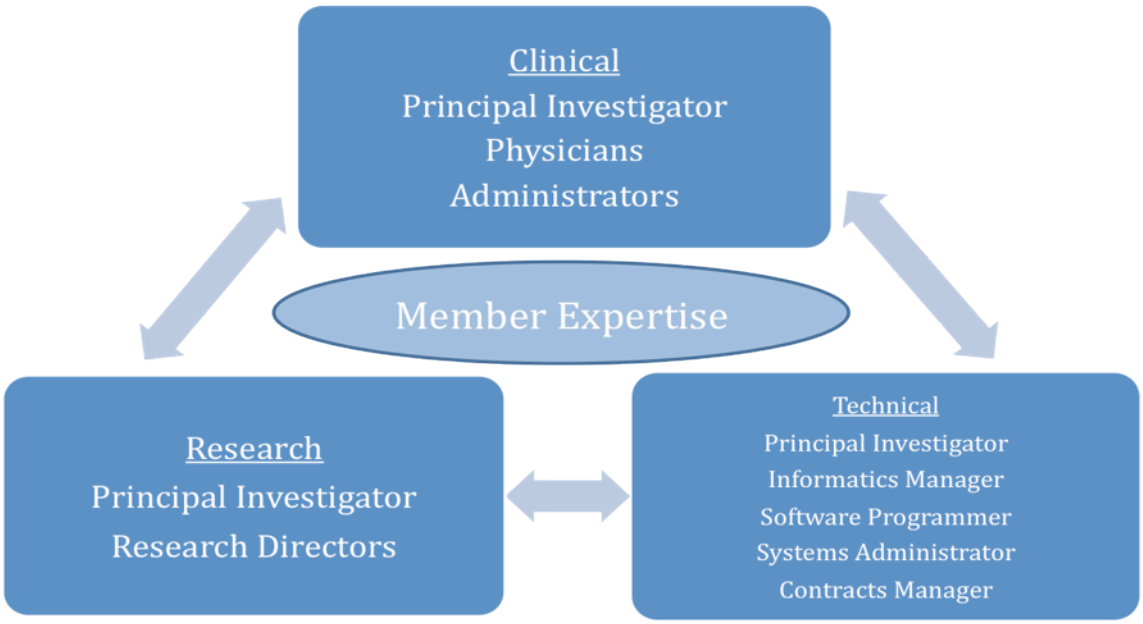


Figure 9. Member Expertise

First, there are members with clinical and research experience, including the principal investigator, physicians, research directors, and clinical administrators. The other main group consists of technical experts, such as the informatics manager, software programmer, and information technology experts (systems administrator, director of central computing, contracts manager, and manager of systems administration). Obviously, a project that aims to bridge clinical care and research via an electronic network requires both clinical and technical expertise. In the project's beginning, there were weekly meetings attended by all members. This was quickly seen as unproductive

as conversations became bogged down in either clinical or technical detail, depending on the issue at hand. At the end of March, Keith instigates two separate weekly meetings, one for technology (or the "infrastructure") and one for clinical (or "utilization") participants. However, some members attend both meetings, acting as bridges between the clinical and technical sides of the project. Earlier in this chapter, I have highlighted instances of both technical and clinical expertise and how members in these areas were "enabled" to engage in negotiated meaning and practice of the ePCRN. In this section, I focus on the members acting as "bridges" and how these roles were crucial to the cohesive functioning of such a necessarily diverse group.

The senior informatics manager sees his role as a project manager, ensuring the technical aspects of the project are met, which "serves the needs of the researchers and the goals of the project," as he outlines in an interview:

> Jerry: *My responsibilities may be distilled down to effectively one thing and that is ensuring that the infrastructure is built, serves the needs of the researchers and the goals of the project. [T]here are many things that are very clearly spelled out and defined but the method for getting there on an individual basis may be fairly amorphous. And that means that there's a lot of latitude I believe at this point in how I get there. …. But I believe that the greatest success will come from my ability to identify the best people, those people who are best able to do the components of it and trying to get them in contact with the project. And when I'm the best person for a particular aspect I will do that part.*

The other main "bridge" between clinical and technical teams is the principal investigator, who describes his dual roles as follows:

> Keith: *Well, I love family medicine and I love practicing family medicine. It's a great field. And I guess I really feel that this, that what I'm doing is really an element of what family medicine needs to do. Since, if what I need to do as a researcher is understand more about technology so that I*

can provide that in improving the system of primary care, then learning the technology is not a problem to me. …. Anyway, I guess needs must, you do what you have to do. So the technology is interesting. It's kind of fun and it's what we need so that's fine.

The need for a senior informatics manager who can link between the clinical and technical teams is apparent, based on the following excerpt from an interview with the technical team, just prior to the senior informatics person coming to the project. Here, they discuss the "disconnect" between the clinical and technical team, again referring to the initial assumptions pertaining to the UK's system as outlined in the grant proposal.

Martin: *I think the biggest challenge working with clinicians … is a large disconnect with what … our role is as far as making these decisions, these infrastructure components. And I think that's what we saw right away, which is one of the reasons why the grant had to be largely rewritten. … I think it's wise of [the PI] to include us because he can kind of not have to focus on a lot of things that we focus on. … I mean as weeks and months and years go by … they [the clinical team] can focus on research and that sort of stuff and not have to worry about the rest of it, stuff hopefully.*

Although the technical team acknowledged the necessity of bringing on technical experts, as the PI did by involving this group early in the project, the missing link seems to be someone who can negotiate the clinical needs of the network while understanding both the constraints and potential of what that means from a technical perspective. At this time, the technical team, although very capable in the technical aspects, did not have a person who could function as a bridge between the clinical and the technical teams. The senior informatics manager was hired to fulfill this role.

An example of this bridging function is seen at the clinical utilization meeting on 3/31/2005. The informatics manager was present at this meeting and served as a "bridge" between clinical and technical issues relating to the study design of the first randomized

controlled trial (RCT), specifically in the development of "fields" or categories of information that the study will require. My fieldnotes cover the interaction between the clinical participants and the informatics manager:

> *Penny hands out a list of fields [categories of information] for a suggested trial. There is some discussion between the clinicians (Keith, Penny, and Christy) and the IT team (Jerry, Matt, and Martin) over how to present the fields (drop-down menu, blank space, etc.) Penny [representing the clinical side] says she doesn't care, as long as the fields she has just handed over are represented. [Seems to be some confusion between the teams over how much information the IT team needs before they can just take it and run with it.] Jerry asks if this is everything she wants. Penny confirms. Matt confirms this is everything they need then. They'll come up with a design for her approval. Then Penny asks if they can test for randomization on this. Some discussion over whether they should randomize by forms (or patient) or by physician assignment. Since time is almost up, they decide to take this discussion to the directors*.

This issue was taken off site and worked out between Jerry, Matt, and Martin. They were able to create a sample screen for mock patients, as part of the Phase II trial to test the completeness and accuracy of entered data and length of time it takes a participant to complete these tasks (basically, a usability test of the network). This sample screen was then presented to the clinical utilization meeting, which also included the directors of practice-based research networks, the following week and was met with approval. This task was successful because the senior informatics manager was provided with a sense of "enabled engagement" to take on the clinical team's desires and work directly with the technical team to translate it to a functioning solution, also freeing up Keith (and the other clinical team members) to concentrate on the clinical side of the network.

Having said that, it was still important that the PI remain engaged in the technical team so that the project was kept on track. Although he instills a sense of "enabled engagement" in his team members, Keith is ultimately responsible to the NIH for meeting project deadlines and working to budget. To do so, he kept abreast of the technical team's progress, which required an ability to understand, on some level, the issues they faced and the capabilities and cost of the technology being used to build the network.

Another, perhaps more important "bridge" was that between the clinical and research worlds. As a practicing physician, a clinical researcher, and a leader in practice-based research networks whose aim is to connect clinical research and primary care, the principal investigator already walked that line.

It is a role he continued within the context of the ePCRN as he tried to ensure the needs of both clinicians and researchers were met by the ePCRN. In fact, the importance of balancing the needs of clinicians and researchers was reported in a study examining communities of practice as a way to enhance research capacity for tobacco control research (McDonald, 2007). "Models of research translation frequently emphasize independent roles for research producers and intended users. [McDonald's study] describes a novel approach for enhancing exchange between researchers and practitioners. …. Research-based practices and policies emerge when research producers and users mutually engage one another about specific health promotion problems through negotiation and by creating and sharing technical standards and other resources" (ibid., p. 140). This study recommends that groups aiming to facilitate both research and practice "should include a combination of research producers and research users" (ibid., p. 143),

which through the inclusion of practice-based research networks, the ePCRN follows. The important issue of bridging the needs of those producing research evidence (e.g., academic researchers) and those who use the evidence (e.g., primary care practitioners) is taken up further in my discussion of implications in Chapter 7.

Another issue I will examine in Chapter 7 is the reasons for participation in communities of practice. Why do people choose to be part of the ePCRN? What do they hope to achieve? What are the implications for the network and its aims?

Mutual Relationships

Mutual engagement creates relationships among people, whereby a "community of practice can become a very tight node of interpersonal relationships" (Wenger, 1998b, p. 76). The ePCRN team comprised clusters of interpersonal relationships that formed around the project's work to fulfill the ePCRN's joint enterprise. Some of these relationships evolved from existing relationships among team members, such as between Christy, Penny, Matt, and the principal investigator, who had worked together on previous projects connecting primary care and clinical research. In addition, a group of 10 practice-based research network directors, all of whom already knew each other, also formed a closer working relationship while engaging in the ePCRN project. As seen previously, the principal investigator drew on his existing relationship with the Federation of Practice-based Research Networks to recruit directors interested in helping develop the ePCRN. These directors now worked closely among each other, and with the ePCRN team, to provide feedback on the Web portal (as we saw in the example above

regarding IRB approval for the mock trial). Technology team members, some of whom had worked together on other projects, joined forces on specific tasks for the ePCRN, literally forming their own sub-group as explained earlier (the "infrastructure" group which met weekly). Finally, the UK team begins to coalesce as a team, but also forms new relationships with their clinical and technical counterparts based in the United States.

While much of the work conducted fell along either clinical or technical lines, and teams formed accordingly, relationships nonetheless existed across the entire ePCRN team. Those members I interviewed had experience, to varying degrees, of working with nearly everyone on the project, or at the very least, knew each team member through meetings or other communications (e.g., emails, telephone). It is important to note, however, that despite this community of practice exhibiting "a very tight node of interpersonal relationships," it did not always function as a "haven of togetherness" (Wenger, 1998b, p. 77). There is disagreement, challenges, and even competition among team members, all of which are still "forms of participation" (ibid.). That is, mutual relationships do not require homogenous perspectives or opinion. In fact, the community of practice benefits from diversity, as explored above. In addition, the team worked through the challenging issues of adopting the UK's system, also explored above.

Despite evidence of enabled engagement, a well-functioning diverse membership, and development of mutual relationships, it is important to understand power dynamics in communities of practice. According to Joanne Roberts (2006), who examined knowledge creation and dissemination in communities of practice, "Power is the ability or capacity to achieve something, whether by influence, force, or control. While meaning may be

negotiated within communities of practice, it is vital to recognize the role of power in this process" (p. 627). Implications of this issue, as it pertains to the ePCRN, are further examined in Chapter 7.

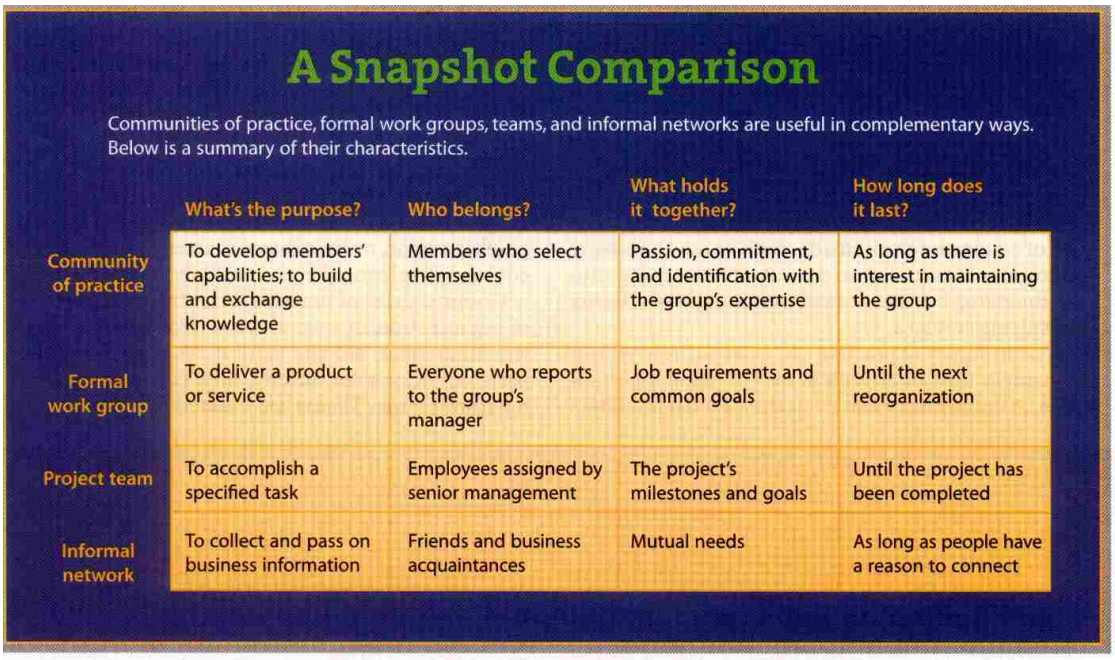
Thus far, I have outlined how the ePCRN team functioned as a CoP through:

- its joint enterprise of facilitating clinical research in primary care settings;
- a developing shared repertoire of a Web portal, patient registries, and open-sourced Internet2 technology; and,
- mutual engagement where members engage in commonly negotiated activities toward the group's joint enterprise.

Other Types of Community

The ePCRN, as a community of practice, differs from other types of groups or communities. Figure 10 (Wenger & Snyder, 2000) compares communities of practice with other types of groups, teams, and networks, based on characteristics of purpose, membership, motivation, and duration. In this section, I examine the ePCRN against each

of these characteristics.



A Snapshot Comparison

Communities of practice, formal work groups, teams, and informal networks are useful in complementary ways. Below is a summary of their characteristics.

	What's the purpose?	Who belongs?	What holds it together?	How long does it last?
Community of practice	To develop members' capabilities; to build and exchange knowledge	Members who select themselves	Passion, commitment, and identification with the group's expertise	As long as there is interest in maintaining the group
Formal work group	To deliver a product or service	Everyone who reports to the group's manager	Job requirements and common goals	Until the next reorganization
Project team	To accomplish a specified task	Employees assigned by senior management	The project's milestones and goals	Until the project has been completed
Informal network	To collect and pass on business information	Friends and business acquaintances	Mutual needs	As long as people have a reason to connect

Figure 10: "Community" Comparison Chart (Wenger & Snyder, 2000, p. 142)

First, although the ePCRN project is funded by the NIH to achieve specific objectives (i.e., its shared repertoire), its purpose is ultimately to develop the capabilities of research in primary care, which in turn, leads to the expansion and exchange of knowledge. The ePCRN's purpose goes beyond merely to "deliver a product or service" (as a formal work group) or to "accomplish a specified task" (project team). The ePCRN exists beyond the initial three-year NIH funding period (see subsequent section on the ePCRN's stages of development), and thus its scope is beyond the "product" of its shared repertoire, as outlined in the NIH proposal.

Next, regarding membership, communities of practice members "select themselves," which certainly occurred with the ePCRN project. During the development

of the ePCRN proposal, the principal investigator connected with others interested in facilitating clinical research in primary care settings. Involvement was not prescribed (such as one being assigned to the project by a manager), but grew out of voluntary interest. It was also more than a loose connection of friends and business acquaintances as membership required passion for its joint enterprise and particular sets of expertise.

The ePCRN's cohesiveness also points to characteristics of a community of practice. Its members are committed to its joint enterprise and the members, whether belonging to the clinical or the technical side, or somewhere in between, identify themselves as part of the group based on the expertise they bring to the project. While the ePCRN's milestones and goals are important to the group, these factors are not what hold it together. Nor is the ePCRN anyone's sole job requirement.

Finally, its duration as a community of practice will last based on the interest of the members, rather than being bounded by a grant or an institution's organization. Although the initial funded period has passed, the group still functions in pursuing the ePCRN's joint enterprise.

ePCRN's Stages of Development as a CoP

In addition to having these characteristics, communities of practice also move through various stages of development "characterized by different levels of interaction among the members and different kinds of activities" (Wenger, 1998a, p. 2). The ePCRN project certainly shows development along Wenger's five stages (see Figure 11).

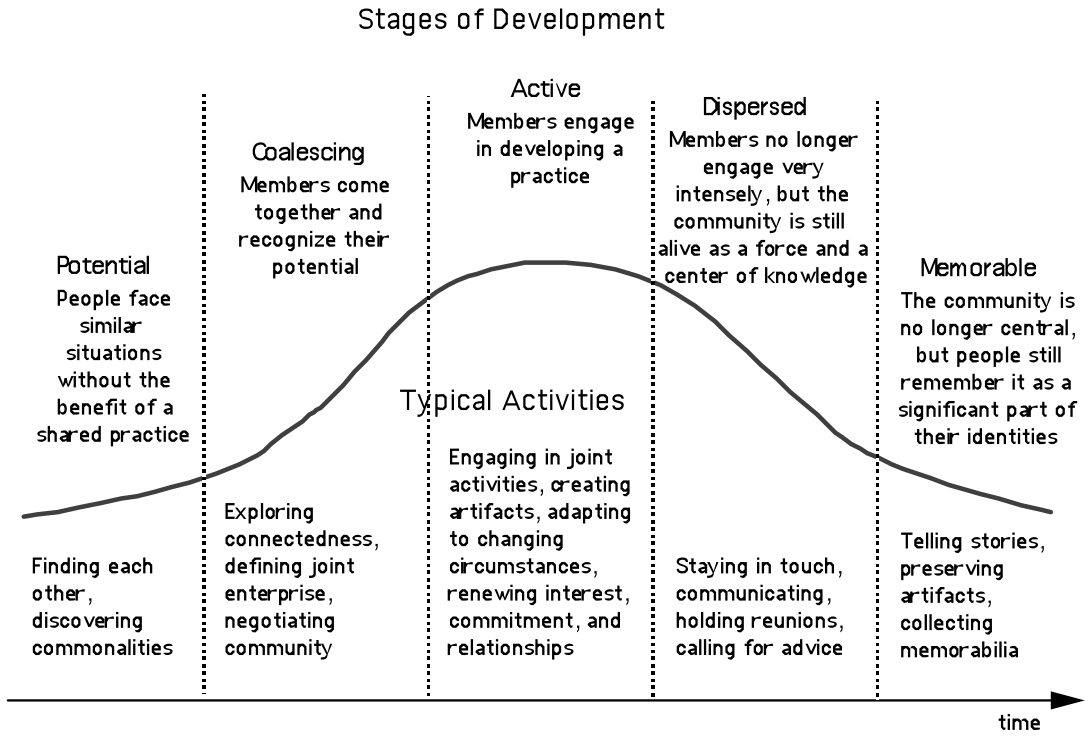


Figure 11: CoP Stages of Development (Wenger, 1998a, p. 3)

The beginning of the project, during which the principal investigator was evaluating the intention of the NIH Roadmap and practice-based research networks' interest in developing an electronic network to facilitate clinical research in primary care settings, represents stage one: "potential." At this stage, the principal investigator had formed the idea of an electronic research network and was engaged in finding other interested parties and understanding their commonalities. Prior to drafting his proposal to the NIH, he connected with those people who faced similar situations but without the benefits of a shared practice (i.e., wanting to facilitate research in primary care settings).

The next step, "coalescing," involved working with those who had expressed interest in developing an electronic network and submitting a proposal to secure NIH funding. At this stage members came together in recognizing the ePCRN concept's

potential, and together, they began to form the ePCRN's joint enterprise and shared repertoire, which was articulated in the NIH proposal. Also at this stage, the identity of the "community's" members was formalized, including the UK team and the involvement of a core group of practice-based research networks.[49]

Once the project was funded, the ePCRN began the main or "active" stage where the team worked to "develop a practice" (i.e., realize its joint enterprise by developing its shared repertoire). As mentioned earlier, this stage involved mutual engagement of the members as they engaged in joint activities, formed relationships, and navigated challenges by drawing on each other's expertise and commitment.

Finally, it could be said the project has moved on to a "dispersed" stage. Although the group is no longer bound by the NIH-funded contract, the commitment to continue the work of the ePCRN to facilitate clinical research in primary care settings still exists in many of the members. This stage of the project is beyond the scope of my research here, but is a topic I hope to examine in the future.

Output and Implications

I have provided evidence of how the ePCRN functions as a community of practice, but what do communities of practice give us? In a 2000 *Harvard Business Review* article, authors Wenger & William Snyder state: "Communities of practice can drive strategy, generate new lines of business, solve problems, promote the spread of best practices, develop people's professional skills, and help companies recruit and retain

[49] It should be noted that the first two stages (potential and coalescing) were not observed firsthand by this researcher, and so I rely on the reported descriptions of this period from the ePCRN team, taken from my interview and field note data.

talent" (p. 140). Creating an environment in which passionate members have agency to negotiate meaning and practice to reach a mutually agreed joint enterprise provides an infrastructure for transforming ways of working, and in the case of the ePCRN, of how medical knowledge and best practices of care can be obtained and implemented. The ePCRN project aimed for the articulation of a joint enterprise for the future of clinical research and primary care and, through a shared repertoire of tools, a means to answer pressing and relevant research questions and effectively disseminate new findings for improved health care—all of which appear noble.

Yet, operating as a community of practice is neither inherently beneficial nor harmful. "They [communities of practice] are not privileged in terms of positive or negative effects. … As a locus of engagement in action, interpersonal relations, shared knowledge, and negotiation of enterprises, such communities hold the key to real transformation—the kind that has real effects on people's lives. From this perspective, the influence of other forces (e.g., the control of an institution or the authority of an individual) are no less important, but they must be understood as mediated by the communities in which their meanings are to be negotiated in practice" (Wenger, 1998b, p. 85).

It is to the influence of these "other forces" that I turn to in the next chapter as I examine the ePCRN within the larger social context of how this type of technology is embedded in structures or systems that affect how we progress as a society. Through critical theories of technology I examine the assumptions behind decisions leading to potentially asymmetrical hierarchies of who controls and uses the ePCRN and,

subsequently, its potential influences on the intersection of clinical research and primary care practice.

Chapter Six:
Merging Technical Affordances with Primary Care and Clinical Research "Lifeworlds"

This chapter further examines the combined influences of technology and society on a potentially "democratizing" project to advance clinical research. In Chapter 4, I examined cultural and institutional demands for greater efficiency and inclusiveness in clinical research—specifically, that the conduct of research studies and implementation of their results into clinics be more efficient, and that the pool of research participants and the scope and focus of research be more inclusive and representative of the nation's overall population. This movement was then placed in the context of technical affordances, as the National Institutes of Health (NIH) and practice-based research networks identified technology as a means to achieve the goals of greater efficiency and inclusiveness. Potential ethical issues were also examined. In Chapter 5, I turned to the electronic Primary Care Research Network (ePCRN) team's response to the NIH Roadmap initiative's aims of efficiency and inclusiveness in clinical research and saw that the ePCRN's development phase operated as a community of practice. Within a community of practice framework, the ePCRN model attempts to "democratize" how clinical research is conducted via the network's overall aim, or *joint enterprise*, of efficiency and inclusiveness in clinical research, and through *mutual engagement* activities of key players in primary care and academic research, supported by the network's technological features and affordances (constituting its *shared repertoire*).

However, to fully examine the ePCRN and its potential effects on clinical research, I move beyond the initial aims of efficiency and inclusiveness that served as the network's impetus, as well as the dynamics of the project's development, and place the ePCRN, as a technical artifact, within a larger cultural, institutional, and social context. Critical theories of technology allow me to examine the network's abstract technical elements alongside its social context: that is, how underlying societal and cultural assumptions of efficiency and inclusiveness influenced the choice of technologies and the network's subsequent design, affecting potentially asymmetrical hierarchies and/or democratizing capabilities of the network's use in clinical research. Finally, these theories provide a crucial framework in identifying what I believe to be a central issue in the network's development: the gap between the ePCRN's technical affordances[50] and potential challenges of implementing the network in primary care clinics. Specifically, the ePCRN may possess technical affordances for increased participation in clinical research and more efficient ways of conducting research; however, clinical settings must be able to support this type of capability through administrative, financial, and/or infrastructure means. If this is not possible, such technology could be irrelevant. I discuss these issues later in the chapter.

This chapter examines the ePCRN around the theoretical concepts of *social, cultural, and organizational aspects of technology*; *non-neutrality of technology*; *participatory design of technology*; and *"democratic" potential of technology*. Although I draw on a rich literature of critical theorists of technology, my main focus of analysis

[50] By technical affordances, I mean opportunities afforded by technology through its design and use. See also Chapter 2.

employs instrumentalization theory (Feenberg, 2002, 2008b) and "technology-practice" model (Pacey, 1983).

Social, Cultural, and Organizational Aspects of Technology

As seen in Chapter 2, a "technology-practice" model broadens examination of technology beyond technical aspects to include cultural and organization aspects. Applying this model to the ePCRN exposes the "background values" that shape the network's development and potential use in clinics (see Figure 12). First, the ePCRN's technical aspect includes the "tools" identified in the proposal necessary to "build" the network: the Web portal, registry, and Internet2 capabilities. This represents the "restricted" meaning of the ePCRN's technology, but also the most visible elements of the network. Its cultural aspects include the overall aim of the project to promote inclusiveness of primary care in clinical research and increase efficiencies to integrate new research findings into primary care; ethical codes and values in clinical research and primary care; and inclusiveness and efficiency. Finally, the organizational aspects comprise professional activity (e.g., clinical care and clinical research) and users (e.g., practice-based research networks; primary care providers, clinical researchers, and patients).

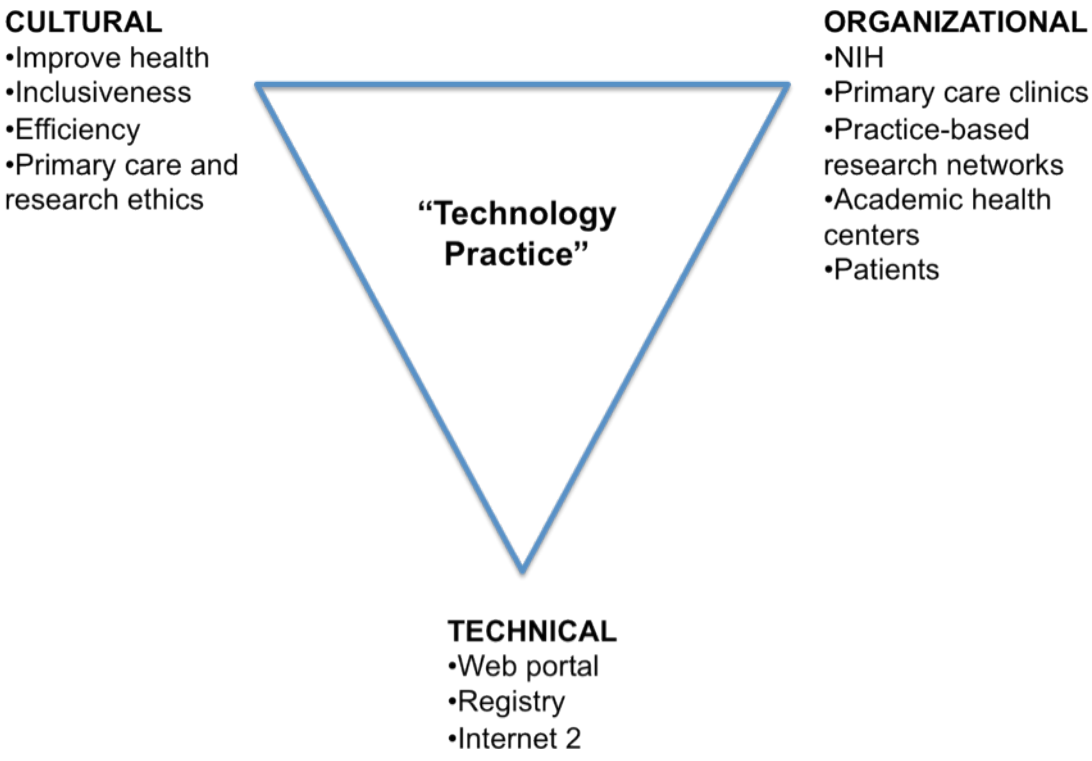


Figure 12. ePCRN "Technology Practice" Model

As mentioned in Chapter 2, "technology practice" is defined as "the application of scientific and other knowledge to practical tasks by ordered systems that involve people and organizations, living things, and machines" (Pacey, 1983, p. 6). Figure 12 illustrates how the ePCRN fits this definition.[51] The network is designed to apply scientific (clinical practice and research) knowledge to practical tasks (the conduct of research) by ordered systems (the network, clinical research protocol) that involve people (care providers,

[51] Interestingly, as a "technology practice" model, the ePCRN has some commonalities with the "community of practice" model. "Cultural aspect" matches CoP's "joint enterprise" (i.e., the overall aim of the ePCRN: to promote inclusiveness of primary care in clinical research and increase efficiencies to integrate new research findings into primary care). "Technical aspect" matches CoP's "shared repertoire" (i.e., the tools of the ePCRN's Web portal, registry, and Internet2 capabilities). Finally, "organizational aspect" matches CoPs "mutual engagement" (i.e., the activity of the users and professionals). Key in both theories is the concept of "practice."

researchers, patients/participants) and organizations (academic health centers, clinics, National Institutes of Health, practice-based research networks), living things (humans), and machines (computer-based networks). The "technology practice" model provides an introduction to further analysis of how the ePCRN's technical components interact within a social context.

ePCRN's Primary and Secondary Instrumentalizations

Instrumentalization theory provides a framework to analyze the ePCRN's technical components or "functions" and its intended social context, the "lifeworlds" of the participants who are involved in the clinical research enterprise—both separately and alongside each other. In the following sections, I look at the ePCRN during its three-year NIH-funded period to determine its primary and secondary instrumentalizations. To analyze the ePCRN's primary instrumentalization, I examine the technical components, functions, and affordances of the network's proposed Web portal, patient registry, and Internet2 capabilities. However, my analysis only partially extends to its secondary instrumentalization. Although the network has been developed for its participants' uses in their "lifeworld," it has not yet been implemented in clinics. Therefore, the full implications of the lifeworld's effects on the ePCRN cannot be determined at this time.[52]

From the beginning, the ePCRN project was organized by a clearly defined "function" or designated purpose (Feenberg, 2008b, p. 22). The ePCRN's function was to develop a platform with the ability to "perform large national collaborative studies

[52] See Chapter 7 for potential future research in this area.

throughout the United States, improve efficiency, reduce costs for individual trials, provide easier access for data retrieval and analysis, and involve primary care in recruitment, performance, and translation of findings into practice" (Peterson, 2004, p. 3). This function was to be orchestrated in the features of a Web portal, patient registry, and Internet2 capabilities (identified in Chapter 5 as the ePCRN's "shared repertoire"). Analyzing the primary instrumentalization shows the ePCRN team negotiate for the most appropriate materials with the necessary affordances to meet this purpose. At the same time, the team was operating with an intended social context in mind—the clinical research enterprise, specifically primary care providers and academic researchers. In this way, secondary instrumentalization was present as the project's technology was being constrained by this context. That is, the ePCRN's affordances were being developed in a way that would be acceptable to the network's eventual users, who exist in the social contexts of primary care and research.

Primary Instrumentalization of the ePCRN

In examining the ePCRN's primary instrumentalization, I first break down the network into its three constituent parts: the Web portal, patient registry, and Internet2 capabilities. Then, I "decontextualize" these objects from their ePCRN environment to determine their affordances. That is, these ePCRN's "parts" are decoupled from the context in which and for which they were developed. Second, I simplify the objects to their useful properties that can be "functionalized in terms of a goal" (Feenberg, 2008b, p. 16). That goal is the *joint enterprise* of the ePCRN: to enable the development of an

electronic infrastructure so that researchers can more easily recruit participants and conduct research within primary care settings, and primary care providers can rapidly and easily access new research findings. In summary, instead of looking at the ePCRN's "function" in context of clinical research and the players involved, I take a step back and look at the basic elements of the technology itself and the affordances inherent in these elements.

At the primary level, technical affordances are identified by "decontextualizing" technologies from their social contexts and reducing them to their "useful properties" (2005, p. 50). To identify and examine the affordances of the ePCRN, I turned to the proposal, field notes, and interview transcripts for clues. In particular, the proposal provided information on the "technical objectives" of the ePCRN's "parts" (i.e., Web portal, patient registry, and Internet2 capabilities). In this section of the proposal, the principal investigator outlined the necessary functions for the network, including aspects of both its design and use. By culling the information pertaining to the technical affordances, and at this point, disregarding the social context of its use, I noticed that the ePCRN's intended affordances mirrored many aspects of the Internet/WWW's technical codes (Flanagin et al., 2000), identified earlier in this chapter. Table 9 outlines the ePCRN affordances; those affordances in italics are also identified in Flanagin et al.'s study.

Table 9. Affordances of the ePCRN

Web portal	Security	*Inclusive-ness*	*Free flow of information*	*Sharing of diverse information*	Efficiency	*Flexible capabilities*
Patient registry	Security	*Inclusive-ness*	*Free flow of information*	*Sharing of diverse information*	Efficiency	*Flexible capabilities*
Internet 2	Security	*Inclusive-ness*	*Free flow of information*	*Sharing of diverse information*	Efficiency	*Flexible capabilities*

The technical components of the ePCRN have identical affordances, although their "functions" and eventual "use" diverges in its specificity (i.e., the portal serves as the starting point for ePCRN users when connecting to the network, while the patient registry is accessed through the portal but its function is specific to providing patient information through database technology; Internet2 components are used to enhance functionality provided by the Web portal and patient registry). All offer features of *security*, *inclusiveness*, *free flow of information*, *sharing of diverse information*, *efficiency*, and *flexible capabilities*. When examining the ePCRN's secondary instrumentalization, we see how these affordances come into play in the network's intended use, but for now, I will outline the technical aspects that allow for these affordances, stripped of the social context in which the network was developed for eventual use, and simplified, as Feenberg points out, to the "qualities perceived as essential to the accomplishment of the technical program" (1999, p. 204).

Security. Both the Web portal and the patient registry have technical elements that allow for secure access and use. In the case of the Web portal, key fobs (small hardware devices that function as security access keys) are used to ensure that access to the site is achieved only by those with the requisite security hardware (i.e., the key fob); only authorized users have access to a key fob. The key fob requires a personal identification number (PIN), which authenticates the user as the device's owner. Once the correct PIN is entered, the device provides a unique number that allows the user to log onto the network. Certain applications via the Web portal are also security-driven, such as access to data in the patient registry. This is achieved by passwords and encryption functions to ensure authorized access and confidentiality of patient data.

Inclusiveness. The Internet's ability to widely share data between remote sites is known as its "reach" (Gurak, 2001). A single Web portal affords limitless access to its content, in theory, requiring only the requisite hardware and software to connect with the site. As mentioned above, security measures may be built into the system to restrict access for any number of purposes. However, the basic physical infrastructure of the Internet, connecting networks of computers with each other, indicates a model built on inclusiveness. In addition, the relevantly intuitive design of Internet interfaces (e.g., icons and user-friendly menus on software applications) facilitates inclusiveness through its ease of use; otherwise, "greater technical skills would be required of the typical user" (Flanagin et al., 2000, p. 422), potentially restricting the number of users.

Efficiency. "Speed" is another characteristic of the Internet (Gurak, 2001). Users can search, locate, and download information with just a few clicks of a key. Information

can be accessed 24 hours a day, 7 days a week. Communication with others, too, is efficient through email, instant messaging, and blogs. These types of efficiencies are built into the Internet and WWW, on which the ePCRN's technology is formed. In the case of the patient registry, efficiency is also a feature of its distributed database, in which data is "distributed" across a network of computers allowing for faster queries and reduced network traffic. Data is centrally managed but users are able to access their portion of the database at their location, ensuring their tasks don't interfere with others' work. The central management system, however, ensures that changes and updates performed at one location will be made across the system. The architecture of this type of database enables faster retrieval and synchronization of information.

Internet2 capabilities provide affordances of *efficiency* through high-speed network communication that allows for more efficient and direct transfer of information. Internet2 offers greater capacity for larger and more complex types of data than standard Internet service. Therefore, through an infrastructure that provides greater capacity, more complex types of data (e.g., multi-media applications as opposed to text-based data) are shared more quickly (Internet2, 2010).

Free flow of information and *sharing of diverse information*. These affordances are achieved through Internet technology's "speed" and "reach" capabilities: the ease at which information can travel to across far-flung distances. Again, this is achieved through the Internet's architecture of connected computer networks, supported by hardware and software that facilitate the ability to share a wide variety of communications and data, such as relevant patient data through patient registries, notices

of clinical research studies, and updates on study findings.

Flexible capabilities. As indicated in Flanagin et al. (2000), the Internet's programming language "allows the creation of a flexible and evolving framework as opposed to the confines of a fixed system" (p. 415). With the ability to jump within and between sites with a click of a mouse, users are able to interact with content in a nonlinear, flexible fashion. This affordance is linked in similar ways to those mentioned above, particularly free flow of information and sharing of diverse information.

This examination of the ePCRN's primary instrumentalization illustrates the basic technological affordances of the network. These affordances constitute the ePCRN's "function." That is, from a technical perspective, these affordances indicate what the network is able to achieve—a "utilitarian evaluation" of the technology (Feenberg, 1999, p. 203). I now turn my attention to the "lifeworld" of clinical research and primary care practice, to see how these affordances may fare in the social context of the network's eventual implementation.

Secondary Instrumentalization of the ePCRN

Moving a technology from its primary to secondary instrumentalization introduces both constraints and opportunities based on the "existing technical and social environment" (Feenberg, 2008b, p. 17). The ePCRN's primary instrumentalization revealed a technical system with affordances of efficiency, inclusiveness, security, free flow of information, ability to share diverse information, and flexible capabilities. What happens to these affordances, however, when placed within the social context of the

clinical research enterprise? What "constraints" as well as "possibilities" exist in this environment and what is the effect on the ePCRN as a technical artifact? Examination of the network's secondary instrumentalization will provide some answers.

While a complete analysis of the ePCRN's secondary instrumentalization cannot be conducted as this time, as the network has not been implemented in its intended clinical setting, the ePCRN has been developed at a secondary level to a certain degree. First, the network was developed by a team including eventual "users" (i.e., academic researchers and primary care providers). In addition, the ePCRN was tested by practice-based research network directors across the country and their constituent primary care practices by conducting "mock trials." The ePCRN model was used by the clinics to collect mock data for a "multi-site" study. Through involvement of these 10 practice-based research networks (PBRNs) and clinics, the ePCRN existed for a time in its intended "lifeworld." The following analysis of the ePCRN's secondary instrumentalization is conducted against this background.

The ePCRN's technical components consist of the Web portal, patient registry, and Internet2 capabilities. In its primary instrumentalization, the ePCRN has certain affordances. But just how these affordances are realized depend on the network's social context—the environment of clinical research and primary care clinics. The "decontextualized" affordances of the ePCRN's technical components must be "recontextualized" for the ePCRN to become a "working artefact" (Feenberg, 2008b, p. 17). The decontextualized objects must be re-coupled and returned to their social context. For the ePCRN's secondary instrumentalization, the components of Web portal, patient

registry, and Internet2 capabilities are brought together to form a network suitable for its intended users in their social contexts. For a network to meet the needs of the context in which it will operate, its components are shaped by the values of that society. That is, the ePCRN's design and use is constrained by the norms and values of its social context of academic clinical research and primary care practice.

For instance, the clinical research context forces a balance between the affordances of *security* with *free flow of information*. Patient data is privileged and protected information, subject to special protection under the United States Health Insurance Portability and Accountability Act (HIPAA) (U.S. DHSS, n.d.). To function in an acceptable way in a clinical research and primary care environment, the ePCRN must have technical capabilities[53] to ensure privacy of data, while at the same time, allow for a free flow of information of data and research findings among researchers and primary care providers and their patients.[54] In the ePCRN's development stage, the team recognized this need, addressing the issue by implementing encryption and de-identifying software for use in the patient registry. This measure was included to provide protection of personal health information, yet retaining the affordance of free flow of information that allows primary care providers to have access to research studies and findings, and academic researchers have access to primary care providers as collaborators on research and to their patients as potential research participants.

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[53] I use "technical capabilities" in the same way as I refer to "technical affordances": the opportunities afforded by technology through its design and use.

[54] Similar concerns of balancing security and efficient availability of information are faced in fields of banking and retail (e.g., see Miyazaki & Fernandez, 2000).

A balance between *security* and *inclusiveness* is also necessary in the ePCRN's intended social context. The team developed restricted access measures to ensure only authorized persons (i.e., identified researchers, primary care providers, and relevant staff) had access to the Web portal and its applications. One way this goal of security was achieved was through the use of key fobs (a device that serves as a security access key). Having this security measure tempers the technology's full potential of inclusiveness, but clinical and research conventions require such a constraint. In addition, inclusiveness is only attained to the degree that users must meet certain criteria (e.g., credentialed academic researchers and primary care providers) to become a part of the network.

The ePCRN's technical capabilities for *efficiency*, *flexibility*, and *sharing of diverse information* may also come up against potential constraints within the primary care practice settings. Internet2 technology allows for complex types of data to traverse the network with potential to speed communication and research tasks such as accessing patient registries; however, clinical settings may not be able to support this type of capability through administrative, financial, and/or infrastructure constraints. Through its technical capabilities, the network may be able to offer flexible ways to search, gather, and disseminate information, but if there is not human capacity at the clinical sites to actually *conduct* these functions (e.g., through lack of time, interest, or skills), such technology could be irrelevant.

In addition, the network's affordance of *efficiency* must co-exist with regulatory issues that favor ethical value over efficiency. Although technical capabilities may be able to compress time needed to conduct certain aspects of clinical research, certain

procedures do not fit this model. For instance, the process of discussing potential research involvement with patients can be delicate and complex. It also usually involves face-to-face interaction between the patient and his/her care provider, as opposed to electronic communication. As mentioned earlier, special care must be taken by providers to ensure that the patient fully understands the differences between care and research, to avoid "therapeutic misconception" (see Informed Consent section, Chapter 1).

Should the ePCRN become implemented in clinical settings, its secondary instrumentalization can be further investigated. Particularly, I anticipate additional legal, moral, and aesthetic issues to arise. In addition, unforeseen possibilities for the network may also surface once implemented in a clinical setting. I address these potential issues in Chapter 7.

Summary of Primary and Secondary Instrumentalizations

It is important to note that the development of technical artifacts involves choices between many possibilities, and that the artifact in question never remains static. Designers as well as users have potential to influence technology, which may occur at every stage of development—from initial concept to finished form, and take into account both technical factors and social contexts. As the ePCRN is developed in its social context, it will be possible to examine how social interests and values from clinical research and primary care settings influence the network as a "working artifact."

Non-Neutrality: ePCRN's Formal Bias and Technical Codes

As stated in Chapter 2, *formal bias* refers to the way a relatively neutral system comes to favor a particular social group and can occur on a "constitutive" level or an "implementation" level (Feenberg, 2008b, p. 10). On the "constitutive" level, in which values are "embodied in the nature or design of a theoretical system" (ibid.), I argue there is a formal bias for efficiency and inclusiveness. These values were identified and articulated both in the NIH Roadmap initiative and the ePCRN's proposal.[55] The project's initial conception and subsequent design during the three-year funded period incorporated decisions that supported efficiency and inclusiveness. For instance, the decision to house the ePCRN architecture (e.g., servers) and data locally as opposed to using the University of Birmingham's resources was made for security reasons, but also to ensure efficiency as the infrastructure at the University of Minnesota proved to be more sophisticated. In addition, the individual design features of the Web portal were constructed so that primary care providers and researchers could easily and quickly access, understand, and navigate the site (see Chapter 5). Layered into the ePCRN model, efficiency and inclusiveness are also affordances of the technology on which the ePCRN is based. Internet technology and distributed databases, for instance, are designed for ease of use, fast data search and retrieval functions, and open communication channels. Of course, this is not to say that the ePCRN, as a technical artifact developed by a team of clinician-researchers and information technicians, favored *only* characteristics of efficiency and inclusiveness; however, these aspects were predominant in the network's initial concept and design.

[55] See Chapter 4.

Characteristics of efficiency and inclusiveness also inform the ePCRN's *technical code*, as much as can be determined at this stage of the network's development. The ePCRN mirrors that of the Internet/WWW's technical code (Flanagin et al., 2000) in relation to design—that is, inclusiveness and free flow of information. These technical codes arise out of the ePCRN's design of connectivity, data communality, and interactive functions. Although the network has been designed with particular users in mind, it is not possible at this stage to determine whether the network truly affords a technical code of diverse information sharing and flexible capabilities accommodating a variety of uses. To determine this, the ePCRN needs to be functioning within primary care clinics. Only when this occurs can the network's technical code be fully determined, as well as any constraints that may impede the ePCRN's potential for inclusiveness and efficiency, such as an inability to access or fully utilize the network due to lack of necessary technical infrastructure in clinics.

This examination of the ePCRN's formal bias and technical codes raises several questions. For instance, do the values of efficiency and inclusiveness lead to any asymmetrical hierarchies of who controls and uses the eCPRN, and if so, to what effect? To some extent, the ePCRN is controlled centrally, through the involvement of the development team in designing the network and administering its functionality. Features identified and deemed relevant by the development team can be implemented as they have "ownership" of the network. Thus far, primary care clinicians and other researchers have less control over its development and use. Although the ePCRN development team sought and obtained input from other clinicians and researchers through the practice-

based research networks, these groups do not have the same level of control over the network as the ePCRN team. Potentially, this inequality could create an asymmetrical hierarchy, particularly if input and feedback from the network's eventual users are not actively pursued, considered, and addressed. The effect cannot be determined until the network's implementation in clinics.

Another question is how do the values of efficiency and inclusiveness fit in the "lifeworld" of clinical research and primary care practices? While there is evidence that these values are supported to some extent in the ePCRN's intended social context (e.g., as evidenced by involvement of practice-based research networks in the ePCRN), it is less clear if they are also shared at a more grass-roots level. Will the rural primary care physician and her staff and patients want to be part of a network designed to link primary care and research? Would the ePCRN meet their needs? To what extent would a participating care provider be able to shape the technologies used for these purposes? At this stage, it is not possible to answer these questions. Only once implemented in a clinical setting will the ePCRN show whether its technical code is "feasible" or "technically workable" within its social context (Feenberg, 2005, p. 52).

Spanning both issues of potential asymmetrical hierarchies and the network's relevance to the primary care "lifeworld" is the following: what assumptions do the ePCRN team make about the technical capabilities of primary care practices and what does this mean for the network's potential as a "democratic" technology? As noted in the ePCRN proposal: "Great potential technology and important discoveries are of no value if they are not put to use. A technologic solution that provides a pipeline to the primary

care clinical practice is useless if the clinic staff never turns on the clinic computer" (Peterson, 2004, p. 10). The ePCRN project was designed to provide affordances of efficiency and inclusiveness, as characteristics built into the technology itself (i.e., through the design of the network and the various applications, such as clinic-based patient registries). However, what assumptions were made about the clinic-based technical affordances? Are primary care practices able to support such a network, both in terms of hardware and software infrastructure as well as clinical staff support?

Some of the assumptions around clinic-based infrastructure and capabilities are outlined in the ePCRN proposal, which cites an electronic-based model for improving diabetes care as a successful case study merging technology and primary care in a randomized controlled trial. This project used a database, similar to that proposed for the ePCRN's patient registry, to connect data in 24 primary care clinics and more than 7,000 patients with diabetes. The network has several security features (e.g., firewall, encryption, de-identified information) and its software supports the main types of activities used in clinics for support of diabetes, such as clinic-specific patient and physician reminders, identification of high-risk individuals, and patient-specific recommendations. The ePCRN principal investigator also led the diabetes project, and was therefore familiar with clinics' technical capabilities. In addition, for the ePCRN, the development team tapped into the expertise of the participating group of practice-based research networks (PBRNs) to advise on numerous issues of linking research and primary care, including issues of technology. What is not clear is whether the assumptions made and the guidance received about clinic-based technology and needs sufficiently matched

the "lifeworld" of clinics. Did relying on practice-based research networks unintentionally lead to a hierarchy of academic researchers at the top (i.e., the decision-makers involved in the project, and also those with the most sophisticated technology), followed by the practice-based research networks (who had input into the network and also a vested interest in combining practice and research), and finally, at the bottom of the hierarchy, individual clinics (likely with limited technical and/or human resources available for connecting research and practice)? In addition, in terms of the ePCRN development team, did the focus on a technical solution to link primary care clinics with researchers also lead to an asymmetrical hierarchy among the clinical and information technology teams? Were there instances when the technology team was able to call the shots on the network's design and functionality, or were the bridging roles of principal investigator and informatics manager able to sufficiently balance the hierarchy?

The ePCRN project met the milestones outlined in the proposal, which in the three-year funded period did not include full implementation of the network across the nation. However, could implementation of the ePCRN into clinics have been facilitated through a more "participatory" model involving primary care clinics from a grass-roots level as well as practice-based research networks? Was enough consideration given to the technical and human support constraints of clinics? Certainly, building the network constituted a major, but incomplete step in potentially linking primary care and research. To work, the clinic computer must be able to support the ePCRN's sophisticated capabilities (indeed, the clinic must have a computer), and staff must have the time and drive to turn it on. In the context of these issues, I now examine whether the ePCRN can

be considered a democratizing technology and to what extent its development characterizes a model of participatory design.

ePCRN as a Democratizing Technology?

Using the definition of democratizing technology as "privileging … excluded values and the publics that articulate them" (Feenberg, 2002, p. 22) by "granting actors who lack financial, cultural, or political capital access to the design process" (Feenberg, 1995, p. 7), I break down the definition's three parts to determine whether the ePCRN meets the criteria for a democratic rationalization of technology: 1.) privileging excluded values; 2.) the publics that articulate them; and, 3.) granting actors who lack financial, cultural, or political capital access to the design process.

First, the ePCRN project grew out of a desire to link primary care practices and practitioners with clinical research. The National Institutes of Health and practice-based research networks (PBRNs), two main players in clinical research and primary care in the United States, backed this aim through funding (NIH) and support in developing the ePCRN model (PBRNs). The "excluded values" in this case constituted primary care: specifically, primary care practitioners and their patients' involvement in clinical research. As previously noted, primary care providers, who see the majority of patients in the United States, are not typically involved in clinical research, as their focus is to provide patient care. Instead, clinical research tends to occur at large academic health centers, although less than 1% of the nation's patients are seen at these health centers (Tierney et al., 2007, p. 243). Over the years, this has resulted in a "disconnect" between

research and clinical practice where research "may not translate expeditiously to everyday practice, and clinical problems encountered in everyday practice are often underinvesitgated" (ibid.). Involving primary care in clinical research could help widen the pool of available study participants for clinically relevant research, and primary care patients could also participate in the research process in ways previously unavailable to them (i.e., through their primary care practices). This could then result in more relevant research results for the general public. The ePCRN's development is geared to address these issues. In this way, at least theoretically, the ePCRN project fulfills the first part of the criteria for democratic rationalization of technology: privileging excluded values.

But who are the "publics" articulating the "excluded values" of primary care in clinical research? Certainly, backing of this "excluded value" is seen through the NIH Roadmap initiative, which provided funding for the ePCRN project. Practice-based research networks also supported the aim to link primary care practices and research through work that pre-dated and informed the ePCRN. Members of PBRNs include both primary care providers and academic researchers, but it is important to note that this is a specialized subset of primary care providers. PBRN members already have an interest in research. What is less clear is the desire of "grass-roots" primary care providers across the United States—those not affiliated with research or academic health centers. To what extent do they constitute the "publics" advocating for greater involvement in clinical research? If they are not included from the outset in the movement to connect primary care and research, is this a top-down initiative from the NIH and others with a vested interest in clinical research? For the ePCRN concept to be truly "democratic" it must

address a need articulated by "publics" for whom the initiative most affects—primary care practitioners and their patients. Although the ePCRN was funded through a competitive process at the NIH, which certainly takes into account relevance and need, one needs to determine the interest of the primary care providers and patients themselves. This aspect links to the next part of the definition.

Does the ePCRN involve those who "lack financial, cultural, or political capital access to the design process"? The principal investigator and the ePCRN development team are, for the most part, based at an academic health center and as such, possess financial, cultural, and political capital in terms of clinical research (e.g., the PI controls the budget, is well attuned to the NIH research culture, and through involvement in practice-based research networks, has political clout in the primary care research circles). In the design stage, they are the ones making the decisions that affect how the ePCRN will function within the social context of primary care clinics. As previously noted, the team involved members of practice-based research networks to help ensure the design meets the needs of some of those who will use the network. However, it could be argued that these members also enjoy a certain level of clinical research "capital" in their relationship to academic health centers and experience conducting NIH-funded research. A stronger case of democratic rationalization could be made if there were clear instances of direct involvement from "grass-roots" primary care providers and their patients in some aspects of the ePCRN's design. This was not clear during the project's development phase, as observed by this researcher.

Participatory Design: ePCRN's "Democratic" Future?

A "participatory design" model of democratic rationalization may have an important role to play should the ePCRN be implemented in clinics. In participatory design, "experts" and "lay actors" collaboratively influence, change, or reinvent technology to create a product to meet their needs. Certainly, "experts" are represented in the ePCRN's development, including academic researchers, PBRN directors, and information technicians. However, how have "lay actors" been involved? For a truly "participatory," and therefore "democratic" development of this technology, potential users of the network would need to be involved in shaping the ePCRN's design and function. This would include primary care providers and patients, who could provide valuable input from their perspective on how to achieve the aims of the ePCRN.

The role of the "new professional" (Pacey, 1983) could be instrumental in achieving the aims of participatory design. The new professional is one who actively broadens his/her perspective, outside of one's area of expertise, to solve problems in an interdisciplinary approach. This type of approach "forces specialists to look beyond their customary disciplinary boundaries; it involves them in collaboration with people from other disciplines as well as with laymen; and it helps to create awareness of the organizational and cultural contexts of the work" (ibid., p. 152).

This type of relationship already exists with the principal investigator among the practice-based research networks across the country. It could be useful if this role were expanded to include more contact with primary care clinics, providers, and their patients, to obtain their perspectives on what an electronic research network would mean for

providers' practices, staff members' work experiences, and patients' health care. Table 10 provides an example of the questions that should be asked of both experts and laypersons (here, the example is for a public health project).

Table 10. Matrix for Assessing New Technological Developments (Pacey, 1983, p. 155)

The columns representing expert and lay (or user) views are initially blank and are filled in by promoters of the project as a means of testing its appropriateness in the community concerned. The matrix is here shown partially completed; in practice, both questions and answers will usually need to be more detailed.

Queries	Expert views	User views
Practical benefits and costs		
What benefits are sought?	Very specific benefits (e.g. control of a particular disease)	Better living standards in general, including health, amenity, housing, jobs
What costs, what risks, and what environmental impacts are perceived?	Cost of implementation; risks as a statistic to be weighed against benefits	Costs in time, cash, amenity, organization, risk, seen in personal and family terms
Who gains which benefits? Who loses?		Lowest income groups cannot afford the cash costs
Status and political advantage		
What is the impact of the project in terms of status and prestige?	Visible progress, good for national prestige Professional advancement for the experts concerned	Status associated with possession of new household amenity
Who gains or loses status, power or influence?	Some strengthening of central government authority	Some loss of control over lifestyle; fear of bureaucratic power
Basic values		
What is the cultural context?	Scientific/technical; the expert sphere	Domestic/traditional; the user sphere
What are the dominant values?	Technical interest and virtuosity; economic values	Need or user values, family welfare

For the ePCRN, these questions could be asked of key members during the planning process and as they begin to implement the network in clinics. I would further suggest that these questions and issues be shared with representatives from practice-based research networks, primary care providers, and even patient groups. In particular, I believe the category of *practical benefits and costs* would be useful to share with primary care providers and patient groups as a way to obtain their perspectives of conducting clinical research in primary care settings.

My analysis of the intersection of the network's technical aspects and its social, organizational, and cultural aspects leads to a conclusion on the importance of participatory design of technology. The technical pieces may be in place for an advanced network to link primary care providers and their patients with clinical research, but for a technological system to be viable, it must match the needs of those who will use it, in the context in which they will use it. Playing close attention to the perspectives and considerations of those for whom the technology is being designed is crucial. A participatory design approach could help the ePCRN team address these issues.

In the next chapter, I discuss the implications of my findings and direction for future research.

Chapter Seven:

Conclusion

In 2004, a chance conversation with a primary care physician/researcher served as the impetus to my research. Describing his idea for an electronic network that could link primary care practices with clinical researchers at large research institutions, he explained why primary care's greater involvement in research was crucial to improving health: at the time only 14% of research findings made their way into everyday clinical practice, and those that did typically took 17 years (Balas & Boren, 2000). He and others believed it was necessary to find a way to *expedite* the conduct of research and the translation of those research findings into practice. In addition, a more *inclusive* pool of researchers and participants—beyond those based at academic medical centers where only a small percentage of the nation's patients are seen, typically for relatively advanced or rare conditions—could lead to investigation of more relevant research questions supported by a more representative patient population. I was intrigued by the idea of an electronic network's potential to address these needs. In particular, I wanted to examine the evolution of a virtual network and its effect on groups with differing perspectives—patient care for primary care providers versus new knowledge for researchers—yet with ultimately similar aims—improving health.

What began as a close examination of group dynamics in the development of the electronic network expanded to a critical analysis of the network's place within a larger social and technical context. Specifically, I wanted to know to what extent the network might serve as a "democratic" technology through its involvement of previously

unprivileged populations in clinical research—primary care providers and patients. First, could the affordances of technology make research more democratic through efficiencies in the research process that allow primary care providers and their patients to participate in research? Second, what role could affordances of technology play in making the participant pool more representative of the nation's demographics than conventional efforts thus far? To arrive at my conclusions on this matter, however, I first needed to examine the assumptions of *efficiency* and *inclusiveness* as technical affordances (e.g., via concepts of *speed* and *reach* outlined in Gurak, 2001)—as well as in the social contexts of clinical research and primary care—and how the network's development team worked to include these previously unprivileged populations in realizing efficiency and inclusiveness in the network's technical design and use.

Overall, I discovered that while the assumptions of efficiency and inclusiveness, in the context of clinical research and in the technical affordances proposed in the ePCRN model, provided potential benefits for clinical research to ultimately improve health, they also posed potential risks. For instance, the benefits of widening the pool of researchers and participants and streamlining the recruitment process must be balanced against real and perceived security and privacy threats to private health information. In addition, when primary care providers also act as researchers, there is potential for "therapeutic misconception" where patient/participants may not clearly understand the differing roles of research and clinical care and the implications of those differences.

Further, it is not possible to separate technical affordances from their social contexts, and it is precisely how technical affordances are placed within social contexts

that truly shape a technology's impact. The network's development by the ePCRN team provides the first steps in moving the theoretical concepts of efficiency and inclusiveness to the social contexts of clinical research and primary care. Overall, the ePCRN team operated as a "community of practice" (Lave & Wenger, 1991; Wenger, 1998b), whereby team members were given agency to negotiate the network's meaning and practice within a limited social context (i.e., in trial runs among a test population of practice-based research network clinics). Specifically, the team engaged members with a wide range of expertise (e.g., clinical, technical, practice-based research networks), who mutually worked toward a "joint enterprise" of efficiency and inclusiveness in research through realizing a "shared repertoire" of a Web-based portal, patient registry, and Internet2 technology. Although characteristics of "mutual engagement" toward a shared goal were evident within the development team, one cannot overlook the potential effect of other forces (e.g., of primary care clinics and their providers, staff, and patients) on how the network might be mediated and realized within the network's intended social contexts. This aspect would need to be covered in subsequent research.

Finally, I employ a critical theory of technology framework to examine the network's melding of design and use. This reveals that although the team has done much to assure a "democratic" development and use of technology, assumptions of efficiency and inclusiveness in the ePCRN have led to some level of unintentional / unanticipated asymmetrical hierarchies of who controls and uses the network. For example, although the ePCRN project is intended to privilege those previously excluded from the clinical research enterprise (i.e., primary care providers and their patients), the design process did

not fully include the perspective of those who "lacked financial, cultural, or political access" (Feenberg, 1995, p. 7), a factor which may have contributed to the ePCRN's lack of implementation in clinics immediately following the network's development.

In the following sections, I return to my research questions and provide a more detailed summary of my findings, along with implications for other research and direction for future research.

Research Questions

(1) How does the NIH Roadmap's expectations of efficiency and inclusiveness affect the ePCRN's development with potential implications for clinical research?

My close examination of the NIH's cultural assumptions of efficiency and inclusiveness and the corresponding technical affordances in the ePCRN proposal found that potential benefits based on these assumptions and affordances in clinical research must be balanced against potential risks. To maximize the network's potential, the ePCRN team must not only embrace the perceived benefits of efficiency and inclusiveness, but also recognize the risks of pursuing these aims through an electronic research network, and address the benefit/risk trade-off at the earliest stages of the network's development and throughout its eventual implementation and use.

Benefits for efficiency and inclusiveness, cited by the NIH Roadmap and mirrored in the ePCRN's proposal, included: achieving faster research results and implementation of those results into patient care; saving time and money on the conduct of research; involving a wider, more representative study population; and, obtaining more relevant

research findings. Technology, in both the NIH Roadmap and the ePCRN proposal, was cited as a critical means to achieve these aims, for instance, through an improved infrastructure, networked tools and applications to facilitate collaboration and information sharing, and use of high-speed Internet capabilities.

Specifically, I argue that affordances and limitations must be balanced against each other in areas of *participant recruitment*, *informed consent*, *data collection and management*, and *communication*. While an electronic network could provide targeted recruitment tools reducing the time required to identify eligible study participants, as well as to potentially increase the number and diverse representation of study participants through a wider pool of primary care patients, these same patients must be confident in the privacy and security features of the technical affordances used to target them as potential participants and to transfer their data for research purposes. Likewise, primary care providers also must have confidence in the network's safeguards if they are to be advocates and users of the network. While the ePCRN project has built security measures into its design (e.g., firewalls, encrypted transmission capabilities, and password protection), primary care providers and their patients may nevertheless be wary of an electronic network that handles sensitive health information. This may be particularly true of some patient populations who have been under-represented in clinical research and are historically distrustful of research.

Another serious potential limitation involves the concept of "therapeutic misconception" (Appelbaum et al., 1987, Appelbaum, 2002). Although the ePCRN's technology itself is not the main cause of concern for therapeutic misconception in this

context, the assumption of inclusiveness through primary care providers and their patients' involvement means the role of the primary care provider can appear ambiguous for the patient being approached for research purposes by his/her clinician. Care must be taken to ensure potential participants understand the research process, the difference between aims of research and clinical care, and the possible risks and benefits of their involvement in a research study. Addressing these issues likely could be time consuming and require face-to-face time between patients, care providers, and research team members. For instance, it is important that potential participants realize that clinical research aims (to generate new knowledge, where benefits do not necessarily directly apply to the individual participant) differ from clinical care aims (the main purpose of which is to benefit the individual patient). Potential participants should also know there would be no negative consequences to their care should they decline to participate in a clinical study being offered by their care provider. To ensure ethical enrollment of patient/participants and researchers' access to private health information, the research process using the ePCRN model must balance efficiency and inclusiveness with measures of security and a thorough and ethical informed consent process.

An electronic network could also expedite research by centralizing study information, coordinating multi-site studies, and providing efficient data searches and data management tools. Again, these potential benefits must co-exist with appropriate privacy and security measures to ensure private health information is kept safe and that only authorized users have access to authorized information for appropriate purposes. Although security measures are in built into the ePCRN's design, such as firewalls and

encrypted transmission of de-identified data, it would be crucial that these security measures are followed *in practice* (i.e., by the users of the network, the researchers, providers, and other clinic staff).

Finally, the ePCRN's technical affordances of efficiency and inclusiveness would allow faster and widespread communication among primary care providers and researchers. The affordances also support the ability for researchers to notify and provide follow-up on study information and targeted dissemination of relevant research findings that match patients' health concerns and needs. While the ePCRN's technology affords this capability, there may be limiting factors of whether intended clinical sites can support Internet2 technology, or whether appropriate human resources are available to complete the tasks afforded by the technology. (This concern is addressed in more detail below, in the context of my third research question.) In addition, as with the other areas mentioned in this section, the affordances of efficiency and inclusiveness must be matched against the need for appropriate privacy and security.

So, while the NIH and the ePCRN proposal focus on the benefits of efficiency and inclusiveness in clinical research, I argue that these assumptions and affordances come with ethical challenges and potential limitations that must be addressed in the ePCRN's design stage and throughout its implementation and use in clinics. Although the NIH Roadmap initiative and the ePCRN project privilege novelty, speed, and transformation of the clinical research enterprise, obviously it must not be played out at the expense of ethical research conduct involving time and appropriate levels of security and privacy.

To what extent the ePCRN model attempts to address these concerns is seen in how the development team works together to form the ePCRN (see next research question), while the network's effect on the social contexts of clinical research and primary care and its potential as a "democratic" technology are addressed in the third research question.

(2.) During the developmental stage, to what extent does the ePCRN function as a "community of practice"?

I argue that the ePCRN development team builds a network that incorporates assumptions and technical affordances of efficiency and inclusiveness, with which the team must also balance issues of security and privacy. First, with an aim toward collaboration among primary care providers and academic researchers, the ePCRN team functioned as a "community of practice" (CoP) as described by Wenger (e.g., 1998a, 1998b; see Chapter 5). This function was evidenced through the following means: the project and team's "joint enterprise" (its overall aim) to facilitate clinical research in primary care settings; its "shared repertoire" (shared resources in a shared practice) comprising the project's stated objectives of a Web portal, patient registry, and Internet2 capabilities; and, its "mutual engagement" in which members are engaged in a common negotiated activity, evidenced among the team's diverse composition as they formed relationships and worked to implement the project's shared repertoire and joint enterprise.

Working as a "community of practice," team members were charged with the ability to negotiate meaning and practice to shape the ePCRN's development. The ePCRN leadership and team members engaged the perspectives and expertise of their diverse team (e.g., clinical and technical team members, practice-based research network directors), all of whom had an interest in advancing clinical research in primary care. In this way, the project's "joint enterprise" and "shared repertoire" were formed. Through "mutual engagement" of the team members during the project, the specifics of how to create the tools (shared repertoire) to achieve the aims (joint enterprise) were continually re-negotiated. That is, the members were given agency to shape the project in ways relevant and meaningful to them and to the intended context of primary care and clinical research.

The effects of functioning as a community of practice were seen in the mutually respectful and vested ways the team worked together to solve problems and create their vision of a network that they hoped would provide a means to answer pressing and relevant research questions and effectively disseminate new findings for improved health care. Importantly, the group's diverse membership attempted to facilitate the needs of both research and practice, particularly evidenced in the key "bridging" roles of the principal investigator and senior informatics manager, who most often worked to ensure the project fulfilled the needs of both research *producers* (i.e., clinical researchers) and research *users* (i.e., providers and patients).

Throughout the project, there was clear evidence that amongst themselves the ePCRN team functioned as a community of practice, and that such interactions were

beneficial to the project. For instance, they remained focused on the project's joint enterprise, and actively called on each other's expertise and perspectives to guide the development of its shared repertoire. Yet, an important consideration exists beyond the immediate circle of the ePCRN team, and that is the *power dynamic* between the ePCRN team and the intended social context of primary care clinics. Functioning as a community of practice, the ePCRN team was able to build a network with the identified shared repertoire of Web portal, patient registry, and Internet2 capabilities. However, would the ePCRN still be able to function as a community of practice at the stage of implementing the network into clinics? Do clinics share in the ePCRN's joint enterprise? Do they have appropriate means to support its shared repertoire? Further, would key clinic-based members be equally provided with agency to participate in mutually engaged activities to negotiate the meaning and practice of how the ePCRN interfaces in their social contexts? Would these properties of a functioning community of practice ultimately yield a network that would involve primary care providers and their patients for a more representative, diverse research participant pool? These were issues I tried to address by examining the network's potential as a "democratic" technology, the topic of my next research question.

(3.) What values are laden in the ePCRN's technology and in the social/cultural context of its use, and how do these values influence the ePCRN's potential to function as a "democratic" technology?

Following my examination of the assumptions and technical affordances of efficiency and inclusiveness on which the ePCRN is built and the group dynamics of the

ePCRN team as they developed the network, the next stage of my research merges the network's abstract technical elements with its social context. Specifically, I looked at how underlying societal and cultural assumptions of efficiency and inclusiveness influenced the choice of technologies and the network's subsequent design, and how these decisions affect the network's ability to function as a "democratic" technology. I argue that although the ePCRN team included important technical features and worked together to meet the anticipated needs of those in the social contexts of the networks, some unintended / unanticipated asymmetrical hierarchies emerged in terms of its design and potential use in clinics.

First, I examined the ePCRN as a "technology practice" which comprises cultural, organizational, and technical aspects of technology to uncover "background values," oftentimes obscured behind a technology's more obvious "technical" components (Pacey, 1983). These technical aspects include the ePCRN's Web portal, registry, and Internet2 capabilities, representing the "restricted" meaning of the ePCRN's technology, but also the most visible elements of the network. Its cultural aspects include the overall aim of the project to promote inclusiveness of primary care in clinical research and increase efficiencies to integrate new research findings into primary care; ethical codes and values in clinical research and primary care; and inclusiveness and efficiency. Finally, the organizational aspects comprise professional activity (e.g., clinical care and clinical research) and users (e.g., practice-based research networks; primary care providers, clinical researchers, and patients).

Next, I examined the ePCRN's primary and secondary instrumentalizations, or "the level of our original functional relation to reality [primary] and the level of design and implementation [secondary]" (Feenberg, 2005, p. 50). In other words, the primary level breaks down and simplifies technology for incorporation into a particular device, network, or system. The secondary level integrates them in a social environment.

An examination of the ePCRN's primary instrumentalization focuses on its technical components: the Web portal, patient registry, and Internet2 capabilities. The ePCRN's primary instrumentalization reveals affordances of *security*, *inclusiveness*, *free flow of information*, *sharing of diverse information*, *efficiency*, and *flexible capabilities*. These affordances constitute the ePCRN's "function." That is, from a technical perspective, these affordances indicate what the network is able to achieve—a "utilitarian evaluation" of the technology (Feenberg, 1999, p. 203). This analysis shows that the ePCRN model goes beyond the initial affordances of efficiency and inclusiveness, to include security and flexible capabilities—important aspects for the network's eventual integration into its intended "lifeworld" or social context.

An examination of the ePCRN's secondary instrumentalization sheds light on how these affordances may fare in the social context of primary care clinics. (While a complete analysis of the ePCRN's secondary instrumentalization is dependent on its eventual implementation in clinical settings, I argue that the ePCRN has been developed at a secondary level to a certain degree.) Beyond the network's basic affordances seen at the primary level, at the secondary level the ePCRN's design and use is constrained by the norms and values of its social context of clinical research and primary care practice.

At this stage, the ePCRN, as a working technical artifact, must balance affordances of free flow of information and inclusiveness with security issues, and efficiency affordances with ethical and regulatory concerns (such as therapeutic misconception, mentioned earlier). In addition, the ePCRN's technical capabilities for efficiency, flexibility, and sharing of diverse information may also come up against potential technical and user constraints within the primary care practice settings. For instance, although Internet2 technology allows for complex types of data to traverse the network with potential to speed communication and research tasks such as accessing patient registries, some clinical settings may not be able to support this type of capability because of administrative, financial, and/or infrastructure constraints. Through its technical capabilities, the network may be able to offer flexible ways to search, gather, and disseminate information, but if there is not the necessary staff at the clinical sites to actually carry out these functions (e.g., through lack of time, interest, or skills), such technology could be irrelevant. Only when the ePCRN is developed in its social context, will it be possible to examine how social interests and values from clinical research and primary care settings influence the network as a "working artifact."

Regarding the ePCRN as a democratic technology, what I can say at this point is its aim appears democratic. The ePCRN attempts to include previously excluded primary care providers and their patients in the clinical research process; doing so could help widen the pool of available study participants for clinically relevant research and allow them to participate in the research process in ways previously unavailable to them.

Finally, this would hopefully result in more relevant research results for the general public.

However, it is less clear to what extent the project may have unintentionally left out those who "lack financial, cultural, or political capital access to the design process" (Feenberg, 1995, p. 7). For the most part, those making decisions at the design stage possess financial, cultural, and political capital in terms of clinical research (e.g., the PI controls the budget, is well attuned to the NIH research culture, and through involvement in practice-based research networks, has political clout in the primary care research circles). Certainly, the team involved members of practice-based research networks to help ensure the design would meet the needs of some of those who will use the network. However, it could also be argued that these members also enjoy a certain level of clinical research "capital" in their relationship to academic health centers and experience conducting NIH-funded research. A stronger case of democratic rationalization could be made if there were clear instances of direct involvement from "grass-roots" primary care providers and their patients in some aspects of the ePCRN's design.

Having said this however, it appears that the team and the network technology possess the requisite building blocks to become a democratic technology. Opportunity exists for a "participatory design" model of democratic rationalization if a representative range of "experts" and "lay actors" were to collaboratively influence, change, or reinvent technology to create a product to meet their needs. I believe this alternative would involve expanding the ePCRN's members to include "lay actors" such as patients and "grass-roots" primary care providers, alongside the "experts" of practice-based research

networks and academic researchers. Expanding the group in this way could build a more inclusive community of practice in which mutually engaged input is exchanged regarding the intersection of the network's technical affordances and its intended uses in primary care clinics.

However, until this type of involvement is obtained, and while the ePCRN remains a model that has yet to be implemented in its intended lifeworld, my analysis is that unintentional asymmetrical hierarchies exist. These hierarchies favor academic researchers and practice-based research networks with their attendant financial, political, and cultural capital in the clinical research enterprise.

(4.) To what extent are unintended consequences likely to occur during the ePCRN project?

Several unintended consequences stand out from my examination of the ePCRN project. First, the ePCRN team had to revise the original technical plan to build the network from an existing network in the United Kingdom. Second, an asymmetrical hierarchy exists in the network, pending its implementation into primary care clinics. Both examples focus on the intersection of technology and social context: the first concerning how technology fits into its intended social context and the second, how the technology's design and use is influenced by social hierarchies.

The need for the ePCRN team to revise their plans to use the University of Birmingham-based technical model as the basis of the ePCRN illustrates challenges of incorporating technical affordances seen in a primary instrumentalization level to a

lifeworld context or secondary instrumentalization. At face value, it seemed Birmingham's model offered the necessary technical requirements and affordances for the ePCRN. However, once the ePCRN's technical team was formed and analyzed the system, they determined there were significant constraints[56] for its incorporation in the *ePCRN's intended context*. While the team was able to address this issue, this incident highlights potential issues the ePCRN model may face in its eventual implementation into clinics.

As discussed above, the ePCRN represents a democratic aim, but at this time possesses some unintended / unanticipated asymmetrical hierarchies favoring those with financial, cultural, and political capital in terms of clinical research over "grass roots" primary care practices and their patients. It will be interesting to see to what extent these previously excluded groups will be represented in the process of implementation, and how their input and feedback would shape the ePCRN's development as it operates in its intended social context—areas I hope to be address in future research.

Implications and Future Research

Because my study is an examination of the intersection of an electronic network technology and its social contexts of clinical research and primary care, the implications of my findings also reside in these areas. From the perspective of critical theory of technology, this study concurs that technical affordances and cultural assumptions influence technical design and use, and that the social contexts in which these

[56] For instance, the UK's system was located in a physical environment that was inappropriately secure, as their servers were located in a closet, not a server room, and there were no back-up power capabilities. In addition, storing clinical data, even de-identified data, in a foreign country was not acceptable protocol.

technologies are placed also affect the ways technology is ultimately used, with potential to change the original scope or intent of the technology. The implications of my study in this area concern how assumptions of efficiency and inclusiveness must be balanced against other concerns, such as ethical considerations and limitations of the social context. While my study concerns clinical research and primary care practices, I believe the principle of balancing the benefits and risks of these affordances would apply to other social contexts—for instance, in online commerce, use of technology in classrooms, and social networking. Regardless of the social context, an analysis of the technical affordances and cultural assumptions behind a technology sheds important light on the factors for its use, whether the aim is to maximize efficiencies while maintaining securities, to ensure a more participatory process, or to foster inclusive yet safe online applications.

Further, I believe that by layering frameworks of communities of practice and a critical theory of technology, this study provides insight on how group dynamics influence development of technology and its subsequent place in the "lifeworld." A communities of practice framework allows examination of how a group functions together to create tools that help them attain a shared goal. Much research has been conducted on communities of practice across a variety of contexts (e.g., business, education, health), including online versions. Using this framework to focus on a group's dynamic certainly helps uncover potential imbalances of power, activities, and aims. However, for communities of practice working to develop new technologies, placing its examination within a critical theory of technology broadens one's ability to analyze the

group dynamics to include the technology's place in its social context and its overall effect on that social context. This, I believe, is a strength of my research: that it begins with a thorough examination of the assumptions and affordances behind a technology, followed by how the group made decisions in developing the technology, and then an analysis merging the affordances, the aims, and the dynamics used to determine the technology's role within its social context. In the case of the ePCRN, affordances of efficiency and inclusiveness were balanced with issues of security and ethical considerations in a "communities of practice," participatory model. Nevertheless, certain asymmetrical hierarchies are evidenced in the ePCRN model at this stage, favoring academic-based clinical researchers and primary care clinics attached to practice-based research networks.

Future research is promising. Most importantly, I would like to follow the ePCRN's implementation into clinics, extending my use of communities of practice and critical theory of technology frameworks to advance research within clinical research. For instance, my future research would focus on reasons patients do or do not participate in clinical research. Because primary care patients typically have not been involved in clinical research (at least to the extent aimed at by the ePCRN), opening up the potential for their involvement could lead to interesting research and greater understanding of the factors involved in research participation, which in turn could help improve communication between providers and patients and inform researchers on how to address barriers to participation. In addition, with the ePCRN model in place, further research on therapeutic misconception can be obtained by examining the interactions among primary

care providers and their patients concerning clinical research participation. Other issues I would like to address include: How is the project received by primary care physicians? Of those physicians who do participate, what is the experience they have with the ePCRN? What are their motives for participating? Does the ePCRN meet those goals? Is the interaction between the primary care physicians and the lead researchers successful? Likewise, what is the experience of the participants? What are their motives? If they have been participants in other clinical trials, how do the experiences compare? Coming back to the architects of the project, what are their overall experiences with the primary care physicians and researchers? Does the project meet their goals? Does it meet the goals of the NIH?

I anticipate that future research on this topic would not only inform understanding of the ePCRN and the aim to link research and primary care but would also add to research concerned with online and health-based communities of practice and how knowledge is collectively owned and maintained within communities of practice. In addition, its critical theory of technology framework would advance understanding of participatory design in technical development and evolution of technologies toward democratic design and use.

Regardless of the future direction of my research, this current study provides a comprehensive baseline for affordances, the group dynamics of the technology's development, and its potential place in the social context of clinical research and primary care. Time will tell if the ePCRN model is truly democratic, or whether its activities lead to improved health.

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Appendix A
Definitions of Technical Terms Used in the Project

Access grid:

Access grid technology is advanced videoconferencing that allows groups at different physical locations to interactively collaborate using high-quality audio, multiple video streams, and digital presentation resources.

Clinic / patient registry:

A registry is a "list of all the patients in a physician's practice who share some characteristic, such as a certain condition or medication regimen" (Darves, 2005, para. 2). Registries are most often computer-based, whose applications capture and manage patient information. Sophisticated registries are able to produce "detailed reports on both individual patients and patient populations," including providing reminders to conduct a particular test on a patient to identifying patients not receiving a certain level of care (ibid., para. 3).

Data warehousing:

Data warehousing provides the ability to retrieve, analyze, load, and manage data.

Distributed database:

In a distributed database, "portions of the database are stored on multiple computers within a network. Users have access to the portion of the database at their location so that they can access the data relevant to their tasks without interfering with the work of others. A centralized distributed database management system (DDBMS) manages the database as if it were all stored on the same computer. The DDBMS synchronizes all the data periodically and, in cases where multiple users must access the same data, ensures that updates and deletes performed on the data at one location will be automatically reflected in the data stored elsewhere."

(From: http://searchoracle.techtarget.com/definition/distributed-database)

Internet2:

Internet2 provides advanced, high-speed, high-capacity networking applications. Internet2 is led by an international consortium of over 60,000 institutions from academia, industry, government, and not-for-profit networking organizations representing more than 50 countries. (Internet2, 2010).

Key fob:

A key fob is a security token. The ePCRN's key fob is a small hardware device with authentication features that controls access to the network's services and information. The key fob is a physical object, so it is easy to know if it has been stolen or missing. It also has a second level of authentication, a personal identification number (PIN), which authenticates the user as the device's owner. After the user correctly enters their PIN, the device displays a number, which allows the user to log on to the network.

Open-source software:

Software in which there is free access to the source code, as opposed to proprietary software requiring users to pay licensing fees.

Web portal:

A Web site that acts as an entry point to other Web sites or Web pages.

Appendix B
List of ePCRN Members

Clinical side:

- Keith P: principal investigator, primary care physician and researcher
- Penny F: Department of Family Medicine, University of Minnesota
- Tom M: Department of Family Medicine, University of Minnesota
- Christy L: Department of Family Medicine, University of Minnesota
- 10 directors of Practice-based Research Networks from across the United States

Technical side:

- Jerry S: senior informatics manager
- Sean B: Networking and Telecommunications Service
- Nate C: senior manager, Office of Information Technology (OIT)
- Matt J: technology, Department of Family Medicine
- Steve S: Bioinformatics, Medical School
- Martin C: networking specialist, OIT
- Andrew P: contracts specialist, OIT
- Jonathan H: manager, OIT

UK [sometimes identified by UK or B'ham, not always able to tell the individual]:

- Brent D
- Doug D
- Terrence A

Syntech (outside vendor):

- Joel C
- Joel R

Administration:

- Jody H: Department of Family Medicine, University of Minnesota

Appendix C
Pilot Ethnographic Project: Background and Findings

The pilot ethnographic study from which my dissertation research evolved was conducted during spring semester 2005, as part of an ethnography methodology graduate course (RHET 8012). This chapter outlines my initial interests and findings from the pilot study, which informs my current research on the ePCRN.

When deciding on a research topic for my course, I was already aware of the ePCRN project, which had just been funded by the NIH. I had spoken to the principal investigator about his objectives and was intrigued by the various types of interplay inherent in such a project: interplay between professionals (IT and physicians; physicians and researchers), between primary care and research (areas that traditionally do not closely work together), between research and practice (the process of translating findings back into practice), and between technology and care (the use of technology to improve patient care). How will these elements all come together to meet the aims of the project? What hurdles might there be? What synergies? Becoming involved in the project at the early stages, when the team was discussing how to "build" the ePCRN's infrastructure, my initial research question focused on how new technology, and particularly new *applications* of new technology, would affect human-based decisions in developing and eventually using the electronic network. What special concerns does technology bring to issues fundamentally associated with clinical research, such as security and effective communication between researcher and study participant? How are these concerns

addressed? Also, in developing the network, how do teams with differing expertise work together and make themselves understood?

My pilot study focused on the technical problems involved in the development of the ePCRN and how the teams interacted. In particular, I identified four types of technical problems (delays, audio and/or visual problems, connectivity, and other) and six themes pertaining to the group relationship (metaphors, complexity, roles, evolution of the ePCRN, the UK's involvement, and code-switching). (See Table 11.)

Table 11. Pilot Study: Technical Problems and Themes

Technical problems	Themes
Delays	Metaphors
Audio and/or visual problems	Complexity
Connectivity	Roles
Other	Evolution of the project
	UK's involvement
	Code-switching

For information on methods used in the pilot study, see Chapter 3.

FINDINGS

Technical Problems

Although initially I did not intend my ethnographic study to focus on the technology itself, it became apparent that I had to have some understanding of the technology being used. Some of that understanding came through attending the meetings,

almost by osmosis. It was also helped by several interviews with the technical team. In addition, some of the technical issues were grasped first-hand from technical failures at the meetings. In fact, these instances of breakdown became fascinating to me. I began to examine not only what happened, technically speaking, but how people reacted, what was done to resolve the issue, and what happened when it couldn't be resolved. As there was usually a problem of some sort during the meetings, this topic became prominent during the open coding of my field notes. It also proved a useful chronological, linear backbone to my ethnographic narrative, which I examine here first.

When examining the various technical hitches that occurred during the weekly meetings, categories of problems began to appear. I identified these as: *connectivity*; *audio and/or visual quality*; *delays*; and, *other*.

From each of these categories, I examined the responses and resolution of the various incidents. It seems to me that the types of technical problems that evolved over the course of my field work, as well as the reactions and resolutions, tell a story about the project's evolution. For instance, the types of problems that occurred were indicative of the project's status. Initially, issues would hinge on the conference calls between the teams at the University of Minnesota and in Birmingham, England as the access grid infrastructure was not yet in place (a multicasting application where the Birmingham team was projected in real-time on site in Minnesota and vice versa). During these calls the teams would discuss how to set up the infrastructure to ensure functionality for the purpose of their network's goals and how to avoid or minimize any potential problems. Once the access grid was in place, it gave me a chance to see the effects of "system

breakdowns" as well as participants' reactions and system resolutions. Examining the categories of problems as they occurred during the project's progression was useful in tracking the evolution of the ePCRN, in terms both of the technology and the resulting human interaction.

As mentioned, initially the meetings were conducted by conference call. The Minnesota-based team met in a conference room on campus and was connected by telephone to members in the UK, as well as other to University members who couldn't make it to the site and members of an external technology company. The first glitch I witnessed (Feb. 8) was the telephone cord not being long enough for the phone to reach the middle of the conference table. This was unlike any other problem subsequently experienced, and so I have categorized it under "*other*."

The following excerpt from my field notes takes place at the first meeting I attended. It occurred prior to Keith [the principal investigator] arriving, and prior to making the phone connection with the UK.

> *The man* [Nate from IT] *next to me asks Jody* [Keith's office administrator] *where the phone is for the conference call. She points to the table in the corner of the room. He gets up, tries to bring it to the center of the table, but the cord is too short. "Maybe we should all move down this way," he says, meaning toward the end of the table where the phone reaches. No, Jody says, the phone's pretty good, people will be able to hear from where they are.*

However, as soon as the meeting begins, the off-site members have difficulty hearing everyone. During introductions to the UK team:

> *When we get to Tom* [one of the clinical team members]*, someone from Birmingham asks us to speak up, that they can't hear. Jody says, only loud enough for us to hear, something to the effect of, we don't need to start again, they don't need to know us. Keith interjects, saying loud enough for*

Birmingham to hear, "We're just introducing ourselves to each other," but says that we'll speak up. The introductions pick up where we left off. Interestingly, the people on the phone don't make introductions.

The lack of visual contact certainly seemed to affect the way in which the two sites coped with the audio problem of the conference call. First of all, Jody was comfortable excluding the UK team when she vocalized, audible only for our site, her opinion that they didn't need to hear our introductions. This was somewhat validated by Keith in that we did not start our introductions over, although he did make the point that we should all talk more loudly. And finally, it seems likely that if this had been a face-to-face meeting the UK team would have introduced themselves as well—particularly as we were making introductions by going around the table. The fact that they weren't "present" seemed to make them "separate" in this regard.

Throughout this meeting, on-site members would have to repeat or reframe their responses when the UK team reported they didn't catch something. The poor audio quality seemed to be stressful, in particular to Keith. When the meeting neared its end, Keith stated he wanted the access grid up and running soon, "so we can have better communication with England." The UK team (who have an access grid node) laughed, saying "absolutely." Keith again acknowledged the need, saying that after an hour of teleconferencing, "you're exhausted," but with the access grid, you can talk for hours. However, even once the access grid was working, there were still communication problems (such as, when the connection dropped off or when the audio levels were too low). These technical issues were also "exhausting" to the members, who would have to backtrack or repeat themselves, much in the manner of the example above. So, the

technology itself did not make communication easier, but its *function* (if it was working properly) did.

Delays

The frustration felt by Keith might have been due in part to his desire to get the access grid working. However, several unforeseen delays had occurred, mainly with finalizing various contracts between the University and outsides vendors. (This topic, the finalizing of contracts, continued to be an issue throughout the meetings and is something I examine later.) Nevertheless, at the meeting on Feb. 22, Keith announces they hope to test the grid node the following week.

As I arrive on March 1, there has been a location change because the conference room has been double-booked. Keith explains they'll have to reschedule the testing of the grid node for next week. This is another delay for the team, even though the equipment is ready. Beyond a brief apology, Keith does not spend any more time on the delay or its cause. A conference call is made to the UK and there is no subsequent glitch in the meeting.

This may be the first time I notice Keith's tendency to stay on track, despite delays. As evidenced here and later, he seems to focus on what he can control and carry on as best he can when faced with something he cannot control. That something is usually of a technical nature, but also pertains to instances where members get off track or in the general time management of the meetings. I believe his ability to handle delays

will be important as the project progresses and collaborative efforts between teams continue to affect the project's timeline.

Audio/Visual Quality

The next week, March 8, the team is able to use a personal grid node, run from a laptop. The system uses a Windows-based application to beam images and audio from the UK's site here, like a projector. At the same time, the UK receives images and audio from our site. It takes about 15 minutes to set up, delaying the meeting. Once running, there is a general chattiness between the two sites with a lot of over-talking, something that hadn't really occurred during the conference calls. People simultaneously held the floor, unlike previously where only one person tended to speak at a time. However, Keith is the first to remark that the quality of the video is low. Sean says he will have to "fine tune" some of the equipment later. At that point, Keith starts the formal meeting.

Again, Keith shows the same response to technical setbacks here (his perception of the video's low quality) as he does regarding the delay in testing the access grid, mentioned above. He verbalizes the problems ("we'll have to test the access grid next week" and "the video quality is low"), takes in feedback (suggestion that they have a formal booking system for the conference room and Sean's response that he will "fine tune" the equipment), and then proceeds. This will prove to be his typical response, and by not focusing on what he can't change, is able to keep the meetings on track.

Connectivity

During the same meeting, about mid-way in, the video connection is lost. The thread of discussion stops and Jerry informs the others on the conference call (who can't see) what is happening with the link. While Sean and Matt work to reconnect the system (they are both sitting in front of the laptop, it's hard to tell what they're doing but they're focusing on the equipment rather than what is being said around them). Keith asks, "What happened there?" Everybody is waiting, people begin to talk among themselves, between two or three people at most, it seems. After a minute or two, they are back on line. The UK team asks what system is being used and Sean says he's "kind of mystified as to what is going on" then offers some ideas about what happened, but Keith steps in saying, "I hate to spend too much time on this. Let's just keep pushing on." Later, when the connection is lost again, there is a similar reaction with Keith saying, "Let's carry on," while Sean and Matt work to re-establish the connection. When reconnected, Keith sums up what was discussed during that period for the UK team. Later, Keith brings up the subject of the access grid node again. From my field notes:

> *Sean says he has to get [a technical company] to figure out what the problem is. UK, someone off camera, says this happens all the time. Keith identifies the person, saying "You're just a voice from the Internet." P [the man at the UK site] moves the camera to show himself, gives a demonstration on how he can move the camera for different configurations. [This is something our site cannot do, since we only have one camera.]*

No further talk of the system breakdown is mentioned. Instead, focus has moved on to the system's capabilities, displayed by the UK team's multi-camera system. Again, Keith commands the flow of action following a technical problem. Here, he steers the

conversation from what went to wrong to encouraging the UK to display their capabilities of the system, in this way turning the situation into a learning experience.

Audio Quality

At the next meeting, March 15, Keith arrives to see that the visuals from Birmingham are up, but that there is a problem with the audio. Although our site can hear the UK team, they say we're cutting out. Keith makes a joke, saying "Houston, we have a problem." When there's no response from Birmingham, Keith asks if they understand the reference, but they say they couldn't hear him. Jerry moves the microphone while Matt makes modifications on the laptop. They spend about five minutes working on the technology at which point Keith says, "Let's get going then," even though the problem hasn't been solved. From my field notes:

> *Keith starts by welcoming Martin back from the UK. "Did we get everything done that we needed to?" he asks. Awkward pause, UK didn't hear, says there's still a bad connection. Keith says "we're certainly having some connectivity problems which is why we wanted to test to the access node." (This comment and his earlier joke make me think he is the type to see the bright side of things, to not get bogged down by what can't be immediately fixed.) UK asks if anything is different from last time, when there wasn't a problem with audio. Jerry says, "we updated our software for better connectivity." Everyone laughs.*

The audio problems remain throughout the meeting. At times, the UK can hear, other times, without warning, they can't. This results in the need to backtrack, with Keith usually summing up what had been discussed when the UK was "offline." At the end of the meeting, once the UK had signed off, Keith says, "that was pretty horrible. Is it the mic[rophone]?" Steve and Matt confirm it was not the microphone. Matt says his

colleague (Sean? I'm not sure) "needs to tweak something on the network." This leads into an informal meeting, discussing some of the upcoming deadlines and issues. At the next meeting, March, 29, the UK team is on holiday so the grid node is not in use. On April 5, the system runs perfectly. However, Keith tells the UK that this system is not the permanent system they'll be using, that they're waiting for final approval for the permanent site set-up. He apologizes to the UK for the quality of visuals. "Right now it's like you're looking down a tunnel," he says. The UK responds, "If we met you before, we'd recognize you, but it wouldn't pass muster on a passport." Everyone laughs.

At subsequent meetings, I notice the continued use of humor when a technical glitch occurs. I wonder if this is because they are more accustomed to each other and to the technology to be more comfortable when something goes wrong. Also, it may be that Keith feels the pressure is off somewhat, in that the grid node actually exists now.

I wonder if it's only taken a few weeks to feel comfortable with the technology, whether moving on to more complicated functions and applications as the project progresses will incite some of the same stress and seriousness toward technical problems. Will there be an ebb and flow concerning reaction to the technology? How will different members, with differing roles in the project, react? Keith has the greatest responsibility for the project's success, but the technology team is equally invested. Might some of Keith's frustrations be due to his inability to "do" anything about the technical aspects, beyond supervising the project?

During the pilot project, I noticed that the clinical members tend to talk among themselves while the technology team works to fix the situation. Keith always pays

attention to what the technology team is doing, but also bridges the situation with others, particularly the UK team by providing an update of what is happening.

Themes

Broadening my examination to include interviews as well as a recorded informal meeting, I selected six categories for further investigation: metaphors; complexity; evolution of the ePCRN; the UK's involvement; roles; and code-switching (see Table 12).

Table 12: Pilot Study Themes

Metaphors	Types of metaphors used for the technology and its application included physical characteristics, cognitive and creative writing metaphors, and behavioral metaphors.
Complexity	Complexity mentioned in general and of certain components, the project's timeframe, members' roles within the project, the project's evolution, and of *not* having an electronic network.
ePCRN evolution	How the ePCRN evolved from previous, single clinical projects, to the vision outlined in the ePCRN proposal, to changes required when the IT team began to build the network.
UK involvement	How the UK team contributed a technological knowledge base with their existing electronic network and how the UK and the US teams developed a collaborative relationship.
Roles	Two teams within the project: information technology and clinical.
Code-switching	An individual's ability to navigate between two separate areas of expertise, evidenced mainly by the principal investigator (across clinical and IT areas).

Like the categories for technical problems, these too seemed almost to present themselves by their recurrence. Unlike technical problems, which lent itself to a linear analysis, these

categories are more "flexible," appearing at various times throughout my research, through various members.

Metaphors

What metaphors are used to describe the technology and application of the ePCRN? Who uses them and for what purposes? These are some of the questions I hoped to address in my examination of metaphors.

Metaphors certainly were used to describe the network and its applications. For instance, Martin, the network specialist, used a fairly common metaphor to describe the components of the network working together: "*these systems talk to each other.*" Later, when talking about potential difficulties working with a partner who is thousands of miles away in the UK, Martin states the problem using words of physical closeness. He says:

> [*a]ll those things would have to be tightly integrated, which means dual administration purposes, and you know, working I guess you know,* ***side by side****, literally,* ***elbow to elbow*** *with that administrator when we've got six hours difference and we work a completely different time schedule and it just, [the technical company] just did not see that working very well.*

It seems odd that Martin chooses metaphors pertaining to physicality, when describing a "virtual" network. In this instance, he sees the physical distance between his group and the UK as a disadvantage. Does this pertain only to the function of disaster recovery, or are his concerns applicable across the board? If there is an issue working with a team halfway across the world, doesn't that go against the very nature of this

project, which promotes boundary-less connections? This would be a topic to pursue in future.

Jerry, the senior informatics manager, used cognitive and creative writing metaphors to describe not just the network, but technology in general. In his interview, he says:

> *Technology is actually the thought process of other people. Essentially it is a language people use in the vocabularies of basic sciences and it's very fascinating and captivating for me to try to figure out how somebody thinks. So when you're dealing with computer operating systems or applications, word processors, and spreadsheets, you're dealing with the way someone else is thinking, and the way they choose to present in the contexts that they use.*

When asked about how he sees the project progressing, he says:

> *It is strongly storylined. I'm not sure that the actual script, the dialogue and the script is written, but clearly the storyline is very strong developed. . . . . So, in a sense, I look at the contract as an overall story. Chapters are written sort of in terms on a quarterly basis. But the paragraphs and sentences are done in the meetings if you will. So, it's very clear we're supposed to write the next paragraph and when you need to write it by.*

(This reference also provides clues as to how the team approaches the ePCRN's overall aim, and will be examined further as evidence of the project's "joint enterprise" as a community of practice [see Chapter 5]).

I note that Martin, who is involved in the technical aspects of the projects, uses metaphors to explain those components. But as Martin also deals with translating the technology, he used metaphor to point out usability concerns. That is, Martin moved beyond the technical application to describe its effect on how the network is run. In this case, he is concerned about the physical distance, not of the system itself, but of the system's users. On the other hand, Jerry, who is a bridge between the clinical and

technical teams, used metaphor more broadly in explaining how he sees technology as a whole (as a language and cognitive ability) and how the project (as a story) fits into that.

From clinical team members, metaphors were used mainly to describe behavior, rather than the technology. This was particularly true in Christy's case. For instance, she says in an interview on March 8:

> *I did this observation about how health care people have this tribal behavior.*

And later about her own behavior:

> *I test what he does. Basically if I can break it or not, that's what I do.*

And in developing the project:

> *We won't all be re-inventing the wheel twenty times over. That's a goal.*

Christy does not use metaphors to describe the network itself. Instead, she uses them to describe the working relationship, the behaviors in relation to the technology. This is interesting because her expertise in the project is: "*knowing how to get things done in the clinic side of things*." Not surprisingly, then, her focus is on the application side of the technology and how it works within the clinical setting.

Keith, however, uses metaphors to describe both the technology and its function and working relationship. In an interview on March 30, regarding the access of data, he says:

> *We can take new tools on Internet2, and it's a bit like a spider on the Web. That spider can go out and go out to a clinic and get into the registry and say, "oh these patients are eligible for an NIH clinical trial" and can flag those patients. And then walks over to the next clinic and does the same there.*

Here he is describing how the system will work in terms of gathering data. (He even makes his metaphor speak!) In another part of the interview, he describes the connectivity of the network:

> *[W]hat we're building is really a highway to connect primary care practice across the country.*

This metaphor illustrates at once the technology itself (as a highway) *and* its function (connecting practices across the country). In the same response, he goes on to describe the function of the registry as: *a snapshot of a patient's care.* Again, this is a very clear illustration of what a technology application, in this case the patient registry, can provide. Similar to Christy, the final metaphor used in his interview focuses on the relationship side of the technology. When asked how the ePCRN project fits with the UK's system, he responds:

> *Well, they have the RCT* [randomized controlled trial] *piece and we have the translation piece, and we were going to marry them. And have both of them at both sites. . . . both systems are stronger when we work together.*

It is interesting to note the evidence of metaphors is only in the interviews, not the weekly meetings. Is this because among themselves, they have an understanding the network and what it can do, so metaphors are not needed? But during the interviews, explaining their goals for the network and how it will run, perhaps the members felt they needed metaphors to help me understand.

Complexity

Complexity is a topic that bridged categories. People mentioned the complexity of the project in general and of certain components, its timeframe, of their own roles within

the project, and of the project's evolution. Only one person mentioned the complexity in relation to *not* having an electronic network: Keith discussed the complexity of competing demands in primary care practice and the need for a system that will help coordinate and simplify procedures for physicians and researchers, resulting in better care.

Certain components of the project were labeled as complex. For instance, a seemingly uncomplicated task—the acquisition of a rack, a piece of equipment that houses the servers—was fraught with delays and problems. On February 21, Nate says:

> *We needed a rack for the project. Well that still hasn't, the rack still has not been ordered. Of course the servers are here, and they need to be set up so about two weeks ago, we figured this is just, is not going to get done through the normal channels, because nothing else is getting done in a normal amount of time that one would expect, so our department just went out and bought a rack . . . . we went out and invested . . . four or five thousand dollars just to get, just to help them. So, when finally the ePCRN rack comes in we'll just make the swap at that point. But that was one of the things we decided would be in the best interest for the project because we knew we weren't going to get the rack in time.*

The rack issue continued to play out for until April. Eventually the completed rack arrived and was switched with the previously purchased rack, as Nate mentioned. In this instance, the IT team faced bureaucracy with initiative and the delay of the rack did not delay setting up the servers (evidence of "enabling engagement," a function of the network as a "community of practice" as described in Chapter 5).

Another bureaucratic complexity for the IT team led Nate to bring another expert on board. On February 21, he describes his decision to include Andrew on the team:

> *But as the project became more and more complex, that's when I felt Andrew needed to play the special role that he plays on this project, as well as maybe others here in this department. It got to be far too complex*

> *and* [the] *number of contracts that needed to be done for me to work on and so Andrew's experience here is great, and I knew that it would take somebody with that kind of experience and knowledge of getting things done, and so that's now Andrew got involved in the project a couple of months ago.*

The bureaucracy of the project was perhaps hardest felt by Andrew, being in charge of shepherding contracts through the NIH and University systems. At the same interview on February 21, describing his perspective on the project's status, Andrew says:

> *I guess in terms of contracts and getting things purchased, I don't think we made as much progress by now as I would have thought we would. This has been a lot more difficult, because, partly because of University of Minnesota purchasing rules are getting tightened. But then throwing the NIH in there, that was a big curve because I had no idea how they operated and how long the turn-around times were for approvals from them, and so we had to try and after we made the first set of quotes and stuff, we had to go back and completely change them and break them out into a way that we could put them to the NIH and get approval on them. And now, I mean still, there's three or four big pieces out there that the NIH hasn't approved, that they've actually been sitting on for well over a week. So and then after that's over, then there's the contract language stuff over here with the Office of the General Counsel. Normally my job would have been done by now, but this is much worse. This is probably the most, most complicated and [unintelligible] thing I've ever been involved in.*

Inventiveness, previously displayed by the IT team in regards to the rack, was not applicable in Andrew's case with the contracts. The constraints of the University's and NIH's regimented procedures were very frustrating to Andrew (and to others in the team, including Keith). Later in the interview, when asked about his upcoming deadlines, Andrew says:

> *Well, I mean, the only* [thing] *I can do is keep bringing people together [laughter] and keep reminding them that they need to look at documents and approve them. So, yeah, I mean it's a frustrating position to be in because I'm just in the middle . . . there's nothing* [Martin interrupts at this point and says]: *We keep going to Andrew for status and he goes,*

> *"Nothing's changed. They don't do anything, they don't send me anything." We're like, yeah, right.* [After some back and forth, Andrew says]: *Once that contract stuff is done, I'm done.*

More generally, Jonathan had concurred earlier regarding the organizational complexity of the project:

> *[K]eeping a lot of things organized and communicating with all the right people has taken some more effort than I thought it might.*

Complexity in terms of timeframe was also mentioned. Martin, in the interview on Feb. 21 says:

> *There's a lot that I'm concerned about [laughs]. . . . So we're talking about ten clinics, now I don't* [know] *whether that's actually doable, that's the goal at this point. You know, again, kind of our frustration with just how long these individual steps take, it's not necessary, you know, really feasible to see that happening, but it's not necessarily unreachable either. . . . There's a lot of infrastructure that needs to take place, there's lots of information that needs to be gathered and then actually utilized to build these systems and make it happen. But like I said, everybody's hopeful.*

Again, the lack of control over the pace of certain elements of the projects is frustrating. Martin is not sure whether particular deadlines can be met. Despite potential delay, however, he makes a point to say "everybody's hopeful," speaking for the group as a whole. These concerns, however, are borne out, as evidenced in the weekly meetings. At the first meeting I attend (Feb. 8), Keith expressed his concern. From my fieldnotes:

> *Keith then comes in, reminding everyone of the milestones coming up. "We're already a couple weeks behind and I don't want to justify delays to the NIH, especially this early." General agreement.*

The issue of delays comes up again on March 29:

> *Keith says, "we're running behind." He will have to justify this in the quarterly report to NIH, due April 10. Jerry suggests mentioning the U's new legal restrictions on purchasing holding them up. "Let's just get these things done," says Keith.*

Delays and lagging contracts continue to be an issue until late April, when most of the contracts have been signed and the technical company is scheduled to install the software.

From a clinical perspective, in her interview on March 8, Christy mentions how the complexity of a previous project she worked on ties into this project:

> *My personal interest just in seeing how difficult it is to get an ACCORD trial, where people get all these benies* [benefits] *and finding people who fit the criteria and there's going to be many, many hundreds of studies out there that have the same issues.*

Here, Christy seems to be looking forward to the complexities of the project by focusing on what the network will allow health care workers to do. Her positive attitude may be a result of her experience in similar projects. She has seen the rewards such a project can bring, although on a much smaller scale.

Similar to Christy, Keith mentions complexity in terms of the network's potential. Regarding the network's translation capabilities, he says:

> *You see, the clinical trials are, is a pretty easy technology. They* [the UK] *have a nice technology. The translation is a different thing completely because instead of pulling information from the primary care practice, you know, the researcher potentially wants to go out and not affect practice, but just measure it and pull the information away. And the translation person wants to do the opposite, he wants to go out and affect everybody's, and he wants to affect everybody in the clinic and take information he has and disseminate it to everybody in the clinic. And so that because the idea is that it's information flow in different directions. And so it makes the electronics completely different.*

And as mentioned earlier, Keith expresses complexity from a care perspective, by describing the challenges of primary care *without* the network's support:

> *The average visit's 12 minutes long. They're coming in and the doc's dealing now with an acute medical problem and they have, what, all of 12*

> *minutes and they have to add on diabetes at the end, it's not surprising that opportunities are missed to do something. That there just doesn't seem to be the time to cover all those bases. It's a challenge in primary care because, primary care particularly, there's, because of the complexity of competing demands in practice. Things that are the most important or the most symptomatic tend to be dealt with first. And that's the way people want it. And that's one of the reasons that chronic care, diabetes as an example of chronic care, doesn't get the attention it would be nice to have. We can't just go out and demand that everybody do this for all their diabetes patients, because what happens among these competing demands is that something else is forced out. So now, your diabetes patient comes in with an acute visit, you take care of the diabetes, but you miss the acute problem? You can't do that.*

Again, as in the use of metaphors, we see the IT team focus on certain components of the project (e.g., the rack, the contracts, the timeframe), whereas the clinical members address the complexity of the network in terms of its use and potential, and in the case of Keith, of its absence.

Evolution of ePCRN

As I began coding fieldnotes and interviews, I was interested to see how the ePCRN changed as the project progressed. Keith had an initial vision for the project that evolved from his work on previous projects. However, that vision faced challenges when the IT team came on board and the network began to be "built." Here I examine how these changes were identified and communicated.

As mentioned, the initial vision for the ePCRN came from Keith. He talks about what led to that vision in his interview on March 30:

> *[I]t really developed because there was a need on behalf of the Federal of Practice Based Research Networks. We have, we had over 6,500 physicians across the country and they were all working together on a variety of things, usually regionally organized, some of them nationally*

> *organized. But I found that we began to develop an electronic infrastructure that helped us a great deal. But every time that happened, every network across the country had to reinvent this infrastructure. So there was, you know, we had 55 networks, all the networks were putting together a basic connection, a basic infrastructure that did data collection. And there really wasn't any reason because on the Web, it doesn't matter if you're in California or Minnesota. You can all connect to the same site. So it was really starting from that idea, that we really wanted to respond to the need of these doctors to be able to do research and do data collection from their practice. How could we connect them better to do research? Of course the other piece was that we really wanted to look at improving practice.*

So, from a clinical point of view, the ePCRN evolved from previous projects in which Keith and his team was involved. Christy discusses this more specifically, describing the ePCRN's beginnings out of the East Metro Disease Initiative (EMDI):

> *For my first project in this realm was the development of the East Metro Disease Initiative, the registry and you hear components of that mentioned periodically, and the ePCRN piece of it, we started with a pilot of nine clinics and continued to grow. That then developed into an IMPACT study where we were looking at measuring the, does it make a difference basically, and then I found work with a variety of other practice based research network around the country . . . . within the IMPACT study then I have worked with the registry element in the clinics, collaboration with the rest of the team.*

And later:

> *There was a group of us who had this, well first of all, the belief that if you're going to make a difference in the chronic disease care it wasn't going to happen at the hospital setting . . . . You needed to be in the community or at the clinic level to prevent people from, as we called them, our "frequent flyers" in the hospital.*

From these beginnings, Keith formed the idea of the ePCRN and led the NIH submission for funding. One of the first project revisions resulted once the IT team was brought on board and visited the UK facilities with Keith. As described by Martin in Feb. 21's interview:

> *I think initially, I guess as the project, I guess, matured and kind of transpired from the initial meetings, we went through quite a bit of change with respect to just even the beginning, in the initial grant that was written, was written with the knowledge of the ePCRN project that they had running over in England . . . even some of the things, some of the knowledge that we bring to the table is not even really being utilized over there so we saw deficiencies in the initial grant the way it was written . . . . so we basically had to rewrite the grant and put in all the different components that we and/or Syntech wanted involved.*

Although the project was initially based on the UK's model, several members mentioned how the ePCRN may soon exceed their system. For instance, Keith says:

> *So, they* [the UK] *do wonderful things and they have done. But there's a sense that as we move forward we have the ability to step in some ways, to step beyond them, in what the resources have the potential of doing. And so that's why you hear comments like, well, we're learning from them, but in learning from them, we're probably going to leap frog in a sense and have a system that will have more capabilities than their system has.*

Other changes in the system from a technical point of view include deciding which database system to use, how many key fobs[57] the project will need and how to distribute them, and details of licensing agreements, to name a few. Decisions occurred through group discussion, led by Keith who would ask questions of his team. He tended to summarize what they said and then made a decision on the spot based on the information given. He would also ask for agreement. An interaction during the weekly meeting on March 1 provides a good example of this. Here they are deciding how many licenses to buy. From my fieldnotes:

> *Keith says "hard to know what RCTs* [randomized clinical trials] *will look like. Could they decide and order what might be needed to get them through the first three years?" Martin* [who is on conference call from the UK] *says Microsoft requires the number of licenses to match the number of potential users. He suggests if we have 20 users now, we can buy 20*

[57] A key fob is a small hardware device with built-in authentication features to ensure security of a system.

licenses now and build as we get users. Keith says "I like that idea." (Some back and forth, debating how many to buy, whether it'd be better to wait.) Keith says, "So, what are you saying, Martin?" (I don't catch what he's saying, people around me are talking.) Keith says, "So you're telling us you want us to buy 20 licenses now?" Martin says yes, but then asks, "What's your timeline?" Keith says starting demonstrations in May at [name of clinic practice]*, in summer at all 10 sites in MN, and after that all sites in U.S. He says, "We could buy 10 licenses." Someone from the UK says "I'd definitely go with that." Suggests they build a demonstration test for Martin is there. Keith acknowledges this, but then returns to Steve saying before they move on, "Steve, you were objecting." Steve says if buy Microsoft licenses, "you'll be committed to Office." Keith then says, "Martin and Steve, you're not agreeing and I need you to decide." (Back and forth between Martin and Steve.) Keith asks the UK if they using Office right now. UK confirms have Office but don't always use it. "Researchers use it, but clinics don't." Martin says "we have to decide how functional we want it to be for the users."* [Keith] *raises questions about how much time they're taking on something that, in comparison, is of little money. Keith suggests buy a set of Office licenses. Use it until the summer. If not being used, will throw them away and buy Access, basically spending between $500 and $1,000 for a "pilot." Believes US will use system more than UK does. The decision has been made.*

Here, Keith kicks off by throwing out a question to the group (could they order enough licenses to get by for the first three years?). Responses are elicited from the team members, with Keith breaking in to offer a summary of what's been discussed ("So, you're telling us you want us to buy 20 licenses now?"). Keith is also seeking general agreement. In the case above, he notices that Steve does not agree with Martin. He draws this out of Steve and asks Steve and Martin to come to a decision. When they don't, Keith states his concern over the amount of time being taken over by something that is relatively insignificant. At this point, he proposes a compromise (buying Microsoft as a "pilot"), states his reasons (he believes they will use this system more than the UK does), and having made a decision, moves on. This was a traditional pattern in dealing with decisions in the weekly meetings.

Moving beyond the short-term, technical goals of the project, in his interview on March 2, Jerry talks about the ePCRN's evolution in terms of future use:

> *When this bears its fruit, there will be an infrastructure which can be used, I believe, in ways that I can't even conceive of yet.*

He is not the only one to view the ePCRN with a wide-angle lens, beyond the immediate decisions, such as which database system to purchase, as illustrated above. Keith also discusses the long-term implications of the project, of how he sees the ePCRN evolving:

> *I think it could be* [the] *foundation of a revolution in primary care. I think that if we have even two or three, if have a few thousand clinics in primary care that are doing research and pushing the envelop of modern care and technology, in the delivery of up-to-date, consistent and safe care, then I think that will help the entire, I think it would help all of primary care medicine.*

Certainly the project is constantly evolving. The weekly decisions around those changes are managed by Keith, although he relies heavily on the expertise of the various team members. Some members have more responsibility than others (as we'll see later in the category of roles). Some members are able to discuss translation of technology better than others. For instance, some of the IT members are called on to address specific technical questions; others, such as Martin, are adept at grasping implications of technical decisions in light of their intended use (as seen in the example of licensing from March 1). Keith, not surprisingly, seems to view the project in the broadest terms, evidenced by the answer he provides regarding how he sees the project evolving (above), a vision that he communicates to his team.

UK's Involvement

This category could be considered a subset of the previous category, as the UK's involvement is inextricably linked to the ePCRN's evolution. The UK was brought in because they already had an electronic network in place, similar to what Keith imagined the ePCRN would be. Therefore, the UK provided a knowledge base for Keith's team to build the ePCRN. However, in addition to examining which elements of the UK's network are utilized in the ePCRN, I wanted to explore the relationship between the two groups as the ePCRN was being built. For instance, how is information communicated between teams? Do the dynamics of the groups change as the project progresses?

Here, Keith describes an early encounter with the team and their system:

> KP: *The people that are our co-investigators in England, you know, they're wonderfully bright. It's great to work with them. But the National Health Service is limited by a real limitation of resources. And sometimes when we go over, that's a bit of a slap in the face . . . .*
>
> BH: *To them?*
>
> KP: *To us! I mean it's a, it's startling how much they can do with so little . . . . . When we . . . walked into their information system, and we, you know, they have a great connection, they have . . . an electronic connection to virtually all the clinics in the UK already. So we thought we were going to walk into a very sophisticated system and we were surprised because it is a bit cobbled together.*

It is clear from this excerpt that although the UK had a system in place to connect clinics with researchers, it was somewhat lacking from the Minnesota-based team's perspective. The encounter mentioned here is early on in the development of the ePCRN and shows Keith's surprise at how the UK's system is set up. From this same initial experience of the UK's system, Jonathan [IT manager] describes what he found from an IT perspective:

> *Initially Keith had laid out that we were going to use the UK as part of a DR* [disaster recovery]. *We visited with them and they do not have their servers in a server room. It's quite literally a closet that they have in their office building. It's behind a locked door, so that was good, but it was, when they first set it up, we learned they didn't have air conditioning into the room, it was running off the building air conditioning, which means at the end of every day, air conditioning would turn off in the building and the servers would tend to overheat . . . .* [They had] *no back up power . . . and we visited the data center and to be frank the data center was not quite at the level we hoped it would be…. They had carpeting on the floor, there was carpet fiber in the air, which was evident when you looked at air filters on some of the equipment. I found one piece of equipment that had an air filter that was pretty well covered, covered with fibers. And it was very humid and fairly warm, warm enough so that when we went in there, I had to take off my coat and eventually my sweater.*

As a result, the IT team determined that the UK could not serve as the ePCRN's data recovery system. When asked how this was communicated to the UK team, Nate says:

> *Yeah, there was a conference call about that. They* [Keith and Steve] *came at it from a security point of view, as having patient data actually in a foreign country and that pretty much killed it right there. I don't think anyone really thought of that beforehand, because when you're a disaster recovery site, it implies you either have your data there, or can very easily port it over there and having patient information, even if it doesn't have your social security number or any identifier, getting that, having that in a foreign country wouldn't pass muster in too many places around here. I think that helped kill it as much as anything, as a security site.*

So, as lead investigator, Keith communicated the findings; however, he was able to do so in terms of security, not in relation to any drawbacks of their system per se. That is, Keith did not have to articulate the inadequacies of the UK's system to them. I wonder if this could have been a potential conflict or sensitivity (had the security regulations not been an issue) and how it would have been handled.

In March, Martin went over to Birmingham to obtain experience with the UK's network system, including building the infrastructure and testing applications. On his

return, there was a long, informal discussion of potential changes to the network, which I recorded and transcribed (using discourse analysis). Martin raised various concerns about the relevance of the UK's system for the ePCRN:

> Martin: *There .. there's nothing transferable and that's that's one thing I learned last week, last two weeks. There's nothing. I mean, these Access front ends are literally .. three or four radio buttons and I just told this over here, that the best study that they're doing is .. is literally they booted up in 15 minutes last week, it's two fields, date of birth and severity of back pain. That's it.==*
> Keith: *==I'm sorry, =I got to get this … I=*
> Jerry: *=that's their entire study .. =*
> Keith: *They have two fields in a study. How do you do that?*
> Martin: *I've no idea. I mean, I looked at the form. That's what, that's the two, I mean I'm assuming there was some sort of requirement that was sent out to the identification of these patients.*
> Keith: *yeah*
> Martin: *But .. so it was date of birth and it was severity of back pain, that's it. And it was in a simple little drop down in Access .. =and=*
> Steve: *=That= seems to be the nature of their applications. They're basically one off and…*

And later in the conversation:

> Martin: *but again, if ah .. and it would be easy if we used Access and they used Access, because then we, we avoid any licensing issues but with java or html or or visual basic .. they could they publish those, they use that right now just as a like in a developmental mode right now. So, and I guess I'm not aware of .. anybody understand visual basic and and programming licensing =with=*
> Andrew: *=no=*
> Jonthan: *=no=*
> Martin: *respect to front =ends=? I mean*
> Jerry: *=no=*
> Jonathan: *other than buying a developer's kit which anybody knows is ( )*
> Steve: *so, tell me if I'm understanding this wrong. Basically what we have bought so far .. is secure access to PC functionality at remote sites.==*
> Jonathan: *==That's exactly what this system what this system is.*
> Martin: *yes =and and and=*
> Jonathan: *=I was thinking=*

> Martin: *And it gives them a a < > a defined desktop that we control centrally, so these clinics will log in and get, >instead of us sending< out a a 60 page research paper, we give them a front end to enter that data in and collect the data. So, and and in that sense, I mean .. K .. their previous attempts at this have been to put that research, or that, that ah, that document on a laptop and send clinics laptops. < >That's what they did before.==*
> Keith: *==Alright, well that wouldn't work.*

Martin is providing, for the first time since his return from the UK, certain drawbacks of the UK's system, which he witnessed during his time spent there, getting to know the system. At this point, Martin knows enough about what the Minnesota team is hoping to accomplish with the applications, that he has been able to identify the shortcomings of the UK's systems. However, while these exchanges provide examples of how the UK's involvement is communicated among the team here, it does not provide insight into how communication is handled with the UK directly.

Roles

Roles within the team basically fall in two areas of expertise: IT and clinical. Jerry, as senior informatics manager, at times straddles IT and clinical; however, for the most part, his expertise is in the area of IT. Keith, as we have seen, has the broadest view of the project, as one would expect of the lead investigator. Some of the members' roles relate closely with the evolution of the project. For instance, Nate saw IT's involvement expand once it was identified that aspects of the UK's system would not be applicable to the ePCRN. In addition, Nate felt he had to bring Andrew aboard because the process of sorting out the contracts became quite complicated (see example under theme of complexity). Also, some members had more responsibility than others. For instance,

Martin's expertise in networking was regularly called on during the weekly meetings, whereas Sean's contributions were more sporadic and mainly pertained to the installation and maintenance of the access grid node.

The following is a snapshot of the team members' perceived roles for themselves, which also provides insight into the project's diverse membership, an aspect also covered in Chapter 5.

Martin's role:

> *Basically my role or my job I guess is systems administrator that means, I guess, it means a lot of different things, I guess, but in my world it means we administer windows servers and network servers, I guess, and every part of those, so installing them, integrating them with end users and building print and file sharing solutions for those people.*

Although Martin's description may seem fairly specific (administering the servers), his scope is actually quite broad with the inclusion of "integrating them with end users," meaning ensuring usability with the physicians and researchers. At the time, I imagined his involvement in the project would extend beyond completion of the infrastructure, to include modifications as necessary.

Jonathan's role:

> *I'm the manager of the systems administration group in central computing operations and the way that plays a role here, is I'm Martin's supervisor and so I help Martin with prioritizing tasks related to ePCRN and also because I'm closer to the technical level, I kind of see myself as being a little bit of a bridge between the stuff going on technically and the stuff going on at the higher management level. . . . kind of foot in both camps.*

Jonathan had strong involvement in the beginning of the project. He went with Nate and Keith to the UK to examine their system and was one who recommended that the ePCRN be a separate system. Once he assigned Martin to the job as systems administrator,

however, he had less involvement in the day to day role of the project. He did not always attend the weekly meetings, unless Martin was absent.

Nate's role:

> *I think my role has evolved from the first meeting. Initially we thought we'd have actually a really small role in the project. Basically we assumed that the hardware going to be purchased because Dr. Patterson did a real good job at itemizing what the infrastructure needs to be, but after our first meeting or two with Syntech . . . the hardware software vendor, and more importantly Jonathan and I went to England and . . . our roles changed substantially after that . . . .*[he explains how the UK system was not appropriate in certain aspects] *we recommended to Dr. Patterson that we should build our own infrastructure and be completely separate from the UK group. So, given that, our role really changed and we got way more involved with the project and spent a lot more time on it. But I think the end result will be much more better for the ePCRN project as a whole. So, you know, I guess my role is I don't know, help coordinate, help break down road blocks, that kind of stuff.*

Again, we see roles evolving as the project progresses. After the initial weekly meetings, Nate has taken a role behind the scenes. He may have contact with the project through Martin, back at the IT headquarters, but he does not participate in the meetings any longer.

Andrew's role:

> *I deal with contracts and vendors and things like that and special projects. And whatever nobody else wants to do I guess. [laughs a little] And my role in this, in the ePCRN thing has mostly been in hardware and software acquisition, um, working on the contracts, kind of in the middle. Really the middle point among the NIH, the Office of the General Counsel from the U, purchasing from the U, and of course Dr. Patterson in family medicine. Trying to get everybody on the same page in terms of what we're going to purchase, how we're going to purchase it, who has to sign off on what and um, yeah, that's about it.*

Andrew was looking forward to completing his tasks on the project. Once the contracts were signed, he would no longer be involved in the ePCRN. As mentioned earlier, he

called the ePCRN the most complicated job he's ever had and found the bureaucracy frustrating. Toward the end of my ethnographic study, it appeared that his involvement in the project was winding down.

Jerry, on the team's collaboration:

> *There are several groups and they have many priorities with strenuous demands on their time. What impresses me about this particular collection of individuals is that there is a, that there is a common mind set that this is a very important project. And from my perspective, it looks like this is virtually the only thing on their plate. Quite impressive. So, it fosters a very cooperative spirit. It's very refreshing to see.*

Interestingly, Jerry describes the project in terms of the whole group. This may be due to his position on the project—straddling the IT and clinical teams. When asked further about the make-up of the project and others' roles, he had this to say:

> *To make this work, you have to have the inceptor, and that is Keith. And you need to have a strong university infrastructure and that is the OIT* [Office of Information Technology] *folks. The OIT has a group that is dedicated to the high speed data, computer data communications network and that is like the NTS* [Networking and Telecommunications Service] *people and you have an organization that understands high reliability, high security, facilities and access and that's the OIT CCO* [IT's Central Computing Operations] *group. . . . And there are other groups too that will play a role in the success of the access grid node.*

Again, what we see from Jerry is a relationship view of the team, starting with Keith and progressing, I would say, through the teams in order of function and responsibility on the project. However, he leaves out the collaborators off site (the UK, the technology company, UCSF). Is this a case of out-of-sight, out-of-mind, I wonder?

On the clinical team, Christy describes her role in terms of why she was selected to be involved in the project:

> *I think more of knowing how to get things done in the clinic side of things, that's why I was asked to be 20% time on ePCRN, to kind of how know things really get done. [laughs] And getting the lab and the billing systems and all to hook into the system. And what really works in the clinic side of things.*

Christy too, is a bridge between the technology and clinical aspects of the project. However, whereas Jerry's split duties fall more on the technology side, Christy is more responsible for the clinical perspective.

Keith did not discuss his own role in the project. He talked about the influence of others, for instance in getting the project started (the Federation of Practice Based Research Networks, the UK team) and the role of the ePCRN itself (for instance: *it brings information out to the clinical practice*). However, going back over my notes, I notice I did not directly ask him about his role in the project.

A telling insight into Keith's role, however, was provided by Martin. Toward the end of the interview on February 21, Martin offered his perception of Keith's role: *"[he] was a one-man show. He did, I mean, he did everything."* This provides an excellent transition into my next theme.

Code-switching

In conversation analysis and linguistics, code-switching refers to the use of two languages or language variations within a conversation or text, mainly by bilingual or multilingual speakers (Sankoff & Poplack, 1981). Here, I use this term to refer to an individual's ability to navigate between two separate areas of expertise.

As lead investigator, Keith is responsible for melding together the clinical and technical aspects of the project. As a result, he must be conversant, at least on some level, with both clinical and technical components. I have identified instances where Keith engages in code-switching; that is, where he moves from his traditional area of expertise—research and family practice, to another area of expertise—technology. Overall, based on responses from the IT team, Keith's ability to code-switch is appreciated and fairly successful. However, I also point out some instances where Keith's code-switching is not appropriate.

At first, prior to submitting his proposal to the NIH, Keith did not consider himself "an electronics person." However, "as needs must," and here, he describes the process of becoming familiar with technology in order to write the proposal:

> *So, I just jumped on board and I spent a lot of time, I mean basically all my time, day and pretty much all night, for about five weeks, pretty solid. And at the time, I had very little of* [unintelligible]*, I didn't know what Internet2 was, so I had a great deal to learn. And luckily I was working with some wonderful people in England . . . . and I was able to talk to* [the director of IT] *and he was very supportive of the idea. So he introduced me to the Internet2 connection that we have here and some of the architecture that we have at the University, and the more I learned, the more things seemed that this was just a wonderful opportunity for the University. And so I sat down and wrote it.*

I notice in his description that he is talking about technology, but also includes aspects about relationships. For instance, he mentions the "wonderful people in England" and the director of IT's support for the project. Indeed, he also states that the project seemed to be a "wonderful opportunity for the University." Clearly, this is a person who values relationships, as well as the importance of technology—these characteristics illustrate what I see as a predisposition for code-switching capabilities. (I wonder, too, if

family medicine as a practice—with such a broad and varied remit, in contrast to a specialist—might point to a propensity toward code-switching.)

How does Keith see his ability to code-switch? Toward the end of his interview, when specifically asked about the interplay of technology and family medicine, Keith discusses his involvement not as separate areas, but as mutually beneficial:

> *Well, I love family medicine and I love practicing family medicine. It's a great field. And I guess I really feel that this, that what I'm doing is really an element of what family medicine needs to do. Since, if what I need to do as a researcher is understand more about technology so that I can provide that in improving the system of primary care, then learning the technology is not a problem for me. I mean, I'll kind of pursue the avenues that I think need to be pursued. And for now, one of the big demands in primary care is somebody's got to learn this technology and get it implemented.*

In this excerpt, Keith covers the main areas of interplay in this project. Although he is a practicing family medicine physician, he is also a researcher, and technology is now a part of both areas—and, it's all for the improvement of primary care, that is, for improved patient care. In several sentences, he touches on the different elements of the project, and rolls them into one concern. Perhaps it's not surprising that he is able to code-switch, with such a broad view of the project and the belief that all elements are important to the goals.

In addition, I wanted to examine what others, particularly those in IT, thought of Keith's technical knowledge. I thought this would give a perspective both on the relationship and professional aspects of the collaboration. First of all, Jonathan is surprised at Keith's technical knowledge. He says:

> *I expected as a doctor that he would sort of be speaking in vague, general terms. But the first time Nate and I sat down with him, he had a list of all the servers that he needed, and he had gone out on the Web and got some*

> *prices together. Of course he had to do this all for the grant, but it was like, I totally did not expect that from someone who was a researchers. I did not expect that.*

The other IT members in the interview generally concurred, adding comments about what a "nice" person he was, who was "smart" but also very "easy" to work with.

However, Keith did not always engage in successful code-switching, as evidenced in his initial designation that the UK serve as the disaster recovery site, subsequently identified by the IT team as impractical. Although Keith certainly understands the technology component of the project, there are instances when his ability to code switch is not appropriate. One instance where Keith recognizes this is relayed by Martin:

> *He goes out and meets with all these researchers and discusses this and he's got presentation after presentation. And he said last week that he's completely dropped almost all the computer slides because as soon as he starts talking about anything computer-related, infrastructure-related, data entry points, databases, the whole crowd, he just watches and they all just start looking at their watch, they're on their PDAs; they're , they just and then they and he, and I don't even know the words, but he starts talking about clinics and patients and this and they all perk back up and they get their notepads out and he said that he just completely dropped all the computer slides because they just don't get it. So, it's interesting.*

While his ability to code-switch may be understood and even appreciated within his own team, in this instance Keith recognizes the importance of "audience" and the implications of engaging in this behavior. Other physicians, he found, are not interested in the technology *per se*, as they are not involved with building the infrastructure and do not need to know about the technical details. Rather, they want to know what the technology can do for them as practicing clinicians and researchers. Once he recognized this, he altered his presentation material to that group, sticking to his primary area of expertise. Code-switching is not relevant in all circumstances.

Pilot Study Conclusion

As examined in Chapter 3, the eventual focus of my dissertation grew out of these initial findings—first on a close examination of the group's dynamics using a communities of practice framework, and then a broader critical examination using instrumentalization theory. At the end of my pilot study, I strongly believed that important information resided in further examination of the team's developing relationships as well as how the network fit into a larger social and technical context. Clinical research and primary care are complicated fields, with various elements working simultaneously, whereby an equally complex electronic network is deemed necessary to tie it all together. But the technology does not do this by itself. There are people holding the strings, or pressing the buttons, as it were—people who need to interact across the boundaries of profession, individual goals, and expertise to execute a shared goal of improved research and clinical care. But how does this happen? *Does* this happen? These are the questions I aimed to answer in my dissertation research.