HOW CAN APPRECIATIVE INQUIRY BE USED TO IMPROVE CANCER CLINICAL TRIALS EFFICIENCY? THE UNC LINEBERGER CASE STUDY

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Abstract

WENDY ELIZABETH SARRATT: How Can Appreciative Inquiry be Used to Improve Cancer Clinical Trials Efficiency? The UNC Lineberger Case Study
(Under the direction of Suzanne Hobbs, DrPH)

Cancer is a leading cause of death world-wide and the number of new cases diagnosed annually is expected to double by 2050. Better treatments are urgently needed. Clinical trials, the gold standard for testing therapies for safety and efficacy, are conducted in settings including academic medical centers. Long-standing difficulties with the clinical trials system are exemplified by the slow pace of clinical trial activation and low rate of trial completion.

Descriptive case study research was conducted at the UNC Lineberger Comprehensive Cancer Center to explore how Appreciative Inquiry (AI), a generative form of organization development, can be used to improve clinical trials efficiency. The literature on clinical trials efficiency, organization development, appreciative inquiry, and case study research was reviewed. The case study protocol included six questions for two units of analysis, research coordinators and disease team leaders. A process improvement initiative using AI had been completed and documentation was available for analysis. AI was conducted with the disease team leaders and interview notes were analyzed. Participant observation was employed with both groups.

Themes and provocative propositions were identified or created. Changes attributable to the use of appreciative inquiry and potential contributions to improved efficiency were documented along with limitations, barriers, or obstacles to the use of the technique with each group. Together the case study protocol questions described the extent and effect of applying AI with the two groups.

A plan for change included six recommendations to advance and sustain change towards improving the clinical trials system. These included presenting the case study report to the Protocol Office Executive Committee; initiating a system-wide application of AI with the CPO; monitoring efficiency metrics and assessing impact of AI; assessing other potential AI applications at UNC Lineberger; publishing and presenting findings. Leadership theory and practice will continue to guide efforts to create a more efficient cancer clinical trials program.

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"Call it a clan, call it a network, call it a tribe, call it a family. Whatever you call it, whoever you are, you need one."

-- Jane Howard (1935-1996)

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Preface

"Research that produces nothing but books will not suffice."

-- Kurt Lewin (1890-1947), the father of organization development

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List of Abbreviations

AACI: American Association of Cancer Institutes

AACR: American Association of Cancer Research

AI: Appreciative Inquiry

ASCO: American Society of Clinical Oncology

Cooperative Group: The National Cancer Institute's Clinical Trials Cooperative Group Program

CPO: Clinical Protocol Office

CTEP: Cancer Therapy Evaluation Program

CTWG: Clinical Trials Working Group

FDA: Food and Drug Administration

IIT: Investigator-Initiated Trial

NCAB: National Cancer Advisory Board

IOM: Institute of Medicine

NCI: National Cancer Institute

NIH: National Institutes of Health

OD: Organization Development

OEWG: Operations Efficiency Working Group

POEC: Protocol Office Executive Committee

PPC: Program Planning Committee

RaPID: Re-engineering of Protocol Implementation and Development

SPORE: Specialized Program of Research Excellence.

UNC: University of North Carolina

UNC Lineberger: UNC Lineberger Comprehensive Cancer Center

US: United States

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Chapter 1: Background

Cancer is a leading cause of death world-wide and in the United States (US). It is estimated that 1.5 million new cases will be diagnosed and nearly 600,000 people will die from cancer in 2010.[2] About one-third of all women and half of all men in the US will develop cancer in their lifetimes and the number of new cancer cases diagnosed per year is expected to double to nearly 3 million by 2050.[3, 4] Better treatments are urgently needed to decrease mortality from cancer.

Cancer is a group of more than 100 diseases where the cells become abnormal and divide without order or control.[5] Scientific advancements over the last decade hold great promise for marked improvements in cancer therapy.[6] Clinical trials are the mechanism through which these biomedical advances can be translated into treatments for patients and they are considered the gold standard for testing the safety and efficacy of novel therapeutics.[6]

Cancer clinical trials are conducted in many settings including academic medical centers. Cancer centers recognized by the National Cancer Institute (NCI) are the centerpiece of the nation's effort to reduce cancer incidence, morbidity, and mortality. NCI-designated cancer centers initiate their own trials and partner with pharmaceutical companies to test new drugs. Many of these cancer centers are based at academic medical institutions and play an important role in the national clinical trials system by comparing the effectiveness of treatments already in use,

finding the optimal duration and dose of approved drugs, combining therapies developed by different pharmaceutical companies, and developing treatments for rare cancers.[6] Academic institutions pursue research questions critical to the health of the public that may be lower priority to the pharmaceutical industry.

The UNC Lineberger Comprehensive Cancer Center (UNC Lineberger) is one of 40 NCI-designated comprehensive cancer centers. The mission of the UNC Lineberger is to reduce cancer occurrence and death in North Carolina and across the nation through research, treatment, training and outreach. Established in 1975 on a strong foundation in the basic sciences, the UNC Lineberger began focusing on clinical research in the 1990s. This growth included a significant increase in the number of faculty conducting clinical trials at UNC, accelerating between 2005 and 2010 with the addition of 17 new clinical research faculty to the existing group of 63.

Clinical trials conducted at the UNC Lineberger are managed through its Oncology Clinical Protocol Office (CPO). The CPO is comprised of 58 nursing, regulatory, and data management staff. In recent years, clinical guidance has been provided to the CPO primarily via a medical director and six disease team leaders. A Protocol Office Executive Committee comprised by the Cancer Center Director, Associate Director for Clinical Research, Associate Director for Outreach, the CPO Medical Director, and the disease team leaders advises the CPO's management staff and adjudicates prioritization of resources and trials. In 2010, more than 1000 patients were enrolled to treatment trials through the CPO. In 2010 the CPO managed 148 active trials and had 136 trials in follow up. About 50% of patients accrued to trials in 2010 were enrolled on investigator-initiated trials that were

designed and led by UNC faculty, a strategic priority for the center. Ten additional clinical research faculty are expected to be recruited by 2015 and this continuing growth brings increasing leadership and management challenges.

A primary goal of conducting clinical trials is to make safe, effective new therapies available to patients as quickly as possible. Key to this is minimizing the time that elapses between the creation of an idea by an investigator and the enrollment of the first patient on the trial, known as time to activation. Recent national analyses have shown that time to activation is often more than two years long, during which time the concept may lose relevancy given the rapid pace at which new basic or preclinical scientific findings are made.[7]

Another key to efficient clinical trials is enrolling a sufficient number of patients to draw statistically meaningful conclusions. The number of patients targeted for enrollment is specified in the protocol by statisticians and reaching this number is referred to as meeting the accrual goal. Trials that accrue few patients or take a long time to complete are considered non-performing and trials that close without meeting accrual goals are considered to have failed. Opening trials that fail to meet accrual goals are costly, both financially and because they use scarce patient resources, with no scientific gain.[8]

In 2010, the Institute of Medicine (IOM) reported that the clinical trials system was “approaching a state of crisis.”[6] The system was described as “bloated, cumbersome, inefficient, slow-paced, over managed, and expensive.”[9] At the UNC Lineberger and across the nation, there are serious obstacles to efficiently developing new cancer treatments. Difficulties with the national clinical trials system

in the United States are long-standing and have been difficult to address; concerns were first expressed shortly after the creation of NCI's Cooperative Group Program more than 50 years ago.[10] Three previous directors of the NCI each commissioned reviews of the system and their reports are described in the literature review. Innovative solutions are urgently needed to improve the clinical trials enterprise at the UNC Lineberger and nationally.

Topic Selection and Research Question

In order to decrease suffering and death from cancer, it is imperative that academic medical centers including the UNC Lineberger be able to conduct cancer clinical trials efficiently and effectively. Investigators and leaders at the UNC Lineberger share national concerns about the length of time it takes to activate and complete trials; the current system is not working well. A sense of urgency is present but no solutions or best practices have been identified for application at the UNC Lineberger. A major national report states that the key to bringing about change in clinical trials efficiency will be based on "doing things differently rather than undertaking new activities."[11] There is consensus that things need to be done differently, but how?

This study was designed in response to the need to investigate new options for improving cancer clinical trials efficiency. To transform the call for novel solutions into a researchable topic, first the literature was reviewed to understand what recommendations and improvement initiatives pertaining to clinical trials had been undertaken thus far. The fact that no cancer center in the United States was able to demonstrate positive results from implementation of the recommendations from

national reports issued over several decades underscored the need for a different approach. To focus the inquiry at the local level, stakeholder analyses were conducted at the UNC Lineberger. With a better understanding of the current situation and of the literature on clinical trials efficiency, organization development, and Appreciative Inquiry (AI), a hypothesis was generated that AI could be applied with the UNC Lineberger's CPO and that doing so would directly and indirectly lead to improvements in clinical trials. This case study was designed to investigate the question of how appreciative inquiry can be used to improve clinical trials efficiency and to deliver a case study report on a trial application of AI.

Appreciative inquiry has been applied in health care organizations but has not previously been used as an approach to improving clinical trials efficiency. This dissertation tests its application in a unique setting not accessible to outside investigators. If AI is to be viewed as effective in healthcare, a broader evidence base is needed. This case study seeks to contribute to that body of work and to improve the health of the public by identifying tools that can be used to build a more efficient cancer clinical trials system.

Chapter 2: Review of the Literature

To assess the current status of cancer clinical trials efficiency improvement initiatives nationally, a literature review was conducted using formal identification, selection, extraction, and synthesis methods. Literature on organization development (OD) was reviewed to understand the evolution of the field and the emergence of AI. An overview of case study research methods is also provided.

I. Clinical Trials Efficiency

Systematic Literature Review Methods

To identify articles on clinical trials efficiency, primary keywords "clinical trials" were combined with efficiency, leadership, activation, administration, organizational design, and organizational change in a bibliographic database search using PubMed, CINAHL, and the Cochrane Library. Because the topic could be covered by literature not included in these databases, Google Scholar was used to informally search for additional sources. The snowballing technique (perusing the reference lists of selected articles and books browsing books with adjacent call numbers) was used to identify relevant literature. The Clinical Trials Toolkit from the Association of American Cancer Institutes (AACI) identified seminal reports on clinical trials efficiency. A gray literature search was completed by contacting colleagues and known experts in the field. The review was performed in March 2011.

Thirty-three articles on cancer clinical trials efficiency were included in the review, including four major reports, as well as presentations from recent AACI, ASCO, and AACR meetings. The results of the search were uploaded into reference management software, EndNoteX4, to store citations, connect citations to electronic copies of articles, and to categorize the results.

Clinical Trials Efficiency Literature Review Results

Several articles described overarching problems with the clinical trials enterprise. First among these was the undervaluation of clinical research. For example, the president of the Association of Community Cancer Centers wrote:

> The historic undervaluation of clinical research is exemplified by the sizeable voluntary effort required by physicians to enroll patients, the philanthropic support that must supplement many clinical research programs, and the second-tier status allocated to clinical investigators by university leadership. Ironically, the turmoil affecting clinical research within the American healthcare system comes at a time when the potential to unmask some of the complexities of human tumor biology has never been greater.[12]

An editorial responding to a 2010 report on clinical trials efficiency from the Institute of Medicine (IOM) summed it up in lay language:

> In other words: quit relying on investigators to design and conduct studies as a hobby, something that folks can only find time to do after dinner, when the kids are asleep. Novel concept. This might have something to do with the fact that as many as 40% of cancer clinical trials are never completed.[13]

Another common problem has been described allegorically as silos, referring to lack of interactions across individuals and work groups that comprise clinical trials operations. The problem of silos has been observed at all levels, locally at the UNC Lineberger and nationally between institutions, and the lingo is pervasive among clinical researchers. Four major reports have been commissioned by directors of the

NCI over the last 15 years and provide insight into persistent problems with the clinical trials enterprise.

A. National Reports on Cancer Clinical Trials Efficiency

The NCI funds a large portion of the cancer clinical trials conducted in the US. For more than 50 years, the largest component of NCI's clinical trials research has been the Clinical Trials Cooperative Group Program (Cooperative Group). The Cooperative Group has been instrumental in establishing the standards of cancer patient care and clinical research methods. Advances include the increase in childhood cancer survival rates to nearly 80% from less than 10% in the 1950s; establishment of breast-conserving surgery as standard of care for localized breast cancer; improvements in cancer survival through the use of adjuvant treatment; and the identification of drugs that help prevent colon, breast, and prostate cancers in high risk patients.[6] The Cooperative Group involves 3100 institutions and 14,000 investigators who enroll 25,000 cancer patients each year.[6]

Persistent and growing problems with the clinical trials enterprise in the US prompted four reports, some focused on the Cooperative Group Program but all applicable to improving the conduct of clinical trials at academic medical centers. These are: the NCI Clinical Trials Program Review Group report (1997), the Clinical Trials Working Group report (2005), the Operational Efficiency Working Group report (2010), and the Institute of Medicine Report on a National Cancer Clinical Trials System for the 21st Century (2010). All emphasized the need to decrease time to trial activation. The charges to the groups, key findings, and recommendations from the four reports are described here.

1. Report of the National Cancer Institute Clinical Trials Program Review Group (The Armitage Report).

In 1996, the NCI director and the chair of the Extramural Board of Scientific Advisors commissioned an external review of the Cooperative Group Program in response to concerns that it was becoming increasingly inefficient and unresponsive to evolving needs. The charge to this Clinical Trials Review Group was to recommend changes that would: 1) take advantage of the most promising opportunities in therapy and diagnosis; 2) prioritize the most important research questions so that they can be explored in the fastest possible time; 3) improve the organization, funding, review, and cooperation in the Cooperative Group Program; and 4) attract both patients and researchers to participate in clinical trials.[14]

Recommendations in the Armitage Report (so named for the group's chair) focused on organization, prioritization, participation, and funding. These were grouped into several categories: data collection, standardization, and management; cooperation; process improvement; organizational and structural improvement; accrual; funding; and investigator recruitment. The organizational and structural improvement recommendations were geared toward inter-institutional issues (e.g., within the Cancer Therapy Evaluation Program or the Community Clinical Oncology Program) rather than organization development at institutions conducting trials.[14] An implementation committee report was completed in 1998. This group concluded that the clinical trials system was hampered by the complexity that resulted from attempted collaborations that included multiple parties, such as investigators, physicians, industry, academia and NCI. The report said, "This complexity has bred inefficiencies and eroded the ability of the system to generate new ideas to reduce the cancer burden."[14]

2. Report of the Clinical Trials Working Group of the National Cancer Advisory Board: Restructuring the National Clinical Trials Enterprise (CTWG Report).

In 2004, the Director of the NCI established the Clinical Trials Working Group (CTWG) to advise the National Cancer Advisory Board (NCAB) on the development, conduct, infrastructure, support, and coordination of cancer clinical trials across the NCI.[15] The working group was asked to provide recommendations and a plan to improve coordination and research infrastructure for clinical trials research by removing institutional and regulatory barriers that inhibit collaboration. The CTWG was asked to envision how clinical trials should be conducted in the era of bioinformatics and molecular medicine. The group recognized that NCI-designated Cancer Centers were the primary source for clinical investigators and that federal funding for investigator-initiated trials (IITs) was critical. In addition to the Armitage report, this group built on a 2003 report from NCI's P30/P50 ad hoc working group: *Advancing Translational Cancer Research: A Vision of the Cancer Center and SPORE Programs of the Future,* so that cancer centers and translational science funding mechanisms (including P50, P01, and R01 grants) would be part of the framework.[15]

The report was a detailed blueprint subtitled, *Restructuring the National Cancer Clinical Trials Enterprise*, that aimed to support clinical trials research in the 21st century that would be driven by individualized oncologic medicine.[15] The group reached consensus on four goals:

> 1. Improve coordination and cooperation among the functionally diverse components of the current system, including industry and federal regulatory agencies;
>
> 2. Improve prioritization and scientific quality by developing an open and transparent process for the design and prioritization of clinical trials that are science-driven and meet the needs of patient care;

3. Improve standardization of tools and procedures for trial design, data capture, data sharing, and administrative functions to minimize duplication of effort, and to facilitate development of a shared infrastructure to support an integrated national cancer clinical trials network;

4. Improve operational efficiency by increasing the rate of patient accrual and reducing operational barriers so that trials can be initiated and executed in a timely, cost-effective manner. [15]

The CTWG recommended 22 initiatives grouped into four themes: coordination, prioritization/scientific quality, standardization, and operational efficiency. Coordination initiatives sought to enhance information sharing by providing incentives for collaborative team science and coordination of regulatory processes. The prioritization/scientific quality initiatives suggested new processes for design and prioritization of clinical trials and for facilitating the conduct of correlative science and other ancillary studies. Standardization initiatives supported development of tools and procedures to minimize duplication and reduce the effort required to initiate and conduct clinical trials. Operational efficiency initiatives focused on improving patient accrual rates and reducing operational barriers to speed of both the initiation and conduct of clinical trials. Options for restructuring the management and oversight of NCI's clinical trials program were also included.

Of particular relevance to the proposed research was Operational Efficiency New Initiative #2: "Identify the institutional barriers that prolong the time from concept approval to the accrual of the first patient, and develop solutions for overcoming these barriers." The CTWG reported that while specific barriers to rapid protocol activation had been documented at individual sites, no generalizable systems analysis had been conducted to clarify barriers and to identify solutions. The CTWG suggested engaging academic management experts knowledgeable about evaluating workflows

to examine the clinical trial start-up process in real-world settings to understand the constrictions on trial initiation and develop recommendations for relieving bottlenecks.

Also of note was Coordination New Initiative #2: “Realign NCI and academic incentives to promote collaborative team science.” The CTWG found that NCI’s project selection and funding practices, as well as the deeply-ingrained promotion and recognition criteria of academic institutions, did not support collaborative research. The CTWG recommended realigning incentives by modifying NCI funding mechanisms, giving credit and adequate resources for participation in collaborative clinical trials and by modifying faculty performance evaluations at academic institutions, giving credit for participation in federally-funded clinical trials. The goal was to create a culture in which investigators collaborate across disciplines, institutions, and programs to advance the design and conduct of cancer clinical trials.

3. The Operational Efficiency Working Group of the Clinical Trials and Translational Research Advisory Committee: Compressing the Timeline for Cancer Clinical Trial Activation (OEWG Report)

In December 2008, the Operational Efficiency Working Group (OEWG) was established.[11] This group was asked to recommend strategies and design an implementation plan to reduce activation time for Cooperative Group trials, early drug development trials, and IITs at NCI-designated cancer centers, with a goal of reducing activation time by at least 50%. The group was also charged with identifying strategies to increase the percentage of studies that reach their accrual targets in a timely fashion. The work was divided into two phases and recommendations from the first phase on reducing trial activation time were issued in March 2010.

The OEWG excluded matters beyond NCI's jurisdiction from its deliberations including: consent forms regulated by the Department of Health and Human Services; state laws and requirements; and congressional funding mandates. The group reviewed available data on clinical trial timelines, identified the tasks required for trial activation, looked for barriers to timely activation, and discussed issues arising in the Cooperative Group and Cancer Center settings. Separate target timelines were established for different categories of trials. For IITs at Cancer Centers, a 90 day timeline was set for protocol review and revision, forms development, IRB review, and ancillary committee review. All steps from protocol submission to trial activation, including institutional financial review and industry negotiations, were to be completed within 180 days.

The OEWG developed 14 initiatives and implementation plans in two broad categories: management issues that directly addressed time to trial activation and important collateral issues. Process improvements were recommended for IITs:

1. Develop a center-specific action plan to achieve the OEWG target timeline for each step in IIT trial activation impacted by the cancer center

2. Develop and implement new NCI and Cancer Center initiatives designed to streamline university contracting and financial review processes. Though reducing time on contracting and financial review is beyond the direct control of the cancer centers, it requires institution-wide changes that have the potential to benefit all types of trials.

3. Develop a coordinated approach to standardization of protocol elements and protocol development tools in order to speed development and review of protocols

4. Enhance funding and capabilities for use of biomarkers in clinical trials in order to speed activation of trials designed to incorporate integral and integrated biomarkers

5. Perform a rigorous cancer center review of each proposed clinical trial concept in advance of protocol development in order to optimize use of clinical trial resources, speed trial development, and improve trial quality.[11]

The OEWG recommended that each cancer center develop its own action plan for achieving the target timeline because processes are impacted by structural factors such as the size of center, status as an independent or matrix cancer center (e.g., UNC Lineberger) within an academic medical center, and characteristics of its parent institution. Processes are also influenced by the complexity of a cancer center's clinical trials portfolio as well as center-specific factors such as decision-making procedures, protocol development infrastructure, and leadership. The report suggested that each center establish standards by which to judge success in meeting the target timelines and identify concrete steps for improvement such as: adding professional protocol writers and editors to staff; convening face-to-face meetings to resolve differences and minimize serial tweaking of protocols; convening regular clinical trials office staff meetings for timeline management and problem solving; and deploying project management software tools to track protocol development timelines.

Recognizing the need for the NCI and the cancer centers to work together to improve time to activation, the OEWG recommended that the NCI provide supplemental funds to support implementation of action plans. This resulted in the NCI's Re-engineering of Protocol Implementation and Development (RaPID) grant program. UNC applied for and received funds through this initiative, the details of which are provided below with local reports on efficiency at UNC. Efforts continue locally and nationally to enact the recommendations of the OEWG report.

4. A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program (IOM Report)

At the request of the NCI director, the Institute of Medicine (IOM) conducted a study of cancer clinical trials and the Cooperative Group Program to develop recommendations on how to improve the system. The IOM's review built on work that had resulted from the CTWG and the OEWG recommendations. In its 2010 report, the IOM encapsulated its findings with the following statement:

> In sum, the academic, government, and commercial sectors must join with the public to develop a 21st-century multidisciplinary clinical trials system to more effectively leverage scientific advancements and translate them into public health benefits by improving the science; technology; efficiency; and timely creation, launch, and completion of the highest-priority cancer clinical trials. With adequate funds and support, a more effective and efficient clinical trial system will speed the pace of advances in cancer patient care.[6]

The IOM found that the NCI's Cooperative Group Program had become stagnant, inefficient, cumbersome, underfunded, overly complex and managerially redundant. The average time required to design, approve, and activate trials was two years and many – about 40% -- trials were not completed at all. Inefficiencies led to lengthy delays at each step of trial development, during which time trials lost scientific relevancy and communication between stakeholders became ineffective. The IOM focused their recommendations on four broad goals:

> 1. Consolidation and Efficiency. Improve the efficiency and reduce the average time for the design and launch of innovative clinical trials by consolidating functions, committees, and Cooperative Groups; streamlining oversight processes; facilitating collaboration; and streamlining and standardizing data collection and analysis
>
> 2. Science. Incorporate innovation in science and trial design, for example, in studies identifying biomarkers that can predict therapeutic response.
>
> 3. Funding and Support. Adequately support those clinical trials that have the greatest possibility of improving survival and the quality of life for cancer patients, and increase the rate of clinical trial completion and publication.

> 4. Participation. Incentivize the participation of patients and physician in clinical trials by providing adequate funds to cover the costs of research and by reimbursing the costs of standard patient care during the trial.[6]

The IOM reiterated that publicly-funded clinical trials, vital to advancing science and patient care, are growing in importance as industry trials are conducted outside the United States with increasing frequency. The report also urged researchers to publish negative results, an important step in setting standards of cancer patient care. The committee's vision for an ideal cancer clinical trials system included support for clinical investigators; the IOM found that the current system does not adequately recognize, reward, or support collaborative work. The IOM underscored the ideas that translating discoveries into benefits for patients requires a robust clinical trials system and that clinical researchers need training, mentoring, and paid time set-aside to master this challenging endeavor. As did its predecessor committees, the IOM recommended that academic medical centers develop policies and evaluation metrics for promotion and tenure decisions that recognize and reward clinical and team research. This group noted that effective R&D organizations don't just do research, they allocate resources to improving *how* they do research. The IOM report posited that expertise from a range of disciplines including social science, management, and marketing would be necessary to develop novel approaches to solving the intractable clinical trials efficiency problems. The authors believe that at the heart of the issue is a clinical trials infrastructure that has not evolved to accommodate the rapid pace of biomedical discovery and that many of the challenges derive from systems problems rather than scientific ones.

B. Literature on Cancer Clinical Trials Process Analyses

In addition to national reports, there is a body of literature describing work to better understand cancer clinical trials processes and analyze barriers to completion. These efforts have been spearheaded by David Dilts, a management scientist, and Alan Sandler, an oncologist. They developed what is now known as the Dilts and Sandler method with two parts: 1) process steps are identified and mapped; and 2) timing analyses are conducted.[16] A process map is created as one large complete diagram, graphically portraying all the processes required to activate a trial. The Dilts and Sandler method examines three types of barriers: procedural, structural, and infrastructural. Procedural barriers arise from processes or steps which are required to activate a study but may inhibit problem-solving actions. Structural barriers result when different participants in the process follow a different ordering of steps, which can lead to miscommunication and misunderstandings. Infrastructural barriers relate to the design of the underlying system and its support of interconnections.[16] For Cooperative Group studies, there is a fourth type of barrier, synchronicity, the need to compile various components before a trial can proceed to other parts of the process.[17]

Dilts and Sandler have analyzed barriers and published more than six papers with staggering results. In a study using four cancer centers (including the UNC Lineberger), two Cooperative Groups, and the NCI Cancer Therapy Evaluation Program (CTEP), they found that opening a phase III Cooperative Group therapeutic trial required 769 steps, 36 approvals, and a median range of 2.5 years from concept review to opening.[18] They used the children's game, Chutes and Ladders, to

describe the process because while it is possible to bypass steps (ladders), trials may be returned to an earlier point in the process (chutes). Dilts and Sandler also found that a large number of redundant or overlapping steps added no value to the process. Eliminating these would be one way to decrease elapsed time.[17]

Dilts and colleagues confirmed their hypothesis that the amount of time elapsed between the letter of intent or concept initiation and the activation of a trial is inversely related to the likelihood the trial will reach its accrual goal.[19] To decrease delays due to process barriers, Dilts and Sandler call for researching on streamlining internal and external groups and processes, stressing that even simple changes may lead to extensive looping that substantially slows time to activation.[17]

Kurzrock and colleagues described the outcomes of Project Zero Delay, undertaken in partnership between MD Anderson Cancer Center and AstraZeneca Pharmaceuticals. The objective was to enroll a patient without significant delay after FDA approval of the trial's investigational new drug application by focusing on: communication; identifying and matching key timelines; alignment of priorities; and tackling administrative processes in parallel.[20] The team determined the most common obstacles to trial activation were: frequent and complex amendments to protocols; contract and budget negotiations; IRB communication delays; and a complicated web of approval processes with interdependent steps. An important finding was that significant efficiency could be gained, without compromising patient safety or research quality, by allowing processes to occur in parallel rather than sequentially.[20] The team found the following were necessary to ensure rapid activation of trials conducted through industry-academia partnerships:

- Frequent interactions and sharing of information by people at all levels
- A highly motivated protocol champion (the PI) with authority over a well-qualified team of personnel;
- Support from upper levels of administration.
- Experienced management teams coordinating from start to finish;
- Mutual understanding of motivations and willingness to examine timelines.
- A master agreement to streamline contracting and budgeting
- A shared goal of bringing novel cancer drugs to patients faster while maintaining safety and quality.[20]

Adjei, Yasko, and colleagues at Roswell Park Cancer Institute described their strategies to increase the number of high-impact intervention studies, increase accrual, and improve activation speed.[21] They hypothesized that having a large number of trials open to accrual at the same time, especially asking similar questions or targeting the same patients, was a significant obstacle to efficiency. In order to streamline the protocol development process while maintaining a portfolio of high-impact trials, a committee was established to review and approve study concepts before the protocol could proceed to scientific review. An accrual-to-study ratio metric, defined as the total annual accrual divided by the number of active studies, was established at ≥ 5 and used as a review criterion. After three years, the team found: the number of submitted concepts decreased by 50%; the accrual to trials increased by 45%; and the time from concept submission to study activation was reduced by 25 days to a median of 107 days. In addition, their study portfolio had improved and included more IITs, phase I studies, and collaborative studies.

Another mandate of national reports was to share best practices and lessons learned. Yasko et al. provided several from their experience, noting that clinical

research culture change takes time and the need for change agents to remain patient and positive in the early phases. Recommendations included:

- establish written goals and a set of metrics to measure the goals, distribute the metrics widely, and frequently measure the goals using the established metrics; be consistent in review of all studies for all investigators;
- ensure a well-functioning partnership between clinical research leadership and committee leaders and members, with frequent counsel from leadership to committee leaders and members about handling appeals from investigators whose protocols are denied;
- be aware that the importance of disease-specific research groups will increase since they will determine which studies to close or focus accrual efforts to meet the study ratio;
- know the accrual target and accrual to date of industry-sponsored or Cooperative Group studies when evaluating for approval to avoid opening cost-ineffective studies of these types.

Yasko also joined with two facility leaders from the UNC Lineberger's CPO and others in 2010 to co-author, *Clinical Research Site Infrastructure and Efficiency*, a synthesis of ASCO abstracts included in a series of articles on attributes of exemplary research sites.[22] This article summarized information including:

- Work by Dilts, Adjei, et al. showing that in 2.5 years of trial development time, enthusiasm dropped and scientific relevance decreased due to standard-of-case changes. This trial had an accrual goal of 1,200 patients but only enrolled 23 patients and closed early;
- Work by Cheng et al. demonstrating that trials that do not enroll a patient within two months of activation are significantly less likely to meet accrual goals no matter how long they stay open;
- Work by Durivage et al. on the need for trial selection strategies and closure rules for non-performing studies to conserve resources. In their study of 14 NCI-designated cancer centers, $81,000 was spent on average per center per year on trials that accrued no patients;
- Analysis by Durivage et al. on 170 phase II trials at 9 cancer centers showing that 47% closed before completion and 21% of enrolled patients were on a trial that closed due to poor accrual. Slow accruing trials remained open for a median of 28 months, using substantial resources.[22]

C. Clinical Trials Efficiency Assessments and Initiatives at the UNC Lineberger

On several occasions in the last decade, the UNC Lineberger has sought advice from external cancer research advisors regarding its clinical trials operations. Reports from three key consultations are briefly summarized here. In 2002, the Scientific Advisory Board concluded the center's large number of non-performing trials was a significant problem. The board recommended: 1). filtering out protocols that are highly unlikely to accrue or that address trivial scientific questions at an early stage of development and reviewing concepts at the highest level of the center, not the CPO; 2) analyzing past non-performing protocols and preventing protocols with similar characteristics (e.g., target patients, physicians) from moving forward; 3) establishing a policy to address competing protocols; and 4) predefining time points by which trials will be closed and rigidly enforcing the standards.[23]

In 2004 the advisors returned to find that despite the increased number of creative protocols addressing cutting edge questions, many were not meeting accrual goals. The advisors noted that with more investigators conducting trials, there was increased stress on a system that was overburdened by studies that would never reach accrual goals. Advisors found the system to be "inefficient and likely overly expensive." They recommended: establishing and enforcing better prioritization methods to limit active trials to a manageable number; recruiting full-time clinicians to expand the clinical base, staff the new hospital, and accrue to clinical trials; and increasing the number of dedicated research nurses with dual reporting to the CPO and to the disease team leader.

In 2010, the UNC Lineberger received funding from the NCI's RaPID initiative

(described above) to implement recommendations of the OEWG report. UNC's RaPID grant hypothesized that efficiency and speed of activation depended on: 1) appropriate prioritization of work including rigorous review at the outset and ability to fast track high priority trials; 2) dedicated personnel to aid in development of protocols and Letters of Intent, to track progress of each protocol, and to identify barriers; 3) metrics for monitoring processes and work flow, managing portfolios, and modifying the activation processes based on identified barriers. Major areas of focus included: 1) self-study of barriers and examples of fast activation that used checklists and tracking methods; 2) development of additional checklists and a dashboard to track milestones; 3) hiring an activation specialist to monitor progress; and 4) development of automated reports to help with prioritization.[24]

In March 2011, Dr. Alex Adjei, Senior Vice President of Clinical Research and Chair of the Department of Medicine at Roswell Park Cancer Institute (whose work is referenced in section B above), completed a review of UNC Lineberger's clinical trial operations. Dr. Adjei reported a concerning disconnect between the CPO management and the clinician investigators. Most striking was that the report of protocol development timelines he received from the CPO management differed significantly from reports he received from investigators (6 and 12 months, respectively). He recommended that a physician be given the resources, budgetary authority, and reporting relationships necessary to manage the clinical trials enterprise and undertake a reorganization of the clinical trials office in consultation with UNC Lineberger leadership. Dr. Adjei recommended that clinical investigators be asked about their impressions and suggestions for improvement.

Discussion and Conclusions

The literature makes it is clear that having an effective and efficient clinical trials program is essential to making progress against cancer, a leading cause of death in the United States. Patient lives are lost when the development of new treatments is delayed. Clinical trials efficiency issues have been analyzed, implementation plans have been devised, and some institutions have made some small improvements in targeted areas. There is hope amongst the cancer research community that the OEWG's timelines by which specific steps must be reached and the IOM's proposal to consolidate functions within the Cooperative Group system will lead to improvements. It has been stated that there is no singular fault in the clinical trials system; rather it is a complex process with weak links between key components. The lack of timely trial activation trials has been criticized since the beginning-- the NCI's Cooperative Group Program was first chastised for inefficiency in 1959, only three years after its creation.[10] However, the problems had not been systematically analyzed until recent decades.

The changes and recommendations from the four reports are summarized in the table on the following page. The persistence of issues despite the identification of potential solutions suggests a new approach is needed. Perhaps the key to improving cancer clinical trials is a better understanding of the people, their motivations, and behaviors, rather than a better understanding of the processes in the system. A clinical trials blog encapsulated the sentiment heard nation-wide and at the UNC Lineberger: "The US cancer clinical trials system is broken. Fix it."[13]

Table 1: Summary of National Reports

	Armitage Report	CTWG Report	OEWG Report	IOM Report
Charge	Recommend changes to 1) take advantage of the promising opportunities in therapy and diagnosis; 2) prioritize most important research questions;3) improve organization, funding, review, & cooperation; and 4) attract patients and researchers to clinical trials participation	1) Develop recommendations & implementation plan to improve coordination & research infrastructure by removing institutional and regulatory barriers that inhibit collaboration. 2) Envision conduct of clinical trials in era of bioinformatics and molecular medicine.	Recommend strategies & implementation plan to reduce time to activation by ≥50% and to increase percentage of studies that reach accrual goals	1) Conduct a consensus study of cancer clinical trials and the Clinical Trials Cooperative Group Program and 2) Develop recommendations to improve the current system
Focus	Organization, prioritization, participation, and funding	Coordination, collaboration, adoption of new technologies	Institutional barriers to activation	Efficient and effective translation of research discoveries into timely clinical applications
Recommendation groupings	Data collection, standardization, & management; cooperation; process, organization and structural improvement; accrual; funding; investigator recruitment	Coordination, prioritization/scientific quality, standardization, operational efficiency	Management issues directly addressing time to activation and collateral issues of importance to clinical trials system.	Consolidation & efficiency; science; funding & support; participation
Key points relevant to this proposal	Clinical trials system is hampered by the complexity of attempted collaborations	Engage management experts to understand processes in real-world settings. Culture/practices of academia don't support collaboration.	Key to change lies in doing things differently rather than doing different things	Effective organizations don't just do research, they improve how they do research. Systems issues not scientific ones are impeding progress

Many talented individuals have sought to improve the cancer clinical trials system. Additional barriers to achieving the desired goals must be present -- can the improvements not be successfully implemented or do the suggestions not work when implemented?

From the review of literature on clinical trials efficiency, several clues about possible next steps were gleaned. The OEWG report said the key to change would lie in doing things differently rather than doing different things. Adjei et al. said that clinical research culture change takes time and that change agents would need to remain patient and positive. Kurzock et al. found that frequent interactions and sharing of information by people at all levels, a mutual understanding of incentives, and a willingness to openly examine processes in context of those drivers were key to reducing delays. Dilts et al. found that miscommunication and misunderstanding were significant problems and that the impact of lack of resources paled in comparison to that of lack of coordination. Dilts also said that it will take more than recommendations and hope to solve the problems with clinical cancer research. The IOM suggested that novel approaches involving disciplines such as social science, management, and marketing be used.

All of these statements suggest that organization development could be used to improve the cancer clinical trials enterprise, bringing strategies from multiple social sciences to bear on the challenges. Organization development could provide an alternative or supplement to the ideas generated previously. The relevant literature is described below and no applications to clinical trials organizations were found, making the proposed research a potentially novel application.

II. Organization Development*

Organization Development (OD) is a field of applied behavioral science that focuses on understanding and managing change in organizations. OD draws on theories and approaches from a wide range of disciplines including anthropology, economics, political science, psychology, and sociology to make organizations more effective. OD involves implementing change and developing the organization itself, to the benefit of both the institution and the individuals who comprise it. French and Bell articulated this duality of purpose:

> The idea is this: it is possible for the people within an organization collaboratively to manage the culture of that organization in such a way that the goals and purposes of the organization are attained at the same time that human values of individuals within the organization are furthered.[25]

Over the last fifty years, there have been many definitions of OD with debate over its defining characteristics. This discussion has expanded in recent years in response to new patterns of practice. What many consider the first formal definition of OD was put forth in 1969 by Richard Beckhard describing an effort that is "planned, organization-wide, and managed from the top, to increase organization effectiveness and health through planned interventions in the organization's processes, using behavioral-science knowledge." [26] Another early leader in the field, Warren Bennis, defined OD as "a response to change, a complex educational strategy intended to change beliefs, attitudes, values, and structures of organizations so that they can better adapt to new technologies, markets, and challenges, and the

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* The field was inaugurated as and continues to be referred to by many scholars as "Organization Development," parallel to "human development." Though "Organizational Development" has increased in use, this dissertation uses the conventional term.

dizzying rate of change itself."[26] More recently, Thomas Cummings sought to integrate emerging aspects of OD as "a system-wide process of applying behavioral-science knowledge to the planned change and development of the strategies, design components, and processes that enable organizations to be effective."[27]

Kurt Lewin, a social psychologist considered the father of OD, believed that science and actions should be iterative. Lewin sought to join science with practical applications and became famous for the maxim, "no action without research and no research without action."[28] In creating action-research, Lewin advanced the concept that diagnosing problems in organizations was not enough to lead change and research could be of value to practitioners. In his 1946 article, *Action Research and Minority Problems*, Lewin describes a situation familiar to the UNC Lineberger:

> "Two basic facts emerged from these contacts: there exists a great amount of good-will, of readiness to face the problem squarely and really to do something about it. If this amount of serious good-will could be transformed into organized, efficient action, there would be no danger for intergroup relations in the United States. But exactly here lies the difficulty. These eager people feel to be in a fog. They feel in the fog on three counts: 1) what is the present situation? 2) what are the dangers? 3) and most important of all, what shall we do?"[29]

Lewin had been asked, in the wake of the holocaust, to assist communities in understanding and eliminating prejudices through new methods of social inquiry.[30] This work to improve intergroup relations became known as sensitivity training and led to the establishment of the National Training Laboratories, where training groups learned about group dynamics, leadership, interpersonal relations, and personal growth.[30] Once these methods were applied to industry, the field of "organization development" took root.[30]

OD is built on core psychological concepts about the nature of humans in organizations, the motivations underlying behavior, resistance to change, and

focusing on groups to enact organizational change and is influenced by humanistic psychology, which prompts examination of subjective experiences, values, intentions and perceptions that influence choices.[27] The field places a high value on human potential, asserting that humans have tremendous capacity for self-determination, creativity, and psychological growth.[27] At the same time, OD recognizes that organizations are often structured in ways that inhibit this precious human potential.[27] For example, "command and control" management presumes that some members of the organization are inferior to others. In organizations of this type, connections between individuals are expected to be rational and exist to further organizational goals, when the relationships themselves are not valued. OD seeks to create work environments that promote maturity and interpersonal competence and values relationships.[27]

Since its inception, OD has been used in many different types of industries and organizations, with a body of literature published by practitioners and academicians. Marvin Weisbord's 1976 article, "*Why Organization Development Hasn't Worked (so far) in Medical Centers*" is particularly relevant. Weisbord found it difficult to used OD with academic medical centers for three reasons:

1. Medical centers have few of the formal characteristics of industrial firms, where OD, like all management science, was first recognized, tested, and developed.
2. Physicians and scientists are socialized to a form of rational, autonomous, specialized, expert behavior, which is antithetical to the organization of any but the more narrow individualized pursuits.
3. Medical centers, therefore, require three different social systems, not one, as in industry. The links among the task system which administrators manage, the identity systems which undergirds professional status, and the governance systems, which sets standards, are extremely tenuous.[31]

Weisbord found that organizations functioned well when four structural elements were balanced, contributing to the synergy of the organization: task interdependence, concrete goals, performance measures, and formal authority.[31] He observed that academic medical centers tended to have abstract goals, diffuse authority, low interdependence, and few performance measures.[31] Weisbord found that high synergy institutions can use OD to develop procedures that increase productivity and self-esteem.[31] Weisbord recommended increasing the synergy of academic medical organizations by working to clarify goals and better align key elements. He also suggested that the field add "structure-creating interventions" to OD's repertoire, meaning approaches that enhance and improve relationships within an organization rather than stifle them (e.g., generative forms of OD).[31]

Soon after, Kenneth Gergen published his article, "*Toward Generative Theory,*" which would have a significant impact on the evolution of the OD field and emerging forms of practice.[28] In Gergen's view social psychology theory failed to "challenge prevailing assumptions regarding the nature of social life and to offer fresh alternatives to contemporary theory."[32] He thought that social psychology theory, which served at the time as the underpinnings of OD, needed to move away from establishing and verifying facts upon which to intervene. At the same time, OD practitioners began reporting that the pace of change in organizations made it difficult to obtain accurate data on which to base objective assessments and that they were finding that problem-centric approaches prompted increased resistance to change.[28] As generative forms of OD became more common, the field underwent what some scholars consider a bifurcation. Bushe and Marshak detailed similarities

and differences between two branches of OD practice that they characterize as diagnostic (or classic) OD and dialogic OD.[28] A key difference is that dialogic OD works to change the frameworks that influence behavior rather than attempting to directly change behavior.[28] AI is one of several forms of dialogic OD. Its development, principles, methodology and prior applications will be described below.

Discussion and Conclusions

With the evolution of the OD field toward generative theories, current options such as AI seem better suited than classic OD for use in academic medicine. Gergen noted that when the pace of change in organizations is high (as is the case at the UNC Lineberger), diagnostic forms of OD are difficult to use and dialogic forms may be a better choice. Dialogic forms of OD have been used successfully with nurses and at medical schools (described in the next section), suggesting that applying a dialogic form of OD could at the UNC Lineberger could be beneficial to the organization. The distinctive multidisciplinary nature of cancer care and research at UNC, which gives it high levels of synergy, may make the organization amenable to a generative form of OD. A systematic review of AI literature was performed to further examine the potential appropriateness of using AI in this case.

III. Appreciative Inquiry

Systematic Literature Review Methods

Key words “appreciative inquiry” were combined with healthcare, medicine, medical centers, physicians, and cancer using PubMed. Because relevant literature about AI could be housed in other databases, Google Scholar was used. The

snowballing technique was used to identify relevant literature from reference lists. A gray literature search was also completed by contacting colleagues and known experts in the field and produced numerous sources, including extensive training materials for AI practitioners. The search was conducted in April 2011.

Fourteen articles and books on AI were included in the review. The PubMed keyword search revealed that AI has been applied in a wide range of healthcare settings including nursing, primary care, HIV care, acute care, and pain management and applied in support of nurse retention, to prevent burn-out among physicians, to investigate how faculty in academic medicine experience collaboration, and to improve nurse-physician communication. One article related to cancer services was identified but none were found about cancer research or cancer clinical trials. Several books were included in the review including Cooperrider's *Appreciative Inquiry Handbook*, Hammond's *The Thin Book of Appreciative Inquiry*, and Stavros and Hinrich's *The Thin Book of SOAR*. The results of the search were uploaded into reference management software, EndNoteX4, to store citations, connect citations to electronic copies of articles, and to categorize the results.

Through completion of an online AI workshop in May 2011, additional materials were obtained including six articles, 15 recorded lectures, five interview guides, summit materials, and a link to the AI commons (http://appreciativeinquiry.case.edu) where 16 classic articles, 22 case studies, and links to other positive change websites are available. Titles of dissertations that have used AI are also posted in the AI commons. There is an AI journal, *AI Practitioner*, and its website provides an index by subject. One issue (May 2004) was dedicated to positive change in health care.

AI Literature Review Results

David Cooperrider first articulated his ideas about the theory and practice of AI in 1986 in his doctoral dissertation at Case Western Reserve University. Cooperrider and his advisor, Suresh Srivastva, introduced AI to the OD field with their article, "*Appreciative Inquiry into Organizational Life*," that called for a shift from deficit-based theory of change to "a positive, life-centric theory."[33] In a recent publication, Cooperrider and Whitney recounted the many ways AI has been characterized, summing it up as "a philosophy of knowing, a normative stance, a methodology for managing change, and as an approach to leadership and human development."[34]

This strengths-based, collaborative approach to change revolves around the idea that in every organization, something works well. [35] Cooperrider established four foundations for the practice of AI:

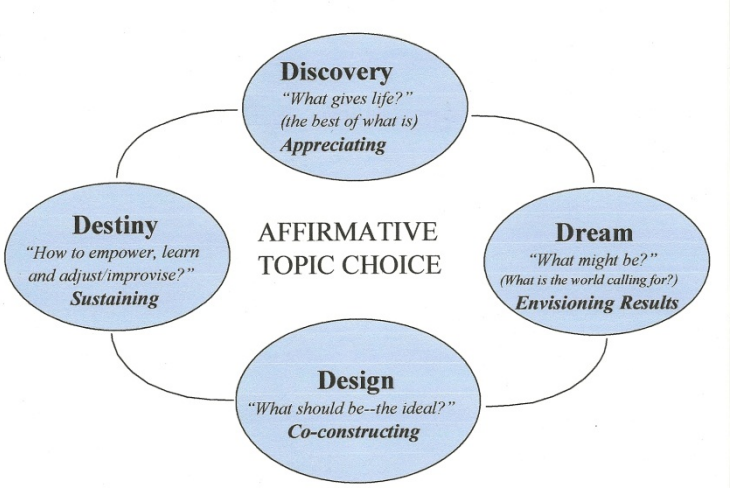
1. Inquiry into "the art of the possible" in organizational life should begin with appreciation.
2. Inquiry into what is possible should yield information that is applicable.
3. Inquiry into what is possible should be provocative.
4. Inquiry into the human potential of organizational life should be collaborative.[36]

Cooperrider speculated that human systems grow in the direction of what they study, so that asking questions about what is good and what is possible would be more likely to lead to positive change than studying an organization's problems.[37] That is to say that when organizations study problems and conflicts, they find that their problems grow and conflicts increase but organizations that study ideals and achievements find these aspects flourish.[36] The Pygmalion effect (aka self-fulfilling prophecy) is often used to explain this: a phenomenon where the greater the

expectation placed on people (notably students and employees), the better they perform. From this, five central principles for the application of AI were developed:

1. The Constructionist Principle: Social knowledge and organizational destiny are interwoven.
2. The Principle of Simultaneity: Inquiry and change can and should happen simultaneously.
3. The Poetic Principle: Any topic related to the human experience in systems or organization can be studied and the choice of inquiry affects the focus of change.
4. The Anticipatory Principle: Collective imagination and discourse about the future is the most important resource for constructive organizational change.
5. The Positive Principle: Change requires positive affect and social bonding. The more positive the questions, the more effective the change.[36]

The two fundamental points about AI are that organizations move in the direction of what they study and that AI makes a conscious choice to study the best of an organization, its "positive core."[36] To concisely describe the steps used to build on this positive core, the action research phases of AI are called the 4-D Cycle of Discovery, Dream, Design, and Destiny.[38] This cycle has also been described as five generic processes: 1) Choose the positive as the focus of inquiry; 2) Inquire into exceptionally positive moments; 3) Share the stories and identify life-giving forces; 4) Create shared images of a positive future; and 5) Innovate and improvise ways to create that future.[39]



Cooperrider & Whitney 2007[1]

The first step in AI is selection of the affirmative topic, which represents what people in the organization genuinely want to learn more about. Most inquiries adapt or expand on four foundational questions about the selected topic:

1. What was a peak experience or high point?
2. What are the things valued most about yourself, the nature of your work, your organization?
3. What are the core factors that “give life” to organizing?
4. What are three wishes to heighten vitality and health?[36]

The AI process has been applied effectively in many industries, including healthcare. Noteably, AI has been applied to bring about culture change in medical schools and to improve communication between nurses and other healthcare providers. At the Indiana University School of Medicine, interest in generating culture change sparked its “Relational-Centered Care Initiative.”[40] The Steering Team’s goal was to foster a more caring, respectful, and collaborative culture throughout their medical school. The team used a theoretical framework of Complex Responsive Processes of Relating, which describes how large-scale patterns of interactions can be changed by changing local, small-scale behaviors.[40] Through the AI process, attention was brought to exemplary professional behavior which led to more mindful and intentional behavior within the organization. The team found that the impact of the AI initiative was observable in numerous ways including the conduct of daily work and meetings, through increased participation in the initiative, and by sharp measurement increases in student satisfaction. This case study demonstrated that AI can be used to generate culture change in a medical school at a public university (like UNC).[40]

AI initiatives with nurses have demonstrated that it can be applied effectively with health care organizations, where moving away from a diagnostic approach to change is particularly challenging. Havens, Wood, and Leeman partnered with nursing leaders at six community hospitals to improve work environments for nurses. The project sought to improve communication and collaboration among nurses and other health care professionals; enhance nurse involvement in organizational and clinical decision making; and to enhance cultural awareness and sensitivity.[41] The team found significant challenges to initiating an AI process in a healthcare organization because the AI approach was perceived by participants as very foreign. However, AI provided several advantages over traditional quality improvement techniques for addressing communication, collaboration, decision-making, and cultural sensitivity issues.[41] Effects of the AI process were observable in individual interactions and in meetings. This case study demonstrated that, with time and patience, paradigm shifts in healthcare organizations can be made using AI and that a positive approach to change can spread across an institution.

Wood also published case studies about using AI with nurses to improve the organizations and professional practices at Lovelace Health Systems and at the Children's Hospital of Philadelphia.[42] At Lovelace, the topic focused on nurse retention (why nurses choose to stay employed there) and at the Children's Hospital of Philadelphia the focus was creating a positive future for the Department of Nursing. After the initiative at Lovelace, nurse turnover was reduced by 13%, the vacancy rate was reduced 30%, its rating as a place for nurses to work increased 16% and patient satisfaction rose 20%.[42] Both cases demonstrated that AI could

be used effectively to improve environments for nurses and their patients.

In the United Kingdom, one of the first applications of AI in healthcare was to evaluate a change process related to cancer services. The Cancer Services Collaborative (CSC) is a National Health Services Programme focused on improving patient experiences that was established to address the fact that cancer outcomes in England varied by geography and social class.[43] Previous evaluations of the CSC had found the program had met many of its goals and the goal of this evaluation was to discover the ways in which the services had been successful and what worked in changing services. AI was selected as the evaluation tool to study the process of change because its leaders wanted an evaluation approach that would support the CSC's work to encourage innovation among staff.[43] The use of AI to evaluate the cancer service changes was considered successful. In addition, using AI had a positive impact on the staff conducting the evaluation and on the stakeholders who were interviewed because the AI process helped discover the organization's shared commitment to improving the lives of people with cancer.[43]

A meta-analysis of AI case studies found that AI is more likely to be transformational when the focus is on changing how people think rather than what they do.[44] Bushe and Kassam learned that AI is less likely to be transformational when it used to try to change existing practices than when new practices are improvised.[44] Barrett and Fry wrote that AI is "not about implementing a change to get somewhere; it is about changing…convening, conversing, and relating with each other in order to tap into the natural capacity for cooperation and change that is in every system."[45]

Discussion and Conclusions

The literature on AI provides a thorough introduction to its philosophy and application. Detailed educational materials are available on how to construct and carry out an AI initiative. AI has been used successfully with nurses and at medical schools, supporting the idea that it could be effectively used with the UNC Lineberger's clinical trials personnel. The literature provides caution that using AI in academic medicine poses particular challenges due the diagnostic culture of the profession, but the distinctive multidisciplinary nature of cancer care and research at UNC may make the organization reasonably receptive to this form of OD.

Because AI builds on what works, it brings the potential to generate change with minimal risk of negative impact on the organization. This makes it a good choice for study at the UNC Lineberger where there are reservations about the potential negative effects of change efforts. Diagnosing conditions and seeking cure is the basis of medical practice, but organizations cannot be cured of themselves, so a dialogic form of OD is a better choice than diagnostic (or classic) OD in this case. Problem-based approaches generally fail to address systemic issues and can further erode trust, but appreciation enables people to see beyond obstacles and limitations. Even when AI is not transformational (and sometimes it is), experiences described in the literature suggest it can generate significant positive change.

The lack of effective national recommendations had left stakeholders at the UNC Lineberger to simply hope that their efficiency will improve. The AI literature says that dwelling on problems is an inherently conservative approach and AI practitioners often quote Einstein: "The significant problems we face cannot be

solved at the same level of thinking we were at when we created them". [39] Operating from a problem solving mentality risks affirming the status quo and the status quo is not acceptable if we are to save more lives from cancer. AI may provide an alternative approach to creating change in the efficiency of cancer clinical trials. A descriptive case study could provide useful information about whether and how it could be used. To best formulate the framework for this research, the literature on case study research design and methods literature was reviewed.

IV. Case Study Research

The case study is a research strategy often used to address descriptive or explanatory questions in the social sciences.[46] In the 4th edition of his book on case study research design and methods, Yin provides this definition:

> A case study is an empirical inquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident.[47]

Qualitative, quantitative, or both types of data can be used in case studies, generally obtained from one or more of six sources: documentation, archival records, interviews, direct observation, participant-observation, and physical artifacts.[47] Case study research design can comprise single or multiple cases with single or multiple units of analysis (holistic vs. embedded designs).[47] A multiple case study may be preferred when sufficient resources and opportunities are available; however, a single case study may be justified when it represents a critical case testing a well-formulated theory, embodies an extreme or unique case, is representative or typical, is a revelatory case; or is longitudinal.[47]

Case study research is distinct from case study teaching. Though in the past, case study research was disparaged by some as “soft science” or quasi-experimental, views have evolved and the current literature provides a clear methodology and rationale for its use.[47] Strategies can be employed to address historical concerns such as: lack of rigor; ungeneralizable results; lengthy processes that produce expansive documents; and inability to establish causal relationships.[47] Three key principles for data collection are suggested in consideration of construct validity and reliability: use multiple sources of evidence, create a case study database, and maintain a chain of evidence.[47] To strengthen case study analysis, Yin proffers four general strategies: rely on theoretical propositions, develop a case study description, use both qualitative and quantitative data, and examine rival explanations.[47] These strategies can be incorporated into several techniques for analysis such as pattern matching, explanation building, time-series analysis, logic models, and cross-case synthesis.[47]

More than other forms of research, case studies have the potential to reach multiple audiences. It is suggested that case study reports account for this and, to the extent possible, prospective audiences for the report be identified prior to conducting the research.

Discussion and Conclusions

Case study methods can be a good choice for research that seeks to answer “why” or “how” questions, such as how AI can be used to increase clinical trials efficiency? The literature on case study design provides guidance for addressing essential issues of construct validity, internal validity, external validity, and reliability

that can be applied as appropriate to the proposed research. Case study analysis benefits from theoretical propositions, which AI can provide in this case.

A multiple case study (i.e., including more than one cancer center) is beyond the scope of this dissertation; this research met several criteria for using a single case design. The UNC Lineberger is representative of university-based matrix cancer centers, the application of AI with the UNC Lineberger's CPO represents a unique test of AI theory, and it may serve as a revelatory case. Case study methodology was followed in designing the research plan.

V. Implications for Future Research

The fact that no cancer center in the United States has been able to respond adequately to the recommendations of major national reports on increasing clinical trials efficiency underscores the need for innovative change. From this literature review it can be induced that innovative approaches are needed to improve the efficiency of the clinical trials enterprise; that OD encompasses much of the expertise and strategy suggested for use in addressing intractable problems with the clinical trials system; that the outcomes of previous applications and AI principles suggest that it is a form of OD well suited to this purpose; and that case study research is an appropriate design for the proposed research.

In 2006, Havens et al. wrote that the effectiveness of AI in healthcare remained largely untested and Bushe noted in 2010 that none of the published cases of AI took contextual variables into account.[41, 48] AI has been applied successfully in healthcare organizations, particularly with nurses (who are central to clinical trials), but not in institutions with context and interpersonal dynamics directly

comparable to those of cancer centers. This study is needed to describe if and how AI can be used under these circumstances and with what outcomes.

Case study research is appropriate when “the boundaries between phenomenon and context are not clearly evident” which is relevant to the application of AI.[47] This case study seeks to contribute to the body of knowledge about the use of AI and reports on a test of a potential solution to an important and intractable systems problem that needs solving.

Chapter 3: Methods and Case Study Protocol

A descriptive case research study was designed to better understand how AI can be used to improve the efficiency of cancer clinical trials. Qualitative data from a single case, the UNC Lineberger, was used because of the potential for this case to be both revelatory and typical; the investigator had unique access to this center, AI has not been applied at other cancer centers, and the UNC Lineberger is comparable to other university-based cancer centers. So that multiple sources of evidence could be used, two units of analysis were embedded into the single case. AI theory was used to define the scope of the case and the domain to which the case study's findings could be analytically generalized. A case study protocol and a case study database were developed.

Case Study Description

Propositions and Descriptive Theory. The propositions of this research were that AI could be applied with the UNC Lineberger's CPO and that doing so would directly and indirectly lead to improvements in clinical trials efficiency. Direct improvements may result from implementing ideas garnered through document review or interviews. Indirect improvements may result from the positive effects of AI on the CPO, such as higher morale, better retention, a shared vision, or better communication.

The scope and depth of the case study were derived from the theory and principles of AI and from the needs of the institution. As a descriptive study, this case did not seek to establish a causal relationship between the use of AI and improvements in efficiency; rather it sought to observe and describe how AI might be used to facilitate development of a better clinical trials system.

Units of Analysis. A single-case with two embedded units of analysis was designed. The UNC Lineberger constituted the case because access and opportunity to apply AI were attainable. The units of analysis were the CPO's research coordinators and its disease team leaders. The CPO's research coordinators were included because of a pressing need to use a generative form of inquiry to learn more about how to improve their recruitment and retention; continuity of research coordinator employment directly impacts efficiency. Evidence for this unit of analysis was obtained from documentation and participant observation

The CPO's disease team leaders were selected as the second unit of analysis because as the individuals who set trial priorities and provide medical leadership for teams, their work also has direct impact on efficiency. Additionally, the disease team leaders are more likely to be knowledgeable about national efforts to improve efficiency which could generate ideas for efficiency improvements at UNC. Evidence for this unit of analysis was obtained from interviews and participant-observation.

Buy-in from the research coordinators and the disease team leaders would be essential to any future applications of AI, so an understanding of whether they are receptive to its use and how they respond is needed.

Case Study Protocol

Unit of Analysis 1: Research Coordinators.

Permission was obtained from the UNC Lineberger's Clinical Research Leadership Team (CRLT) for the use documentation on file regarding an AI process improvement initiative conducted with the CPO's research coordinators. In reaction to a steep increase in resignations in early 2011, the Director of the UNC Lineberger tasked two members of the CRLT, the outgoing CPO Medical Director and the Cancer Center Assistant Director, with interviewing the research coordinators. Though charged with gaining an understanding of reasons for the turnover, the interview team felt that identifying potential solutions was essential. It was also desirable for the inquiry process to contribute positively to morale rather than insinuate blame. These factors, combined with an aspiration to bring about positive change in real-time, led the team to select AI as the format for the interviews.

Email invitations were sent to fourteen research coordinators (see Appendix 1). A semi-structured AI interview guide (see Appendix 2) was constructed and pilot tested. Research coordinators who were no longer employed at UNC by the time of the interviews or responded that they did not have time to participate in an interview were provided with the interview guide questions and invited to submit written responses. Ten research coordinators participated in the initiative, including three who had recently or would soon resign. A report describing the process and themes ascertained from the interviews was presented to the CRLT. Subsequent discussion and actions were documented.

Unit of Analysis 2: Disease Team leaders.

A modified version of the 4-D cycle of AI was applied with the disease team leaders. Disease team leaders were identified by the CPO Medical Director (n=6) for inclusion in the second unit of analysis. Invitations and a description of the study were sent by email (see Appendix 3). Interviews were conducted over a three week period in January 2012.

A semi-structured interview guide was constructed (see Appendix 4) and pilot tested. Participants were provided with information about the study in the invitational email and given the opportunity to ask questions prior scheduling an interview. Appointments for interviews were made in advance and held in private offices.

Verbal consent to participate was confirmed prior to any data collection. Consent for collection of detailed field notes during the interviews was also confirmed with participants. Notes were subsequently typed up and stored securely under password protection. Analysis of the AI interview data was conducted by visually identifying and tallying themes from the interview notes. The most commonly cited themes were converted into provocative propositions. Subsequent discussion and actions were documented.

Case Study Protocol Questions

The case study protocol for both groups included the following questions

<u>From analysis of AI report or interview documents:</u>

1. What themes were identified from the interviews?
2. What provocative propositions were created from the themes?
3. To what extent was the AI cycle applied with this group?

Participant observation

4. What changes were observed during or since the interviews that could be attributed to the use of AI?
5. In what ways was the use of AI with group effective towards the goal of improving clinical trials efficiency?
6. What were the limitations, barriers, or obstacles to the use of AI with this group?

IRB Review and Approval

This study involved direct contact with human subjects so application was filed with the Public Health-Nursing IRB. The submission was reviewed by the Office of Human Research Ethics and determined to be exempt from further review (i.e., "exempt from continuing review"). All interviews were conducted in confidential settings and all field notes were stored under password protection on an encrypted computer. Written consent was not required; verbal consent was obtained from the disease group leaders.

Limitations and Opportunities

The interactive and humanistic nature of research such as this case study requires the investigator to build rapport and credibility with the participants. The degree to which this occurs may vary by participant and may impact the data that is collected. Though an interview guide was used, follow up questions were adapted to the responses of the participants and were, consequently, not uniform. Responses may have been limited by concerns about expressing negative information about the CPO or the UNC Lineberger. The selection of themes from the interview notes was subject to bias but validated by a second reader.

An important limitation of all action research described in the OD literature is that outcomes of action research studies should not be expected to be reproducible without a thorough consideration of the context. The case study protocol provides a certain degree of reliability should future researchers desire to undertake a similar case study. In terms of external validity, this case study seeks to generate knowledge about the use of AI in a university-based cancer center and may be analytically generalizable to the extent the context is taken into account. An advantage of using AI for action research is that it is designed to adapt and account for the uniqueness of each organization. The principles and techniques used in this case study may be applied elsewhere and the results can inform future AI initiatives at UNC and other cancer centers.

Chapter 4: Results

This chapter describes the results of a case study that was designed to better understand how AI can be used to improve clinical trials efficiency. AI was applied with research coordinators and disease team leaders at the UNC Lineberger and case study protocol questions were addressed using document analysis and participant observation as follows:

Research coordinators: Questions 1 and 2 were answered through analysis of documentation from a process improvement initiative (described below and in Chapter 3). Questions 4 and 5 were answered through participant observation. Questions 3 and 6 drew on both.

Disease team leaders: Questions 1 and 2 were answered through primary analysis of interview notes. Question 3 was answered using interview notes with additional information from participant observation. Questions 4, 5, and 6 were answered through participant observation.

A brief introduction, including rationale for inclusion and topic selection, is provided for each group followed by findings.

I. Case Study Protocol: Research Coordinators

Introduction

A process improvement initiative using AI with the CPO's research coordinators was conducted in June 2011. An increase in turn-over had prompted a

request from the CRLT that the research coordinators be interviewed and AI was selected as the format for the interviews based on: an interest in shifting away from deficit-based problem solving; a need to think outside the box to find solutions; and a sense that appreciating what had worked well in the CPO would be beneficial.

The AI topic was constructed by reframing the most pressing concern about turnover as a generative topic: fantastic research coordinators shepherding the best clinical trials in the US. The interviews focused on how best to recruit and retain outstanding research coordinators, an essential factor in the efficient conduct of clinical trials. The selection and recruitment processes are described in Chapter 3. Topics mentioned in the interviews by two or more research coordinators were included as themes. No theme was mentioned by all 10 participants.

Results from document review (report on AI process improvement initiative)

1. What themes were identified from the interviews?

Research coordinators would like to see:

- better training for new nurses
- that they are located with each other and near the cancer hospital
- sanctioned flexibility about hours and schedules
- more competitive salaries and opportunities to increase take-home pay.
- more recognition
- career ladders
- use of workload metrics
- a more supportive culture

2. What provocative propositions were created from the themes?

1. Research coordinators receive orientation from colleagues who are actively enrolling patients and are knowledgeable about logistical details. Other relatively new coordinators share their experiences to smooth and shorten the learning curve. A checklist is used so that new coordinators and their colleagues feel confident they are well prepared for the challenges of being research coordinators and are cognizant of the differences between research nursing and floor nursing. All coordinators are part of a supportive team.
2. Research coordinators are located together in close proximity to their patients in the NC Cancer Hospital, facilitating support, information exchange, and cross-coverage. Coordinators meet as needed with members of their team who, due to less frequent patient contact, are in other locations.
3. Workload metrics and staff input are used iteratively and transparently in making work assignments. Research coordinators customize their schedules to optimize performance and meet the needs of their trials and their work teams. Research coordinators may work overtime when necessary to cross-cover while positions are being filled. Each week, time is included for "downtime" aka paperwork and organizing so that trials run smoothly. Research coordinators participate in meetings focused on issues of relevance. Research coordinators receive recognition of superlative work in the form of raises when possible but through a wide range of other mechanisms on a consistent, on-going basis.

4. A career ladder enables research coordinators to strive and grow (whether HR-official or designed internally). New responsibilities are assumed as experience and knowledge increases. Mentoring and career development conversations are provided regularly by other members of the CPO.

5. The whole organization fosters and operates through open communication and teamwork at all levels (investigators, management, nurses etc.). CPO management is receptive and responsive to input. Silos across groups are made irrelevant by shared goals and collaborative operations.

3. To what extent was the AI cycle applied with this group?

The research coordinators participated in the Discovery phase of AI through interview questions that comprised the process improvement initiative. Stories about the best of "what is" were shared in response to interview questions about peak times. The documentation provided to the CRLT included high points mentioned by more than one participant: their interactions with physicians; coordinator's relationships with patients; the pride they feel for the institution; and opportunities to learn, especially about the science of cancer. Whether the research coordinators shared their high points with each other informally after the interviews is unknown.

The Dream phase was initiated by asking questions about "what might be" with a standard AI question customized to the CPO ("We could all use more rest, so let's say we have a great sleep that last for 10 years. You wake up to find the CPO is everything you ever dreamed of. What does that look like?").

For the Design phase, the sense-making (analyzing the stories) and generation of provocative propositions were conducted by the interview team not by

the participants. These propositions were shared with the CRLT but have not yet been shared with the research coordinators. Research coordinators have not officially participated in the Destiny phase, though some steps have been taken to implement pieces of the propositions. Both the Design and Destiny phases could be continued as part of the plan for change, following presentation of the results.

Results from participant observation

4. What changes were observed during or since the interviews that could be attributed to the use of AI?

Several major administrative changes were made by the CRLT immediately after receiving a report from the interviews with the themes and provocative propositions. In particular, major management changes were made, corresponding to provocative proposition #5 (would like to see more receptive and responsive managers) and announced at a "town hall" meeting to which the entire CPO was invited. The facility director was reassigned and a nurse management group was established. A new medical director was appointed (position had been vacant) with authority to make change that had not been given to previous medical directors. CPO staff were encouraged to share input and numerous suggestions were received.

After the town hall, a meeting was held with a core group of research coordinators and clinical research associates (CRAs) to begin a group discussion. At this meeting, it was reported that morale among the research coordinators had improved as a result of the AI interviews and that turnover had slowed. The group expressed general optimism that things had taken a turn for the better. A pair of research coordinators volunteered to draft a proposal outlining parameters for

flexible work hours (part of provocative proposition #3) and a collaboration between two nurses had been initiated to work on changing the orientation process for new research coordinators (part of provocative proposition #1).

Through numerous discussions with senior research coordinators, the first part of provocative proposition #2 was implemented: the majority of the research coordinators were co-located in the NC Cancer Hospital by the end of 2011. Discussions were initiated about how to enact the second part of proposition #2 (meet as needed with members of the team in other locations) and are ongoing.

For proposition #3, administrative changes were made so research coordinators could be paid overtime (they could only accrue comp time previously). Efforts are ongoing to shift responsibility for assigning trials from a single manager to a group of senior research coordinators, with input from the disease team leaders. Effort tracking software was purchased and planning for implementation was begun.

5. In what ways was the use of AI with this group effective towards the goal of improving clinical trials efficiency?

The propositions generated through the AI process led to several actions that could increase efficiency in the long run, including better training for new research coordinators and relocation of the research coordinators to the NC Cancer Hospital. Implementation of additional items from the provocative propositions is underway (i.e., flexible hours) and members of an advisory team of senior coordinators reported that optimism was high. No research coordinators have resigned since the AI interviews. Improved morale among the research coordinators could have a secondary effect on improving clinical trials efficiency, both by preventing turnover and by improving interactions.

6. What were the limitations, barriers, or obstacles to the use of AI with this group?

The documentation noted that majority of research coordinators (10 out of 15) were willing to participate in AI interviews, suggesting they were open to engaging in its use. However, the extent of the effect was limited by the fact that the research coordinators were only minimally empowered to make changes; a system-wide AI initiative with the necessary stakeholder support could lead to greater impact.

II. Case Study Protocol: Disease Team Leaders

Introduction

The CPO's disease team leaders were selected for inclusion in this research about how AI might be used to improve clinical trials efficiency because they design trials, set trial priorities, and provide medical leadership for the disease teams, all of which are key to efficiency. The disease team leaders would be key stakeholders in deciding whether to undertake a system-wide AI initiative, so understanding whether they are receptive to its use and how they might respond was needed.

The AI topic for this group was constructed by reframing the overarching question at issue: building on what works well to make the CPO one of the most efficient clinical trials organizations in the country. The primary focus of the disease team leader interviews was the circumstances under which clinical trials run most efficiently. Additionally, an emerging issue about how best to organize staff in the disease teams prompted addition of a question as a sub-focus. Procedures for selection and recruitment of participants are described in Chapter 3. Topics that were mentioned by three or more disease team leaders were included as themes.

Three themes were mentioned by all six disease team leaders.

Results from document analysis (interview notes)

1. What themes were identified from the interviews?

Disease team leaders would like to see:

- exciting trials with interesting science that are opened and completed quickly
- a good safety record; issues found early
- high quality, clean data with no errors ready for use by investigators
- clarity about roles and expectations for all personnel (faculty leaders, staff)
- well trained and mentored staff who enjoy their work and have adequate control over workload to perform well
- a central office that handles some administration but a strong sense that the disease groups are teams; staff are accountable to disease team leaders
- transparency of CPO systems, operations and structure especially work assignments and workload determination
- assistance writing papers; reduced time from activation to publication

2. What provocative propositions were created from the themes?

1. UNC Lineberger concentrates its efforts on novel, interesting trials with exciting science. High levels of energy and enthusiasm contribute to opening and completing these trials quickly.

2. The safety record of trials managed by the CPO is impeccable. Any safety issues are identified early and trials are conducted with no errors.

3. Excellent data management produces data that are clean and tight. Data quality is monitored and anomalies are corrected quickly. Time from trial initiation to publication of results is minimized because data are provided to investigators in a useable format. Biostatistics personnel are actively involved and writing assistance is available.

4. Centralized CPO systems and processes are transparent and clearly articulated. Information describing procedures, policies, and structure (what are pods, POEC) is distributed on a regular basis, especially to new investigators.

5. Disease groups are cohesive teams. Research staff are responsible to disease team leaders, who have access to workload metrics in facilitate assignment of work to their team members.

6. Everyone involved with the CPO – disease team leaders, investigators, managers, research coordinators, coordinator assistants CRAs – knows what is expected of them and what they can expect of each other. Roles are clearly defined even if there is variation between individuals holding similar roles on different disease teams.

7. Research staff are well trained and mentored. They have enough control over their workload that they are able to do a good job and be satisfied with their work. The work environment is pleasant; faculty and staff at all levels are cooperative and collaborative.

Results from document review and participant observation

3. To what extent was the AI cycle applied with this group?

By responding to the interview questions, the disease team leaders completed the Discovery phase of AI. All participants recalled multiple trials (identified by trial number) that ran smoothly and efficiently. "Peak times" occurred most often when a high level of enthusiasm about the science was present and when the trial was a high priority for both UNC and for the sponsor. Some participants recalled high points when trials were planned well in advance at UNC and when a cohesive team was involved. These high points will be shared through presentation of the case study to the Protocol Office Executive Committee (POEC). It is not known if the disease team leaders have shared highlights with each other.

The "overheard question" served as a first step of the Dream phase. In many cases it was necessary for the interviewer to follow the scripted question ("you overhear a fellow disease team leader telling a clinical trialist from another institution about our clinical trials office, what do you want to hear him say?") with clarification that the question pertained to an imagined a future where the CPO was functioning well. The "three wishes" question was met with mixed response. Some participants had responded to the overheard question with the equivalent of three wishes and others found the question too abstract (i.e., did not find wishing for change to be a useful exercise). Though most were able to think of either a simple step that could be taken, a bold step or both, some found these questions a bit perplexing.

For the Design phase, the sense-making (analyzing the stories) and generation of provocative propositions were conducted by the interviewer not by the

participants. The Design phase will be continued as part of the plan for change. Several concrete ideas about how to configure the disease teams were elicited from the pertinent question and could be a focus of discussion following the presentation of the case study. Suggestions elicited in response to the small steps and bold ideas questions that did not constitute themes (mentioned by only one participant) could also be included in the presentation. The Destiny phase may be initiated as part of the plan for change depending on the outcomes of the presentation.

Results from participant observation

4. What changes were observed during or since the interviews that could be attributed to the use of AI?

Several ideas described in the interviews (including two bold steps) were overheard in conversations or meetings in the week following the interviews. In at least two instances, the statement was made by a non-participant who had recently interacted with the participant who suggested it. Some of the provocative propositions may be implemented; most will take a substantial time to be realized. These changes will be tracked in the plan for change.

5. In what ways was the use of AI with this group effective towards the goal of improving clinical trials efficiency?

Several provocative propositions were generated that, if implemented, could improve clinical trials efficiency. By aggregating the opinions of the disease team leaders, their collective request for changes with the potential to improve efficiency may carry more weight with stakeholders.

Because the disease team leaders are empowered to make changes within their own teams, participation in the inquiry may prompt small positive changes that could lead to greater efficiency and which might then be shared with other teams. Asking the disease team leaders to imagine a preferred future may generate additional ideas in the future. The interviews concluded with a statement that people who participate in AI sometimes find the questions spark ideas after the interviews. Participants were asked to contact the interviewer should this occur.

6. What were the limitations, barriers, or obstacles to the use of AI with this group?

All of the disease team leaders agreed to participate and were engaged by the opportunity to provide information that might help improve efficiency. However, conducting appreciative interviews using the topic of improved efficiency with the disease team leaders proved more challenging than using the topic of recruitment and retention with the research coordinators. The efficiency topic, though relevant and important, was less personal and more abstract. AI prompts consideration of whether the right questions are being asked and, if the disease team leaders had selected the topic as a group themselves, perhaps they might have chosen a more tangible or smaller-scale question to address first.

The degree to which the disease team leaders were able to envision a positive future seemed to vary. As anticipated from the literature, some physician participants found the positive focus foreign. The majority of the responses could be framed as things they would “like to see more of” rather than deficits that needed fixing but seeing past the deficits to a preferred future was not simple.

Chapter 5: Plan for Change

As stated in Chapter 1, this case study was designed to investigate how appreciative inquiry can be used to improve clinical trials efficiency and to deliver a case study report on a trial application of AI at the UNC Lineberger Comprehensive Cancer Center. This plan puts forward six recommendations to advance and sustain change towards creating a more efficient cancer clinical trials system.

Recommendation 1: Present case study report to the POEC

Presentation of the process and findings of the case study will be made to the POEC (comprised of the disease team leaders and other cancer center leaders). POEC is an open meeting and other members of the CPO can be invited to attend, especially the research coordinator participants. A discussion will be facilitated about whether the provocative propositions can be used to design an action plan (AI Design phase); whether additional ideas about improving efficiency have been generated since completion of the interviews; or whether an alternative approach to guiding the change process can be envisioned. The members of the POEC are the key stakeholders for future change efforts in the CPO and would decide whether to proceed with more extensive (e.g., whole-system) AI initiatives to improve efficiency. If so, a steering committee comprised of representatives from various CPO groups would be assembled and charged with implementing Recommendation 2.

Recommendation 2: Initiate system-wide application of AI with the CPO.

As outlined in Chapter 2, AI is predicated on the idea that organizations move towards what they study. The steering committee representing all members of the CPO would be responsible for selecting the affirmative topic choice and designing the scope of the initiative. Key issues to resolve with cancer center leaders when defining the scope will include cost and establishing boundaries for potential change (i.e., what the group is not empowered to change). The results of this case study can contribute to initial topic discussions; concerns identified by this research such as the composition of and roles in disease teams or the organizational structure of the CPO (i.e., what functions should be centralized and what should be managed by the disease teams) will be suggested as possible areas of inquiry, though the steering committee will define the topic. Relevant concepts in leadership theory and practice (see Recommendation 6 below) should guide this change effort.

Recommendation 3: Monitor efficiency metrics and assess impact of AI

This case study report describes how AI was used with the CPO and the extent to which it had a proximal impact on clinical trials efficiency. Downstream effects on time-to-activation and percentage of trials meeting accrual goals will be measured over the subsequent 12-18 months. As described in the literature review, quantitative data on these measures is being captured by members of UNC's RaPID team. If improvements in these metric are observed, qualitative data will be obtained to assess the contributions of AI to the improvement. Follow-up interviews can be designed and conducted with research coordinators and disease team

leaders (and other participants if a system-wide initiative occurs) to assess changes attributable to the use of AI.

Recommendation 4: Assess other potential AI applications at UNC Lineberger

Applying concepts from leadership theory and practice (see Recommendation 6), key stakeholders will be identified and invited to consider other potential change efforts that would benefit the UNC Lineberger, including the use of AI with other groups. For example, UNC Lineberger's Program Planning Committee (PPC) is comprised by leaders of the 10 programs of cancer research but expectations of the programs and their leaders are not clear. With significant growth of the UNC Lineberger in recent years, including faculty additions, the programs have an opportunity to play a larger role in setting scientific directions, mentoring young faculty, and supporting collaborations within and between programs. A number of topics could potentially be selected for an AI initiative with the programs and leaders. Members of the PPC could potentially serve as a topic selection steering committee.

Jacqueline Stavros and others have demonstrated that in some cases where stakeholders are not familiar with AI, or perhaps less amenable to it, a positive approach to change is more easily adopted if it is first introduced as the SOAR (strengths, opportunities, aspirations, and results) model.[49] SOAR is a positive approach to strategic thinking used in place of the SWOT (strengths, weakness, opportunities, and threats) model, with which most cancer center faculty are familiar. Other leadership concepts, which are relevant to strategic planning and may be employed to bring about change at the UNC Lineberger, are described in Recommendation 6.

Recommendation 5: Publish and present findings

Findings will be disseminated as appropriate to cancer clinical trials organizations, the cancer research community, AI practitioners, and the field of OD through publications or presentations. The AI Commons invites doctoral students to post completed dissertations that used AI on their website. The journal, *AI Practitioner,* publishes on the use of AI as does the Journal of Applied Behavior Sciences, the source for numerous articles in the literature review for this dissertation. The Association of American Cancer Institutes has a Clinical Research Initiative group that meets regularly. The users group of the OnCore database, a data management system for cancer clinical trials, holds national meetings twice a year and invites presentations on relevant issues such as efficiency.

Recommendation 6: Apply and disseminate leadership theory and practice

Applications of leadership theory and practice can significantly contribute to improving the cancer clinical trials system at UNC and elsewhere. Though many leadership concepts could support the change effort with the CPO, several specific examples are provided as part of this recommendation.

Starting with the POEC, a guiding coalition will be built, tracking with the advice of John P. Kotter: the right people need to be involved, including individuals who have strong position power, high credibility, and leadership skills.[50] Kotter entreats leaders to develop a vision and strategy, communicate the change vision, empower employees for broad-based action, and generate short-term wins.[50] On numerous occasions, the UNC Lineberger's leadership team has discussed the

need to create a mission statement and a shared vision for the CPO. The practices that comprise Kotter's action plan for leading change can facilitate this process.

In his plenary address, *Escape Fire: Lessons for the Future of Health Care,* Don Berwick's ties together several sources of leadership advice, including that of Karl Weick who Berwick considers a student of organizations under stress (characteristic of the CPO).[51] A central function of organizations is sensemaking, the process through which order is created and "people can orient themselves, find purpose, and take effective action."[52] Berwick recounts Weick's story of a group of soldiers who, desperate to find their way out of the Alps, find and use a map to successfully guide themselves out, only to realize later it was a map of the Pyrenees. From this Weick points out that part of the value of sensemaking is that sometimes "when you are lost, any map will do." [51] Whether sensemaking in the CPO is accomplished using the phases of AI or another mechanism, caution should be used as staff roles are redefined. Berwick related this "recipe" for the collapse of sensemaking from Weick:

> Thrust people into unfamiliar roles; leave some roles unfilled; make the task more ambiguous; discredit the role system; and make all of these changes in a context in which small things can combine into something monstrous.[51]

Berwick also shared an applicable personal lesson, noting that he experienced that in a hospital, "the people work well, by and large, but the system often does not."[51] The CPO has many hard working individuals but systems that may not. A systems view, and changes to systems, will be needed to advance change in the CPO.

The CPO could benefit from becoming what Weick and Sutcliffe deem a "high reliability organization." In a high reliability organization, a mindful infrastructure tracks small failures; resists oversimplification; remains sensitive to operations;

maintains capabilities for resilience; and takes advantage of shifting locations of expertise.[5353] If the CPO were to become a high reliability organization, it would have greater capacity to manage unexpected events that threaten its efficiency.

There are many other leadership lessons and tips that can benefit the CPO and its personnel. Disease teams rely on lower-level staff to ensure necessary steps are taken. To facilitate important information exchange processes, these individuals are often called upon to lead people over whom they have no control. The CPO encompasses individuals with many competing interests and priorities. To lead the organization through its many inevitable conflicts, mediation tools are needed to transform that conflict into opportunity.

Conclusion

Finding better treatments for cancer is a global priority. Academic medical centers like the UNC Lineberger make unique contributions to the nation's cancer clinical trials program. Innovative approaches to improving the efficiency of clinical trials are needed. This case study describes how AI was applied with two key groups within the UNC Lineberger's clinical trials organization, demonstrating that receptivity and responsiveness to AI can be found in such an organization and that application of AI with these groups can generate ideas that may lead to improved efficiency. Further research is needed to establish a causal relationship between applications of AI and improvements in efficiency. This work also demonstrates that continued applications of leadership theory and practice, including strategic planning and organization development techniques, can contribute to the advancement of efforts to develop better treatments for cancer.

Appendix 1: Email Invitation to Research Coordinators

The CPO is the largest core in the Cancer center and critical to the LCCC mission. The clinical trials efforts have been very successful over the past few years. Accrual reached over 1000 pts on therapeutic trials this year. Important trials have been presented at national meetings and published in top journals. Our cancer center core grant was rated outstanding by the NCI. The cancer center leadership is very proud of the CPO. However, we are all worried about the nursing shortage. We are soon to be operating with only 11 nurses, which is down 30% from our planned staff capacity.

Dr Earp has asked Wendy Sarratt (Assistant Director at LCCC) and me to interview all the CPO nurses to get some perspective on the potential reasons for the nursing shortage and how we can improve hiring and retention of top quality research coordinators like you. We are interested in talking to you about what is working well and how we can make things better. All of your answers will be confidential and will not be reported individually, only in aggregate.

We hope you will be willing to help us in this process. Are you free to talk for 15 min later this week or next? If you are not comfortable talking, would you fill out a 5 question questionnaire?

Thanks,

Claire Dees and Wendy Sarratt

Appendix 2: Research Coordinator Interview Guide

1. Think back to when you decided to accept your position in the CPO. What inspired you to say yes to coming here? What keeps you here?

2. Tell me about a high point for you during your time as a CPO nurse.

3. If we were to ask people who know you well, what are the three best qualities or capabilities they would say that you bring to the CPO?

4. If you had three wishes for yourself and your research coordinator colleagues, what would they be? What would you like to see more of?

5. Thinking about the CPO as a whole, what does it look like when it's at its best?

6. We could all use more rest, so let's say we have a great sleep that last for 10 years. You wake up to find the CPO is everything you ever dreamed of. What does that look like?

7. What is the simplest step we could take to make that dream a reality? What is the boldest step you can think of?

8. Anything else you want to share?

Appendix 3: Email Invitation to Disease Team Leaders

Dear Disease Team Leaders,

Some of you know that I am a candidate for a DrPH (doctorate of public health) from UNC's executive doctoral program in health leadership. I am interested in integrating my dissertation into our efforts to improve the efficiency of the CPO. One piece of the data collection for my case study involves interviewing the pod leaders about your experience with the CPO, what works well, and what we might do to make it run more efficiently.

I am writing to ask if you would be willing to participate in my research study. If you are, can we schedule about 30 minutes to talk? All of your answers will be confidential and will not be reported individually, only in aggregate. Because there are a small number of you, there is a chance that your input might be discernible to your colleagues. My dissertation committee has asked that I give a presentation of my results to the folks who are part of the case study, so I will hold a forum and invite the faculty and staff involved with the CPO to that. If the presentation were to include information that had any chance of being linked back to you, I would let you review the slides before they are presented and make changes if necessary (the topics we might touch on in the interview are not sensitive information). I am also hoping to publish results and would be happy to share drafts before they are submitted.

Let me know if you have any questions about this and I look forward to speaking with you.

Thanks, Wendy

Appendix 4: Disease Team Leaders Interview Guide

As you know, our conversation today is part of a case study I'm doing for my dissertation research on clinical trials efficiency as part of a doctoral program in health leadership. This study has been exempted from full review by the IRB and the email you received inviting you to participate covered issues related to confidentiality and reporting the results of the study. Would you like me to go over those with you? I'm going to read a brief introduction and then ask you six questions. Is it OK if I write down your responses? Do you have any questions before we get started?

Clinical trials efficiency is a national concern that we share here at the UNC Lineberger. There are numerous efforts underway nationally to try to improve the system, like our RaPID grant working on time to activation goals and the new scoring system we've started using in POEC to prioritize trials. Even with the concerns we are trying to address, there are many things about the CPO that work well. As we move ahead, we want to see if there ways we can build on what works well to move towards making our clinical trials organization the best in the country.

1. Tell me about a time when a trial in your pod ran smoothly and efficiently? Who was involved? What was different about that trial that made it stand out?

2. You're at a national meeting and you overhear one of your fellow disease team leaders telling a clinical trialist from another institution about our clinical trials office. What would you want to hear him say?

3. We're currently in a state of transition with disease teams trying out new ways of assigning tasks and redefining roles. If you could reconfigure your team any way you wanted, what would that look like?

4. If you had three wishes for yourself and the CPO, what would they be? What would you like to see more of?

5. What is the simplest step we could take so that our CPO conducts trials more efficiently and successfully than you ever imagined it could? What is the boldest step you can think of?

6. Anything else you want to share?

Thank you very much for your time. I appreciate you sharing your thoughts with me on this topic, which will help both with our work to optimize the CPO and with my health leadership doctoral work. I will be looking for themes across the interviews and then the POEC can talk as a group about how we might move forward. Also, people who participate in appreciative inquiry sometimes find that the questions spark ideas after the interviews are over and if you think of other changes you'd like to see, please let me or Bert know. Thanks again.

Appendix 5: List of Definitions

ACCRUAL: The process of placing patients on trial; a patient on a trial. .

ACCRUAL GOAL: the number of patients sought for a clinical trial.

ACCRUE: to enroll a patient on a trial.

ACTIVATION/ACTIVATE: the point when patient enrollment on a trial may begin. .

CLINICAL: Pertaining to or founded on observation and treatment of participants, as distinguished from theoretical or basic science.

CLINICAL INVESTIGATOR: A medical researcher in charge of carrying out a clinical trial's protocol.

CLINICAL TRIALS: a research study to answer specific questions about new therapies or new ways of using known treatments. Clinical trials are used to determine whether new drugs or treatments are both safe and effective in four phases (see below)

ENROLLING: The act of signing up participants for a study by evaluating whether they meet the eligibility criteria for the study and by going through the informed consent process.

INVESTIGATIONAL NEW DRUG: A new drug, antibiotic drug, or biological drug that is used in a clinical investigation.

NEW DRUG APPLICATION (NDA): An application submitted by the manufacturer of a drug to the FDA - after clinical trials have been completed - for a license to market the drug for a specified indication.

OPEN: the point at which a protocol is available to patients

PHASE I TRIALS: Initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.

PHASE II TRIALS: Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.

PHASE III TRIALS: Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended

to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling.

PHASE IV TRIALS: Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use.

PROTOCOL: A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

TARGETED ENROLLMENT: the number of patients needed for a trial (see also accrual goal).

TREATMENT TRIALS: Refers to trials which test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy

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