Study Title: Engaging disadvantaged patients in sharing patient generated health data and patient reported outcomes through health information technology

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SPECIFIC AIMS

This application in response to Special Emphasis Notice NOT-HS-16-015 proposes a pilot study to demonstrate the feasibility of using patient-centered commercial off-the-shelf (COTS) health information technology (IT) solutions to: 1) collect patient-generated health data (PGHD) and patient-reported outcomes (PROs) from diverse, disadvantaged populations, and 2) report PGHD and PROs in a way that will allow them to be integrated into clinical information systems and used to improve care. This study addresses four of the five research areas of interest to the Agency for Healthcare Research and Quality: *design* (Aim 1), *use* (Aim 2), *impact on outcomes* (Aim 2), and *implementation* (Aim 3).

Patient engagement is particularly critical to achieving good chronic disease self-management. This is especially important for disadvantaged patients, who are disproportionately affected by chronic disease. A key component of chronic disease self-management is the ability for patients to record and monitor their ongoing performance on indicator measures. While health IT solutions have been shown to improve chronic disease self-management, adoption and use of costly, specialized technologies among disadvantaged patients is lower than among higher-income populations. In contrast, COTS technologies such as mobile phones are more accessible to and widely adopted by disadvantaged patients, thus bridging the gap of the digital divide.

The central research hypothesis posits that 1) low-income, disadvantaged patients both can and will provide high quality PGHD and PROs through COTS-based health IT solutions, and 2) these data can be integrated into clinical systems and used to improve health care quality and delivery. PGHD can be collected through patient interaction with COTS health IT solutions such as mobile health apps and fitness trackers. PROs can be collected via patient response to questionnaire-based PROs measures, or PROMs. These data can be transmitted to clinical information systems, integrated into clinical workflows and used by providers to improve health care quality and delivery. Using a sequential integrated mixed-methods approach, we propose to test the central hypothesis through three specific aims, as follows:

Aim 1: To assess the needs and preferences of disadvantaged patients and safety net health care providers regarding the use of health IT for communicating PGHD and PROs.

Aim 1 Research Questions: What specific features in COTS solutions meet the needs and preferences of disadvantaged patients for communicating PGHD and PROs to their providers? What PGHD and PROs are deemed most important by providers and patients for improving health care and health outcomes?

Answering these questions will inform health IT solution selection, design, usability, and utility; assist with prioritizing PGHD and PROs collection by data element and measure type; and identify potential discrepancies between patients' and providers' perceptions of PGHD and PROs importance.

Aim 2: To demonstrate the feasibility of PGHD and PROs collection through COTS health IT solutions in a patient-centered pilot intervention for weight management among disadvantaged patients.

Aim 2 Hypothesis: Providing PGHD and PROs through COTS solutions will improve engagement among disadvantaged patients. Secondary outcomes include improving key health indicators (e.g., weight, physical activity) and PROMs (e.g., quality of life, mental health symptoms).

Weight management is important in delaying, averting, and reducing the effects of multiple chronic diseases, including diabetes, hypertension, and obesity. A weight management-related intervention also serves as an effective test of PGHD and PROMs collection, due to the existence of numerous COTS solutions which use different methods for tracking common data elements related to weight, physical activity, and fitness.

Aim 3: To create an ontology mapping and set of interoperability resources which can be used to support integration of PGHD and PRO into clinical information systems.

Aim 3 Hypothesis: PGHD and PROs can be characterized by distinct types, elements, and structures which, once described, may be modeled and mapped to existing vocabularies for health data management.

In order to make PGHD and PROs actionable, these data must be integrated into clinical information systems such as electronic health records (EHRs) where it can be used by clinicians in their practice. Creating a "translation" by matching PGHD and PROs data elements to comparable ones in existing clinical vocabularies will provide a tool to support future data integration into the EHR. Creating a resource set which can be used with multiple EHRs will improve the generalizability and broad usability of the ontology mapping tool.

RESEARCH STRATEGY

1. SIGNIFICANCE

1.1. The problem of chronic disease is both severe and deadly. In April of 2011, the World Health Organization (WHO) confirmed that chronic diseases have become the leading cause of death worldwide (1). That effect has continued to worsen, with 68% of annual global mortality (38 million deaths) now due to chronic disease, the majority of which are from cardiovascular disease, diabetes, cancer, and chronic lung disease (2). As these illnesses are all affected by obesity, we have chosen to use obesity as an exemplar for this study. Obesity is a complex chronic disease associated with increased mortality and higher risk for more than 20 other chronic diseases and health conditions, including hypertension (HTN), diabetes (DM), hypercholesterolemia, heart disease, stroke, and certain cancers (3-11). Fully a third of HTN cases can be attributed to obesity, and more than 80% of people with DM are overweight or obese (12). The lifetime risk of coronary heart disease is 7% higher among obese people than those of normal-weight (13). Among persons aged 20-30 years, obesity contributes to lower life expectancy by 5-20 years (13, 14). A total of 112,000 people die annually from obesity-related causes (10). People who were obese as children are twice as likely to die before reaching age 55 as are those who were at a healthy weight during childhood (10). In the last 30 years, obesity rates have doubled in the United States (US) among adults to 35% for men and 40% for women, and tripled to 17% among children (13, 15-17). This affects 85 million people in the US and 500 million people worldwide (13, 15-17). The impact on the health system associated with obesity-related expenditures is likewise overwhelming. Over $150 billion is spent annually on obesity-related direct medical costs, which equals nearly 10% of all medical costs (7, 18) and $1,429 more spent annually per patient among obese people as compared to expenditures for normal-weight patients (15, 19).

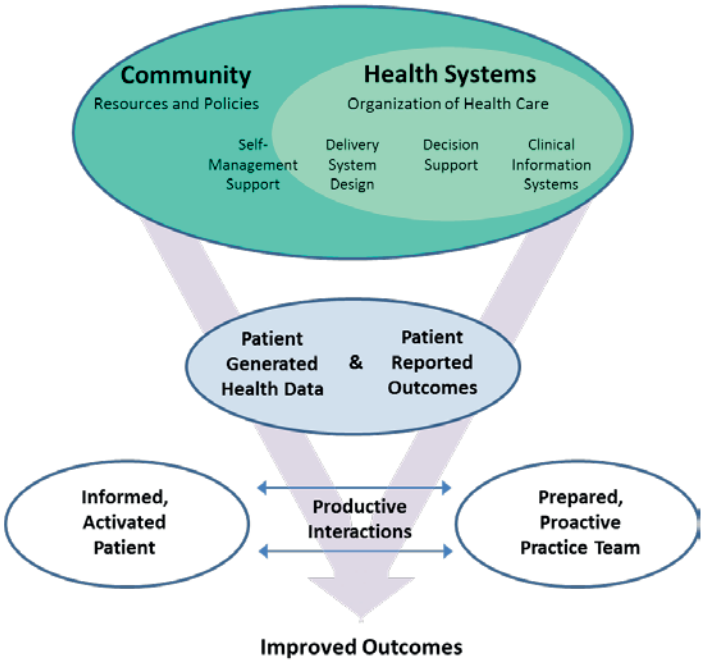
1.2. The impact of chronic disease is much worse for disadvantaged patients. The appellation of "disadvantaged patients" is here synonymous with the "priority populations" of interest to the Agency for Healthcare Research and Quality (AHRQ). These are patients who are primarily served by the health care safety net (20), which is comprised of health systems and providers who care for patients regardless of their ability to pay. These patients represent racial and ethnic minorities, low-literacy populations, people with disabilities, children and the elderly, those living in rural areas, the uninsured, the underinsured, and those with low income. On a global scale, nearly 75% of deaths from chronic disease occur in low and middle-income countries, with nearly half (48%) occurring before age 70 (2). Similar trends are reflected in the US, where disadvantaged patients are more greatly burdened by chronic disease (21-23) and also experience disparities in treatment. Significantly higher prevalence of chronic disease has been observed among blacks, Latinos, and Asians than among whites, as well as among those near or below the federal poverty level as compared to those 200% or more above it (24-26). Blacks and Latinos receive worse care than whites (40% and 60%, respectively) and have more difficulty accessing care (33% and 83% of the time, respectively), and the poor receive worse care and have worse access than those with higher incomes (27-29). As with other chronic diseases, the impact of obesity is much worse for disadvantaged patients (12, 15-17, 30). Black adults are one and a half times as likely as whites to be obese; 38.2% of black men and 57.2% of black women are obese, compared to 35.4% of white men and 38.7% of white women (16). Among Latinos, the fastest-increasing population in the US, 43% of adults are obese (12, 15, 16). Of the 10 states with the highest rates of obesity, (31.7% - 35.1% obese), 9 are among the poorest in America, with 30% or more of their population living in poverty (12, 31).

1.3. Patient reported outcomes (PROs) and patient generated health data (PGHD) are critically important for good chronic disease management. In contrast to treatment for short-term acute conditions, care for chronic disease depends on engaging patients in successful self-management of their conditions over time, outside the setting of the infrequently-occurring, traditional 20-minute primary care clinic visit (25). This is even more important for disadvantaged patients, who have less access to clinic settings and more severe burden of chronic disease (21-23, 27-29). Regular daily and weekly logging of PGHD such as fasting glucose levels, blood pressures, minutes of physical activity, and weight has proven beneficial in chronic disease management (32-34). Such logs not only give patients an ongoing picture of their health and success at self-management, but also give providers a valuable source of information that can be used to monitor disease trends and performance over time on key indicators. In addition to the value of PGHD logging, regular collection of PROs measures, or PROMs, through administration of validated instruments can provide critical ongoing information about a patient's overall health status, quality of life, co-occurring conditions, "activation" or engagement in care, activities of daily living, and perceived self-efficacy at chronic disease management (35-

39). Having this information readily available to providers through integration into clinical workflows and EHRs makes it actionable for use in care planning and during clinical visits, thus improving the quality of care.

Returning to obesity as our exemplar condition, experts have concluded that obesity is a complex chronic disease which requires long-term behavioral changes (40). Evidence-based strategies for weight loss success, according to recently-updated clinical guidelines (40, 41), include engaging in comprehensive lifestyle interventions that include regular contact with and support from trained interventionists (40-42). Provider counseling has been shown to have significant positive impact on patient attempts to lose weight (43), but the time constraints of primary care clinic visits limit what advice can be given (30). Moreover, a dependency on visit-based primary care for obesity management in particular may even cause unintended harm. Providers are often reluctant to counsel patients about weight loss, or do so less effectively due to the influence of weight stigma and weight bias (44-47). Patients who experience weight stigma have lower levels of trust in their Providers and may avoid or delay needed health care (6, 48, 49); in addition, stigmatization itself is associated with increased physiological and psychological difficulty in losing weight (50-53). It is therefore clear that a solely visit-based model is insufficient for good chronic disease care. The Chronic Care Model (CCM), as developed by Wagner et al. (54-56), describes an interactive approach to chronic disease management that is based on a dynamic partnership between health systems, providers and patients. The CCM incorporates the use of health data for decision support, for care planning, for performance monitoring, and for self-management support intended to empower and engage patients in their care (57, 58). PGHD and PROs collection provides a strong foundation for a CCM-based approach. Figure 1 depicts a modification to the CCM that illustrates how PGHD and PROs can be incorporated to influence patient activation and health team preparation by making patient-provider interactions more productive.

Figure 1. Modified Chronic Care Model

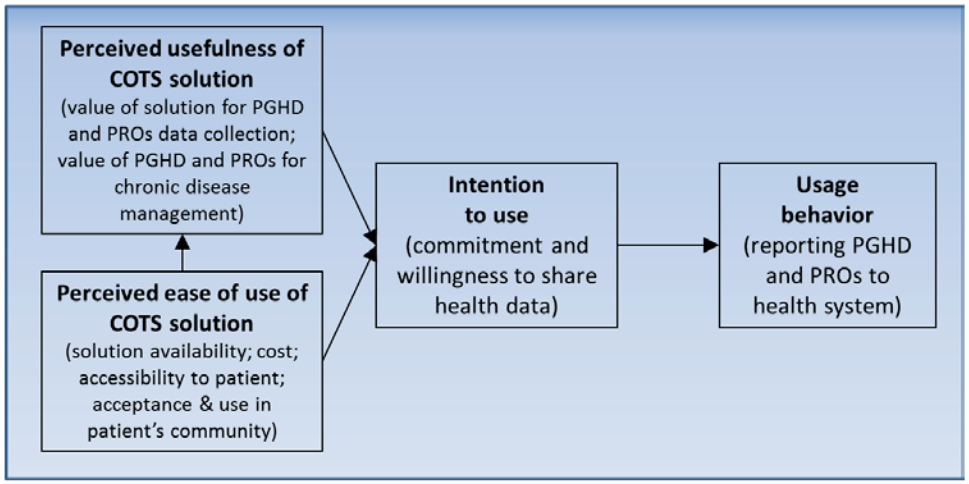


1.4. <u>Patient-centered commercial off-the-shelf (COTS) health IT solutions can facilitate collecting PGHD and PROs from disadvantaged patients between clinical visits.</u> Health IT is well suited to support health systems and communities in the four identified domains of the CCM (54-57, 59). Patient-engaging health IT solutions have proven effective in chronic disease management (60), with results that include improved blood pressure control in patients with HTN (61, 62), improved glycemic control in patients with DM (63, 64), and improved medication adherence in asthmatic patients (65). Such solutions have likewise proven effective for weight loss, with outcomes that include clinically significant decreases in weight, better-sustained weight loss, and positive social support (66, 67). Despite a still-pervasive belief that disadvantaged patients are not effective users of technology, disadvantaged patients have shown clear receptivity to and interest in patient-centered health IT solutions (68-76). Studies among patients at Denver Health (DH), an urban integrated safety net health care system that predominantly cares for a diverse population of low-income, disadvantaged patients, have demonstrated patient engagement with reporting PGHD to the health care system by text message (77-79), and have shown improvements in weight loss outcomes among patients participating in a text-message based intervention aligned with the Centers for Disease Control and Prevention's (CDC) evidence-based Diabetes Prevention Program (78, 80). Additional findings among DH patients (81) indicate a significant, positive association between IT-based health information seeking and general health status (66, 67, 81) and widespread interest in using health IT to obtain information about food, nutrition, and diet (79% of respondents) and exercise and physical activity (72% of respondents). These results mirror nationwide findings (82). Moreover, for information and communication technologies (ICT) such as computers and cell phones, use among DH patients was similar to use reported both nationwide and in other disadvantaged populations (81, 83-88). This offers significant potential for health interventions that are a good fit with patients' established health IT use patterns (81) and which utilize technologies that have reached the point of widespread commercial availability. These commercial off-the-shelf

(COTS) solutions (89)are ideally suited for collecting PROs and PGHD from patients due to their high degree of adoption and integration into daily use. The market-standard lower prices associated with widespread adoption also reduce barriers to access for disadvantaged patients. In addition, COTS technologies such as smartphones and fitness trackers have the potential to support the collection of patient contextual data through consent-based passive methods that do not impose an excessive data entry burden on patients. Examples of such data include neighborhood and other location-based characteristics drawn from GPS readings and physical activity type and duration information based on accelerometer readings.

The impact of COTS technologies on PGHD and PROs collection can be predicted by health behavior theory. The Theory of Planned Behavior (TPB) (Ajzen, 1991) describes how a person's behavior can be predicted by the strength of that person's intention to perform the behavior. Intention is influenced by the person's 1) *attitude* toward the behavior, 2) subjective *norms*, and 3) perceived behavioral *control* (90). The more positive the person's attitude, belief in normative behaviors, and perceived behavioral control, the stronger their intention, and the more likely they will achieve the intended behavior. The Technology Acceptance Model (TAM) (Davis, 1989, original; Venkatesh & Davis, 2000, extended) describes how TPB constructs can be applied to predict IT adoption and use (91, 92). The stronger the influence of the TPB constructs, the more likely a person is to use an IT solution. COTS solutions are more likely to be perceived as easy to use and accepted as everyday, normalized technologies. These perceptions then influence the patient's intention to use and subsequently increase the patient's likelihood of performing the desired behavior, in this case the collection and reporting of PGHD and PROs. Figure 2 illustrates the application of the TAM to the provision of PGHD and PROs through COTS health IT solutions, showing the theorized impact.

Figure 2. Technology Acceptance Model for COTS Influence on PGHD and PROs Collection



1.5. Collecting PGHD and PROs through patient-centered COTS health IT solutions also aligns with national trends for care delivery and long-term goals for knowledge management.

The plan proposed by the Office of the National Coordinator for Health IT (ONC) to achieve an interoperable health IT infrastructure (93) includes recommendations for empowering patients to integrate information from electronic health records (EHRs) into personal software apps and digital health tools, with a 10-year goal set for patient management of health information across multiple platforms from their own COTS devices. The ONC's plan also calls for bidirectional data interchange between health care providers and public health systems, with the intention of improving care quality, clinical processes, health outcomes, and the overall public health (93). Integrating PGHD, PROs, and patient contextual data obtained from engaged patients through COTS health IT solutions into interoperable systems where it can be made actionable for use in health care directly supports the ONC's recommendations.

At present, achieving interoperability remains a considerable challenge. Despite efforts begun under the Health Information Technology for Economic and Clinical Health (HITECH) Act and expanded under the Patient Protection and Affordable Care Act (ACA) (60, 94, 95), health data remain fragmented across disparate systems and solutions. The JASON report (96, 97) highlights this lack of integration and calls for an

orchestrated architecture based on open standards as the solution. Health Level Seven International (HL7) has been accredited by the American National Standards Institute (ANSI) as an organization with the goal of creating interoperability for the health care field by developing a comprehensive framework and related standards to govern the exchange, integration, sharing, and retrieval of electronic health information from EHRs and other information systems. Currently, HL7's >2,300 members represent over 90% of health IT vendors (98). The newest standard from HL7 is the Fast Healthcare Interoperability Resources (FHIR) specification, which is intended to provide a set of resources that will define the information content and structure shared by the majority of implementations (99). FHIR resources can be represented in the widely-adopted eXtensible Markup Language (XML) and JavaScript Object Notation (JSON) formats, which ensures ease of use by health IT vendors and developers. The Argonaut Project (100, 101) represents a coalition of 11 organizations, including EHR vendors (e.g, Epic, Cerner) and health systems (e.g., Intermountain, Mayo Clinic) who have joined to implement JASON-based recommendations by accelerating the adoption of FHIR as an interoperability standard. The Substitutable Medical Apps & Reusable Technology (SMART) Project (102, 103) has adopted FHIR in its latest platform architecture release; SMART on FHIR is a set of open specifications that support the integration of mHealth solutions with EHRs and other health IT systems (104). It seems clear that the growing adoption of FHIR as the next-generation standard will accelerate the interoperable exchange of data between COTS health IT solutions and EHRs. It will be critically important to address the structured inclusion of PGHD, PROs, and patient contextual data in the information being exchanged.

Multi-institutional distributed data research networks are also addressing the challenges inherent in establishing and sustaining big data infrastructure to support health research, public health surveillance and health data exchange. Besides interoperability, these challenges include questions of governance, security, database architecture, data warehousing, and methods for querying data systems. Examples of such networks include the Health Maintenance Organization Research Network (HMORN) (105); the Food and Drug Administration's (FDA) Mini-Sentinel Program (106); and the Patient Centered Outcomes Research Institute's patient centered outcomes research clinical research network (PCORnet), launched in late 2013 with the creation of 11 clinical data research networks and 18 patient-powered research networks as components of a national infrastructure (106-108). Part of PCORnet's mission is to include PGHD elements together with EHR data in the network architecture. Doing so establishes a foundation for including PROs and patient contextual data as other patient-centered data elements important to health care quality and delivery. Creating a model and a set of resources to support this data integration will be of benefit to this process.

1.6. In summary, this study will demonstrate the feasibility of using COTS health IT solutions to collect PROs and PGHD from low-income, disadvantaged patient populations that are of priority interest to AHRQ. The PGHD and PROs data collected from these patients will then be mapped for transmission to clinical information systems, integration into clinical workflows, and use by providers to improve health care delivery and quality. This work can help circumvent barriers to health care access, improve chronic disease management for disadvantaged patients, improve communication and knowledge sharing between patients and providers, support the collection and integration of actionable health data into clinical systems and big data infrastructures, and offers potential for creating better health care interventions that utilize technology-based means of delivery.

2. INNOVATION

The results of this study are expected to challenge existing preconceptions about the ability and willingness of disadvantaged patients in AHRQ's priority populations to use technology such as smartphones and mobile devices to share patient-provided health information with their care providers between clinic visits. By demonstrating the feasibility of PGHD and PROs data collection through COTS health IT solutions, this study will show the capability of engaged patients from priority populations to actively participate in their own chronic disease management. Furthermore, by providing a road map and standards-based set of resources to facilitate integrating PGHD and PROs data into a multitude of clinical systems, this study will create a means to make these data actionable for use in improving health care quality and delivery. If the aims of the study are achieved, the results will substantially expand options for conducting high-quality health care interventions with disadvantaged patients using health IT.

The research proposed under this award is innovative in three ways:

2.1. It will identify specific needs and preferences for PROs and PGHD data collection, along with features and design elements common to COTS solutions that are preferred by disadvantaged patients and the providers who care for them (Aim 1). Ascertaining these factors will inform health IT solution selection, design, usability, and utility for AHRQ priority populations. This will support the future development of more extensible solutions with broad applicability; aid with prioritizing PGHD and PRO collection by data element and measure type; and identify potential conflicts between patients' and providers' interests and relative perceptions of the value of PGHD and PROs data.

2.2. It will demonstrate the feasibility of collecting PGHD and PROs data from disadvantaged patients through COTS health IT solutions (Aim 2). Using extant patient-preferred COTS technologies rather than limiting patients to interaction through single-purpose, high-maintenance health IT solutions will increase engagement, promote adoption, and support flexible, expandable options for future interventions. Obtaining actionable PGHD and PROs data for use by providers will improve care planning and chronic disease management for a disadvantaged patient population that is in considerable need.

2.3. It will address the integration of PGHD and PROs data into EHRs (Aim 3). To make PGHD and PRO actionable for use by providers, these data must be made available within the clinical information systems that providers already use. Existing EHR-based import methods for these data have proven ineffective. Creating a "translation" by mapping PGHD and PROs data elements to comparable ones in existing clinical vocabularies will provide a tool to support data integration. Creating a FHIR resource set which can be used for implementation with multiple EHRs and clinical information systems will improve the generalizability and usability of the mapping tool.

3. APPROACH

The overall design proposed for this research is a sequential integrated mixed methods study (109, 110). The study will consist of three phases, one for each specific aim, each of which informs and supports the next: (1) a qualitative formative phase to refine intervention design; (2) a randomized controlled trial to assess the feasibility of collecting weight management-related PGHD and PROs data through COTS health IT solutions; and (3) the creation of a data model, ontology mapping tool and set of FHIR resources to support integration of PGHD and PROs data into clinical information systems.

3.1. Setting

This study will be conducted at Denver Health (DH), an urban integrated safety net health delivery system that serves as the primary health care safety net for the city and county of Denver, Colorado. DH serves an estimated one in four Denver residents, or approximately 190,000 individuals per year. Almost two-thirds of the patients seen are members of racial/ethnic minority groups. The majority of DH patients are low-income, with over 70% living beneath the poverty line, and over 95% living within 200% of the federal poverty level. DH includes a 525-bed acute care hospital with an academic Level 1 Adult and Pediatric Level II Trauma Center, nine federally qualified community health centers, sixteen school-based clinics in the Denver public school system, a 100-bed non-medical detoxification facility, correctional care services for Denver's jails, a health maintenance organization, the 911 medical response system, a 24-hour nurse line, the Rocky Mountain Poison and Drug Center, and the Denver Public Health department.

3.2. Research Team

The research team for this study is comprised of a multidisciplinary group of investigators with expertise in health IT, mobile and digital health, health informatics, distributed data networks, primary care, chronic disease management, qualitative methods, mixed methods research, health services research, public health, and delivery system and implementation science. The diversity of this group represents the broad interdisciplinary nature of teams needed to address treatment for complex chronic conditions through health IT solutions that involve human factors and infrastructure considerations for PGHD and PROs data collection and knowledge management. Team members include:

- **Susan L. Moore, PhD, MSPH (Principal Investigator).** Dr. Moore is a health services researcher and the Assistant Director of the Center for Health Systems Research at DH, where she has been involved in research projects concerning the use of health IT to improve public health emergency preparedness, patient safety, and care for chronic conditions.. She also serves as the mobile health research core lead in the Adult and Child Consortium for Outcomes Research and Delivery Science (ACCORDS) at the University of Colorado. Prior to her research career, Dr. Moore worked in IT for ten years, focusing primarily on implementation and support for software systems and technical education, training, and evaluation. Her ongoing research interests include consumer health informatics, clinical decision support, the application of mixed methods to health systems research, and the use of mobile health technology to deliver patient-centered care.

- **Arthur J. Davidson, MD, MSPH (Co-Investigator).** Dr. Davidson is the Director of Public Health Informatics, Epidemiology and Preparedness at Denver Public Health, a division of DH. He has served on two federal advisory committees, the Health IT Policy Committee to the Office of the National Coordinator for HIT (ONC) and the Board of Scientific Counselors for the National Center for Public Health Informatics, and as a board member for the National eHealth Collaborative. His current research is focused on integrated informatics applications and distributed data networks that support both clinical care and public health initiatives. He is the site lead on DH's collaboration with Kaiser Permanente of Colorado to develop a clinical data research network funded by PCORI.

- **Henry H. Fischer, MD (Co-Investigator).** Dr. Fischer practices internal medicine and has been the Director of the DH Diabetes Collaborative since 2010. His research interests include the exploration of new modalities for chronic disease management, including the use of health IT, text messaging, and nurse-based algorithmic care. He currently oversees the system-wide operation of DH's text messaging programs for appointment reminders, weight loss support, flu vaccination, and well child visits.

- **Andrew W. Steele, MD, MPH, MSc (Co-Investigator).** Dr. Steele is a general internist, the Chief Medical Information Officer at DH, and one of the first board-certified clinical informatics subspecialists in the nation. His research interests include an emphasis on cost-effective utilization of computer technology in the clinical arena, the use of patient-reported data for chronic disease management, and the use of automated clinical decision support to improve patient safety and quality of care. He currently oversees the Epic EHR design and implementation activities for DH.

Further detail on the investigators and additional research team staff is included in the Biosketches and Budget Justification sections.

3.3. Preliminary Studies

For the last six years, our research team has collaborated on projects designed to improve health care quality and delivery for disadvantaged populations through health IT solutions. Common research themes among the projects described include 1) using qualitative methods to elicit patients' perspectives about employing specific familiar technologies, 2) creating and/or enhancing data infrastructure, and 3) patient-generated data collection through text messaging. The proposed work will build on this foundation by engaging disadvantaged patients in the use of COTS health IT solutions that are more advanced, feature-rich, and secure than text messaging alone. It will also enhance patient-reported data collection by including not only PGHD but also more complex data elements, such as multi-question validated PROM instruments and patient contextual data, and will define a route to integrating these discrete data elements into interoperable EHRs, clinical information systems, and big data infrastructures. Brief descriptions of pertinent studies are included below.

3.3.1. Chronic care and patient relationship management proof of concept (internal funding)(77).

This mixed methods proof of concept study involved the creation of a health IT system to support chronic disease management through bidirectional text messaging. Adult patients with diabetes self-reported fasting glucose levels on a daily basis in response to a text message prompt; a nurse case manager reached out to follow up by phone with patients whose glucose levels were outside an accepted clinical range. Patients also

received text message reminders of upcoming appointments in an urban safety net health care system. Patients responded to 68% of prompts and reported feeling more connected to the health system.

3.3.2. *Expanding comparative effectiveness research (CER) capability through complex patient relationship management. AHRQ, grant 1R24HS019453*. (79, 111)

This mixed methods feasibility study built on the previous proof of concept to demonstrate the use of an expanded health IT infrastructure for patient-reported data collection and subsequent data integration into an EHR. Adult patients with diabetes used a text message-based mobile health infrastructure to report fasting blood glucose levels, blood pressure measurements, and/or step counts in response to regularly-scheduled prompts. Reported values were automatically formatted into a self-reported data log, transmitted to the EHR, and made available to providers through attachment to the patient's medical record as an image file.

3.3.3. *Integrated model of individualized ambulatory care for low-income children and adults (21st Century Care). CMMI, Health Care Innovation Award 1C1CMS331064.*(112, 113)

This program sought to improve outcomes associated with the Triple Aim (114) through an integrated approach combining revised staffing models, updated approaches to team-based care, and the use of health IT infrastructure tailored to support care management, complex data reporting and analysis, and between-visit text message outreach initiatives. As part of the project, the RE-AIM framework (115) was used to assess (a) pilot and expansion-phase process and health outcomes for each of 5 separate text messaging initiatives targeted at improving service delivery and health promotion, and (b) the implementation and adoption of new health IT infrastructure to improve care coordination and management for safety net patients across 8 primary care clinic settings.

3.3.4. *Developing infrastructure for patient-centered outcomes research (PCOR) at Denver Health. AHRQ, grant 1R24HS022143-01.*(116)

This project created multiple PCOR infrastructure components at Denver Health: a research support core, a new investigator training program, a community advisory panel, and three research projects. The first research project was a randomized controlled trial to examine the use of text messaging for weight loss support among patients with pre-diabetes, which resulted in clinically significant weight loss. Another pertinent component of the overall grant-funded initiative involved the expansion of an existing virtual data warehouse (VDW) to incorporate mental health data from two partnering health for public health surveillance and PCOR purposes.

3.4. Study Design and Methods

3.4.1. *To assess the needs and preferences of disadvantaged patients and safety net health care providers regarding the use of health IT for communicating PGHD and PRO.*

Design. Semi-structured interviews with providers and focus groups with patients will be conducted in the qualitative formative phase of this proposed study. These sessions will elicit in-depth information that is expected to yield a rich contextual understanding of needs and preferences for COTS health IT-based PGHD and PROs reporting, including perceived self-efficacy at doing so and an assessment of gaps in current systems.

Settings/ populations. Provider interview participants will be identified from among the 1,087 credentialed providers employed by and affiliated with DH. Patient focus group participants will be recruited from the 9 federally qualified health centers (FQHCs) that provide primary care services to DH patients.

Methods. Semi-structured protocols will be developed for use in both interviews and focus groups. Protocols will be tailored to elicit factor data that can be used in qualitative comparative analysis (QCA). QCA is a case-oriented approach based on set theory and Boolean algebra, and uses configurational methods to evaluate complex causal relationships and factors deemed necessary and sufficient to influence outcomes (117, 118). Unlike regression models, QCA assumes multiple paths lead to intended goals ("equifinality"), and explicitly assesses the effect of combinations of factors ("multiple conjunctural causation") (117-119). QCA has been used to study health care models and practices as well as structures and processes linked to weight loss outcomes (118-120). Questions anticipated to elicit QCA factor data include inquiries about user-preferred

technologies, willingness and ability to use technology to support weight loss, and social and behavorial factors affecting both weight loss and technology use. Protocol questions will also be informed by previous findings from a consumer health informatics-focused survey of DH patients (81) and by qualitative evaluations conducted during the preliminary studies (Section 3.3), and will address health IT design considerations of usefulness, usability and user experience, and care process impact. A draft protocol is included as Appendix 1. Purposeful sampling (121) will be used to enroll overweight and obese adult patients (BMI 25.0-39.9, 18+ years) in focus groups stratified by two domains: primary language (English or Spanish) and self-reported technology use (high or low). Focus groups will be conducted by a trained facilitator in English or Spanish based on patients' primary language, with the assistance of a bilingual research assistant trained in qualitative methods as an observing note-taker. Patients will be classified as technology users based on their responses at enrollment to screening questions about IT use type and frequency. In order to reach saturation, defined as the point at which no new topics and themes emerge from discussion, 2 focus groups will be conducted for each domain, for a total of 8 groups. Six to 8 patients will be recruited per group, for a total of 48 to 64 patients. Provider interview participants will be solicited as key informants identified by their peers as those who are likely to be particularly knowledgeable about the topic of interest (121). Both patient and provider participants will receive a $25 gift card incentive. Two to 3 interviews are anticipated per FQHC site, for a total of 18 to 27 interviews. All focus group and interview sessions will be audio recorded and transcribed; additional observations will be documented through detailed note-taking.

Data Analysis. Transcript and note data will be subjected to content analysis. A list of codes will be developed *a priori*, with additional codes added through a heuristic approach, which supports the incorporation of emergent topics and themes. Data will be independently coded in Atlas.ti by both the focus group facilitator/interviewer and the observing note-taker, with interrater reliability assessed through the kappa statistic (122-124). Identified patterns will be incorporated into an overall synthesis that will be used to inform the development of the intervention and to create set-theoretic groups for QCA (see Specific Aim 2). Results are anticipated to reveal commonalities about the types of technology that patients use; data types, frequencies and methods for reporting data as preferred by both patients and providers; and contextual factors that affect technology use and weight loss (economic, educational, geographic, social, and behavioral). These will be used to refine the list of specific PGHD and patient contextual data elements for patients to report.

3.4.2. Specific Aim 2: To demonstrate the feasibility of PGHD and PRO collection through COTS health IT solutions through a patient-centered pilot intervention for weight management among disadvantaged patients.

Design. This phase of the study will be conducted as a randomized controlled trial (RCT).

Settings/ populations. Intervention and control patients for this trial will be recruited from among DH overweight and obese adults (BMI 25.0-39.9, 18+ years) who are considered to be at medium health risk according to a risk stratification algorithm developed by DH and used in its 21st Century Care model to tailor care to patients according to level of need (125, 126). Risk stratification is based on a combination of clinical criteria, a patient's diagnostic score (127), and health care utilization (127, 128). Previous findings indicate an association between good general health status on the CDC's Healthy Days measure (HRQOL-4) and the use of health information among patients in the medium risk group. This association was absent among patients in the lower risk group and thus may indicate a point in chronic disease progression when health IT-based interventions could positively affect chronic disease management through patient engagement, with the long-term goal of delaying or avoiding poor health outcomes (81).

Methods. Recruited participants will be randomized to one of two arms, intervention or control. Both intervention and control groups will engage in a 16-week program where they will receive regular health promotion messaging about (a) food, nutrition, and diet; and (b) exercise and physical activity. Existing content in these topic areas is available in a DH text messaging library aligned with the Centers for Disease Control and Prevention's (CDC) evidence-based Diabetes Prevention Program (80), for which a previous study demonstrated clinical efficacy (116). Additional messaging content will be informed by focus group and interview findings. Intervention patients will be asked to track PGHD elements related to weight management through a mobile health app loaded on their phones and/or through using a fitness tracker, depending on patient preference, and to share that information with the research team. If intervention patients do not have a fitness tracker, a low-cost COTS option will be provided for them. Both iOS and Android phone options will be

supported. The app will be selected from a limited set of well-established options such as LoseIt!, MyFitnessPal, Apple Health, or Google Fit. The PGHD requested through active tracking and patient data entry will include self-monitoring elements previously shown to be successful at encouraging obesity-related behavioral change (129), such as calorie intake, food logging, minutes of physical activity, and weight. Patient contextual data requested through passive tracking may include items such as geographic location, sleep quality, and heart rate. Any additional data requested will be determined based on the results of Aim 1 and in consultation with the research team to identify social, behavioral, and clinically relevant information. Both intervention and control patients will be weighed on a clinic scale and asked to complete three PROMs pre- and post-intervention. These include the short form of the Patient Activation Measure (PAM-13), which is a validated PROM that assesses an individual's knowledge, skills and confidence in self-management behaviors (35, 36); the HRQOL-4, which is a validated PROM that assesses patients' overall physical and mental health status over the prior 30 days (37); and the Healthy Days Symptoms Module, which is a validated PROM that assesses physical and mental health symptoms which may have affected patients' lives over the prior 30 days (37). Intervention patients will also be asked to complete the three PROMs once each per month over the course of the 16-week intervention by email, online web form, text message, or app-based private message. Only privately submitted PROM data will be used in analysis, to protect patient privacy and to avoid social desirability bias due to self-curation behaviors associated with public reporting. One PROM will be collected per week, to avoid overburdening patients while ensuring a monthly collection of PROM data. The fourth week will include a simple check-in request, to maintain the weekly communication pattern. PGHD and PROs data will be extracted from shared systems, online forms, and messages as appropriate and placed into a REDCap (130) research database created for the project. These data will also be made available to and actionable by DH providers monthly through manual transfer to practice-standard patient-reported data forms and subsequent entry into the EHR. As this is a feasibility study, automated data exchange is beyond the scope of this initial project; however, the product of Specific Aim 3 will support future automated integration.

Outcomes and measures. The primary outcome of interest for the RCT is *patient engagement*. This outcome will be measured by patient response rates to data requests; by the frequency of unprompted messages sent by patients to research personnel; and by performance on the PAM-13. Secondary outcomes include weight loss and performance on the HRQOL-4 and Healthy Days Symptoms PROMs pre- and post-intervention. Weight loss will be assessed as change in body mass index (BMI) and absolute percent weight.

Data Analysis. Descriptive statistics will be computed for participant demographic characteristics (e.g., age, gender, race/ethnicity). Group differences (intervention vs. control) will be evaluated to ensure that the random group assignments were similar. If statistically significant differences ($p<0.05$) are found between the groups for demographic or baseline measures, these will be controlled for in subsequent analyses. Logistic regression or the Chi-square test of proportions will be used to test differences in response rates and PROM scores between the RCT intervention and control groups. The distribution of the number of unprompted messages will be assessed and either analyzed using Poisson regression or dichotomized based on a clinically relevant cut-off and analyzed with either logistic regression or the Chi-square test of Proportions. Weight loss will be analyzed using the most appropriate and parsimonious multivariable regression technique, based on the nature of the outcome variable (e.g., continuous, time-varying, dichotomous, etc.). Fuzzy-set QCA will be conducted to examine the impact of factors identified through work conducted under Specific Aim 1.

Power. A total sample size of 256 patients is necessary to detect a proportional difference of 20% (0.55 intervention; 0.40 control) in the primary outcome between the intervention and control groups with 90% power (alpha=0.05). A sample size of 192 patients would be needed at 80% power. Given the nature of this feasibility study, we will attempt to recruit 300 patients for the RCT, but will consider the study adequately powered with 200 patients enrolled (100 intervention, 100 control). This also allows for some loss to follow-up.

3.4.3. *Specific Aim 3. To create an ontology mapping and set of interoperability resources which can be used to support integration of PGHD and PROs into clinical information systems.*

Design. In this phase of the study, an enhanced entity-relationship (EER) data model will be created for the common set of PGHD elements and PROMs identified and collected in Aim 2. Knowledge representation techniques will be utilized to describe the model in ontological terms, and concepts from the UMLS Metathesaurus will be used to create a mapping to the SNOMED-CT clinical vocabulary. The model will used to create a set of FHIR resources which can be used for future implementation to facilitate interoperable data

transfer between FHIR-compliant mobile health IT solutions, EHRs and other FHIR-compliant clinical information systems.

Methods. The PGHD elements and PROMs used in Aim 2 will be reviewed for confirmed feasibility and used to establish a final, feasible set list of feasible data elements that are perceived to be valuable to patients and providers engaged in obesity-related chronic disease management. Each data element will be documented as a FHIR resource and represented in the XML format. An assessment of data exchange and common technical interface requirements will be conducted for the COTS solutions used by patients in Aim 2 (e.g., MyFitnessPal on iOS and Android, integrated with a fitness tracker and/or mobile phone as a passive data collection source). The results of this assessment will be documented as a FHIR interface description and profile. Relationships between model elements will be portrayed using common knowledge representation techniques. An "inside-out" design will be used for three-phase model development, including classification, in which similar data elements are grouped into entity types; identification, in which types are assigned unique identifiers; and relationship identification. Relationship identification is a four-part approach that includes specialization, in which too-general types are refined; generalization, in which too-specific types are abstracted; aggregation, in which composite objects are created; and association, in which objects from independent types are linked (131, 132). The knowledge representation process will incorporate inferential reasoning and the creation of correspondence between model concepts (entities and attributes) and their real-world analogues (132, 133). Once the model is developed, a formal syntactic description will be created by mapping meaning-equivalent concepts in the UMLS Metathesaurus to the SNOMED-CT clinical vocabulary (134-136). This description serves as an ontology, utilizing Guarino's expansion on Gruber's definition of an ontology as "a specification of a conceptualization" to include a language-dependent set of relations (the vocabulary-mapped model) defined on a particular domain space (the patient-reported data elements) (137, 138). Should model elements be defined that have no direct mapping, the closest equivalent will be identified and an update will be proposed for the next SNOMED-CT release.

Results. The detailed EER model schema, data exchange and interface assessment, ontology mapping, and comprehensive list of UMLS concepts and SNOMED CT terms used in the ontology mapping are the expected products of this aim. The data model schema and ontology mapping will be documented as FHIR resources. The term "resource" is used to refer to all exchangeable content, and each FHIR resource includes: 1) common definitions and representations based on data types with reusable patterns; 2) a common metadata set; and 3) a human-readable part to aid user interpretation. FHIR also includes an interface description and a profile for each implementation. The data exchange and interface assessment will be used to create the FHIR interface description and profile. All FHIR resources created will be packaged as an extensible set which can subsequently be used for integration of PGHD and PROs into interoperable EHRs, clinical information systems, and big data infrastructures.

3.5. Project Timeline

Table 1 illustrates the proposed timeline for activities under this award.

Table 1. Proposed Timeline

Month	*3*	*6*	*9*	*12*	*15*	*18*	*21*	*24*
Specific Aim 1: Qualitative Formative Phase								
IRB submission and approval								
Patient and provider recruitment and enrollment								
Focus groups and interviews								
Qualitative data analysis								
Specific Aim 2: Randomized Controlled Trial								
Patient recruitment and enrollment								
RCT conducted, incorporating SA1 results								
Data analysis								
Specific Aim 3: Data Model, Ontology Mapping, FHIR Resources								
Dissemination: conferences, manuscripts, resource set sharing								

3.6. Plan for Privacy and Security Protections in the Development and Implementation of Health IT Systems

While clinical information systems within health care organizations are required to be HIPAA-compliant, the COTS health IT solution market is more complicated. Many solutions, especially ones that focus on wellness and fitness, have no specific requirement for data encryption, much less adherence to HIPAA standards. Given the potential sensitivity of collecting PGHD and PROs data from COTS health IT solutions to inform future patient care purposes, we intend to thoroughly address privacy and security considerations as part of this project. While institutional review board protections may be sufficient to govern research data protections, the intended use of the results of this project to inform delivery system implementation requires that we adhere to standards governing patient care. Therefore, in addition to the research team, DH's legal department, health information management team, and information security team will be engaged in the process. Appendix A contains a detailed description of our proposed plan.

3.7. Anticipated Results, Dissemination, and Future Directions

We anticipate that the results of this work will demonstrate the feasibility of using COTS health IT solutions to collect PGHD and PROs data from disadvantaged patients. We believe that this holds the potential to address perceptions and follow-on health system inequities currently extant regarding the use of health IT to support disadvantaged patients outside primary care clinic visits, and that our work will further the development and extension of better health IT-based interventions and care processes to these AHRQ priority populations. We also anticipate that the data model and ontology mapping made available as a FHIR resource set will help contribute to the integration of PGHD and PROs as actionable data in interoperable EHRs, clinical information systems, and big data infrastructures. In addition to presenting at health IT-focused conferences and publishing manuscripts with the results of our research, as DH is a participant in PCORnet through the PORTAL clinical data research network led by Kaiser Permanente (139), this work will be conducted in alignment with that research endeavor and shared with that research consortium to inform distributed data network architecture development. The FHIR resource set will also be made available to Prime Health, which is a Colorado-based collaborative of 120 mobile and digital health companies, and to the High Value Healthcare Collaborative (HVHC), which is a provider learning network of 13 health systems committed to improving health care value through data and collaboration, of which DH is a founding member (see Facilities and Resources for more detail on Prime Health and the HVHC). We expect this will help promote adoption and integration into EHRs and health IT solutions by industry partners and health delivery systems nationwide.