STUDYING AND FACILITATING THE DEVELOPMENT, INSTALLATION, AND INITIAL IMPLEMENTATION OF AN INTERDISCIPLINARY BUPRENORHINE TREATMENT/ PRACTICE WITH A PUBLICLY FUNDED, HIV PRIMARY CARE, DESIGNATED AIDS CENTER IN NEW YORK CITY: A PRACTICE-FOCUSED, ACTION RESEARCH, IMPLEMENTATION STUDY

by

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A dissertation submitted to Social Welfare in partial fulfillment of the requirements for the degree of Doctor of Philosophy, The City University of New York

2013

This manuscript has been read and accepted
by the Graduate Faculty in Social Welfare in
satisfaction of the dissertation requirement
for the degree of Doctor of Philosophy.

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Abstract

STUDYING AND FACILITATING THE DEVELOPMENT, INSTALLATION, AND INITIAL IMPLEMENTATION OF AN INTERDISCIPLINARY BUPRENORHINE TREATMENT/ PRACTICE WITH A PUBLICLY FUNDED, HIV PRIMARY CARE, DESIGNATED AIDS CENTER, IN NEW YORK CITY: A PRACTICE-FOCUSED, ACTION RESEARCH, IMPLEMENTATION STUDY

by

Nancy Murphy

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Using Action Research, Implementation Science, and Institutional Ethnography, this practice-focused research explored inhibiting and promoting factors related to implementing buprenorphine treatment within HIV primary care while simultaneously developing, installing and initially implementing an interdisciplinary buprenorphine treatment/practice. Data was collected and analyzed using constructivist grounded theory method strategies. Data collection/generation included documentary analysis, key informant interviews, field data from collaborative interdisciplinary team processes, researcher reflective practice, a patient focus group, and an interdisciplinary buprenorphine treatment/practice manual.

The research had several achievements. It identified three key implementation inhibiting categories, (1) significant and persistent bias, (2) plaguing and difficult questions, and (3) buprenorphine expectionalism. It also developed countering implementation promoting categories, (1) be an educated advocate and dispel myths, (2) identify core components of interdisciplinary buprenorphine treatment and uniformity of care, and (3) dementionalizing interdisciplinary treatment/practice. It exposed scope of practice issues and mapped out the

specifics of the types of services each discipline would provide, the detail of those practices, their coordination, as well as the areas of practice where there was joint responsibility and overlap. It increased the capacity and competences of the research organization and the 18 interdisciplinary buprenorphine team members. It also explicated the many forms of power operating in the study and the importance of power sharing, adapting treatment, leadership support, structural components and resources on the development and implementation process.

This study shed light on the reality that prescribing buprenorphine and taking up the practice of treating opioid dependence/addiction means that clinicians must be prepared and skilled to provide care where issues of life and death, emotional distress, and significant uncertainties are part of the landscape. The study findings also highlight that balancing safety (both patient and staff) with control and authority is an important aspect of buprenorphine treatment. An interdisciplinary focus expanded the concept of treatment and addressed many important aspects of caring for people with opioid dependence/addiction that often go unaccounted for and/or unnoticed. Without an interdisciplinary frame, patients are at risk for receiving substandard care. This study demonstrated that the interdisciplinary practices needed to provide quality care and improve health outcomes are interdependent.

Acknowledgements and a Million Thanks

First, to all the people who have trusted me and allowed me to provide them health care these past three decades. Your lives and your stories have been my constant teacher and I carry you all in my heart. I honor our relationships and take you with me as I continue on this journey.

To Cak and Jeanette and Amy, who have always believed in me, celebrated every tiny accomplishment toward this degree over the past eight years and given me an unbelievable amount of support. I especially want to thank them and Nora for helping me finish this race.

To the buprenorphine team and all the staff at the research organization, with whom I spent ten years of my life; thank you for your commitment to high quality interdisciplinary care, for all the knowledge sharing, for answering all my questions and for providing a place where this kind of research could happen.

To my dissertation advisor Mimi and many others who taught me and mentored me so well along the way, especially: Jeanette, Jean, Jerry, Alison, Mary, Jan, Stephen, Sioban, Lynne, Leonard, Lia, Claude, Sister Alice Margaret, Mrs. Curr, and the research key informants and the focus group participants.

To my family, for all their love, support and encouragement, especially my Aunt Gertrude, Lillian and Ed.

To my mother and father, for loving me so much, for being my fan club, for showing me what it meant to care about people and how to be a good decent human being. I hope I have made them proud and made all their hard work worthwhile.

To Jerry and Alex, for our family and our life together, for everything you gave me along this path to make it a success, for more than words can express. This is a joint accomplishment!

And a special thank you to President Barack Obama for being a shining example of a hardworking, balanced, smart, thoughtful person, who now, as a second term president, can openly express concern for all people. It is a personal pleasure to hear Obama relay the importance and need for greater fairness for all members of society in the US, especially those who struggle with significantly low incomes. I am delighted to hear him discuss more fair distribution of resources. It's overdue and much needed. I also really want to thank him for working so hard to win the election of 2012; it inspired me to keep on keeping on. And most importantly, thank you for being the president of my county.

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Chapter 1: Introduction

This practice-focused, action research, implementation study is concerned with improving the delivery of services within a primarily publicly funded, hospital-based HIV primary care practice, by studying and facilitating the development, installation and initial implementation of an interdisciplinary buprenorphine treatment/practice (IBT/P) for people with opioid (heroin, pain pills) dependence/addiction.

In the US, treating opioid dependence/addiction with buprenorphine in an office-based setting only became possible following the regulatory changes that accompanied the passage of the Drug Addiction Treatment Act (DATA) of 2000 (DATA, 2000) and the Food and Drug Administration (FDA) approval of buprenorphine in 2002. Prior to these changes it was illegal for physicians to treat opioid dependence/addiction with maintenance medications (such as methadone) in an office-based setting. When methadone was approved for treatment of opioid dependence/addiction, The Methadone Regulations of 1972 and the Narcotics Act of 1974 came with extensive restrictions, which only allowed methadone treatment to take place in highly regulated methadone maintenance treatment programs (MMTPs). This resulted in keeping the treatment of opioid dependent/addicted individuals outside of mainstream health care (Rettig & Yarmolinsky, 1995). It also resulted in a service delivery gap for people with opioid dependence/addiction, as there are significantly smaller numbers of MMTP "treatment slots" available, compared to the number of people with this diagnosis (Joseph, Stancliff & Langrod, 2000; Livert & Winick, 2006). DATA 2000 allowed for treatment of opioid dependence/addiction to expand to office-based settings and the FDA approval of buprenorphine, allowed for treatment options to expand beyond methadone. However, despite these regulatory changes, buprenorphine has been slow to be adopted into care (Gunderson & Fiellin, 2008).

Approximately 2 million people in the US are opioid dependent; approximately 1.9 million people are dependent on pharmaceutical opioids (pain relievers) and approximately 359,000 people are dependent on heroin (Substance Abuse and Mental Health Services Administration (SAMHSA), 2011). However, in 2008, only 272,352 people received methadone maintenance in the US (Bruce, Kressina, & Cance-Katz, 2009). In New York City (NYC), which has the largest number of heroin users in the county, it has been estimated that approximately 160,000 people are opioid dependent (Frank, 2000; Johnson & Rosenblum, 2003), but true prevalence is not well understood. New models are being developed to better understand the basic size and characteristics of this population as problematic users of heroin and pharmaceutical opioids in NYC, "constitute a hidden population engaged in illegal and highly stigmatized activity and may only come to attention at times of crisis" (McNeely, 2008).

The MMTP services in NYC only have a treatment capacity for 37,000 people (New York City Department of Health and Mental Hygiene (NYC DOH MH, 2008), and in June 2011, only 5,877 unique individuals had received prescriptions for buprenorphine (D. Heller, personal communication, October 31, 2011). In addition to long standing limited access to treatment for opioid dependence/addiction through MMTPs and slow adoption of buprenorphine, there has been an increase in the number of deaths related to opioid overdoses in the past decade (Okie, 2010) and between 2004 – 2008, a more than doubling of visits to emergency room related to opioid misuse abuse (Kuehn, 2010). Untreated, opioid dependence/addiction carries significant morbidity and mortality risks (Bruce & Altice, 2007).

The nature of this problem merited investigation and action. The researcher initiated, studied and facilitated the collaborative development, installation and initial implementation of an IBT/P within an HIV primary care/Designated AIDS Center (DAC) where she had been

working as a nurse practitioner/HIV primary care provider for many years. Of the forty-four DACs in New York State (NYS), most had not integrated buprenorphine treatment (D. Rudnick, personal communication, October 16, 2009), including the practice setting of the researcher. In addition to developing, installing and initially implementation of an IBT/P, the researcher set out to explore and describe:

1. What factors promote or inhibit the development, installation and initial implementation of an IBT/P within a primarily publicly funded, hospital-based, HIV primary care/ DAC in NYC?
2. How can Action Research (AR), Implementation Science (IS), and Institutional Ethnography (IE) inform the development, installation and initial implementation of an IBT/P within a hospital-based HIV primary care/DAC in NYC?

Purpose of the Research and its Relevance to Social Welfare

Social welfare is committed to "developing strategies for effective change at the individual, agency, community, and larger political economy levels" (Doctoral Programs, 2013). This study was developed to address effective change on all these levels. It has three main interdependent goals, all of which are relevant to the commitments of social welfare.

1. Improve the Delivery of Services, Increase Access to Treatment and Improve Health Outcomes for Individuals with Opioid Dependence/Addiction

The first purpose of this study was to improve the service delivery at the DAC by developing, installing and initially implementing IBT/P, thereby increasing access to treatment, with the expectation of improving health outcomes for people with opioid dependence/addiction. Individuals with this diagnosis and often their families and communities are at high risk for related morbidities such as accidents and violence, HIV infection, viral hepatitis and other life threatening infections, as well as being subject to a range of social and legal issues. In addition,

people with opioid dependence/addiction are at higher risk for mortality from disease, suicide, homicide, and overdose (Bradley & Zarkin, 1997; Bruce & Altice, 2007; NIDA, Robertson, 1998). The expansion of buprenorphine treatment could contribute to the reduction of the morbidities and mortalities related to opioid dependence/addiction (Gunderson & Fiellin, 2008). "Although there are challenges to implementing drug treatment programs for maximum impact, the scientific literature leaves no doubt about the effectiveness of drug treatment as an HIV prevention strategy" (Metzger, Woody, O'Brien, 2010).

2. Prevent the Risk of the Development of a Two Tiered Treatment System

A second purpose of this study sought to create a more equitable distribution of buprenorphine office-based treatment, by implementing an IBT/P within a primarily publicly funded, hospital based clinic. Gunderson & Fiellin (2008) point out that while buprenorphine treatment has been adopted slowly, where it has been used "it has expanded with disproportionate accessibility to white patients of higher socioeconomic status" (p. 105). They add, "Efforts are needed to prevent the development of a two-tiered system in which disenfranchised patients receive treatment at government-sponsored traditional programs with methadone, while more affluent patients receive buprenorphine in private offices", p. 105).

3. Address the Science-to-Service Gap

The third purpose of this study was to addresses the challenge known as the "science-to-service" gap, by developing knowledge about how to bring evidence-based interventions and best practices into clinical care. In US health care, the science-to-service gap gained attention in 1998, when the National Institute of Mental Health issued *Bridging Science and Service: National Advisory Mental Health Councils Clinical Treatment and Services Research Workshop.* This and subsequent National Institutes of Health reports, (Figure 1) concluded that many

evidence-based treatments exist, (such as buprenorphine) yet there is a paucity of evidence-based strategies to implement these treatments.

Figure 1: Federal Reports Highlighting Science-to-Service Gap

1998: National Institute of Mental Health Bridging Science and Service: National Advisory Mental Health Council's Clinical Treatment and Services Research Workgroup
1998: Institute of Medicine Bridging the Gap Between Practice and Research: Forging Partnerships with Community-Based Drug and Alcohol Treatment
2000: National Institute of Mental Health Translating Behavioral Science into Action: The National Advisory Mental Health Council
2001: Institute of Medicine Crossing the Quality Chasm: A New Health System for the 21st Century:
2002: National Cancer Institute Designing for Dissemination Conference Summary Report:
2003: National Cancer Institute Diffusion and Dissemination of Evidence-based Cancer Control Interventions:
2004: National Institute of Drug Abuse Blue Ribbon Task Force Report on Services Research:
2006: National Institute of Mental Health The Road Ahead: National Advisory Mental Health Council's Workgroup on Services Clinical Epidemiology Research
2006: Institute of Medicine Improving the Quality of Health Care for Mental and Substance-Use Conditions: Quality Chasm Series
2007: National Institute of Mental Health Strategic Plan

Beginning in 2001, the NIH began to fund "Dissemination and Implementation Research in Health" (Department of Health and Human Services (DHHS), 2009), a new field designed to build evidence-based knowledge regarding implementing evidence-based treatments. In 2007, the NIH began holding annual conferences on the Science of Dissemination and Implementation

Research (NIH Conference, 2007), to facilitate research in this field. This research hopes to contribute to knowledge development in the field of implementation research.

Buprenorphine and Opioid Dependence/Addiction

Buprenorphine is a relatively new medication for the treatment of opioid dependence/addiction which has been demonstrated to be safe and effective (Strain, 2011). The *Diagnostic and Statistical Manual of Mental Disorders IV* (American Psychiatric Association, 2000) defines opioid dependence/addiction by physical dependence on opioids (e.g. tolerance and withdrawal) in combination with other features; most significant is the compulsive use or loss of control over opioid use despite ongoing harm. Opioids include both natural (e.g., opium and morphine) and synthetic (e.g. heroin, methadone, oxycodone, hydromorphone and buprenorphine) substances. On a physiological level, opioid dependence/addiction affects the neurobiological function of the brain (Fiellin, Friedland & Gourevitch, 2006). Along with biological factors, opioid dependence/addiction is also mediated by environmental and behavioral factors and is often experienced as a chronic relapsing condition (Baxter, 2011, p. 131).

Buprenorphine Compared to Methadone

In general, outcomes with buprenorphine are similar to those with methadone and both are considered very good choices for the treatment of opioid dependence/addiction (Strain, 2011, pp. 67- 69). However, as noted above, extensive federal regulations govern methadone treatment (Rettig & Yarmolinsy, 1995) and many opioid dependent/addicted individuals are reluctant to access treatment at MMTPs because of the way services are provided, including: medication administered under observation, onerous attendance schedules, dose adjustment without patient consultation and required toxicology testing. These issues have contributed to patient/clinician

mistrust in the MMTP settings as well as stigma and discrimination (Dunn, 2007; Fiellin & O'Connor, 2002; Stancliff, 2002; Vanderkloot, 2001).

Buprenorphine treatment offers multiple benefits over methadone. Because buprenorphine is a partial opioid agonist (methadone is a full opioid agonist), and does not fully bind to the opioid receptor, there is a lower risk of respiratory depression and overdose due to this pharmacological property and therefore buprenorphine is considered a safer medication than methadone (Ling, et al, 2010). It has been demonstrated that neonates, whose mothers are treated during pregnancy with buprenorphine in comparison to methadone, have better outcomes relative to lower need for morphine, shorter hospital stays, and less severe neonatal withdrawal syndrome (Czerkes, 2010; Kraft, et al., 2011). Buprenorphine also has fewer drug-drug interactions with HIV medications (Batkis, Treisman & Angelino, 2010). Other benefits of treating opioid dependence/addiction with buprenorphine over methadone derive from it being available in an office-based setting, where each patient's treatment plan is determined on a case by case basis. Similar to the treatment of other conditions, this allows for privacy, individualized care, a prescription that is filled at a pharmacy, and a medication that is self-administered at home (Ling, et al, 2010). The critiques of buprenorphine are related to concerns about diversion, its higher cost compared to methadone, the need for special training, record keeping and DEA visits along with reimbursement and attitudinal barriers on the part of clinicians (O'Connor, 2010, p1612; Schackman, 2010, p. S29).

Study Goals & Objectives

As discussed above, this study had multiple interdependent goals and seeks to:

- Improve Service Delivery, Increase Access to Treatment and Improve Health Outcomes for Individuals with Opioid Dependence/Addiction.

- Prevent the Risk of the Development of a Two Tiered Treatment System

- Address the Science-to-Service Gap

The study objectives can be subdivided into Practice, Policy and Research objectives:

Practice: Clinical & Organizational

1. Establish a frame and involve staff: Development and communication of a common language, conceptual framework, vision, and mission so staff can be kept informed about the IBT/P and can participate in the shaping and delivery of services. (Organizational)

2. Facilitate a working team to develop the interdisciplinary buprenorphine treatment: Organize and facilitate an IBT/P development, installation and implementation team for the research project that (a) is authorized to determine job roles, responsibilities and distribution of labor (who does what, when, where how and why), (b) will develop a communication structure (which includes a feedback loop for staff, leadership and IBT/P team), and (c) will becomes the lead IBT/P clinicians and administrators once this research is completed. (Clinical & Organizational)

3. Staff Training: Provide in-house staff training as well as facilitate outside training for new skills and knowledge needed by the IBT/P team and staff. (Clinical & Organizational)

4. Treatment: Develop a menu of options and descriptions of the range of interdisciplinary services/treatment that will be part of the IBT/P and indicate how they will be coordinated into the patient's treatment plan. (Clinical)

5. Coordination: Liaison with targeted departments within the hospital affiliated with the research organization and outside community programs, treatment centers, etc. (Organizational)

Policy: Organizational & Legislative

6. Develop associated policies, procedures and protocols, including referrals process, documentation, patient eligibility criteria, screening, assessment, induction, stabilization, maintenance, monitoring, discontinuation, pain management, inpatient issues, billing, etc. (Organizational)

7. Develop associated policies and procedures for care coordination with the IBT/P team, with general staff, outside providers of care, etc. (Organizational)

8. Insure that the agency is in institutional compliance with DATA 2000 requirements and other regulatory and legal issues. (Organizational)

9. Work toward amending DATA 2000 legislations to allow prescribing of buprenorphine by nurse practitioner's once study is completed. (Legislative)

Research

10. Identify state of the art knowledge about the multiple dimensions of treating opioid dependence/addiction (clinical complexities, structural, and patient, clinician-personal, clinician-professional).

11. Design research to study and facilitate the development, installation and implementation of IBT/P using AR, IS and IE.

12. Carry out interviews, collect data and documents, analyze data, and other research activities related to the study design so as to answer the research questions.

13. Determine which treatment, implementation and patient outcomes will be evaluated the first year of service delivery.

14. Establish an IBT/P within an HIV primary care DAC and produce a detailed IBT/P manual in collaboration with the interdisciplinary team to guide practice.

15. Produce a dissertation related to studying and facilitating the development, installation and implementation of an IBT/P within an HIV primary care DAC.

16. Disseminate findings from the research.

Health Care: Defining Implementation Research, Science and Stages of Implementation

Achieving the sustainability of a new treatment/intervention within a health care setting is an effort that can span many years. From the time that an intervention begins as an idea to the time when it is sustained in clinical practice, it has often gone through multiple stages. In the field of health care implementation science, various definitions and descriptions have been offered for these stages. Fixsen, et al. (2005) writes about the challenges of reviewing the literature in this field, "due to a lack of well-defined terms. Diffusion dissemination, and implementation sometimes referred to the same general constructs and, at other times quite different meanings" (p. 4). This challenge has been reiterated by many other implementation science researchers and a glossary for dissemination and implementation was been put forward

in 2008 by Rabin, Brownson, Haire-Joshu, Kreuter & Weaver. In this study, implementation is defined as "the process of putting to use or integrating evidence-based interventions within a setting" (Rabin, et al., 2008, p. 118). Implementation research is defined as, "the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality and effectiveness of health care" (Implementation Science, 2010). The field of implementation science "is inherently an interdisciplinary research area," (Implementation Science, 2010). Implementation research, "addresses the level to which health interventions can fit within real-world public health and clinical service systems" (NIH, 2009).

Despite various definitions, there is academic agreement that implementation is not an event but as a complex process with various stages that are interdependent, can be thought of as occurring along a continuum and movement between the stages is often nonlinear and dynamic. After an intervention has been developed and proven safe and as effective or better than what is currently available, the early stages of the implementation process include assessment of the need for an intervention (Straus, Tetroe & Graham, 2009) and identifying and accessing the intervention (referred to as exploration by Fixsen, et al. 2005, p. 15 and as dissemination by Proctor, 2004, p. 231-232). Deciding, accepting and adopting the intervention usually follows (this stage has been referred to as dissemination by Greenhalgh, Macfarlane, Bate & Kyriakidou, 2004, p. 582). After adoption, Fixsen, et al. (2005) identified a second stage which they called program installation, which includes all the development and installation work that needs to be completed before any treatment commences (p. 16).

These early stages, which are directed at the agency and staff level (Fixsen, et al., 2005, p. 5) are then followed by implementing, (divided into initial implementation and full operation

by Fixsen, et al. 2005, p. 16), embedding, and sustaining the intervention, which includes evaluation along the way. Although there are differences in naming the stages of implementation, there is also academic agreement that strategies such as capacity building for the agency and the staff in the form of training and other activities, collaboration, ongoing identification and resolution of barriers, and modification to the intervention (core components of an intervention should be preserved while other aspects of the intervention are adapted) and the organization of care are key components of implementation. (Damschroder, et al., 2009; Fixsen, et al., 2005; Greenhalgh, et al., 2004; May & Finch, 2009; DHHS, 2009; Proctor, 2004; Proctor, et al., 2009; Rogers, 2003; Straus, et al., 2009).

Fixsen et al.'s (2005) "Stages of the Implementation Process" (pp. 15-17) have been used to guide this work, as stage two, Installation and stage three, Initial Implementation match well to the above definition of implementation and the work done in this study. Fixsen et al.'s identification of a separate stage for development and installation is important because it highlights the work that is required to actually bring a new treatment into practice. Without this identification, this work could get subsumed and not completely accounted for when the general term implementation is used. Stage one, Exploration and Adoption, was completed prior to the start of this study. The remaining three stages of the Fixsen, et al. (2005) Stages of the Implementation Process are, (4) Full Operation, (5) Innovation, and (6) Sustainability, which are beyond the scope of this study.

Grounding Philosophy: Critical & Feminist Scholarship

The grounding philosophy for this research is critical and feminist scholarship because its values and principles mesh well with those of the researcher and the goals of the study. Both of these traditions identify and explore power differentials that operate as vehicles of domination

and control (Freire, 1970; Thompson, 1987). Both challenge premises of unfair legitimacy, authority, and meaning (Lorde, 1984) and seek to use power to generate justice, fairness and civil society. Critical and feminist scholarship pays attention to language and behaviors that contribute to oppression, violence and subjugation (Giroux, 1993) and asks researchers to "look closely at our own practices in terms of how we contribute to dominance in spite of our liberatory intentions" (Lather, 1991, p. 15). It promotes a fair distribution of resources by examining who in society benefits from various policies and actions and encourages actions of resistance to unfair outcomes.

As noted by Guba & Lincoln (1994), "Questions of method are secondary to questions of paradigm, which we define as the basic belief system or worldview that guides the investigator, not only in choices of method but in ontologically and epistemologically fundamental ways" (p. 105). In this research, the critical and feminist paradigm undergirds the: (1) ethics of the study, (2) interpretative lens of the research, (3) choice of theories and methods, and (4) the behavior of the researcher, as values only become meaningful when they are reflected in behavior

Underlying Values of Critical and Feminist Scholarship

- Personal expertise: meaning people are knowledgeable about their own lives.
- Equality of worth of all individuals.
- Historical situatedness.
- Representation of multiple perspectives.
- The understanding of societal structures and relations for purpose of creating change where the benefits of society are more evenly distributed.
- Describing and power sharing as opposed to dividing and conquering.
- Accountability for responsible use of power.

- The power of the whole as opposed to the power of division.
- Using agreement and negotiation as a basis for interaction.
- Speaking truth to power.
- Creating a language of inclusion, empathy and respect for diverse perspectives.
- Providing friendly critique and caring critique.
- Creating practices that reflect these values, creating possibilities, creating a more just society.

Theories

The theories used in this study: AR (Coughlan & Brannick, 2010; Minkler & Wallersten, 2008; Stringer 2007), Normalization Process Theory (NPT) (May & Finch, 2009), and IE (Smith, 1987, 2005, 2006) are philosophically commensurate with critical and feminist scholarship. They were chosen because they are all grounded in the everyday world and experiences of the people involved in the study and are oriented to inquiry with people. This approach is directed to claim and create a subject position for both the researcher and research participants. They emphasize learning and explicating the various ways the object of the inquiry is organized and the consequences of that construction, so as to enact change. Also of significance is that AR, NPT and IE hold that knowledge is socially constructed and highlight the importance of collective, local, situated, practical, tacit knowledge within the multiple ways that knowledge is generated and developed. These theories provided methodological direction for the study and will be discussed in detail in chapter 4.

Methods, Frameworks & Models

In addition to the above theories, additional methods, frameworks and models were used to provide guidance in this study. Damschroder, et al.'s (2009), Consolidated Framework for

Implementation Research provided a comprehensive foundation for understanding implementation of a new treatment into a health care practice. Fixsen, et al.'s (2005), Stages of Implementation were used to guide the phases of implementation and Proctor, et al.'s (2009) Conceptual Model of Implementation Research, were used to focus attention on both the intervention and implementation and work toward evaluating buprenorphine and implementation outcomes once this study was completed. The writing of fieldnotes and journal notes was directed by ethnographic practices explicated by Emerson, Fretz and Shaw (1995) and insider AR practices explicated by Coughlan & Brannick (2010). Strategies from grounded theory method (Bryant & Charmaz, 2007; Charmaz, 2006) influenced data collection and guided data analysis. These methods, frameworks and models will be discussed in detail in chapter 5.

Racial/Ethnic and Other Issues of Diversity in Research Organization & Research

Assessing and including racial/ethnic and other issues of diversity within research is an important principle of AR (Minkler & Wallerstein, 2008) and GTM (Green, Creswell, Shope & Clark, 2007). The research organization and staff have decades of experience working with a mostly African American and Hispanic/Latino patient population and organizing services with a sensitivity to diversity issues as evidenced by: availability of Spanish language materials and many Spanish speaking clinicians, attention to literacy levels in patient education material, focused services not just for racial/ethnic diversity but also for diversity related to economic status, gender, sexual orientation, substance use, housing status, parenting status, religion, incarceration history, etc. The research organization has a significant tract record of ongoing diversity education and training with staff as evidenced by: several "special population" grant programs, journal club presentations, HIV Grand Round topics and specialized conference trainings. The research organization's staff and hiring practices are reflective of their

commitment to diversity and the interdisciplinary buprenorphine team mirrored the larger staff diversity.

Additional Research Guidance

One of the underlying assumptions of AR, "is that you as the researcher are yourself an instrument of data generation" (Coughlan & Brannick, 2010, p. 31) and inquiry into your own, "assumptions and ways of thinking and acting are central to the research process" (p. 106). This is referred to in AR as first-person inquiry (Coughlan & Brannick, 2010; Marshall & Mead, 2005) which requires ongoing reflective/reflexive practices throughout the study. These practices enable the researcher to learn about themselves and the events of the research as they unfold, so that measured, thoughtful steps can be taken, which facilitate achieving the goals of the study. To accomplish this, the researcher engaged in various self-supported cognitive practices of reflection and journaling about her reflections, as laid out by Coughlan & Brannick (2010, Ch. 2). AR also recommends researchers engage with an advisor outside of the research setting to facilitate and compliment the individual work (Marshall & Mead, 2005, p. 236-237) and as a way of managing politics, negotiating power relations and supporting praxis-reflection (Coughlan & Brannick, 2008, p. 649). Advisement in three areas: (1) Inter (ra) personal, (2) Clinical/Milieu, and (3) Grounded Theory Method was obtained when the study commenced and was accessed throughout the study year. Further detail of this additional research advisement will be provided in chapter 5.

Organization of the Dissertation

Following this introduction, chapter 2, Background and Context reviews the history and policy of opioid dependence/addiction and treatment in the US. Chapter 3, The Empirical Literature Review discusses findings from identified buprenorphine barrier and facilitator studies

and implementation barrier and facilitator studies and their application to this to the research. Chapter 4, Theoretical Frameworks explores the theories that frame this study. Chapter 5, Research Design & Methods describes the processes undertaken to conduct the study, which includes the detail of data collection, data production, and the procedures for data analysis. Chapter 6 reports the results of the study and chapter 7 provides a discussion of the study findings in relationship to the existing literature and the implications for patients with opioid dependence/addiction, social work, interdisciplinary health care, and implementation research.

Chapter 2: Contextual Background

Implementing an intervention is a context dependent endeavor (Bhattacharyya, Reeves, Zwarenstein, 2009; Greenhalgh, et al., 2004). The specifics of the setting, the people involved, and their interactions are integral to the success of an implementation initiative (Greenhalgh, et al., 2004, p. 615). Because of the complexities related to opioid use, opioid dependence/addiction and opioid treatment in the US, the idea of context is extended to include the related historical, psychological, biological, economic, regulatory and political background. When discussing implementation, Fixsen, et al (2005) writes that these factors, directly or indirectly, influence people, organizations and systems and need to be considered when undertaking implementation (p. 12). A firm understanding of these elements is meant to provide grounding for the researcher/facilitator, as it was anticipated that these issues would arise during the study and would need to be negotiated. This chapter will cover:

1. A review of the multiple discourses related to why people use drugs.
2. A description of opioid use in the US over the l9th century: who was using, how opioids were being used, where people used as well as its associated commerce.
3. A continued description of opioid use in the US in the 20th century, along a review of regulation and treatment debates and decisions.
4. A review of the leading paradigms related to addressing substance use and addiction treatment: Punitive/Drug-Free -- Public Health -- Harm-Reduction.

Multiple Discourses Related to Substance Use

In 1980, the National Institute of Drug Abuse (NIDA) produced a monograph, *Theories on drug abuse: Selected contemporary perspectives,* in which over 40 theoretical overviews are presented (Lettieri, Sayers & Pearson, 1980) thereby demonstrating that there are no shortages of ideas related to the complex question: Why do people use drugs? In this section, six different

discourse categories, relative to the question of "why do people use drugs" have been identified and will be reviewed here to create a larger contextual understanding within which opioid dependence/addiction is discussed, understood, researched, treated, etc. They are: (1) American moral discourse, (2) Structural/deviance discourse, (3) Competitive capitalism discourse, (4) Pleasure discourse, (5) Fear mongering discourse, and (6) Autobiographical discourse. These discourses were evident and established in the early twentieth century with maturation, expansion and development over time. A seventh discourse, the disease discourse, is then reviewed separately from the others because while it was evident and established in the early twentieth century, yet it was officially rejected as a valid reason as to why people have ongoing continuous opioid use. It was not until the 1960s that this discourse was taken up again and began to be endorsed in relationship to opioid dependence/addiction.

The underlying belief as to "why people use drugs" will be explored for each of the discourses. In addition, this analysis identifies unique features of each discourse, the accompanying typification accorded the individual who is using drugs relative to the specific discourse, as well as the identifying those who generate, participate, develop and reproduce these discourses. In the twenty-first century, the primary discourse regarding why people use drugs is often a combination, a biopsychosocial (Engel, 1977) discourse, which reasons drug use from a multifactoral (biological, psychological and social) perspective, rather than from a single underlying cause. The discourses are presented here individually, so that an understanding can be had of what constitutes a multifactoral perspective relative to the question, why do people use drugs?

Discourses 1-3: American/Moral – Structural/Deviance – Competitive Capitalism

The first of the discourses regarding why people use drugs is the American moral discourse, which has connections to religious traditions and is based in the belief that those who

use drugs are: innately weak, have nature driven character flaws and are fundamentally bad. A unique feature of the American moral discourse is the association between drug use and violence and crime. Adherents of this discourse see individuals who use drugs as easily tempted, sinners and criminals. This discourse has historically been generated and used by religious leaders, politicians, media, and bureaucrats, particularly those in law enforcement and regulation (Incardi, 1986). The structural/deviance discourse is based on the belief "of the deeply damaging effects of urban life" (Singer, 1999, p. 235), and it reasons that the structural outcomes of poverty, racism, sexism, patriarchy, capitalism, etc., is what drives substance use. In this discourse (as developed by sociologists from the Chicago School) the drug user is viewed as alienated, isolated, powerless, and oppressed. The belief is that the drug user becomes addicted to both drugs and to a particular way of life and is typified as deviant (Singer, 1999). A competitive capitalist discourse views the drug user as a consumer and believes that people use drugs based on their proximity to available drug markets (whether legal or illegal) and the advanced operations of drug commerce. This intersects with a view that the fast pace of modern life, created by forces such as competitive capitalism, have people over stressed, uneasy and anxious and drugs are used as a way of coping and relaxing (Courtwright, 2001).

Discourses 4-6: Pleasure – Fear Mongering – Autobiographical

The pleasure discourse believes the underlying reason that people use drugs comes from the desire to experience the mind-altering, euphorigenic and creative effects of drugs. Opium use for this reason was well understood in the nineteenth century and drug users in this discourse are typified as artists of various forms: musicians, writers, performers and others (Hodgson, 2002). The fear-mongering discourse is closely associated with intra-bureaucratic warfare, both nationally and internationally where eugenics, social Darwinism and other racist reasoning is

used to frame the drug user as fearful, foreign, and criminal. This xenophobic and patriarchal discourse has been taken up by a range of discourse users, especially in relation to regulatory debates (Musto, 1999). The autobiographical discourse has long been around, where the individual drug user often describes how and why they initiated drug use, their struggles, stories, life on drugs, etc. These accounts offer, "socially contextualized and quasi-ethnographic account of drug use (Singer, 1999, p. 238) during different periods and by different people. As stated above, these six discourses developed as the twentieth century progressed, but early on in the century these basic discourses about why people used were circulating in the media, the academy and in politics.

The Disease Discourse

At its core, the disease discourse is the belief that drug use, in particular, problematic drug use, is a disease, an ailment that emanates from some type of disregulation. This discourse is complex as the "disease of opioid dependence/addiction" can originate from different types of disregulation, where cause and effect may be difficult to separate out. The disease discourse believes that the number one underlying reason as to why people use opioids is to treat or manage pain or other symptoms such as sleep disorders, depression, psychosis, anxiety, etc. It also includes the critique that the medical, pharmaceutical, nursing professions, etc., are participants/causative agents in opium and morphine dependence/addiction (Courtwright, Joseph, Des Jarlais, and Brown, 1989). Regardless of the uncertainty of cause, once ongoing opioid use is established and continues over a period of time, opioid dependence/addiction, with its hallmark symptoms of cravings, tolerance and withdrawal, is then understood as a neurobiological/metabolic disregulation. Other underlying causes of what brings someone to use opioids, particularly in chaotic, problematic and harmful ways, are often understood within the

frame of psychoanalytic and psychological constructs. In some cases, mental health issues may precede drug use; in other cases, drug use may be causing or contributing to one's mental health issue. As well, genetic predisposition may be a driving or a contributing force in some types of drug dependence/addiction. Despite the multiple underlying possible pathologies within the disease discourse, the person who uses drugs is viewed as a patient in need in of some kind – or multiple kinds of treatment (Robertson, 1998).

To continue to give the contextual background and a full understanding of opioid dependence/addiction, the following section gives a brief overview of opioid use in the US over the l9th century addressing: who was using, how opioids were being used, where people used as well as its associated commerce.

19th Century: US Opioid Use

Pre-Civil War 1800-1860

The most common use of opioids during this period was through the ingestion of elixirs which contained tincture of opium. These products were made by apothecaries, manufactured by newly emerging drug companies or imported from European pharmaceutical companies (Crellin, 2004). With very few drugs available to treat illnesses, opium derivatives were effective in relieving symptoms for a wide range of ailments such as pain, dysentery and coughs for both adults and children. The use of opium preparations such as laudanum (a mixture of tincture of opium, often in combination with a variety of other ingredients - usually alcohol/wine and various spices) and other elixirs, pills and powders was widespread in the population and in general consumed within the home (Hodgson, 2002). These preparations could be obtained by prescription as well as over the counter in the form of patent medicines. The term opioid dependence/addiction was not a widely used the 19th century. However, when regular opioid use

subsided, its three classic features of cravings, tolerance and withdrawal were well understood by many physicians and those who were dependent. This was not well publicized and not well understood by the general public (Musto, 1999, p. 74-75).

Post-Civil War 1865-1895

The use of opium during this period expanded, "per capita imports of medicinal opiates doubled in the US between 1870-1890" (Courtwright, 2001, p.36). Using the growing American press, patent medicine manufacturers, "were the first business entrepreneurs to seek national markets through widespread advertisement" (Incardi, 1991, p. 4), and this industry flourished, yet ingredients were often kept secret. In addition, the discovery and production of morphine, (the chief alkaloid of opium which was isolated in 1803) in combination with the development of the hypodermic needle in 1853, had a significant effect on medicine and society. In the United States, morphine by injection was first used during the Civil War which, ". . . granted the procedure legitimacy and familiarity to both physicians and the public" (Incardi, 1991, p 5). This form of opium and method of administration rendered opium more concentrated and more addictive, and near the end of the 19th century hypodermic kits were produced for mass use. Injection use was concentrated in the upper and middle classes, primarily in women.

Opium smoking was introduced to America by Chinese immigrants who had come to the US as laborers. It "spread widely in the US in the 1870s and 1880s, becoming an important ritual for the white underworld and laying the groundwork for a criminal drug subculture" (Courtwright, 2001, p. 36). While no formal federal drug regulations were enacted during this period, San Francisco prohibited the smoking of opium in 1875, which has been characterized as not health-related, but rather as racist legislation enacted because of the association of use with Chinese immigrants (Brecher, 1972). As well, a few states enacted antimorphine laws in the

1890s, yet most of the country tolerated unrestricted opium, morphine, and later heroin use in addition to cocaine use. For the majority of the 19th century, opioid use, opioid dependence/addiction, and drug use in general in the US lacked any real formal institutional expression and was mostly considered a private vice and not perceived as problematic.

The following section continues with a description of opioid use in the US in the 20th century along with providing a review of regulation and treatment debates and decisions.

20th Century US: Changing Opioid Use

The Beginnings of Drug Regulation 1895 -1920

Decrease in per capita opium consumption.

As the 19th century was coming to a close, opioid dependence/addiction increased. Heroin became available during this period and initially was thought to be less addicting than morphine, however this turned out not to be true. "Whatever the cause – over prescribing by physicians, patent medicine, self-indulgence, or weak will – opium addiction brought shame. As consumption increased, so did the apparent frequency of addiction" (Musto, 2002, p. 185). The time had come where the dangers of regular opium consumption leading to dependence/addiction were now openly recognized and acknowledged. As this knowledge became part of general public information, there was a steady declined in the per capita consumption of opium, starting from about 1890 (Musto, 2002).

Exposes, changing populations, fear mongering and shifting attitudes.

Incardi discusses a series of articles written in *Collier's* weekly magazine from October 1905 - January 1906 titled "The Great American Fraud" that exposed dubious and secretive practices by the patent medicine industry and the publication of Upton Sinclair's *The Jungle* in 1906 that exposed the horrors of the meat packing industry in Chicago and their impact on public and political awareness of the health dangers being posed by these industries.

> By mid-1906 the Pure Food and Drug Act was passed, prohibiting the interstate transportation of adulterated or misbranded food and drugs. The act brought about the decline of the patent medicine industry because henceforth the proportions of alcohol, opium, morphine, heroin, cocaine and a number of other substances in each preparation had to be indicated (Incardi, 1991, p. 15).

Also during this period "a pronounced attitudinal shift related to changing perceptions of who drug addicts were, how they acquired their habits, and how they behaved under the influence of drugs" (Courtwright, 1989, p.3) occurred, as drug use among nonwhite groups became a focus of attention. Nativist and racist fears were promulgated by politicians and the media and drug use by African-Americans and immigrant groups were represented as associated with sexual promiscuity, criminal activity, seduction and corruption of white women by nonwhite men, sexually transmitted infections, violence, prostitution, as well as concerns about nonwhites forgetting their inferior position in society. Fear mongering contributed to changing attitudes and shifting sentiments about drug use and drug users by the public, clinicians, and policy makers. This "sinister transmogrification" (p. 5) of the substance user was a critical precondition for the legal developments that were to come. "Medical experts as well as laymen commonly believed that addiction promoted criminal appetite and inclination, ruined reproductive organs and caused insanity (Musto, 1999, p. 64)

Regulation and treatment - debates and decisions.

As the nineteenth century was drawing to a close, the US began to have a growing involvement in Asia with the acquisition of Philippines in 1899 (after the Spanish-American war) as well as trade and missionary interests in China. This launched the US into association with the opium trade, which at this time was dominated by British merchants.

> In 1909 the US convened the first international meeting to consider opium traffic between nations...but the US, on the eve of entering an international conference it had called, to help China with its opium problem, discovered it had no national opium restriction. To save face, it quickly enacted one (Musto, 1999, p. 4).

Musto writes that "this helped inaugurate an American tradition in narcotic control-enactment of strict domestic legislation in the US as an example to other nations" (p. 36).

These events were occurring while internally the US was debating whether it was appropriate or not to continue providing or prescribing opium type substances to individuals who had long term chronic use. Early in the 20th century opposing camps developed in medicine. Some felt that addiction was a disease and it was within the physician or pharmacists purvey to provide opium maintenance until a cure came along. Others felt this was pandering to "dope fiends". In addition,

> The number of physician-addicts was high (about 2 percent according to one survey)…Medicine was (and is) the leading profession in rate of addiction….The profession was commonly believed to be one of the causes of most of the addicts in the nation (Musto, p. 64).

The AMA, which was consolidating its power during this period, was increasingly opposed the maintenance of opium users by physicians, and became a voice of authority against drug use.

These multiple factors converged to bring about the first federal prohibition on drugs, which came in the form of the Harrison Act of 1914. The act defined opium and coca-based drugs as narcotics, and anyone caught with these agents (unprescribed) were guilty of violating the law and subjected to fines and imprisonment. This act was administered by the Treasury Department which made narcotics a federal concern. The Harrison Act did not address the issue

of maintenance, and the Treasury Department sought the counsel of the Supreme Court, which in 1919 ruled in favor of an anti-maintenance position. In 1920, the AMA passed a resolution opposing opioid maintenance treatment. The AMA worked together with the Treasury Department and state enforcement groups to identify, punish and prosecute physicians who violated the Harrison Act (Acker, 2002). On January 1, 1920, a Narcotic Division in the Prohibition Unit of the Internal Revenue Bureau of the Treasury Department was established, thus beginning the formal federal bureaucratic oversight of drug control and prohibition in the US (Musto, 1999, p. 131).

The Classic Era of Narcotic Control 1920s-1960s

The Punitive Paradigm

David Courtwritght (1989) coined the term "classic era of narcotic control" and writes, "From the early 1920s to the middle 1960s American narcotic policy was unprecedentedly strict and punitive…"classic" in the sense of simple, consistent, and rigid" (p. 1). After the Harrison Act was passed, some state and local municipalities around the country set up "Narcotic Clinics" for the emergency care of those who were opioid dependent/addicted. In fact, "from the mid-nineteenth century until about 1920, physicians continued to tell one another that withdrawal and perhaps a few weeks of aftercare would lead to a cure of addiction in most cases" (Musto, 1999, pp. 77-78). These clinics operated with much diversity, but eventually came to be seen as antithetical the work of the Narcotic Division. Under threat and/or persuasion they were all closed. Courtwright highlights the date of February 10, 1923, when the last narcotic clinic in Shreveport, New Orleans closed, "as the beginning of the period of classic narcotic control, since it represented the end of legal access to organized opioid maintenance treatment.

Once physicians and druggists' trade were constrained in providing opioids, it was evident that a lively street trade had developed and the issue of opioid dependence/addiction was not going away. Singer (1999) sites Lindsmith's 1965 work, *The Addict and the Law,* in relaying that 10,000 Federal arrests on drug charges were made by 1925. Lower income white men became more associated with opioid dependence/addiction during this time. Singer quoted Goode's 1993 work, *Drugs in American Society,* "through media and other reports of these arrests, the link between addiction and crime - the view that the addict was by definition a criminal - was forged" (p. 221). Because of the increase of arrest of opioid dependent/addicted individuals, federal narcotic farms were opened in Lexington and Fort Worth to separately deal with the "addict-prisoner" (Musto, 1999, 204). In addition, after the Harrison Act,

> Criminal syndicates emerged in many cities to meet the illicit demand for heroin and cocaine. Exploiting the prohibition of both alcohol and narcotics in the 1920s, American organized crime grew from localized gangs into nationwide syndicated with substantial economic and political influence in the cities of the industrial Midwest and Northeast…Thus, the events of the 1920s mark a major transition in the history of global drug trade. For 150 years opium had operated as a normal commodity, expanding into global trade that linked the highland poppy growers of Asia with urban consumers in Europe and America. Following Prohibition in the 1920s, narcotics moved from legal commerce to illicit traffic, acquiring thereby a peculiar politics while still retaining many attributes of ordinary commodities (McCoy, 1991, p. 10).

Moving into the 1930s, an increase in drug addiction was seen in African-Americans communities, then with WWII, many drugs were blocked from entering the US, and there was a decrease in drug use and drug users. However, immediately after the war, heroin coming into

the US increased, as did the number of inner-city drug users (Singer, 1999, p. 238). According to Bertram, Blackman, Sharpe, and Andreas, (1996) a "punitive paradigm" was well entrenched by the 1950s. The Federal Bureau of Narcotics was securely operating and engaged in many fear mongering tactics to advance a harsh, punishment agenda around drugs and drug use in the US (pp. 84-85), while simultaneously, the Central Intelligence Agency began carrying out covert operations internationally in which they participated in the global drug trade, often in the name of fighting communism (McCoy, 1991).

Despite the fact that prohibition and punishment had taken control of the direction of policy and regulation around drug use, some health professional and public officials continued to highlight that drug addiction was a disease which required treatment. Advocates for treatment also continued to articulate that thousands had been put, "into jails and prisons simply because they could not legally secure the medicine upon which depended their integrity of mind and body" (Bertram, et al., 1996, p. 83) and that "prohibition and lack of treatment supported, billion-dollar drug rackets" (p. 83). By the 1950s the Federal Bureau of Narcotics initiated the idea of mandatory minimum sentences, tied drugs to communism, and had a sympathetic and willing Congress interested to work with them to advance these policies. The Narcotic Control Act of 1956, "raised mandatory minimum penalties (five to twenty years for a second offense; ten to forty for the third offense) and permitted juries to impose the death penalty on any adult who sold heroin to a minor" (p. 84).

Public Health Joins the Punitive Paradigm 1960-1980: Treatment & Prevention

Several dynamics in the 1960s contributed to expanding the approach to drugs and drug use to include treatment and prevention. The election of Kennedy, the 1962 ruling of the Supreme Court that addiction was a disease, the 1963 Presidential Commission on Narcotic and

Drugs Abuse recommending relaxation of mandatory minimums, increased research on drug use and the reorganization of the government agencies. The commission recommended the dismantling of the Federal Bureau of Narcotics with responsibilities reassigned to the departments of Justice and Health, Education and Welfare, which contributed to bringing treatment and prevention services into being. In addition, various forces influenced treatment and prevention becoming one of a range of acceptable, valid approaches to drugs and drug use in both the eyes of the health care, the government and the public in general: the rise of mental health professions, community mental health programs, the expansion of the health bureaucracy in general, as well as major legislative changes (Musto, 1999, pp. 234-235; Bertram, et al., 1996, pp. 86-87). It was also during this period that the physicians Dole (an endocrinologist) and Nyswander (a psychiatrist) (1965) conducted their research on treatment of opioid dependence/addiction at Rockefeller University in NYC which led to the establishment of methadone as a treatment for heroin dependence/addiction. Musto writes, "Methadone's appeal was in no small measure due to its reputed effectiveness in cutting into crime attributed to drug use, especially heroin addiction" (p. 249). The AMA now argued for opioid medical management and MMTPs became the model of care. As identified in the chapter 1, The Methadone Regulations of 1972 and the Narcotics Act of 1974 came with extensive regulations requiring a closed-system of distribution and use because of concerns of methadone diversion and misuse, thereby keeping the care of opioid dependent/addicted individuals outside of mainstream health care (Rettig & Yarmolinsky, 1995).

In, *Drug War Politics,* (1996) the authors make an important point that key actors who were advocating for drug treatment and prevention (a public health paradigm) avoided confrontation and chose "not to launch a more frontal assault on many of the assumptions behind

punitive drug control" (p. 90) and "the theory and practice of treatment that took hold in the 1960s and 1970s thus did not seriously threaten the punitive paradigm and policy agenda. But it did hold within it the seeds of an alternative paradigm" (p. 92). This period saw an increase and expansion of different types of drugs and drug use into many different sectors of society and the beginnings of the emergence of a decriminalization/legalization paradigm (Musto, 1999, p. 285). The Vietnam War also played a part in the history of opioid use. The number of American servicemen using heroin in Vietnam has been estimated to be, "…as large as 25 percent"… "One of the most interesting aspects of returning veterans who had tested positive for heroin was that very few continued using it once back home" (Musto, 1999, pp. 252-253).

The 1960s and 1970s also saw the initiation and escalation of Nixon's war on drugs, "The twin goals were to cut off the foreign supply of heroin and at the same time to increase drug treatment programs" (Musto, 1999, p. 250). In 1970, the five schedules for controlled substances were established by the Drug Enforcement Agency (DEA). This is a ranking, "…depending on the potential for abuse and dependency and the accepted medical use of each drug" (p. 255). Heroin falls into Schedule I, drugs that have a high potential for abuse, no medical use and severe safety concerns. They are not permitted to be used in medical practice. Prescription pain pills (such as morphine, oxycontin, etc.) and methadone, fall into Schedule II, a category for drugs with a high potential for abuse and dependence, an accepted medical use and the potential for severe addition. When it was approved, buprenorphine was placed in Schedule III, which is a class for drugs that have a lower potential for abuse than the first two categories, an accepted medical use and mild to moderate possible addiction (Office of Diversion Control, 2010).

As the 1970s progressed, a swing back to a less aggressive rhetoric against drugs was initiated under Ford and under Carter there was again renewed but failed efforts toward drug

tolerance. However, during both administrations there continued an increase in drug law enforcement budgets.

> Deeply rooted institutional interests created centers of resistance in the bureaucracy and Congress. Equally tenacious were the widely shared assumptions about the nature of the drug problem, its links to crime, and the need for a tough enforcement response led by government (Bertram, et al., 1996, p. 110).

Enter Harm Reduction: HIV and Ongoing Drug Wars: 1980-Present

Reagan initiated a return to a punitive/drug-free paradigm with an increase of both national and international drug law enforcement, zero-tolerance drug policy, abstinence only education and prevention, work-place and school drug testing and stiffer penalties for drug possession and sales (Musto, 1999). Between 1980-1992, "the drug war escalated as never before, with budgets for drug law enforcement surging from $855 million to more than $7.8 billion in 1993" (Bertram, et al, 1996, p. 110). Unlike Nixon's war on drugs, Reagan's did not provide for equal or adequate spending on drug treatment, however the public health paradigm was firmly established and ongoing work in the field of drug treatment and prevention continued. Then, alongside the punitive/drug-free paradigm and the public health paradigm, a new paradigm came into prominence, harm-reduction. This innovative policy and practice emerged in different parts of Europe in the later 1970s and early 19080s. In 1981, Amsterdam declared that "absolute drug abstinence was abandoned as the primary goal of all treatment efforts" (van Brussel, 1998, p. 55). Recognizing that for some individuals, substance use was a chronic relapsing condition, the Dutch decided that "the next best thing is to limit harm, e.g. overdose death, infections and social degradation as the foremost goal of intervention…This resulted in the formation of low-threshold methadone programs (1981) needle exchange (1984) and close cooperation with

abstinence-oriented treatment approaches" (p. 55). As the role of injection drug use in the spread of HIV became clear, the harm-reduction model spread to Australia, Canada and eventually made its way to the US (Springer, 1991).

All three of these major paradigms, punitive/drug-free - public-health - harm-reduction, came to maturity during this period. While the Republicans can be credited with reinitiating a punitive/drug-free paradigm, the majority of Democrats and Republicans from the 1980s to present are both associated with the ongoing drug war escalation and an entrenched punitive paradigm. In 1998, out of the total National Drug Control Budget of $16 billion dollars, two thirds was allocated for drug law enforcement, interdiction (destruction of drug crops), and supply reduction in the US and abroad. Only one third was allocated for treatment, prevention, and research (Drucker, 1999). While Clinton tried to articulate more of a disease model and greater funding for treatment and prevention, his administration was unable to shift the national debate away from a punitive paradigm. In New York, the proportion of drug offenders incarcerated increased from 11% in 1980 to 36% in 2007. Despite the evidence that most drug users and sellers are White, 90% of the drug offenders in New York State prisons are African-American or Latino (Correctional Association of New York, 2008).

Punitive/Drug-Free - Public-Health - Harm-Reduction

Each of these three paradigms continues to operate in the world of drug policy and addiction. Relative to drug regulation, prevention, addiction treatment goals, opioid treatment goals, harm goals and authority there are some overlap among these approaches, yet there are also key differences (Figure 2). Given the history and ongoing politics, the IBT/P was planned by the researcher to be incorporated under a biopsychosocial philosophy and patient-centered care model, which is congruent with a harm reduction approach.

Figure 2: Comparison of US Paradigms/Approaches to Drugs and Drug Use

Paradigm:	Punitive/Drug-Free ----------Public Health----------Harm Reduction		
Regulatory:	Punitive/Prohibition	Punitive/Prohibition/Tolerance Decriminalization	Tolerance/Decriminalization Legalization
Prevention:	Support - Drug Free	Support - Public Health	Support - Harm Reduction
Treatment Goals:	Abstinence Only	Prefer Abstinence Accept Harm Reduction	Accept Individual Goal
Opioid Treatment:	Anti-maintenance	Pro-Maintenance	Maintenance Option Individual Choice
Harm Goals:	Stop Harm/Control	Control/Stop - Reduce Harm	Accept/ Reduce - Stop Harm
Authority:	Government Authority Medical Authority	Medical Authority Government Authority	Individual Authority in Consultation with Clinician

While all paradigms are interested in promoting health, "A harm reduction approach to substance use accepts that some use will persist despite the best efforts at prevention" (Bertram, et al., 1996, p. 208). Acceptance is a key feature of a harm-reduction approach (Robertson, 1998). This is in opposition to a drug-free approach which has zero-tolerance for any illegal drugs and the only treatment goal that is acceptable is abstinence and different from the public health approach where abstinence is preferred. The legacy and ongoing use of a punitive/prohibition approaches to substance use has resulted in many individuals with substance use issues feeling stigmatized, judged and discriminated against by a range of health care

workers, often resulting in avoiding coming in for service and delaying coming in for care when sick (Bright, 2002; SAMHSA, 2000; Weiss, McCoy, Kluger & Finkelstein, 2004). Harm-reduction treatment models and theories have specifically addressed this issue and organized practices and techniques to counter the effects of the punitive approach (Majoor, 1996, Murphy, et, al, 1999; Heller, McCoy, Cunningham, 2004). Its major themes have always been nurturing a therapeutic alliance between the patient and provider by providing nonjudgmental, low threshold services for the purpose of "meeting the patient where they are at" and engaging individuals in health care (Springer, 1991).

However, because harm-reduction does not require abstinence of all drugs as the goal of treatment and is focused on patient preferences and values, it has been criticized by zero-tolerance supporters and even some public-health supporters as sending 'the wrong message' and in some way condoning drug use (McCoun, 1998). This is especially true relative to syringe exchange. Despite overwhelming empirical support which demonstrates that syringe exchange programs (SEPs) significantly interrupt HIV transmission and do not cause or increase drug use (Office of the Surgeon General, 2000) the Clinton administration was unable or unwilling to challenge the ban on federal funding for SEPs. DesJarlais (2000) noted, "This opposition is best considered an aspect of cultural wars in the United States and not a function of the scientific data on needle exchange" (p.1393).

> This opposition to harm-reduction carried itself into the Bush administration. In 2003, The Department of Health and Human Services began special reviews of all current research grants that involved harm reduction, sex and drugs, and continues its ban on funding of needle exchange. With Bush's second term, the campaign was extended to all

> US funded international programs that dealt with these issues and populations (Drucker, 2005, p.1).

Despite the Obama administration successfully removing the federal ban on needle exchange, supporting medication-assisted treatment such as buprenorphine and methadone, and no longer prohibiting funding for harm-reduction related research, the US rejected the use of the term "harm-reduction" in the political declaration that was being endorsed at the United Nations (UN) meeting on drug policy in Vienna, in March 2009 (Clear, 2009). According to Geoffrey R. Pyatt, deputy chief of the US mission to the UN in Vienna, "the United States continues to believe that the term 'harm-reduction' is ambiguous. It is interpreted by some to include practices that the United States does not wish to endorse" (Lillis, 2009). The practices Pyatt was referring to is drug decriminalization/legalization, which is not supported by the Obama administration, and remains very controversial.

As noted in the opening of this chapter, it is highly important to understand as fully as possible the debates, politics, funding, etc., that surrounds opioid use, dependence/addiction, policy and treatment as these contextual issues influence people, organizations, systems and ultimately the implementation of buprenorphine. Having a solid knowledge of this background is meant to support the researcher/facilitator in the navigation of implementing a treatment with a long and complex history and serve as a tool to achieve the research goals and objectives.

Chapter 3: Review of the Empirical Literature

To learn what knowledge exists relative to studying factors that promote or inhibit the development, installation and initial implementation of an IBT/P within a primarily publicly funded hospital-based HIV Primary Care Center/Designated AIDS Center, research was sought in the social sciences and health sciences data bases. Literature that had been published after 2000 was sought for two reasons. First, the Drug Addiction Treatment Act, which made treating opioid dependence/addiction within office-based setting legal, was passed in 2000. Second, the discussion of the limited amount of evidence-based strategies to implement evidence-based treatments, (as asserted in multiple NIH documents, Figure 1, p. 4) demonstrated it was during the 2000's that the field of implementation science was just emerging. The keywords used in this search, alone and in various combinations were: buprenorphine, implementation, interdisciplinary, multidisciplinary, interprofessional, treatment, practice, research, action research, opioid dependence, opioid treatment, substance abuse, addiction, implementation research, technology transfer, research utilization, evidence-based, primary care, HIV, health care organization, social work, nursing, medicine, counseling. Searches were conducted with a focus on locating research articles related to the study question, in Academic Search Complete, CINAHL, ERIC, MEDLINE, PsychINFO, Social Work Abstracts, Social Service Abstracts, SocINDEX, Sociological Abstracts as well as ProQuest.

After reviewing hundreds of abstracts, no research was located that focused on studying the implementation of buprenorphine within primary care or HIV primary care, interdisciplinary or otherwise. However, from this review, it was noted that a large body of literature existed for each of the two main topics of this study (1) buprenorphine and (2) implementation, and this material was further explored. Over 150 abstracts in each main topic were selected and

reviewed. After several reading of the abstracts, various categories for each of the main topics were identified in which the literature could be grouped.

The categories for the buprenorphine abstracts were 1) Professional and public health commentary related to buprenorphine, (2) Office-based buprenorphine studies that focused on treatment outcomes, (3) HIV and buprenorphine studies related to drug-drug interactions and the relationship of treating opioid dependence and preventing and treating HIV, (4) Methadone and buprenorphine comparison studies, (5) Clinical management of buprenorphine and, (6) Barrier and facilitator studies related to prescribing and/or providing buprenorphine treatment. The categories for the implementation abstracts were (1) Studies implementing clinical practice guidelines in medicine, (2) Studies implementing continuous quality improvement, (3) Development and/or evaluation of various implementation theories, models, tools, (4) Process of care and patient outcome studies, (5) Adoption and diffusion of innovation studies and, (6) Barrier and facilitator studies related to implementing evidence-based practices, best practices or new innovations into health care settings.

Over 100 full text documents from the buprenorphine abstracts were obtained and read and over 100 full text documents from the implementation abstracts were obtained, read and placed into their corresponding categories. This confirmed that while there was no research identified that studied barriers and facilitators related to the interdisciplinary implementation of buprenorphine into HIV primary care, there was research related to barriers and facilitators in the two main topics initially noted, (1) buprenorphine and, (2) implementation. These studies were determined to be the most relevant research available related to the study question: What factors promote or inhibit the development, installation and initial implementation of an IBT/P within a primarily publicly funded health care delivery organization? Based on this determination, 13

barrier and facilitator studies related to prescribing and/or providing buprenorphine treatment and 17 barrier and facilitator studies related to implementing new practices into health care settings were selected for in-depth review and serve as proxy literature to inform this study. The predominant themes and findings from these two groups of studies (total 30 studies) and their application to the research question will be discussed. While this literature review reports statistical findings from several of these studies, the statistical analysis of the various studies was not vetted by the researcher. Therefore, where it

Overview of Barrier and Facilitator Studies Related to Buprenorphine

Various attitudes and beliefs toward buprenorphine prescribing and providing buprenorphine treatment, mostly from physicians, were explored in the 13 chosen studies. Knudsen, Abraham, Johnson & Roman (2009), investigated counselor attitudes toward buprenorphine and Roose, Kunins, Sohler, Elam & Cunningham (2009), included nurse practitioner and physician assistant, along with physicians' interest in prescribing buprenorphine, and these studies were included in this review. No studies on social workers', registered nurses' psychologists, or clinic administrators' attitudes toward buprenorphine were identified. No studies were identified where buprenorphine treatment was approached from an interdisciplinary perspective or where interdisciplinary practices were explicated.

Overall, these barrier and facilitator studies related to buprenorphine demonstrate a trend toward a slow increase overtime in physician's comfort, willingness, confidence, interest and actual prescribing of buprenorphine since it was FDA approved in 2002. This is congruent with the study by Netherland, et al. (2009) that reported prescribing of buprenorphine was slowly increasing, however "it has not fully penetrated general practice settings" (p. 244). It is important to note that six studies (Cunningham, Sohler, McCoy, & Kunins, 2006; Gunderson,

Fiellin, Levin, Sullivan & Kleber, 2006; McMurphy, Shea, Switzer & Turner, 2006; Sullivan, Tetrault, Bangalore & Fiellin, 2006; Turner, Laine, Lin, & Lynch, 2005; West et al., 2004) focused on the perceptions of barriers and facilitators by physicians who had not yet prescribed buprenorphine. Moving to published work from 2007 onward, these seven investigations included in their studies physicians who had prescribed buprenorphine and identified barriers and facilitators from their practice experience (Barry et al, 2009; Cunningham et al., 2007; Knudsen, Ducharme, Roman, 2007; Knudsen, et al., 2007; Netherland et al., 2009; Roose, Kunins, Sohler, Elam, & Cunningham, 2008; Thomas, Reif, Wallack, Hoyt & Ritter, 2008).

Nine of the 13 studies in this group are atheoretical, with four studies (Knudsen et al., 2007; Knudsen et al., 2009; Netherland et al., 2009; West et al., 2004) using some form of Everett Roger's theory of diffusion of innovations. Ten of the 13 studies share the same justifications for their research, which are the limited availability of opioid treatment and the slow adoption of buprenorphine by physicians. Sullivan et al. (2006) and Knudsen et al. (2006; 2009) justified their studies based other issues. Sullivan, et al. (2006) discussed the association between opioid dependence and HIV, stating that little was known regarding HIV physician's' level of preparedness to prescribe or the impact of training to engage them in this practice Knudsen, et al.'s (2007; 2009) justification was based on evaluating the effect of participation in a clinical trial network on buprenorphine.

Many of the 13 studies (Cunningham et al., 2006; Cunningham et al., 2007; McMurphy et al., 2006; Netherland et al., 2009; Thomas et al., 2008; Turner et al., 2005; West et al., 2004) had either a pre-established list of barriers and facilitators related to buprenorphine or developed one based on their study findings. In fact, West, et al., (2004), who conducted their study in 2002, prior to the FDA approval of buprenorphine, and is the earliest study in this group of 13,

published in their paper an extensive list of factors related to the adoption of buprenorphine and developed a conceptual model of these factors (p. 514). Seven of the 13 buprenorphine barrier and facilitator studies, (Cunningham et al., 2006; Cunningham et al., 2007; Knudsen, et al., 2007; McMurphy et al., 2006; Netherland et al., 2009; Thomas et al., 2008; Turner et al., 2005) all conducted after the West, et al study, reference the West, et al, 2004 paper. There is a great deal of content overlap in these lists. These barriers and or facilitators items were incorporated into the list of complexities related to buprenorphine developed by the researcher prior to the start of the study (Figure 7, p. 87).

Findings from Buprenorphine Barrier and Facilitator Studies

The main findings from these studies will be discussed as barriers and facilitators related to buprenorphine. The barrier factors have been grouped under four categories: (1) Lack of Knowledge and Experience, (2) Negative Attitudes (3) Regulatory and Record Keeping Concerns, and (4) Reimbursement Concerns. The facilitating factors have been grouped under two categories: (1) Practitioner Specialty and (2) Available Resources.

Barriers related to buprenorphine.

1. ***Lack of knowledge and experience.***

Several of the studies reported lack of knowledge and experience providing opioid addiction treatment as a barrier to prescribing buprenorphine (Cunningham et al., 2006; Cunningham et al., 2007; Gunderson et al., 2006; Sullivan et al., 2006; Barry et al., 2009). Cunningham et al. (2006) reported that lack of knowledge was the most frequently stated reason (47.5%) for not prescribing buprenorphine among the 99 physicians who were interviewed about their attitudes and beliefs (p. 338). Similar findings were also noted by Cunningham et al. (2007). Of the 375 physicians with complete survey data, 54.9% identified lack of knowledge

about opioid addiction treatment as the most common barrier to obtaining a waiver to prescribe buprenorphine (p. 1327).

Gunderson et al. (2006) evaluated a combined online and in person training of buprenorphine (*n*=53) and found that 33% of the physicians were hesitant to prescribe after they completed the training. Among those who reported they were hesitant, the primary barrier was lack of experience (41%) (p. 43). Sullivan et al. (2006) also evaluated barriers to prescribing with physicians (*n*=257) who had completed an 8 hour buprenorphine training course. In a post-course preparedness evaluation, 9% of HIV physicians and 15% of non-HIV physicians felt that lack of experience was the biggest barrier to prescribing buprenorphine (p. 16). Barry et al. (2009) concluded "many of the respondents noted that they would feel uncomfortable implementing buprenorphine maintenance treatment given their perceived lack of expertise in treating addiction" (p. 220). These researchers conducted 23 face-to-face interviews with practicing physicians in New England about buprenorphine, between Oct 2002 and June 2005.

2. Negative attitudes.

Negative attitudes related to buprenorphine treatment have been identified as a barrier. In this group of studies, stigma about the patient population (McMurphy et al., 2006; Thomas et al., 2008, Turner et al., 2005) and concerns about abuse and/or diversion of buprenorphine (Turner et al., 2005; Thomas et al., 2008) were among the top attitudinal barriers.

A. Stigma about opioid dependent/addicted patients.

McMurphy et al. (2006) reported that stigmatizing attitudes about drug users was the most commonly cited barrier to managing treatment of opioid dependence. Among the 27 NY State clinic directors who participated in in-depth interviews, "respondents often viewed opioid-dependent persons as, manipulative, demanding and disruptive" (p. 544). Ninety-three percent

of respondents said that, "negative personality characteristics of persons on methadone treatment presented the greatest barrier." (p. 546). Thirteen medical directors (48%), raised concerns about bringing a "street culture" into their clinic, and, "many were concerned about exposing other patients to treated drug users" (p. 247). In the Turner et al. (2005) study that surveyed 261 clinic directors in NY State, nearly half of all respondents had at least 1 negative opinion about patients treated for opioid dependence (p. 1774). However, "Only 25.4% of the clinic directors endorsed all four negative statements about persons receiving methadone (i.e., noncompliant, severe mental health problems, threatening to other patients, and threatening to staff)" (p. 1771), suggesting that more severe attitudes about opioid dependent/addicted patients are less likely.

Thomas et al. (2008), assessed a range of barrier and facilitators to prescribing buprenorphine for addiction (*n*=271) and non-addiction (*n*=224) psychiatrists, and they reported that "among top barriers for both groups were, "It does not fit in with my practice" and "It would change the patient mix undesirably" (p. 913). In the discussion section of this study, the authors raise concern that this finding may indicate that psychiatrists do not want to treat opioid-dependent patients because of stigma and stereotypes about this patient population (p. 915).

B. Concerns about abuse and/or diversion of buprenorphine.

Two studies that inquired about concerns regarding abuse or diversion of buprenorphine found it to be a barrier to providing this treatment. In Turner et al. (2005), "greater concern about abuse of buprenorphine was strongly negatively associated with willingness to prescribe it", among the 261 clinic directors in NY State who were surveyed (p. 1771). Thomas et al. (2008) found that 40.3% of the 375 physicians surveyed identified concern about buprenorphine diversion as one of the most common barriers to prescribing (p. 1327).

3. Regulatory and record keeping concerns.

Four studies found that regulatory and recordkeeping were barriers to using buprenorphine (Barry, et al., 2009; McMurphy et al., 2006; Netherland et al., 2009; Turner et al., 2005). In qualitative interviews with twenty-three practicing office-based physicians in New England, Barry, et al. (2009), addressed the issue of regulatory concerns and they found, "some physicians expressed concerns that providing buprenorphine maintenance treatment would invite greater regulatory oversight of their clinical activities and charting procedures" p. 223). Netherland et al. (2009), surveyed physicians with different levels of buprenorphine experience about factors affecting their willingness to prescribe and across all levels of experience, record keeping requirements were rated as fairly strongly (3.0 full group mean) as a negative affect (p. 247). In McMurphy, et al. (2006), seven medical directors out of the 27 (26%) who were interviewed noted that both regulations and excessive paperwork were areas that would keep physicians away from buprenorphine (p. 548). Of the 261 medical directors of primary care and/or HIV specialty clinics in NY State who were surveyed, Turner, et al. (2005) found that 65.7% identified burdensome paperwork as a barrier.

4. Reimbursement concerns.

Eight of the studies directly addressed the issue of reimbursement, (Barry et al., 2009; Cunningham et al., 2007; Gunderson et al., 2006; McMurphy et al., 2006; Netherland et al., 2009; Thomas et al., 2008; Turner et al., 2005; West et al. 2004) to determine how this affected buprenorphine treatment. Six studies found it an important and significant area of concern, while two studies (Cunningham et al., 2007; Barry et al., 2009) that addressed reimbursement found it of no or little significance.

West et al. (2004), surveyed psychiatrists (1,203) and found that those who had no capitated payment arrangements were more likely to be comfortable providing buprenorphine compared with psychiatrists who had capitated payment arrangements ($p<.01$) (p. S13). Turner, et al. (2005), surveyed 261 medical directors of NY State clinics that provided care for patients with Medicaid and found that slightly less than half of all directors regarded greater payments for buprenorphine treatment as important (p. 1771). Of the 54 physicians who completed training for buprenorphine and were surveyed in the Gunderson et al. study (2006), a subset reported they were hesitant to begin prescribing. Of this group, 24% cited inadequate reimbursement as a primary barrier (p. 43). In McMurphy, et al. (2006), seven medical directors out of the 27 (26%) who were interviewed, cited poor Medicaid reimbursement as a barrier to providing buprenorphine treatment. Eighteen out of 27 (70%) raised the issue of financial incentives and discussed enhanced Medicaid reimbursement rates and creating monetary rewards for physicians who were salaried as a way to engage physicians in providing office-based buprenorphine treatment (p. 548).

Thomas, et al. (2008) surveyed both addiction specialists (n=271) and generalist psychiatrists (n=224) in four market areas (Boston, Chicago, San Francisco and Miami) and found that prescribers of buprenorphine reported higher proportions of self-pay patients (36%) compared with nonprescribers (21%) and this was found to be significant ($p<.01$) (p. 912). In Netherland et al. (2009), where physicians with different levels of experience with buprenorphine (experienced, n = 78; novice, n = 45; trained-nonprescribers, n = 49) were surveyed, experienced prescribers differed from both novice and trained-nonprescribers when it came to reimbursement. Experienced prescribers rated reimbursement as significantly more important (3.46) than novices (2.78) or nonprescribers 2.65; $p<.01$) (p. 248).

Facilitating factors related to buprenorphine

1. Practitioner specialty.

More than half of the studies (Cunningham et al., 2006; Cunningham et al., 2007; Gunderson et al., 2006; Sullivan et al., 2006; Thomas et al., 2008; West et al., 2004) actively pursued questions related to the effect of practitioner specialty on their interest or willingness to prescribe buprenorphine or treat patients with buprenorphine.

A. Addiction specialists reported greater comfort with buprenorphine treatment compared to general psychiatrists.

In an early study (West et al., 2004) that was conducted between February and September 2002 (prior to the FDA's approval of buprenorphine), researchers assessed psychiatrists comfort with using office-based opioid treatment. In a randomized, self-administered, cross-sectional national survey, offered to 2,323 psychiatrists (52% response rate n = 1,203) from the AMA master file of Physicians, (n = 49,000), 80.6% were not comfortable prescribing office based opioid-treatment. Those who identified themselves as comfortable were more likely to be addiction certified and already treating substance abuse patients (pp. S10 – S11). A similar finding was also noted by Cunningham et al. (2007) where both addiction specialists (drawn from American Society of Addiction Medicine and the American Association of Addiction Psychiatrists) and generalist psychiatrists (drawn from the American Psychiatric Association master file) in four market areas (Boston, Chicago, San Francisco and Miami) were surveyed in the fall of 2005. Respondents included 271 addiction specialists (72% response rate) and 224 psychiatrists who were not listed as addiction specialists but who had patients with addictions in their practice (57% response rate). Large differences were seen between these two groups. Eighty-seven percent of addiction specialists had been approved to prescribe buprenorphine

(72% were using it to treat patients) compared with non-addiction specialists, where 13% had received training and only 4% were actually prescribing (p. 911).

B. *Primary care oriented physicians compared to nonprimary care oriented physicians reported a greater interest in prescribing buprenorphine. General internists, nurse practitioners and physician assistants reported greater interest in prescribing of buprenorphine compared to infectious disease physicians.*

Several studies demonstrate a difference in attitudes about prescribing buprenorphine when comparing various types of providers and practice specialties. In purposive face to face structured interviews (Cunningham et al., 2006), conducted with ninety-nine residents and attending physicians (between June 2003 and March 2005) from six ambulatory clinics, physicians involved in primary care oriented programs versus physicians not involved in primary care oriented programs were more likely to report interest in prescribing buprenorphine (43.2% versus 12.5%, p <0.5) (p. 338). Cunningham, et al. (2007) also found a difference between physician specialties, relative to obtaining waivers to prescribe buprenorphine. This study conducted anonymous, purposive, self-administered, cross-sectional surveys with 954 HIV physicians attending an HIV educational conferences in six cities in 2006 (420 responded RR = 44%, 375 with complete data). These researchers identified that physicians who had obtained a waiver to prescribe buprenorphine were more likely to be general internists (43.6% versus 33.5%, p <0.5) and less likely to be infectious disease trained (25.5% versus 41. 6%, p <.05) (p. 1327). Roose et al. (2008) also reported on questions that evaluated interest in prescribing buprenorphine among infectious disease trained physicians, nurse practitioners, physician assistants and generalist physicians. Compared to infectious disease trained physicians, nurse practitioners and physician assistants (adjusted odds ratio [*AOR*] = 2.89%, 95% confidence

interval [*CI*] = 1.22-6.83) and generalist physicians (*AOR* = 2.04, 95% *CI* = 1.09-3.84) were significantly more likely to be interested in prescribing buprenorphine (p. 458).

C. *In surveys conducted with physicians who had completed buprenorphine training, no differences in intention to prescribe were noted between practice specialties.*

While the above studies point out that practice specialties demonstrate differences in interest and/or prescribing of buprenorphine, other studies (Gunderson et al., 2006; Sullivan et al., 2006) conducted with physicians after the completion of buprenorphine training demonstrated no differences between practice specialties in intention to prescribe. In a study by Gunderson et al. (2006), 70 physicians were asked to complete a voluntary, confidential survey after a combined online and in person buprenorphine training. Of the 53 who completed the survey (76% response rate), 57% were psychiatrists and 40% were either in internal or family medicine. Most respondents intended to begin using buprenorphine treatment after the training (67%) and intention to prescribe did not vary by specialty (p. 43). In Sullivan, et al. (2006), who surveyed and compared HIV physicians (*n* = 113) to non HIV physicians (*n* = 144) preparedness to prescribe buprenorphine, (93% response rate) both groups (88% HIV physicians and 89% non HIV physicians) felt similarly prepared to prescribe after 8 hour in person training (pp. 16-17).

2. Available resources.

A. *Having an addiction specialist available for consult and counseling ranked as one of the highest facilitators for prescribing buprenorphine.*

Physicians ranked having an addiction specialist available for consult, in a timely fashion (Cunningham et al., 2007; Gunderson et al., 2006; McMurphy et al., 2006; Netherland et al., 2009; Sullivan et al., 2007; Turner et al., 2005) high on a list of various buprenorphine facilitators. In a NY State survey (Turner et al., 2005), of 249 directors of primary care and/or

HIV specialty clinics, that provide care for patients on Medicaid, more than two-thirds of the respondents "affirmed the importance of sharing management with an addiction expert" (p. 1771). Immediate telephone access to an expert was associated with willingness to provide buprenorphine (*AOR* 2.08; 95% *CI*, 1.13 – 3.76)" (p, 1769). A similar sentiment was identified by Gunderson et al. (2006) where physicians who intended to prescribe buprenorphine were more likely to agree that having telephone access to an experienced provider would improve their confidence compared to physicians who were hesitant to prescribe (mean score 4.6 vs. 4.2, respectively, $p < .05$, p. 43). In 2003, three physicians from the University of Pennsylvania conducted 27 in-depth interviews with 27 NY State clinic directors (McMurphy et al., 2006) and 13 (48%) sited on-call addiction specialist as a facilitating factor to prescribing buprenorphine (p. 549).

Seventy-eight to 82% of all 257 physicians (HIV physicians n = 113 and non-HIV physicians *n* = 144) surveyed by Sullivan et al. (2006), agreed that they would feel more comfortable prescribing buprenorphine if they had telephone contact with an expert mentor (p. 16). HIV physicians surveyed (317- 44% response rate) at an HIV educational conference (Cunningham et al., 2007) also identified that lack of immediate access to consultant with an addiction expert as a prescribing barrier (42.9%). Of the 317 respondents, 94 physicians (25%) had already been trained and held waivers to prescribe buprenorphine "when adjusted for physician characteristics and confidence addressing drug problems, the only perceived barrier significantly associated with not having a waiver to prescribe buprenorphine was concern about no immediate access to consult with an addiction expert (*AOR*=0.56, 95% *CI*=0.32-0.97) (p. 1327). In another study (Netherland et al., 2009) where physicians with different levels of experience with buprenorphine (experienced, *n* = 78; novice, *n* = 45; trained-nonprescribers, *n* =

49) were surveyed, again access to a specialist came up high as a facilitating factor. The 172 physicians surveyed were given a list of 20 hypothesized factors related to buprenorphine prescribing and they were asked to rate them on a scale of 1 (doesn't affect at all) to 5 (strongly affects) and access to substance abuse counseling (full group mean = 3.48) ranked the highest facilitator across all levels of experience.

B. Buprenorphine training and education were also identified as an important facilitating factor.

To prescribe buprenorphine physicians must hold a waiver to practice opioid addiction therapy. To receive a waiver, a physician must undergo a CSAT (CSAT is a component of the SAMHSA) approved eight hour buprenorphine training. Once training is complete, the physician applies to SAMHSA for their intention to begin prescribing and they are assigned a special DEA number (also known as an X number) which allows buprenorphine prescribing. Many of the studies (Cunningham et al., 2006; Gunderson et al., 2006; Knudsen, et al., 2007; McMurphy et al., 2005; Turner et al., 2005; Netherland et al., 2009) identified training and education as an important facilitating factor in prescribing buprenorphine. In Turner et al. (2005), 248 clinic directors of primary care and/or HIV specialty clinics in NY State were asked about methadone barriers and facilitators and not about buprenorphine, however, methadone is a close proxy for buprenorphine and these findings are relevant. Of the 248 physicians surveyed, the importance of training to learn about methadone treatment ranked number 2 (203, 81.9%) out of a list of 17 barriers and facilitators to office-based methadone therapy (importance of referring difficult patients to MMTPs ranked number 1 - 241 of 248 surveyed, 97.2%) (p. 1773). Of interest, the survey also asked about willingness to provide methadone and or buprenorphine. One third of clinic directors reported willingness to provide methadone, while 59.8% reported willingness to

prescribe buprenorphine (p<.001) (p. 1771). Using face-to-face structured interviews, Cunningham et al (2006), assessed attending physicians' (n = 19) and residents' (n = 78) attitudes and beliefs about prescribing buprenorphine at an urban teaching hospital and found that 72.1% "were willing to prescribe it if they had proper training," however the term, proper training was not defined.

Gunderson et al (2006) evaluated a combined online and in person buprenorphine training, 53 of the eligible 70 physicians who attended the training completed the survey (76%). On a scale of 1 (very poor) to 7 (superlative), the online course rated significantly lower than the in person training components (p <0.001). "The session in which participants met with patients and the clinical psychologist rated highest among training components (mean 6.3, p < .001 for all comparisons)" (p. 43). In in-depth interviews with clinic directors in NY State (McMurphy et al., 2006), 17 of the 27 (63%) relayed the importance of training, stressing specialized, professional training. One participant was quoted as saying, "*I think the training that took place for this would have to be by people who have done it and would have to be down and dirty basic stuff on how to do this, not sort of textbook academic type stuff, but real day to day…"* (p. 549). West et al. (2004), identified that training of clinical staff on buprenorphine ranked second in importance by all 172 physicians, regardless of experience (full group mean = 3.42) (p. 247).

Knudsen et al. (2007) compared buprenorphine acceptability between 193 private NIDA Clinical Trial Network (CTN) affiliated counselors and 368 public NIDA CTN affiliated counselors (response rate to counselor-level mail back questionnaires was 60.9%). Both training and implementation were significantly associated with positive counselor attitudes towards buprenorphine. Greater specific buprenorphine training was associated with significantly greater acceptability ratings (private β= .257, p<.001; public β = .283, p<.001). The association between

routine buprenorphine implementation and perceived buprenorphine acceptability was also positive for both private center counselors (β = .237, $p<.001$) and public center counselors (β = .189, $p<.001$). Adding specific buprenorphine training and routine implementation to the model resulted in substantial increases in the percent of variance explained, from 10.9% to 28.7% in the private center sample and from 9.6% to 25.2% in the public center sample (p. 369)

C. *Various organizational factors were also found to be important facilitators for providing buprenorphine.*

Findings from four studies (Knudsen et al., 2009; McMurphy et al., 2006; Thomas et al., 2008; Turner et al., 2005) highlight various organizational factors as buprenorphine facilitators. In Turner et al. (2005), which surveyed clinic directors in NY State (103 provided HIV care, 146 did not) they looked at adjusted association of clinic characteristics with being likely to prescribe buprenorphine. In multivariate analysis, providing HIV specialty care was associated with 2-fold greater adjusted odds of willingness to prescribe buprenorphine (*AOR*=2.16, 95% *CI*=1.18-3.95) (p. 1774). This study also found that extra clinic personal (e.g. social workers) was ranked as very important (number 3 on a list of 17 barriers and facilitators) by 170 of the clinic directors included in the survey (p. 1773). In McMurphy et al. (2006), nine out of 27 clinic directors relayed that clinic adjustments, such as a smaller case load would be a facilitating factor to providing buprenorphine, *"...this patient has a large number of emotional, psychosocial, physical problems that needs time, as opposed to giving them a pill or medication and let them go on out the door...you simply can't do it in 10-15 minutes"* (p. 549).

In Thomas et al. (2008), which examined the use of buprenorphine among addiction specialists (n = 271) and general psychiatrists (n = 224), the variable "organization supports training and the use of buprenorphine" was highly predictive in relationship to having received

training (*OR*=7.75, 95% *CI*=2.79-21.51, *p*<.001) and prescribing buprenorphine (*OR*=2.66, 95% *CI*=1.32-5.37, *p*<.01) (p. 914). Knudsen et al. (2009) conducted face-to-face interviews with administrators from 206 community-based treatment programs (CTPs) to examine the adoption of buprenorphine over a two year period (at baseline in 2002 and at 24 months in 2004). The CTPs contacted (*n*=262) for the study were all affiliated with NIDA's Clinical Trial Network (CTN). The strongest bivariate correlate of baseline adoption of buprenorphine was involvement in the CTNs buprenorphine protocols (*OR*=9.100, *p*<.001) (p. 309). At 24 months there continued to be a strong difference in adoption between CTPs with buprenorphine-specific protocol experience and those without such experience (p. 310).

Implications of Findings from Buprenorphine Barrier and Facilitator Studies

This group of studies provides valuable insight into the attitudes and beliefs regarding using buprenorphine and providing treatment for opioid dependence/addiction in office-based settings. Understanding that physicians report adequate knowledge and experience, training, and availability of an addiction specialist as facilitating factors to providing buprenorphine, directed this research to operationalize these factors in the study design, not just for physicians, but for the whole interdisciplinary team. Given the absence in the literature on the explication of IBT/P, and what social workers, nurses, and administrators believe is important for interdisciplinary buprenorphine treatment/practice in primary care, this study will provide insight in these area, as members of each of these disciplines will be participating in this study.

Stigmatizing attitudes about drug users are clearly a barrier to buprenorphine; however they are not surprising, nor are they new. It is well documented that providers are often judgmental and mistrustful of substance-using populations (Finkelstein & Ramos, 2002;

Robertson, 1998; SAMHSA, 2000; Weiss, Kluger, McCoy, 2000). This reminded the researcher that this long standing barrier still exists and needs to be further explored and more targeted to buprenorphine. It was not surprising that several studies found that regulatory issues and record keeping were barriers to buprenorphine. The researcher has planned to assure these areas are well fleshed out and understood so they do not inhibit implementation. The finding regarding concerns about buprenorphine misuse and diversion highlighted the importance for the researcher to explore this concern with the team and key informants.

The identification that infectious disease physicians are less interested in prescribing buprenorphine than general internists is cause for concern as this research is about implementing buprenorphine within HIV primary care, where the majority of the physicians are infectious disease specialists. However, as part of the work done in the exploration and adoption stage of this study, it was identified that several of the infectious disease physicians within the research setting had already completed the eight hour buprenorphine training, obtained their waivers to prescribe and reported an interest to prescribe buprenorphine. Despite this, it is important to understand the attitudes and beliefs that different physician specialists reported in these studies, as infectious disease physicians were actively recruited to participate in the buprenorphine development, installation and implementation team.

Not all factors identified as facilitating (smaller caseloads, financial incentives) were able to be integrated into the study, however, several buprenorphine facilitating factors identified in this group of studies were already in existence in the research setting, (1) clinicians who provide HIV care and, (2) social work case management. It was encouraging to see involvement in buprenorphine protocols as a facilitating factor as the research was designed to develop an IBT/P manual that would be used by the staff at the research organization as guidance. These contextual

components were a strong baseline from which to build upon and were expected to be support the study to achieve its goals.

Overview of Barrier and Facilitator Studies Related to Implementation

In the general implementation science literature it has been noted that there is heterogeneity relative to defining the term implementation (Proctor et al., 2009). In the group of studies chosen for this review, the majority do not provide any definition for the term implementation or other key words such as sustainability. It has also been noted that "theory has not been commonly used in the field of implementation research" (The Improved Clinical Effectiveness Through Behavioral Research Group, 2006, p. 1), however, in this group of 17 barrier and facilitator studies related to implementing new practices within health care settings studies, only four are atheoretical relative to implementation (Belkora, Edlow, Aviv, Specula & Esserman, 2008; Gagnon, Duplantie, Fortin, & Landry, 2006; Koester, et al., 2007; Strauss, et al., 2009). Of the other 13 studies, two used the Ottawa model of research use, (Scott et al., 2009; Stacey, Pomey, O'Connor & Graham, 2006), five of the studies used Roger's innovations theory in some form, (Ashton et al., 2009; Greenhalgh, et al.,2004; Kramer & Burns, 2008; Magnabosco, 2006; Proctor, et al., 2007) and the remaining six studies used other theories/models: ground-level approach (Brekke et al., 2009), process migration and theory of the solution of creative problems (Fixsen, et al., 2005), normalization (Hopp, Hogan, Woodbridge & Lowery, 2007) nested systems framework (Kirsh et al., 2008), microsystems (Nemeth, Feifer, Stuart, & Ornstein, 2008), organizational change and quality improvement theory (Lucas, et al., 2008)

Participants in 15 of the 17 studies (excluding the two systematic reviews, Fixsen et al., 2005; Greenhalgh et al., 2004) came from a range of disciplines: A - administrative managers, D

– doctors, N – nurses, S - social workers, P – psychologists, and O – other (volunteers, respiratory therapists, other administrative staff members, physician assistants, health educators, and medical office assistants).

Figure 3: Participants by Discipline in Implementation Studies

STUDIES	A	D	N	S	P	O	Total
Ashton, et al., 2009	√	√	√				3
Belkora, et al., 2008		√	√	√		√	4
Brekke, et al.,2009	√			√	√	√	4
Fixsen, et al., 2005	N/A						N/A
Gagnon et al., 2006	√	√					2
Greenhalgh, et al., 2004	N/A						N/A
Hopp, et al. 2007			√				1
Kirsh, et al., 2008		√	√		√		3
Koester, et al., 2007	√	√	√	√		√	5
Kramer & Burns, 2008	√			√	√		3
Lucas, et al., 2008	√	√	√			√	
Magnabosco, 2006				√	√		2
Nemeth, et al., 2008	√	√	√			√	4
Proctor, et al., 2007	√			√	√		3
Scott, et al., 2009	√	√	√			√	4
Stacey, et al., 2006	√		√				2
Straus, et al., 2009		√	√	√		√	4
Total	9	9	10	7	5	7	

As noted in Figure 3, 11 of the 15 studies included participants from 3-4 disciplines, often referred to in the studies as "the team," thereby demonstrating the interdisciplinary nature of implementing new interventions into health care settings.

There is also considerable diversity relative to the types of interventions that were implemented: Stacey et al. (2006), studied decision support for patients facing values-sensitive health decisions, Ashton et al. (2007) studied thiazide-based treatment for hypertension, Koester, et al. (2007) studied prevention interventions for people living with HIV/AIDS, Nemeth et al. (2008) studied clinical guidelines for primary and secondary prevention of cardiovascular disease, Belkora et al. (2008) studied consultation planning, Kirsh et al. (2008) studied shared medical appointments for diabetics, Lucas, et al. (2008) studied advanced clinical access,

Brekke, et al. (2009) studied clinical database system, Scott et al. (2009) studied the use of a multi-dose inhaler/spacer for the administration of asthma medication, and Strauss, et al. (2009) studied screening and brief intervention for alcohol reduction. Three studies were related to implementing behavioral mental health treatments (Kramer et al., 2008; Magnabosco et al., 2006; Proctor et al., 2007) and two were related to the implementation of telehealth (Gagnon et al., 2006; Hopp et al., 2007).

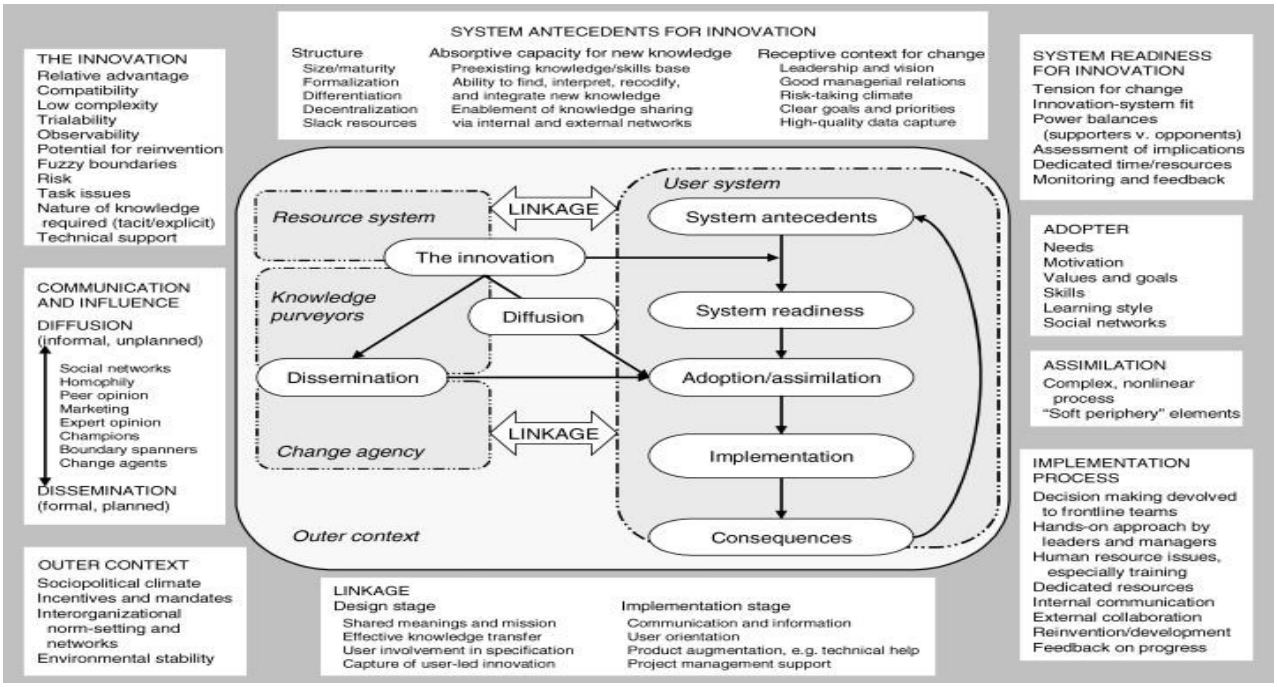
Setting wise, six studies were primary care related (Ashton et al., 2007; Gagnon et al., 2006; Hopp et al., 2007; Nemeth et al., 2008), four involved community-based mental health agencies (Brekke, et al., 2009; Kramer et al., 2008; Magnabosco et al., 2006; Proctor et al., 2007), two were in HIV primary care (Koester, et al., 2007; Strauss, et al., 2009) and the other three settings were a call center (Stacey et al., 2006), a breast cancer center (Belkora, et al., 2008) and a pediatric emergency department (Scott et al., 2009). It is interesting to note that in these studies the terms intervention, technology, innovation, program, treatment, and practices are frequently used interchangeably.

Findings from Barrier and Facilitator Studies Related to Implementation

Before turning to the findings of the barrier and facilitator studies related to implementation as a group, the Greenhalgh, et al. (2004) research, "Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations" will be highlighted for two reasons. First, there is a general academic agreement that Greenhalgh et al. (2004) is a landmark study. It is recognized as a distinct and important contribution to the field of implementation science (Institute of Medicine, 2006, pp. 169-170; Damschroder et al., 2009; Perla, Bradbury, Gunter-Murphy, 2010) and will be discussed below. Second, the findings from the other 16 barrier and facilitator studies related to implementing interventions into health care settings are

closely connected with the findings established by Greenhalgh, et al.'s (2004) review and the findings from these studies will be discussed in relation to the Greenhalgh, et al., 2004 findings. Below is the model.

Figure 4: Greenhalgh, et al. (2004) Conceptual Model for Considering the Determinants of Diffusion, Dissemination and Implementation of Innovations in Health Service Delivery (p. 595). ***Image used with permission.***



Using a novel approach to a systematic review, meta-narrative (pp. 583-585), Greenhalgh, et al. (2004) appraised a total of 1,024 full text papers and book chapters and choose 495 sources (213 empirical studies and 282 non-empirical studies) from inside and outside the sector of health care (p. 581). Eight main determinants and their corresponding features and dimensions were identified as the areas in which research had been done and findings published. The implementation determinants were graded based on the evidence supporting their conclusions using a modified version of the WHO Health Evidence Network criteria. A: strong direct evidence, B: strong indirect evidence, C: moderate direct evidence, D: moderate indirect

evidence, E: limited evidence and F: no evidence (p. 586). Below is the conceptual model developed by Greenhalgh, et al. (2004).

Greenhalgh, et al. (2004) noted that most studies in their review failed to take a comprehensive approach to implementation and only focused on a few of the components depicted in their model (p. 614). This is congruent with findings from the other barrier and facilitator studies related to implementation in this review. They confirm elements of Greenhalgh, et al.'s (2004) determinants, but they do not take a comprehensive approach to implementation. Because of this finding, each of the Greenhalgh, et al. (2004) determinants, their features and dimensions, along with the grade of their related evidence are presented individually, followed by a discussion of findings from the studies in this review related to each determinant.

Determinant #1: Innovation Attributes

Features of Innovation	**Grade of Evidence:**
Advantage	A, D, C
Compatibility	A, A
Complexity	C, A, B, D, E
Trialability	A, B, C
Observability	A, E
Reinvention potential	A, E
Fuzzy boundaries	C
Risk	A, C
Task issues	A, E, A, E
Knowledge Required (tacit – explicit)	B, C
Technical Support	A, C

Greenhalgh et al. (2004) point out that the attributes of the innovation are, "necessary but not sufficient to explain the adoption and assimilation of complex innovations in organizations" (p. 597). In the studies chosen for this review, the features of trailability and reinvention of the innovations were identified in several studies as important to implementation. Hopp, et al.

(2006) conducted in-depth interviews with clinicians who implemented monitoring and messaging devices (MMDs) for patients with diabetes in a VA Medical Center in the Midwestern US. They identified that initially all diabetes patients were referred for MMDs and this resulted in many patients who were not appropriate for the system. Overtime they developed a set of clinical and nonclinical factors in enrollment decisions, to be considered before referral, and this adaptation was identified as a facilitating factor to implementation. Nemeth, et al. (2008) examined the processes of change used to implement clinical guidelines for primary and secondary prevention of cardiovascular disease in eight small private primary care settings in Seattle. They interviewed 28 staff members and clinicians who were involved in the implementation and "taking small steps" was a theme that emerged as a facilitating implementation factor. "All the practices had taken small steps, trying new methods and adjusting to the changes in their practice as they sought to embrace the clinical guidelines" (p. 7).

Kirsh, et al. (2008) discussed the implementation of shared medical appointments (SMAs) for patients with diabetes within one primary care clinic in an urban academic medical center that provided care for 11,000 patients (25% with diabetes). They conducted a retrospective study evaluating notes from reports, meetings and debriefings of this quality improvement, along with interviews with key informants. They reported that the system redesign that resulted from implementing SMAs included, "continuous tailoring of the intervention to and continuous adjustment of the local context" (p. 10). The same study identified that at the outset, SMAs were identified by the staff as a vague, unknown type of clinic care and this constituted a barrier to implementation. The authors relay that they decided to have a trial period with small numbers of patients as well as having clinic practitioners sit in on one to three SMAs and this served to facilitate implementation (p. 10). Brekke, et al. (2009), reported

from the field on work done implementing evidence-based interventions for individuals with schizophrenia in a mental health rehabilitation agency in California. They identified a six-step process that supports implementation in which the clinicians learn the intervention as designed, "then engage in a process of local adaptation using the notions of core ingredients and shell ingredients, always with feedback from the external specialist" (p. 597).

Twenty-five of 31 nurses involved in the training and implementation of a decision support protocol, responded to a survey to measure adoption of the protocol, (Stacey, et al. 2006). Decision support in this study was an intervention that directed call center nurses to assist patients with becoming informed and clarifying their values regarding sensitive health decisions. This study took place in a Canadian province-wide call center. Of the 25 nurses, 11 (44%) had used the decision support protocol in their practice within one month of the intervention and 21 nurses (84%) agreed that they were "comfortable using the decision support protocol" (p. 5). However, even with a high degree of comfort using the new intervention, a focus group conducted with 8 of the 31 nurses demonstrated that several adaptations (decision aids in the data base needed to be easier to locate and revised for use over the phone; linking the decision aids into the documentation system, p. 6) would facilitate further implementation. Koester, et al. (2007) discussed modifying the HIV prevention counseling delivered in their study, (p. S23), and Belkora, et al., (2008) discussed adapting their consultation planning intervention for non-English speaking patients as supporting implementation.

Fixsen, et al., (2005) who conducted a synthesis of implementation research from fields both inside and outside the world the human services (1,054 articles identified, 743 articles met study inclusion/exclusion criteria, 377 articles determined to be relevant for implementation and were included in their synthesis, p.vi) also discussed the concept of reinvention as an

implementation facilitator, but cautioned about timing. They reported that the core components of an intervention "may best be defined after a number of attempted applications of a program or practice, not just the original one" (p. 25). They cited a study done by Panazano, et al. (2004) that evaluated implementation of evidence-based interventions in behavioral healthcare organizations which found that negative consumer outcomes were associated with reinvention during initial implementation (p. 19). Throughout their monograph, Fixsen, et al., (2005) continually stress that knowing the intervention well, which includes its underlying practices and principles, are an important aspect to successful implementation.

Determinant #2: Adoption by Individuals & Assimilation by the System

Features of Adoption by Individuals	**Grade of Evidence**
General Psychological Antecedents: Individual Traits	(beyond scope of study)
Context-Specific Psychological Antecedents	A, B
Meaning	B, C, D, A, E
The Adoption Decision	D
Concerns in Preadoption Stage	B
Concerns during Early Use	B
Concerns in Established Users	B
Features of Assimilation by the System	A
Complex Nonlinear - Process Oriented	
Soft Periphery Elements	

Adoption of an innovation in service organizations has been characterized as a process as opposed to an event, "with different concerns being dominant at different stages" (Greenhalgh, et al., 2004, p. 600). These findings were also reported by Fixsen, et al. (2005). They relayed that deciding to adopt an innovation should not be confused with putting a practice into use (p. 16). The meaning of the innovation to the adopter and the adopter's motivation were also been noted as important to implementation, "an intended adopter who is motivated and able (in terms of values, goals, specific skills and so on) to use a particular innovation is more likely to adopt it"

(Greenhalgh, et al., 2004, p. 599). Several of the barrier and facilitator studies related to implementation in this review also support these findings.

Gagnon, et al. (2006), conducted a qualitative field study in four remote regions of Quebec to explore physicians and hospital managers' perceptions of telehealth, after several telehealth projects had been implemented, evaluated as generally positive, and then failed to normalize in their initial form (p. 2). A purposive sampling technique identified 40 physicians and 14 managers who had involvement in previous telehealth experimentation and they were asked about conditions that would facilitate telehealth integration into clinical practice. The authors relayed that participants identified that the motivation of healthcare providers was determined to be an important facilitator. They relayed that participants were interested in a "bottom-up implementation strategy where end-users are first consulted to identify their needs and expectations, followed by an iterative approach where they are involved in decisions at different stages of the project development" (p. 6).

In a study by Kramer & Burns (2008) that evaluated the implementation of CBT for depressed adolescents within two publicly-funded mental healthcare centers, they identified clinicians who were able to adopt and sustain CBT and clinicians who were not. Clinicians were randomized into either intervention (n=11) or usual care (n=14). Nine intervention clinicians completed the CBT training and participated in qualitative interviews. The clinicians who adopted and delivered CBT were identified from the beginning as having positive attitudes about the intervention. They remarked, "*I really enjoyed doing the CBT, "I feel like I've learned a lot doing this,"* and *"I can now add this to my clinical repertoire*" (p. 6).

A prospective qualitative study, (Proctor, et al, 2007) with a focus on developing and testing implementation strategies, conducted interviews with seven directors of mental health

agencies to obtain their perspectives on implementing evidence-based practices (EBP). On an individual level, several directors identified provider resistance to learning new practices as a challenge, "even those with an established efficacy base" (p. 483). The directors' strategies to address this were to try and hire clinicians who were closer to their training and more dynamic in their thinking. The authors identified that these comments highlight the importance of increasing provider receptivity to EBP (p. 483). Koester, et al. (2007) also identified provider resistance to implementing HIV prevention interventions for people living with HIV/AIDS, which was countered by "enthusiastic and public support of the medial directors" who were able to both, endorse and enforce the intervention (p. S28).

Determinant #3: Communication and Influence

Features of Communication and Influence	**Grade of Evidence**
Diffusion (informal, unplanned)	
Dissemination (formal, planned)	B
Dimensions of Diffusion & Dissemination (on a continuum)	
Social Network	B, C
Homophily	A
Peer Opinion	
Marketing	
Expert Opinion	A, C, B, C
Champions	A, C
Boundary Spanners	B, C
Change agents	

The implementation determinant communication and influence, identified by Greenhalgh, et al. (2004) were also found by Fixsen, et al. (2005) to be two of the five essential components for implementation (p. 12). A communication link, referred to in the Fixsen monograph as a "purveyor", actively works to implement a practice and is a key element to overall implementation success (p. 12). Influence is also a component of Fixsen, et al.'s implementation model and is defined as the, "social, economic, political, historical, and psychological factors

that impinge, directly or indirectly on people, organizations or systems" (p. 12). Greenhalgh, et al. (2004), identified that there is strong indirect and moderate direct evidence that adoption of innovations by individuals in an organization are more likely, if it is supported by a key individual in their social networks. This person is often referred to as a champion and different champion roles (organizational maverick, transformational leader, organizational buffer, network facilitator) were identified. It is interesting that Greenhalgh, et al. (2004) also noted, "There is little direct empirical evidence on how to identify and systematically harness the energy of, organizational champions" (p. 603). Three other studies in this review identified the importance of an internal champion relative to the success of their implementation (Belkora, et al., 2008, p. 4; Brekke, et al., 2009, p.596; Lucas, et al., 2008, p. 105).

Determinant #4: Inner Context (System Antecedents for Innovation)

Features of Inner Context	**Grade of Evidence**
Structural Determinants of Innovativeness Nonstructural: Absorptive Capacity of Knowledge Nonstructural: Receptive Context	
Dimensions of Structural Determinants of Innovativeness Size, Maturity, Formalization, Differentiation Decentralization, Slack resources	A
Dimensions of Absorptive Capacity for Knowledge Pre-Existing Knowledge/Skill Base Ability to Find, Interpret, Recodify and Integrate New Knowledge Enablement of Knowledge Sharing via Internal and External Networks	A
Dimensions of Receptive Context Leadership and Vision Good Managerial Relations Risk-Taking Climate Clear Goals and Priorities High Quality Data Capture	B, C, A

In discussing inner context as a determinant of implementation, Greenhalgh, et al. (2004) make the distinction that some of the dimensions are objective, such as the size, maturity,

formalization, and resources of an organization and others are not objective or given, such as the ability to find, interpret, recodify, integrate new knowledge as well as knowledge sharing. The latter are described as "socially constructed and frequently contested and must be continually negotiated among members of the organization or system (p. 606). Scott, et al. (2009) found that despite well-established effectiveness of their intervention (a multi-dose inhaler/spacer for the administration of asthma medication), some providers remained skeptical (p. 3). Kramer & Burns, (2008) reported on the challenges of integrating CBT, with several of the interventionists reporting it was too complex (p.6)

Several studies found receptive context as an implementation facilitator. Stacey, et al (2005) identified clear goals and priorities from administration as a factor important to sustaining the value-sensitive decision support by call center nurses (p. 6). Similarly, Nemeth, et al. (2008) identified leaders setting a vision with clear goals as a core theme related to their work in implementing change in primary care practices. Gagnon, et al. (2006) reported that one of the conditions for success in implementing telehealth had to do with good managerial relations, in the form of promoting participation of the physicians and including them in decision-making about the implementation (p. 6).

Four of the studies in this review were conducted within Veteran Affairs Medical Centers (Ashton, et al., 2007; Hopp, et al., 2006; Kirsh, et al., 2008; VanDeusen, et al., 2008) and they highlight the importance structural components as implementation facilitators. The ability to implement innovations in these settings, often with large numbers of patients and staff (Ashton, et al., 2006; Lucas, et al., 2008) or using state of the art technologies (Hopp, et al., 2006; Kirsh, et al., 2008) were tied to their inner context of size, maturity, formalization and resources. This could also be said of the two studies that implemented their innovations within HIV/AIDS

clinics. Koester, et al. (2007) worked with 15 clinic-based projects across the country, while Strauss, et al. (2009) worked with seven DACs in NYC. The majority of these settings were comprehensive, hospital-based, university-affiliated, state-licensed treatment centers and their structural components facilitated the implementation of the innovations.

Other studies also identified inner context determinants as important to implementation. Proctor et al. (2007), who conducted interviews with directors of mental health agencies, found key leverage points for implementation were: director leadership, support to providers, and partnerships with universities as (p. 484-485). Along similar lines, Brekke, at al. (2009) also found that support for researchers and community mental health providers (p. 596) and establishing working and sustainable partnerships (p. 597) facilitated the implementation of evidence-based mental health services.

Determinant #5: Features of System Readiness for Change

Features of System Readiness for Change	**Grade of Evidence**
Tension for Change	C
Innovation System Fit	B, C
Assessment of Implications	B
Power Balances (supporters v. opponents)	B, C
Dedicated Time and Resources	B, C
Capacity to Evaluate	B, C

It is recommended that an organization take steps to assess and anticipate the impact of an innovation, however there is "relatively little systematic research on the development of system readiness" (Greenhalgh, et al., 2004, p. 619). Fixsen et al. (2005) echoes this finding (p.8) and reported that while various readiness assessment scales were in development, at the time of their writing there were no established predictive validity (p. 10). The field of assessing organizational readiness for change in clinical care continues to evolve and to date there is no

research supporting any one instrument (Helfrich, et. al., 2011; Weiner, Amick & Lee, 2008). Of all the features of system readiness discussed in the papers for this review, several studies reported increased workload as a barrier to implementation of intervention. In-depth qualitative interviews (*n*=10), conducted by Hopp et al. (2006) found that while nurses found the monitoring and messaging device (MMD) was a useful tool, in qualitative interviews, a major theme to emerge was that the MMD added to the telehealth provider's workload (p. 4). Burdensome workloads and staff shortages were identified by Proctor, et al. (2007) as barriers to implementing evidence-based interventions in community mental health agencies (p. 483). Kramer & Burns (2008) also reported that seven of the nine intervention clinicians who had been trained in CBT relayed that productivity demands limited their ability to participate in the study (p. 6).

Belkora, et al. (2008) found that in post-training follow-up interviews about barrier and facilitators to implementation of consultation planning (CP), four of the 18 responding trainees (from four different community centers) did not implement CP because of scarcity of program resources (p. 6). In assessing HIV care providers' (*n*=115) implementation of routine alcohol screening and brief intervention (SBI), one of the findings by Strauss, et al. (2009) was that "providers were significantly (p <0.05) more likely to have routinely provided more than the median number of alcohol SBI components with patients with HIV if they had "a specific case load" (p. 215). In this study having a specific caseload meant that they had a lower number of patients than other providers. Scott et al. (2009) found that the participants in their study cited the extra time it would take to administer the mediation using the newly implemented multi-dose inhaler/spacer as a barrier to implementation (p. 4). This study conducted both individual interviews (*n*=16) and focus groups (*n*=21) with staff (physicians, nurses, respiratory therapists,

as well as medical and nursing directors) in nine Canadian pediatric emergency departments where the MDI/spacer had been implemented.

Determinant #6: Outer Context: Interorganizational Networks and Collaboration

Features of Outer Context	**Grade of Evidence**
Social and Political Climate	A
Incentives and Mandates: Intentional Spread Strategies	C, C
Informal Interorganizational Norm Setting and Networks	A, B, C, C
Wider Environment Incentives and Mandates	C
Environmental Stability	C
Political Directives	A, C, B

A number of factors in the external environment effect implementation. "An important influence on an organizations decision to adopt, is whether a threshold proportion of comparable organizations have done so or plan to do so" (Greenhalgh, et al., 2004, p. 608). The studies in this review did not address the issue of the effects of norm setting and networks related to implementation. However, relative to the outer context, two studies reported concurrent events occurring in their wider organizations, at the time of their implementation, which were likely to have influenced the outcomes of their study. Stacey, et al. (2006) reported on changes in supervisor role restructuring, major changes in staffing patterns and contract renewals (p.4). Ashton, et al. (2007) relayed that after their intervention period ended, they learned of a quality improvement project in their organization that was also geared to increase thiazide prescriptions, and the effect of their intervention was probably muted because of the quality enhancement project (p. 10). Fixsen, et al. (2005) wrote that, "organizations exist in a shifting ecology of community, state, and federal social, economic, cultural, political and policy environments that variously and simultaneously enable and impede implementation" (p. 58).

Determinant #7: Implementation Process

Features of Implementation Process	**Grade of Evidence**
Decision Making Devolved to Frontline Teams	A, B
Hands on Approach of Leaders and Managers	B, C
Multiple Human Resource Issues especially Training	C, B, B, C
Dedicated Resources (funding/finances)	A
Internal Communication	B
Interorganizational Networks (external collaboration)	D
Reinvention/Development	B, C
Feedback on Progress	B, C

Greenhalgh, et al. (2004) reported that formal facilitation initiatives with early and widespread staff involvement, along with high-quality, on the job training make successful and sustained implementation more likely (p. 611). They also found that, "establishing semiautonomous multidisciplinary project teams is independently associated with successful implementation" (pp. 605-606). Many studies in this review also identified the features of staff involvement, training and implementation teams as important and relevant to implementation.

Brekke, et al. (2009) reported on a unique model of implementing evidence-based interventions (EBIs) within community based mental health programs. They describe a new position they created called the embedded generalist purveyor, who carries one-half the caseload of their colleagues and is schooled in general principles of implementation research, practice and organizational dynamics. In addition to providing direct client services, their work focuses on assessing the needs and desires of the agency in terms of EBIs not currently in use. After the EBI is selected, this person receives training in the EBI and then they train and supervise their colleagues as well as supervise local adaptations. This study was a report from the field and the authors relay they were in the process of assessing the expense of such a model and in what situations it would be best utilized (pp. 595-596).

Stacey, et al. (2006) in their study with call center nurses, distinguished various types of training as important to implementation, (1) simulation and practice, (2) in-services focused on sharing experiences from decision support calls, (3) mentoring and coaching by supervisors, and (4) education beyond initial orientation (p. 6). Kramer & Burns, (2008), in evaluating the implementation of CBT in community mental health programs, reported that "implementation may have failed, in part, because ongoing supervision, collaboration with other clinicians, and booster training sessions were not adequately supported by the larger system" (p. 7). Magnabosco, (2006) also noted various types of training and education that mental health systems in the US used when implementing a range of evidence-based practices, (1) meetings, (2) workshops, (3) conferences, (4) demonstrations, (5) toolkits, and (6) technical assistance.

In training providers to implement HIV prevention interventions, Koester, et al. (2007) noted a conflict between the amount of training time needed (two-three days) and the amount of time providers could be available. "The clinics either had to be shut down, or providers asked to attend after-hours trainings. Few clinics could afford an entire day dedicated to training providers" (p. S28). Training costs and "time is money" issues were also noted by Proctor, et al. (2007) in their study with mental health agency directors (p. 483). Nemeth, et al. (2008) also reported on the importance of having dedicated time to develop templates and systems during the implementation of primary and secondary prevention of cardiovascular disease in primary care using a common electronic medical record (p. 7). Scott, et al. (2009), in studying the multi-dose inhaler/spacer implementation, reported on the importance of educating staff, patients and families about the new intervention (p. 4) and Strauss, et al. (2009) reported on the importance of the staff learning, "both the negative impact of excessive alcohol use on patients with HIV and the importance and value of alcohol screening and brief intervention" (p. 211).

Relative to the use of teams to support implementation of interventions, Fixsen, et al. (2005) identified seven core implementation components that can be used to implement evidence-based practices. Three of the seven components are congruent with the features of implementation teams and training, (1) staff selection, (2) pre-service training, (3) consultation and coaching (pp. 28-29). Ashton, et al. (2006), who implemented an intervention to increase the use of thiazide-based treatment regimens for people with hypertension, reported that the implementation plan was team-base, which they subdivided into four groups with specific responsibilities. They describe an iterative process, over a 10.5 month period, where the teams met at weekly or biweekly steering committees to present various assigned tasks such as data analysis and product development (pocket cards with treatment algorithms and comparative drug costs, posters, lectures, electronic reminders) and obtain feedback and advise (p3). They reported that the team process was feasible and effective, however they gave no detail regarding the number of staff on the team, the make-up of the team, or who had the authority to determine distribution of labor or how time to participate in the team and produce the various products and analysis was determined.

One of the main findings by Nemeth, et al. (2008) was noted as "involve the team". They relayed that when staff members were involved in decision making, had clear vision and goals and, "were responsible for leading some component of the work plan to achieve results, they adapted to make change happen" (p. 5). Kirsh, et al. (2008) who implemented shared medical appointments within a primary care clinic, over a two year period, reported on a number of factors that promoted implementation. They wrote, "we believe that the most essential factors were the formation of a core team committed to quality and improvement, and the leadership provided by the clinic director that was supported strongly by the team members" (p. 7). Unlike

the Ashton, et al. (2006) study, this study gave extensive detail about the team, who was included, how they worked and divided labor and who had authority related to their processes. Brekke, et al. (2009) also reported on the success of a team effort, which included consumers, practitioners, supervisors, administrator and researchers, who participated in weekly workshops for 6 months in the building and implementation of a clinical database. They relayed that, "clinicians, clients, and administrators can be engaged in this process, they can take ownership of it, and the product can be developed with proper expertise from multiple perspectives" (p. 599).

Determinant #8: Linkage of Model Components

Features of Linkage of Model Components	Grade of Evidence
Design Stage	B
Implementation Stage	B

Greenhalgh, et al.'s (2004) eighth determinant within their conceptual model, stresses that each determinant does not operate on its own. "There is some empirical evidence (and also robust theoretical arguments) for building strong links among the different components of the model" (p. 612). Fixsen also reported on the importance of coordination and linkages. No other studies in this review approached implementation from the level of comprehensiveness described by Greenhalgh, et al. (2004) and Fixsen, et al (2005). However, all studies in this review identified communication and coordination as important for implementation.

Implications of Findings from Barrier and Facilitator Studies Related to Implementation

Like the barrier and facilitator literature related to buprenorphine, this group of studies also provides many interesting insights. Of particular interest is that many of the facilitating factors identified in these studies were integral to the research design prior to reading the barrier and facilitator implementation literature because of AR. The very nature of AR, with its process oriented, collaborative, participatory, interdependent, nonexploitative, capacity building, and

context dependent approaches are congruent with many factors reported in these studies to facilitate implementation. For example, findings noted to facilitate implementation such as the use of: (1) semiautonomous teams and involving front line workers, (2) process oriented approaches, (3) internal champions, (4) good managerial relations, and (5) training, education and mentoring were all planned from the outset. Seeing these factors identified in this literature as promoting implementation bolstered and reinforced their use in this study.

Other factors found in these studies, not related to AR, also provided important insights and were included in the research design. Barriers to implementation, such as staff resistance directed the researcher to assess this aspect when recruiting team members and be prepared for it when speaking with the general staff. Concerns about the intervention being burdensome and/or increasing staff's workload highlighted for the researcher the importance of addressing this issue upfront with staff and to use the development aspect of the study to counter this potential negative factor.

Several studies identified the importance of being prepared for emerging organizational and/or institutional issues beyond the knowledge and control of the researcher that could either impede or enable implementation. This provided sound advice and a good reality check about the limits and possibilities of what might be accomplished in this study. Facilitating factors, such as, (1) taking small steps, (2) identifying core components of the intervention, (3) being able to modify and adapt buprenorphine to the local context, (4) having clear goals and objectives, and (5) linking multiple components of the implementation process also influenced the study and these approaches were operationalized in the research design. Finally, several other aspects found to facilitate implementation such as, (1) leadership support, (2) available

resources, and (3) size and maturity of the organization were aspects of the research organization that were assessed as available and worked in the favor of this project.

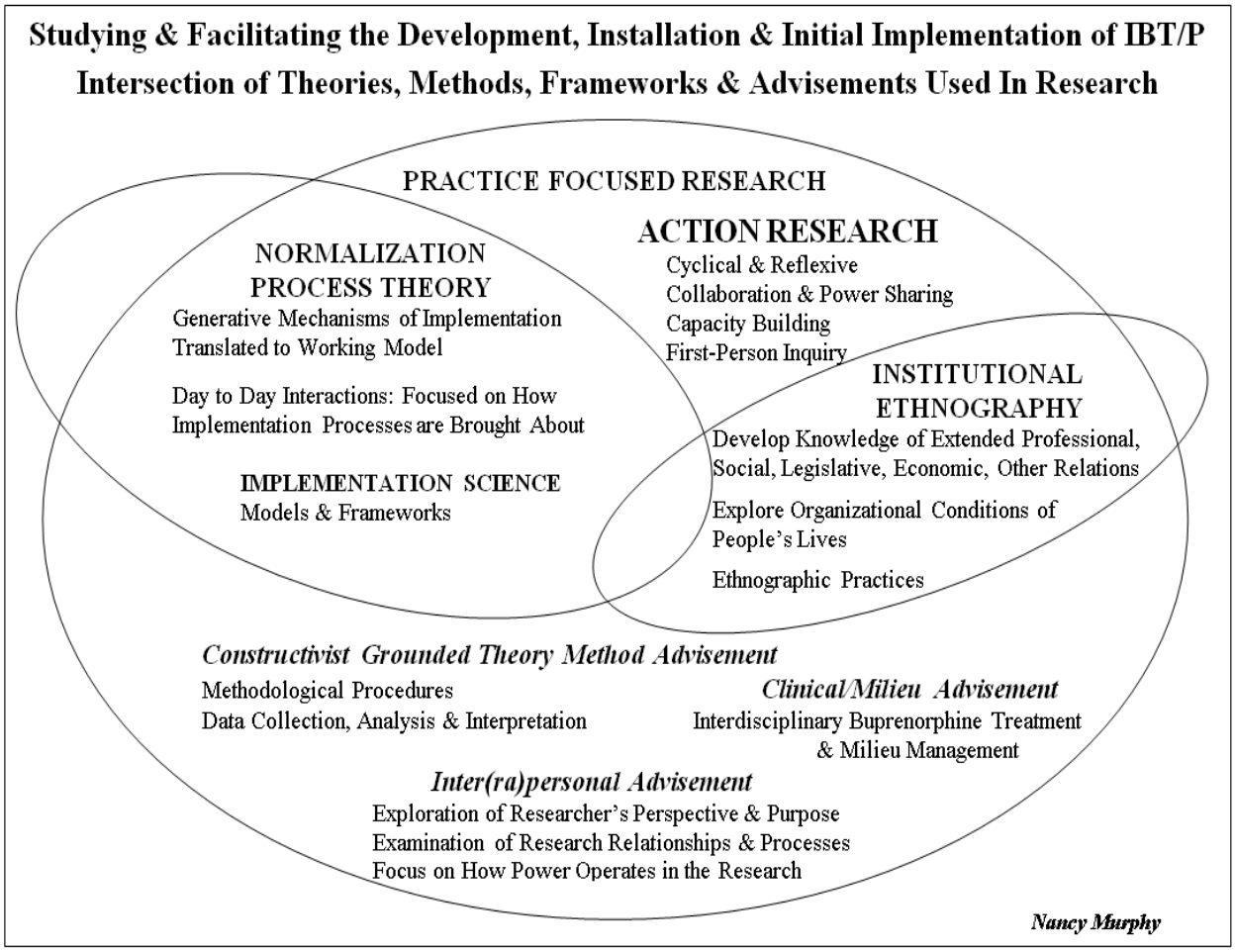
Greenhalgh, et al. (2004), also identified that the determinants of their model were not exhaustive and they identified conspicuously absent determinants such as internal politics and power relations. They acknowledged that these are both critical to implementation and extremely difficult to study (p. 614). They also highlighted that "context and "confounders" lie at the heart of diffusion, dissemination, and implementation of complex innovations. They are not extraneous to the object of the study: they are an integral part of it" (p. 615). Managing power relations and attending to local context are also key features of AR and were also factored into the research design.

Grouping the findings from these studies under the eight determinants from Greenhalgh et al.'s (2004) conceptual model provided a useful framework for thinking and planning comprehensively about implementation. In addition to using this model and the research findings for guidance, the researcher also followed the recommendation of Greenhalgh, et al. (2004) regarding how the next generation of implementation research should be conducted: (1) theory-driven, (2) process rather than "package" oriented, (3) ecological, (4) addressed using common definitions, measures, and tools; (5) collaborative; (6) multidisciplinary and multi-method; (7) meticulously designed and (8) participatory (pp. 615-616). It is interesting to note that five (process, ecological, collaborative, multidisciplinary and multi-method, and participatory) of the eight recommendations are all aspects of AR. The next chapter will discuss more fully AR and the other theories employed in this study and how each provided methodological direction for this study.

Chapter 4: Theoretical Frameworks and their Application to the Research

Three main theories, AR, NPT, and IE were chosen to guide this study because: (1) all are theories of action that emphasize learning and explaining the phenomena under study so as to enact change, (2) they are all grounded in the everyday world and experiences of the people involved in the study, (3) they are oriented to inquiry with people (as opposed to inquiry on people), and (4) they are commensurate with each other and commensurate with critical and feminist scholarship, the grounding philosophy of this study. Below is a diagram depicting the intersection of the theories, their main features as well as other methods and practices used in this study.

Figure 5: Intersection of Theories, Methods and Practices



As represented in the above diagram, AR, NPT and IE provided the majority of the methodological direction for this study; however, other models, frameworks and practices were necessary to adequately address the research questions, as well as assure appropriate reflective practices and quality data collection, analysis and interpretation. These will be discussed further in chapter 5. This chapter provides a history and overview of each theory, their application to the research questions and concludes with a discussion regarding the advantages of combining the three main theories.

Action Research

AR is an approach to inquiry that bridges the gap between theory and practice through reflection and inquiring into the cyclical AR processes of constructing, planning action, taking action and evaluating action, which are central to the development of actionable knowledge (Coughlan & Brannick, 2010, p. 8-12). Reflection on the content, process, and premise of the project is critical to the AR cycles and learning, as reflection is the activity that integrates action and research (p. 25). AR is also oriented to address the negative effects of authoritarian processes and throughout the research there is a focus on collaboration (with those directly affected by the research), engagement, power sharing and capacity building (Stringer, 2007, pp. 20-24).

AR has been referred to as a family of approaches with a rich theoretical and practical history (Reason & Bradbury, 2008, p. 11). Kurt Lewin (1890-1947), the social psychologist is credited as being one of the founding social scientists of AR. He developed AR when applying collective group action to address societal conflicts, particularly in organizations and the workplace and is credited with articulating the AR processes as cyclical (Bradbury, Mirvis, Neilson & Pasmore, 2008). AR has been shown to be useful with implementing practices and

services in health care settings (Minkler & Wallerstein, N, 2008; Hughes, 2008; Waterman, et al., 2001). The AR tradition allows for the degree of participation, action, research (p. 386) and the commitment by either or both the researcher and system, to intended self-study in action (Coughlan & Brannick, 2010, p. 103) to be determined by each project depending upon the context, situation and available resources. For purposes of this study, the staff that would eventually be delivering buprenorphine treatment were the main participants in the study.

AR, "seeks to develop and maintain social and personal interactions that are nonexploitative and enhance the social and emotional lives of all people who participate" (Stringer, 2007, p. 27). Its main factors are focused on: (1) context, (2) quality of relationships, (3) quality of AR processes, and (4) outcomes of AR efforts (Coughlan & Brannick, 2010, p. 3). AR recognizes that power and control are a significant factor in professional, bureaucratic, and organizational life (Coughlan & Shani, 2008, p. 651; Stringer, 2007, p. 33) and they are an object of study. This is achieved through reflecting on the various kinds of power that are at play in the research so to develop actions that work toward thwarting reducing, or neutralizing the negative and destructive effects of power and control. Reflections on how power was operating in the study will be discussed in chapter 6.

Knowledge development and capacity building in this study was influenced by an aspect of AR known as co-operative inquiry, which focuses on four kinds of interdependent knowing: (1) Experiential: direct, lived, being in the world knowing, (2) Presentational: the knowledge expressed when shaping experiential knowing into a communication form such as images, music, language, etc., (3) Propositional: knowing about something in intellectual terms of ideas and theories, and (4) Practical: knowing "how to do" appropriately, skillfully and competently (Heron, 1996, Heron & Reason, 2008). Heron (1996) describes this view of knowledge as a

"dynamic pyramidal process" (p. 33), with experiential knowing as the base, building up to practical knowledge. He explains this as a, "systematic whole, an interdependent up-hierarchy … what is below supports, grounds, empowers what is above" (Heron, p. 33). In this model and in this study, the development and exercising of practical knowledge was considered "the fulfillment of the knowledge quest" (p. 34).

This study is further differentiated as insider AR (Coughlan & Brannick, 2010; Torbert, 1976), because the researcher/facilitator conducted the study within the organization where she had been employed for eight years. The inside action researcher differs significantly from those who enter a system temporarily for the purpose of conducting research. Of particular importance is the need to recognize, "that politics are not only a fact of organizational life but *the* fact" (Coughlan & Shani, 2008, p. 651). Three interlocking challenges have been identified for those who undertake research within their own organizations, (1) preunderstanding: building on the closeness they have with the system while simultaneously creating space so as to see things critically and make change happen, (2) dual roles: managing the ambiguities and conflicts between being an organizational member and the action researcher, and (3) organizational politics: negotiating the political dynamics of organizational life and balancing the requirements of their future career plans with requirements for the success and quality of their AR (p. 646).

From an AR perspective, there are two forms of inquiry occurring simultaneously, which are interrelated. Zuber-Skerritt and Fletcher (2007) have identified these as the (1) core AR and (2) the thesis AR. The core AR consists of two aspects. First is the collaborative inquiry, (referred to in AR as second-person inquiry) where a group or team works collaboratively and recursively through the AR cycles to achieve the action component of the project's aims. In second-person inquiry the team is a significant focus of attention in the study and the source of

decision making (Stringer, 2007, p. 25- 27; Zuber-Skerritt & Fletcher p. 429). The second aspect of the core AR is the independent inquiry (referred to in AR as first-person inquiry) where the researcher undertakes ongoing reflective/reflexive practices throughout the study. This self-study is undertaken by the researcher to learn about their assumptions, ways of thinking of the events of the research as they unfold, and the impact of their own behavior so that measured, thoughtful steps can be taken (in action), to facilitate achieving the goals of the study. (Coughlan & Brannick, 2010, p. 141). "*First-person skills* entail learning to act politically within the values of action research…This praxis-reflection methodology involves attention to and reflection on the personal questions and dilemmas which arise in the political dynamics of the action research project" (Coughlan & Shani, 2008, p. 651). The second simultaneous form of inquiry in AR, the thesis AR, is also independent inquiry, where the researcher is addressing the research questions, along with evaluating the AR project and what is being learned (Coughlan & Brannick, 2010, pp. 11-12; Zuber-Skerritt & Fletcher, 2007, p. 429).

Using the AR frame described above, the researcher received approval from the director of the organization to assemble an interdisciplinary team from the existing staff (administration, medicine, mental health, nursing, social work and specialists) to work together to develop, install and initially implement an IBT/P. As AR is grounded in the everyday world of the people involved in the research, the study was designed so that the interdisciplinary team working on the development of the IBT/P would become the lead clinicians and administrators, once practice was ready to commence. A full explanation of how the various aspects of the AR work was undertaken in this study will be addressed in the following chapter and a description of the how AR informed implementation of IBT/P will be discussed in chapter 6.

Normalization Process Theory

NPT is a recently published mid-range theory of implementation that focuses on collective action relative to implementing new practices into health care settings (May & Finch, 2009). It was developed by English sociologists and is based on findings from ethnographic studies evaluating telemedicine implementation processes, in which May & Finch were key investigators (May, et al., 2009). It is concerned with the social production and organization of the work (both mental and material) related to implementation, the ways in which this involves participants, its outcomes (which are contingent upon this work) and its effects. It provides a set of definitions, a systematic explanation about relationships among its concepts, and analytic propositions that help to understand and explain the social processes through which new or modified practices of thinking, enacting and organizing are operationalized in health care (May et al, 2010).

May & Finch (2009), the authors of NPT, lay out how NPT differs from more traditional theorizing about implementation that includes: social influence theories, such as Everett Rogers', Diffusion of Innovations Theory, (2003) that focuses on the process of adopting and championing innovations, particularly from an entrepreneurial perspective; social shaping theories, such as Bruno Latour's Actor-Network Theory (2005) that focuses on exploring the relational ties within a network of things, which includes the agency of nonhumans; and management theories, such as Jonathan Linton's work (2002), that focuses on technological innovations and management of behaviors (May & Finch, 2009, pp. 536-537). While these theories may be meaningful in their respective fields, May & Finch relay that these theories are not useful for students who are interested in implementation processes, as they do not address, "how these processes are brought about" (p. 537). They also articulate how NPT differs from

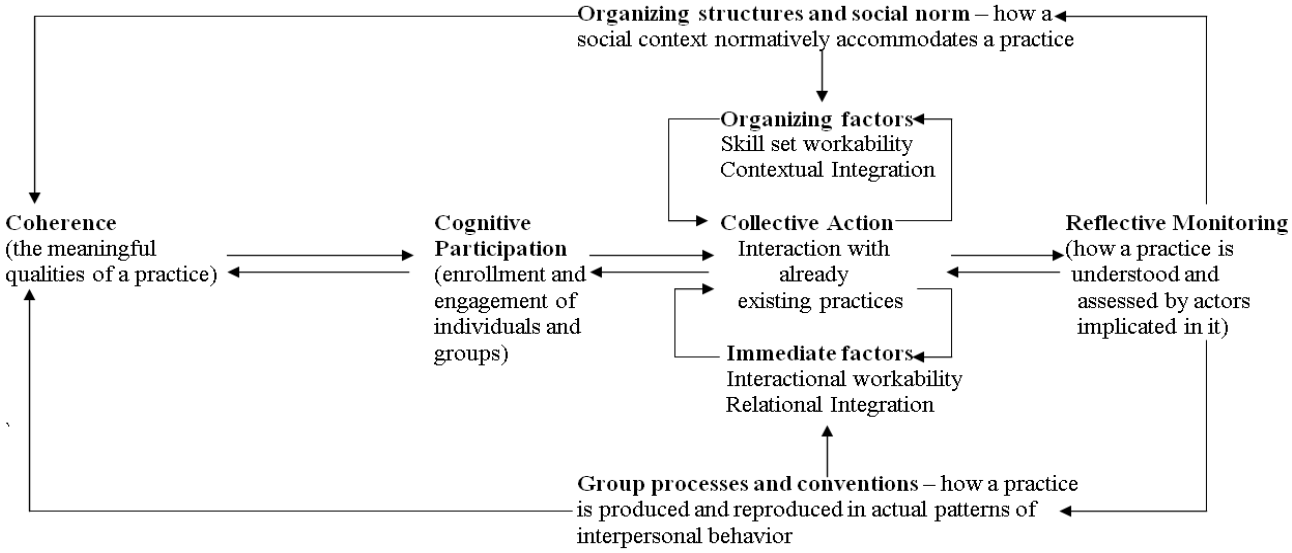
individual action theories of implementation that focus on individuals' intentions, volitions, and purposes as the basic unit of analysis. This includes such theories as behavioral economics (Becker, 1976), rational choice theory (Coleman, 1986) and Theory of Planned Behavior (Ajzen, 1991). They argue, "Although it is undoubtedly the case that actors do have preferences and intentions that they seek to express, there are always social factors that promote or constrain particular expressions of agency. . . individual intention and preferences are thus necessary, but not sufficient, explanations for collective action" (p. 538).

NPT's Generative Mechanisms

Coherence, Cognitive participation, Collective Action and Reflective Monitoring

NPT advances the conceptualization of implementation from general processes and effects to identifying four specific generative mechanisms **(coherence, cognitive participation, collective action and reflective monitoring)** by which implementation is produced. These mechanisms specify what processes, 'brings about or prevents some change in a concrete system' (Bunge, 2004, p. 193)" (May & Finch, 2009, p. 546).

Figure 6: Model of Normalization Process Theory (May, et al., 2010)
Model reproduced with permission



Each of the four generative mechanisms contains four components that specify the qualities of work related to each mechanism; these mechanisms and their related components are the main thrust of the theory. Below is a model of NPT, depicting the four generative mechanisms within the larger organization. This is followed by an explanation of the mechanisms and their associated components.

1. **Coherence**

Coherence is the sense-making work of implementation and focuses on: What is the work? It means that a practice (an ensemble of beliefs, behaviors, and acts that manipulate or organize objects and others) is made possible by a set of ideas about its meaning, users, and utility; and by socially defined and organized competencies. These meanings and competencies hold the practice together and make it possible to share and enact it (May & Finch, 2009, p. 542).

Differentiation – attributes an identity to the intervention – establishes coherence by defining the components of a practice, and its differences from other already established practices (p. 542).

Individual Specification – how the practice is rendered by individuals – concerned with fit between the work of communal (externally imposed) and individual (p. 543).

Communal Specification – how the practice is rendered in terms that are understandable to, and shaped by, the people who work with it in relation to its distinctive features and perceived suitability of the task at hand. (p. 542).

Internalization – the meaning of the practice that is learned, shared, and experienced by actors in specific social contexts, as they work and practice through – when internalized, as noted above, it contributes to embedding by anchoring the practice to lived experience of individuals (p. 553).

2. Cognitive Participation

Cognitive participation is the engagement work of implementation and focuses on: Who gets to do the work? Within the purposive interaction chains that make up an implementation process, a practice is framed through cognitive participation, the symbolic enrolments and engagements of human actors that position them for the interactional and material work of collective action. (p. 543)

Initiation – actors initiate a practice - they possess powers of invention and agency and are both able and prepared to exercise them - initiation involves work that brings a practice forth (p. 543).

Enrollment – involves actors working together and organizing themselves to participate in a new practice – sometimes mandatory, but sometimes highly negotiable – involves work that brings about and organizes a community of practice (p. 543).

Legitimization – requires the work of interpreting and 'buying in' to that practice in relation to institutionally shared beliefs about the propriety and value of knowledge and other existing practices - it is essential for a practice to be generally activated in context.

Activation – legitimization work leads to activation of a practice, bringing forth the materials and means by which it can be effectively operationalized in a clinical setting (p. 544).

3. Collective Action

Collective action is the enactment work of implementation and focuses on: How does the work get done? The chains of interaction in which the cognitive participation of actors can be traced, which involves collective and purposive action (and interaction with already existing practices) about organizing and enacting practice (p. 544).

Immediate Factors:

Interactional Workability – how a complex intervention is operationalized in practice by the people using it. This refers to how work is enacted by the people doing it. A complex intervention will affect co-operative interaction over work (its congruence), and the normal pattern of outcomes of this work (its disposal). **Therefore:** ***a complex intervention is disposed to normalization if it confers an interactional advantage in flexibly accomplishing congruence and disposal of work*** (May et al., 2010).

Relational Integration - how knowledge and practice about a complex intervention is mediated and understood within networks. This refers to how work is understood within the networks of people around it. A complex intervention will affect not only the knowledge required by its users (its accountability), but also the ways that they understand the actions of people around them (its confidence). **Therefore:** ***a complex intervention is disposed to normalization if it equals or improves accountability and confidence within networks*** (May et al., 2010).

Organizing Factors:

Skill-Set Workability – how work associated with a complex intervention is distributed and performed in a division of labor. This refers to how the division of labor is determined and carried out. A complex intervention will affect the ways that work is defined and distributed (its allocation), and the ways in which it is undertaken and evaluated (its performance). **Therefore:** ***a complex intervention is disposed to normalization if is calibrated to an agreed skill-set at a recognizable location in the division of labor*** (May et al., 2010).

Contextual Integration – how a complex intervention is lined to, and sourced through, organizational structures. This refers to the organizational sponsorship and control of work. A complex intervention will affect the mechanisms that link work to existing structures and

procedures (its execution), and for allocating and organizing resources for them (its realization). **Therefore:** ***a complex intervention is disposed to normalization if it confers an advantage on an organization in flexibly executing and realizing work*** (May et al., 2010).

4. **Reflective Monitoring**

Reflective action is the appraisal work of implementation and focuses on: How is the work understood? Patterns of collective action and their outcomes are continuously evaluated, both formally and informally, by participants in implementation processes, and the formality and intensity of this monitoring work reflects the nature of their cognitive participation and collective action (May & Finch, 2009, p. 545).

Systematization - methodological formality about judgments about the utility and effectiveness of a new practice (that are made with reference to socially patterned and institutionally shared beliefs) and the rationalities that underpin them (p. 545-546).

Communal Appraisal – regular and organized procedures for monitoring and ongoing assessment of the process and impact of the new practice within an organizational context may involve highly structured and formal mechanisms of institutional knowledge production and interpretations (p. 546).

Individual Appraisal – relies on experiential and unsystematic practices of judging the outcomes of a practice, and from which stem individual commitments to its conduct and performance – co-exist with communal appraisal (p. 546).

Reconfiguration – both communal and individual appraisal may lead to attempts at reconfiguration – where ideas about the use and utility of a practice are subverted, modified, or reconstructed. These play an important part in feeding back into notions of coherence and meaningfulness of a practice (p. 546).

Operationalization of NPT Generative Mechanisms

The use of NPT in this research is in response to the call from the field of implementation science for "the need for more research on mechanisms that determine whether a specific innovation will be successful in a particular health care setting" (Grol, Bosch, Hulscher, Eccles & Wensing, 2007, p. 125; Proctor, et al., 2009, p. 27). Prior to the start of this study, as recommended by May & Finch (2009, p. 549) the researcher translated the abstract core constructs of NPT into a working model with real-world correlates that mapped to the development, installation and implementation of an IBT/P, within an HIV primary care setting. The operationalized constructs were reviewed by Carl May, the lead author of NPT, who relayed that they had been interpreted correctly (personnel communication, December, 7, 2009). The enactment of these operationalized constructs during the study will be discussed in detail in the chapter 5 and the evaluation of the effects of these operationalized constructs will be discussed in chapter 6.

Institutional Ethnography

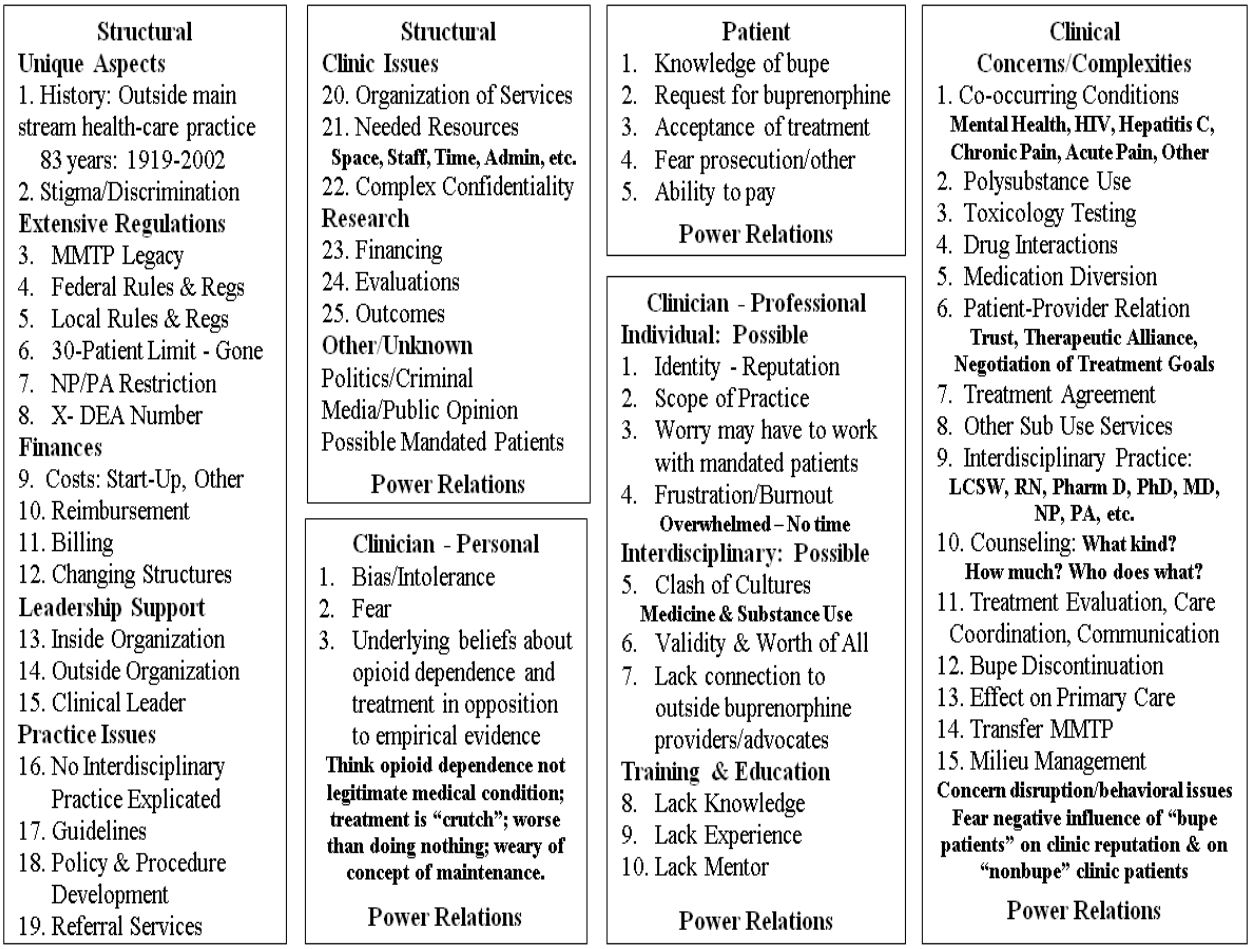
IE is an approach to sociological research that has been developed over the past several decades by the Canadian sociologist Dorothy Smith, (1987, 2005, and 2006) and is committed to grounding inquiry in the ongoing activities of actual individuals. IE provides guidance to explore the organizational conditions of people's lives and the consequences related to these conditions. IE grew out of the critique of the universalization of the male standpoint and feminist consciousness-raising practices (Smith, 1987) and is influenced by Marx's (1976) materialism and Garfinkel's (1967) ethnomethodolology (Campbell, 2003; DeVault & McCoy, 2002). Smith writes, "In different ways, all of these ground inquiry in the ongoing activities of actual individuals" (Smith, 1999, p232).

Throughout Smith's writings there is a sustained critique on mainstream sociological research with claims that it objectifies individuals and blurs, distorts and loses sight of the everyday world in which people live and act. Largely based on this perspective, Smith set out to develop a framework for research that does not subordinate the knowing subject and would ethnographically describe and analyze how coordinating institutional processes and relationships are put together and affect people's lives. The purpose of generating this type of knowledge is for it to be used to identify where or how change may be possible. The commitment of IE research to maintaining a subject position for participants and researcher allows for real life, everyday experiences to inform and direct aspects of the study so as to transform experience into knowledge (Griffith, 2008).

IE highlights "keeping the institution in view" (Griffith, 2008). In IE, "the institution" is not a specific organization, it is, "the multiple activities of individuals, organizations, professional associations, agencies and the discourses they produce and circulate - that are organized around a particular function such as healthcare or education" (Mykhalovskiy & McCoy, 2002, p. 19). By developing knowledge of the extended social, bureaucratic, professional, legislative, economic, and other relations that structure people's lives (and are often not fully visible or observable from any particular local setting) the researcher is able to lay out a complex view of various types of social relations. One way of developing this knowledge is to identify and analyze documents and records related to the institutional processes of the phenomena under study. Based on this direction, the researcher obtained numerous buprenorphine studies and guidance materials (see buprenorphine barrier and facilitator studies, chapter 2 and Appendix A: IBT/P manual, Topic 2) along with various professional and public health commentaries (consensus statements, (NIH, 1997; Kosten, & Fiellin, 2004; Fiellin,

Kleber, Trumble-Hejduk, McLellan & Kosten, 2004), a position paper (World Health Organization/United Nations Office on Drugs and Crime/UNAIDS, 2004), a forum report (Miller, 2006), a policy analysis (Johnson & Rosenblum, 2003), clinical guidelines (Center for Substance Abuse Treatment (CSAT), 2004, New York State Department of Health (NYS DOH), 2006; NYC DOH MH, 2008), and review articles and essays (Fiellin & O'Connor, 2002; Ling & Smith, 2002; Kuehn, 2005; Newman, 2006; Fiellin, Friedland & Gourevitch, 2006: Dunn, 2007; Fiellin, 2007; Meier & Patkar, 2007; Gunderson & Fiellin, 2008) and mapped the multiple complexities related to opioid dependence/addiction and buprenorphine treatment (Figure 7 below).

Figure 7: Complexities of Treating Opioid Dependence/Addiction & IBT/P



The above complexity map was given to the interdisciplinary buprenorphine team members by the researcher when they began their work together, as a way of sharing what she had learned (up to that point) about the complexities of buprenorphine treatment. Smith (2005) recommends producing for people "maps" regarding, "the institutional complexes in which they participate in whatever fashion. People's knowledge of their everyday world is thereby expanded beyond the scope of what can be learned in the ordinary ways we go about our daily activities" (p. 51). In addition to documentary identification and analysis, IE also recommends observation, key informant interviews (both locally and extra-locally) and reflective journaling to investigate institutional processes that coordinate people's everyday activities. This knowledge is then used as a resource to enact change. Chapter 5 provides an explanation of how IE practices were enacted and chapter 6 will discuss how IE informed he implementation of IBT/P.

Combining AR, NPT and IE

The three main theories AR, NPT and IE were used together because one theory alone did not adequately address the needs of this study. AR was selected because the research question focused on developing, installing and initially implementing IBT/P and AR's focus on collaboration, power sharing and capacity building for the researcher, staff and organization was a good fit (Reason & Bradbury, 2008; Stringer, 2007). AR also provided useful guidance regarding how to manage the research process based on iterative and reflective work and the creation of knowledge gained in and through this systematic action. However, AR does not specifically address the complexities of implementation and NPT was sought and chosen because it offers an understanding of the processes and mechanisms of implementing complex interventions in health care settings. In addition, because of NPTs focus on collective action and

the work (both mental and material) related to implementation (May & Finch, 2009) it meshed well with AR.

IE was included in this study because of its perspective on organizational conditions and institutional relations shaping and affecting people's everyday lives. As noted in Figure 7, buprenorphine treatment involves many complex coordinating institutional processes and approaching the treatment as an interdisciplinary practice increased the issue of complexity. Because of these complexities, IE complimented AR and NPT with its focus on developing knowledge regarding the many social relations in organizational life and "extending that knowledge to those she or he works with as well as the knowledge of others similarly situated" (Smith, 2005, p. 42). The ultimate goal of IE is to explicate the social organization of that knowledge for the purpose of taking up "action or organizing" (p. 42) and this is congruent with AR and NPT.

Combining AR, NPT and IE strengthened the overall research endeavor as together they provide a much more comprehensive and thorough approach to studying and facilitating the development, installation and initial implementation of IBT/P than any one of them could provide on their own. As noted in chapter 1, AR, NPT and IE are commensurate in many ways with each other and also with the study's grounding philosophy, critical and feminist scholarship. Of course there are also some ontological differences between the theories, however these differences will not be reconciled here as this is not the focus of this research. The following chapter moves the discussion to the application of the theories to the design and methods of the study.

Chapter 5: Design and Methods

As presented in chapter 4, three main theories were utilized to design and carry out this study: AR, NPT and IE. AR provided the frame and many of the principles of how this study was carried out, such as: cyclical and reflective processes, collaboration, power sharing and capacity building. NPT supplied a mid-range theory of how implementation happens, with a focus on four generative mechanisms. IE directed documentary analysis, conducting the inquiry to include local and extra-local perspectives, the selection of key informants and a conceptual frame for how key informant interviews were conducted. In addition to NPT, supplemental implementation science approaches were used because they highlighted a variety of dimensions of implementation not covered by NPT and these will be discussed following the operationalization of NPTs generative mechanisms. Also, quality and ethical considerations along with advisement sessions were used to guide the design and methods applied in this study. These processes will be discussed in detail in this chapter in addition to explicating data collection/generation, data management and data analysis and interpretation strategies.

Implementation Science Approaches

NPT

The four generative mechanisms of NPT (coherence, cognitive participation, collective action and reflective monitoring) and each mechanism's four corresponding components were operationalized and translated into specific practices and behaviors that mapped to the local context and to the development, installation and implementation of an IBT/P, within an HIV primary care setting. These influenced how the research was designed and conducted, particularly the facilitation of the team collaborative work. Using field experience and field data

the researcher assessed NPTs generative mechanisms and their associated components relative to their promoting influence on implementation. This will be discussed in chapter 6.

First generative mechanism: Coherence

- **Differentiation**: The researcher acquired buprenorphine knowledge and chose the most applicable material for the team and the organization and planned training sessions throughout the research year where the researcher would transfer and develop this information, highlighting the specific and meaningful qualities of buprenorphine. These resources included city, state and federal guidelines for buprenorphine treatment, along with studies and reports that addressed the complexities related to developing, installing and implementing an IBT/P. (Appendix, A: IBT/P Manual, Topic 2). This material served as the foundation of learning, issue identification and resolution, adaptation and organizing the treatment/practice.
- **Individual Specification**: In order to support leadership, the team, and the organization in continuous learning about buprenorphine, the researcher planned to use the existing meeting and practice structure (Shared Care Model-HIV Primary Care/Specialty Care and Social Work Case Management) in developing the IBT/P. The meetings and training and development sessions were organized to allow sufficient time to discuss, answer questions, provider clarifications, and share knowledge regarding individual and co-operative processes. The goal was toward building knowledge and confidence, decreasing apprehensions, sharing uncertainties and concerns, making plans, hearing ideas, giving updates, asking for help, moving the project forward, with a focus on how the development and installation of an IBT/P would cohere with other clinical work.

- **Communal Specification**: As noted above, the Shared Care Model was used as a foundation for development of the IBT/P. Most importantly is that the team is authorized to determine all roles/responsibilities.
- **Internalization:** The researcher planned for the IBT/P team to undertake collaborative work in training and development over a period of eight months. They would be the main vehicle for determining how IBT/P would be carried out in each clinic. Once development and installation was completed and practice was ready to be delivered, this group would then become the main treatment team.

Second generative mechanism: Cognitive participation

- **Initiation:** The researcher conducted the Environmental Assessment and Force Field Analysis and planned to share it with the team to demonstrate the fit of IBT/P within the organization. The researcher also planned to share the "complexities of buprenorphine map" (Figure 7, p. 87) she had constructed at the outset of their work together. The goal was to provide a baseline perspective about the organization, the team, and the treatment and to serve as a launching point from which to determine how to bring the IBT/P forth. And again, as noted above, the team is authorized to determine all roles/responsibilities.
- **Legitimization:** The researcher planned to use general staff meeting, presentations and interdisciplinary buprenorphine team meetings to highlight the meaningful qualities of buprenorphine treatment (especially its role in preventing HIV transmission) and the congruence of this new practice with staff member's commitment, existing organizational practices and the overall mission so as to promote staff buy-in.
- **Enrollment:** The researcher planned to appeal to the interdisciplinary team about the benefits of developing knowledge about buprenorphine as an opportunity for skill building,

expanding clinical repertoire, providing a life-saving treatment and being part of an innovative project.

- **Activation:** The researcher designed the study into five phases of iterative work and planned to present it to the team as a thoughtful, process oriented, doable project with specifics regarding roles and responsibilities of the team and the researcher. The goal was to reinforce an engaging, nonexploitative, voluntary, transparent and friendly collaboration that would encourage colleagues to participate in the team.

Third generative mechanism: Collective action

- **Interactional Workability:** The researcher would encourage the development, installation and implementation of the IBT/P to be grounded in flexible and cooperative team interactions, where multiple options for patient referral, eligibility, and treatment approaches would be built into the IBT/P, as is the case with other treatment/services within the organization.
- **Relational Integration:** The researcher identified foundational theories, models and practices for the IBT/P that were congruent with the overall existing practices and mission of the organization. The researcher determined that a biopsychosocial approach best explicated the theory of treatment and care at the organization (Engel, 1977; Borrell-Carrió, Suchman, & Epstein, 2004), that patient centered care (Institute for Health Improvement, 2010) and the chronic care model (Improving Chronic Illness Care, 2010) were models of care within which the organization delivered services, and that Chronic Disease Self-Management (Stanford School of Medicine Patient Education, 2010), Harm Reduction (Denning, 2004), Motivational Interviewing (Levounis & Arnaout, 2010) and Therapeutic Alliance (Safran & Muran, 2000) best represented the principles and practices that the DAC had worked to

integrate into care. Prior to sharing these with the team, the researcher discussed them with several staff members and leadership in the organization and they endorsed that they matched to the framework of care at the research organization. The researcher planned to share these with the team at the outset of their work and include resources and training regarding the theory, model, principles and practices for the team and leadership throughout the study, so they could be integrated into the IBT/P.

- **Skill-Set Workability:** As noted above, the IBT/P development, installation and implementation team were authorized to decide role and performance, determination/specification (division of labor) among interdisciplinary team, relative to bringing the IBT/P forth. Determination of roles and responsibilities would be based partially on the clinical and professional norms and conventions within the social matrices in which the staff work and also on the development of new practice patterns, with a focus on co-operative processes and quality patient care.
- **Contextual Integration:** The research study design and the necessary resources to carry out the work was approved by the organization's director. The diversity of clinical knowledge and local operational knowledge about the organization and the hospital that would be provided by the team was expected to facilitate the linking of the IBT/P to existing structures and procedures.

Fourth generative mechanism: Reflective monitoring

- **Systematization:** From the beginning of the study, the researcher planned to stress the importance of evaluating the IBT/P. Using the Proctor, et al model, (2009) as a baseline, the researcher planned to pose to the team the question of how the utility and effectiveness of the IBT/P would be formally evaluated once treatment began. The researcher planned to invite

anyone on the team who was interested, to work with her on addressing this question. The researcher had discussed this question with the organization director when she proposed the study and they agreed to take it up when the research was up and running. In March, 2010, the researcher consulted with an NIH/NIDA research advisor to identify grant opportunities that could support future research that focused on evaluating the implementation of evidence-based substance use treatment practices.

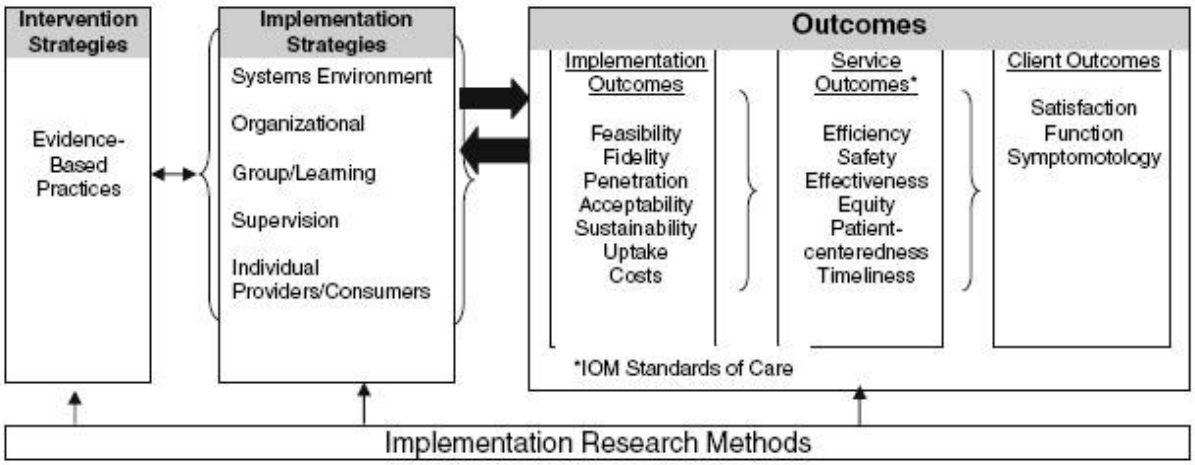
- **Individual Appraisal:** Multiple meetings and trainings were planned for the IBT/P team to have opportunities (individually and collectively) to discuss their judgments about the project and the processes. In addition, various communication processes were planned with leadership and the general staff of the organization to surface their opinions.
- **Communal Appraisal:** The researcher planned that the IBT/P team members would act as liaisons about the development, installation and implementation process to their disciplines and report back to the team on their liaison experiences. The researcher would also encourage and invite the team members to participate in developing an evaluation plan.
- **Reconfiguration:** Structured meetings, training and development sessions, and research updates would be organized with the team to make adjustments to the IBT/P throughout the study year. Discipline specific feedback from team members, as well as ongoing communication with leadership also allowed for modification and restructuring would also be developed. Opportunities for adjustment to the developed practice, once it was underway, would be worked into the implementation plan.

Conceptual Model of Implementation Research (CMIR)

The CMIR (Proctor, et al., 2009, p. 29) distinguishes that implementation research requires two separate and specific knowledge bases and strategies, one for the intervention and

one for implementation. This concept directed the researcher not to privilege either the intervention or the implementation, but to have a comprehensive and grounded understanding of each and to give attention to and develop an evaluation plan as part of the implementation research. The CMIR also identifies that implementation research should be linked to three types of outcomes: implementation, treatment and patient and the researcher included this as one of the research objectives.

Figure 8: Conceptual Model of Implementation Research, Proctor et al. (2009, p. 29)
Image Used With Permission

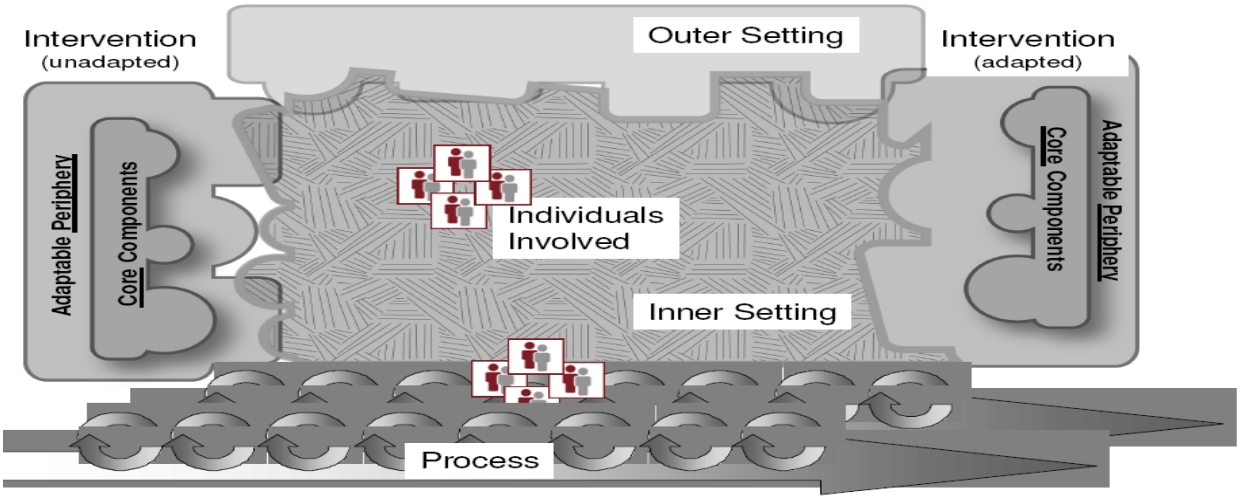


The Consolidated Framework for Implementation Research (CFIR)

The CFIR was derived from 19 different implementation theories. Damschroder, et al. (2009) reported there was considerable overlap in many of the constructs and, "a comparison of theories reveals that each is missing important constructs included in other theories" (p. 1). Using Greenhalgh, et al.'s (2004) implementation model as a starting point, Damschroder, et al (2009), sought and evaluated numerous implementation theories and models and relayed, "we did reach 'theme saturation': the last seven models we reviewed did not yield new constructs, though some descriptions were altered slightly with additional insights" (p 2-3). The CFIR

consists of five major domains, (1) intervention characteristics, (2) outer setting, (3) inner setting, (4) characteristics of individuals, and (5) process. Prior to the beginning of this study, the 27 constructs and 13 subconstructs of the CFIR were defined and assessed in relationship to the local context and to the development, installation and implementation of an IBT/P, within an HIV primary care setting (Appendix B). This extended the Greenhalgh et al. (2004) model and provided a framework so as not to overlook, or forget important aspects of the implementation process. Using field experience and field data, the researcher assessed CFIR's constructs relative to their promoting influence on implementation and this will be discussed in chapter 6.

Figure 9: Consolidated Framework for Implementation Research, Damschroder, et al (2009, Additional File 1, p. 2). ***Image Used With Permission***



Procedures and Processes to Establish Quality Research

A range of research activities were employed in this study to establish, "that the procedures and processes of inquiry have minimized the possibility that the investigation was superficial, biased, or insubstantial" (Stringer, 2007, p. 179). Coughlan & Brannick (2010) identify three main elements by which to judge the quality of AR, "a good story, rigorous reflection on that story, and an extrapolation of usable knowledge or theory from the reflection on the story" (p. 15). Waterman, et al. (2001) developed 20 criteria (pp. 48 – 50) which can be

asked of an AR project to assess the quality of the research and these criteria have been endorsed by other action researchers (Hughes, 2008). Four of the 20 criteria have been identified as discriminating components: (1) Were the phases of the project clearly outlined?, (2) Were the participants clearly described and justified?, (3) Was consideration given to the local context (this includes a critical examination of values, beliefs, and power relationships) while implementing change?, and (4) Was the relationship between researcher and participants adequately considered? (Hughes, 2008 p. 389; Waterman, 2001, pp. 48-49). Both the Coughlan & Brannick (2010) and the Waterman, et al (2001) criteria for quality of AR have been attended to in this study and will be discussed in detail in later in this chapter.

In addition, Stringer (2007) highlights the importance of the cycles of AR and the participants' active and meaningful engagement and involvement with the materials and emerging themes of the research in which they are involved. Strategic updates provided to participants created opportunities for reflection on the materials and the development work in which they have been engaged. As participants, "work through the recursive processes of observation, reflection, planning, and review, they are involved in a constant process of evaluation that enables them to monitor their activities" (p. 161). This matches criterion number 12 of Waterman, et al, 2001, "Were key findings fed back to the participants at key stages? How was the feedback used?" p. 49). This criterion was addressed by providing the team with ongoing updates of the IBT/P manual throughout the year and three intermittent research reports. Subsequent planned group sessions focused on sharing feedback regarding the reports and facilitated an understanding for the researcher and other participants of the various ways emerging issues were being perceived and interpreted.

This research also addressed more general criteria for evaluating rigor and quality in qualitative inquiry. Much debate exists concerning this topic. In a paper by Cohen & Crabtree (2008) regarding evaluative criteria for qualitative research in health care, the authors concluded that there was disagreement on how the concepts of researcher bias, validity, and reliability should be applied (p. 333). They conducted a cross-publication content analysis of 46 health care journals and frequently referenced books and book chapters (1980-2005) that posited criteria for 'good' qualitative research. They found there was, "general agreement across publications on 4 quality dimensions, (1) carrying out ethical research, (2) importance of the research, (3) clarity and coherence of the research report, and (4) use of appropriate and rigorous methods" (p. 333).

Relative to the issues of validity (internal and external), reliability, and objectivity in qualitative research (the rigor criteria traditionally used to judge quantitative research) there are many camps. Guba (1981) and Lincoln & Guba (1985) developed the concept of trustworthiness (which parallels the concept of rigor) to evaluate naturalistic inquiry, where they set out four criteria that parallel quantitative research: (1) credibility parallels internal validity, (2) transferability parallels external validity, (3) dependability parallels reliability, and (4) confirmability parallels objectivity (290 – 301). They were very clear that these criteria were not prescriptions and should not be taken as orthodoxy (p. 331). In response to critiques (Smith, 1993) of philosophical inconsistencies (paralleling positivist criteria while rejecting the paradigm), Guba & Lincoln (1989, p. 245 – 250, 2005, p. 207) introduced a fifth criterion authenticity, a feature unique to naturalistic inquiry, which includes fairness, ontological and educative authenticity, and catalytic and tactical authenticities.

Both critiques (Morse et al, 2002; Sparks, 2001) and endorsements (Flick, 2009, p. 392-393; Patton, 2001, 546-547) of these criteria continue, along with claims that it is not possible to have any agreement on criteria of quality in qualitative research, as there is no qualitative paradigm and each method (and perhaps each study) must be evaluated on its own merit (Rolfe, 2004, p. 310). However, the Lincoln & Guba (1985) criteria continue to be discussed as relevant and important in many qualitative research text books and they have been applied in the fields of social work (Lietz & Zayas, 2010), nursing (Tuckett, 2005), education (Shenton, 2004) and AR (Stringer, 2007).

It is the researcher's position that there is much value in the concept of trustworthiness and its related criteria. They were used in this study to guide rigor and quality, and they were used in the spirit in which they were developed. Lincoln & Guba (1985) made the distinction that the trustworthiness criteria in naturalistic inquiry are open-ended, "they can never be satisfied to the extent that the trustworthiness of the inquiry could be labeled as unassailable. This fact stands in marked contrast to that of the conventional inquiry… the inquiry is, within that closed system, utterly unassailable" (p. 329). They furthered the distinction regarding the use of trustworthiness. In conventional inquiry, "One is *compelled* to accept its trustworthiness. But naturalistic inquiry operates as an *open* system; no amount of member checking, triangulation, persistent observation, auditing or whatever can ever compel; it can at best *persuade*" (p. 329). Below, the Lincoln & Guba (1985) criteria are defined and this is followed by how they were addressed in the study.

In developing the concept of trustworthiness, Lincoln & Guba's (1985) determined their set of criteria based on various anthropological and sociological methodological theorists, from which the rigor of a naturalistic inquiry can be judged. They are defined as follows: (1)

credibility: specific activities that make it more likely that credible findings and interpretations will be produced (p. 301), (2) transferability: description of the time and context of the research to enable others to decide if the study findings can be applied in other settings with other participants (p. 316), (3) dependability: the process of data collection, analysis and interpretations are clearly tracked (p. 317 - 318), (4) confirmability: the findings are grounded in the data and can be tracked to their sources; the logic used to interpret the data is explicated (p. 323), and (5) authenticity: criteria (fairness, ontological and educative authenticity, and catalytic and tactical authenticities) for judging the process and outcomes of naturalistic inquiry (Guba & Lincoln, 2005, p. 207).

This research addressed credibility through the following procedures: (1) prolonged engagement: substantial involvement at the site of inquiry to learn the context, minimize distortions and to build trust (Lincoln & Guba, 1985, p. 301, Stringer, 2007, p 57), (2) persistent observations: sufficient observation for the sake of identifying salient factors and crucial atypical happenings (Lincoln & Guba, 1985, p. 304; Stringer, 2008, p. 58), (3) triangulation: data is collected using multiple and different sources and methods to improve the likelihood that findings and interpretations will be found credible (Lincoln & Guba, 1985, p. 305; Stringer, 2007, p. 58), (4) member checking: concepts and themes are checked and clarified with participants to see that their perspective were adequately represented (Lincoln & Guba, 1985, p. 314; Stringer, 2007, p. 58) and, (5) peer debriefing (external advisement): engaging with an independent peer in a manner paralleling an analytic session for the purpose of exploring various aspects of the inquiry, including research bias (Lincoln & Guba, 1985, p. 308; Stringer, 2007, p. 61). The details of these activities will be presented in chapter 5.

The researcher's past work experience and affiliations also brought credibility to the study. She had been working in the field of HIV/AIDS in NYC since the late 1980s, in clinical practice, education and leadership. In 2001 she completed a two year fellowship as an HIV Clinical Scholar, during which she conducted an AR project linking a methadone clinic and a syringe exchange program in the South Bronx in NYC. In 2002 she began practicing as an HIV primary care provider at the research organization and had many years working collaboratively with both leadership and staff prior to the start of this study. While at the organization she also had other responsibilities: designing and delivering staff and patient education programs, leadership, liaising with outside organizations, and participation in research and grant development. In addition, the researcher is a member of the Guideline Committee for the Care of Substance Users with HIV Infection, NY State Department of Health, AIDS Institute. She has presented at national and international conferences and has published in peer-reviewed journals.

While AR outcomes apply only to the local setting, this does not mean that there is nothing in the study that is applicable to others. The study addressed the issue of transferability by providing detailed descriptions of the context, activities and events of the study so that people reading the research can decide if "the research outcomes may be transferred to their own situation" (Stringer, 2007, p. 59). Providing detailed descriptions, "makes it possible for people who were not part of the study to make judgments about whether or not the situation is sufficiently similar to their own for the outcomes to be applied" (p. 59). Thick descriptions of the research context, stages and phases, relationships, activities and events are presented in this chapter.

Both dependability and confirmability rely on a well maintained audit trail (Lincoln & Guba, 1985, p. 316 – 320), which are the records related to the research processes followed

during the study. These criteria were addressed in this study by maintaining the following audit trail, organized as follows and open to inspection of the research advisor: (1) raw data (audio recordings, advisement notes, fieldnotes from email communications, informal interactions, meetings, presentations, training and development sessions, and interview and focus group notes), (2) transformed data (transcripts, write-ups of advisement notes, fieldnotes, interview and focus group notes), (3) process data (logistic notes and data-timeline), (4) directional and developmental data (resources for clinical guidance & IBT/P manual), (5) first-person inquiry data (personal reflective/reflexive journal), and, (6) analytic data (methodological decision notes, coding notes, analytic notes, and intermediate research reports).

Methodological decision notes are of particular importance in addressing dependability. Because the design of qualitative research is emergent, fluid and shifts throughout the study based on what is learned as the study proceeds (Coughlan & Brannick, 2010, p. 56, Charmaz, 2006, p. 30; Lincoln & Guba, 1985, p. 307), methodological decision notes provide both a tracking and a rationale for decisions related to data collection and evolving areas of exploration made throughout the research process (Charmaz, p. 102- 106). Coding and analytic notes, which demonstrate the work of constant comparison and conceptualization (Bryant & Charmaz, 2010; Charmaz, 2006; Stringer, 2007), and forms the logic for constructing the final interpretation related to the research questions was used to address confirmability. In addition, excerpts from interview transcripts and fieldnotes are presented with page numbers as a means of tracing these to their original source. A detailed discussion of managing, collecting and analyzing data is presented later in this chapter.

The final criteria of authenticity, particularly the aspect of fairness, “deliberate attempts to prevent marginalization, to act affirmatively with respect to inclusion and to act with energy to

ensure that all voices in the inquiry efforts had a chance to be represented in any text" (Guba & Lincoln, 2005, p 207) was also addressed in this study. The direction provided by the theories, methods, and practices used in this research and the operationalization of their related concepts were deliberate attempts at the inclusion and representation of a plurality of views and variation of voices. These activities were woven throughout the research and demonstrated in the research design, methods and activities (chapter 5), in the research findings (chapter 6) and in the IBT/P manual (Appendix A).

Ethical Considerations

For social scientists, a set of ethical rules have been developed by a range or professional organizations, "to regulate the relations of the researcher to the people and the fields they intend to study" (Flick, 2009, p. 36). These rules direct guarding research participants against harm (physical or psychological), deceit, deception, as well as guarding their privacy and confidentiality, in addition to ensuring that data are accurate (Christians, 2005, pp. 144-145; Guba & Lincoln, 1989, p. 120; Olesen, 2007, p. 425). One way of guarding study participants from harm is for the researcher to construct documents known as informed consents that include statements of how privacy and confidentiality will be protected, the purpose and aims of the study, the use of results and the likely consequences of the study, in addition to the right of the individual to refuse to participate or withdraw from the study at any time (Stringer, 2007, p. 55). Informed consents are presented to research participant's prior to their agreeing to take part in a study. They are reviewed and explained, often by the person conducting the study (or their designee) to the research participant, signed by both parties, and safely stored by the researcher.

In this study, informed consents were constructed for those who agreed to be interviewed by the researcher and for those who agreed to participate in a patient focus group that was

facilitated by the researcher. These informed consents and an Institutional Review Board (IRB) research proposal were submitted to two IRBs; one at the researcher's study organization and the other to Hunter College, CUNY. An IRB is an ethics committed whose role is to avoid or prevent abusive behavior by the researcher and to prevent violations and lawsuits against the institutions associated with the research. Both IRBs approved this research, the consents, the interview and focus group guides and recruitment materials.

As the research design included a patient focus group, where participants would be discussing sensitive material related to opioid use, dependence, addiction and treatment, the researcher sought special protection of that data from the NIH. This was done by obtaining a Certificate of Confidentiality (COC) from NIDA prior to the patient focus group. The COC states that the researcher could not be forced to disclose information that would identify focus group participants, even by court subpoena. This was explicated in the informed consent for focus group participants and explained to the patients by the researcher.

In addition to addressing research ethics through IRB approval, informed consents and the COC, other ethical issues needed to be considered that related to the insider AR component of this study. Coughlan & Brannick (2010) discuss a variety of ethical dilemmas that may arise when conducting insider AR, such as maintaining confidentiality when collaborating with coworkers and avoiding doing harm, as AR can have political consequences? (p. 139). "Action research is grounded in principles of democracy, justice, freedom and participation, though as Boser (2006) comments, 'Democratic intentions do not obviate the need for thoughtful examination of the ethical implications of research on individuals and other stakeholder groups'" (p. 132). A range of principles and strategies have been developed within the field of AR to

address acting ethically in organization and workplace inquiry. They are outlined below, they guided this research project and they will also be discussed throughout this chapter.

1. Serve the good of the whole.
2. Treat others as we would like them to treat you.
3. Always treat people as ends, never as means; respect their being and never use them for their ability to do; treat people as persons and never as subject.
4. Act so you do not increase power by more powerful stakeholders over less powerful. (Gellerman, Frankel & Landerson, 1990)
5. Include ethical issues and concerns as part of our reflective journals.
6. Set up a discussion group to provide an on-going review of ethical concerns.
7. Discuss ethics and values with research partners.
8. Negotiate roles and expectations to articulate clear mechanisms for shared decision making.
9. Be prepared to alter or even stop the project if ethical issues arise that cannot be addressed by the group.
10. Develop strategies for making the results of research of direct benefit to the community.
11. Develop innovative strategies for disseminating the results of the group work.
12. Be willing to confront the troubling issues of intellectual property that attend to social science research and that must be a central concern of action researchers.
13. Make our services affordable and available to community groups (Brydon-Miller, Greenwood & Eikeland, 2006, p. 130).

Application of AR Principles and Ethics

Before engaging in recruitment of the IBT/P team, the researcher reflected upon the above principles and discussed them in advisement sessions and several ethical considerations came into strong relief related to (1) audio recording with the team, (2) whether or not to interview team members, (3) role and responsibility of team members and researcher, and (4) confidentiality. The researcher determined that even asking the team members what they thought about recording or recruiting them to be interviewed was too loaded, potentially coercive and could undermine the researcher's rapport with the team and interfere with the team's collaborative work. The researcher had concerns that team participants might feel that recordings or confidential interviews were a kind of surveillance or that they were being used as objects for the research and they would not truly be able to share their opinions. The researcher had gained access to conducting the study through her established trusting relationship with the organization's director and was counting on an established trusting collegial relationship with her coworkers to facilitate the team work and did not want to undermine that in any way.

Based on AR principles and ethics, which are organized to facilitate engaging, nonexploitative, transparent and friendly collaborative processes with participants, the researcher formulated a list of practices and understandings regarding research relationships with the team, shared them with the team during recruitment and served as guidance throughout the study: (1) share with the team the research design, goals and objectives of the study and the researcher's academic institution and advisor's name and contact information and ask team members to please alert her or her advisor if they believe any ethical or other issue of concern arise, (2) during recruitment and intermittently throughout the research project provide specifications regarding the roles and responsibilities of team members: undertake review of buprenorphine

treatment materials, work collaboratively with the team, share their knowledge, experience and ideas with the researcher and the team on how best to develop, install and implement an IPT/P, act as a liaison to their discipline regarding buprenorphine treatment, give feedback and input in process, and become the lead buprenorphine clinicians and administration staff once treatment is ready to commence; (3) provide specification regarding the roles and responsibility of the researcher: all aspects of project: note taking, coordination, communication, liaising, policy and procedure producing, training and education, other research activities, and IBT/P manual and report writing, (4) approach the collaborative work with the team as professional development and improvement of clinical practice and service delivery, therefore no formal consents for the team participation would be obtained, (5) the researcher would take handwritten notes at meetings and trainings which would serve as fieldnote data for the research aspect of the project and also be used in the creation of an IBT/P manual, (6) no audio recording during team meetings or trainings, (7) no individual interviews with any team members, (8) the researcher would maintain confidentiality regarding the research organization and team members identification in the writing of the dissertation and related papers and presentations; however, confidentiality was not absolute, (9) all materials that were produced collaboratively would be the intellectual property of the IBT/P team, and (10) the researcher encouraged team members to use any collaboratively produced materials for purposes of presentations and publications and the organization to use the IBT/P manual for ongoing guidance, and for and patient education.

The researcher also informed the director and the team that while confidentiality and privacy would be maintained during writings related to the research, given the nature of the research, airtight confidentiality could not be guaranteed. The researcher highlighted examples where exposure could occur. For example, the IBT/P team members were known by all staff

within the agency as they served as buprenorphine contacts to their disciplines and were championed as the clinicians and staff who would be the first in the agency to provide buprenorphine treatment and services. In addition, as the researcher had been working in the field of HIV and Substance Use for more than twenty years in NYC and was well known within her community of practice. Her name alone could make the research location easily recognizable to some outside the organization. The researcher reinforced that she was aware that, "The single most likely source of harm in social science inquiry is the disclosure of private knowledge" (Christians, 2005, p. 145) and that protecting the organization and its members from harm or embarrassment was a high priority.

The Research Organization

Because of issues of privacy and confidentiality, the research organization's name, budget, number of patients and staff or other identifying information will not be disclosed, but a general description will be provided. The research organization is a Designated AIDS Center (DAC) in NYC, meaning that the organization's practices are under the guidance of the NYS DOH, AIDS Institute. Many DACs have been operating in NYC for decades. They came into being, under the leadership of the AIDS Institute, as a response to the AIDS crisis of the 1980s and have grown and developed as the nature of care and research related to caring for people with HIV has dramatically changed over time. Like other DACs in NYC, the research organization operates within a large hospital-based medical center, the patient population is largely African American and Latino, and the core model of service delivery is HIV primary care & specialty care (provided by MDs, NPs and PAs) and social work case management (provided by MSWs). The researcher refers to this model as the, "Shared Care Model." The research organization prides itself on organizing services that are sensitive to the diverse patient

population. The research organization also prided itself on staff diversity, interdisciplinary practices, a culture of inclusion and had made many efforts directed toward staff hiring, training and sensitivity around issues of diversity. Again, like other DACs in NYC, the research organization is primarily Medicaid funded and provides a range of co-located interdisciplinary services. And finally, like other DACs in NYC, there is a large interdisciplinary staff of clinicians and administrators and the organization director is a physician who has been in the position for many years. The plan was to develop, install and initially implement IBT/P within two clinics operated by the research organization. They will be referred to as Clinic 1 and Clinic 2. Both sites had similar operations, resources, and staff at the time of the study.

Three Distinct Stages of Implementation

Exploration and Adoption (Stage I), Development and Installation (Stage II) and, Initial Implementation (Stage III) (Fixsen, et al., 2005, pp. 15-17) provided a frame for studying and facilitating the development, installation and initial implementation of IBT/P within an HIV primary care DAC. This study, which was conducted between June 2010 and June 2011, is concerned with Stages II and III. Development and Installation (Stage II), accounts for the majority of this research which took place between June 2010 and May 2011. Stage II was subdivided into five phases to manage the iterative AR processes used in this study. Initial Implementation (Stage III), took place in June 2011 and marked the beginning of providing interdisciplinary buprenorphine treatment. Stage I, Exploration and Adoption, was completed prior to the start of this study, but will be described below to provide the contextual background of this research and an explication of the work that was necessary to construct the foundation upon which this study, Stages II and III, was carried out.

Exploration and Adoption: Stage One

In discussing the first stage of the implementation process, Fixsen, et al. (2005) relays that various efforts need to be undertaken to assess the potential match between the intervention, patient needs, and organization's needs and resources. The first effort was for the researcher to develop proficiency and capability in buprenorphine treatment. This was achieved through self-study, trainings, and a brief apprenticeship with clinicians who were already providing buprenorphine. Despite NPs not being able to prescribe buprenorphine, the researcher had attended and completed the required eight hour buprenorphine physician training course, along with several of her physician colleagues. Using an IE approach to documentary analysis, a wide range of buprenorphine literature was studied (discussed in chapter 4). The researcher then mapped the multiple complexities related to buprenorphine treatment and implementing it within HIV Primary Care (Figure 7, p. 87) and this served as an ongoing reminder of the range of challenges related to buprenorphine. The researcher also undertook an in-depth study of implementation science so as to develop proficiency and capability in implementation research. It was during this study of implementation science that the researcher identified NPT, the CMIR and the CFIR and chose to use them to guide various aspects of implementation.

Second, to provide a larger contextual understanding of buprenorphine, the researcher reviewed and wrote up the historical, psychological, biological, economic, regulatory and political background of opioid use, dependence/addiction and treatment in the US. From this analysis the researcher mapped out the various competing paradigms regarding approaches to substance use and substance use treatment (Figure 2, chapter 2 p. 31). While the above description of knowledge development on the researcher's part, formed the cornerstone of understanding regarding buprenorphine treatment, AR cautions that detailed procedures can end

up being ineffective, "unless enacted in ways that take into account the social, cultural, interactional and emotional factors that affect all human activity" (Stringer, 2007, p. 9).

Environmental Assessment, Force Field Analysis and Preliminary Research Design

To address Stringer's advice, the researcher then turned to the proposed research setting and conducted a force field analysis and an environmental assessment (Appendices C and D), following Lewin's field theory (1951) as described by Brager & Holloway (1992). The force field analysis assessed patient and organization's need for buprenorphine, critical and facilitating actors, intended and unintended consequences and potency and amenability to change relative to implementing the IBT/P. The environmental assessment evaluated influences of stability and change in the proposed research setting. This included economic and political forces, internal structure and processes as well as the meaning of implementing buprenorphine treatment to the organization's staff. These assessments provided a comprehensive understanding of the organization and are congruent with the early tasks of an AR project, in which the facilitator becomes acquainted with the complexity of the issue being researched and constructs a preliminary picture of the research context and research design (Stringer, 2007, pp. 39 - 62). Using all the materials developed to assess a match between the intervention, patient needs, and the organization's needs and resources, along with mapping the complexities of buprenorphine, the researcher developed a preliminary research design to study and facilitate the development, installation and initial implementation of IBT/P.

Proposing the Study and Obtaining Director's Agreement to the Research

The next step in the exploratory process was to, "identify and communicate with people in positions of influence and authority and gain their permission to work, when this is organizationally appropriate" (Stringer, 2007, p. 45). Because the researcher and the

organization's director had a long-standing relationship, access to leadership was not an issue. The director knew the researcher was very interested in buprenorphine treatment as the researcher had made several presentations at the agency about buprenorphine and they had worked together in the past on a grant application (that was not awarded) which proposed integrating buprenorphine into the research organization. The director was also aware the researcher was a doctoral student who was preparing for her dissertation.

In September 2009, the researcher met with the director of the organization and presented a preliminary research design for the development, installation and initial implementation of an IBT/P within Clinic 1 and Clinic 2. The proposal included the research questions, theories, methods, and tentative time frames (study year June 2010 – June 2011), pending approval of the dissertation proposal and IRB permission from the researcher's academic institution. It also covered an estimate of the resources (staff involvement, training, education, physical space, time, liaison activities, etc.) that would be needed, which included the formation and education of a team of interdisciplinary colleagues (approximately nine staff from each clinic) who would work with the researcher on various aspects of the proposed study. As the project was being approached as a practice-focused, action research, implementation study, the team was a key component. To support this aspect of the proposal, the researcher shared with the director that from an implementation science perspective, the Greenhalgh, et al. (2004) study had found that, "establishing semiautonomous multidisciplinary project teams is independently associated with successful implementation" (pp. 605-606). The researcher explained that once the study was approved, she would speak with various staff members and recruit them to be part of the IBT/P team and that participation in the team would be voluntary and it would be made clear that they had the option to decline.

In addition, the researcher stressed she wanted to construct the team work so that it did not add to her colleagues already busy work schedule, as this would be unethical and would also serve as a deterrent to staff participation. Therefore, it was proposed that meetings and trainings would take place during the usual work day and staff would be released from their clinical and/or administrative responsibility to participate in the team. To accomplish this, the researcher would coordinate with the various discipline managers so that the team member's schedules would be adjusted to accommodate their participation. The researcher presented the team members and the researcher's role and responsibilities (pp. 107-108). The director was very interested, supportive and gave permission for the study to go forward as designed. Of significant importance, the researcher proposed and the director agreed that the interdisciplinary buprenorphine team would have the authority to determine job role, responsibility, and distribution of labor (meaning who would do what, when, where, how and why). These determinations would be presented for approval and coordinated with discipline directors in process.

The logistics of the funding and evaluation of the study were also addressed at this initial meeting. At the time of the proposal, the researcher was working three days/week (being paid for 21.5 hours/week) and the director agreed that during the study year, the researcher could shift work responsibilities and four hours/week out of the 21.5 hours could be used for the research, the other 17.5 hours would be for clinical practice. The researcher estimated that all research activities would require anywhere from two to four days/ week during the study year and planned to self-fund, as well as apply for research grants to fund the time necessary to achieve the research goals beyond the four hours/week the organization was providing. It was also agreed that questions such as future funding for purposes of evaluating buprenorphine and

implementation outcomes once treatment was underway and continuing related buprenorphine research would be addressed once the project was underway.

Research Advisement

As discussed in chapter 1, outside advisement was sought to support first-person inquiry, and as a way of managing politics, negotiating power relations and supporting praxis-reflection (Coghlan & Shani, 2008, p. 649; Marshall & Mead, 2005, p. 236 - 237). In addition to the chair of the researcher's dissertation committee (the main advisor for this project), the researcher incorporated three types of advisement into the study. Inter(ra)personal (IP) advisement was arranged with a certified social worker and licensed psychoanalyst because the researcher anticipated that a range of potential power issues, conflicts of interests, uncertainties and challenges could arise due to the complex nature of the study and the researchers' multiple roles. Grounded theory method (GTM) advisement with an experienced qualitative researcher trained in symbolic interactionism, grounded theory and dimensional analysis and this facilitated mentoring in the processes and logic of data gathering, data analysis, and addressing research bias. Clinical/Milieu (C/M) advisement with a psychiatric nurse practitioner who specializes in addiction, is also a licensed psychoanalyst, and has experience supervising other mental health clinicians. This allowed for feedback on the development and adaptation of clinical and interdisciplinary buprenorphine practice with attention to the practice setting and milieu management. All advisors facilitated the process of peer debriefing. The researcher had a preexisting relationship with each advisor prior to the study and contracted for advisement sessions in their specific fields. Advisors were accessed throughout the study year and reimbursed for their advisement work.

Researcher's Presentation of Self as an Engagement Practice

Many of the constructs of NPT were directed toward engaging the individuals with whom implementation work was undertaken and the researcher's stance is an important aspect of this engagement. Stringer (2007) writes about the importance of the researcher's presentation of self. "Body language, speech, dress, and behavior should be purposeful, inquiring and unpretentious" (p. 48). The researcher reflected upon a variety of behaviors that could work toward engaging the various individuals in the organization who would be participating in the study, (1) knowledge sharing provided in a friendly, skilled and supportive fashion, (2) avoiding authoritative or expert like behavior, (3) following appropriate channels of command, (i.e., seek leadership input and consent on issues before discussing with staff), (4) providing information sharing in a timely manner, (5) being highly organized and highly flexible, (6) create as little additional work for participants as possible, (7) be as inclusive as possible, (8) work on not demonstrating favoritism, and (9) avoid overly aligning with particular individuals or groups.

Identifying the above practices is a one area of importance when conducting an insider AR project; being able to consistently carry out the practices is another. All forms of advisement contributed to the researcher "negotiating with complexity" (Lather, 2008, p. 182), dilemmas, power issues, etc. Advisement sessions provided the researcher opportunities for support and exploration regarding her experiences and interior thoughts about the many interpersonal interactions involved in the study. Having a forum to articulate them and understand them provided the researcher an opportunity to resolve conflicts that might affect her behavior and compromise her planned "presentation of self." In addition, using first-person inquiry cognitive practices, to learn in action, such as the ladder of inference, right-hand/left-hand column, attention to distorted thinking, focusing and reflective journaling (Coughlan & Brannick, 2010,

pp. 24 – 28) provided a skill set to work consciously on and maintaining the above presentation of self, so as to continue to engage staff, achieve the goals of the study and have responsible use of power.

Stage II: Development and Installation of an IBT/P: June 2010 to May 2011

The development and installation of the IBT/P included a variety of focused research activities: advisements, email communications, meetings, training and development sessions, presentations, key informant interviews, a patient focus group, process oriented data analysis and intermittent research reports. These worked toward building an understanding about factors that promoted or inhibited the eventual implementation of buprenorphine and toward achieving the goals and objectives of the study. Following AR's method of using cyclical processes of constructing, planning action, taking action and evaluating action to build knowledge (Coughlan & Brannick, 2010, pp. 8-12; Stringer, 2007, p. 8-9), Stage II was subdivided into five phases: Phase I: June 2010-August 2010, Phase II: September 2010-November, 2010, Phase III: December 2010-January 2011, Phase IV: February 2011-March 2011, and Phase V: April 2011-May 2011. Below is a description of the study participants, their recruitment and the processes related to the key informant interviews and the patient focus group. This is followed with a phase by phase description of various research activities and an associated data collection timeline.

Criteria for Inclusion of Study Participants

The theories and methods used in the research are oriented toward learning what is important to people directly involved and affected by the issue under investigation. They are also geared to learn how things work and to create action and change in relationship to this knowledge. Working with and speaking with individuals who were differently located was

undertaken in this study, so as to gain diverse perspectives and build a comprehensive understanding about developing, installing and implementing an IBT/P. People involved in the study were divided into five groups: (1) organization staff who made up the interdisciplinary buprenorphine team, (2) organization staff who the researcher worked with on various research activities, but were not members of the interdisciplinary buprenorphine team such as, the director of the organization, discipline directors, and specialty directors, (3) external consultants, (4) key informants both inside and outside the organization who participated in confidential, individual interviews, and (4) patients from the organization who participated in a confidential focus group. The criteria for study participants' inclusion varied depending upon the individual's role, knowledge, experience. For example, once the director of the organization makes a decision to adopt a new service or treatment, the various discipline directors are required to take up the work involved in implementation as part of their management responsibilities. Some participants' inclusion was part of their work responsibilities, some volunteered, and others were purposeful and openly recruited because they had particular attributes (Flick, 2009, pp. 123-124). Below is a description of the various study participants and an explanation as to why they were included in the study. The order in which key informant interviews occurred was determined based on two strategies from GTM. First is point of departure sampling, where the researcher makes a strategic decision who to interview initially, following this is theoretical sampling, where the researcher chooses the next people to talk to based on evolving data analysis for the purpose of elaborating and refining constructed categories (Charmaz, 2006, pp. 100 - 101).

Interdisciplinary buprenorphine team members.

Team members were drawn from the clinical and administrative staff because the research was focused on having the staff that would eventually be responsible for providing

buprenorphine treatment at the organization also be responsible to determine how best IBT/P should be developed and delivered. Because the research called for developing, installing and implementing IPT/P, the team needed representatives from the main organizational disciplines of administration, medicine, nursing, psychology, psychiatry and social work. Team member inclusion was also based on study need, staff member interest, specialty knowledge/experience, job responsibility, availability and leadership consent. Based on the number of staff available and the interdisciplinary need, the researcher calculated that approximately nine staff from each clinic should make up the team. The goal was for team members from Clinic 1 and Clinic 2 to be as identical as possible as it was planned the IBT/P would be implemented in both clinics.

Organization leadership: Director, discipline directors and specialty directors.

While the director had approved the study and agreed to provide organizational resources, it was important for the director to continue to be included in the study for several reasons. First, several questions which were presented at the outset of the study, remained unanswered and the decision of how to move forward with these issues needed to include from the director. These included future funding for purposes of evaluating buprenorphine and implementation outcomes and continuing related buprenorphine research. In addition, the director's ongoing support served as a continuous endorsement of the research and encouraged involvement and accountability from other staff members.

The discipline directors interacted with the researcher/facilitator on a variety of issues. As just noted, their inclusion was part of their role and responsibility in the organization and was necessary to move the research forward. For example, the program director determined that each discipline director would need to approve staff members' participation in the team, as they had most relevant information about clinician fit, availability, schedules, and other organizational

activities. In addition, a number of other interactions between these discipline directors and the researcher were necessary in order to bring about the development, installation and initial implementation of IBT/P: arrangement of meeting and training times, adjustment of schedules, information sharing, feedback and eventually approval of newly developed roles, responsibilities, and related policies.

Another group of directors, referred to as specialty directors were included as part of their management responsibilities. The operations director, financial director, and data management director were included to provided knowledge and facilitation regarding a variety of activities related to buprenorphine treatment such as: clinic space, patient flow, appointment making, billing, and record keeping. The inclusion of the directors of specialty services provided knowledge about pharmacy, OB/GYN, adolescent care and integrative medicine in relationship to buprenorphine. The specialty directors' inclusion was more focused and limited compared with the organization director and the discipline directors. As noted above, they were included because they contributed important issues related to their specialty that directly impacted on the research project.

Key informants.

Key informants were individuals with whom confidential interviews were conducted. Three case types of key informants were purposefully selected because a range of perspectives about implementing an IBT/P was sought: (1) critical cases: individuals in key leadership positions in the research organization, chosen because they were vitally important to the overall approval and functioning of the IBT/P and knowing their perspective was essential, (2) meaningful cases: buprenorphine leaders outside the research organization with a range of experiences and perspectives (clinical directorship, practice, research, public health, policy,

education), chosen because they were known to have necessary, diverse, and important buprenorphine knowledge which would be instructive, useful and applicable for the development, installation and implementation of buprenorphine and (3) typical cases: individuals who were clinical staff within the research organization, not in leadership nor a member of the interdisciplinary buprenorphine team, chosen because the researcher wanted to have the perspective of staff within the organization that were not participating in the research (Flick, 2009, pp. 123-124).

Focus group participants.

Patients from the organization who were receiving primary care and who were, (1) currently or in the past receiving buprenorphine, and/or (2) currently or in the past receiving methadone, were sought for inclusion in a focus group so the researcher could obtain their perspectives about treatment for opioid dependence/addiction in general, as well their thoughts about buprenorphine treatment. Patients who met the criteria were included because the research process was focused on obtaining a plurality of views and the researcher believed the perspectives of patients' was a unique and important resource for the study. It was planned that if any patient for whom the researcher provided HIV primary care reported an interest to participate in the focus group, they would be excluded due to the nature of that relationship and the potential for coercion.

External consultants.

Individuals outside the organization worked with the researcher as external consultants and were included to explicate a range of specialty areas related to buprenorphine treatment that were focused and specific: toxicology testing, buprenorphine billing, DEA regulatory issues and

specialty addiction services. Their involvement was also part of their professional employment responsibilities in their associated agencies and/or companies.

Procedures for the Recruitment of Team Members, Key Informants and Focus Group Participants

Interdisciplinary buprenorphine team members.

As an employee of the organization, and a clinician who practiced in both Clinic 1 and Clinic 2, the researcher had long standing collegial relationships with many different staff members and this was a foundation which supported recruitment of the interdisciplinary buprenorphine team members. The researcher openly recruited various staff members to be part of the IBT/P team in two primary ways. First, the researcher presented the study at a general staff meeting and announced she was looking for volunteers. Four staff members (two physicians, one psychologist, and one social worker) approached the researcher after the meeting and reported their interest to be on the team. Second, the input of the discipline directors was solicited by the researcher to discuss who they thought might be best suited to participate in the IBT/P team. Based on these discussions, individual staff members were approached about participating in the IBT/P team. The researcher discussed the buprenorphine project, explained the major aspects of the study, the roles and responsibilities of team members and the researcher as well as various ethical issue (see earlier discussion p. 14). The researcher relayed the reason why each specific staff member's participation was being sought, the value they would bring to the process of implementing buprenorphine, (i.e., they had past experience working in methadone, there was a need for psychiatry, there was a need for leadership, they were Spanish speaking, etc.) as well as an opportunity for developing a new skill set and working on an innovative project. The researcher made it clear that participation in the team was voluntary and that they had the option to decline.

This open recruitment process took place in Phase I of Stage II, over a period of two months, July and August, 2010, so as to provide time for the researcher to dialogue with discipline directors and allow adequate time for recruited participants to consider the offer, evaluate their schedules, other responsibilities, etc. A total of 17 staff members were openly recruited, 14 agreed to participate and three declined. At the end of August, 19 staff members formed the interdisciplinary buprenorphine team. Of the 19 members, five (including the researcher) had volunteered and 14 had been openly recruited. The team consisted of: five HIV primary care providers (four physicians and one nurse practitioner), four social workers, two registered nurses, three psychologists, one psychiatrist, and four administration staff members.

Key informants: Critical cases and meaningful cases.

Based on the researcher's employment and the various roles she had in the research organization over time, she had strong collegial relationships with key organization leaders (critical cases) and this facilitated access to recruitment. Based on the researcher's work history and affiliations, she also had professional relationships with a variety of individuals in leadership outside the organization (meaningful cases) who were knowledgeable about buprenorphine from a variety of perspectives, and this facilitated access to several of these cases. However, there was not a preexisting relationship with all meaningful cases, several were referred by other key informants and this facilitated access to those cases.

All critical cases and meaningful cases were recruited by email to participate in confidential interviews regarding buprenorphine implementation. The potential key informants were sent emails by the researcher relaying information about the research project and the researcher's interest in interviewing them for the study at a place and time of their choosing. They were told that they had been targeted for an interview based on their specific knowledge

and involvement with the organization or about buprenorphine. The researcher relayed an interest to speak with them as she had determined they had important information that would be valuable to the study. They were told that the interview would be completely voluntary, confidential, about one hour in length, it was IRB approved, and they would be required to sign consents. They were informed of the process of the interview; that the researcher had some prepared questions, it would be audio recorded and the researcher would also take notes. Three critical case key informants were recruited and all agreed to participate. Nine meaningful case key informants, outside the organization, were targeted and seven agreed to participate.

Key informants: Typical cases.

Recruitment for interviews with organization staff, not involved with buprenorphine research (typical cases) was conducted through IRB approved flyers placed in staff mailboxes. Again, being an employee at the research organization facilitated access to the general staff. The recruitment flyers described the purpose of the research and an interest to interview staff members who were not affiliated with the buprenorphine implementation. It also identified that the research interviews would be completely voluntary and confidential and had been IRB approved. The researcher's contact information was provided on the flyer. When interested staff contacted the researcher, they were told that the interviews would run between 30 – 60 minutes, be conducted at a place and time of their choosing, would be audio recorded and they would be required to sign a consent They were also informed that the researcher would ask and answer questions and take notes during the interview. Flyers were placed in approximately 40 interdisciplinary staff members' mailboxes in February 2011. Two staff volunteered to participate and they were interviewed in February and May 2011.

Focus group participants.

Patients for the focus group were recruited through IRB approved flyers posted and left in the clinic reception areas. The recruitment flyer described the focus group as a group discussion about treatment for opioid dependence/addiction, it also identified that participation was completely voluntary and confidential and the research had been IRB approved. In addition, clinical staff members were asked to refer patients using the IRB approved recruitment flyer. To minimize the potential for informants feeling obligated to participate when they were offered the recruitment flyer, the referral person was asked to only inform appropriate patients about the study, give them a flyer and instruct them to contact the researcher if they would like to participate.

The Recruitment Flyer for Patient Focus Group relayed that the focus group would consist of one 90 minute meeting at a time and date to be arranged and participants who completed the process would be provided with a reimbursement for their time (a $15 CVS gift card) and a $4 metro card to cover their transportation. As the researcher spoke with interested patients, their eligibility was determined and a short synopsis of the research and an explanation of the consent and focus group process were provided, highlighting that participation was completely voluntary and confidential. Patients were also told that the focus group would be facilitated by the researcher, it would be audio recorded and notes would be taken when the group was discussing the different questions. Information regarding the location and directions were provided. In addition, the researcher relayed that a certificate of confidentiality (COC) from NIH/NIDA had been obtained because of the sensitive nature of the material about opioid dependence/addiction/treatment. It was explained that by having a COC, the researcher could

not be forced to disclose information that would identify focus group participants, even by court subpoena.

Flyers were put out in the clinic reception area of the clinics and given to clinical staff members in March 2011, about 3 weeks prior to the focus group. Ten patients called and eight patients were determined to be eligible. During recruitment, the patients who were determined to be eligible were asked by the researcher for permission to contact them three days prior to the focus group for a reminder and they all agreed. A list of eligible and interested patients' names and phone numbers was kept in a locked cabinet. Six of the eight patients came the day of the focus group and participated in the discussion. Focus group participants were between the ages of 40 and 50, there was one woman, all had history of opioid addiction, all had at one time been in a MMTP. Two of the participants were taking being treated with buprenorphine in an office-based setting. The list of patient names and numbers was destroyed after the patient focus group was completed.

Approach to Interviews and Focus Group Discussion and Development of Questions Guiding Interviews and Focus Group Discussion

The IE tradition of interviewing that focuses on learning, "how things happen," provided a conceptual framework for interviews, in which informants are regarded as knowledgeable and competent. "The point of interviews is to have the informant share these competencies, thereby extending them to the interviewer (Smith, Mykhalovskiy & Weatherbee, 2006, p. 173). IE interviews are not used to uncover the emotional state of the informant, but are focused on learning about institutional processes, the organizational conditions of people's lives and if possible, documents related to these processes and conditions (Griffith, 2008). IE researchers have identified the emerging nature of knowledge building when speaking with key informants. DeVault & McCoy (2002) discuss the idea of the IE researcher checking their understanding as it

develops, "I offer it up to the informant for confirmation or correction (DeVault & McCoy, 2002, p. 757). IE interviews are often thought of as "co-investigation … where the participant and interviewer construct knowledge together" (p. 758).

Key informant interviews were conducted in a semi-structured format, which allows for flexibility. Topics and questions to be covered are developed beforehand, but can be adapted and new questions can be generated during the interview based on the informant's response. Interview guides contained questions related to topics and concepts about buprenorphine treatment and implementation. Different interview guides were developed for each key informant case type. Initial concepts for key informant interviews were derived from the literature and the researcher's experience. The questions were focused on gaining key informant's knowledge about conditions and processes of buprenorphine treatment in general and more specifically their perspective regarding barriers and facilitators to developing, installing and implementation. The researcher also offered up questions emerging from the AR aspect of the study. The patient focus group was facilitated with the emphasis on having as much dialogue generated among the participants as possible, in which they actively compare their experiences and opinions (Morgan, 1998, p. 32-33). Focus group questions were also prepared beforehand and directed to obtain participants' perspectives about treatment of opioid dependence/addiction and buprenorphine treatment.

AR (Coughlan & Brannick, 2010; Stringer, 2007) and GTM (Bryant & Charmaz, 2007; Charmaz, 2006) also influenced how interviews were conducted. Both emphasize a cyclical process of data collection and data analysis throughout the research (Dick, 2007), whereby interview guides are modified as the study proceeds to allow for inclusion and exploration of concepts identified in the ongoing data analysis. The initial interview guides and focus group

guide were submitted and approved by the IRB with the understanding that the questions for the key informant interviews could be adapted in context as well as over the course of the research, based on evolving analysis. The researcher conducted all 12 key informant interviews and facilitated the patient focus group.

Phase I: June 2010 – August 2010

The first activity of Phase I was to access research and inter(ra)personal advisement to undertake reflexive/reflexive work in identifying and explicating the researcher's assumptions about the project and also to assess issues of power in research relationships with organization participants. Another major focus of Phase I was communication and meetings with leadership and staff to form the interdisciplinary buprenorphine team in Clinic 1 and Clinic 2. The researcher engaged in a variety of meetings, emails, conversations (both formal and informal) to recruit team members. In addition, the researcher presented the study at a general staff meeting, conducted interviews with three members of leadership in the research organization, continued with advisement session, and met with a specialty director and an external consultant. The researcher also engaged in first-person inquiry, journaling and methodological decision making. Below is a description of major activities in June 2010, followed by a data timeline that includes all activities during Phase I.

Identifying and Explicating Researcher Assumptions

The first research advisement (6/1/10) was focused on ways of managing the researcher's influence over the study. The researcher was advised to identify her own assumptions about the research and document them in her journal, reflect upon them, try and identify where they may be coming from and what was influencing them. The researcher documented her assumptions as she was advised and also wrote reflective journal notes on this process and on the advisement

session. The researcher shared this with her research advisor. The exercise helped the researcher to gain awareness of her biases and assumptions related to the research project. The researcher used this awareness throughout the study which assisted her in working toward not overemphasizing her perspective, managing expectations, and not forcing her ideas in the processes of facilitating, data collection and data analysis. It also worked to help the researcher from jumping to conclusion, to be attentive to listening and to be open to learn and discover.

Assessing Issues of Power in Research Relationships with Organization Participants

The grounding philosophy of this research project, Critical and Feminist Scholarship, as well as AR, NPT and IE all acknowledge that balancing power relations are an important aspect of research and negotiating change processes, as power can make action possible or can constrain action. In an evaluation of five projects that implemented complex service innovations in primary health care, Greenhalgh, et al. (2004) found that power relations, "were critical to successful implementation but that they were extremely difficult to explore systematically and raised ethical issues for the research team" (p. 614). The first (6/10/10) and subsequent inter(ra)personal advisement session included assessing and reassessing power relations between the researcher and the larger staff, the researcher and various study participants, as well as power relations between the disciplines along with continuous explorations of responsible use of power by the researcher.

The researcher's relationship with all members of the organization who participated in the study stemmed from long standing collegial work relationships (eight years) and a general shared commitment to treating people with HIV. It was also assessed that even though certain members of the organization who participated in the study would be key to the success of the implementation, basic service delivery issues such as appointment making, billing, and coverage

would be necessary and involve staff beyond the IBT/P team; therefore, efforts to provide information about the research project and include updates to the larger staff also needed to be attended to throughout the study.

It was assessed that ultimate authority and power over the research proceeding was held by the director of the organization as there were no external mandates or requirements for the study to take place. The researcher's power to access organizational resources and to direct and facilitate the multiple processes associated with the research and implementation of buprenorphine treatment was mediated through the power and authority given to her by the director. The researcher also had authority and credibility that stemmed from her past work experience and affiliations. The director and the researcher shared an interest and a commitment of adding buprenorphine treatment to the range of services provided at the organization; therefore, from this perspective there was some mutual dependency that existed in their relationship.

As previously discussed, the discipline and specialty directors were required to work with the researcher as part of their managerial responsibilities, whether they were part of the IBT/P team or not. It was assessed that they too held considerable power within the research relationship. Their interest and enthusiasm for participating in the implementation of buprenorphine was gauged as variable. For example, some leadership people were big bupe supports and early volunteers for the buprenorphine team, while others were somewhat reluctant.

Given the nature of the research, the staff that would make up the interdisciplinary buprenorphine team was of central importance to the study because they would be working closely with the researcher on the development and installation of the IBT/P. It was the team who the researcher would rely upon to contribute their knowledge and experience. It was team

who the researcher/organization was asking to learn a new skill set. It was team who the researcher would depend upon to work collaboratively and reflectively, so as to develop and create a new practice and eventually deliver the treatment. It was the team who would ultimately take up the practice and provide buprenorphine treatment. Given the centrality of their work, the team too held considerable power. Ultimately, no one involved in the study was powerless. This advisement session brought into strong relief that the researcher was highly dependent upon many organization members to accomplish the goals of the study. It was assessed that this dependency would require a significant amount of ongoing engagement of participants, negotiation, flexibility, advisement, and carried a high degree of uncertainty. The potential for power issues between disciplines was also considered as there are long standing hierarchies in health care. The action research process of collaboration, the engagement of multiple disciplines, power sharing (in the form of knowledge sharing among the team and authority sharing from leadership to the team, for the purpose of knowledge creation and increase collective power) and the constructs of NPT were operationalized to express and enact equality of worth for all team members and facilitate the management of power issues should they arise.

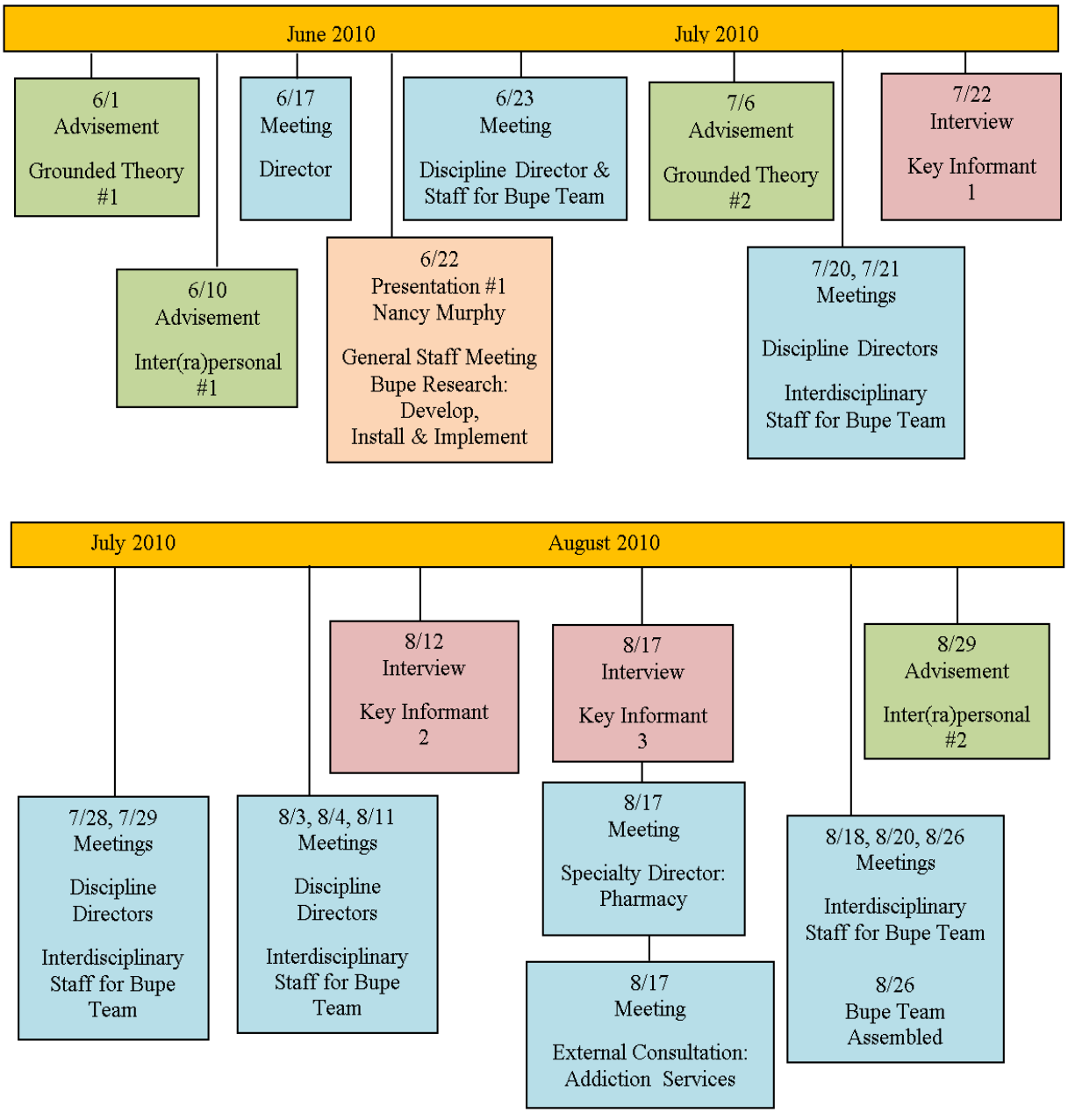
Meeting with the Director and Initial Staff Presentation

Early in Phase I the researcher and director met to review the research. Many specifics were shared, feedback provided and a few adjustments were made based on recent organizational changes and staffing issues. They decided that the researcher would present the study at the upcoming monthly staff meeting, which the researcher used to publicly launch the research, engage the staff and begin soliciting IBT/P team members. Below is a timeline of all research activities in Phase I, June 2010 – August 2010 and is followed by a discussion of Phase III.

Phase I: June 2010 – August 2010

Data Timeline

Advisements, Interviews, Meetings, Presentation



Phase II: September 2010 – November 2010

During Phase II, the researcher began actively working with the team on a variety of levels. The team consisted of 19 members, 14 were not in leadership positions, two were clinic managers and three were discipline directors (1 PhD: Director of Mental Health Services; 2 MDs were the Associate Medical Director's from Clinic 1 and Clinic 2. The full team makeup:

- 4 Social Workers (MSWs): 2 social workers from each clinic.
- 2 Registered Nurses (RNs): 1 registered nurse from each clinic.
- 3 Psychologists (PhDs): 2 psychologists from Clinic 1 & 1 psychologist from Clinic 2.
- 5 Physicians (MDs): 2 physicians from each clinic (1 HIV primary care provider and 1 Psychiatrist from Clinic 1 and 2 HIV primary care providers from Clinic 2) & 1 physician (HIV primary care provider) with buprenorphine experience from a clinic associated with the research organization.
- 1 Nurse Practitioner (NP): 1 nurse practitioner practicing as HIV primary care provider in both Clinics 1 and 2, researcher, facilitator.
- 4 Administration Staff: 1 clinic manager from each clinic & 1 front desk staff person from each clinic.

Given the established shared care model of HIV primary care/social work case management at the research organization, these two disciplines were the most represented on the IBT/P team. Therefore, meetings and training sessions focused on knowledge development and beginning formulation of bupe MD/NP practice and bupe social work practice began in Phase II. Small group interdisciplinary training and development sessions also took place during this phase and addressed practice issues that crossed disciplines, such as treatment eligibility and methadone transfer. The IBT/P manual was started in Phase II and the team agreed that it would take the form of a PowerPoint presentation. The researcher took responsibility for creating topic areas and inputting material as it was developed during meeting and trainings. This was used as a vehicle to share the developing IBT/P information with the team and allowed for feedback and updates. Three full interdisciplinary team meetings occurred monthly (September, October and November) and this provided an opportunity for presentation of developed materials, resources,

updates, feedback, large collaborative interdisciplinary discussions and decision making questions, and future plans. By mid-November the team had agreed that the bupe social workers would be the first point of contact for patient education, screening and referral to bupe MD/NP.

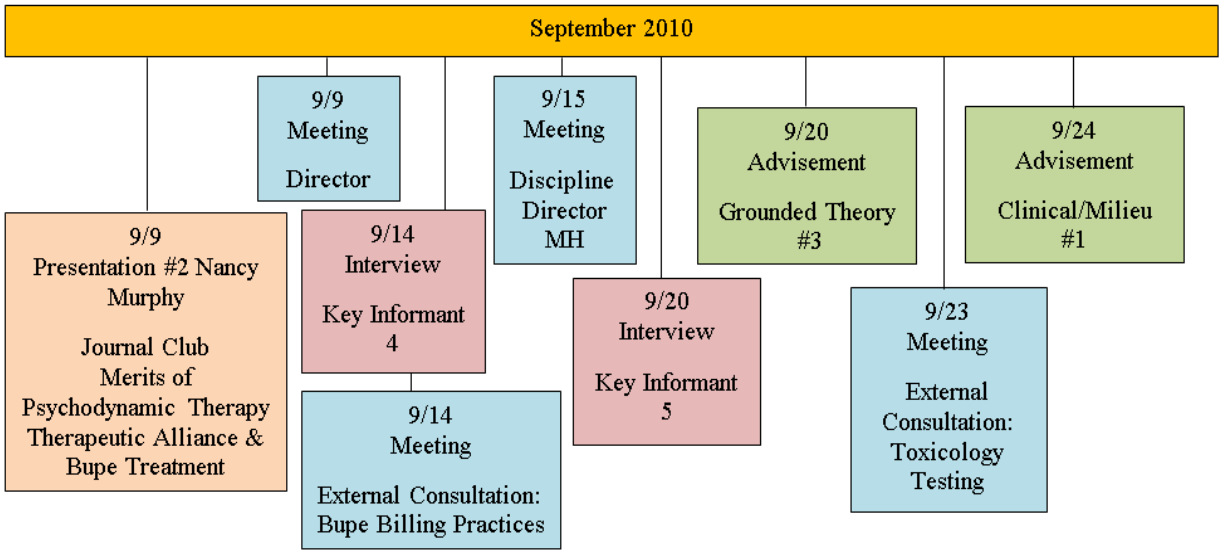
The researcher gave a second presentation early in September 2010. She lectured at the organization's journal club on, The Merits of Pyschodynamic Therapy, Therapeutic Alliance and Buprenorphine Treatment. This presentation provided an opportunity to share knowledge on this topic, interact with the larger staff, announce the interdisciplinary team members, remind the larger staff that the IBT/P work was proceeding, encourage feedback and field questions. The director was present at this presentation and endorsed the importance of the topic and the research. In addition, three key informant interviews with buprenorphine leadership outside the organization were conducted in September. Meetings continued in Phase II with discipline directors for various coordinating activities, updates and feedbacks. A specialty director meeting with OB/GYN focused on the use of buprenorphine in pregnancy and external consultation meetings focused on toxicology testing and buprenorphine billing practices.

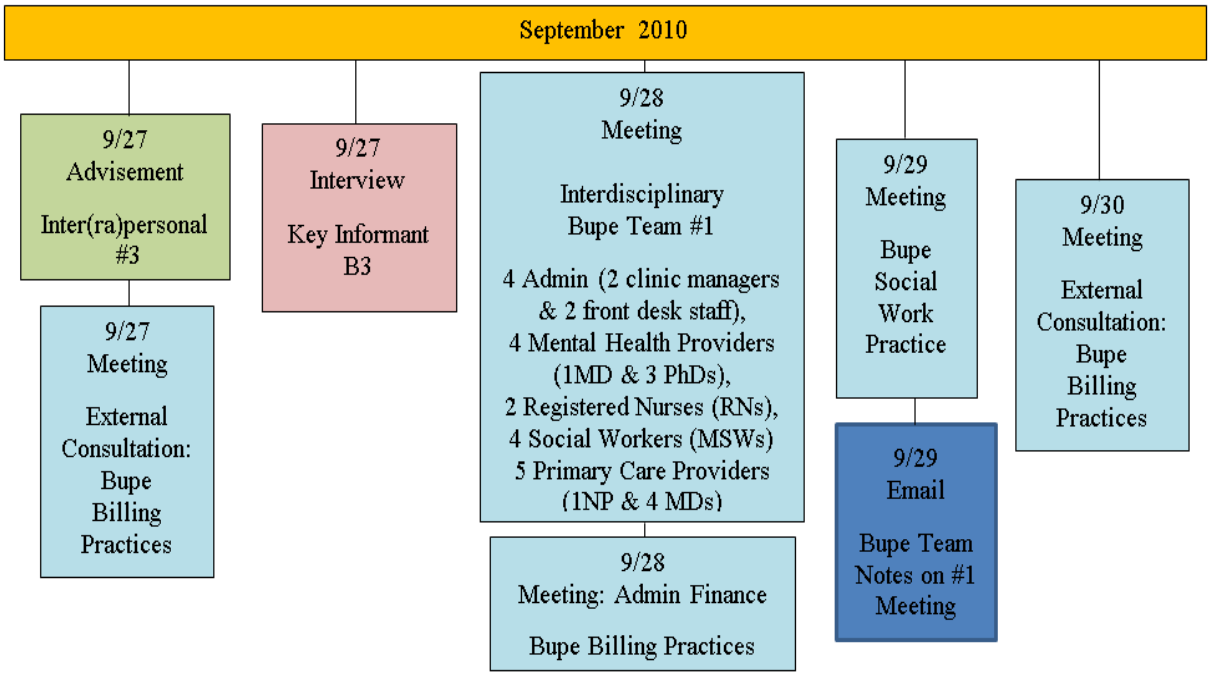
Seven advisement sessions (the greatest number in any phase of the research) took place over the three month period of Phase II. As there was much activity in all areas, the researcher wanted to maintain a close connection to the advisors to address conflicts of concern, prevent isolation of thought, identify blind spots, code and analyze data with feedback and explore personal feelings. Two advisements were dedicated to C/M, two were dedicated to IP and three were dedicated GTM advisement. The researcher continued journaling, write-ups, coding, comparing and analyzing data. Toward the end of November the researcher began work on the first intermediate research report. Below is a timeline of research activities in Phase II, September 2010 – November 2010 and is followed by a discussion of Phase III.

Phase II: September 2010 – November 2010

Data Timeline

Advisements, Email Communications, Interviews, Meetings, Trainings, Presentation

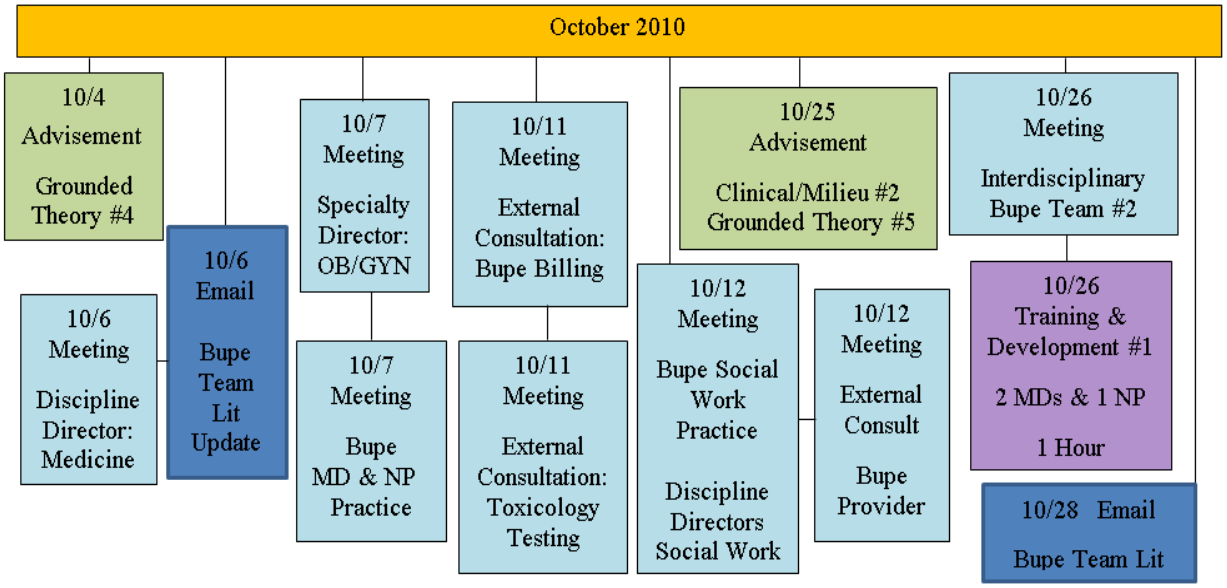


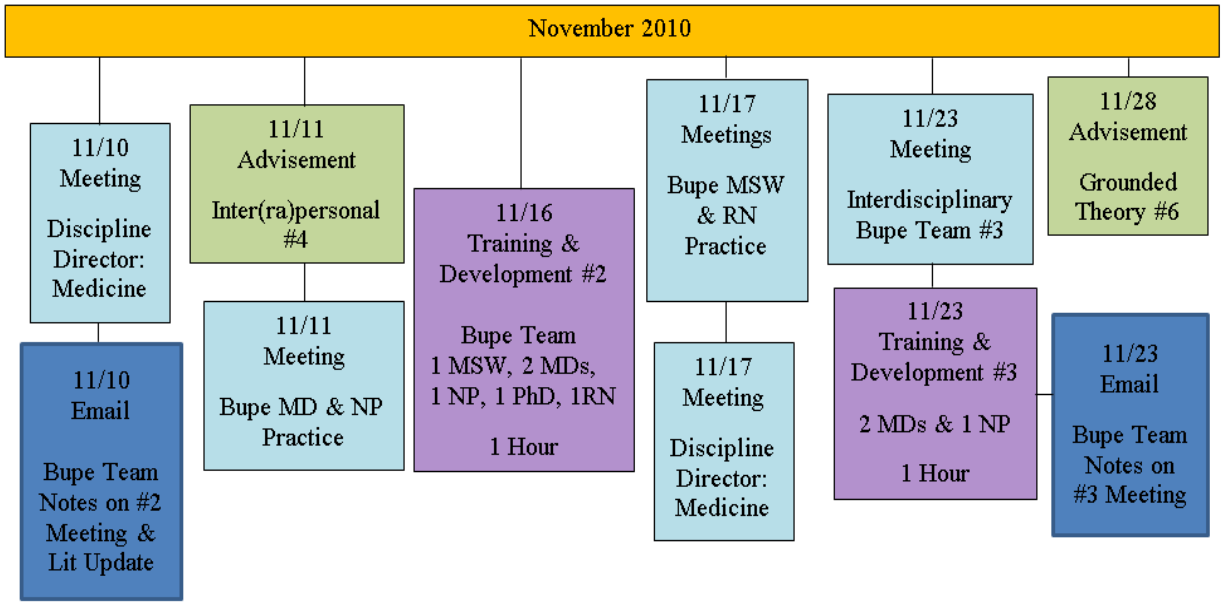


Phase II: September 2010 – November 2010

Data Timeline

Advisements, Email Communications, Interviews, Meetings, Trainings, Presentation





Phase III: December 2010 – January 2011

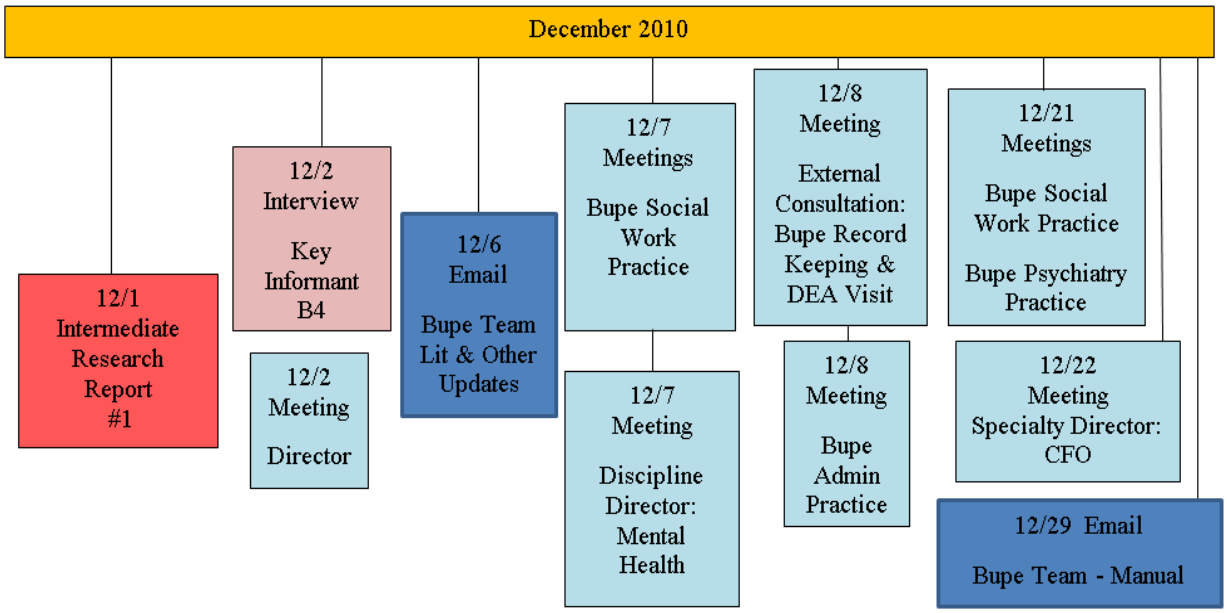
Ongoing training and development sessions, meetings, advisements, key informant interviews and a research update presentation at a general staff meeting took place in Phase III. In addition, the first intermediate research report was produced at the beginning of December. As data was analyzed in process, preliminary findings from Phase I and II were presented. The report also addressed questions that had been posed at the outset of the study, but remained unanswered. These questions included: what outcomes related to both buprenorphine treatment and implementation might be evaluated/studied once IBT/P commenced, who would do this, when would it be done, how might it be funded? The report was sent to leadership, the buprenorphine team with a process for reflection and feedback on the reports interpretations.

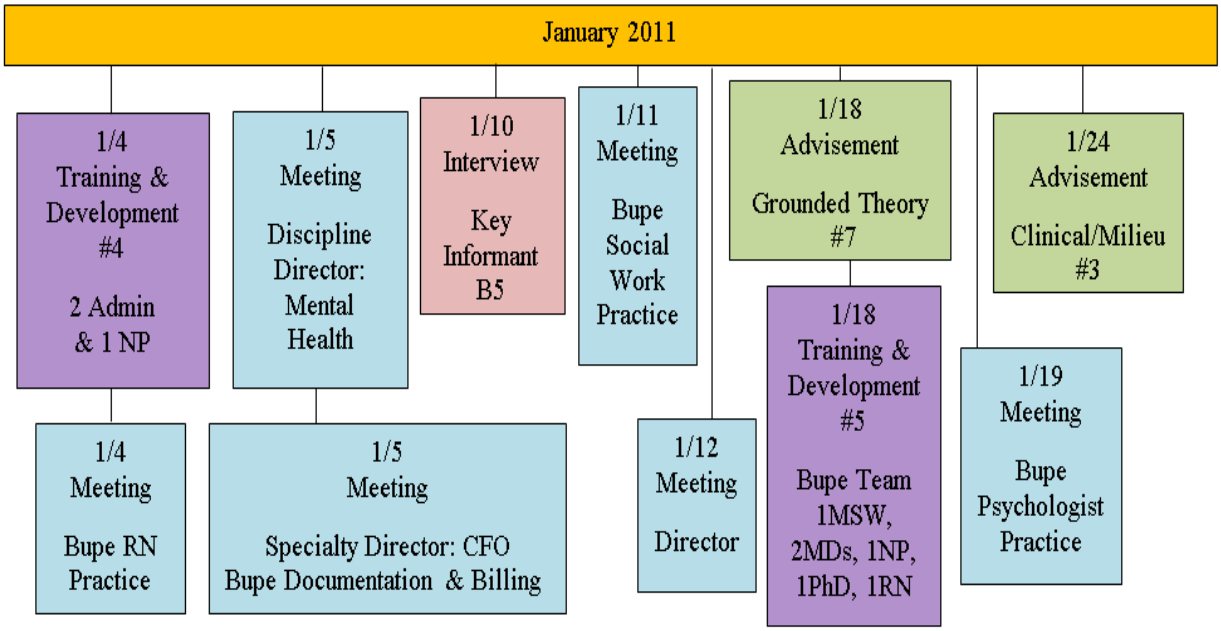
The researcher had two meetings with the director in Phase III. The first meeting took place in December, directly after the first intermediate research report was shared and a second in January 2011. During this meeting the researcher proposed a plan for future buprenorphine research which included: (1) the identification of a NIDA grant related to implementing evidence-based practices, (2) domains of potential future buprenorphine research, including outcome evaluations, (3) the time frames for the grant application, and (4) the researcher's interest to lead or co-lead the grant application process. Because of other activities that had priority for the organization, the director relayed the above proposed research was not possible. The researcher relayed she would continue to think about alternative options for future buprenorphine and implementation research funding. Other aspects of the intermediate research report were reviewed along with next steps of the research and a plan was made to meet for follow-up in March. Below is a timeline of research activities in Phase II, September 2010 – November 2010 and is followed by a discussion of Phase IV.

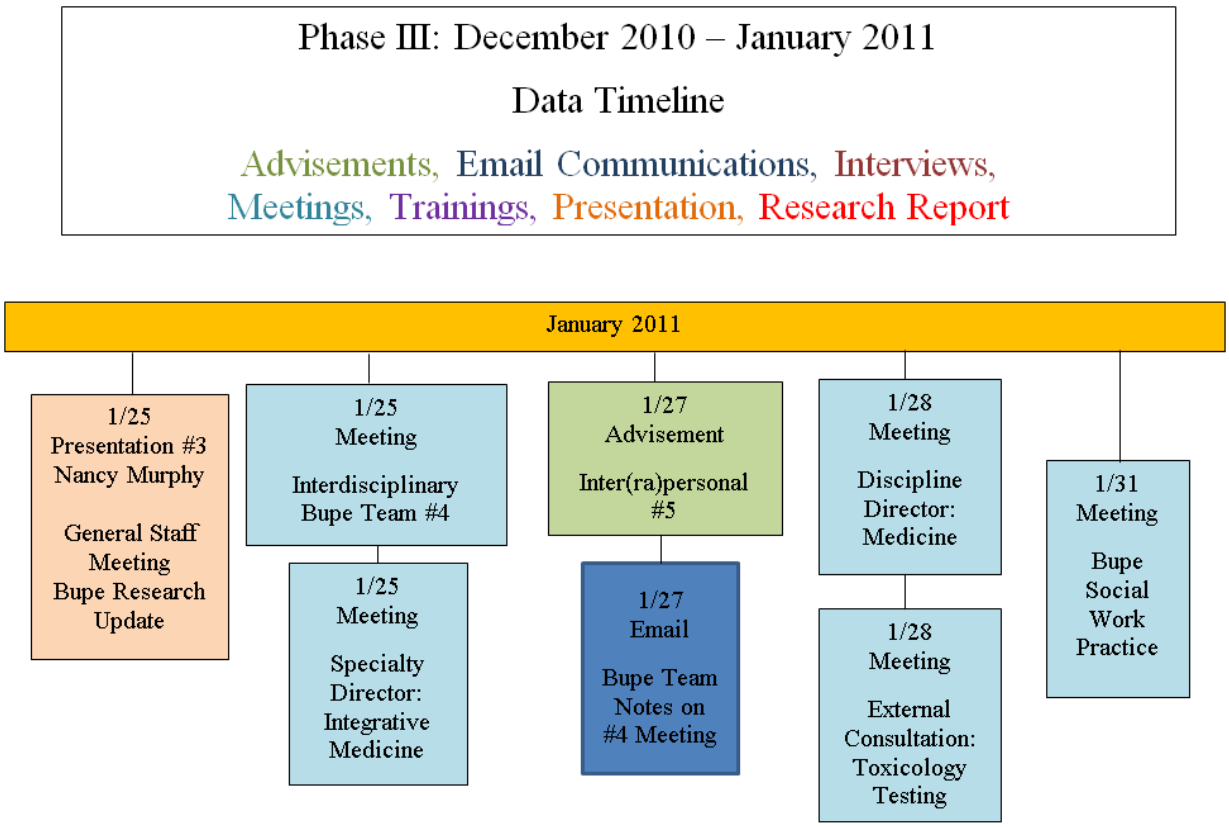
Phase III: December 2010 – January 2011

Data Timeline

Advisements, Email Communications, Interviews, Meetings, Trainings, Presentation, Research Report







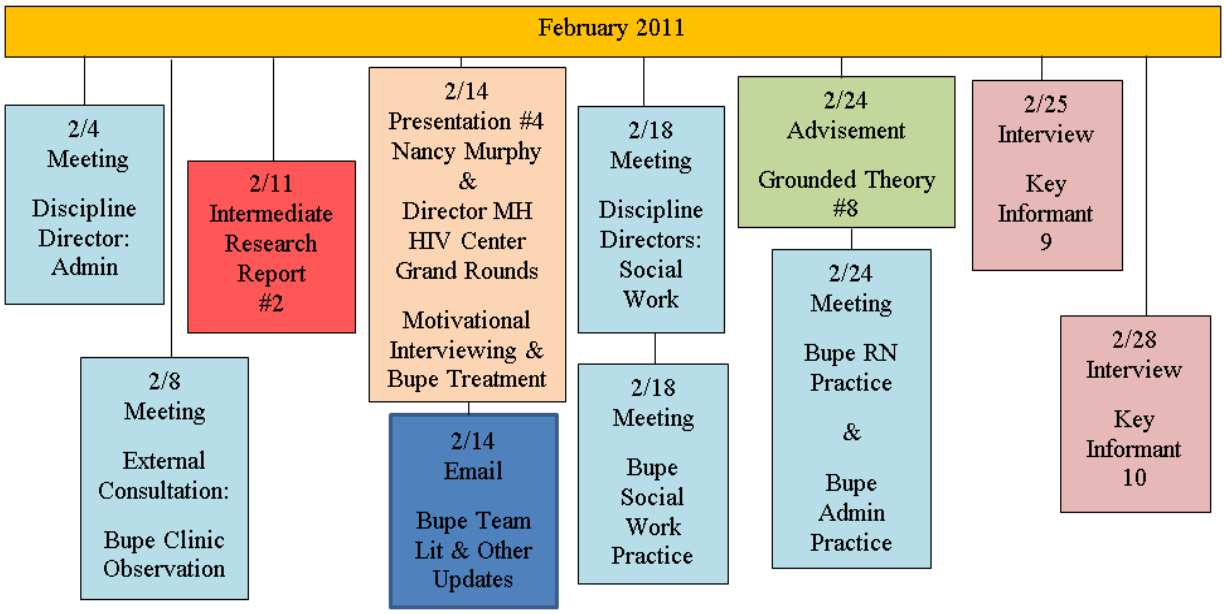
Phase IV: February 2011 – March 2011

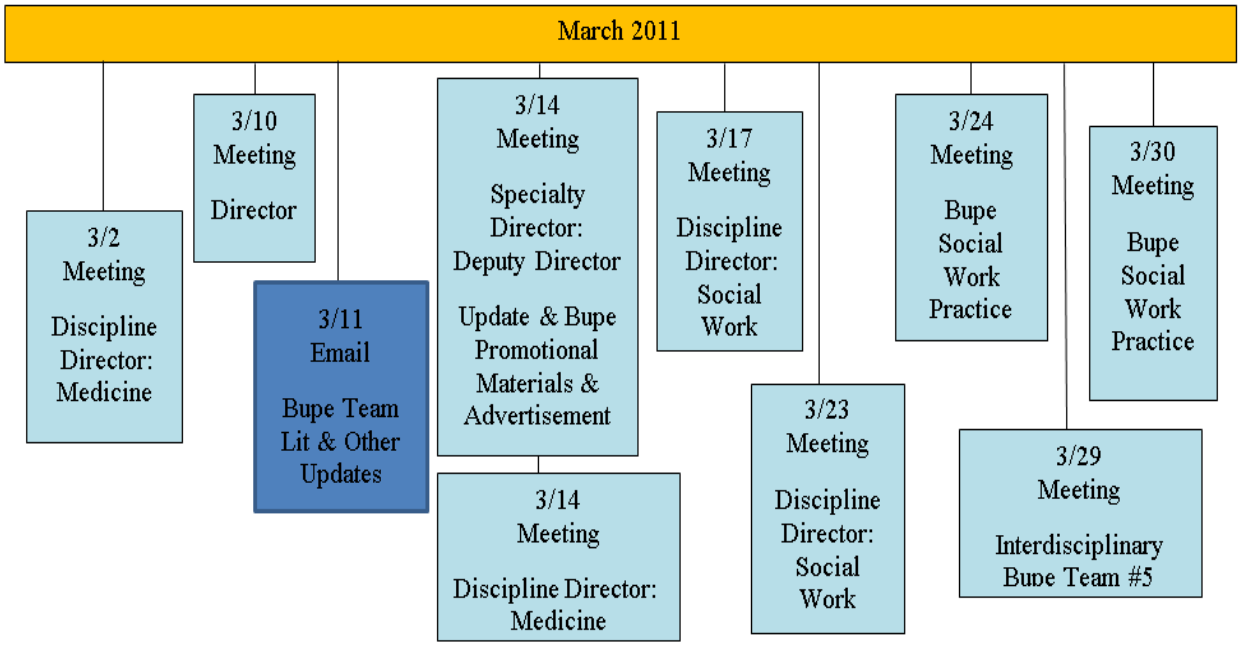
Phase IV included all the research activities that had been carried out in the previous phases, except for training and development sessions. A second intermediate research report was produced, (which had been presented at a general staff meeting at the end of January) and sent to leadership and the team in early February, with a process for reflection and feedback. Phase IV also included the first key informant staff interview. In addition, a presentation on Motivational Interviewing and Buprenorphine at the organization's weekly grand rounds was conducted by the researcher and the Director of Mental Health and provided another opportunity to share knowledge and highlight the upcoming IBT/P.

Phase IV: February 2011 - March 2011

Data Timeline

Advisements, Email Communications, Interviews, Meetings, Trainings, Presentation, Research Report





Phase V: April 2011 – May 2011

The final phase of Stage II of the research, Phase V, was a very active period as time was approaching to complete all aspects of the development and installation of IBT/P and move to initial implementation. The patient focus group was conducted in April and much training and development time took place during Phase V. As the four social workers and the five primary care providers had been determined to be the lead bupe clinicians, they were scheduled for the most training hours. The administrators, nurses and the psychologists also participated in training and development sessions, but to a lesser extent.

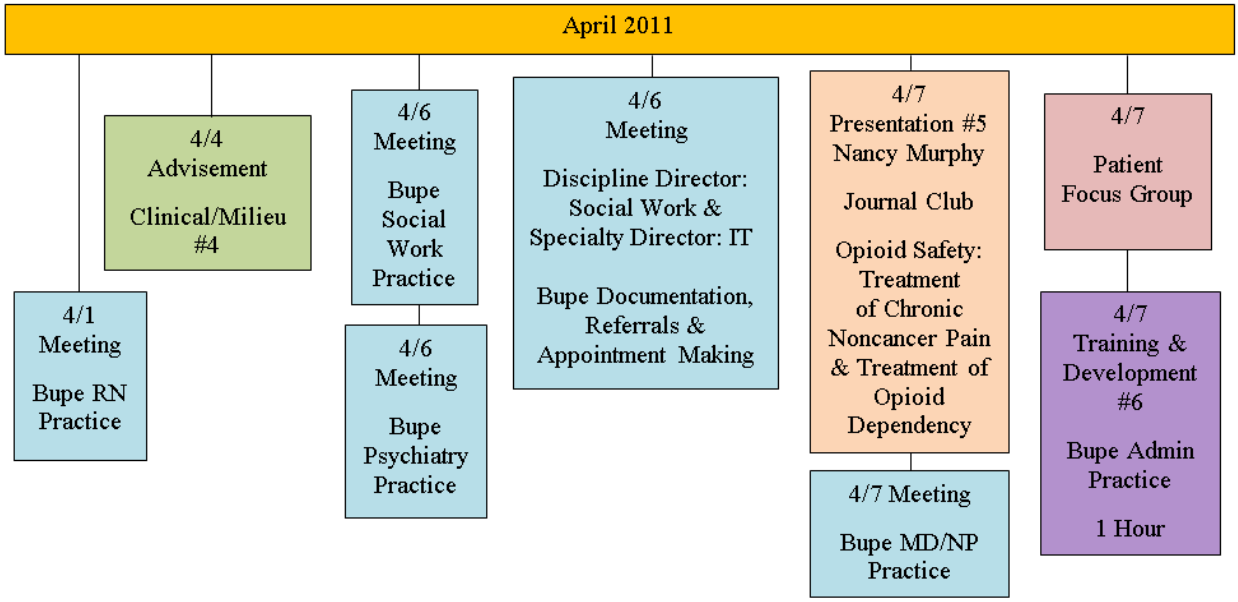
Two presentations were also conducted during this phase along with final meetings and interviews. A third intermediate research report was produced in April that shared research updates and included the information that the researcher had not been successful in identifying funding for research beyond the current study. The researcher relayed she was committed to continue to work with the team in delivering treatment, would track and monitor referrals, maintain the list of patients receiving buprenorphine and would remain available to coach and guide the treatment team as needed.

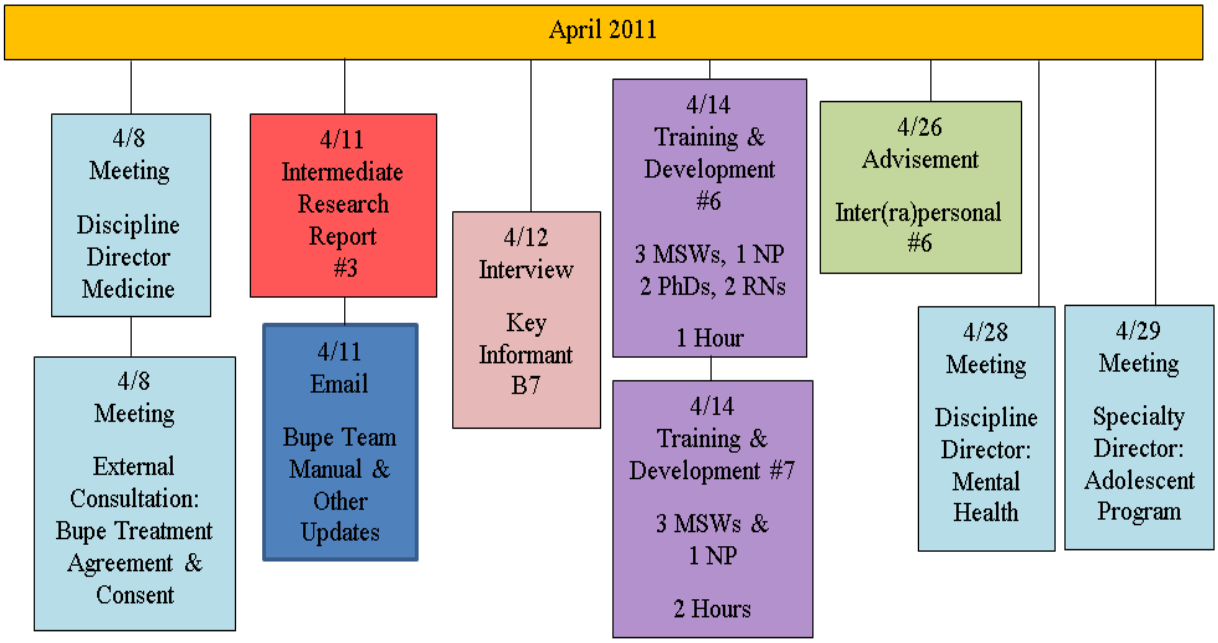
Unforeseen staff issues during this phase resulted in three team members withdrawing from participation. In addition, the physicians from Clinic 1 ended up having too many competing priorities and they were unable to attend their buprenorphine training. Updates on the implementation were shared with the director in May and the plan was adjusted to implement IBT/P in Clinic 2 in June 2011 and not in Clinic 1. A final three hour team meeting/training and development session took place at the end of May, in which twelve members of the team attended. Below is a data timeline of all activities in Phase V followed by a discussion of the research moving to Stage III and the initial implementation of the IBT/P at Clinic 2.

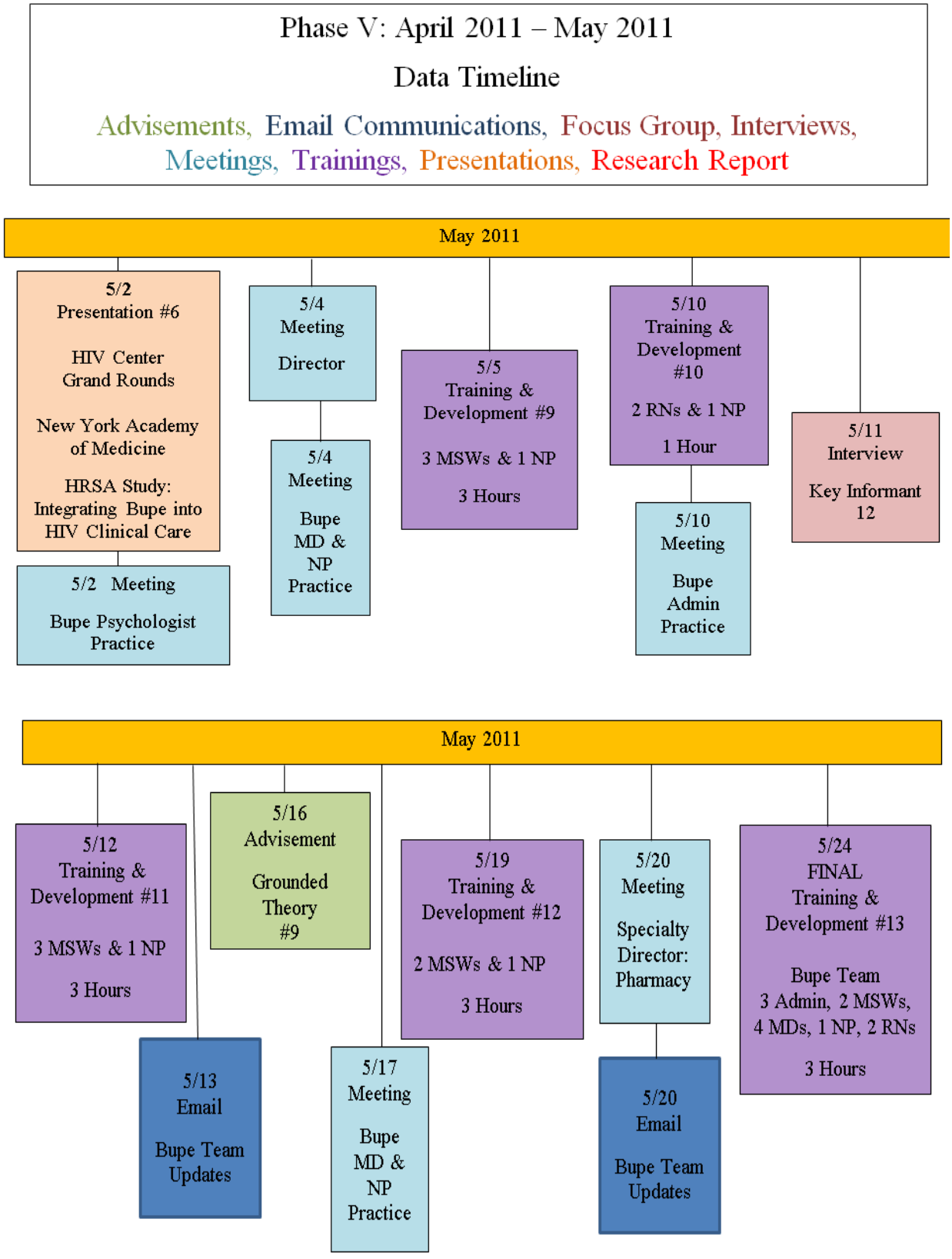
Phase V: April 2011 – May 2011

Data Timeline

Advisements, Email Communications, Focus Group, Interviews, Meetings, Trainings, Presentations, Research Report






Phase V: April 2011 – May 2011
Data Timeline
Advisements, Email Communications, Focus Group, Interviews, Meetings, Trainings, Presentations, Research Report
May 2011
5/2 Presentation #6
HIV Center Grand Rounds
New York Academy of Medicine
HRSA Study: Integrating Bupe into HIV Clinical Care
5/2 Meeting
Bupe Psychologist Practice
5/4 Meeting
Director
5/4 Meeting
Bupe MD & NP Practice
5/5 Training & Development #9
3 MSWs & 1 NP
3 Hours
5/10 Training & Development #10
2 RNs & 1 NP
1 Hour
5/10 Meeting
Bupe Admin Practice
5/11 Interview
Key Informant 12
May 2011
5/12 Training & Development #11
3 MSWs & 1 NP
3 Hours
5/13 Email
Bupe Team Updates
5/16 Advisement
Grounded Theory #9
5/17 Meeting
Bupe MD & NP Practice
5/19 Training & Development #12
2 MSWs & 1 NP
3 Hours
5/20 Meeting
Specialty Director: Pharmacy
5/20 Email
Bupe Team Updates
5/24 FINAL Training & Development #13
Bupe Team
3 Admin, 2 MSWs, 4 MDs, 1 NP, 2 RNs
3 Hours

Stage III: Initial Implementation, June 2011

As planned, IBT/P began in June 2011; however, as just discussed it occurred only in Clinic 2. The researcher began coaching sessions with the team to review the IBT/P created and keep connected in preparation for referrals. Coaching sessions were conducted both with the team and disciple specific. The researcher used Clinic 2's regularly scheduled Wednesday Case Conference to remind the clinic staff that the bupe team was open for referrals and field any questions. On June 16, 2011 the first patient to receive buprenorphine was seen. Updates and reports were presented and sent to staff and leadership and the team celebrated!

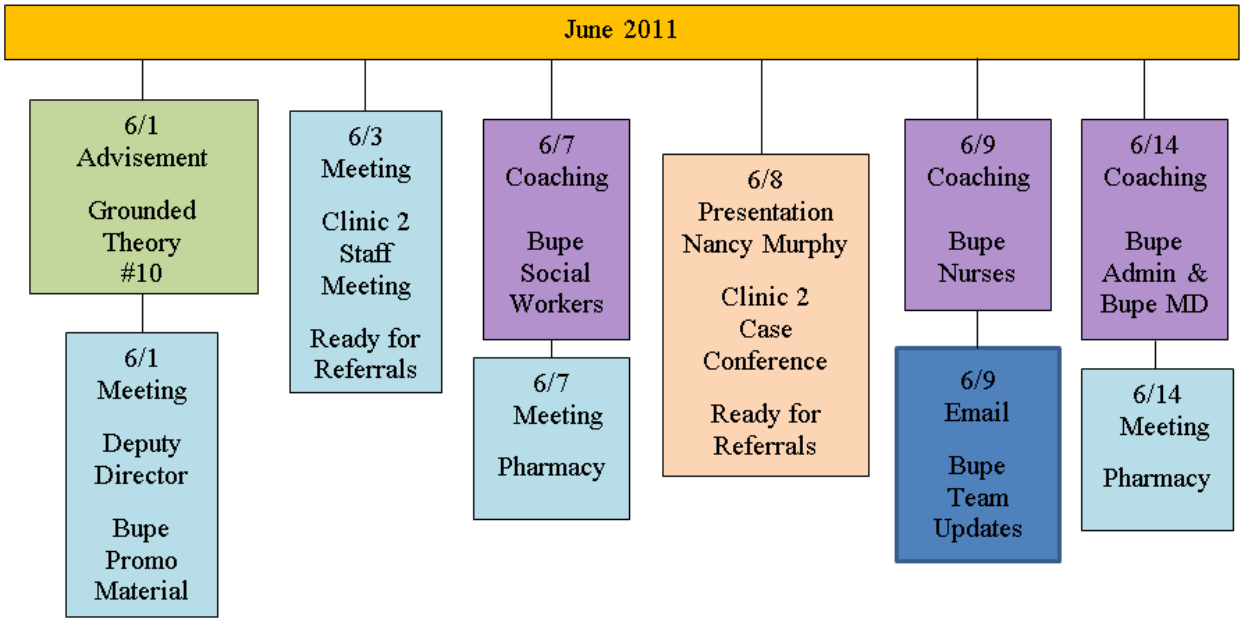
The researcher also completed a first draft of the IBT/P Manual during this final stage (Appendix A). The manual has 16 distinct topics regarding IBT/P. Several topics were produced in collaboration with team members and other topics were produced by the researcher alone. The manual was sent to all leadership and team members and placed on the common drive of the organization. This manual can be accessed by any staff member in the organization and provides guidance for discipline specific practice, shared care practice, record keeping, billing, documentation, etc. Some aspects of the manual were constructed specifically for the social workers to guide buprenorphine education and screening sessions and use various visuals (in particular opioid receptors) to help patients in understanding how buprenorphine works.

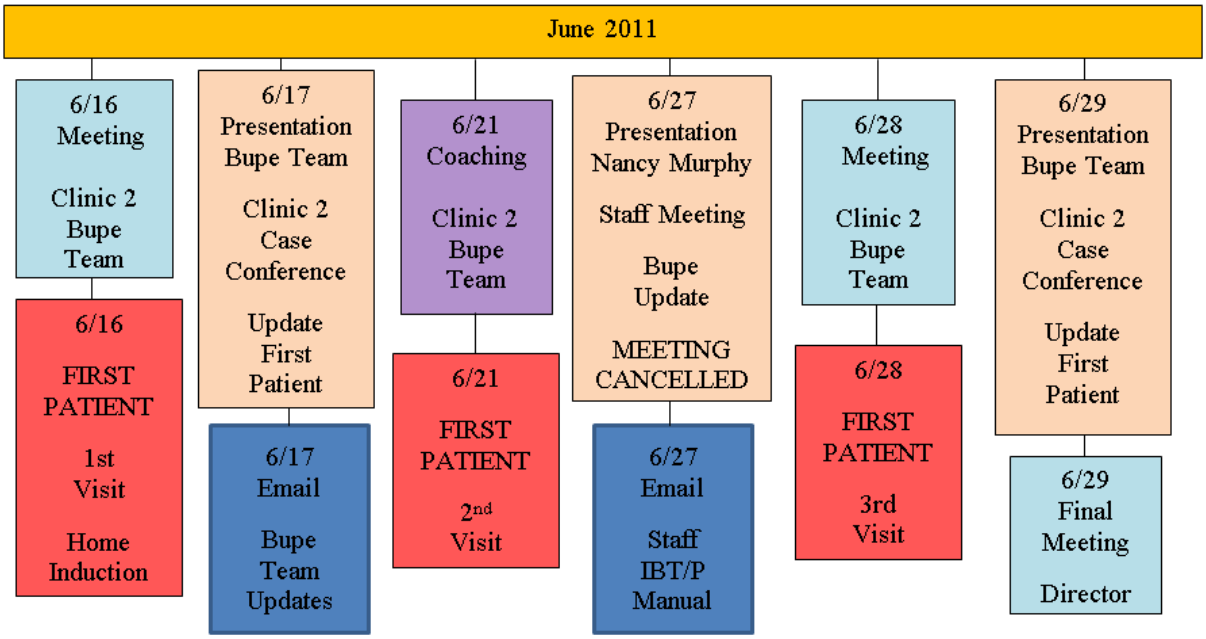
The researcher was scheduled to present the completion of the research and the manual at the June 2011 staff meeting; however, the meeting was cancelled. The researcher used various informal opportunities to share it with the general staff. The researcher had her last meeting with the program director in June 2011, and gave a final update on the IBT/P and reviewed the manual. Plans to extend the IBT/P to the other clinics of the research organization were discussed.

Stage III: June 2011

Data Timeline

Email Communications, Meetings, Coachings, Presentations,
First Patient





Data Overview

As noted at the beginning of this chapter, there were several types of data operating in this study. An audit trail (Lincoln & Guba, 1985, p. 316 – 320), of the data was maintained during the study, organized as follows and open to the inspection of the research advisor: (1) raw data (audio recordings, advisement notes, fieldnotes from email communications, informal interactions, meetings, presentations, training and development sessions, and interview and focus group notes), (2) transformed data (transcripts, write-ups of advisement notes, fieldnotes, interview and focus group notes), (3) process data (logistic notes, data-timeline), (4) directional and developmental data (resources for clinical guidance & IBT/P manual), (5) first-person inquiry data (personal reflective/reflexive journal), and, (6) analytic data (methodological decision notes, coding notes, analytic notes, intermediate research reports). Handwritten data and printed data were stored in a locked cabinet to which only the researcher had access. Electronic documents and audio recordings were stored in the researchers computer which was password protected.

Raw Data

Throughout the study year, handwritten notes were taken during, 20 advisement sessions field interactions and observations (110 documented meetings), 13 training and education sessions (22 hours), 6 presentations, 12 interviews, and 1 patient focus group.

Interviews and the patient focus group were audio recorded by the researcher on a small hand held recorder. These notes documented aspects of what was being relayed during the interviews that the researcher took to be significant, different, or raised new questions. Advisement notes were structured around an agenda of issues and questions that the researcher developed prior to each session. Fieldnotes were focused on: communication patterns, group

roles, problem solving, decision making, relations with others, elements of culture (Coughlan & Brannick, 2010, p. 74), activities, feelings, conditions under which work was being done, task which was being addressed (Stringer, 2007, p77), initial impressions, key events or incidents, interactions (both verbal and nonverbal) and actions, interactions, events are significant participants (Emerson, et al., 1995, pp. 26-28).

Transformed Data

Audio recordings of interviews were sent to a professional transcription service and were returned about two weeks after they occurred. The researcher listened to the audio recording of the interviews while reviewing the returned transcripts to confirm the content was correct. The researcher transcribed the audio recording for the patient focus group and also confirmed its accuracy.

Advisement notes, fieldnotes and interview and focus group notes were written up as electronic documents as close to the events as possible, either the day they occurred or within a few days after they occurred, using the handwritten notes as a guide. These three types of notes were written based on recommendations of Emerson, et al. (1995). They were written for the researcher as a future reader with an understanding that they would be coded and analyzed. They were written in a loose and flowing style, without concern of voice or style and with the assumption, "that these accounts will only be read by and only be comprehensible to myself" (p. 44). They were also written with the understanding that should they be shown to another reader, "the field researcher can at that time take control of this process; she can select, focus and edit any notes before making them available to others" (p. 44).

Process Data

Logistic notes on the day to day workings of the research were recorded on a routine basis; from June 2010 - June 2011. There are approximately 200 dated entries. These were used to keep track of all research activity and to construct the data time line.

Directional and Developmental Data

The list of resources used to clinically guide the bupe team were documented over the course of the research as a topic within the larger IBT/P manual, which was maintained as a power point document. The researcher took responsibility for generating topic areas for the IBT/P manual and inputting the related material as it was developed during meeting and trainings. The manual was used initially as a vehicle to share the developing IBT/P information with the team and allowed for feedback and updates. The final IBT/P manual was placed on the research organization's common drive and was used by the bupe team as a reference document to support the IBT/P, once treatment commenced.

First-Person Inquiry Data.

In-depth self-reflections on what the researcher was learning about herself and the inquiry process were documented in a personal journal; over the 13 months of the research there are approximately four-six reflections documented each month (total 60 dated reflection notes).

Analytic Data

The various types of data described above were organized into three main areas for purpose of data analysis, (1) field, (2) key informant, and, (3) first-person. Field data included the various fieldnotes (raw and transformed) taken over the course of the study, (mostly related to the work done with the team and the organization), the logistics notes and the IBT/P manual that was developed through the field work. Key informant data included recordings, notes (raw

and transformed), and transcripts from interviews and the patient focus group. First-person data included both advisement notes and the researcher's personal reflective/reflexive journal. The continuous analytic process produced methodological decision notes, coding notes, analytic notes, and intermediate research reports. Field data and first person data were analyzed on a monthly basis, key informant data was initially coded/analyzed about two weeks after it had been collected and intermediate research reports were produced, 12/10, 2/11 and 4/11.

Data Collection/Generation and Data Analysis

AR (Coughlan & Brannick, 2010; Stringer, 2007) and GTM (Bryant & Charmaz, 2007; Charmaz, 2006) directed the researcher to undertake recurring cycles of data collection/generation and data analysis. Because of the nature of AR, data is understood to be both collected and generated as,

> …data comes through engagement with others…acts which are intended to collect data are themselves interventions. So asking an individual a question or observing him at work is not simply collecting data but is also generating learning data for both you the researcher and the individual concerned. In short, you are not neutral. Every action, even the very intention and presence of research, is an intervention and has political implications across the system (Coughlan & Brannick, 2010. pp. 73-74).

However, AR does not provide an adequate explanation for how to analyze data (Dick, 2007, p. 402), therefore, GTM, with its well established data collection and analytic strategies was used in this study. Like AR, GTM has also been identified as a family of methods, which falls into three schools: (1) Glaserian, (2) Strauss and Corbin, and (3) Constructivist (Bryant & Charmaz, 2007, p. 9 - 13). This study used the constructivist version of GTM which, "emphasizes how data, analysis and methodological strategies become constructed, and takes into account the research

contexts and researcher's positions, perspectives, priorities and interactions" (p. 10). Data was collected and analyzed under the advisement of a seasoned GTM researcher. Data collection strategies included point of departure sampling, theoretical sampling and strategic sampling. Data analysis strategies included coding (initial and focused), constant comparative methods, analytic memo writing (initial and advanced). Other techniques such as clustering, sorting, diagraming and integrating contributed to data analysis. These procedures are interrelated, were employed from the beginning of the research and will be discussed below.

Field data was collected/generated through iterative cycles, using AR processes of constructing the picture, planning action, taking action, and evaluating action. Initial key informant interviews were collected based on GTM strategies of initial sampling or point of departure sampling, where the researcher makes strategic decisions who and where to begin interviewing (Charmaz, 2006, p. 100). After initial sampling, coding, comparisons and analysis, the aim is to explore and expand the researcher's understanding of the categories generated, their dimensions, properties, variations, and relationships, in addition to being open to the development of new categories. This is achieved through a data collection procedure in GTM known as theoretical sampling, where the researcher, "seeks people, events or information to illuminate and define the boundaries and relevance of the categories" (p. 189).

In this study, the researcher determined that individuals in leadership within the research organization (critical cases) would serve as a point of departure because their perspectives needed to be well understood and incorporated as needed, as they had ultimate control over the research going forward and were essential to the implementation of IBT/P. It also provided an opportunity to surface any questions or clarification leadership might have about the research early in the process. Three critical case interviews were conducted in July and August 2010.

Based on the analysis of the three critical cases and fieldnotes from June, July and August, the researcher selected three key informants, meaningful cases, from a tentative list that was developed prior to the start of the study. The initial meaningful cases (3) were interviewed in September 2010, after the team was assembled but before the first full buprenorphine team meeting took place so that any new perspectives or feedback could be shared with the team at the first meeting. The subsequent four meaningful case, key informants were interviewed between December 2010 and April 2011. The rationale for the order in which these key informant interviews were conducted and the adjustments to interview questions were tracked throughout the study and documented in the methodological decision notes.

The researcher also determined that the patient focus group and typical case, key informants would be conducted later in the research process so that there would be specific information to share about the IBT/P and the researcher could obtain some patient and staff feedback prior to initial implementation. Staff interviews (typical cases) were conducted between February and May 2011 and the patient focus group was conducted in April, 2011.

Data Analysis

In GTM, coding is a procedure of asking a range of questions of the incidents and statements in the data to learn what the data is suggesting, with an emphasis on studying actions and processes (Charmaz, 2006, p. 46). "Coding means categorizing segments of data with a short name that simultaneously summarizes and accounts for each piece of data" (p. 43). The process of coding, "distills data, sorts them, and gives us a handle for making comparisons with other segments of data" (p. 3). The constant comparative method is inductive and is focused on working with the data in both a sequential and back and forth manner, as the research progresses. The statements, incidents (pieces of data) which are distilled into codes are compared within the

same interview or observation for similarities and differences and then these pieces of data are compared across interviews and observations over time. Clustering is a mapping of codes and categories which facilitates thinking about their properties, comparisons and relationships. It is non-linear, visual and flexible in helping to organize material, studying data, and defining essentials. Like coding and constant comparison, analytic memo writing also begins early in the research process and is a critical step in the data analysis. "Memos catch your thoughts, capture the comparisons and connections you make, and crystalize questions and direction for you to pursue" (p. 72). Memo writing raises codes to a conceptual category and is the process of developing an analytic framework. In early memo writing, ideas are tentative and incomplete.

A category, "may subsume common themes and patterns in several codes" (p. 91). Categories are given definitions and made as conceptual as possible, while, simultaneously remaining "consistent with your data" (p. 91). As the research proceeds, and more select data that addresses analytic problems is collected, focused coding and advanced memo writing takes place. Categories are 'saturated' when collecting new data reveals no new properties or new insights (p. 113). Three procedures of working with memos: sorting, diagramming, and integrating are then undertaken. Sorting, "gives you a logic for organizing your analysis and a way of creating links that prompts you to make comparisons between the categories" (p. 115). Diagramming provides a visual representation of categories and their relationships (p. 117) and integrating, "makes relationships intelligible" (p. 120). Collectively these procedures facilitate the researcher in working toward the final interpretative understanding of what was found in the empirical world (p. 120).

Chapter 6: Results

This research identified three goals and 16 objectives at the outset of the study (chapter 1, pp. 8-9). Objectives 15 and 16, produce a dissertation and disseminate results are still in process. As discussed in chapter 5, this study was not successful in obtaining funding or support for future research, therefore objective 13, the determination of treatment, implementation and patient outcomes, which was to guide the future research was never addressed. Also, the IBT/P commenced as planned in only one of two clinics that participated in the study, due to unforeseen staff issues. All other objectives, except for number 13 were achieved.

Two main areas of results were generated from this study in relationship to the two research questions:

1. What factors promote or inhibit the development, installation and initial implementation of an IBT/P within a primarily publicly funded, hospital-based, HIV primary care/ DAC in NYC?
2. How can Action Research, Implementation Science, and Institutional Ethnography inform the development, installation and initial implementation of IBT/P within a hospital-based HIV primary care/DAC in NYC?

The conceptual explanations of the inhibitors and promoters related to developing, installing and implementing an IBT/P will be presented first, followed by the conceptual explanations of how action research and implementation science and institutional ethnography informed the study.

Interaction Between Key Informant and Field Data and Action Research

The key informant and field data sets were collected/generated and analyzed throughout the study, moving from one to the other and then back again, with a focus on identifying promoting and inhibiting factors about implementing buprenorphine. Information shared by key

informants, about buprenorphine implementation, deemed as promoters was brought by the researcher/facilitator back to the bupe team for consideration. This data was used alongside the multiple other sources and guidance material assembled, distributed by the researcher to the team and used in the development of the final IBT/P. Conversely, questions about buprenorphine, that were puzzling the bupe team, were brought to the key informants for their interpretation and guidance and this information was again brought back to the team.

Across key informant interviews and throughout the organizational work of this study, significantly more inhibitors to developing, installing and implementing buprenorphine were identified than promoters. The researcher conceptualized three key inhibitor categories, from key informant and field data and brought them to the team throughout the study to problematize and develop countering promoters that could be integrated into the IBT/P. As the key informant and field data was analyzed in process, the first key inhibitor category was brought to the team in month five of the study (October, 2010), the second in month eight of the study (January, 2011) and the third in month 10 of the study (March, 2011). This process allowed the team time to consider the inhibitor category and work on developing countering promoters. This was done as part of the ongoing development work that was taking place in both small interdisciplinary groups and discipline specific group work. The categories were considered provisional and incomplete until study ended because the possibility existed that the categories might take a different form and/or a new category could emerge while data collection was still in process.

Because there were limited findings relative to promoters of buprenorphine implementation, they will be presented as factors because the data did not support the development of conceptual categories. Key inhibitor categories and countering promoter

categories will be presented first, followed by promoting factors and recommendations.

Key Inhibitor Categories and Countering Promoters to Implementing Buprenorphine

The three key inhibitor categories determined over the course of the study ended up having staying power, with new data continuing to support the categories and often providing new dimensions to the conceptual ideas. Once data collection ended, the categories were finalized. The first key inhibitor category is Dancing with a Bear: The Never Ending Biases Against Treating Opioid Dependence/Addiction Extended to Buprenorphine, and its countering promoter is, Be Educated, Be an Advocate, Dispel Myths and Take Action. The second inhibitor category is Plaguing Questions and its countering promoter is, Identifying Core Aspects of Buprenorphine Treatment and Developing Uniformity of Care. The third inhibitor category is Buprenorphine Exceptionalism: Unique Aspects of Treatment not Otherwise Encountered and its countering promoter is, Dimensionalizing IBT/P and Identifying and Detailing Discipline Specific Practices, Cross Discipline Practices and Coordination of All. The inhibitors and promoters are subdivided into their corresponding dimensions to present the complexities of issues operating in each category.

Key Inhibitor Category #1
Dancing with the Bear: The Never Ending Biases Against Treating Opioid Dependence Extended to Buprenorphine

Former Surgeon General Jocelyn Elders used the metaphor, “Dancing with a Bear,” to describe what it’s like to do HIV prevention work. “When you are dancing with a bear, you can’t get tired and sit down, you have to wait until the bear gets tired, then you can sit down” (Elders, 2002). The persistent, pervasive, and sometimes overpowering nature of biases demonstrated in the research data and experienced by the team, against buprenorphine and treating opioid dependence/addiction, can also make one feel like they are “dancing with a bear,”

hence the use of the term. While bias is not an unknown inhibitor in relationship to buprenorphine, it emerged as a key inhibiting concept early in the research data and then its place was maintained and confirmed as its many dimensions continued to come up across key informant interviews, throughout the organizational work and in the patient focus group. At the end of October 2010, using the data collected over the first five months of the research, this key inhibiting category was presented to the team so work could begin in developing countering promoters. The category contains aspects of some long standing biases against treating opioid dependence/addiction in general, in addition to new and emerging biases specific to buprenorphine. The dimensions have ben subdivided and grouped as, (1) Biases Related to the Association of Buprenorphine with Methadone, (2) Public Bias, (3) Patient Bias, (4) Clinician Bias, and (5) Institutional Bias.

Biases Related to the Association of Buprenorphine with Methadone

A discussion about buprenorphine, with all key informants, always included a discussion about methadone. Unfortunately the pharmacologic merits of methadone are often overshadowed by the less than redeeming aspects of methadone maintenance treatment programs (MMTPs) and the negative images that circulate about patients who attend these programs. The close connection of buprenorphine with methadone creates a unique type of bias by association.

> And providers already feel a certain way … about methadone; they're going to feel the same way about buprenorphine – unsafe, high acuity, too much hassle … that will be a barrier. And it will be hidden because nobody's going to come out and say, well I don't like methadone (U, p. 26).

This issue was raised repeatedly when discussing barriers to buprenorphine implementation and as the statement above relays, it can be further complicated by it being

hidden. However, the researcher had many experiences throughout the project where sentiments such as the above were not hidden. In fact, making blatant negative comments about patients on methadone and relaying not wanting to "deal with them" was shared quite freely,

> …everybody knows the methadone clinic where, you know, folks are just, you know, completely, hanging out, and high, and in all sorts of disarray (W, p. 4).

Public Bias

Public bias against treating people with opioid dependence/addiction has been played out in a variety of ways, often with NIMBY type responses to MMTPs. One key informant likened the restriction of treating opioid dependence/addiction at MMTPs to abortion clinics and the negative consequences of these services/treatments being outside main stream health care.

> …although the origins are different I think the ultimate outcome is the same…where everyone knows that's methadone or that's abortion and they become targets for either, you know, community disapproval or the kinds of things we've seen around abortion…if we had kept abortions mainstream…what's gone on around abortion centers …try that at the entrance to a hospital that has a big powerful board (B, p. 5)

Several key informants (W, p. 1, M, p. 6, and C, p. 27) recalled the infamous announcement by then Mayor Giuliani, in 1998, to put an end to methadone treatment in NYC, accusing MMTPs of promoting drug use by substituting one addiction for another.

> …if you were ignorant, and out there, and conservative, if you like politically – like Giuliani said it: he wanted to close down all methadone clinics – then you were against methadone and it was kind of very much like, I don't know, safer sex in the earlier parts of the HIV epidemic (R, p. 18).

Comparing opposing methadone for opioid dependence/addiction with opposing safer sex for

HIV prevention highlights the anti-science nature of much of the public bias against treating opioid dependence/addiction and the negative nature of this perspective in the hands of people with public power.

In considering public bias and the media, an article in the NY Daily News, which appeared October 20, 2010 with this title, "Picking 'ex-cons' poison" came up repeatedly during the course of the study. The article discussed a study where inmates with a history of opioid dependence/addiction were offered buprenorphine treatment before discharge, to prevent relapse when back in the community. The article opens with this statement, "State officials plan to give some junkies an addictive drug while they are still in prison and supply them with it when they're paroled." Special Narcotics Prosecutor Bridget Brennan is quoted in the article, "Hooking inmates on an addictive opiate drug as they're about to be released from prison sounds like a poorly thought out policy" (O'Shaughnessy, 2010). The continued misinformation and the negative representation of "junkie" that is presented in the media, fans the flames of public bias.

This article was brought to my attention three times throughout the study. A copy was brought to the second buprenorphine team meeting in October, 2010, by one of the team members to share and highlight to the group "what we are up against" (October Fieldnotes, p. 27). The article was also mentioned in a key informant interview in December, 2010 in which it was relayed, "I have been interviewed for some of these articles and no matter you say, this is how they frame it" (L, p. 6). It also appeared again when a participant in the patient focus group, which took place in April, 2011, brought a copy of the article to the group with the interpretation, "see, they can force people to take Suboxone" (Focus Group, #5, p. 15). This article is a classic example of the ongoing struggle to bring dignity, privacy and quality (which

include accurate and factual buprenorphine information) to the treatment of opioid dependence/addiction. It is not surprising that a number of key informants referred to implementing buprenorphine as an, "uphill battle" (R, p.14,) and a "losing battle (C, p. 15).

Patient Bias

Bias against buprenorphine has an interesting spin when it comes to patient bias. Repeatedly one hears that many patients are not interested in maintenance treatment, even when they have experienced significant morbidity related to relapse after stopping medication. Three of the six focus group participants, who reported long histories of opioid dependence/addiction, relayed not wanting to stay on methadone (Focus Group #6, p. 19, EWF, p. 4) and buprenorphine (#5, p. 19). During the time spent observing buprenorphine at a primary care clinic, two patients, who had come in that day for an intake, also with long histories of opioid dependence/addiction, both relayed wanting to come off buprenorphine in a few months. Of course, given the negative opinion of maintenance treatment in society, it is no surprise that patients are anti-maintenance and the concept of continued treatment is unacceptable to many.

Throughout the work with the bupe team, many members highlighted that Narcotics Anonymous is also anti-maintenance, and has a rule that allows people on methadone to attend meetings, but they are not allowed to speak, as they are not considered drug free. This fuels both public, patient and clinician biases. Key informants also relayed a range of patient bias against buprenorphine which included: fear of the unknown, knowing methadone much better (from the street as well as treatment), higher cost of buprenorphine compared to methadone, not wanting to undergo induction, not fully believing buprenorphine will do the job, and not liking the taste or the texture of the tablet.

Another type of patient bias against buprenorphine comes in the form of patients asking for treatments that are known to be less effective, like detox or naltrexone, despite being counseled otherwise.

> And that's what my primary concern is: not what you do if somebody does not do well on buprenorphine, but what you do when somebody would prefer to be on naltrexone… If somebody does come in suffering from the illness of opioid dependence and asks what should I do to treat my opioid dependence, then our first-line thinking should be a buprenorphine maintenance treatment, not detox, but maintenance (R, p. 6).

In an educational document from SAMHSA, Medication-Assisted Treatment for Opioid Addiction (2009), methadone, buprenorphine and naltrexone are presented as three medication choices as if they were all of equal efficacy, which is clearly not true. Naltrexone is a pharmacotherapy option for treating opioid dependence/addiction, it blocks the effect of opioids, but it does not stop cravings for opioids; it is less effective than methadone or buprenorphine and is not considered a first line treatment (National Health and Medical Research Council, 2010; Stotts, Dodrill & Kosten, 2009).

Clinician Bias

Key informant M relayed a story where providing buprenorphine exposed clinician bias against patients with addictions that had otherwise been unknown. During a difficult induction,

> … they had to, kind of, move the patient somewhere and the clinician said, "Oh, you know, I hate those patients. I hate those drug using patients." And the (other) clinician was really surprised. He's like, "These are all our patients." So he didn't really realize (M, pp. 22-23).

Key informant T, made a more broad statement,

> …providers just don't want to have anything to do with those addicts. And when you say yeah, but you know you already have a huge number of addicts in your population, yeah, but I don't like to deal with that (T, p. 34).

While clinicians clearly have biases against patients with addictions, both statements also highlight that no matter what field you are in, you cannot work in health care without encountering addiction issues. Yet, despite this reality, patients with addictions continue to be on the receiving end of negative clinician judgments or may be receiving substandard care because of the "I don't want to deal with them" attitude. Not all clinicians like working with all conditions, but there is no other condition where it would be acceptable for a clinician to openly say they were going to ignore or not deal with a condition when it presents itself in the clinical setting, as is found with addiction.

Both in key informant interviews and in informal interactions with physicians about buprenorphine, several relayed that they had experienced bias, directed against them, when it came to their working with patients with active substance use or providing buprenorphine. They recounted being labeled, "junkie doctor" (L, p. 6) and "doctor of the drug addicts" (July Fieldnotes, p 8). One key informant relayed he had experienced being told that treating patients with opioid dependence was,

> …even worse than doing nothing because you are taking away the motivation to free themselves of this (T, p. 33).

Institutional Bias

Bias against buprenorphine has also expressed itself on many institutional levels. Various agencies and bureaucracies were identified during key informant interviews as opposing and being hostile to office-based buprenorphine treatment. Unfortunately, "…the methadone

program establishment – fought tooth and nail – to prevent buprenorphine (T, p. 39). One key informant referred to methadone as,

> …a new enemy which was an old friend, which is methadone. So it's kind of very difficult for us now. I mean I was one of the biggest proponents of methadone before buprenorphine came in, and I'm finding myself now having to fight the methadone community because – why? Because something better came along (R, p. 19).

Some have attributed buprenorphine office-based treatment as being in competition and MMTPs fears of losing patients and revenue. Other people sight the issue of control.

> I feel like there is still some sort of belief out there (drug treatment programs) that people need to be controlled in programs and the idea that you are giving prescriptions and sending them home with prescriptions … is that you are losing control. And they need to be controlled (C, p. 38).

During an informal interaction with one of the staff members at the research organization, this comment was made, "So how are you going to deal with the politics with MMTP?" I asked what the concerns were and the staff member explained that by bringing buprenorphine treatment to the clinic, I would be competing with MMTP (August Fieldnotes, p. 9). I acknowledged that I had heard this point and used the opportunity to explain that not all MMTPs oppose buprenorphine as many addiction clinicians are supportive of expanding treatment for opioid dependence/addiction as the number of people with this diagnosis far outstrips the current availability of treatment. Throughout the study, the issue about the possibility of MMTPs feeling in competition with office-based buprenorphine was expressed by many people in the field. Most participants expected this competition would take the form of MMTPs not cooperating

with patient's requests for transferring to buprenorphine by ignoring communication from our clinic and bupe clinicians.

The NYS Office of Alcoholism and Substance Abuse Services (OASAS) was also identified by a key informant as not supportive of buprenorphine office-based treatment.

> I wonder how OASAS would feel about this study…In terms of some do-gooder trying to treat addiction, which is their bag, and to do it outside of their system it might be very, challenging (T, p. 38).

> Oh I am sure they hate it (office-based buprenorphine treatment), because it's a way to circumvent their authority (T, p. 38).

A similar sentiment was raised about SAMHSA,

> I see a lot of the troubles come from, you know, the silo'd nature of these professions and these ideas that addiction, addiction period. I don't even want to call it addiction medicine. But addiction is dealt with through SAMHSA. And SAMHSA, historically does not talk about delivering drug treatment in a doctor's office (C, p. 17).

In addition, the Drug Enforcement Agency (DEA) was noted as working at cross-purposes and scaring physicians away from treating opioid dependence.

> …the DEA, has done great damage to the buprenorphine effort because of these letters they have sent out … they actually say to the physicians, "Give up your license. Give up your waiver if you don't use it very much. If you give it up now, then you will reduce your risk of being audited by us." And they do come and audit, the guns in hand… (R, pp. 13 – 14).

One of the physicians on the buprenorphine team relayed that she had received one of these letters and that the DEA had visited her at the clinic, despite the fact that she had never

prescribed. They told her given that she hadn't prescribed in the year since she had gotten her certification she should consider giving it up so she wouldn't have to go through the hassle of getting inspected/audited. She explained to them despite not yet having prescribed, she was planning to do so in the near future. She relayed she was really perplexed by the visit and it had an arm-twisting quality (November Fieldnotes, p. 30).

Key informant T went further with his critique of institutional biases by claiming in general, the government has no real interest in the well-being of people with substance use issues.

> …government has determined – I don't want to be crude about, they don't give a shit about the patient – they want to show the voting public that you know we are coming down on crime, we are coming down on this. So that's all they care about (T, p. 19)

Countering Promoter: Be Educated, Be an Advocate, Dispel Myths and Take Action

Many strategies were developed by the team to work toward countering the negative effects of the multiple forms of bias against buprenorphine. It was acknowledged that there were clearly areas that we could have little impact, such as on DEA and OASA practices or regulations, however, the idea of being educated, being an advocate, dispelling myths and taking action became the cornerstone of a range of strategies that were developed, taken up by various team members and integrated into the IBT/P when applicable, to work against biases. They are, (1) Knowing What We are Up Against: Speak the Truth, (2) Team Takes Over: A Life-Saving Treatment, (3) Credibility (4) Learning and Using Therapeutic Alliance and Motivational Interviewing.

Knowing What We are Up Against: Speak the Truth

This countering promoter strategy was named "Knowing What We are Up Against" because this is what the buprenorphine team member said when she brought in the Daily News article cited above, to the second bupe team meeting. The team member was shocked and

dismayed that such a slandering, negative article was written about something she knew was a valuable, life-saving treatment. She wanted very much to share the article with her colleagues on the team to give them a direct experience with negative and inaccurate buprenorphine messages in the media, so we could be prepared to speak the truth (October Fieldnotes, p. 27). This was an organic form of strategizing about bias and came unsolicited from a team member. It was agreed that other forms of bias that was found in the media should be brought in and shared so we could dialogue about it and be prepared to address it and speak out against it at work, with patients, and even in our communities. This kind of advocacy, from several of the team members, brought encouragement and energy to the interdisciplinary work and countered the often corrosive effect that ongoing biases can take. The researcher shared with the team that at that point in the study, biases against buprenorphine had emerged as a key inhibiting category and we would begin to consider countering promoters as part of our development work.

Team Takes Over: Life-Saving Treatment

Once bias was presented as a provisional key inhibitor category, another strategy that worked to counter the negative effects of bias against buprenorphine, within the organization, is that several members of the team decided to use their scheduled presentations at the weekly Interdisciplinary Journal Club to focus on buprenorphine and highlight its life-saving qualities and their discipline role. This was directed to develop the idea among the staff that it was not just the researcher who was championing bringing buprenorphine to the clinic and that there were others who also were behind the effort. It was also felt that buprenorphine was not often understood, especially for those who were opposed to it, as a life-saving treatment, so this aspect was planned to be high-lighted. One of the physicians on the team presented and focused on the safety of the buprenorphine and its life-saving qualities. He also was also able to share his experience in another setting of having treated many patients with buprenorphine and

this brought a level of credibility, confidence and worked toward countering clinician bias (January Fieldnotes, p. 64).

One of the social workers on the team also presented on buprenorphine at journal club focusing on it as a life-saving measure and sharing with the staff how the bupe social workers were thinking about their developing practice (March Fieldnotes, p. 75). And finally, one of the bupe administrators presented on the role she was playing on the team and what kinds of bupe activities she would be involved in once treatment commenced. She also highlighted the life-saving aspects of the treatment and the training and education work the bupe admin staff members had done. In addition, she presented to the staff that the team had done considerable work in determining the ins and outs of the touchy issue of DEA visits, in which the administration staff would play a lead role, as they would be the first point of contact if agents came to the clinic (May Fieldnotes, p. 85).

Role Modeling and Credibility

The team often identified that the collaborative, interdisciplinary process and having an insider researcher facilitating the project were ways of countering bias. Working with our colleagues to be more accepting to the idea of buprenorphine and patients who needed this treatment, was identified as part of our mission. The team was an identified entity within the organization, training in a new area of treatment, and developing an innovative practice in which they would morph into the lead clinicians/staff. Based on these processes, there was a sense among some team members of being 'role models' or 'ambassadors' for buprenorphine, hoping to demonstrate skill sets we hoped the larger staff to would emulate. Statements from key informants speak to this issue. Here, key informant P identifies the idea of "making for greater sensitivity"

> …have done a great job – to make for greater sensitivity … with regard to how we accept and receive and embrace our population and – I'm going to include the

buprenorphine population (P, p.7).

Key informant W addressed the issue of credibility and the process of 'not top down" as a facilitating and influencing factor,

> …but I also think the fact that you are a member of the team, that you're doing the work yourself, that it's not top down…you have that street cred and you're going to have your, you know, - - your colleagues who you feel connected with that, you know, will be onboard and then whoever they hold more sway with then they can hopefully influence (W, pp. 24-25).

Sometimes role modeling took place within the team, as members had varying degrees of commitment and interest in buprenorphine. For example, even after many months of work together, there were times when some members would question the effort we were putting into the project, trying to understand the value and worth. During the January 2011 team meeting, one member asked, "Is all this really worth it? This is a huge effort; there is so much to do." While this question was directed to the researcher, she did not answer directly so as to facilitate the group process. Almost immediately one of the physicians on the team responded to the colleague and said, "Absolutely – this can really turn people's lives around – it can be life-saving – it may be a lot of work for us but for the patients – the benefits can be unbelievable." (January Fieldnotes, p. 65).

Learning and Using Therapeutic Alliance and Motivational Interviewing

Another strategy that was identified to counter bias against buprenorphine was to learn and use the constructs of therapeutic alliance (TA) and enacting a motivational interviewing (MI) style/spirit in the clinical and milieu encounter with patients. TA and MI were identified by the researcher at the outset of the project, as practices that could support providing buprenorphine treatment. TA, with its focus on the patient/clinician relationship and the negotiation between them regarding the tasks and goals of treatment (Safran & Muran, 2000, p.

15) and MI, with its focus on empathy and collaboration and exploring and working with ambivalence using techniques such as 'rolling with resistance' (Levounis & Arnout, 2010, pp. 11-23) were embraced by many team members. Several referred to these approaches as 'humane' and 'engaging', feeling that some of the biases directed toward buprenorphine or treating opioid dependence/addiction were related to staff experiencing very tense and/or adversarial interactions with patients around addiction issues or treatment. They posited that TA and MI could be a way to bring a dignity, respect and skills to the treatment/practice and could work toward decreasing bias. One team member said it would be the "opposite of MMTP's" (April Fieldnotes, p. 82).

The team very much understood patient's opposition to the setting and structure of MMTPs and that patients in need of treatment for opioid dependence/addiction often rejected methadone because of feeling controlled or being treated poorly by the staff. The two social workers from clinic 2 had several years of experience working in MMTPs and attested to this unfortunate situation, reporting that many MMTP staff were not well trained or only knew how to be "cops" and not clinicians (April Fieldnotes, p. 82). Many team members were very interested in learning to use TA and MI approaches and felt these approaches could also be useful toward working with patient's bias against the concept of treatment maintenance. One team member was highly trained and skilled in MI and promoted and encouraged its use. This provided a direct resource and role model for the team and made learning and taking up this approach more accessible (February Fieldnotes, p. 70). TA and MI were woven into the various training and development sessions with the bupe team throughout the research.

Key Inhibitor Category #2
Plaguing Questions

This second key inhibitor category began to take shape as the question about needing to deal with potentially life-threatening situations, as part of buprenorphine treatment, continued to present itself in key informant and field data. Over the course of the study other significantly

difficult and challenging questions to which there were no easy answers also came to the forefront of the data and they were grouped together in this second key inhibitor category named Plaguing Questions. The dimensions were subdivided as, (1) Issues of Life and Death, (2) Emotional Distress, (3) Disruptive Behavior, and (4) Uncertainty and Trade-Off Thinking. Using the data collected over seven months of the study, the researcher presented this key inhibiting category to the team early in January, 2011 and development work on countering promoters was begun. This category was named 'plaguing questions' based on this statement made by key informant L,

> …because I think a big barrier to doing this is all the stuff that you're running up against and how do you balance it… you've got to come up with some answers to these questions that plague everybody (L, p. 25).

Issues of Life and Death

Discontinuing buprenorphine treatment is one of the most serious and concerning aspects of treating opioid dependence/addiction and brings questions of life and death into sharp relief. Should treatment be determined not to be benefitting the patient and a plan to stop the medication is made, this could be potentially life threatening for the patient. This is because if buprenorphine is stopped, the likelihood of relapse with heroin or other opioids or alcohol or other drugs is very possible, and these behaviors are very high risk and could lead to death. As described by key informant T,

> …if you don't, within 24 hours they are going to have withdrawal and… They are going to shoot dope or they are going to buy methadone on the street, or they are going to take more alcohol or benzos or whatever and maybe overdose (T, p. 50).

The clinical scenarios that might lead to discontinuing a patient's buprenorphine are complicated and there is a significant amount of trade-off thinking and negotiation that must be done.

Several key informants (Q, p. 37, L, p. 29, Y, p. 14) gave examples of the processes involved in discontinuing treatment. It is rarely done immediately, often involves consulting with the clinical team (if working in an interdisciplinary model) and takes place over a period of time so there are opportunities for the patient to be assessed and the risks versus safety can be judged. If the patient is continually late for appointments, misses many appointments, loses prescriptions and is calling in for refills, it is very difficult to determine if the patient is getting any benefit from the treatment. If the patient is very sedated and/or has shallow breathing at appointments, is intoxicated and/or their urine toxicology tests demonstrate they are taking unprescribed sedating medications, this raises concern about respiratory depression and overdose. If the patient's urine toxicology tests repeatedly demonstrate negative buprenorphine, despite the patient coming to appointments and reporting that they are taking their treatment, this raises red flags about the possibility of diversion. In any of these situations, the first action would be to have the patient return to the clinic on a more frequent basis so they can be evaluated more closely. If over time it is determined that the risks are outweighing the benefits, this is shared with the patient and a plan to discontinue treatment is made and must include referring for either in-patient treatment, transferring care to an Opioid Treatment Program (OTP) or MMTP, or tapering and stopping treatment. Whatever plan is put into action, it is approached in a process oriented fashion. The therapeutic alliance is greatly challenged or may rupture at this point because there can be significant differences around the goals of treatment and the physician will have to tell the patient, "I can no longer safely prescribe you controlled substances" (Q, p. 35). Key informant Y put it this way,

> If you think about addiction as a disease where people don't always – don't always act as their best selves, and you are concerned about them not getting better or not benefiting from the treatment, you're used to doing things that sometimes patients might not be happy about (Y, p. 6).

If it is determined that the best course of action is to stop office-based treatment and refer the patient to an OTP or MMTP, and the patient disagrees, negotiating that conflict, in the safest way possible, is part of the clinician's responsibility. Should the patient decline referral for either in or out patient treatment, then buprenorphine will be tapered and discontinued and the patient is educated and advised of the dangers, which can be potentially life threatening.

> It's one thing to go without their hypertension meds and even with their anti-retrovirals (HIV medications) for a couple of weeks, it's not life threatening, but it's life threatening for them, to go without, it can be, without the buprenorphine for a couple of weeks (L, p. 31).

The life-threatening possibilities for patients who stop buprenorphine and are in need of treatment are related to relapse which could result in overdose, fatal accidents, and/or potentially life threatening infections associated with injection drug use.

Despite educating the patient and providing warnings of these potentially life threatening scenarios, if the patient declines the referrals, clinicians often have to manage extremely difficult dialogues with patients. As relayed by key informant L,

> It makes things tough because it's harder to hold onto your principles, which one has to do, because patients will say, well okay I guess I've got to use, so then you say I guess so buddy, that's the situation (L, p. 31).

This issue of challenges related to discontinuing buprenorphine treatment also came up in the field data. Early in the study, when the social workers and the researcher were beginning to map out the dimensions of buprenorphine social work practice, one of the social workers commented, "There are going to be treatment failures, what are the safety issues we have to plan for?" (October Fieldnotes, p. 22). Also, when developing the buprenorphine MD/NP practice, one of the physicians on the team referred to discontinuing buprenorphine as one of the most serious issues we would have to address and relayed, "we need to think it through carefully and be well prepared, it's a big reason clinicians stay away from bupe, nobody wants to deal with this process" (November Fieldnotes, p. 42).

Emotional Distress

Another inhibiting factor to buprenorphine, which surfaced across key informant data, is that clinicians can experience considerable emotional distress when managing some aspects of buprenorphine treatment. Several key informants described how troubling it can be to work with patients where polysubstance use is more the norm than the exception, and the distress engendered when witnessing patients fail treatment, relapse, etc.,

> …have this pit of the stomach feeling (L, p. 27).

> I feel very nervous, uncomfortable, and a little bit like scared … I envision death (W, p. 32).

> …always using Xanax and cocaine and he drinks too much … you're kind of frustrated, horrified, concerned (Q, p. 34).

> …the clinical comfort with active substance use is very low, like a clinicians comfort level, cause they are not prepared, nobody is prepared for that (C, p. 52)

Other key informants relayed that clinician's feel unsafe treating patients with buprenorphine, and that the mandated training creates a feeling that buprenorphine itself is unsafe,

> Buprenorphine makes people feel unsafe. That's exactly what it is (X, p. 27).

> I mean the actual message is that, you know, buprenorphine is safe and effective and go ahead and do it. But the context that this message is being delivered through this mandatory eight-hour course in a direct way reinforces…that there is something unsafe or extraordinary about buprenorphine (R, p. 16).

Disruptive Patient Behavior

In key informant interviews, with highly experienced buprenorphine providers, the issue of disruptive patient behavior was raised as a reality and presented as an inhibiting factor.

> …the most challenging …it's the patients who are disruptive. Like I'm trying to avoid the language but that's how the practice experiences it (Y, p. 17).

> …pound for pound more of a burden for the desk staff and the clinic staff…It's definitely more of that than they are otherwise seeing in primary care (Q, p. 50).

Approximately 10 % of the patients in the research setting were also receiving methadone treatment. Approximately another 15% were receiving opioids for chronic non-cancer pain. Many clinic staff in the research organization relayed experiencing opioid dependent patients as more disruptive (explosive, demanding, manipulative, threatening) than patients who are not opioid dependent. Throughout the study, a range of staff raised concerns that implementing buprenorphine would increase the already challenging level of disruptive behavior in the clinic.

Uncertainty & Trade-Off Thinking

Having to manage questions without any solid answers and engaging often in trade-off thinking is an intricate part of buprenorphine treatment. Many people are psychologically averse

to trade-off reasoning and prefer simpler mental strategies such as ordering or ranking when making decisions (MacCoun, 1998, p. 1206). Several aspects of buprenorphine treatment that presented with uncertainties were also identified as inhibiting factors. Key informant L gave several examples where there is no clear guidance or one must engage in trade-off thinking. In discussing results of urine toxicologies and trying to determine safe and appropriate follow-up visits based on this evidence, L relayed this challenge,

> If somebody goes from opioid, opioid, opioid and then no more opioids, we are checking for bupe … and nothing else ever shows up and so forth, we'll back down to visits every month and in some cases every other month … what's much more difficult is if somebody has chronic intermittent cocaine positive urine or something, so what's the right frequency of visit for them…you just really aren't sure (L, p. 13).

In discussing how to handle patients calling in for refills and not attending appointments,

> We don't want to penalize somebody from being at a distance – at the same time want to practice safely – we really are very keen not to be just handing it out (L, p. 14).

In discussing ways to determine treatment success,

> If somebody continues to use some and despite all attempts of the contrary, we can't get them to be using none, through our treatment, and they used to be using much more or in a much more dangerous way, I count that as a success, but it's less of a success than if they use none (L, p. 17).

Key informant Y discussed trade-off thinking when determining if counseling should be a mandatory part of buprenorphine treatment,

> We don't, you know, make their pharmacotherapy contingent upon their participation in other things…the risks of bupe are lower than they are, for example, of methadone, lower

> risks of overdose and risks of diversion still are not going to hurt other people or not likely to hurt other people, so it feels like reasonably safe (Y, p. 10).

Another significant area where there are many uncertainties is in transferring patients from methadone to buprenorphine. This was raised as a major concern and its difficulty and related uncertainties were described by key informants. Because of the high rate of patients receiving methadone treatment in the research organization, the question of how the team would address this issue became an ongoing topic of discussion. This is an example where the researcher took a puzzling question from the team to key informant interviews and then the key informant interpretation and guidance was brought back to the team.

> And it is very hard to switch people practically from high to moderate dose of methadone. It's just not easy. They really have to carefully taper down the dose and then even at these, like, "OK, well, I'm tired of getting methadone, I'm ready to switch, like, that's got to be easier, the induction week sucks, I'm kind of sick … And a lot of people just couldn't make it, and then they'd go back to their methadone program (Q, p. 39).

> It seems to be no pretty way to do it. If you do it slowly then people go through this, the long slow taper and certain amount of anxiety sometimes around that. It can't be too abrupt, but we have had people sort of plan it for a while and then other people who were sort of at sixty and come down kind of quickly over a couple of days and then we switch them over or sixty or higher. I can't say that I have an intuitive sense that one is better than the other. Almost everybody feels kind of crummy (L. p. 33).

Countering Promoter:
Identifying Core Components of Buprenorphine Treatment and Uniformity of Care

Figuring out a way to address the 'plaguing questions' became one of the central pieces of action for the interdisciplinary buprenorphine team. The team conceptualized that the most

important countering promoter would be to develop actions and processes within the IBT/P that would promote feelings of safety and work toward decreasing tension and distress among the team and larger staff, while balancing issues of control and authority over the patient. Based on this idea a four step process was initiated. First was to negotiate agreement among team members as to what were the core components of buprenorphine treatment. Second was to explicate the actions and processes involved in each component during the training and development sessions. Third was that the team endorsed the concept of uniformity of care, whereby the explicated actions and processes of the components would be followed by the team members, with flexibility for clinical judgment. Fourth was to have this material document in the IBT/P manual so that uniformity of care could be promoted and a reference for the developed actions and processes would be available once treatment commenced (January Fieldnotes, pp. 53, 54, 55, 62).

The team reached agreement on 10 core components of buprenorphine treatment at the end of January 2011, and then over the remaining four months of the project worked to explicate the actions and processes related to each component. Five of the 10 components were specifically directed to address the plaguing questions and these were (1) Goals of Treatment, Visit Frequencies, and Evaluating Outcomes, (2) Parameters of Care: Buprenorphine Treatment Plan Agreement, (3) Counseling Requirements and Treatment Intensity, (4) Discontinuation of Treatment and Transfer of Care, and (5) Methadone Transfer. The other five core components were directed to address uncertainties and questions identified by the team and these were, (6) Inclusion and Exclusion criteria, (7) Toxicology Testing: What Clinicians Need to Know and What the Patient Can Expect, (8) Education, Assessment, Care Coordination, Case Management and Communication, (9) Opioid Safety, and (10) Privacy Issues, Record Keeping and DEA Visits. As noted above, balancing issues of control and authority over the patient was a concern when developing these actions and processes. Striking this balance was important

because of the loathing patients express over being controlled by MMTPs. This was reinforced by patients during the focus group when discussing their experiences receiving treatment at MMTP and this finding was also brought back to the team to highlight the importance of balance.

> Even after years, with not using, they still mandate that you come 1 – 2x /week. Which is insanity, insanity (agreement from group members). You know even after 5 years of clean urine I had to battle them down. That is so…..Well then they say, you're not doing anything – like working – not doing anything. Let's get real (Focus Group EWF, 2, pp. 3-4).

> …that is the reason I got off methadone before. It is like being in another jail; they regulate everything (Focus Group #5, 3, p. 6).

> …feeling that every day you are in liquid handcuffs and people are judging you (Focus Group Brown, #5, p. 10).

> …they want to put you in a box and keep you there (Focus Group Blue, 4, p. 10).

The five components directed toward countering the inhibiting nature of the plaguing questions will be discussed below. Full explication of all components can be found in the IBT/P manual (Appendix A).

The Goals of Treatment, Visit Frequencies, and Evaluating Outcomes

Before explicating the specifics of this core components, the team wanted to lay out some foundational ideas related to substance use that were influencing their thinking. They wanted to establish that they understood that polysubstance use is often the rule, rather than the exception, and that it is not uncommon when someone stops using one substance they may start reusing or overusing other substances. Polysubstance use was not an automatic exclusion from being eligible for buprenorphine treatment, and each patient would be evaluated on a case by

case basis. As key informant Q said,

> ...we're realistic. We don't expect a ton of full polydrug abstinence in hard to treat people. And no treatment program ever gets very good results with those people period Q, p. 37).

Coming from a patient centered approach, the clinicians would work with patients to identify their interest and motivation for treatment as well as assist them with setting and achieving individual treatment goals. It was the team's clinical opinion that continuous uncontrolled opioid use is unhealthy and that less use or no use is healthier. The team would explain that the goal of buprenorphine treatment was stabilization of life. However, because the team was coming from a harm reduction philosophy, they understood that abstinence was not always achievable or desirable. The treatment goals would be worked on over time and the patient would be considered to be benefitting from treatment if they were either infrequently or not using substances, keeping appointments, able to maintain their treatment according to the parameters of the buprenorphine treatment plan and achieving their personal treatment goals. Early in treatment the patient would be seen weekly or more often if necessary and as they demonstrated benefit from the treatment, the visit frequency would decrease. If the patient was determined to be eligible for treatment, counseling, therapy and psychiatric services were available to support the patient in achieving the treatment goals, but these were not a required to start buprenorphine treatment. Each patient would have both a bupe social worker and a bupe MD or NP, who would work with the patient to achieve the goals of treatment.

The Parameters of Care: Buprenorphine Treatment Plan Agreement

The following buprenorphine treatment plan was developed by the researcher in tandem with the bupe team members. Several permutations were produced and reworked until team agreement was reached. It was then sent to leadership for review and was approved. The team felt the terms of the agreement clearly laid out what was expected of the patient to maintain

ongoing treatment and balanced the issues of safety and control. If the patient was determined to be eligible for buprenorphine, the treatment plan agreement was reviewed with the patient by their bupe doctor and bupe social worker prior to starting treatment. The bupe social worker was responsible for having the agreement signed and a copy was given to the patient and a copy was placed in the patient's medical record. The patients' bupe providers would stress initially and during treatment that the parameters of care in the treatment plan agreement would be used as one of the ways to evaluate if the patient was benefitting from treatment.

Buprenorphine Treatment Plan Agreement

- I understand that bupe is a highly regulated medication and I agree not to sell, share or give away any of my medication. I understand that selling, sharing or giving away medication can result in being discharged from bupe treatment and referred elsewhere for treatment.

- I understand that bupe could be harmful to children, household members, guest, and pets. I agree to store my bupe in a safe place, out of the reach of children. If anyone besides me ingests the bupe I should call 911 immediately.

- I will take my bupe as prescribed. I also understand if I have questions or concerns about my bupe treatment, if I think I need to change my dose, I can call the general clinic number (xxx-xxx-xxxx) and make a sooner appointment to address these issues; I do not have to wait until my scheduled appointment.

- I understand that prescriptions will be given only at regularly scheduled appointments and I will do my best to keep my regularly scheduled appointments. If I miss an appointment or lose my prescription or my medication, I understand I may not be able to get my refill before my next scheduled visit. Prescriptions will not be called into pharmacies. Prescriptions will not be given on weekends, holidays or after bupe hours of operation.

- I understand that taking unprescribed benzodiazepines (such as klonopin, ativan, valium or xanax) while I am also taking bupe, can be dangerous; deaths have been reported in this situation.

- I understand that bupe is not swallowed like other pills. It is placed under the tongue and let to stay there for 5-10 minutes while it dissolves. If it is swallowed or chewed, it becomes inactive, meaning it will not work to relieve opioid withdrawal symptoms.

- I understand should I take my bupe other than it has been prescribed (under the tongue): injecting, smoking or snorting, this is also considered diversion and can result in being discharged from bupe treatment and referred elsewhere for treatment.

- I agree to keep my bupe providers updated about any other substance use and mental health treatment I may participate in, and about any changes in my medications.

- I understand that urine toxicology testing will be a routine part of monitoring in bupe treatment and my bupe providers and I will discuss ahead of time what the urine is being screened for and the consequences of positive results.

- I understand that tampering with urine tests in any way can result in being discharged from bupe treatment and referred elsewhere for treatment.

- I understand poppy seeds can sometimes produce positive opioid results in the urine. I agree to do my best to avoid poppy seed products to avoid confusion.

- I understand that medicines for pain that are opioid-based will not work well while I am taking bupe, and that I should contact my bupe providers at least one week before having any surgical or dental procedures. If I am in an accident or have severe pain for any other reason, I understand I should tell the emergency medical staff and doctors that I am taking bupe so they can treat my pain accordingly. I should also give them the contact information of my bupe providers so they can coordinate care.

- I understand the following are the hours at the clinic for bupe services by appointment:

Monday	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
9-12 & 2-4	11-1 & 2-4	9-12 & 2-4	11-12 & 2-4	9-12 & 2-4

- I understand walk-in appointments are also available for bupe, but not after 3pm and if I come as a walk-in I should expect that I will have to wait.

- I understand that being intoxicated or under the influence of drugs or disruptive can result in my not being seen by my bupe providers.

- I understand that repeated disruptive incidents can result in being discharged from bupe treatment and referred elsewhere for treatment.

- I understand that receiving my bupe is dependent upon me working with my bupe providers within the parameters of care set forth in this agreement. I am aware should I have trouble keeping to these parameters, miss appointments, overtime be unable to decrease heroin or pain pill use, demonstrate unsafe use of alcohol or other drugs, a plan for treatment intensity will be put forth by my bupe team. This could include requiring counseling or other services, increased visit frequency, smaller number of bupe pills per prescription and/or the eventual discontinuation of my buprenorphine treatment here in the clinic and referral to and opioid treatment program.

- I understand that keeping in touch is an important part of my bupe treatment and a contact plan has been made for me. I give permission for my bupe providers to contact me and I understand how to contact my bupe social worker. I understand I can leave a message

Monday – Thursday (except holidays) between 9am and 3pm and expect to get a return call either that day or the following day. I understand if my bupe social worker is not available, an alternate contact will be provided.

- If female, I am not pregnant, and am not planning to attempt to become pregnant. I am aware that the safety of bupe in pregnancy is unknown, and I will notify the program immediately if I become pregnant.

- I understand that my records, course of treatment and medical care will be kept in an electronic medical record system and visible to healthcare professionals at SLRHC involved in my care.

Counseling Requirements and Treatment Intensity

As the optimal amount of counseling or behavioral treatment for patients receiving buprenorphine is unknown, the team did not make it a requirement for starting buprenorphine treatment. The bupe social workers collaborated with the researcher in developing and explicating a range of counseling services: supportive, relapse prevention, and risk reduction, that were available for all patients receiving buprenorphine, should they be interested (Appendix, A, IBT/P manual, Topic 9, Bupe Social Work Practice). Should a patient receiving buprenorphine be determined not be benefitting from the treatment (as described in the previously presented clinic scenarios, p. 171), the first course of action would be to intensify treatment. This could include increased visit frequencies and required counseling or other services, so that the patient could be evaluated more closely. Should the patient continue to demonstrate they are not benefitting from treatment, the next course of action would be to share with the patient that discontinuing treatment would occur and a plan for transfer of care would be made.

Discontinuation of Treatment and Transfer of Care.

If the patients' bupe providers feel the best course of action is to stop office-based treatment and refer the patient to an OTP or MMTP, this would be shared with the patient and if acceptable, options for referrals would be discussed and a referral plan made. The bupe social worker and doctor would contact the referring treatment program and coordinate the

transfer of care. The patient would be given and appointment date and time and also given a prescription for enough buprenorphine to last until the appointment date. If the patient disagreed with that plan of action, negotiating that conflict, in the safest way possible is part of the bupe provider's responsibility. Should the patient continue to decline referral to an OTP or MMTP; they could also be offered a referral for in-patient treatment. If they continue to decline these offerings, buprenorphine treatment would be tapered and discontinued. The patient would be educated and advised of the potential life-threatening dangers related to relapse when stopping treatment. The patient would also be provided with a range of resources such as alternate office-based buprenorphine treatment providers, OTPs and MMTPs, harm reduction programs, NA/AA/Other meetings, federally funded health care centers, and food pantries.

Methadone Transfer

The team developed a protocol for managing requests from patients to transfer from methadone to buprenorphine and planned to encourage patients receiving care at a MMTP to look into their options, if this was their interest. The protocol relied heavily on recommendations from Casadonte, (2006). This included an assessment of the patients' current treatment situation and the factors motivating the desire for transfer, education about needing to taper their current dose down to 30mg in preparation for the transfer, and the related discomfort and risk of relapse. If the patient was interested, the bupe social worker and bupe doctor would give the patient a letter for their MMTP regarding the patient's interest to transfer and the bupe clinician's interest to work with the patients MMTP to coordinate this process. All necessary consents would be signed and the consent and letter would be given to the patient to take their MMTP. Copies of consents and communication with MMTP would be maintained in the patient's medical record. Working closely with the methadone clinic staff was identified as very important to insure continuity of care and a smooth transition, especially if the treatment failed buprenorphine treatment, they could return to methadone treatment.

If a methadone taper and plan for transfer was arranged and begun, and the patient began to experience withdrawal that interfered with their functioning or led to relapse, they would be advised that transfer at a later time may be available. If the patient was successfully tapered down to a dose of 30mg, an office-based induction would be planned. This would be done early in the week and the bupe providers would need to make themselves available for contact. It was determined the patient's transferring from methadone would need to be provided with reassurances and telephone consultation up to 3 times daily for the first few days would be made available. After 3-5 days, the patient would likely be stabilizing, but it could be necessary to add medications to assist with some of the discomforts associated with the withdrawal-transfer process. The patient's bupe providers need to work closely with the patient's MMTP as the patient might lose patience with the discomfort and want to return to methadone.

Key Inhibitor Category #3
Bupe Exceptionalism: Unique Aspects not Encountered in Other Treatments

In discussing barriers to implementing buprenorphine, many key informants highlighted aspects of buprenorphine treatment that were unique to buprenorphine compared to other treatments that were used in a primary care setting. Throughout the research year, the field data has many examples of the team raising concerns about buprenorphine not being the same as other primary care treatments and the difficulties these differences would cause implementing this new treatment. Bupe exceptionalism was presented to the team in later March, 2011, as the third key inhibitor category, prior to the upcoming training and development sessions, so that creating countering promoters could be included in those sessions. Key informant and field data demonstrated a range of dimensions related to how buprenorphine is 'not like any other treatment' and were identified as, (1) More Regulated, (2) Fear of Government, (3) Inductions, (5) Protecting Primary Care, and (5) Unable to Use Existing Systems.

More Regulated

A very obvious difference between buprenorphine and other treatments is the degree to which it is regulated.

"Bupe is unlike other primary-care treatment, in that it's more regulated" (Q, p. 27).

In order for physicians to be able to prescribe buprenorphine they must first complete an approved eight hour training. Next they must send a notification to the CSAT of their intent to prescribe. The notification must contain information on the physician's qualifying credentials and additional certifications including that the physician has the capacity to refer patients for appropriate counseling and other non-pharmacologic therapies, and that the physician will have no more than 30 patients on buprenorphine any one time for the first year. One year after the date in which the physician submitted the initial notification, the physician would be able to submit a second notification stating the need and intent to treat up to 100 patients. The DEA assigns the physician a special identification number also known as an X number, which must be included on all buprenorphine prescriptions (Buprenorphine, 2010). The usual time between submitting the notification and receiving the special DEA number is approximately 45- 60 days. As key informant R relayed,

> But for God sakes, why do you need eight hours to prescribe a medication that's just so user friendly as buprenorphine? (R, p. 16).

As it turned out for this research project, the required training for physicians ended up being a significant inhibiting factor, as the 2 physicians from clinic 1 ended up not getting trained and the IBT/P ended up only being implemented in clinic 2.

Throughout the study year the researcher provided the physicians with ongoing information about the required training. The organization had agreed to provide a day off for the

physicians to attend the training or do an on-line training at home and that day off would not be counted toward to usual five conference days allotted for training during the year. The organization also agreed to reimburse the physicians for the cost of the training which was approximately $175 and the researcher offered to facilitate the CSAT notification process. Many reminders were provided to the physicians about the training and the director was kept updated about this process (Fieldnotes: June, p. 2, October, p. 20, November, p. 42, December, pp. 46, 48, February, p. 81, March, p. 75, April, p. 84, May, p. 87). However, as time drew closer to when buprenorphine would be implemented, both physicians in Clinic 1 had completing priorities and were not able to get trained and this stopped the implementation of IBT/P in Clinic 1.

Fear of Government

Another rather obvious difference and a significant inhibiting factor about buprenorphine, is that the DEA is required by law to conduct regular inspections of physicians having an "X" number. The process includes two DEA agents, or one DEA agent and one FBI agent to come to the clinic unannounced and present a notice of inspection. The DEA is authorized to look at any part of the medical record of patients receiving buprenorphine, but in general don't review clinical practices. Their main role is to determine that buprenorphine is being prescribed according to regulations and that the physician is adhering to the 30 or 100 patient limit. The practice is required to keep a log of all patients receiving buprenorphine and copies or records or all prescriptions written for buprenorphine. These records must be kept for at least 2 years, and be available for inspection and copying by officers. This regulatory component engenders suspicion and fear on the part of many clinicians and clinic staff as demonstrated in both key informant and field data.

> …it's already an uphill battle to convince physicians to see opioid-dependent patients. If you add to that the fear of the government or the DEA coming and auditing you and going through all your charts (R, p. 14).

> I am afraid of all that government oversight (August Fieldnotes, p. 11)

Several times while discussing and planning for DEA visits, team members brought up the issue that the agents coming to the clinic would be carrying guns:

> So we are preparing for people with guns to come visit us in our office (November Fieldnotes, p. 34)

> Remember, when the DEA comes, be friendly and welcoming, they are the ones with the guns (January Fieldnotes, p. 53).

> If they don't like the way we keep records, do we get shot? (April Fieldnotes, p. 82).

While these comments are attempting to bring some humor to the situation, there idea of having armed agents coming to the clinic to inspect records was very off putting, was an issue of concern for many people and something they had never experienced in relationship to any other treatment.

Inductions

Because of buprenorphine's unique pharmacologic qualities, a special procedure known as an induction must be followed when starting treatment. This is also an aspect of buprenorphine that is unlike any other treatment and this has been identified as an inhibiting factor to implementing buprenorphine. In order for a patient to begin treatment they must be having moderate withdrawal symptoms that are observable when they take their first dose. If a

patient takes their first dose of buprenorphine, and they are not in withdrawal, the buprenorphine will put them into withdrawal, which is rarely an emergency situation, but the patient experiences considerable discomfort. This is known as precipitated withdrawal. The goals of induction are to prevent precipitated withdrawal, relieve the moderate withdrawal symptoms and begin treatment for opioid dependence/addiction. This means that the last dose of the opioid the patient is currently using needs to be carefully timed, so they will be ready to take their first dose of buprenorphine. The patient and their bupe physician work out the timing issue when they plan the induction.

An induction can take anywhere from 1-3 hours. Sometimes a patient can take one dose of buprenorphine and have their withdrawal relieved and feel well within an hour. Other times a second dose must be taken, usually about 45 minutes after the first dose, and then the patient is further evaluated to see the effect. When talking about inductions, one of the key informants relayed this about the physicians she was working with, "They were nervous about the induction" (M, p. 48). This same sentiment was raised by various team members during the development and installation phases of the research. In addition to feeling anxious about inductions, doing inductions in the clinic requires a dedicated room in the clinic and staff to observe and evaluate the patient and these aspects were also raised by team members as an inhibiting factor. (Fieldnotes: June, p. 7, October, p. 27, November, p. 39, February, p. 71, April, p. 83).

Protecting HIV Primary Care

Another unique aspect of using buprenorphine that could inhibit implementation was the issue related to, Who should be the patient's bupe physician? Some models promote the patient's primary care provider also being the buprenorphine provider and integrating opioid

dependence/addiction treatment into their primary care, just like treating their hypertension or diabetes or any other condition that arises. However, should a patient fail buprenorphine treatment and need to go elsewhere for treatment, what then becomes of their HIV primary care that they were receiving from that MD or NP? Two key informants raised this issue:

> Pre-think which is – so you piss somebody off by stopping their suboxone. What's going to happen to their HIV? Right? Like so in some ways keeping those separate has the potential to protect the rest of the medical care, right? (Y, p. 26).

> is that going to in any way affect the care I get for my HIV/AIDS? And so some people may say listen, I know I am going to have trouble. I am having trouble with my addiction, the opiate use and so on, and the last thing I want to do is to lose my HIV care (T, p. 16).

This is not a consideration that comes into play with other treatments. Organizing buprenorphine treatment services so that there were options regarding who was treating patients for their opioid dependence/addiction added a level of complexity to the development work. However, patients dropping out of primary care, especially care that may be well established is not something that should be risked. It was agreed that primary care relationships could be complicated by integrating buprenorphine, especially as it engenders more rules and more limit setting.

> …lots of limits and sometimes it adversely I think affects the patient doctor relationship (Y, p. 6).

Not Accessing Usual Systems

Another area where buprenorphine exceptionalism was identified as a possible inhibiting factor was related to prescription facilitation and the nurses on the bupe team were the first to point this out. Facilitating prescription refills is a major part of the clinic nurses responsibility,

and they were aware that the usual system for medication refills could not be used for buprenorphine because of the restriction of prescribing being limited to physicians who were trained and had the special X number. They foresaw that this restriction and the limited number of physicians with an X number would present challenges (November Fieldnotes, p. 40, January Fieldnotes, p. 55). This challenge was echoed by key informant Q,

> … you could come into primary care on a Friday afternoon and get a refill of your metformin (diabetes medicine) from any old doctor who's handling walk-in refills. . . But there's not other non-bupe docs who can write you for your bupe, so you really can't access that system as a bupe person … So there's tension (Q, p. 48).

Countering Promoter:
Dimensionalizing IBT/P
Identifying and Detailing: Discipline Specific Practices, Cross Discipline Practices & Coordination of All

Addressing the issue of buprenorphine exceptionalism was the other central pieces of action for the interdisciplinary buprenorphine team. They conceptualized that the most important countering promoter to this inhibitor category would be to develop actions and processes within the IBT/P that would attend to these issues. Using the method employed for addressing the plaguing questions, a four step process was initiated. First was to negotiate agreement among the team as to what were the major dimensions of IBT/P. Second was to map out the specifics of the types of services each discipline would provide, the detail of those practices and their coordination during the training and development sessions. Third was to identify areas of practice where there were joint responsibilities and overlap among the disciplines. Fourth was to have this material documented in the IBT/P manual so that it could be used as reference to guide IBT/P once treatment commenced (March Fieldnotes, pp. 79 -80, April Fieldnotes, p. 80 – 83).

Determining the dimensions of care and the discipline specific aspects of care was dependent upon the distribution of care among the disciplines and this involved considerable negotiation. Following the established shared care model of the research organization (HIV primary care and social work case management) the bupe team decided that all patients receiving buprenorphine would have a bupe social worker and a bupe MD or NP and these two clinicians would form the core of the patient's bupe team. In this practice model, NPs perform assessment and treatment in collaboration with physicians who are buprenorphine trained, hold an xDEA number and provide the bupe prescription, therefore MD/NP bupe practice is linked and they follow the same practice specifications. Given that the bupe social workers were in clinic daily, had designated offices, and the most availability in their schedule, and were interested in creating and taking up new role, it was agreed they would be the first point of contact for patients interested in buprenorphine. The bupe social workers would conduct the initial education, screening and referral to the bupe MD/NP and then work with the patient as their bupe social worker. Flexibility was built into the referral system, whereby the possibility existed for patients to first be evaluated by the bupe MD/NP, depending upon various clinical scenarios and then referred to a bupe social worker.

Involvement for bupe admin and bupe nurses were also delineated, but their involvement was more circumscribed. Because of the robust nature of the research organizations mental health services (psychopharmacology and psychotherapy) which had clearly established practices for referral, intakes and evaluations, the team decided that the mental health clinicians would serve as consultants and become a member of the patient's bupe team if they became a treating clinician. The researcher kept close contact with the discipline directors of social work and medicine, giving them updates on how work distribution and patient flow was being

organized by the team and obtaining their approval for these newly established processes. The meetings and training and development sessions in April and May served to fill in the specifics of the outlined practices. Below are the outlines of the: (1) Dimensions of IBT/P, (2) Bupe Cross Discipline Practices, (3) Bupe Social Work Practices, (4) Bupe MD/NP Practices, (5) Bupe Admin Practice, and (6) Bupe Nursing Practices. The detail of the specifics of the practices and the accompanying flow and coordination can be found in the IBT/P manual.

Dimensions of Interdisciplinary Buprenorphine Treatment/Practice

- Assessment: Initial and ongoing.
- Education and Safety.
- Referrals and resources.
- Counseling: Supportive, Relapse Prevention, Risk Reduction.
- Medication: prescribing and prescription facilitation.
- Goal setting and treatment planning.
- Monitoring and coaching.
- Evaluation of outcomes.
- Care coordination.
- Case management.

Cross Discipline Bupe Practices:

- Establish Therapeutic Alliance: Enacting a Motivational Interviewing Style/Spirit.
- Opioid safety.
- Establish contact plan with patient.
- Understand bupe record keeping and DEA inspection visit process.
- Understand bupe treatment agreement, specialty consent and the roles and responsibilities of bupe team.

- Communicate and coordinate care with team.

Bupe Social Work Practice:

- Establish Therapeutic Alliance: Enacting a Motivational Interviewing Style/Spirit.
- Buprenorphine Education & Screening for Opioid Dependence/Addiction.
- Case management.
- Complete buprenorphine treatment agreement and specialty consent.
- Referral for bupe MD/NP visit.
- Relapse prevention counseling using the following approaches.
  Anticipatory guidance, Contingency planning for basic relapse prevention, Supportive Counseling, Bupe monitoring and coaching, Treatment planning (goal identification) and action planning (goal achievement), Self-management skills building counseling for advance relapse prevention, Evaluation and update of treatment and action planning.
- Risk reduction counseling:
  Safer sex practices, Safer injection & safe disposal practices, Overdose prevention
- Resources & Referrals:
  Opioid Treatment Programs, NA/AA Meeting List (Inform Regarding Issue Treatment/Bupe Friendly), Mental Health Services, Addiction Treatment Options, Harm Reduction Programs, Pharmacies, Food Pantries
- Establish contact plan with patient.
- Review and monitor opioid safety.
- Understand bupe record keeping and DEA inspection visit process.
- Understand bupe treatment agreement, specialty consent and the roles and responsibilities of bupe team.
- Communicate and coordinate care with team.

Bupe MD/NP Practice:

- Establish Therapeutic Alliance: Enacting a Motivational Interviewing Style/Spirit.
- Clarify appointment is for Bupe Assessment
- Assess current/past substance use: opioids (heroin, pain pills, methadone, other); cocaine, alcohol, benzodiazepines, etc.
- Assess readiness for change.
- Assess substance use treatment history.
- Assess PMH, Past Mental Health History, etc.

- If eligible offer bupe treatment – offer alternative office-based bupe treatment.
- Review current medications, examine patient, labs, urine toxicology, make induction plan, follow-up appointments.
- Participate in induction, stabilization, maintenance, discontinuation, etc.
- Discuss and monitor opioid safety.
- Establish contact plan with patient.
- Understand bupe record keeping and DEA inspection visit process.
- Understand bupe treatment agreement, specialty consent and the roles and responsibilities of bupe team.
- Communicate and coordinate care with team.

❑ After hour coverage for patients receiving bupe are the same as for any other patient calling after clinic hours.

❑ Calls are directed to the physician who is covering the inpatient HIV Service.

Bupe Admin Practice:

- Establish Therapeutic Alliance: Enacting a Motivational Interviewing Style/Spirit.
- Milieu management. Understanding and supporting opioid safety.
- Understand buprenorphine as a uniquely regulated treatment, which includes possibility for unannounced DEA visit.
- Understand bupe record keeping and DEA visit process.
- Facilitate DEA visit and sign notice of inspection at completion.
- Understanding of unique aspect of bupe induction and why patient's need to be in withdrawal to begin bupe treatment.
- Room facilitation on induction day.
- Understanding of bupe treatment agreement & special consent.
- Understand the roles and responsibilities of bupe team.
- Communicate and coordinate care with team.

Bupe Nursing Practice:

- Establish Therapeutic Alliance: Enacting a Motivational Interviewing Style/Spirit.
- Risk Reduction Counseling (1) Overdose Prevention Counseling, (2) Safer Injection and Disposal, (3) STI Risk Reduction

- Induction Day Assessment, Monitoring, Psychological Wellbeing.
- Participate in stabilization, maintenance, etc.
- Bupe & Other Health Education/Counseling.
- Review of urine toxicology.
- Medication management.
- Establish contact plan with patient.
- Review and monitor opioid safety.
- Understand bupe record keeping and DEA visit process.
- During DEA visit, provide guidance to the DEA in using buprenorphine prescription monitoring and limit monitoring records.
- Understand bupe treatment agreement, specialty consent and the roles and responsibilities of bupe team.
- Communicate and coordinate care with team.

Promoting Factors for Implementing Buprenorphine

There are so many prominent inhibiting factors related to implementing buprenorphine, it was a challenge for key informants or the team to identify promoting factors. However, three factors were identified as promoting implementation and they are, (1) Home inductions, (2) Pharmacology of Buprenorphine, (3) Staff and Patient Satisfaction.

If patients could be educated to induce themselves at home, there would not be a need for clinic space, staff time, etc. and this would clearly make implementing the practice easier. Several key informants discussed home inductions as feasible, safe and effective.

> …started out doing clinic (inductions) and then they got used to it and then did…home (M. p. 23).

> We did not have the clinical set up to do in-office inductions. And we had kind of taken a pulse of the land, and most people we talked to who had been prescribing bupe at that

> point were doing home induction anyway, private-practice people. So we went with that and it seemed to work, so that's what we stuck with the whole time (Q, p. 16).

> Pretty much all home (inductions). I haven't now done an induction (in clinic) in probably like four years. Like a really long time (Y, p. 50).

While the federal guidelines recommend office-based inductions, NYS DOH and NYC DOH MH buprenorphine guidelines support either home inductions or office-based inductions, based on clinical judgment. Initially the team was thinking it would be safer for office-based inductions, however after speaking to experienced buprenorphine providers and brining this information back to the team and reviewing the guidelines, the team decided not to lock ourselves into only office-based inductions. The team did need to plan for processes and resources for office-based inductions, but the idea that there was flexibility lessened the degree of difficulty the team was feeling, should we have to do all inductions in the clinic.

Another promoting factor was related to buprenorphine itself. Overall key informants spoke very highly of it being an excellent treatment for "extinguishing" cravings and an excellent treatment especially compared to treatment for other addictions.

> Take bupe as prescribed, which means you're taking an adequate dose every day. If that's the case, it extinguishes (cravings), I mean bupe works pharmacologically (Q, p. 33).

> …there are some addictions for which we have no medications. I'm thinking about cocaine, of crystal amphetamines, and the stimulants in general. And then there are some addictions for which we have medications, but they are kind of weak. I'm thinking about alcohol . . . for opioids we do have a fantastic medication that really can carry the burden of the illness on their shoulders…I have enough faith that the medication alone has a good chance of success of carrying the day (R, p. 26-27).

The idea that clinicians and patients are pleased and satisfied with buprenorphine was also presented as a factor that would promote its implementation from the perspective that the staff, once they learned what a good medication it was, and saw good patient outcomes, would be supportive of its implementation.

> I think it's a great drug -- that's my experience -- they don't want to go to a program every day, and they are trying to have a sense of normalcy in their life, and something they could just get once a month. And I think with that it works really harmoniously with those patients (A, p. 1).

> …you are going to be ending up with incredibly grateful patients who are very consistent and very, very motivated (R, p. 23).

Theory Informing the Development, Installation and Implementation of Buprenorphine

In the next section, the conceptual explanation of how the theories utilized in this study informed the development, installation and initial implementation of IBT/P within a hospital-based HIV primary care/DAC in NYC. Each theory and its contributions will be presented separately.

Action Research

The AR features of cyclical action, collaboration, capacity building and reflection provided the foundation for knowledge development and the eventual implementation of the IBT/P. The flexibility of these features, which were tailored to the context and the content of the project, made a significant contribution toward incorporating a diversity of perspectives and producing an approach to the treatment of opioid dependence/addiction that was inclusive and acceptable to a wide range of participants. The use of constructs from insider AR, related to role duality and organizational politics provided a frame for managing ambiguities and negotiating power dynamics. The ethical principles of AR, which mesh well with the commitments of social

welfare, directed the researcher to design the study and enact behaviors that were grounded in fairness and justice. Analysis of field data (fieldnotes, logistic notes and the IBT/P manual) and first-person data (advisement notes and the researcher's personal reflective/reflexive journal) brought into focus key components related to each feature of AR and provides a conceptual explanation how the theory and method of AR informed the study. While the features are presented separately for purposes of explanation, it is important to note that it is the use of the features in concert that works toward the goal of AR, which is to produce practical knowledge.

Cyclical Action: Flexible Structure, Bringing People Along, Making Adjustments

Laying out the phases of the study and highlighting the steps of the AR cycle (building an understanding of a situation, planning action, taking action and evaluating action) provided useful tools for the researcher and the study participants. It assigned a structure of how the project was going to proceed and the steps of the cycle that would be used to move it along. Flexibility was an important component which allowed the researcher to respond to what was happening in the field. The researcher started off each phase with a loose idea of what needed to be accomplished and crafted the specifics based on participants' availability and other contextual circumstances. The flexible structure of AR was used to create a non-pressured and non-urgent approach, which promoted good working relations between the researcher and participants. During the early phases, uncertainties regarding two issues surfaced that created a kind of gloomy attitude about implementing buprenorphine. However, the iterative nature of the AR served as a self-correcting strategy, which facilitated bringing people along and helped to resolve apprehensions. Then in the later phases, the flexibility promoted developing and adapting practice in action.

Within the team there was an ongoing uncertainty about the involvement of nursing because of a staff shortage. As the team was forming and making connections, the near absence of nursing left a hole in their representation and voice, to which there was no immediate answer. It made it difficult for the team to imagine how the work was going to happen without nursing involvement. The researcher organized a special process whereby updates on meetings and developing processes were brought to the one or two nurses on a routine basis, to keep them updated and solicit their feedback and recommendations, and this was then shared with the team. Slowly nurses were hired, one in the fall, who had experience using buprenorphine; however nursing involvement remained minimal during the first six months of the research. Later in the process, more nurses were hired. The cyclical processes of AR made it easy for them to easily step into the implementation team and contribute to defining and specifying the IBT/P.

A second uncertainty was focused on the issue that there were "low numbers" of patients within the research organization who needed buprenorphine treatment. Concerns were raised about the degree of effort and resources being used to develop an IBT/P. The researcher used these opportunities to explain that this was known by herself and the director and there were other compelling reasons to expand treatment services. Over time, as the team and staff learned more about the larger picture of opioid dependence/addiction outside of the organization, the reality of the gap in service delivery, the hidden nature of the condition and the number of untreated individuals and the life-saving nature and importance of treatment, this concern slowly dissipated. There was a shift in thinking that a new service should only be developed if there were immediate large number of patients interested and ready for treatment.

While it is the nature of AR to have multiple action research cycles operating concurrently, within each phase emerged a theme that focused the inquiry and the action. Phase

I (June-August, 2010) was dedicated to laying a foundation about the research, about IBT/P and working closely with leadership and building the team. Phase II (September-November, 2010) was dedicated to working with participants in bringing together all types of buprenorphine knowledge and all types of organizational knowledge. Phase III (December 2010 – January 2011) saw the greater concretizing of practices and principles. Utilizing the processes of building and understanding, planning, taking action and evaluating that action were extremely important in outlining the universe of necessary information and collectively determining how it would be operationalized to produce an IBT/P. As the study proceeded, the researcher used the flexibility of iteration to shorten the upcoming phases of the project to two month increments. Based on the work that had been done and what still lay ahead, it was determined that the goals and objective of the study would best be accomplished with shorter phases.

In later phases, several important adjustments were made to aspects of the IBT/P that had been developed and created in earlier phases. For example, in Phase V (April – May 2011), when reviewing inclusion and exclusion criteria established earlier, one of the bupe social workers suggested that the original idea of only accepting patients receiving HIV primary care should be reconsidered. The social worker relayed that a small cohort of HIV negative patients who were seen for care at the research organization could also benefit from IBT/P and they too should be included. The researcher and the other social worker were very supportive of the idea. The researcher brought the idea back to the team who all agreed and the inclusion criteria were amended. The bupe social workers also suggested that when they would be screening patients for opioid dependence/addiction, if the patient screened positive and was interested for referral to the bupe MD/NP, the social workers would discuss the purpose of urine toxicology in treatment and obtain the specimen as part of the screening. They relayed that this would facilitate having

results when the patient returned for the bupe MD/NP visit and provide a piece of objective evidence that could assist in treatment. This too was agreed upon by the team and incorporated into IBT/P.

Collaboration: Context Dependent, Expanding the Concept of Treatment, Interdependency

As noted in chapter 4, the AR tradition allows for the degree of collaboration and participation to be decided by each project depending upon the context, situation and available resources. Given that the research organization had a very busy practice with high patient volume, the researcher organized the collaborative work to be as easy, accessible, and as non-burdensome for the team as possible. The team were asked to review buprenorphine treatment materials provided by the researcher, attend meetings and trainings (where they would work collaboratively with the team, share their knowledge, experience and ideas with the researcher and the team on how best to develop, install and implement an IPT/P) and provide feedback and input in process. All meetings and trainings were arranged well in advanced and the team's schedule was adjusted to provide them time during the work day to participate. This was done with an intentionality to cultivate an experience that was meaningful, enjoyable and non-exploitative and would encourage thoughtful contributions. Because the research organization had an existing structure where degrees of interdisciplinary collaborative processes occurred both clinically and administratively, team members had experience and an understanding of this model of interaction.

Acknowledging the equality of worth of all participants and value of various types of knowledge was an AR principle that nurtured the collaborative team work. The researcher used this principle as an engaging technique when recruiting team members and as a facilitating technique during the development work, encouraging all members to bring their ideas to the

table. The team members started by working through the buprenorphine literature and began contemplating how they wanted to operationalize an IBT/P. Over time the collaborative effort brought to light the question, what does treatment actually mean? The team felt that treatment was often thought of just as coming to the clinic and getting a prescription for a pill or medication. While it was clear that buprenorphine was an excellent medication for stopping withdrawal and preventing cravings, it was also clear that there was more to treating opioid dependence/addiction than just a pill. This perspective also raised the issue of how often in health care, the services provided by physicians are considered central and most important, and services provided by other disciples are considered ancillary or supportive, thereby diminishing their value.

As the team learned more about buprenorphine and they spent more time thinking what was involved in IBT/P, it became apparent that there were many aspects to the treatment that needed to be considered. For example, the social workers brought up education and screening as part of treatment, as aspect of care in the developing IBT/P model in which they would be taking the lead. Working collaboratively provided opportunities for different disciplines to relay what their various contributions were to treatment or what they saw as their colleagues' contributions to treatment. Nursing raised the issue of facilitating prescriptions when patients are due for refills as an aspect of the treatment. One of the physicians highlighted that the social worker providing case management services was part of treatment, because without insurance, you can't even get the medication. Administration raised the issue of milieu management and their responsibility of maintaining a healing environment in the clinic. All disciplines talked about care coordination as an aspect of treatment that often gets overlooked.

Having the opportunity to participate in interdisciplinary collaboration and contemplate IBT/P resulted in the team expanding the concept of treatment. During this process, they made the point that if treatment was limited to thinking only about the pill, this would impact on the kind of services and the quality of care patients would receive. It also highlighted the interdependent nature of treatment. As opposed to thinking dualistically about services being either central or ancillary, the collaboration brought out how one aspect of treatment is often dependent upon the other. The team recognized that this was an important part of working toward the goal of developing IBT/P. The new knowledge gained through collaboration, 'expanding the concept of treatment' contributed to a new understanding. This was used in a later process where the team explicated the dimensions of buprenorphine treatment as part of developing a countering promoter to the inhibiting category of buprenorphine exceptionalism.

Capacity Building: Building Skills and Competencies, Explicating Scope of Practice

AR has as a goal the outcome of capacity building. Developing and building the team members skills and competencies about buprenorphine was a major part of this research. It was expected that this would produce knowledgeable team members, confident and educated and ready to deliver an innovative model of care: the IBT/P. All team members required training and the director of the organization sanctioned whatever amount of time the researcher determined would be necessary. Several of the physicians had already completed the mandatory eight hour training required to get the special x number. Despite not being able to prescribe, the researcher had also competed the same mandatory training, in addition to undertaking an extensive self-study of buprenorphine. Using this knowledge base, the researcher facilitated additional buprenorphine training for the physicians (5 hours) and the primary buprenorphine training for the social workers (15 hours), administrators (5 hours), nurses (5 hours) and psychologists (1

hour). The training and development sessions took place over the course of the study, the half of it occurring in the final two month of development and installation, before treatment began.

The researcher organized for the training sessions to be coupled with development work, so that the learning also produced actionable knowledge. To facilitate the 12 hours of training for the social workers and the final three hours for the whole team, significant advance planning (2 months) was required to accommodate many different schedules All training and development sessions were held during work hours and again, schedules were adjusted to facilitate attendance. Also, to receive approval for the 12 hours social work buprenorphine training and development, the researcher was required to submit a buprenorphine training curriculum to the Directors of Social Work (Appendix E). During the discipline specific sessions, the clinicians worked collaboratively with the researcher in mapping out the specifics and detail of the treatment and services they would be providing as a member of the bupe team and their associated coordinating activities. The researcher then produced each as a topic in the IBT/P manual.

The researcher began the discipline specific development work with the physicians because several had already completed their mandatory training and there was an abundance of literature related to medical buprenorphine practices. This served as a template for how the other disciplines would proceed. Collaboratively, the first step was to walk through all the components of the bupe physicians practice for both initial and subsequent patient appointments. These components were specified and labeled, ordered, and put into a list named Bupe MD/NP practice. Once the practice components were labeled and listed, the detail of how each component would be performed was explicated. The researcher documented this material in the IBT/P. This satisfied the uniformity of care countering promoter that the team had developed to the inhibiting category, plaguing questions.

Next the researcher worked with the nurses to develop bupe RN practices. In trying to replicate what had been done when developing the bupe MD/NP practice, there were several challenges. First, there were much less resources describing bupe RN practice compared to bupe MD practice. What also presented as a challenge was that the nurses could articulate some specifics of the components of care they would be providing, but they were challenged in thinking comprehensively and more challenged in explicating detail. A similar experience occurred with the social workers. There existed even more limited resources describing bupe social work practice and they too were challenged in coming up with both specifics and details of bupe social work practice. After more training and more collaborative development work with each discipline, a bupe RN practice and a bupe Social Work practice was produced and the detail of how they would be performed was explicated. This was accomplished over time using the steps of the AR cycle, collaboration and reflection. The researcher took to calling the process of explicating scope of practice: Name it, Claim it, and Explain it. The social workers and the nurses liked this term and were pleased with the final construction of the scope of practice.

Reflection: Gaining Insight into the Many Forms of Power, The Importance of Advisement

Reflection is the procedure whereby the researcher systematically and openly steps back to question the content, process, and premise of specific project activities, so as to gain insight and plan further action. Reflection is,

> the critical link between the concrete experience, the judgment and taking new action…it is the key to learning as it enables you to develop an ability to uncover and make explicit to yourself what you have planned, discovered, and achieved in practice…it helps you to see how your knowledge is constructed (Coghlan & Brannick, p. 25).

Reflective practice is done both in action (as events unfold) as well as formally scheduling time to stop and think about: the issues of the project and what was happening (content), the strategies, procedures and how things were being done (process), and the researcher's underlying assumptions and perspectives (premises), (p. 12) and document what is being learned. A fundamental frame in AR for undertaking reflective practice is to, "break it down into three key stages: (1) understanding the social construction of reality; (2) recognizing one's own contribution to that construction; and (3) taking action to reshape that construction" (Taylor, Rudolph & Foley, 2008, p. 656). The understanding gained from these formal reflective sessions undertaken in this study (60 individual reflective sessions, 20 advisement reflective sessions) were then fed back into the steps of the AR cycle and informed future action. Presented here are insights acquired through reflective practice/first-person inquiry that are relevant to treating opioid dependence/addiction and implementation research, (1) the many forms of power, and (2) the importance of advisement.

Many forms of power.

As noted in chapter 3, Greenhalgh, et al., (2004) identified that both critical to implementation and extremely difficult to study were internal politics and power relations and these constructs were missing from their model because these area were not addressed in the literature (p. 614). As discussed in chapter 4, from an AR perspective, power and control are a significant factor in professional, bureaucratic, and organizational life (Coughlan & Shani, 2008, p. 651; Stringer, 2007, p. 33) and they are an object of study. This is achieved through reflecting on the various kinds of power that are at play in the research so to develop actions that work toward thwarting reducing, or neutralizing the negative and destructive effects of power and control. Balancing power and politics, among the team, between the team and leadership, among

leadership, between the researcher and the team, between the researcher and leadership as well as between clinicians and patients when developing and delivering treatment, was an expected part of the researcher's work, especially when doing insider AR.

Through individual and advisement reflexive practice, the researcher gained awareness of how power was operating and its multiple forms. This provided new knowledge and insights from which to act and facilitated achieving the goals and objectives of the study. Below are the results.

1. Power differentials: This took the form of first acknowledging that different types and degrees of power are a fundamental reality of life. The next step was to evaluate and understand how various types of power relations functioned in research relationships (as discussed in chapter 5) and relationships among the team members and between disciplines. Relative to IBT/P team there were no apparent or overt issues of power struggles among the disciplines that was observed or reported. The research design as well as the research organization's internal structure is steeped in everyday interdisciplinary clinical and administrative practices likely contributed to the disciplines working well together.
2. Power sharing: This took the form of knowledge sharing (as opposed to knowledge holding) among the team as well as authority sharing from leadership to the team. This built capacity and competences and generated new knowledge and practices.
3. Researcher's responsible use of power: This took the form of following AR ethics, designing the study and enacting behaviors that were directed to prevent exploitation of research participants and promote fairness. It also included the researcher and advisors spending a significant amount of time identifying and explicating the researcher's biases, assumptions, preferences, perspectives and working to manage their influence on the study.

4. Collective power of the IBT/P team: As discussed several times, the team was authorized to determine roles and responsibilities and division of labor within the IBT/P. Knowledge sharing and authority sharing increased the team's collective power and contributed the team's power of invention.
5. Speaking truth to power: This took the form of doing the uncomfortable work of dialoging and navigating tense and difficult issues with leadership and staff.
6. Consolidating power: This took the form of both historical and present political and institutional power operating against opioid treatment/buprenorphine. For example, when the AMA opposed the maintenance of opium users and worked with the Treasury to punish and prosecute physicians; when the MMTP community opposed buprenorphine office-based treatment; when the DEA sent out letters encouraging physicians to surrender their X DEA licenses, etc.

The importance of advisement.

As already discussed, the researcher understood the complexity her multiple roles presented and intentionally obtained advisement. A total of 20 sessions were undertaken over the course of the research year.

Figure 10: Advisement Sessions

ADVISEMENT	Phase I	Phase II	Phase III	Phase IV	Phase V	Stage III	Total
	6/2010 8/2010	9/2010 11/2010	12/2010 1/2011	2/2011 3/2011	4/2011 5/2011	June 2011	
Inter(ra)personal (IP)	2	1	1	0	1	0	6
Grounded Theory Method (GTM)	2	4	1	1	1	1	10
Clinical/Milieu (C/M)	0	2	1	0	1	0	4

As noted in chapter 1, advisement in three areas was sought to support first-person inquiry and praxis-reflection on a range of research topics (Coghlan & Shani, 2008, p. 649;

Marshall & Mead, 2005, p. 236 - 237). IP advisement provided an opportunity for the researcher to discuss her perspectives and purposes and was especially important regarding understanding and negotiating organizational politics and managing various dilemmas and power relations. GTM advisement provided mentoring in data collection, coding, and analysis, as well as managing the researcher's bias and influence on the study. C/M advisement provided for clinical review of developing IBT/P, scope of practice evaluation and attention to milieu management, particularly as it related to creating practices that promoted safety for patients and staff.

In addition to the specific advisor's specialties, other areas have been identified by the researcher where there was overlap and cross over in advisement support that was critical to the researcher studying and facilitating this project. At various times during the study the researcher began to experience considerable fatigue with keeping up her role as champion, advocate, and enthusiastic engaging leader, which was a necessary and important aspect of her role. During these times, doubts and isolation became a considerable challenge. In addition, a range of disappointments, frustrations and also some ethical concerns affected the researcher's mood and energy and resolve. While these circumstances were not unexpected and were even predicted, the difficulties they presented in reality were more considerable than had been anticipated by the researcher at the outset of the study. It is possible that these challenges might have been insurmountable or the outcomes of the research may have been different without the space for support and encouragement that the advisement provided. Along with all the clear and knowledgeable direction given by the advisors, these sessions also served as a place for contemplation, stress reduction, rejuvenation, and self-regulation which positively affected the overall facilitation of the study.

Implementation Science

The researcher used the implementation science theory, NPT to inform this study by operationalizing NPTs generative mechanisms prior to the study (chapter 5). To gain insight into the degree to which these mechanisms had a promoting influence on the development and installation of the IBT/P, the researcher established a process of assessment. At the end of each phase of the study, the researcher rated each feature of the mechanisms as having either high, medium, low, or unknown potency as a promoting implementation influence based on analysis of field experience and field data. The potency ratings were based on Kurt Lewin's Force Field Analysis (1951), as described by Brager & Holloway (1992), where driving and restraining forces (relative to a particular organizational change) are rated based on their potency and determined to be high, medium, low, unknown. The researcher had experience with this procedure as she had conducted a force field analysis in relationship to buprenorphine (Appendices, C & D). When this study was completed the researcher assessed the potency ratings across the phases of the study. Features that were rated the highest potency, the lowest potency, and those that demonstrated the greatest change in potency over time will be presented and discussed.

Normalization Process Theory

As discussed in chapter 4, NPT is a mid-range theory of implementation that focuses on how the processes of implementation are brought about (May & Finch, 2009). Each of the four generative mechanisms contains four components that specify the qualities of work related to each mechanism.

Figure 11: NPT Generative Mechanisms and Associated Components

1. COHERENCE A. Differentiation B. Individual Specification C. Communal Specification D. Internalization	**3. COLLECTIVE ACTION** Immediate Factors A. Interactional Workability B. Relational Integration Organizational Factors C. Skill-Set Workability D. Contextual Integration
2. COGNITIVE PARTICPATION A. Initiation B. Enrollment C. Legitimization D. Activation	**4. REFLECTIVE MONITORING** A. Systematization B. Communal Appraisal C. Individual Appraisal D. Reconfiguration

Components with highest potency: skill-set workability and contextual integration.

The components of NPT rated to have the highest potency, from the beginning of the study and through to the end, relative to being a promoting influence on the development and installation of IBT/P, were skill-set workability (how the division of labor is determined and carried out) and contextual integration (how a complex intervention is lined to, and sourced through, organizational structures and sponsorship). Skill-set workability was rated highly potent because throughout the study the team (both collaboratively and discipline specifically) exercised their authority in determining roles and responsibilities, created new practices, identified the importance of not 'dumping' on any one discipline, and embraced the concept of shared care. These aspects promoted an interest and enthusiasm for the development and implementation. Contextual integration was also given a high potency rating throughout because the developed practices were created and linked to structures that were made evident through the local knowledge of the team. The researcher was responsible for getting approval from discipline directors for the newly developed clinical responsibilities and processes and the discipline directors never opposed a single piece of the IBT/P created by the team. In addition, the research organization provided without question all the staff meeting, training and

development time that the researcher deemed necessary and leadership supported the teams' work throughout the whole process.

Components with lowest potency: communal appraisal and individual appraisal.

The features of NPT rated to have the lowest potency relative to being a promoting influence on implementation were communal appraisal (regular and organized procedures for monitoring and ongoing assessment of the process) and individual appraisal (experiential and unsystematic practices of judging practices and processes), both features of the mechanism reflective monitoring. These components were rated low at the outset of the study and remained low throughout. This was an interesting finding. From a communal perspective, the team was asked to be a liaison to their disciplines and to bring any questions to the team that might arise in their discipline specific meetings about buprenorphine, but no discipline specific questions were ever presented. From the first team meeting and throughout the study team members were invited and encouraged to think about how the implementation process and the IBT/P might be evaluated, but no team members expressed an interest in this aspect of the research. From an individual perspective, there were great contributions to the development work of IBT/P, but no individual critique or feedback to the researcher on the processes and procedures organized by the researcher despite much encouragement, time and interaction opportunities. Several possibilities exist in understanding this low potency. One is that the team members already had many responsibilities, were willing to work on developing and eventually delivering the IBT/P, but concerning themselves with evaluation was either burdensome or they considered it outside their interest, scope or time availability. Another possibility that exists is that there were individual appraisals about the process, but the members decided not to share this with the

researcher. Also, the fact that the researcher was unable to secure funding for formal future evaluation greatly limited the possibility for organized monitoring and assessment.

Components with changing potency: interactional workability and reconfiguration and all features of coherence.

The components of NPT rated to have the greatest change potency over time (starting out as unknown and ending up high), were all four components of coherence, (differentiation, individual specification, communal specification and internalization), interactional workability (how work is enacted by the people doing it), a component of the mechanism collective action and reconfiguration (practices are modified or reconstructed), a component of the mechanism reflective monitoring. These components were initially rated low and unknown potency and they increased during the study relative to being a promoting influence on implementation. It was assessed that the process oriented incremental team building and knowledge building over time and the interdisciplinary focus of the work (where each had distinct and specific contributions and responsibilities and one discipline was not privileged over another) were what incrementally increased the potency of these components. As the team went through a range of small and large group meetings and greater involvement with the development work, they became more coherent, more competent and more comfortable with operationalizing the IBT/P as well as reconstructing and modifying practices they had originally developed.

Consolidated Framework for Implementation Research (CFIR)

As discussed in chapter 5, the CFIR was derived from 19 different implementation theories and consists of five major domains (Damschroeder, et al., 2009). Each of the domains have various features and subfeatures which were defined in relationship to this study and assessed prior to the start of the study and used to comprehensively address the implementation work of this study. As was done with NPT, the CFIR's features were also assessed throughout

the study relative to the degree to which they had a promoting influence on implementation and will be discussed below.

Figure 12: CFIR Constructs and Associated Features

1. INTERVENTION CHARACTERISTICS A. Intervention Source B. Evidence Strength & Quality C. Relative Advantage D. Adaptability E. Trialability F. Complexity G. Design Quality and Packaging H. Cost **2. OUTER SETTING** A. Patient Needs & Resources B. Cosmopolitan C. Peer Pressure D. External Policy & Incentives **3. INNER SETTING** A. Structural Characteristics B. Network & Communications C. Culture D. Implementation Climate 1. Tension for Change 2. Compatibility 3. Relative Priority 4. Organizational Incentives & Rewards 5. Goals and Feedback 6. Learning Climate	**3. INNER SETTING (Continued)** E. Readiness for Implementation 1. Leadership Engagement 2. Available Resources 3. Access to Knowledge & Information **4. CHARACTERISTICS OF INDIVIDUALS** A. Knowledge & Beliefs about Intervention B. Self-Efficacy C. Individual Stage of Change D. Individual Identification with Organization E. Other Personal Attributes **5. PROCESS** A. Planning B. Engaging 1. Opinion Leaders 2. Formally appointed internal implementation leaders 3. Champion 4. External Change Agents C. Executing D. Reflecting & Evaluating

Features with highest potency: leadership engagement, available resources, access to knowledge and information, planning, engaging and champion.

The features of the CFIR rated to have the highest potency relative to being a promoting influence on the development and installation of IBT/P were leadership engagement (commitment, involvement, and accountability of leaders and managers to implementation), available resources (level of resources dedicated for implementation and on-going operations including training, education, physical space and time) and access to knowledge and information (ease of access to digestible information and knowledge about the intervention) all features of the domain inner setting. The director of the research organization was from beginning to end of the

study exceptionally supportive of implementing buprenorphine, which was demonstrated to the larger staff at meetings, presentations, journal clubs, grand rounds, etc. The director included this research in a presentation that was delivered to NIDA about integrating addiction treatment within HIV primary care, spoke proudly and publicly of the work the team was doing and was very forthcoming with necessary resources for implementation. As has been discussed the various discipline directors were also supportive and involved. In particular, the co-directors of social work were especially encouraging of the training and education, the newly developed roles for the social workers, and were interested to expand the bupe social work knowledge and practice to the other social workers in the organization. Having this level of support facilitated implementation.

In this research, the on the job training and development work was a significant high potency feature. The interdisciplinary knowledge sharing, the coupling of training with development and the creation of the IBT/P manual, which was used as a resource in delivering care all had positive impact on implementation. The features of planning (degree to which the scheme or method for implementing an intervention are developed in advance and their quality), engaging (attracting and involving appropriate individuals in the implementation and use of the intervention) and having a champion (individual who dedicates themselves to supporting, marketing and driving through implementation), all features of the domain process were all assessed at the beginning of the study as having high potency for implementation and these remained high throughout. Repeatedly staff and leadership commented about the thoroughness of the planning and the high level of commitment and involvement of the team. As has been previously been discussed, the researcher being an internal champion was viewed by many to add credibility to the project and facilitate implementation.

Features with lowest potency: patient needs and resources, peer pressures, and external policy and incentives.

The features of CFIR rated to have the lowest potency relative to being a promoting influence and remained low throughout the study were patient needs and resources (the extent to which patient needs are known), peer pressure (competitive pressure to implement), and external policy and incentives (external strategies, mandates to implement), all features of the domain outer setting. In addition, tension for change (the degree to which stakeholders perceive the current situation needing change) a feature of the domain inner setting, was also assessed as having a persistent low potency for promoting implementation.

The features of patient's needs as a low promoting factor and a challenge to implementation have already been discussed. While there were a low number of patients within the research organization immediately in need or interested in buprenorphine, there was not a low number of patients who were receiving treatment at MMTPs. There were hundreds of patients in this category. Given what patients from the research organization reported in the focus group, there were many who would like to have the option to consider transferring to buprenorphine. However, outside of the IBT/P team, the degree to which the larger staff perceived the current situation needing change was low and remained low throughout the study.

The low potency of the features of peer pressure and external policy and incentives speaks to several issues. First, this implementation of buprenorphine project was without any external policies, mandates or financial incentives. Since its FDA approval in 2002, neither the NYS nor the NYC Department of Health had earmarked any funding for expanding buprenorphine treatment. There have been no grants, no demonstration projects or special needs project money dedicated to promoting implementation. In 2010, the NYS DOH did launch a media campaign about buprenorphine to bring attention to the public about this treatment and

also sent letters to physicians encouraging them to become qualified to treat and to pharmacies encouraging them to display buprenorphine posters (NYS DOH, 2010). In addition, there was no competitive pressure to implement. While there were individual physicians who had become certified to treat opioid dependence/addiction in some of the Designated AIDS Centers in NYC, only one DAC in NYC had integrated buprenorphine within HIV primary care, and this was through funding provided by Health Resources and Services Administration (HRSA) (2009), Special Project of National Significance grant. Based on all of these factors, these features were low potency to implement at the outset of the study and remained low until the end.

Features with changing potency: evidence strength and quality, relative advantage and self-efficacy.

The features of the CFIR rated to have the greatest change potency over time (starting out as unknown, then increasing, and ending up high potency to promoting implementation) were evidence strength and quality (stakeholders perceptions of the quality and validity of evidence supporting the belief in the intervention) and relative advantage (stakeholders' perception of the advantage of implementing the intervention versus an alternative solution), both features of the intervention characteristics domain, and self- efficacy (individual belief in their own capabilities to execute courses of action to achieve implementation goals) a feature of the characteristics of individuals domain. At the outset of the study it was unknown to what degree these features would promote implementation. Like the NPT components that had changing potency over time, the process oriented incremental team building and knowledge building facilitated the team members in learning and understanding the quality and advantage of buprenorphine as well as team members developing confidence as bupe providers and feeling ready to begin delivering treatment.

Institutional Ethnography

IE was first used in this study to direct documentary analysis that resulted in the mapping of the multiple complexities related to buprenorphine and opioid dependence/addiction. This was shared with the team at the outset of the research so as to provide an overview of the challenges related to the upcoming implementation work. It was also used to identify and analyze documents and records that addressed institutional processes and practices related to buprenorphine so as to understand guidelines, regulations and mandated practices. Throughout the study, when new references and documents were identified, contradictions between texts and approaches were highlighted so the team could evaluate the differences and make choices about the utility of the literature and its congruence with the teams treating philosophy. In addition, when there was a noticeable abundance or scarcity or absence of literature this was also brought to the attention of the team.

IE's focus on exploring the organizational conditions of people's lives was an important aspect of the IBT/P developmental work, especially around explicating scope of practice and creating new professional roles. During interviews, IE's focus on learning "how things happen," and having key informants share their knowledge and competencies regarding buprenorphine and its related institutional features supported implementation. When working with the team and the other organization participants, IE directed the researcher to keep the 'institution in view' and carefully explicate the relations, functions and responsibilities among various disciplines relative to doing the work of IBT/P. And because IE is dedicated to grounding inquiry in the ongoing activities of the actual individuals affected by the study, it guided the researcher to develop the process where the development team morphed into the treatment team, thereby the staff who ended up delivering the treatment were the same staff that generated and developed the practice.

The multiple theories and approaches used in this study strengthened the overall research endeavor and provided a much more comprehensive view of buprenorphine and implementation. Each contributed and filled in areas of importance with the goal of trying to address as many aspects of implementation as possible and identify blind spots that could be missed or forgotten, which in the field implementation there can be many. The following chapter is the concluding chapter and will address the results in relationship to previous research as well as implications and limitations of the study.

Chapter 7: Discussion and Implications

This concluding chapter will discuss the results of the study and examine them in relationship to some of the existing research described in chapter 3. This will be followed by a discussion of the implications of the study for patients with opioid dependence/addiction, social work practice and interdisciplinary practice and implementation research.

The results of this study suggest that the development, installation, and initial implementation of an IBT/P occur within the context of key inhibitors: (1) ongoing, significant and multiple biases, (2) plaguing and difficult questions, (3) challenges uniquely related to buprenorphine. It also suggests that these barriers can be overcome and that implementation was facilitated by (1) AR and the ability to adapt the treatment, (2) training and education of the team and having an internal champion, and (3) leadership support and structural components and resources.

Implementing Buprenorphine in the Context of Key Inhibitors

Ongoing, Significant and Multiple Biases

The continuous and multiple forms of biases against treating people with opioid dependence/addiction and against methadone and buprenorphine was discussed, observed and experienced on a fairly regular basis throughout the study. The legacy of MMTPs with their signature control, shame and punishment approaches have clearly had a damaging effect on the treatment of opioid dependence/addiction. Of course there are some MMTPs where efforts are made for greater dignity and quality; however the very nature of lining people up and giving them their treatment through a window conjures up images of Cuckoo's Nest and Nurse Ratched type treatment. This coupled with persistent public misinformation and antimaintenance positions and clinician's lack of skills, knowledge, abilities and interest in treating opioid

dependence/addiction makes this barrier seem almost insurmountable, especially when you add in destructive and undermining institutional bias.

These study findings confirm the existing research literature that identified negative attitudes by clinicians as a barrier to implementing buprenorphine (e.g., McMurphy et al., 2006; Thomas et al., 2008, Turner et al., 2005) and extends it beyond simply clinician bias. Identifying a much larger and more complex web of biases and their negative impact on expanding treatment for people with opioid dependence/addiction adds depth to the understanding of this barrier. As was done in this study, this knowledge can be used to develop strategies to counter the corrosive effect of this negativity. Unlike the existing literature findings that negative attitudes by physicians about diversion and abuse of buprenorphine (e.g., Turner et al., 2005; Thomas et al., 2008) are a barrier to implementation, this was not a significant topic of the key informant interviews and was not an issue with the IBT/P team. The clinicians on the team had extensive experience treating chronic pain with opioids and managing diversion and abuse are part of the larger picture of opioid safety. They came to the IBT/P work with this knowledge and background and their existing knowledge and experience with these issues may explain why it did not present itself as a barrier when working with the team.

Plaguing and Difficult Questions

This study sheds light on the reality that prescribing buprenorphine and taking up the practice of treating opioid dependence/addiction means that clinicians involved in this kind of work must be prepared to walk in a world where issues of life and death, emotional distress, and significant uncertainties are part of the landscape. Based on the findings from this research, encountering very challenging clinical scenarios, which can include high risk taking and disruptive behaviors on the part of the patient population, is an aspect of buprenorphine

treatment to which there are no easy answers. This does not mean that there are not also rewards and successes, but it does mean that the treating clinicians will contend with some very difficult and disturbing experiences. These findings highlight that balancing safety (both patient and staff), with control and authority is an intricate aspect of treating an individual with buprenorphine, and this skill sets does not come easily. In the federal buprenorphine guidelines for physicians (CSAT, 2004), and the federal buprenorphine guidelines for nurse (CSAT, 2009), the only time the word disruptive is used in these documents are in statements about this being something that is a problem and comes with risks of discharge. There is no discussion about best interventions or approaches to responding to this issue and the importance of engaging and maintaining the patient in care. "Dangerous or inappropriate behavior that is disruptive to the clinic and others will not be tolerated and may result in discharge from treatment" (p. 33). "I agree not to steal, deal or conduct any illegal or disruptive activities in the doctor's office" (CSAT, 2004, p. 148). Lack of thoughtful guidance from leading government agencies meant to be promoting treatment sets the tone for destructive clinical practices, and is itself a barrier to treatment.

While the specifics of plaguing questions found in this study were not previously described in the existing literature on barriers to buprenorphine, lack of knowledge and experience was found in many studies to be a significant inhibiting factor to prescribing buprenorphine (Cunningham et al., 2006; Cunningham et al., 2007; Gunderson et al., 2006; Sullivan et al., 2006; Barry et al., 2009) and training and education was found to be an important facilitating factor to prescribing buprenorphine (Cunningham et al., 2006; Gunderson et al., 2006; Knudsen, et al., 2007; McMurphy et al., 2005; Turner et al., 2005; Netherland et al., 2009). It is possible that concerns about plaguing questions were subsumed under these factors. For

example, in McMurphy et al., (2005) the statement, "*I think the training that took place for this would have to be by people who have done it and would have to be down and dirty basic stuff on how to do this, not sort of textbook academic type stuff, but real day to day…"* (p. 549) expresses a sentiment that learning about treating opioid dependence/addiction goes beyond knowing the correct dosing of buprenorphine. It is also possible that prior research that reported having an addiction specialist available for consult, in a timely fashion, as facilitating implementation (Cunningham et al., 2007; Gunderson et al., 2006; McMurphy et al., 2006; Netherland et al., 2009; Sullivan et al., 2007; Turner et al., 2005), may be related to physicians having plaguing questions and wanting a mentor available to support them with these challenges. None of the clinicians on the IBT/P team were addiction certified and the idea of having an addiction specialist available for consult never came up in this study.

Challenges Uniquely Related to Buprenorphine

The range of issues unique to buprenorphine found in this study highlight how complicated an endeavor it was to implement buprenorphine. The requirement for training was a significant barrier and ended up preventing the implementation of IBT/P within Clinic 1. This confirms the findings in the existing literature that found regulatory issues as a barrier (Barry, et al., 2009; McMurphy et al., 2006; Netherland et al., 2009; Turner et al., 2005). While fear of government was not specifically identified in the established research about barriers to buprenorphine, again like the plaguing questions this could have been an aspect of regulatory issues that did not have an opportunity for expression in earlier studies. This study certainly underscores that unannounced inspection visits by armed government agents is an aspect of buprenorphine treatment that any implementer needs to take seriously and be prepared to address. Other aspects unique to buprenorphine identified by this research as possibly inhibiting

implementation, such as the need to protect primary care and the inability to use existing systems, was not described in prior research, and these findings add to the general knowledge about factors that need to be accounted for when developing and implementing this treatment.

Overcoming Barriers with Key Implementation Promoters

Action Research and the Ability to Adapt the Treatment

Overall, the factor that most facilitated implementation of the IBT/P was the iterative AR design which provided the opportunity to simultaneously explore inhibiting and promoting factors and then work with the team to include and/or develop promoting factors. This back and forth, process oriented method, along with involving frontline workers and using a team approach confirmed previous research findings that these factors promoted implementation (Ashton, et al., 2006; Brekke, et al., 2009; Greenhalgh, et al., 2004; Kirsh, et al., 2008; Nemeth, et al., 2008). The ability to configure and adapt buprenorphine to the local context was also a significant factor in facilitating the implementation of the IBT/P and this also has been demonstrated by prior research (Brekke, et al., 2009; Fixsen, et al., 2005; Hopp et al., 2006; Kirsh et al., 2008; Stacey, et al., 2006).

Training and Education of the Team and Internal Champion

Several studies in the implementation literature related to barriers and facilitators highlighted the positive impact that training and education played in promoting implementation (Kramer & burns, 2008; Magnabosco, 2008; Scott, et al., 2009; Stacey, et al., 2006; Strauss et al., 2009). This study also found that on the job training and education and ease of access to knowledge and information about buprenorphine facilitated the implementation of buprenorphine. In addition, this research found that the development of the IBT/P and the manual, by the team, and then the use of the manual during initial implementation was a strong

promoting factor that had not previously been described in the existing literature. In addition to training and education, previous research identified having a champion as a facilitating factor (Belkora, et al., 2008; Brekke, et al., 2009; Fixsen, et al., 2005; Greenhalgh, et al., 2004; Lucas, et al., 2008). Damschroeder, et al. (2009) defined champion as "individuals who dedicate themselves to supporting, marketing and 'driving through' an implementation, overcoming indifference or resistance that the intervention may provoke in an organization" (p. 11). As discussed, there were no mandates or incentives for implementing buprenorphine and the researcher's role as champion, was a significant factor in the successful implementation of the IBT/P.

Leadership Support and Structural Components and Resources

Several studies in the implementation literature identified that leadership support was important to implementation (Brekke, et al., 2009; Greenhalgh, et al., 2004; Kirsh, et al., 2008; Koester, et al., 2007; Nemeth, et al., 2008; Proctor et al., 2007) and this research confirmed this finding. In this research, not only was the director of the organization supportive, so were the discipline directors, and the specialty directors. This was encouraged by the director as well as many in leadership believing in buprenorphine, its life saving capabilities as well as an intervention to prevent HIV. Leadership support was also facilitated by their established, long standing relationship with the researcher and confidence in the project having a positive effect on the organization.

A major promoting implementation factor found in previous research and also found in this study was the structural aspects of the organization (size, maturity, number of patients and staff) and resources provided to carry out the project (Ashton, et al., 2007; Fixsen, et al., 2005; Greenhalgh, et al., 2004; Hopp, et al., 2006; Kirsh, et al., 2008; VanDeusen, et al., 2008). The

research organization was mature and financially established with a large staff and patient population. These factors promoted implementation. In addition, the director dedicated on the job training and development time, physical space, director and discipline director time, use of organizational materials (email, copying, paper, staff meetings), and team size, all at a level determined by the researcher, without question. The director also shared the resource of power by agreeing that the team had the authority to determine division of labor. The organization had the capacity to release 19 staff members from their work responsibility, sometimes collectively and sometimes in smaller groups over the course of a year. Without these resources IBT/P would never have been implemented.

Not discussed in much detail in the existing research (except for Fixsen, et al., 2005 and Kirsh, et al., 2008), is the quality, ability, motivation and commitment of the staff involved and its effect on implementing the intervention. Proctor, et al. (2007) did identify staff resistance as a barrier to implementation. Scott, et al. (2009) found some ongoing staff skepticism about the intervention, despite excellent evidence, and Kramer & Burns (2008) noted failure for the intervention to be implemented based on staff reporting it was too complex. This critically important resource, was described by Greenhalgh, et al. (2005) as, "not objective or given" and as "socially constructed and frequently contested and must be continually negotiated among members of the organization or system" (p. 606). This study's findings support the findings by Kirsh, et al., (2008) who wrote, "we believe that the most essential factors were the formation of a core team committed to quality and improvement, and the leadership provided by the clinic director that was supported strongly by the team members" (p. 7). Based on being an insider, the researcher entered the study already knowing the high level of skills, knowledge, ability and commitment of the team, and this too facilitated implementation.

Implications of the Research

Patients with Opioid Dependence/Addiction

Patients with opioid dependence/addiction continue to be at a disadvantage because of the limited availability of treatment and the slow adoption and implementation of buprenorphine. This study was successful in making a small contribution to increasing access to care and providing an alternative to MMTP. However, patients with public insurance with opioid dependence/addiction continue to face challenges finding an office-based buprenorphine provider who accepts Medicaid and the threat of a two-tier system continues to be a very real concern. Ongoing efforts to implement buprenorphine office-based treatment in public clinics, not under the jurisdiction of OASAS, needs to continue so patients with opioid dependence/addiction and Medicaid have options outside of MMTP. The Affordable Care Act, with its focus on increasing health insurance to the uninsured and underinsured and embracing a chronic illness perspective for substance use disorders, will present new opportunities to increase access to treatment (Clay, 2010; Ling, Farabee, Liepa & Wu, 2012). Of course, the hope is that this will be done within the context of better trained and prepared clinicians, who are skilled and knowledgeable in a range of approaches (including harm reduction) and can address the plaguing questions identified in this study from a platform of respect and dignity.

As described in chapter 6, this research also developed a protocol for managing requests from patients to transfer from methadone to buprenorphine office-based treatment and planned to encourage patients receiving care at a MMTP to investigate their options, if this was their interest. While there are certainly a subset of patients receiving care from MMTPs who would not be eligible for transfer, there is also certainly a group who might be very eligible and be able to tolerate and succeed in transferring. This protocol was developed because there has been very

little attention given to this group. For example, in the HRSA special project of national significance, which studied integrating buprenorphine into HIV primary care at 10 sites around the country between 2005-2009 (BHIVE Collaborative, 2011), there were no methadone patients transferred to buprenorphine, despite low enrollment numbers in the study (Weiss, et al., 2011, p. S10). Greater efforts need to be made to educate and evaluate patients who are stable on methadone at MMTPs and work with those who are interested and eligible to shift treatment to an office-based setting.

Social Work Practice

In this research, social work turned out to be the discipline with whom the researcher did the most collaborative work and training and development. This was not planned, it occurred organically, and there were several local contextual issues that contributed to this development. First, the baseline "Shared Care Model" at the research organization, HIV primary care/specialty care and social work case management provided a large pool of masters prepared social workers from which to recruit for the team. Second, the social workers who participated in the research came to the work with knowledge and experience in MMTPs, addiction and harm reduction practice, and most importantly, the bupe social workers were interested in learning and taking up a new role. In addition they were also in clinic on a daily basis, had designated offices, and the most availability in their schedule. Based on these factors, along with the collaborative team work and the training and development work, the bupe social workers created a new practice where they became the first point of contact for patients interested in buprenorphine. They conducted the initial education, screening, and if eligible referral to the bupe MD/NP. If the patient engaged in treatment, they then became the patient's bupe social worker.

To take on this new role the bupe social workers trained in aspects of neurobiology

related to buprenorphine, as they needed a basic understanding of opioid receptors, agonists (full and partial), ceiling effect, withdrawal, tolerance, cravings and blocking. Together, the researcher and the bupe social workers developed how best to put these complex ideas into phrases and statements that patients could understand. The process of creating the education and screening material, deciding what to include, how to adjust it, was a constant back and forth between practical knowledge, experience and the resource material (Appendix A, IBT/P, Manual, Topic 5, Bupe Patient Education, Screening, How Bupe is Provided - Phases of Treatment, Resources & Referrals). A similar process was undertaken in developing and explicating a range of counseling services (supportive, relapse prevention, and risk reduction) engagement practices, buprenorphine coaching, goal setting and treatment planning, services that were available for all patients receiving buprenorphine, should they be interested (Appendix, A, IBT/P Manual, Topic 9, Bupe Social Work Practice)

This establishes that social workers, who are interested, can assume a significant role in treating patients with opioid dependence/addiction, especially in the areas of education, screening, referral, counseling, and buprenorphine coaching. The bupe social workers in this study quickly started expanding their role soon after initial implementation and began screening and recommending patients for buprenorphine treatment who they were seeing them for other issues, but presented with opioid dependence/addiction issues. The social workers, the patients and the team thought this was important and there was satisfaction and benefits all around. The collaboration and training and development between the NP and the LMSWs focused on explicating the detail of the various aspects of treatment that the bupe social workers were providing. This highlights the importance, especially within interdisciplinary practice, of being able to name and claim and explain what services one is providing. Especially when budgets

tighten, or new work responsibilities come along, being able to state specifics of clinical practices and work responsibilities contributes to increasing one's ability to advocate for appropriate workload, as well as increases one's value and professional standing within an organization.

Interdisciplinary Buprenorphine Treatment/Practice, Implementation Research and Interprofessional Exclusionary Practices

This study clearly demonstrates that IBT/P is possible, important and meaningful to a range of health care providers. An interdisciplinary focus expanded the concept of treatment and addressed many important aspects of caring for people with opioid dependence/addiction that often go unaccounted for and/or unnoticed. Without an interdisciplinary frame, patients are at risk for receiving substandard care. Over the past several decades, the concept of disciplines collaborating and providing patient-centered care has progressed from multidisciplinary, to interdisciplinary, to the latest expression being identified as interprofessional practice. In 2010, a group of dentists, nurses, osteopaths pharmacists, physicians, and public health professionals came together and produced

The report, "Core Competencies for Interprofessional Practice" (Interprofessional Education Collaborative Practice Expert Panel, 2011), relaying that this, "requires moving beyond these profession-specific educational efforts to engage students of different professions in interactive learning with each other. Being able to work effectively as members of clinical teams while students is a fundamental part of that learning" (p. 1). The absence of social workers from this interprofessional collaboration is a considerable loss for safe, high quality, accessible, patient-centered care, which is the goal. It is my hope that research such as this encourages interprofessional practice to include social work. This must be advocated for by social workers and their interprofessional colleagues. It also raises the question as to why social

work was not included? As noted in this study, without the social determinants of health such as health insurance, housing, access to food, etc. in place, (a foundational concern and practice of social work) medication and health care provided by other disciplines becomes meaningless.

The timing of this research coincided with the maturation of implementation science and 2012 saw the publication of the first text of its type "Dissemination and implementation research in health: Translating science to practice" (Brownson, Colditz & Proctor, 2012), written by leaders in the field. In the preface, the authors write, "The target audience for this text is broad and includes researchers and practitioners across many different discipline, including, epidemiology, biostatistics, behavioral science, economics, medicine, social work, psychology, and anthropology" (p. xiii). Of course this statement begs the question, why nursing is not included, a discipline that has been hugely involved in implementation in health care. It is the opinion of the researcher that the apparent lack of social work in one important document/collaboration and nursing in the other points to interprofessional exclusionary practices that must be identified, addressed and resolved.

It is well documented that patient outcomes are negatively affected when disciplines cannot work and do not work together. If ***we*** (researchers, clinicians, academics, health care workers, practitioners, etc. – who are simultaneously patients) cannot see and acknowledge the damage caused by interprofessional exclusionary practices and work together to create something bigger and better, we will remain stuck and bankrupted with our broken, fragmented, siloed system. While ***we*** say ***we*** want to improve health outcomes and change practice patterns, ***our*** behaviors seem to work against this goal. This study has demonstrated that it could be otherwise and that the many, diverse, and specialized practices needed to provide quality care and improve health outcomes are interdependent. ***We*** need to keep moving in this direction.

Study Limitations

Conducting insider AR, knowing the culture, the people, and the context provides for many study benefits (access, familiarity, influence) but also poses limits on a variety of levels. First, there is the limit of overfamiliarity, where the insider has too much knowledge about the setting and people and too many assumptions which may lead them to jump to conclusions or be unable to listen and learn. This is most definitely a concern and was addressed through accessing various types of advisements that facilitated reflection and brought awareness to these issues, so that assumptions and biases could be monitored and managed. Another insider limitation is the possibility that some co-workers would be reluctant to give certain opinions, especially negative ones, possibly leading the researcher to develop a distorted image. This was addressed by having prolonged involvement with participants, organizing a range of feedback processes and working on interpersonal interactions that engendered and welcomed friendly critique. It was also addressed with ongoing advisement, in particular ongoing exploration of the researches purpose and perspectives. However, it remains a limitation.

The one-year time frame in which the study was carried was an arbitrary determination by the researcher. She decided one year based on not wanting the team or organization to feel rushed and to give the staff time to adapt to the idea that buprenorphine treatment was coming. She was hopeful that for those who had some ambivalence, reticence, or resistance, over the year they might change their mind, and many did. While the research goal of implementing IBT/P was achieved, it is unclear what might be the best time frame for such a study and this is a limitation. Also, AR outcomes apply only to the local setting and this is another limitation of the study. Nevertheless, this does not mean that there is nothing in the study that is applicable to others. As noted earlier, the thick descriptions of the research context, stages and phases,

relationships, activities and events presented, “makes it possible for people who were not part of the study to make judgments about whether or not the situation is sufficiently similar to their own for the outcomes to be applied” (Stringer, 2007, p. 59).

This study is also limited in that it failed to develop a plan to evaluate the implementation, intervention and patients and produce outcomes in these areas. As discussed in chapter 5, this was a result of competing organizational priorities. The failure to do so draws attention to the need of having an evaluation plan in place prior to starting an implementation research project. Planning to develop an evaluation plan as part of the implementation project proved to be an ineffective, was a limiting factor, and the researcher recommends against this practice. Also, while it is recognized that treating addiction is a form of HIV prevention (Schackman, 2010), the fact that the study was conducted within HIV primary care may be limitations in its application to other clinical settings.

Appendix A

Outline: Interdisciplinary Buprenorphine Treatment/Practice Manual

16 Topics

1. Background on Buprenorphine Practice-Focused, Action Research, Implementation Study
2. Literature/Materials Guiding Development, Installation & Implementation of Interdisciplinary Bupe Practice
3. Therapeutic Alliance & Motivational Interviewing
4. Bupe Eligibility, Polysubstance Use, Referrals & Appointment Making
5. Bupe Patient Education, Screening, How Bupe is Provided - Phases of Treatment, Resources & Referrals
6. Bupe Treatment Agreement
7. Bupe Administrator Practice
8. Bupe Physician & Nurse Practitioner Practice
9. Bupe Social Work Practice
10. Bupe Nursing Practice
11. How Does Bupe Work?
12. Opioid Safety – Bupe Diversion, Prevention & Patient Monitoring
13. Visit Frequency & Urine Toxicologies in Bupe Practice
14. Methadone Transfer, Precipitated Withdrawal, Bupe Taper
15. Pain Management Strategies for Patients Taking Bupe
16. Bupe Documentation, Billing, Record Keeping, DEA Visit

Appendix B

Constructs of Consolidated Framework for Implementation Research Defined

I. Intervention Characteristics

A. **Intervention Sources**: Interest in buprenorphine implementation is internally driven by the researcher.

B. **Evidence Strengths & Quality**: There is strong evidence regarding the quality, safety and efficacy of buprenorphine and the research is designed to spend a considerable amount of time devoted to buprenorphine training.

C. **Relative Advantage**: Participants will be educated about the meaningful qualities of buprenorphine and it's the potential to make a significant impact on service users lives.

D. **Adaptability**: Some aspects of buprenorphine treatment have a high degree of adaptability and other aspects are nonnegotiable. The team is authorized by the director to decide collectively about how the treatment/practice will be delivered.

E. **Trialability**: The director agreed to a small scale start up and this will be presented to the team so as to gain confidence and ally fears about being overwhelmed with large number of patients.

F. **Complexity**: Buprenorphine treatment, particularly IBT/P, is a highly complex intervention, which is expected to require numerous and intricate steps to implement. The research is designed to devote a significant amount of staff training and education to buprenorphine and to reorientation of routine processes as well as the development and installation of new processes, to bring the intervention to fruition.

G. **Design Quality and Packaging**: Multiple evidence-based practice and best practices related to addiction treatment (buprenorphine, therapeutic alliance, motivational interviewing, transtheoretical model, action planning and readiness assessment) will be bundled together to support comprehensive, quality, interdisciplinary buprenorphine treatment. The team already uses several of these practices, will be trained in their application to IBT/P so as to increase their clinical capacity, skill set and confidence in addressing addiction treatment.

H. **Cost**: Resources for the staff to participate was determined by the researcher at the outset of the study and was agreed to by the director as available and accessible. Buprenorphine treatment is a billable practice and a revenue generating service for the organization; specifics about billing and reimbursement rates for the treatment of opioid dependence/addiction in primary care will be undertaken and explicated in the early phases of the study.

II. Outer Setting

A. Patient Needs & Resources: It was assessed that there was only a small internal patient need but a potential larger external patient need that could engage new patients in treatment at the organization.

B. Cosmopolitan: The organization is networked within a larger medical center that includes comprehensive addiction services, both inpatient and outpatient. The organization also has linkages to a range or community based organizations.

C. Peer Pressure: Key peer organizations have not implemented buprenorphine treatment, making this implementation research potential for recognition and model replication.

D. **Extended Policy & Incentives**: There are no external policies, regulations, mandates, or incentives to provide buprenorphine treatment. Federal, state and city buprenorphine guidelines have been developed. There are also a series of best practices and recommendations published by various professional organizations which can be used to guide practice.

E. **Inner Setting**

A. **Structural Characteristics**: The organization's structural characteristics were described at the beginning of this chapter. There is a long standing "Shared Care Model" of HIV primary care and social work case management. Social workers and physicians at the research organization have the greatest number of clinicians compared with other disciplines.

B. **Networks & Communications**: The nature of the social networks of the staff tend to be discipline specific: administrators, care coordinators, dental staff, integrative medicine staff (acupuncturists, massage therapists, health educators, nutritionists) primary care providers (MDs, NPs, & PAs), mental health staff (MDs, NPs, PhDs), registered nurses, social workers. There are several formal interdisciplinary meetings and educational sessions each week. There is also an open door policy for any staff to interact, seek advice, and coordinate care with any other staff member. There are also organization parties, picnics, and outings throughout the year.

C. **Culture**: The organization prides itself on providing a wide range of high quality treatment and service with a focus on providing nonjudgmental, harm reduction focused, patient centered care. All discipline directors are engaged in both administrative work and direct patient care. There is a high level of commitment

from the staff to treating and preventing HIV from a biopsychosocial perspective and interdisciplinary care is a well-established practice. The organization provides financial and scheduling support for staff to participate in continuing education, conference attendance and/or presentations. There is a strong history of innovative programing, grant funding, peer and consumer advisory involvement and ongoing research and publications. And, as discussed in chapter 1, diversity in many forms is an important aspect of the research organization's culture.

D. Immediate Climate

1. **Tension for Change**: There is neither tension for change nor any immediate clinical issue to be resolved relative to implementing buprenorphine.
2. **Compatibility:** Treating opioid dependence/addiction fits with preventing HIV as well as a way to engage people in treating HIV. Addressing addiction in general has long been a part of treating HIV, and buprenorphine is an extension of the organizations existing practice. There are several aspects of buprenorphine treatment that do not fit with existing workflows and systems and new processes will need to be developed and installed.
3. **Relative Priority**: There is general agreement among staff that alternatives to MMTPs are important, but there is no shared perception of importance to implement buprenorphine over other new treatment or services.
4. **Organizational Incentives & Rewards:** There are no extrinsic organizational incentives or rewards to participate in being part of the interdisciplinary team. There is a respect from leadership for staff that take up new practices, learn new

skills and deliver evidence-based treatments. Individual team members report an interest in skill building and participating in innovative treatment.

5. **Goals & Feedback**: Goals and objectives of research and implementation (see chapter 1) will be clearly communicated. Multiple and varied plans for information sharing, staff input and feedback are planned.
6. **Learning Climate**: Researcher/facilitator stance is planned to promote the benefits of collaborative and cooperative processes. The researcher will stress that she was not the all-knowing authority. The majority of decision making regarding the IBT/P will be determined by the team. The researcher/facilitator will convey to team that they were valued, knowledgeable partners in the change process. This will be done not just in words but in behaviors about how the implementation process proceeds. Education and implementation will be process oriented and enrollment of patients in treatment will be low and slow with an emphasis on sufficient time for reflective thinking and evaluation.

E. Readiness for Implementation: There are many indicators of organizational commitment to the implementation of buprenorphine.

1. **Leadership Engagement**: The organization director and several others in leadership have reported both to the researcher and at larger staff gathering their support for bringing IBT/P to the organization.
2. **Available Resources**: Clear levels of resources from the organization (training, education, physical space, time, liaison activities) have been agreed to by the organization director for the purposes of implementing buprenorphine. There is a clear level of researcher commitment to the project.

3. **Access to Knowledge and Information**: An extensive resource of buprenorphine literature will be provided to the team by the researcher (see IBT/P Manual – Bupe Literature, Topic 2). A clear plan for knowledge transfer from the researcher to the team, from team member to each other, as well as organizing and attending outside buprenorphine training and education will allow for ease of access to information and overall capacity building for the staff and agency.

III. **Characteristics of Individuals**:

A. **Knowledge & Beliefs about the Intervention**: Mixed attitudes from the staff exist regarding buprenorphine implementation. Some staff report an interest in more directly treating addiction, while others relay an interest in learning and becoming familiar with facts, truths and principles related to buprenorphine; however, they did not want to participate in treating opioid dependence/addiction.

B. **Self-efficacy**: There are varied beliefs in capabilities to execute course of action to achieve buprenorphine implementation.

C. **Individual Stage of Change**: There are varied baseline skills and enthusiasm related to buprenorphine treatment.

D. **Individual Identification with Organization**: There are varied perceptions of individuals' relationship to the organization, with an overall high level of commitment to quality patient care and HIV prevention and a varied commitment to addiction treatment.

E. **Other Personal Attributes**: There is varied tolerance for ambiguity, intellectual ability, motivation, values, competence, capacity and learning style.

IV. Process

A. Planning: There is extensive planning by the researcher regarding methods of behavior and tasks for implementation. The researcher has extensive knowledge of buprenorphine and implementation.

B. Engaging: The processes and behaviors to engage leadership and team members throughout the study included: friendly encouragement, role modeling, process oriented activities, continuous information sharing, high availability and accessibility of researcher.

1. **Opinion Leaders**: The researcher/facilitator will seek out and engage known opinion leaders who have formal and informal influence relative to implementing buprenorphine. The plan for interdisciplinary staff involvement will focus on capacity building, knowledge sharing and power sharing.
2. **Formally Appointed Internal Implementation Leader**: The researcher will champion the buprenorphine implementation.
3. **Champions**: The researcher/facilitator is a longtime staff member and is strongly identified as "the champion" who is dedicated to implementing buprenorphine in a collaborative and cooperative fashion. The researcher/facilitator is dedicated to addressing indifference or resistance that buprenorphine provoked in some members of the organization. The research design is dedicated to engaging the team in skill building, decision making, knowledge sharing and power sharing as a means to produce high quality IBT/P.

C. **External Change Agents**: The researcher will engage individuals who are established buprenorphine leaders, affiliated with outside entities, to contribute knowledge regarding buprenorphine treatment and she will work to share that knowledge with the team. This is expected to influence the IBT/P in the research organization**.**

D. **Executing**: All practice, policy and research goals and objectives, are outlined in chapter 1. It is expected that IBT/P will commence in Clinic 1 and 2 in June 2011.

E. **Reflecting & Evaluating**: The researcher has planned team, staff and leadership information sharing and feedback in a process oriented fashion to allow for sufficient reflection about the development and installation of the IBT/P. Participants will continually be invited to be involved in developing a plan to evaluate the buprenorphine treatment and the implementation. The researcher will seek out funding options to evaluate buprenorphine treatment and implementation as well as supporting expanding buprenorphine training to the larger staff, outside the IBT/P team.

Appendix C

Force Field Analysis
Implementing buprenorphine within into HIV primary care

Critical & Facilitating Actors:
Intended and Unintended Consequences

Potency & Amenability

Driving forces for change	H-M-L-U	H-M-L-U	Restraining forces against change
1. Ideology -H/H			1. Space – H/L
2. Revenue Generating Treatment-H/L			2. Staff acceptance -H/H
3. New Ct base – increase numbers - H/H			3. Training –L/L
4. + Impression for the from DOH (city and state) – H/H			4. Admin/Legal –M/U
5. Established Buprenorphine Grant Proposal -M/H			5. Will grow too fast-M/M
6. New Division - U			6. New Division - U

REFLECTIVE COMPONENT

Treatment Force Field

Positive	Unknown	Negative
1. Commitment to a segment of the HIV+ population who would benefit from this treatment option.	1. Services: min required/expanded	1. Stigma & Myths
2. Stories from Europe very compelling	2. Treatment planning – diff process	2. Env. Disruption
	3. Toxicology Issues	3. Colonial Project
	4. Tx termination & primary care	
	5. Patient participation	
	6. Evaluation of Program	
	7. Will program include involuntary pts??	
	8. Involvement with criminal justice??	

H – High
M - Medium
L - Low
U - Unknown

Appendix D

Environmental Assessment: Forces Influencing Stability and Change

Implementing Buprenorphine within HIV Primary Care

Economic - ACA 2010

(1. Financing, 2. Technology)

1. Revenue: Medicaid 75% ADAP 10% Medicare 10% PI 5%
   New Medicaid SNPs & APGs Managed Care
   State, Federal & Foundation Grant Funding
   New Division
   2009: HIV Negative h/o Incarceration

2. Information Technology
   Hospital & Research Org Technology / EMR
   Other

Political– ACA 2010

(1. Sentiment Systems, 2. Powerful Actors)

1. Research Org within large urban medical center
   Commitment to substance use/addiction treatment
   MMTPs - New Division

2. Director, Leadership & Staff of Research Org
   Individuals & Communities affected
   Leadership of Hospital
   Leadership City, State, Federal DOH
   Buprenorphine Researchers

Internal Structure and Processes

1. Ideology	2. Goals	3. Structural Factors
Progressive	Quality Care	Space Limitations
Include pts	Increase pt base	Unions
in Operations	Research	Regulatory Issues
	Address Stigma	Staff Time
		New Division

Meaning to Research Org Participants

1. Actor Definitions	2. Preferences & Commitments
Manifest & Latent Roles	High Commitment to:
3 Clinic Environments	HIV Care - Collaboration
similarities & differences	Professional Codes
	Social Justice
	+/- Drug Use - Addiction

Appendix E
Buprenorphine Curriculum – Social Work Training

I. Opioids
A. Receptors
B. Full Agonist
C. Partial Agonist (Agonist – Antagonist)
D. Antagonist
E. Ceiling Effect
F. Drug – Drug Interactions
G. Overdose Prevention

II. Substance Use Disorder
A. DSM IV Criteria for Substance Use Dependence
B. Opioid Dependence
C. Tolerance
D. Withdrawal
E. HIV Prevention

III. Screening
A. DSM IV / Other
B. Parameters of Care
C. Readiness for Change
D. Insurance
E. Referral

IV. Buprenorphine Treatment
A. Pre-Induction
B. Induction
C. Stabilization
D. Maintenance
E. Discontinuation of Treatment

V. Specialty Subjects
A. Urine Toxicology
B. Pain Management
C. Pregnancy
D. Liver Disease
E. Family Issues
F. Legal Issues
G. Diversion Issues
H. Motivational Interviewing
I. Other

Appendix F: Interview Guides Approved by IRB

1. Interview Guide: Key Informant Leadership at Research Organization

- Thank you for speaking with me about our developing and implementing a buprenorphine treatment/practice. May I ask you to please sign the consent form as this interview is being used for research and as discussed it will be audio recorded.
- Review consent form and answer any questions, then begin recording.
- As discussed we have set aside about x minutes to speak and I have prepared a series of questions related to the topic. The format is open with some structure. I am interested to hear what you think about buprenorphine and the plan to implement it here as well as thoughts you may have about buprenorphine that may not covered in the prepared questions or as different issues come up.

1. First I am interested what you know of buprenorphine programs or practices here in NYC, elsewhere? How they got started, how do they work, pt populations, finances?

2. In terms of our bup program development, are there any specific ideas you have that you think are important to a successful program or a specific way that you think the treatment should be delivered/administrated? Referrals, linkages, etc?

3. Are there any specific people you think I should speak with or any specific texts (regulations, guidelines, etc) that should be consulted that could help with developing a successful program?

4. What do you see as the biggest barriers/facilitators to buprenorphine integration?

5. What do you know about financing/billing for bup? Here in NYC, elsewhere?

6. What kind of community liaison work do you think is important relative to a successful buprenorphine program? Specific people/programs? What do you think about mandated pts?

7. Do you have any concerns about integrating a buprenorphine program? Anything specific about SLRHC that you think is important to know?

8. Is there anything in this dialogue that we did not cover that you would like to mention/discuss? Are there any questions you have of me that you would like answered?

2. Interview Guide: Key Informant Outside Research Organization Adapted Over Time

- Thank you for speaking with me about developing and implementing buprenorphine.
- May I ask you to please sign the consent form as this interview is being used for research, and as discussed and it will be audio recorded.
- Review consent form and answer any questions, then begin recording.
- As discussed, we have set aside about x minutes to speak and I have prepared a series of questions related to the topic. The format is open with some structure. I am interested to hear what you have to say about buprenorphine and implementation, as well as thoughts you may have about buprenorphine that may not covered in the prepared questions or as different issues come up.

1. First I am interested to hear how is your program going? How it got started - Where it is - Patient Population - Successes –Problems – Model – Staff – Finances – Referrals – Linkages – Mandated Pts – Etc.?

2. What kind of community liaison work do you think is important relative to a successful buprenorphine treatment/practice? Specific people/programs?

3. Are there any specific people you think I should speak with or any specific texts (regulations, guidelines, etc) that should be consulted that could help with developing a successful program? What do you know about other programs here in NYC?

4. What do you see as the biggest barriers/facilitators to buprenorphine integration at the CCC?

5. What can you tell me about financing/billing for bupe? Here in NYC, elsewhere?

6. In terms of developing bupe treatment, are there any specific ideas you have that you think are important to a successful program or a specific way that you think the treatment delivered/administrated? Referrals, linkages, etc?

7. How do things work with reporting – dealing with regulators, etc? What has been your experience? – Other programs experiences?

8. Is there anything in this dialogue that we did not cover that you would like to mention/discuss? Are there any questions you have of me that you would like answered?

3. Interview Guide: Key Informant – Staff at Organization (not on bupe team)

- Thank you for speaking with me about the developing buprenorphine treatment/practice.
- May I ask you to please sign the consent form as this interview is being used for research as discussed and it will be tape recorded.
- Review consent form and answer any questions, then begin taping
- As discussed we have set aside about x minutes to speak and I have prepared a series of questions related to the topic. The format is open with some structure. I am interested to hear what you have to say about buprenorphine and the plan to implement it, as well as thoughts you may have about buprenorphine that may not covered in the prepared questions or as different issues come up.
- Let me tell you briefly where we are with the implementation (Give update).

Background

1. Basics - Few closed ended questions?
   -Position/Degree/License: MD - NP – PA, etc.
   -Years in practice/at clinic

Experience/Knowledge

2. For Prescribers: Are you currently prescribing buprenorphine ?
   -what has been your experience? how do you do this? what were the processes involved? glitches? issues?
   (looking for processing interchanges)
3. How did you first come to learn about buprenorphine?
   -what was going on at the time?
   -in training?
   -mentors or others who prescribed buprenorphine?
   - community work?
   -discussed at conference?
   -patient request?
   -other?
   -what kinds of questions did it raise for you?
4. What do you think now abut buprenorphine compared to when you first learned?

Experience

6. Have you discussed buprenorphine with any patients?
   - how did you do this?
   - do you know of any patients receiving buprenorphine treatment?
   - what do you think it means to the patient compared to other interventions?
   - have you ever made referrals for buprenorphine?

   For Prescribers:
   - have you had any patients request buprenorphine?
   - how would you describe your patients knowledge of buprenorphine?

Opinion

7. What do you think about integrating buprenorphine here in our organization?
   - how do you see this happening?
8. What do you think others think?
   - colleagues, leadership, others?
   -in your estimation, what accounts for that perception?
9. Can you tell me about any concerns you might have about implementing buprenorphine treatment?
   -clinic, professional, legal?
   -can you talk about any opposition to buprenorphine that you have encountered?

Sensory

10. What are some of the tensions / challenges that come up with buprenorphine?
    -what do you think are the biggest barriers to buprenorphine?

Ending

11. Is there anything in this dialogue that we did not cover that you would like to mention/discuss?

4. Interview Guide: Patient Focus Group

- Thank patients for attending.
- Review and obtain consent for research – read aloud and answer any questions that informants may have.
- Brief review of the research project and parameters of the focus group.
- Review with informants you are interested to have them discuss a range of information related to their treatment for opioid dependence.
- Interested to know how opioid treatment is or is not working in their life – what they are doing in their everyday life related to their treatment for opioid dependence/addiction – what they know and what they think about buprenorphine.
- Ask for Introductions and explain focus group process and your role as facilitator.

Background

1. Basics

-Current treatment for opioid dependence/addiction ?

-What has been your experience? how do you do this? what are the processes involved? glitches? issues?

Experience/Knowledge

2. What is your knowledge related to alternative treatments to methadone?
3. Have you heard about buprenorphine treatment?

-Where/when did you hear? What was going on at the time?

-What kinds of questions did it raise for you?

Feeling/Emotions

4. What was your reaction when you learned about buprenorphine as an office-based practice option?

-Flesh out - history, biography

-Have you discussed or heard others discussing buprenorphine?

5. How do you feel now abut buprenorphine compared to when you first learned?

Experience

6. Have you discussed buprenorphine with any of the staff where you are treated for opioid dependence or for HIV?

- how did you do this?

7. Do you know of any patients receiving buprenorphine treatment?

-describe how this is going for them

Opinion

8. What do you think about the idea of buprenorphine being offered here?
9. How do you think it might best be offered here?
10. What barriers do you think might make it so people would not want to have buprenorphine treatment here?
11. What do you think might make it desirable for people to have buprenorphine treatment here?

Ending

10. Is there anything in this dialogue that we did not cover that you would like to mention/discuss?

Appendix G: Glossary of Terms

AR	Action Research
AIDS	Acquired Immune Deficiency Syndrome
C/M	Clinical/Milieu
CFIR	Consolidated Framework for Implementation Research
CMIR	Consolidated Model of Implementation
CSAT	Center for Study of Addiction Treatment
CTN	Clinical Trial Network
CTP	Community-Based Treatment Programs
Bupe	Buprenorphine
DATA	Drug Addiction Treatment Act 2000
DAC	Designated AIDS Center
FDA	Federal and Drug Administration
GTM	Grounded Theory Method
HIV	Human Immunodeficiency Virus
IE	Institutional Ethnography
IBT/P	Interdisciplinary Buprenorphine Treatment/Practice
IP	Inter(ra)personal
MSW	Masters of Social Work
MD	Medical Doctor
MMTP	Methadone Maintenance Treatment Program
NIDA	National Institute of Drug Abuse
NIH	National Institutes of Health
NYC	New York City
NYC DOH MH	New York City Department of Health and Mental Hygiene
NYS DOH	New York State Department of Health
NPT	Normalization Process Theory
NP	Nurse Practitioner
PA	Physician Assistant
PhD	Doctor of Philosophy
RN	Registered Nurse
SAMHSA	Substance Abuse and Mental Health Services Administration

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