



Development of IT-enabled Chronic Care Management for the Medically Underserved: A Contextualist Framework

Darryl Romanow

Center for Process Innovation
Robinson College of Business
Georgia State University
darryl.romanow@ceprin.org

Lars Mathiassen

Center for Process Innovation
Robinson College of Business
Georgia State University
lars.mathiassen@ceprin.org

Glenn Landers

Georgia Health Policy Center
Andrew Young School of Policy Studies
Georgia State University
glanders@gsu.edu

Chris Parker

Georgia Health Policy Center
Andrew Young School of Policy Studies
Georgia State University
chrisparker@gsu.edu

Abstract:

While efforts to address the management of chronic diseases in the context of large, urban hospitals are underway, the literature is silent on how to facilitate such efforts in the community clinics that provide services to many chronic-care patients who are medically underserved. We offer a contextualist framework for developing IT-enabled chronic care management in community clinics. To understand and support the required collaboration between diverse stakeholders located across institutional boundaries, the framework adapts Pettigrew's Contextual Inquiry as the overarching analytical lens. The framework focuses on the *context* of community clinics, including patients, clinicians, administrators, technology providers, and institutional partnerships; it considers the *content* of developing IT-support based on the Chronic Care Model, and, as basis for the development *process*, it adapts Holtzblatt and Beyer's Contextual Design principles. We demonstrate the workings of the framework through a case study of how IT-enabled support for chronic care management was designed and implemented into a community clinic in the Southeast U.S. over a three-year period, and, finally, we discuss its theoretical and practical implications in relation to extant literature.

Keywords: contextualist framework, IT development, chronic care management, electronic health record

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INTRODUCTION

Healthcare in the U.S. represents a large and growing portion of the GDP, with 2007 per capita spending rising to \$7,421, or 16.2 percent of GDP (Hartman et al. 2009), and chronic diseases are the leading cause of death, consuming roughly 75 percent of all health expenditures (www.cdc.gov/chronicdisease/resources/publications/AAG/pdf/chronic.pdf). To improve management of chronic patients over long periods of time, clinicians have investigated more holistic treatment methodologies, such as the Chronic Care Model (CCM) (Wagner et al. 2001). The CCM is based on six critical elements: (1) community resources with linkages to other healthcare agencies, (2) self-management support to inform, educate, and engage patients, (3) leadership focus on quality of care within provider organizations, (4) delivery system design to ensure coordination between providers for a given patient, (5) evidence-based decision support, and (6) clinical information support for managing lifelong chronic conditions. Developed more than a decade ago, the CCM has become widely adopted in the U.S. and around the world (Coleman 2009). However, to date, research on the CCM has focused on the effectiveness of the CCM in larger healthcare system settings, with little emphasis on smaller primary care facilities that lack the formal infrastructure to support quality improvement efforts (Strickland et al. 2010).

Based on the CCM, several types of Health Information Technology (HIT) are critical enablers of improving chronic care management. Electronic Health Records (EHR) can help institutions manage and share chronic care data. While the promise of the EHR has been espoused for over forty years, their adoption in North America has been limited (Goldschmidt 2005, Simon et al. 2007). More recently, clinical support systems incorporating evidence-based medicine have been integrated into some EHR systems. These systems aim to leverage patient information into recommendations, with the results provided to clinicians in a timely fashion, often in the form of alerts and reminders (Austin et al. 1994). Although these tools are supportive of chronic care management, the predominant share of provider organizations has not yet adopted them (Simon et al. 2007, Yu et al. 2009). Focusing on chronic care patients, personal health records (PHR) are also important. These systems interact with the providers' EHR systems, but there are challenging issues related to the security and confidentiality of records shared via the Internet (Grimson 2001, Pratt et al. 2006, Tang et al. 2006, Halamka et al. 2008) and significant uncertainties relate to who interacts with these systems, what the quality of the clinical data is, and how patient interaction with the PHR impacts health (Agarwal et al. 2010). Hence, effective implementation of the CCM requires integration of several types of HIT and is further complicated by the context of chronic care patient management, which by nature is distributed throughout a community and involves multi-organizational, multidisciplinary stakeholders (Rigby 1999).

Against this backdrop, we report from a case study (Yin 1984) of a three-year project to develop an information technology (IT)-based Chronic Disease Prevention and Management (CDPM) system in the Southeast U.S. The project was initiated by the Centers for Disease Control (CDC), with the intent of improving management of chronic-care patients located in rural or underserved areas. Medically underserved individuals or groups are defined as those who do not have adequate access to primary care (Hawkins and Rosenbaum 1993), including at least 65 million people in the U.S. (Riselbach et al. 2010). Roughly 8000 Community Health Centers (CHC) across the U.S. provide the safety net for many of the medically underserved Americans (Adashi et al. 2010). The growing importance of these centers is highlighted by the expectation that CHCs will serve 30 million Americans by 2015, and 51 million by 2022 (Riselbach et al. 2010).

CONTRIBUTION

Our investigation into *CareTech's* design and implementation of the Chronic Disease Prevention and Management system at *Alpha* provides contributions to current knowledge on how to design IT support for chronic-care management from a contextual point of view. Combining Pettigrew's Contextual Inquiry (1990) with Holtzblatt and Beyer's Contextual Design principles (1993, 1999) and Wagner's Chronic Care Model (2001) helped us understand how *CareTech* approached the design and implementation efforts as they collaborated with *Alpha* to develop a solution suited to their practices and the needs of the local community. The resulting analysis of the design experience confirm existing knowledge on contextual design of IT support for chronic care management and offers new insights that can prove useful as support for future practices.

We worked closely with a small IT-provider, *CareTech* (pseudonym), and two community clinics, *Alpha* and *Beta* (pseudonyms) to study the development of the CDPM system. While *Beta* eventually decided not to implement the system, the clinic played a key role in the initial focus groups and early design of the system. To design useful IT-support, *CareTech* needed to understand the needs of the two clinics and their chronic patients and in particular the complex challenges related to ensuring collaboration across institutional boundaries and between involved stakeholders, including clinicians, administrators, patients, and technologists. Access to rich data from this project allowed us to investigate the following research question:

What are the challenges related to developing IT support for chronic care management in community clinics, and how are these challenges addressed?

Motivated by the complex context of developing IT support for chronic care management in community clinics, we utilize Pettigrew's Contextual Inquiry (1990) as our overarching analytical lens. The project evolved within the *context* of the two resource-constrained clinics which predominately provide indigent care for patients in their communities. The *content* of the effort focused on transformation of a paper-based system to an electronic record that would allow stakeholders to interact in new ways, and, as a framework for understanding the broader areas involved in improving chronic care management, we adopt the CCM. To study the development *process*, we modified Holtzblatt and Beyer's (1993, 1999) Contextual Design principles to make sense of the interactions between the content of chronic care management, the context at the community clinics, and the development process led by *CareTech*. Based on our analysis, we show how the multi-organizational, multidisciplinary, and distributed nature of chronic care management combined with lack of resources for and experiences with technological innovation in the community clinics created challenging conditions for IT design and implementation. In addition, we offer a Contextualist Framework to inform future collaboration efforts to design and implement IT support for the complex context of chronic care management in community clinics.

IT-ENABLED CHRONIC CARE MANAGEMENT

Focusing on IT-enabled chronic care management, we reviewed the literature with a particular emphasis on providing IT-support for the CCM (Wagner et al. 2001). There are three primary sources within the Health IT literature: the mainstream IS literature on healthcare, the health administration literature on health informatics and chronic care management, and the software design literature specifically focused on Health IT. From these diverse sources, we identified four research-topic areas that are supportive of our cumulative understanding of IT-enabled chronic care management, namely stand-alone HIT systems, integrated HIT systems, HIT implementation, and finally Chronic Care Model enabled IT systems. Table 1 below provides a summary of our literature review.

There is a steadily increasing research interest in how IT can be applied to innovate healthcare delivery. As HIT is complex, the literature typically focuses on individual systems, such as EHRs (Angst and Agarwal 2009, Bell and Anil 2001), PHRs (Grimson 2001, Pratt et al. 2006, Tang et al. 2006, Hamalka et al. 2008, Agarwal 2010) or CPOE systems (Lapointe and Rivard 2005, Davidson and Chismar 2007, Cho et al. 2008). These studies reveal some insights that are relevant for IT-based chronic care management. Functionality provided by these systems often overlaps, as drug-to-drug interaction alerts and decision support mechanisms can be found in the EHR, PHR, or CPOE system, depending on the software provider or implementation preference at the clinical site (Agarwal 2010).

EHRs are digital versions of traditional paper-based medical files, but the literature suggests fundamental progress has been inhibited by privacy concerns (Angst and Agarwal 2009, Goldschmidt 2005, Huston 2001, Rindfleisch 1997) because EHRs are perceived to be less secure and more open to abuse than its paper counterpart. Also, despite the development of industry standards such as HL7, interoperability concerns still play a central role because there is no widespread adoption of common standards to enable sharing of medical data across provider systems and institutional boundaries (Grimson 2001, Goldschmidt 2005). While the EHR is owned and maintained by individual medical practices in both acute care and ambulatory settings, the PHR is controlled by the patient (Grimson 2001, Pratt et al. 2006, Tang et al. 2006, Hamalka et al. 2008, Agarwal 2010). A Google Health record is an example of a free version of a PHR that was discontinued in late 2011.

Just over a decade ago, the Institute of Medicine published a watershed report, *To Err Is Human: Building a Safer Health System* (Kohn et al. 2000), which estimated that up to 98,000 American lives are lost annually due to preventable medical errors. The report fully supported the use of CPOE systems as a solution to the problem, and subsequent research has often confirmed that CPOE enables both improved clinical outcomes (Garg et al. 2005, McCullough et al. 2010) and reduced costs (Hillestad et al. 2005). CPOE is defined as a computer-based system that allows a clinician to directly enter medical orders based on best practices (Simon et al. 2007); once orders are entered, the system provides clinicians with potential drug interactions and a patient status tracking mechanism (Hillestad et al. 2005). While CPOE holds the promise of favorable outcomes, full adoption of CPOE remains limited to just 8 percent of U.S. hospitals (Yu et al. 2009). In fact, research has often revealed strong clinician resistance to



the decision support and standardization of care mechanisms inherent to these systems (Kohli and Kettinger 2004, Lapointe and Rivard 2007, Kane and Labianca 2011).

Table 1 Background Literature for IT Enabled Chronic Care Management

<i>Research Area</i>	<i>Description</i>	<i>Relevant Issues</i>	<i>Key References</i>
Stand-alone HIT	Papers in which individual applications such as EMR, CPOE, and PHR are studied in isolation, rather than as a comprehensive system	Resistance to HIT by clinicians	(Rigby 1999, Lapointe & Rivard 2007, Kohli & Kettinger 2004, Kane & Labianca 2011)
		Privacy concerns – electronic records are perceived to be less secure than paper records	(Angst & Agarwal 2009, Goldschmidt 2005, Huston 2001)
		CPOE allows acute care clinicians to enter patient medical orders into a computerized tracking mechanism, rather than relying on a bedside medical chart	Kohn et al. 2000, Garg et al. 2005, Hillestad et al. 2005, Lapointe & Rivard 2005, Davidson & Chismar 2007, Cho et al. 2008 McCullough et al. 2010)
		EHR as a digital version of the patient medical chart	(Goldschmidt 2005, Simon et al. 2007, Angst & Agarwal 2009)
		PHR as a digital record of the patient's medical history owned by the patient	(Grimson 2001, Pratt et al. 2006, Tang et al. 2006, Hamalka et al. 2008, Agarwal 2010)
		Interoperability issues between provider systems limit the ability of providers to share data across institutional boundaries	(Grimson 2001, Goldschmidt 2005, Lumpkin & Richards 2002)
Integrated HIT	Papers focused on fully integrated systems in which EMR and PHR are enabled by decision support to provide patient centered care	Patient self-monitoring and reporting within Veteran's Administration Hospitals	(Coye et al. 2009)
		Provider adoption of an HIT including decision support for chronic diseases	(Simon et al. 2007)
		HIT impact on underserved communities	(Effken & Abbott 2009)
HIT Implementation	Papers focused on issues in IT implementation in a healthcare context	Changes in medical practice routines can lead to unintended consequences	(Anderson 1997, Lapointe & Rivard 2005, Han et al. 2005, Niazkhani et al. 2009)
		Complexities related to infrastructure challenges in developing countries	(Braa et al. 2004, Braa et al. 2007)
Chronic Care Model Enabled HIT	Papers investigating the integration of the Chronic Care Model with IT enabled chronic care	The Chronic Care Model is a patient centered system of care across provider organizations. Coleman finds 944 publications incorporating the model over the past 10 years	(Wagner et al. 2001, Coleman et al. 2009, Strickland et al. 2010)
		Home health monitoring systems which incorporate HIT systems using the Chronic Care Model principles	(Pagnelli & Guili 2011)
		Telemedicine as a home healthcare enabler, using CCM principles	(Toledo et al. 2006, Kirsch et al. 2006)

While the stand-alone HIT literature offers useful insights, these studies do not provide an integrated IT-enabled approach to chronic disease management. Considering research within the integrated HIT literature, Coye et al. (2009) offers an interesting study of IT-enabled decision support and remote patient monitoring in the context of the Veterans Health Administration. The study demonstrates the feasibility of improving chronic care management through technologies that cross institutional boundaries and relies on multiple functionalities. Specifically, this system allowed physicians to make decisions based on patients' remote self-monitoring and reporting of their chronic disease status, and the system demonstrated improved outcomes by reducing the number of required emergency room visits. Also, Simon et al. (2007) focus on provider adoption of decision-support systems for chronic care management. Based on data from multiple contexts, they suggest antecedent conditions for adoption of such technologies, including external reporting incentives and the size and location (urban or rural) of the health institution. Both of these studies emphasize that chronic care management by nature is multi-organizational, multidisciplinary and distributed throughout a community, and integration of IT, therefore, poses very specific challenges (Rigby 1999). In fact, despite the expected benefits yielded by integrated HIT support, half of these innovations fail due to staff resistance (Rigby 1999).



Effken and Abbott (2009) provide a study of the impact of Health IT-enabled care for underserved communities from a nursing perspective. Within the underserved context, they emphasize the importance and promise of PHRs when integrated with provider EHRs, as these systems are able to improve patient confidence in self-care, improve trust with their provider, and assist in the adherence to disease management plans (Effken and Abbott 2009). Still, the emphasis in Coye et al.'s study (2009) is on outcomes in terms of reducing emergency room visits in chronic care management, and the emphasis in Simon et al.'s study (2007) is on antecedent conditions for successful adoption of HIT for chronic care management. And while the Effken and Abbott (2009) study is aligned with integrated HIT for the underserved, a focus on CCM principles is lacking.

Insights into the antecedents of clinician resistance and low adoption of HIT systems are evident in the HIT implementation literature. Through the implementation process, clinicians are often required to change their existing medical practice routines (Anderson 1997, Lapointe and Rivard 2005, Han et al. 2005, Niazkhani et al. 2009), which can lead to unintended consequences. In one study of a "Big Bang" CPOE implementation at a Pittsburgh pediatric hospital, these workflow changes coupled with an expedited implementation strategy led to a statistically significant increase in patient mortality (Han et al. 2005). Given the complexity of these systems, contextual implications such as local practices and available infrastructure must be integrated into HIT implementation strategy. This is especially apparent in clinical practices aimed at the underserved or in developing countries where local clinicians must improvise in the absence of the medical specialists and advanced technology that is commonplace in wealthy, urban centers (Braa et al. 2004, Braa et al. 2007). Finally, the literature suggests that clinician-led implementation teams, as opposed to administration- and IS-led teams, are a common prerequisite to the successful implementation of HIT (Kohli and Kettinger 2004, Davidson et al. 1999). Securing clinician support will emphasize positive patient outcomes as a key success factor, rather than simply focusing on reducing costs through efficiencies.

Within the medical literature, the CCM (Wagner et al. 2001) has gained widespread acceptance as a framework for chronic disease management. Coleman et al. (2009) confirm the ubiquitous nature of the CCM, as well as the minimal exposure in the literature afforded to the CCM from the perspective of smaller community providers. Their literature review found 944 publications referencing the CCM. Of these publications, they focused on eighty-two articles with empirical evaluation of interventions in which at least four of the six elements of the CCM were redesigned with the intention of improving ambulatory care. Their results show that experience with the CCM is limited to larger healthcare institutions, and they argue that limited IT resources and non-physician clinical staff will likely result in difficulties in implementing the CCM and driving improved clinical outcomes (Coleman et al. 2009, p. 281). As a result, a gap in the literature exists with respect to the integration of CCM principles in the context of smaller, resource-constrained community providers (Strickland et al. 2010).

Although the CCM model (Wagner et al. 2001) has been promoted as an important framework for improving chronic care management, few IS researchers have investigated how adoption of the model can be facilitated by IT. We reviewed the Computer Science and Engineering literature, specifically focused on biomedical IT, and several relevant papers emerged (Toledo et al. 2006, Kirsch et al. 2006, Paganelli and Guili 2011), including research into integrating the CCM principles and context-aware computing into system design (Paganelli and Guili 2011). The first two papers focus on the utilization of telemedicine as an enabler of home healthcare, while the third paper presents a prototype home monitoring system where patient environment and vital signs trigger biomedical alarms. Although Paganelli and Guili (2011) mention the interaction of the home monitoring system with patient record systems, the focus is not on the development of the EHR, PHR, or clinical decision-support systems themselves.

To summarize, there are numerous studies in the stand-alone HIT literature (cf. Chiasson and Davidson 2004, Cho et al. 2007) and the HIT implementation literature (Anderson 1997, Lapointe and Rivard 2005, Han et al. 2005, Niazkhani et al. 2009) that investigate specific aspects of IT support with relevance to chronic care management, including EHRs, PHRs, medication management, and decision support. However, we found no studies focused on how to design IT support for chronic care management. Considering the integrated HIT literature, we found a couple of studies specifically focused on HIT for chronic care management. However, none of these report from the context of community clinics, nor do they provide insights into the process of developing HIT for the complex context of chronic care management with many different stakeholders located across institutional boundaries.

Our research is focused on the challenges related to developing IT support for chronic care management in community clinics caring for underserved patient populations. While this context may seem narrow on the surface, this patient population is expected to be represented by 51 million Americans by 2022 (Riselbach et al. 2010), costing taxpayers hundreds of billions per annum. Hence, given the enormous cost of chronic care management and the recent promotion of the CCM (Wagner et al. 2001, Shortell 2007) to support informed patient-physician encounters, this study offers a detailed account of how the CCM and Contextualist Design can be applied to promote collaboration for IT-enabled chronic care management innovations in the context of community clinics with many underserved patients.

A CONTEXTUALIST FRAMEWORK

Theoretical perspectives can be classified as either variance or process models (Markus and Robey 1988), with the predominant share of IS research relying on variance theories (Radeke 2010). The HIT literature has often relied on mainstay variance models such as the Technology Acceptance Model (Davis 1989) or its derivatives, such as the Unified Theory of Acceptance and Use of Technology (Venkatesh et al. 2003). Yet contextual factors inherent to the healthcare domain render important variables, such as perceived ease of use, as not significant (Holden et al. 2010). By their nature, variance theories rely on an invariant relationship between antecedents and outcomes (Markus and Robey 1988) that might be too restrictive in real-world, complex environments. As an alternative, process theories attempt to explain how independent variables (context) shape the process under study and how the process affects outcomes (Radeke 2010). Process theories are more concerned with key events in an organization, and results from these key events can, in turn, be generalized to other settings.

As our study is focused on understanding the process of the development of IT for chronic diseases, we reviewed the literature for suitable process model alternatives. The use of Contextual Inquiry principles (Pettigrew 1987, 1990) has gained acceptance as a theoretical perspective on IS transformation (Avgerou 2001, Frederiksen and Mathiassen 2008). Using a contextual approach to HIT design and implementation is also well-supported in the literature (Chiasson et al. 2004, Cho et al. 2008, Davidson et al. 2005, Paganelli and Guili 2011). While many aspects of HIT can be generalized from the mainstream IT literature, the production of clinical information is contextual in nature (Berg and Goorman 1999). Clinicians often lament that the use of EHRs interferes with the traditional manner in which physicians interact with patients, leading to low acceptance rates (Anderson 1997). Hence, acknowledging that the design and implementation of HIT systems is both difficult and contextual in nature, we embraced a contextual lens to understand in what ways Contextual Design principles and the CCM could be adapted to help achieve greater user acceptance and increased system use of IT-support for chronic care management.

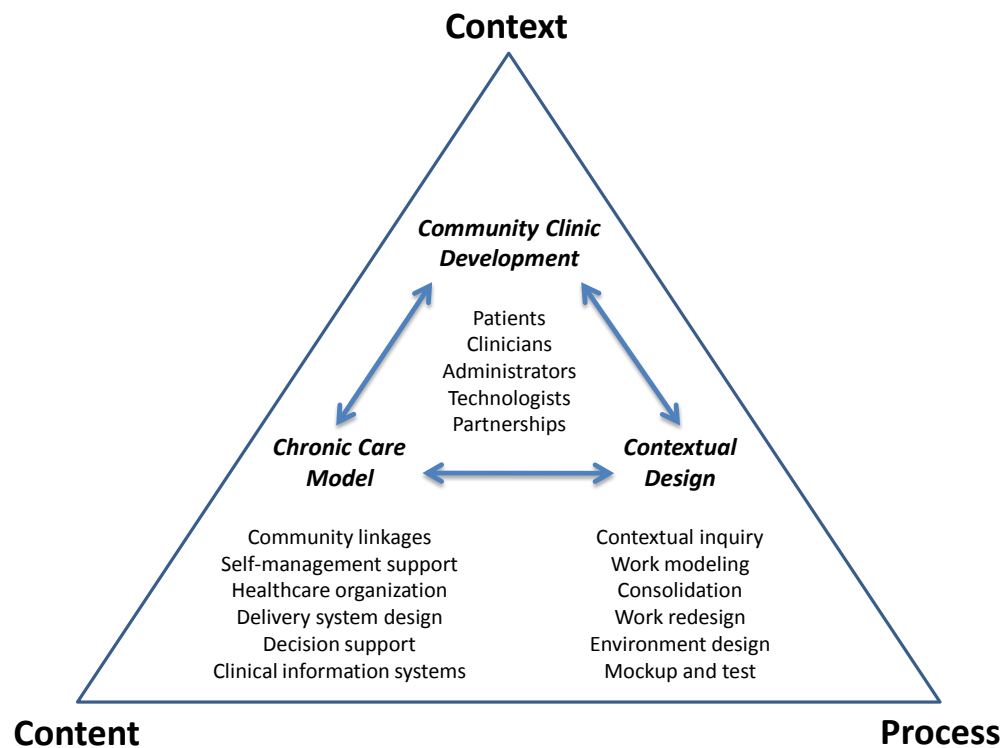


Figure 1: Initial contextualist framework.

Motivated by the complexities of the context in which *CareTech* approached the design and implementation of IT-enabled chronic care management with *Alpha* and *Beta*, we adopted Pettigrew's Contextual Inquiry (1990) as an overarching analytical lens. By combining this approach to understand complex change efforts with Holtzblatt and Beyer's (1993, 1999) Contextual Design principles and the CCM's description of the areas involved in improving chronic care management (Wagner et al. 2001), we developed a Contextualist Framework for understanding and

supporting development of IT-enabled chronic care management. In Figure 1, we have summarized the initial version of this framework that guided our analysis of the collaboration among *CareTech*, *Alpha*, and *Beta*.

Pettigrew's Contextual Inquiry framework is supportive of longitudinal investigations of organizational transformation (Pettigrew 1987, 1990), where outcomes are examined through the interactions among content, context, and process. Pettigrew defines *content* as the area subjected to transformation that could include a new technology, the personnel of a firm, or a new product launch. *Context* refers to the environment in which organizations and stakeholders operate, and is further delineated as outer and inner context. *Outer context* describes the environment that the firm operates in, including social, competitive, economic, and political factors. *Inner context* incorporates the culture of the firm, including social norms, firm objectives, and management structure. Pettigrew posits that context is not a static state from which to base the study of a particular phenomenon; rather there is a constant interaction between the content and context, and outcomes are constrained and shaped by the context. Finally, *process* refers to the specific actions and interactions between stakeholders as they attempt to modify organizational practices. Processes are studied from two dimensions, the vertical and the horizontal. *Vertical processes* refer to the interdependencies between higher and lower units of analysis, while *horizontal analysis* provides a temporal view of the transformation (Pettigrew 1987, 1990).

To frame our research according to Pettigrew's terminology, the content is the transformation from a paper-based health record system to an electronic, IT-enabled chronic care management system. Specifically we study (outer context) chronic care management through the lens of the *Alpha* and *Beta* clinics which provide indigent care for patients with chronic diseases. The volume and nature of clinical care and the organization structure were under considerable flux throughout the system design period (inner context). To guide the analysis of content, we adopt the CCM's description of the areas involved in improving chronic care management (Wagner et al. 2001): community linkages, self-management support, strong leadership, delivery system design, decision support, and clinical information systems.

Previous research on clinical processes highlights the "non-linear, context-dependent, interruption filled, uncertain, and collaborative nature of hospital clinical practice" (Koppel et al. 2005, p. 269). To study the development of IT-support for such processes, we adopted Holtzblatt and Beyers' (1993, 1999) Contextual Design methodology, a participatory approach to IT development. The methodology is ethnographic in nature and follows predetermined steps, with an intended output of paper-based system mockups, rather than extensive field notes. At its core is the belief that quality outcomes is the result of design teams being intimately involved with collection and interpretation of direct customer data and needs, combined with a thorough understanding of the possibilities introduced by a new technology (Holtzblatt and Beyer 1993, 1999). Given the complex, contextual nature of clinical practice, Contextual Design provides a strong foundation for collaborative development of HIT. In the first step, contextual analysis (we have changed Holtzblatt and Beyer's term *contextual inquiry* to avoid confusion with Pettigrew's term) is applied, whereby users are observed in their work environment, with periodic interruptions for clarification or interpretation. Second, work modeling occurs, where models representing the workflow of various users are represented. The following step, consolidation, involves the creation of a single statement of workflow in the specific context. The fourth step, work redesign, envisions a more effective workflow. The fifth step, user-environment design, captures the overall structure of the system from the users' point of view. Finally, the sixth step is a mockup and test, where the design of the system is tested with users on an iterative basis using paper mockups (Holtzblatt and Beyer 1993, 1999).

In summary, our choice of theoretical lens was fundamentally guided by the contextual nature of the healthcare environment, and the transformation under study was conducive to a process, rather than a variance-based model. Using a contextual approach to HIT design and implementation is also well-supported in the literature (Chiasson et al. 2004, Cho et al. 2008, Davidson et al. 2005, Paganelli and Guili 2011). Therefore, we embraced a contextual lens to understand in what ways Contextual Design principles and the application of the CMM to the content of transformation could be adapted to help achieve greater user acceptance and increased system use of IT-support for chronic care management.

RESEARCH DESIGN

Relying on Collaborative Practice Research (CPR) (Mathiassen 2002), the research was organized as a close collaboration between the authors and the health IT provider *CareTech* as part of a contract with the Centers for Disease Control (CDC). The contract focused on development of an IT-based Chronic Disease Prevention and Management (CDPM) system that would enable community clinics to offer chronic care management services to existing chronic-care patients and to educate the community with chronic-disease prevention techniques. The authors were engaged to evaluate the development effort and resulting software provided by *CareTech*. The collaboration began July 2006 and continued until September 2009. *CareTech* collaborated with two community clinics, *Alpha* and *Beta*, located in Georgia to help understand the specific challenges faced by such clinics in

developing IT-enabled chronic care management and to improve the design of CDPM based on real-world implementation experiences. Relatively speaking, *Beta* was more progressive and successful in implementing chronic care management; *Alpha* was a less advanced user of IT, and *Alpha* was located within a small city, whereas *Beta* was located in a rural area.

CPR emphasizes a mixture of understanding practices, designing support for practices, and intervening to improve practices (Mathiassen 2002). Our collaboration with *CareTech* was on understanding IS development for chronic care management for underserved communities. Accordingly, we report a longitudinal, qualitative single case study (Yin 1984) based on the collaboration with *CareTech* and the two clinics. Case study research is generally well-suited to understand IT-enabled innovations in organizational contexts (Darke et al. 1998) and single cases allow for in-depth investigation of real-world phenomena to provide rich description and understanding (Walsham 1995). The how-element of our research question combined with the focus on contemporary events in community healthcare clinics further supports a case-study approach (Yin 1984). Adopting the Contextualist Framework (see Figure 1) as analytical lens to make sense of the case, allowed us to study the challenges involved in developing IT-enabled chronic care management over an extended period of three years within the real-life context of two community clinics.

Throughout the collaboration, we collected data from a variety of sources. Focus groups were conducted on site at *Alpha* (28–29 April 2007) and at *Beta* (19 June 2007) prior to the initial software design, and each session was taped and transcribed. Final focus group sessions were also conducted at *Alpha* to evaluate project outcomes from a user perspective. Throughout the three-year period, periodic update meetings were held between the research team and *CareTech*, resulting in eight semi-structured interviews in total representing twenty-four hours of recordings. *CareTech* issued twenty-nine CDPM update reports to summarize major milestones accomplished during the month. In addition to the regular status update meetings, each member of the research team engaged in ongoing phone interviews with the *CareTech* project manager (also the director), as well as individuals at *Alpha*. Detailed notes were created during these interviews, resulting in additional fifty-five encounters, representing forty-six hours of discourse. Aside from the focus group sessions, the research team engaged in three, all-day site visits to *Alpha*, resulting in field notes and semi-structured interviews. During the system pilot, weekly status reports outlined overall system use and user modification requests. Finally, detailed documentation of the technical proposals and reports to the CDC was provided by *CareTech*.

To interpret data, we used the Contextualist Framework (Figure 1). As the process evolved, so did the content of the chronic care management system and the context in which the project unfolded. We coded data temporally according to key events, challenges, and outcomes, and then mapped these to distinct phases of the project, namely *analysis*, *initial focus groups*, *refinement*, *pilot*, and *evaluation*. Table 2 provides a process overview of these phases and major insights through a Contextual Design lens. Subsequently, Tables 3 through 7 provide a concurrent account of the process, content, and context as they evolved, including a more granular process account according to Contextual Design principles. With respect to content, we analyzed which questions had been in focus and what results had materialized in relation to the CCM. Finally, related to context, the analysis led to an understanding of the issues that had emerged and how the project had intervened to change the context.

RESULTS

Antecedent Conditions

The contract among *CareTech*, *Alpha*, *Beta* and the researchers was sponsored by the CDC and aimed at “developing an interoperable electronic health system with a focus on chronic disease prevention and management” (CDC Presentation 10 July 2006). Hence the expectations were that: (1) the IT-solution would be interoperable with other relevant IT systems; (2) the core of its functionality would be tailored to support chronic care management at the involved clinics for both patients, administrators, and clinicians; and (3) it would support the larger community surrounding each clinic in taking steps toward chronic care prevention by helping individuals evaluate the risks of developing a chronic disease and recommend consequential lifestyle changes. The plan was to develop a first prototype rather quickly and then continue with iterative development and evaluation until January 2009. The resulting process is analyzed in the following as summarized in Table 2.

Analysis

The analysis phase was initiated July 2006 and evolved until March 2008 with a focus on how the collaboration between *CareTech*, the researchers, and the clinics was organized (see Table 3). The goal was to provide direction for developing basic design principles. By October 2006, the researchers delivered two reports entitled “State of the Art Chronic Disease Prevention and Management for Rural Community Health Clinics: A Review of the Literature”



Table 2 Process Overview

Antecedent conditions	<i>Based on CDC support, a contract is signed between Alpha, Beta, CareTech, and the researchers to develop an interoperable electronic health system aimed at community wide chronic disease management and prevention. Existing processes at the clinics are paper based.</i>	
Phases	<p style="text-align: center;">Analysis Jul 06-Mar 08</p>	<i>A literature review by the researchers to help determine best overall design principles and a CareTech led process review on site at Alpha and Beta. We aligned with contextual design principles of contextual analysis and work modeling.</i>
	<p style="text-align: center;">Initial focus groups Apr 08-Jun 08</p>	<i>Research team and CareTech engaged with the community to understand patient and clinician expectations for the new CDPM system. Contextual considerations related to digital divide became apparent. Following contextual design principle of consolidation, feedback from the Alpha and Beta clinics was aggregated to a singular view of best practices for new system.</i>
	<p style="text-align: center;">Refinement May 08-Mar 09</p>	<i>Early versions of the CDPM system were reviewed and tested for compatibility with clinical processes and workflow modifications were implemented, confirming the contextual design principle of workflow redesign. Work on the new patient personal health record began. Given that no prior processes were available, contextual analysis was performed. Beta decided to drop out of the project and lack of a dedicated project resource at Alpha impacted progress.</i>
	<p style="text-align: center;">Pilot Apr 09-Aug 09</p>	<i>Pilot testing of the system using actual patient data occurred along with establishment of a kiosk for selected patients to access their personal health record (PHR) for testing and training. Modifications of CDPM entry screens were made to adapt to the user environment; work redesign, user environment design and mockup and test design principles were applied. Dedicated resource at Alpha adds traction to the project.</i>
	<p style="text-align: center;">Evaluation Sep 09</p>	<i>Following contextual design principle of mockup and test, final evaluation of the system, including the patient personal health record (PHR), occurred. Feedback from user stakeholders was collected during final focus group sessions. While comments were generally favorable, dual entry of clinical data by Alpha clinicians limited their enthusiasm for the CDPM tool.</i>
Outcomes	<i>Overall the CDPM was successful in meeting its core objective of providing support for chronic care management tailored to the Alpha context. However, the system fell short of expectations due to interoperability limitations and a lack of focus on chronic disease prevention in the broader community. CareTech's CDPM system was later recognized as a finalist for a regional healthcare technology award.</i>	

and “Best Practices and Evidence-based Approaches to the Prevention and Management of Diabetes Mellitus and Hypertension: A Review of Literature.” Drawing on insights from these reports, *CareTech* submitted a technical report to the CDC in January of 2007, which incorporated literature review details, previous design experience in chronic care management systems, basic design principles, and *CareTech* personnel data. The project manager remarked, “Our review of the CCM found that it supported most, if not all, of the overall requirements and guidelines for the CDPM.” Later in the report, “We found the CCM to be the best model (or foundation for a conceptual framework) for developing a CDPM system that meets the overall requirements for the project.” These initial literature-based analyses helped the project develop general principles for the CDPM system within the clinics.

Focusing on developing a first prototype, *CareTech* evaluated its current portfolio of healthcare modules that were relevant for chronic care management. For one, *CareTech* had been granted the contract by CDC because of its demonstrated capabilities in this domain of IT support. Moreover, the time dedicated to develop a first prototype was very short. These efforts to effectively reuse existing modules came to impact the design of the CDPM. At the same time, starting July 2007, *CareTech* personnel engaged with administrative staff at the clinics to understand their processes and legacy systems. At *Alpha*, for instance, a total of fifty manual forms were in use to manage patient flow through the clinic. Data was keyed into a legacy system to generate reports for local hospital management, and this legacy system also integrated with a pharmacy module. The pharmacy module was an important part of *Alpha*'s overall operation, as a number of their patients relied on the clinic for free medication. On the other hand, clinical decision support related to drug interactions, patient summary of clinical conditions, or patient access to their medical records were not supported at *Alpha* or *Beta* in 2007. These analyses revealed important insights into current practices and bottlenecks and were documented in an internal *CareTech* report June 2007. During the analysis phase of the project, we confirmed alignment with the contextual design principles of contextual analysis and work modeling.

Already during the analysis phase, it became evident there were important issues in the context in which these clinics operated that would be highly influential on the project. Both clinics offered significant services for the indigent, while *Beta* also provided a portion of their services to patients for payment. Funding was, therefore, a constant struggle, and staffing was not at a state that would easily accommodate resource commitments to design and implementation of new software. Also, in contrast to the situation in large hospitals, there was little tradition for focusing on and improving workflows. Many patients in these clinics were by nature less affluent than the general population and less likely to have experiences and home Internet access that could help them take advantage of PHRs. The impact of these contextual issues increased over time, and, already during the first phase, they delayed the project, and *CareTech* and the clinics would eventually have to resolve them to move the project along. At this point, the most important impacts were lack of project leadership and IT training at the two clinics.

Table 3 Analysis (Jul 06 – Mar 08)

Process		Content		Context	
Phase	Principles	Focus	Results	Issues	Changes
<ul style="list-style-type: none"> Defined collaboration between <i>CareTech</i> and researchers Reviewed literature Evaluated <i>CareTech</i>'s HIT modules Established collaboration with clinics Reviewed work flow and IT usage at clinics Established design principles for CDPM system 	<ul style="list-style-type: none"> <i>Contextual analysis</i> of workflow at clinics <i>Modeling</i> new workflow through design principles for CDPM system 	<ul style="list-style-type: none"> What is known on chronic care management? What are the design principles for IT support? What is the current work flow within clinics? How can clinics establish IT-enabled patient – clinician interactions? 	<ul style="list-style-type: none"> Two literature review reports Oct 06 Technical report to CDC Jan 07 Work flow and IT usage analysis of clinics Jun 07 Integration of CCM principles 	<ul style="list-style-type: none"> Limited project funding in clinics Limited staff resources available to project Little tradition for work flow improvement Clinicians relied on paper based patient records Leadership focused primarily on gaining access to resources to expand community services Many patients had little IT experience and no Internet access 	<ul style="list-style-type: none"> Concerns raised over project leader role at clinics Concerns raised over IT training at clinics

** Note: Bullet points in each column do not align with subsequent columns.

Initial Focus Groups

From April 2008 to June 2008, focus group meetings were organized to further refine system requirements for the CDPM system (see Table 4). The focus group meetings at each site were led by a third party associated with the researchers and included patients, physicians, administrators, and representatives from the local community and *CareTech*. The groups provided rich insights into healthcare in these communities, and they facilitated an open discourse on how *CareTech* could design IT-support for chronic care management. From the *Alpha* focus group sessions, the idea of a transition from their paper records at the site seemed appealing: “Physicians want to use the system to track treatment outcomes and assess patient behavior and history” and “Patients should be able to track progress using results and other quantitative data.” From the *Beta* sessions: “Physicians want the system to allow patients to be aware of the most current treatment options” and “Patients find it a good idea to be able to access records and more fully understand their illness.” Also, “Patients want access to information about diet and exercise as well as where to find local recreational spaces,” suggesting that lifestyle implications on chronic disease was considered an important functionality of the CDPM system. Many of the physician comments were already accounted for within the earlier technical reports to the CDC, in which *CareTech* stated, “The system will integrate the risk assessment, evidence-based recommendations, and outcomes measurement process directly into the care management process.”

However, not all feedback was positive. Remarks at *Alpha* included, “Patients are concerned about privacy, and control of access to records,” and at *Beta*, “Patients have little access to computers in general, and the population is unlikely to use them,” and “Physicians note that the clinic population is largely made up of publicly insured and uninsured.” Hence, it became apparent, that the outer context in which the project evolved included many patients who lacked insurance and Internet access.

Following the contextual design principle of consolidation, each requirement or comment included in the stakeholder feedback was captured according to its source, either at *Alpha* or *Beta*, and consolidated into a form for future prioritization and progress. While most requests could be accommodated as functionality improvements in the software, such as clinical decision support, or links to chronic care management educational sites, many issues were more difficult to resolve through modifications to the software itself. The context of a rural, largely indigent care patient population implied digital divide concerns (Kvasny and Keil 2006, Hsieh et al. 2010), and it became clear that the lack of Internet access and PC skills would negatively impact CDPM usage by patients. During the *Beta* focus groups the following potential solution was earmarked, “Patients want kiosks in clinics and local libraries.” Also, at this point it became evident that *CareTech* would not effectively meet the original expectation to develop IT support

to help the larger communities take steps toward chronic care prevention. This basic requirement was the subject of many discussions between *CareTech* and the researchers, and it was supported by several statements from the focus groups. However, *CareTech* never found a way to prioritize this concern for the larger community, while at the same time supporting care management within the clinics.

Table 4 Initial Focus Groups (Apr 08-Jun 08)

Process		Content		Context	
Phase	Principles	Focus	Results	Issues	Changes
<ul style="list-style-type: none"> Established links between <i>CareTech</i>, research team, and community Analyzed healthcare in communities Documented stakeholder views of CDPM functionality Compared and contrasted requirements 	<ul style="list-style-type: none"> Consolidate requirements and design principles based on feedback from clinics 	<ul style="list-style-type: none"> How do different stakeholders coordinate services for chronic care management? How can patients be informed about their chronic disease to facilitate self-management? How can clinicians plan treatment based on evidence and up-to-date records? How can patients and community make lifestyle changes to prevent chronic diseases? How can leadership visibly promote quality care improvement How can clinical information systems organize patient data to ensure efficient care 	<ul style="list-style-type: none"> Physicians felt the system should interface with providers, pharmacies and diagnostics Patients welcomed access to their medical records to track progress and understand their illness Clinicians wanted access to evidence based protocols and drug interaction warnings Patients wanted functionality related to lifestyle implications, education, and community wellness programs Clinicians and patients noted the importance of system reminders for appointments and lab results 	<ul style="list-style-type: none"> Many patients lacked internet access Many patients considered IT illiterate Clinicians expressed privacy concerns Physicians expressed positive view of more informed patients Positive view of decision support for clinicians and patients Lifestyle information considered important 	<ul style="list-style-type: none"> Change of project scope: <ul style="list-style-type: none"> Possibly combine EHRs and PHRs Consider PC kiosk at clinics Consider expansion of lifestyle and educational programs at the clinics Neglect community support for chronic disease prevention

Refinement

From May 2008 to April 2009, a significant part of the CDPM system was constructed, released in different versions to the staff at *Alpha*, and refined and modified based on their feedback (see Table 5). The other clinic, *Beta*, decided to drop out of the study and instead implement an alternative EHR system. *Alpha* had an offer to utilize their hospital-sponsored EHR free of charge, but the executive team found that this solution would be too cumbersome for their environment. While *CareTech* could now focus all their resources on just one provider, the disengagement of the *Beta* clinic impacted the project. The *CareTech* project manager remarked, "Of the two sites, *Beta* had a much better understanding of their processes and were more prepared for an EHR." Clearly, the refinement phase was impacted heavily by this change in context.

As of August 2008, there were roughly 500 patients in the care of *Alpha*, with twenty-two case managed chronic care patients, and roughly 220 with some form of chronic illness. *Alpha* clinical staff assumed that Internet access would be a serious limiting factor, specifically for implementation of PHRs. Reviewing the case managed chronic patients, they found that of the twenty-two patients, six used the Internet regularly at home. These patients were targeted early on to pilot the PHRs, initially scheduled to start January 2008. Given that there were no prior processes to refer to when designing the PHR for chronic care patients, *contextual analysis* was performed to understand which aspects of the EHR should be transferred to PHR. Already during the initial focus groups, it was noted that Internet access was not universally available to patients. To accommodate this issue, *CareTech* offered funds to set up a kiosk at the *Alpha* clinic with PC and Internet access so patients could access their PHR as well as Internet sites embedded in the PHR with chronic-disease-based education, such as the ICIC (Improving Chronic Illness Care) website based on the CCM model. While the *Alpha* staff was originally against the idea because it would disrupt the waiting area, it was decided that a separate meeting room just off the main reception area would work well.

During the refinement stage, the use of the CDPM system was supported to learn about issues related to implementation of IT-enabled chronic care management at *Alpha*. Integration with systems and services outside the scope of CDPM was also considered, as *Alpha* expanded their free services to include dentistry and prescription of medicines. The main focus remained, however, on improving the process flow within the clinic. "Of the fifty forms in use at *Alpha*, we were able to incorporate roughly half into the CDPM system," thereby confirming the contextual design principle of workflow redesign. *CareTech* also managed the data conversion process to populate as much patient data from existing electronic sources as possible. As a result, discrepancies were identified between electronic data in the legacy systems and manual paper records, and significant *CareTech* resources were applied

to improve data integrity in the CDPM. The *CareTech* project manager noted that “We imported much of this information into the CDPM system back in October–November 2008 and are having to validate and complete each record for patients enrolled in the CDPM programs against their paper records.”

While *CareTech* continued to focus on functionality refinements, it became clear to the project team that key milestones kept drifting because *Alpha* was under-resourced to support the next steps of the project. *Alpha* was led by the director and was, in the fall of 2008, staffed by five full-time employees: a case manager, three nurses, and an administrative assistant. In addition, there were eleven volunteer nurses, five volunteer physicians, three volunteer nurse practitioners, and five part-time office administration volunteers. Patient care was the primary concern of the staff, and very little, if any, time was available to learn the new system and provide feedback on functionality. As part of a regular coordination meeting between *CareTech* and the researchers in late January 2009, the issue of project resources at *Alpha* was addressed. The meeting notes read, “We need an onsite person at *Alpha* who is dedicated to the project, will learn the system, and then train others.” To accommodate this, support was secured from *CareTech* with CDC funds to offset a portion of the salary of an additional hire at *Alpha*. As a result, a patient navigator was hired, and training started in April 2009. The hiring of the patient navigator positively impacted the context at *Alpha* toward active engagement in the CDPM system assessment and redesign, and the project could now reschedule the pilot milestone, which at this point had been missed by roughly eight months.

Prior to the patient navigator position being filled, the case manager at *Alpha* continued to work with the CDPM system and patient data to provide feedback to *CareTech*. At the time, a comprehensive EHR was available to *Alpha*, including a full set of medical codes and clinical decision support. The case manager commented on the earlier version of the system, “We like the recommendations provided by the system, but entering data can be cumbersome.” *CareTech* provided full EHR to support the range of services offered by the clinic, but *Alpha* asked to restrict the entry screens to simplify processing the high volume of case-managed patients. While *CareTech* had initially designed the CDPM system to replace *Alpha*’s legacy systems, this request implied the system would have to integrate with the legacy systems or require duplicate data entry.

At this point in April 2009, the project team was also concerned that the *Alpha* pilot would not generate the usage required to adequately evaluate the system. Eventually, with just six months to go before a final report was due to the CDC, the researchers uncovered contractual uncertainties between *Alpha* and *CareTech* once the pilot had ended. *Alpha* was hesitant to invest a significant amount of time training staff and implementing the system if they could not afford the license fees for various portions of the system outside the scope of the original agreement. At a meeting with *CareTech*, one researcher noted, “It is important that *CareTech* clarifies its fee structure for *Alpha* after the pilot to fully commit the clinic to the project.” When *CareTech* provided *Alpha* with written commitments to an attractive fee structures for the CDPM system, the patient navigator had also been well integrated into *Alpha* and the project, and ongoing testing through the pilot stage could commence May 20 09.

Table 5 Refinement (May 08-Mar 09)

Process		Content		Context	
Phase	Principles	Focus	Results	Issues	Changes
<ul style="list-style-type: none"> Integrated stakeholder ideas Evaluated CDPM in relation to administrative processes Conceptualized integration of CDPM with other processes and systems Explored issues related to patient usage of CDPM 	<ul style="list-style-type: none"> <i>Contextual analysis</i> of patient usage <i>Work redesign</i> focused on integrating CDPM with other processes and systems 	<ul style="list-style-type: none"> How can IT-support for chronic care management be implemented? How would CDPM integrate with existing work flow? How would system wide reporting be impacted by CDPM? How would patients use CDPM? 	<ul style="list-style-type: none"> Adapted IT-support Initial usage by administrators Roughly half of 50 manual forms at <i>Alpha</i> were included in CDPM Simplified data entry for high volume cases Most EHR data transferred seamlessly to PHRs 	<ul style="list-style-type: none"> Lack of dedicated resource at <i>Alpha</i> Contract considerations after low engagement at <i>Alpha</i> Data discrepancies between legacy systems and manual patient records Pending HRSA reporting requirements exceeded legacy system capabilities 	<ul style="list-style-type: none"> Hiring of full-time trainer at <i>Alpha</i> Apr 09 Renegotiated contract for post pilot use of CDPM at <i>Alpha</i> Apr 09 <i>CareTech</i> resource applied to data integrity in CDPM <i>Beta</i> clinic dropped out Kiosk established at <i>Alpha</i> for patient usage of CDPM

Pilot

The pilot was finally launched from May to August 2009. During the early stage of the pilot, the *Alpha* administrative staff became more fully engaged with the CDPM system (see Table 6). Also, some patients started to take advantage of the kiosk to access their PHR. Once on board, the patient navigator quickly embraced the software and commented, “The system is very easy to use, and *CareTech* has been very helpful to make changes.” Data was scrubbed by *CareTech* staff to more closely align with the original manual records, and the patient navigator further

refined and updated the records of case managed patients. However, while daily system usage had spiked during April 2009, usage once again waned considerably during May–June 2009, putting the traction of the project into question.

On 22 June 2009, a plenary meeting was held at *Alpha*. The *CareTech* project manager, the research team, and most of the *Alpha* staff attended the meeting. Once a site tour was conducted, the director of *Alpha* opened the meeting with a few comments that included, “We did not realize the work involved in the support of a pilot project,” and “I don’t see a future for this software after the pilot.” As a result, she had asked staff to refrain from using the system pending further clarification from *CareTech* regarding outstanding functionality requirements and buy-in from the case manager for chronic patients. The case manager commented, “We now have thirty-four case managed patients enrolled, and we are finding the recommendations very helpful.” When entering data on case managed patients, however, she found the entry screens to be onerous: “We need an entry screen that has only the most common chronic disease fields.”

Earlier versions of CDPM allowed for clinic-wide entry of patient data, as the system was specified as a comprehensive EHR for all types of patients. Upon request from the case manager, the screens had been updated to reflect common entry screens for case managed chronic care patients only. While the changes had been implemented for weeks, the case manager had not been using CDPM for some time. She had also been waiting for *CareTech* to engage several patients for the PHR functionality test, while *CareTech* at the same time was under the impression the case manager would engage the patients. During the meeting, the *CareTech* project manager displayed the recently implemented patient registry screens, to which the case manager remarked, “That’s exactly what we need.”

These modifications of CDPM entry screens were made to adapt to the user environment and improve existing work processes, confirming that the contextual design principles of work redesign, user environment design, and mockup and test design principles were applied during the pilot phase.

Table 6 Pilot (Apr 09 – Aug 09)

Process		Content		Context	
Phase	Principles	Focus	Results	Issues	Changes
<ul style="list-style-type: none"> Initiated use of CDPM at <i>Alpha</i> Established actual patient data into CDPM Trained clinicians at <i>Alpha</i> Initiated use of PHR with sample patients Adapted CDPM to meet changing requirements 	<ul style="list-style-type: none"> <i>Work redesign</i> based on CDPM administrative usage <i>User environment design</i> to capture system structure from users’ perspective <i>Mock up and test</i> based on CDPM administrative, clinical and limited patient usage 	<ul style="list-style-type: none"> How do different stakeholders react to using CDPM? How does CDPM interact with other systems? How does CDPM interact with actual work flow? Will patients embrace the CDPM? What level of training is required for clinicians, administrators, and patients? 	<ul style="list-style-type: none"> CDPM adapted to administrative environment More detailed directions for use of PHR Patients recruited to use CDPM during office visits Screens for lab results adapted to match primary provider Patient registry screens adapted Patient data scrubbed by <i>CareTech</i> and patient navigator 	<ul style="list-style-type: none"> Duplicate data entry required Integration with MedBank lacking Only case managed patients use the CDPM system <i>Alpha</i> received incremental grant and expanded case managed patient load 	<ul style="list-style-type: none"> Some patients started to access the CDPM at kiosk <i>CareTech</i> agreed to work towards integration of HRSA data reporting

Unfortunately, *Alpha* was not able to eliminate its legacy systems, so CDPM usage was in many cases considered duplicate entry by the staff: “Unlike our existing Med Services software, CDPM does not integrate with our Med Bank, so there is duplicate entry.” The existing systems, however, had quite limited reporting capability. Roughly one week a month was spent generating reports for the local hospital, whose board provided most of the funding for the clinic. In contrast, the CDPM system was able to automatically generate similar statistics. Yet services at the clinic were expanding, raising the question, “HRSA is asking for extra reporting to comply with funding; could this be built into the software?”

During the pilot phase, refinements to the CDPM system continued to evolve. On the day following the plenary meeting, a separate work session was organized with the patient navigator and case manager to review the new patient registry and next steps. The patient navigator was pleased with recent software changes, yet hands-on use of the system continued to prompt improvement suggestions. “The patient registry screens really help. One issue I see is that the lipid profiles call for random; we usually require a fasting lipid profile.” The patient navigator also noted they usually used the same company for lab results and the screens were out of sequence compared to the standard lab report. While on site, the project manager walked through the issues on the phone with *CareTech* programming staff, and by the end of the morning the screen changes were implemented into the CDPM system.

Evaluation

The final evaluation of the CDPM system occurred September 2009 (see Table 7). Throughout the summer of 2009, regular weekly status reports were issued by *CareTech* to track usage by staff and patients and provide updates on outstanding functionality requests. By this phase of the project, the CDPM core functionality was stable, allowing for full mockup and test according to contextual design principles. System usage continued to trend higher into the fall period, allowing for a reasonable evaluation of the system as a basis for the researchers' final report to the CDC. Final focus-group sessions were organized at *Alpha* to evaluate the performance of the system and *CareTech*'s responsiveness to functionality requests.

Comments from the focus group sessions were directly incorporated into the final report, and, in general, feedback on the design of the system was positive. Notable feedback included, "A total of eight staff members from *Alpha* have used or continue to use the CDPM system to assist their roles in the clinic." "Since August 2009, 90 percent of the 285 staff logons were recorded by the patient navigator who was for the most part updating patient health records and making entries to journals." In terms of ease of use: "Staff indicated that navigating through the system is 'very easy,' and they found the system easy to learn. They are pleased with the PHR component of the system as well." Yet, outstanding issues related to system integration remained: "A significant barrier that prevented *Alpha* from fully embracing the pilot process was the necessity for dual data entries—one entry into their existing system and a second into the new software."

Comments by patients were also generally positive. One individual wrote, "It was awesome. I plan on using this system and advising my endocrinologist to do the same." Another patient noted, "You would have ownership and track for yourself how you are doing." In terms of informing patients of lifestyle considerations, "Having everything in one place—the food log, the activity log, and the blood sugar log—gives you a snapshot of each day," and, "I could see where it would be definitely beneficial. If you get in and use it, you can learn what you're doing and why things happen. You see a pattern, and you know what to do to change your lifestyle." Some patients noted room for improvement, especially when first using the system, "When you first go in, some of the things you need to put in weren't really self-explanatory. I had some problems entering things and looking up things like medications. It needs a little tweaking, not a whole lot." Another patient explained, "I didn't know what I was looking for, so I just explored. When you don't know what's there, you just have to explore to find out. I found things that I didn't realize would be part of it." Hence, while supportive of a number of the CCM components, these assessments made it clear that the CDPM did not effectively support coordination of services across diverse stakeholders because of the inherent interoperability issues within health IT. Also, while patients within the clinic were able to assess risks related to chronic diseases and take appropriate action to change lifestyle, these benefits were not extended to the community at large.

When asked to comment on the *CareTech* development approach, the project manager commented, "We have worked with much larger clients in the past, and they have teams that are able to dedicate full-time help to project design and implementation." "Using a set of sticky notes to conceptualize the completed system was not possible with *Alpha*. They needed to see what was possible." As a result, the ongoing revisions and consolidation of the CDPM system were based on conversations about user experiences rather than on systematic analyses of each related process.

Table 7 Evaluation (Sep 09)

Process		Content		Context	
Phase	Principles	Focus	Results	Issues	Changes
<ul style="list-style-type: none"> Analyze feedback from stakeholders, including clinicians, administrators and patients 	<ul style="list-style-type: none"> Mock up and test based on CDPM administrative and clinical usage and limited patient usage 	<ul style="list-style-type: none"> How do different stakeholders coordinate services for chronic care management? How can patients be informed about their chronic disease to facilitate self-management? How can clinicians plan treatment based on evidence and up-to-date records? How can patients and community make lifestyle changes to prevent chronic diseases? How can leadership visibly support quality care improvement? How can clinical information systems organize patient data to ensure efficient care 	<ul style="list-style-type: none"> Health IT system Integration issues remained Patients gained a sense of ownership for their health Clinicians came to rely on evidence based protocols Leadership was quality care minded but not engaged in the IT innovation System was configured to capture changes in behavior, compliance and clinical outcomes 	<ul style="list-style-type: none"> The CDPM did not provide support for chronic disease prevention in the community Duplicate entry remained main issue The basic interoperability requirement had not been given sufficient priority by <i>CareTech</i> 	<ul style="list-style-type: none"> Integration of HRSA reporting near completion Multiple iterations of code were required to demonstrate the system

As the context at *Alpha* evolved, opportunities arose to incorporate new services into the software that would later solidify usage of the new system. Once the new HRSA data reporting requirements were established as a prerequisite to a substantial grant and the CDPM system was being adapted to meet these requirements, support and usage of the system increased. This important feature, which was unforeseen by *CareTech* at the outset, would overcome objections to use created by the required duplicate entry of case managed patient data into the MedBank system. At the same time, however, this experience demonstrated that *CareTech* had not given sufficient priority to the original expectation to ensure interoperability between the CDPM and other relevant IT systems.

Outcomes

At the end, the project was delayed nine months. While the CDPM at this point fell short of meeting the expectations related to interoperability and chronic disease prevention in the larger community, it was successful in meeting its core objective of providing support for chronic care management tailored to the *Alpha* context and guided by CCM. The director at *Alpha* continued to find the capabilities of CDPM useful for multiple chronic care programs, including patient and nurse diabetes management, and they planned to leverage the software further to provide additional chronic disease management services over the coming year. In addition, *CareTech* scheduled the release of a commercial version of CDPM within the next year, and, as part of that, reevaluated their overall business strategy to target both existing and emergent markets. In April 2010, *CareTech's* CDPM solution received recognition as a finalist in a regional technology innovation award for healthcare.

DISCUSSION

Chronic diseases are a major source of concern within the U.S. healthcare system, and the CCM model has been developed to support chronic care management (Wagner et al. 2001). Current HIT research offers important insights into how systems such as EHR's (Angst and Agarwal 2009, Bell and Anil 2001) and clinical decision support (Kohli and Kettinger 2004) can provide partial support for chronic care management, but there are few studies that focus on an integrated IT solution as espoused through the CCM. The well-documented challenges related to privacy issues (Angst and Agarwal 2009, Goldschmidt 2005, Huston 2001, Rindfleisch 1997), interoperability between different IT systems (Lumpkin 2002, Grimson 2001, Goldschmidt 2005), and changes in medical practice routines (Anderson 1997, Lapointe and Rivard 2005, Niazkhani 2009) needs to be taken into account when considering IT-support for chronic care management. In addition, however, the design of these systems is further complicated by the context of chronic care patient management, which by nature is distributed throughout a community and involves multi-organizational, multidisciplinary stakeholders (Rigby 1999).

In response to this challenge, we conducted a case study into the design of a chronic care management system in close collaboration between the IT provider *CareTech* and two community clinics, *Alpha* and *Beta*. Based on data covering three years of effort, we embraced Contextualist Inquiry (Pettigrew 1987, 1990) as the theoretical lens to analyze the design and implementation of IT support for chronic care management and to understand in what ways Contextual Design (Holtzblatt and Beyer 1993, 1999) principles could be adapted to support the process. In addition, our study was to our knowledge, the first to integrate CCM as guiding principles in a HIT software design process. In the following, we discuss the contributions related to each of these objectives.

IT Support for Chronic Care Management

Our investigation into *CareTech's* design and implementation of the CDPM system at *Alpha* provides several interesting findings as contributions to healthcare-IS research (Chiasson and Davidson 2004), i.e., to our understanding of how the unique aspects of healthcare settings impact IT-enabled healthcare.

First, the context in which the process unfolded had both supportive and attenuating impacts on events and outcomes (Pettigrew 1987, 1990). The outer context was supportive of the effort with funding from the CDC and extensive guidance on how to enable chronic care management from the CCM (Antecedent conditions) (Wagner et al. 2001). In contrast, the inner context at *Alpha* attenuated the effort. As a not-for-profit community clinic, *Alpha* lacked resources and experience with major organizational transformations. They did not possess a deep and readily available understanding of key processes, and they could not provide the development team with clear visions of their future processes to more effectively support chronic care management (Table 3). Moreover, the key stakeholders involved in chronic care management at *Alpha*, i.e., the administrators, clinicians, and patients, engaged reluctantly in the transformation. For the administrators and clinicians, this was due to lack of time and consistent management support. Leadership at *Alpha* had proven extremely adept at garnering incremental resources to expand patient services, yet inconsistent support for the CDPM project had a negative impact. For the patients, this was caused by *Alpha's* largely indigent patient population with limited Internet access and little IT experience. Hence, the attenuating effect of the inner context counteracted the supportive impact from the outer context.

Second, the design and implementation process was shaped in significant ways by this context. The supportive outer context facilitated *CareTech*'s innovation efforts and made it possible for *Alpha* to engage in implementing IT support for chronic care management, thereby extending their service offerings. The inner context, however, made it difficult to develop a shared vision of an ideal future state of IT support for chronic care management between stakeholders at *CareTech* and *Alpha* (Table 3); it led to a nine-month delay in launching the pilot phase, and, in the end, it resulted in a solution that was restricted compared to CDC's original project charter (Outcomes). As a result, key activities during the process were aimed, not directly at designing and implementing IT support, but at shaping the inner context to accommodate the design effort and make implementation progress possible. These activities resulted in providing funds for setting up an Internet kiosk and hiring the patient navigator, changing the project scope, and negotiating a favorable contract for *Alpha*'s continued usage of CDPM after the pilot phase (Table 5). The constant interactions between process and context resulted in a slow horizontal development (Pettigrew 1987, 1990) that required *CareTech* to expend unexpected resources to overcome obstacles largely related to the inner context at *Alpha*. While we observed no inner disconnects or conflicts between management and development inside the small firm context of *CareTech*, vertical relationships (Pettigrew 1987, 1990) inside *Alpha* did shape the overall process. *Alpha*'s engagement in the project allowed management to benefit from close ties to the CDC and to learn about the CCM, but they were not providing the required support and resources for local implementation (Tables 3 and 5). It was only after the funding of the patient navigator and the favorable contract about continued usage of CDPM (Table 5) that the project could move effectively toward pilot and evaluation.

Third, while the project was delayed nine months, it demonstrated that it was possible to implement major components of the CCM into a community clinic enabled by IT. The intention to incorporate all components of the CCM was evident in the focus groups (Table 4), but not all of the principles were met. From the evaluation stage, the finding was that the CDPM provided a new tool for education, self-management, and clinical information support for case managed patients suffering from lifelong chronic conditions (Table 7). The CDPM tool also incorporated the latest evidence-based clinical decision support, which was mentioned as beneficial by both patients and providers (Tables 4 and 7). Some evidence of community linkages to health and wellness seminars, as well as built-in reporting for HRSA and the local community hospital was noted (Table 7). The content of the effort was in this sense successful, as also evidenced by the subsequent assessments and award (Outcomes). Still, compared to CDC's original mandate, key issues related to chronic care prevention and to IT systems interoperability remained unresolved. From a CCM perspective, lack of interoperability mitigated fulfillment of a delivery system design to coordinate care between providers. The CDC requirement to include features into the CDPM that would help individuals in the community acquire information and adopt lifestyles aimed at chronic-disease prevention was explored as part of the initial focus groups (Table 4). However, such features were only sporadically implemented into the system, and the larger community was never engaged in experiments to help make the features useful, thus mitigating the full effects from the CCM on community linkages. Given *Alpha*'s emphasis on serving its existing patients, the CDPM became a tool for resolving the many difficult issues related to serving chronic patients, including lifestyle management that would prevent them from acquiring additional chronic diseases. The CDC requirement that the IT solution should be interoperable with other relevant IT systems was taken into account as part of the project's analyses of the existing workflow at *Alpha* (Tables 3 and 5). However, ensuring interoperability with other relevant legacy systems, even within *Alpha*, was never prioritized as part of CDPM. As a result, *Alpha* had to practice dual data entry, for example, to provide the required information about patient prescriptions (Table 6). This lack of interoperability contributed significantly to the inconsistent support of *Alpha* leadership for the project, albeit leadership concern for quality of care, a core principle of the CCM, was not diminished. This outcome is consistent with the more general finding (Lumpkin et al. 2002) that interoperability performance in healthcare lags behind other industries, despite ongoing efforts to develop and implement shared standards such as HL7. In fact, Lumpkin et al. (2002) suggest that competitive forces among key players in the HIT market encourages continued use of proprietary systems and databases and limits the providers' ability to effectively share data across solutions.

Hence, as a contribution to healthcare-IS research (Chiasson and Davidson 2004), this study demonstrates how the unique context at the *Alpha* clinic shaped and was shaped by the effort to develop IT support for chronic care management. Most importantly, the study reveals how the multi-organizational, multidisciplinary and distributed nature of chronic care management (Rigby 1999) combined with the lack of resources for and experiences with technological innovation in community clinics created very challenging conditions for IT design and implementation. These insights add to our current knowledge of how specific problems related to privacy (Angst and Agarwal 2009), interoperability (Goldschmidt 2005, Lumpkin 2002), and changes in medical practice routines (Lapointe and Rivard 2005, Niazkhani et al. 2009) affect implementation of the PHRs, EHRs, and decision support systems required for effective chronic care management.



Contextual Design of IT Support

Our investigation into *CareTech*'s design and implementation of the CDPM system at *Alpha* also contributes to current knowledge on how to design IT support for chronic care management from a contextual point of view. Combining Pettigrew's Contextual Inquiry (1990) with Holtzblatt and Beyer's Contextual Design principles (1993, 1999) and the CCM helped us understand how *CareTech* approached the design and implementation efforts as they collaborated with *Alpha* to develop a solution suited to their practices and the needs of the local community. The resulting analysis of the design experience confirm existing knowledge of contextual design of IT support for chronic care management and offers new insights that can prove useful as support for future practices.

Our analysis (Tables 2–7) demonstrates that all of Holtzblatt and Beyer's Contextual Design principles have practical relevance for the design of IT support for chronic care management. The contextual analysis principle was applied by *CareTech* in the analysis and refinement phases; the work-modeling principle was applied in the analysis phase; the consolidation principle supported the initial focus group and refinement phases; the work-redesign principle was applied during the refinement and pilot phases; the user-environment design principle supported the pilot phase; and finally, the mockup and test principle supported the pilot and evaluation phases. At the same time, however, the analysis suggests that some principles could be improved and new principles could be added to better fit the complex contexts for chronic care management.

A first observation is that the contextual analysis principle should be elaborated to include "outer context analysis" as well as "work context analysis" (cf. Pettigrew 1987, 1990). While *CareTech* spent considerable and worthwhile efforts on understanding current workflows within the clinics (Tables 3 and 5), they also collaborated with the researchers to analyze principles for chronic care management in general and the CCM in particular. These efforts were documented in separate reports to the CDC, and they proved helpful as guidance for the design of the CDPM throughout the project. In addition, the initial focus groups (Table 4) included efforts to understand how IT support could be provided to prevent chronic diseases in the wider community.

A second observation is that the mock up and test principles was adapted by *CareTech* to an "iterative prototyping" principle. While Holtzblatt and Beyer argue for delaying coding until requirements have been evaluated through mock ups (that are easy and inexpensive to develop), *CareTech* successfully adopted an iterative prototyping approach in which code was created early in the process. The rationale was that, in this way, users could experience early versions of the system, and the development platform allowed for quick revisions to interface design. The value of this approach is demonstrated by the adaptation of screens for lab results (Table 6). Also, the option for having users experience system features early on helped overcome the barriers to participatory design created by lack of resources and experience in envisioning possible future work arrangements (Tables 3 and 7).

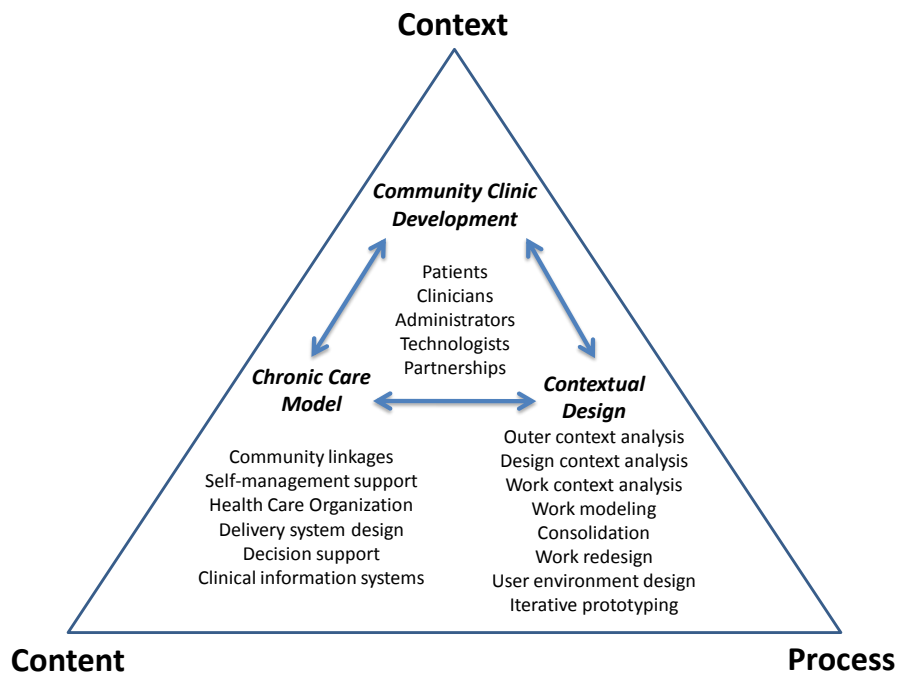


Figure 2: Modified contextualist framework.

A third observation is that the context in general was not amenable for participatory design of IT support: limited funding and staff resources in clinics (Tables 3 and 5), little tradition for workflow improvement (Table 3), many patients with little IT experience and no Internet access (Tables 3 and 4), emerging HRSA reporting requirements (Table 5), and difficulties related to provide IT support for chronic disease prevention in the wider community (Table 7). As a result, the project was delayed and *CareTech* had to expend considerable resources on shaping the context before it could move forward. Key initiatives included changes in project scope (Tables 4, 6, and 7), establishment of kiosk at *Alpha* (Table 5), co-funding and hiring of a patient navigator for training purposes (Table 5), and renegotiated contract for post-pilot use of CDPM (Table 5). These observations are consistent with Pettigrew's position that content and contexts mutually shape each other during complex change processes (1987, 1990). Hence, our results suggest the "design context analysis" principle through which the context for design is analyzed and modified to support participation, collaboration, and progress.

Reflecting these findings from the case study at *CareTech*, *Alpha*, and *Beta*, Figure 2 summarizes the modified Contextualist Framework for development of IT support for chronic care management.

CONCLUSION

This paper investigated the applicability of the CCM and contextual design principles to a chronic care software development project. Innovations related to chronic care are clearly relevant, given the burden these diseases places on patients and society as a whole. The project evolved within the context of two community clinics in which stakeholders operated largely in under-resourced environments. At the outset, the CDC motivation for funding the project was to link clinicians caring for rural and underserved communities with their patients, using the latest HIT. While seemingly narrow in scope, these more than 8000 clinics are expected to serve up to 51 million Americans by 2022 (Riselbach et al. 2010). To this end, *CareTech*, in collaboration with the *Alpha* and *Beta* clinics, successfully developed and implemented the Web-based CDPM tool, linking clinicians and patients to a common EHR accessible via the Internet. To aid in sense-making of the innovation process, we developed the Contextualist Framework to integrate emerging best practices for chronic care management (CCM) with a software design process well-suited to the contextual, nonlinear nature of healthcare delivery. The modified Contextualist Framework (Figure 2) provides a mechanism to evaluate progress during chronic care management innovation projects, maintaining both structure and flexibility as content, context, and process interact across time and organizational levels.

While the research project provided key insights into the design process, the generalizability of our findings are primarily limited to similar contexts. We note that the overall literature on the design of integrated systems for IT-enabled chronic care management remains quite limited. Given the importance of chronic disease management, future research directed toward this nascent technology will undoubtedly accelerate. Our modified Contextualist Framework can provide support for research into the design of these systems in the context of larger HIT developer environments. The integration of the CCM, coupled with a Contextual Design process account, is a useful lens for future IT design research in chronic care management. Despite the ubiquitous nature of the CCM in the medical literature and the importance of context in healthcare IT design, few papers have incorporated such a lens. Similarly, our study can inform research incorporating larger healthcare providers with a stronger tradition for process improvement, as these may benefit from a design process which is more closely aligned with Contextual Design Principles. Studies involving larger healthcare providers extending their current clinical IT systems to include a patient portal with PHR specifically aimed at chronic disease management will also benefit from our Contextualist Framework. Yet, both the IT provider and the clinics involved in our study were modest in size, and, as a result, our theoretical implications were influenced by constrained personnel resources and the ambitious goal of a full community-based solution. As a result, the strongest claims for our Contextualist Framework as a contribution are based on extensive data collected within the context of a modest IT provider designing an HIT solution for small community clinics.

For practitioners engaged in HIT software design in multi-organizational, multidisciplinary, and distributed contexts like chronic care management, this study suggests that singular focus on the deliverable, without careful and constant interaction with the context, can lead to significant delays or even project failure. A well-designed solution, even with exceptional functionality, cannot be deemed a success in the absence of an engaged client to support iteration and learning during pilot and implementation. Therefore, projects like these require significant commitments on behalf of under-resourced clients to help test and implement the solution, and management plans must incorporate these constraints into early project plans.

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ABOUT THE AUTHORS



Darryl Romanow received his BBA from Wilfrid Laurier University, an MBA from Georgia State University, and is a fourth year Computer Information Systems PhD student within the Center for Process Innovation at Georgia State University. His main research area is in domain of Health Information Systems, and his research interests cover adoption and diffusion of IT, implementation strategy, and IT enabled group level coordination. His previous work has appeared in *Harvard Business Publishing*. He is a member of AIS, and is currently the Associate Managing Editor for *MIS Quarterly*. Prior to joining the PhD program at Georgia State, he held a number of senior management positions in companies such as Baxter, Sandoz, John Deere, and Panasonic Automotive where he was engaged in hospital supply chain innovation, as well as ERP software selection and implementation.



Lars Mathiassen is a member of IEEE, ACM, and AIS. He received his master's degree in computer science from Aarhus University, Denmark, in 1975, his PhD in informatics from Oslo University, Norway, in 1981, and his Dr. Techn. degree in software engineering from Aalborg University, 1998. He is currently GRA Eminent Scholar and professor in Department of Computer Information Systems and co-founder of Center for Process Innovation at Georgia State University. His research interests are within information systems and software engineering with a particular emphasis on process innovation. He has coauthored *Computers in Context* (Blackwell 1993), *Object Oriented Analysis & Design* (Marko Publishing, 2000), and *Improving Software Organizations* (Addison-Wesley, 2002). He has served as senior editor for *MIS Quarterly* and his research is published in journals like *Information Systems Research*, *MIS Quarterly*, *IEEE Transactions on Software Engineering*, *IEEE Transactions on Engineering Management*, *Communications of the ACM*, *Journal of AIS*, *Information Systems Journal*, and *European Journal of Information Systems*. He can be reached at lmathiassen@ceprin.org.



Glenn Landers is a Senior Research Associate at the Georgia Health Policy Center. Mr. Landers's primary areas of expertise are in long-term care and access for the uninsured. Since joining the center in 1999, Mr. Landers has led a variety of projects on a range of topics. From 2001 to 2004 Mr. Landers designed and led an evaluation of Georgia's Indigent Care Trust Fund primary care plan. In 2004, he led a three-year research project that analyzed the costs and outcomes of Georgia Medicaid's nursing facility program and four home- and community-based services programs. From 2005 through 2011 he led the external evaluation of Georgia's Enhanced Care program for Medicaid's aged, blind, and disabled population. Mr. Landers's current projects include evaluating the expansion of Georgia's Aging and Disability Resource Connection for the Georgia Department of Human Services, Division of Aging Services, managing stakeholder groups and providing research support to Georgia's health insurance exchange feasibility study, evaluating DeKalb County Georgia's Communities Putting Prevention to Work grant, and evaluating Georgia Medicaid's Money Follows the Person grant. Mr. Landers received a BS from Syracuse University and MBA and MHA degrees from Georgia State University. He is currently pursuing his doctoral degree at Tulane University. His research has appeared in *Community Mental Health Journal*, *Hospital Topics*, and *Long-term Care Interface*.



Chris Parker is a senior research associate at the Georgia Health Policy Center. His policy interests are reflected in the projects that he continues to be engaged in at the Center. These include the examination of select Community Health Initiatives on behalf of the Commonwealth Fund, an assessment of the public health districts in Georgia and an examination of the issues surrounding health care coverage for the Uninsured. Chris holds BSc and MBBS degrees from the University of West Indies, and is a graduate of the Rollins School of Public Health at Emory University, where he completed his MPH degree, focusing in Health Policy and Management in 2001. While there, he authored and presented papers looking at Prescription Drug Benefits for the Medicare population, Improving Access for the Uninsured, and the Prescription Practices of HMO Physicians.



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