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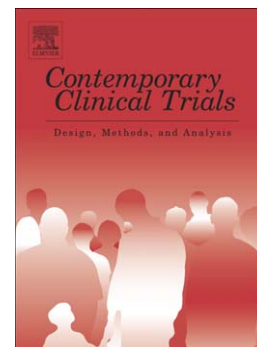
Using IT to improve access, communication, and asthma in African American and Hispanic/Latino Adults: Rationale, design, and methods of a randomized controlled trial

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Using IT to improve access, communication, and asthma in African American and Hispanic/Latino Adults: Rationale, design, and methods of a randomized controlled trial

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ABSTRACT

Asthma morbidity is high among inner-city minority adults. Improving access to care and patient-provider communication are believed essential for improving outcomes. Access and communication in turn increasingly rely on information technology including features of the Electronic Health Record. Its patient portal offers web-based communication with providers and practices. How patients with limited resources and educational opportunities can benefit from this portal is unclear. In contrast, home visits by community health workers (CHWs) have improved access to care for asthmatic children and promoted caretaker-clinician communication.

We describe the planning, design, and methodology of an ongoing randomized controlled trial for 300 adults, predominantly African American and Hispanic/Latino, with uncontrolled asthma recruited from low income urban neighborhoods who are directed to the most convenient internet access and taught to use the portal, with and without home visits from a CHW. The study 1) compares the effects of the 1-year interventions on asthma outcomes (improved asthma control, quality of life; fewer ED visits and hospitalizations for asthma or any cause), 2) evaluates whether communication (portal use) and access (appointments made/kept) mediate the interventions' effects on asthma outcomes, and 3) investigates effect modification by literacy level, primary language, and convenience of internet access. In home visits, CHWs 1) train patients to competency in portal use, 2) enhance care coordination, 3) communicate the complex social circumstances of patients' lives to providers, and 4) compensate for differences in patients' health literacy skills. The practical challenges to design and implementation in the targeted population are presented.

Key words: asthma, patient portal, community health worker, electronic health record, health literacy

Abbreviations

CHW	community health worker
ED	emergency department
PT	patient portal training
PT + HV	patient portal training plus home visits

INTRODUCTION

Asthma, a chronic treatable disease, affects 18.7 million US adults.¹ Despite efficacious medications and national guidelines for management,² asthma has a disproportionate impact on low income and minority adults, particularly African Americans and Puerto Ricans. In 2010, almost 4.5 million non-Hispanic blacks reported having asthma.³ Blacks have more than 3 times the emergency department (ED) visits, 2 times the hospitalizations, and 2 times the death rate for asthma compared to whites.¹ Also in 2010, 3.6 million Hispanics/Latinos reported a diagnosis of asthma.⁴ Puerto Ricans were 3.4 times as likely to die from asthma compared to all Hispanic/Latino groups.⁴ Overall Hispanic/Latino adults were 30% more likely to be hospitalized for asthma than non-Hispanic whites. Compared with children, adults are more likely to die from asthma, 65% of whom are women. There is much less research on asthmatic adults.^{1, 5}

According to the Institute of Medicine, improvements in access and patient-provider communication are needed to reduce health outcome inequities.⁶ Comorbidities including hypertension, diabetes, and obesity, not infrequent in adults, increase the likelihood of adverse asthma-related outcomes and make access to care and patient-provider communication more complex. The patient portal of the Electronic Health Record, increasingly available to enhance patients' web-based communication with providers and practices, has the potential to improve communication and access.

The 2009 Health Information Technology for Economic and Clinical Health Act authorized the Centers for Medicare & Medicaid Services to provide reimbursement incentives for eligible professionals and hospitals who become "meaningful users" of certified EHR Electronic Health Record technology.^{7, 8} Among the core objectives of what is now called Meaningful Use is the promotion of patient portal (portal) use by patients and providers. The

portal allows patients to access parts of their medical record, review test results, make appointments, request refills, and it provides a secure platform for electronic messaging with providers. However, the portal is not widely used by patients and is less available to low-income and minority patients.⁹ Limited availability may actually exacerbate disparities in health care as medical practices increasingly use information technology for communication.^{10,}

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Community Health Workers (CHWs) making home visits in other settings have facilitated patient access and communication with health practices and overcome barriers to care coordination. They potentially can give clinicians insight into patients' lives and the social and economic barriers to access and communication, including barriers to using the portal. CHWs are widely accepted by patients as sharing cultural, economic and linguistic characteristics with them, for knowing the community, and for being able to build trust.^{12, 13}

This study examines the benefits to low-income urban asthmatic adults, predominantly African American and Hispanic/Latino, of using the portal with and without home visits by CHWs who encourage and facilitate portal use, understand patients' social context, and enhance communication with the medical team. As advocated, we report its planning, ongoing delivery, and methodology, and the practical challenges to design and implementation in the targeted population, in order to enhance the value of this research.¹⁴

METHODS

Hypothesis and Aims

The primary hypothesis is that asthma will improve in adult patients from the use of the portal and that the addition of home visits by CHWs will be particularly helpful for those with

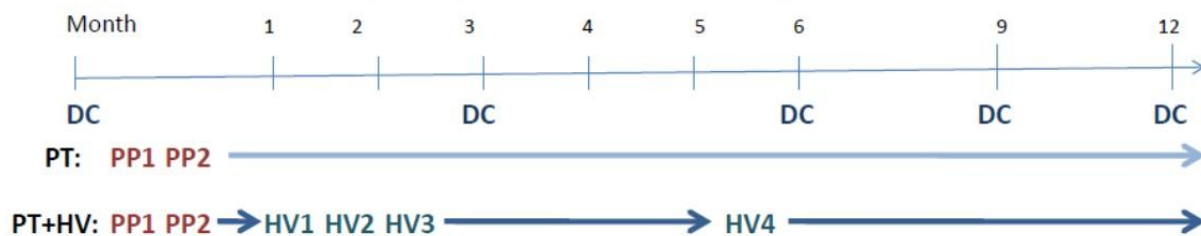
low literacy or language barriers. We compare portal training and home visits by a CHW with an active control of portal training (without home visits). The study is sponsored by the Patient-Centered Outcomes Research Institute as a response to its funding announcement “Treatment Options for African Americans and Hispanics/Latinos with Uncontrolled Asthma.” The study is registered at ClinicalTrials.gov (NCT02086565). This protocol was approved by the University of Pennsylvania Institutional Review Board and all participants gave informed consent.

Specific aims test whether 1-year interventions randomizing adults with moderate to severe asthma to either Patient Portal Training (PT) or Patient Portal Training plus Home Visits from a CHW (PT+HV) result in 1) better within-group asthma outcomes (asthma control, quality of life, ED visits, hospitalizations) over time, 2) better asthma and general health outcomes (ED visits and hospitalizations) in PT+HV over PT, 3) more communication (use of the portal) and access (appointments made/kept) which mediate the interventions’ effects on asthma outcomes, and 4) effect modification by literacy level, primary language, and ease of internet access of the interventions on outcomes.

Overview of study design

Adults with uncontrolled asthma are recruited from outpatient primary care and specialty clinics that serve predominantly but not exclusively low income urban neighborhoods. PT consists of 2 visits: PP1 and PP2. At PP1 a CHW inquires whether internet access by computer, tablet, or smart phone is available at home, work, community hot spots, or participating clinics and together the participant and CHW confirm which is closest and most convenient. (Figure 1)

Figure 1. Time course for participation and data collection (DC)



PT= portal training consisting of PP1 and PP2. PT+HV= portal training plus home visits
 PP1= the first portal training session, PP2= second portal training session and review.
 HV1= first home visit, etc.

The CHW describes the portal and its functions and assists participants in requesting an activation code. At the second visit, called PP2, working with the same CHW, participants activate and access the portal and perform exercises in using it. PP1 and PP2 take place within 2 weeks of enrollment.

At enrollment participants are randomized 1:1 either to PT or PT+HV using randomly permuted blocks of varying block sizes and stratified by practice. Together with the use of opaque envelopes prepared by the project statisticians, this randomization plan facilitates allocation concealment to both health workers and eligible patients. We felt this concealment to be especially important because of the understandable preference among some patients for the added care and contact offered by home visits from CHWs. Participants all sign informed consent to enroll in the study and to undergo Portal Training and data collection. Those randomized to home visits sign a second consent form informing them they are randomized to home visits and giving permission for these visits. Therefore, once randomization occurred, both worker and patient were unblinded to treatment. Only one member of a household can participate in the study. For those randomized to PT+HV there are 4 home visits: HV1, HV2, HV3, and HV4 (Figure 1, Table 1). Those randomized to PT+HV work with the same CHW who conducted PP1 and PP2. At each home visit, the CHW ensures care coordination, including obtaining an asthma action plan that links patients' home and community with the clinic. The CHW provides standard asthma

education, promotes communication with providers, encourages appointment keeping, and facilitates familiarity with health information technology. The final home visit, HV4, which occurs at 6 months reviews and encourages all of these activities. For the remainder of the year there are monthly follow-up phone calls or emails by the same CHW to encourage use of the portal and to check on the patient's asthma control (Table 1).

All participants are followed for at least 1 year with data collection at 3 month intervals and until the study's end. Data collection is carried out by a CHW who is not acting as a home visitor for this patient. The primary outcomes are patient-centered: asthma control, ED visits and hospitalizations for asthma or any cause, and asthma-related quality of life.

Design choices

Randomized controlled trial

We chose a randomized controlled trial because randomization reduces the likelihood of bias from both known and unknown confounders.¹⁵ Randomization is particularly important in a study involving health behavior where many complex influences are not well understood. The longitudinal design allows a real-life assessment as well as the efficiency of having baseline and pre-baseline measures as within-subject controls. Multicenter recruitment enhances generalizability as much as feasible beyond the practices and diversity of social circumstances.

The choices for the randomized trial, portal training and home visits, are attempts to adopt interventions to real-world settings. They are inspired by RE-AIM conceptualization framework¹⁶ and the need for such implementation research.¹⁷ Implementation of portal training and home visits are hypothesized to improve access and communication resulting in improved patient-centered outcomes including asthma control and asthma-related quality of life.

Portal Training and home visits represent different approaches to improve patient-provider communication and care coordination as well as access. Although vastly different interventions, they provide potential synergistic benefit particularly for vulnerable patients exposed to poverty and with prevalent comorbidities.¹⁸ It is important to test the patient portal as a means of communication with vulnerable patients. Although portals have been widely implemented and undergo continuous refinement,^{10, 11, 19} their benefits in patient subgroups remain for formal evaluation. We hypothesized that home visits may be especially effective for low-income inner city patients facilitating 2-way patient-clinician communication; informing clinicians of important environmental, social, and medical barriers; and reinforcing medical information from clinicians to patient.²⁰ We also hypothesized that the home visit may be especially effective for those who speak English as a second language or those with low health literacy. We ascertained portal familiarity and interest through focus groups of patients and providers exploring their knowledge of and use of the portal.²¹ We also conducted a small pilot study introducing patients with no portal experience to it and found patients were able to learn to use the portal.²² The protocol of this pilot became the basis for portal training in the current project. We had piloted the home visits in families with children²³ and the activities to be performed in home visits in adults.²⁴

Internet access

We considered how to assure internet access for portal use for patients, anticipating that many would not have internet access at home. We contemplated providing a tablet to all participants but after obtaining input from stakeholders concluded that even with vendor discounts tablets would need to include costly home internet access, so often not affordable, and would be subject to theft. We searched for affordable prices to install internet in patients'

homes but again found the cost too high. There was also concern among the information technology specialists consulted that in old homes that had never had internet access, it might be difficult to install and maintain such access. Although the Philadelphia Housing Authority, a provider of subsidized housing for low-income city residents, provides computers and internet access not all participants live in these homes. There are internet providers who discount service to low-income families, particularly if there is a school-age child in the home, but not all participants live with school-age children. From patient focus groups and our pilot of portal training, we estimated that half of potential participants had computer access at home or work. Of those with access, only half of these checked email regularly. In sum, real world barriers to accessing the patient portal must be overcome.

Based on this information,²² we will stratify the analysis on the participant's internet availability at enrollment: a) access to internet at home or work, b) access through a friend, family member, c) nearby library or other public facility, d) access by smartphone only, and e) no access other than at the patient's health center or distant community establishments. We ensured internet access for participants at primary care and asthma specialty clinics and in the NIH-funded Clinical and Translational Research Center. The medical facilities of the participating practices are "hot spots." At enrollment we recommended ways to access the internet: nearest library, nearest hot spot (recognizing low income communities have fewer), and if desired for those with smart phones, using smartphone apps.

CHWs make the Home Visits

We selected a Community Health Worker (CHW) to complete home visits. The CHW lives in the community and is familiar with the environment; is acceptable to patients; and connects patients to health education, services, and the health care setting.^{13, 20, 25} In our Community

Asthma Prevention Program (CAPP) we identified and trained CHWs as lay health educators to provide home asthma education and environmental intervention. Over 15 years, CAPP CHWs have visited more than 2000 families with children.²³ These CHWs have worked in both African American (West Philadelphia) and Latino (North Philadelphia) communities, the same communities for the current project. These CHWs have a high school education or greater with at least three years' work experience and personal knowledge of asthma. They bring their knowledge as a community resident to suggest local resources in order to meet daily needs. CHWs are able to establish relationships with participants and their families to promote better asthma self-management, connection with community resources, communication with providers and mitigation of asthma triggers. CAPP's CHWs not only have functioned as home visitors, but also have acted as asthma navigators who have been integrated into the health care team, providing a direct link between families and clinicians. Our experience has allowed us to develop an excellent support system including supervision and training and systems for scheduling visits and data entry, which are essential for the success of this project.²⁶ The retention rate of participating families in CAPP has been more than 90%. Our additional experience with patient advocates who worked in clinics for adults informs the care coordination of this project.²⁴

Thus each home visit includes 1) reinforcement of the use of the portal and 2) care coordination (Table 1). Home visits for children with asthma often include tailored asthma education and environmental remediation of allergen and irritant environmental exposures. By contrast, our activities are unique in utilizing CHWs in the home for promotion of portal use to link the patient to the medical practice, thereby improving patient-physician communication, a known contributor to asthma disparities. The home visits focus on communication and access, the same goals as potentially achievable through the use of the portal.

Eligibility

Inclusion criteria are intended to identify adults living in low-income neighborhoods with moderate to severe asthma requiring urgent care:

- 18 years or older
- living in a Philadelphia neighborhood in which at least 20% of households have incomes below the federal poverty level.
- doctor's diagnosis of asthma
- prescribed an inhaled corticosteroid-containing medication.
- required prednisone or had an ED visit or hospitalization for asthma in the past year.
- Subjects will not have previously signed in to a portal more than 3 times.
- a patient in a participating clinic

Exclusion criteria:

- severe psychiatric or cognitive problems (e.g., obvious mania, schizophrenia, significant mental retardation) that would make it impossible to understand and carryout this protocol.

Recruitment sites

Participating sites include two family medicine, 2 general internal medicine, 2 pulmonary, and 1 allergy-immunology outpatient practice from the University of Pennsylvania Health System (UPHS). Recruiting from these practices in the past has consistently yielded a population that is more than 65% African American and more than 65% female. More than 1000 patients with asthma, prescribed inhaled steroids, and living in

low income neighborhoods have been identified. We also recruit from Temple Physicians at Hunting Park Adult Medicine, a primary care practice serving mainly Spanish-speaking patients, more than 85% Latino, and with more than 700 patients with asthma on their problem lists.

Screening

Using guidance and policies of the supervising institutional review board and the participating health care systems, we recruited patients as follows. After explaining the protocol in staff meetings of participating sites, we received lists of potentially eligible patients for whom further screening was needed. First we sent “opt-out” letters to clinicians asking for permission to contact their patients. If providers either did not respond to two letters or gave permission, we sent letters to potential participant patients (having an electronic health record diagnosis of asthma and prescribed an inhaled corticosteroid) asking to contact them for screening. If patients gave permission, or did not respond, we called the potential participant or approached them at a clinic visit to explain the study and ask for permission to screen for eligibility.

Enrollment and baseline data collection

The IRB-approved consent and all communications are read/spoken in English or Spanish as preferred by the potential participant. Data collection is accomplished by a CHW, called a Data Collector, who is not acting as the home visitor if the patient is so assigned. This choice of Data Collector was made to reduce any pressure on the patient to answer in a way to please the researcher. Baseline questionnaires assess socio-demographics, asthma severity, health literacy,

and comorbidities (Table 2). The first, 6-month, and last visits are in person so that spirometry may be obtained. For the other data collection times, we offer a phone or email or in-person visit to minimize the burden of and effect on participation in a study. The Data Collector enters responses directly into a secure, encrypted, web-based database REDCap (Research Electronic Data Capture).²⁷

Interventions: Portal Training and Home Visits

The intervention activities, portal training and home visits are described below. All participants receive portal training and half additionally are offered four home visits by a CHW. The home visits take place over 6 months. All participants are followed for a year (Table 1).

Portal Training (PT)

To develop and pilot portal training, we had asked 10 patients who did not have portal access to register for it with our help.²¹ We instructed them in its use. We found 6/10 had access to a computer at home or work, 3/10 had access through a friend, family member or other facility, and 1/10 with no access other than at their health center or community establishments. 5/10 had limited typing skills. All were able to obtain an activation code with assistance and open a patient portal account. All were able to use the point and click mechanism within the portal to accomplish 7 tasks: 1) locate a laboratory test result, 2) look up an upcoming doctor's appointment, 3) learn how to schedule an appointment with their provider (the opportunity to actually make the appointment was offered), 4) locate their medication list, 5) locate their immunization record, 6) determine how to request a refill, and 7) send a secure message to their care team. All were positive that they could accomplish the tasks and found them useful. This protocol became the basis for PP1 and PP2 (Table 1).

Home Visit protocol

Home visits link the adult patient to the medical practice through the portal. The visits provide tailored care coordination and coaching to use the portal to communicate and ultimately to improve asthma control.²⁶ These activities were selected after conducting focus groups of patients²⁸ and piloting.^{22, 24} The CHW empowers patients to communicate with their health care providers via the portal, to follow asthma guidelines, reconcile medications, facilitate appointment scheduling, and also control environmental exposures (e.g. tobacco, allergens).²⁶ Each home visit has two parts: 1) care coordination using the portal and 2) improving familiarity with health information technology (Table 1). For care coordination the CHW and participant draft an asthma action plan for review/revision/approval by the participant's asthma care provider and the participant is asked to schedule through the portal an appointment with the provider in which this plan will be discussed. The format of the American Lung Association Asthma Action Plan is used which includes contact information of the providers, preventative and emergency medications.²⁹ The CHW helps patients identify specific care coordination goals that will improve asthma control and quality of life and that with patients' permission can be shared with providers.

In previous home visits for children living in the same urban Philadelphia neighborhoods, we found that about half of families had at least one smoker in the home.²³ Residential exposures to allergens and pollutants contribute to asthma morbidity. CHWs facilitate patients' communication with their asthma clinician for attention to exposures to tobacco smoke, pollutants, potentially relevant allergens, and to participants' comorbidities through the portal. CHWs are knowledgeable in community resources and have access to a resource database which includes smoking cessation programs and housing opportunities.

More details of home visits follow. At the first home visit, HV1, within 2 weeks of PP2, the CHW becomes further acquainted with the participant, if possible meets the family, collects information, and conducts a needs assessment. The CHW gathers information on medications in the home to coordinate with the participant's clinician, facilitates appointment scheduling, and also encourages control of the environment (e.g. exposure to tobacco, allergens). From this needs assessment the CHW creates care coordination goals with the patient. The action plan is then drafted by the participant for review, amendment, and approval by the participant's asthma care provider. The second home visit, HV2, takes place within 2-3 weeks of HV1. The CHW reviews the individualized action plan, asthma control, the goals from the previous visit, and relevant asthma education available from the portal. Use of the portal is reviewed and encouraged. The third visit, HV3, occurs approximately 2-4 weeks later. The final visit, HV4, occurs approximately 6 months after enrollment reviews care coordination and all portal and internet skills (Table 1).

To improve familiarity with health information technology, CHWs review use of the portal as the second part of each visit. In addition, at each visit they teach a relevant activity such as using the internet to access health information, how to obtain educational materials through the portal, how to "Google," how to email, and how to get a weather report.

At the end of each visit the participant and CHW complete a report to the clinician of topics discussed (e.g. action plan, medications, other topics). It is noted if the portal was used for these topics. Goals for the participant to pursue with the asthma doctor to achieve asthma control are also reported, if feasible through the portal. In summary, CHWs empower patients to achieve asthma control and improved asthma-related quality of life by communicating with their health care providers and wherever possible through the portal.

At the monthly phone calls for the remaining 6 months, information on portal training is reviewed along with information from the prior home visits. The use of the portal is encouraged.

Outcomes

The outcomes are selected to be meaningful to patients: asthma control; asthma-related quality of life; and the number of ED visits, hospitalizations, and prednisone "bursts" (a new or increased prednisone prescription for ≥ 3 days) for an asthma exacerbation over the observation period (Table 2). These were among outcomes recommended by the recent Asthma Outcomes Workshop.³⁰ ED visits and hospitalizations both for asthma and for any cause are collected. FEV1 is also monitored.

The primary outcome, asthma control, reflecting symptoms over the past week, is measured by the 7-item Asthma Control Questionnaire (ACQ).³¹⁻³³ The score is the mean of all responses (0=total control, 6=extremely uncontrolled). The minimally important clinical difference is 0.5. A score >1.5 is considered inadequate control.³⁴ Asthma-related quality of life (AQOL) is measured with the Mini Asthma Quality of Life Questionnaire (AQLQ).³⁵⁻³⁷ This 15-item questionnaire has a 7-point response scale that provides a mean summary score. A 0.5-unit change is considered clinically meaningful.³⁷ The AQLQ has been shown to be a useful indicator of AQOL in low-income adults.³⁸ Hospitalizations including ICU admissions, ED visits, urgent medical visits (scheduled < 24 hours in advance), prednisone bursts (a new prescription for > 3 days of prednisone or an increase in an already-prescribed dose for an asthma exacerbation), and other medical visits are obtained by self-report, because not all such events occur within our health system. The medical records will be examined for

documentation as feasible. Spirometry is obtained using American Thoracic Society procedures for FEV1 and FVC.³⁹

Mediators

Mediators explain how the interventions influence asthma outcomes. For this study they are measurements of communication and access: the use of the portal, appointments kept with the asthma clinician, and change in electronic health literacy over time in the study. The two participating health systems (University of Pennsylvania, Temple University) provide downloads of portal use for enrolled patients. The electronic health record is reviewed to assess appointments kept with the clinician. Electronic health literacy is measured with the eHEALS, the eHealth Literacy Scale, an 8-item measure of knowledge, comfort, and perceived skills at finding and evaluating electronic health information.⁴⁰ It has been used in low-income patients.⁴¹ Each item is measured with a 5-point likert scale and the eHEALS score is the sum of items. The mediator is the change in eHEALS score over participation in this study.

Moderators and effect modification

Moderators are baseline variables, gleaned from the literature, hypothesized to affect the intervention-outcomes relationships.⁴² For this study they include participant educational attainment (years of formal education completed), household income, other socio-demographics, comorbidities (participant reported and verified in the medical record including hypertension, diabetes, obesity, cancer, smoking history, etc.), and primary language (English, Spanish).

Baseline health literacy is treated as a moderator and measured with three tools. Numeracy is measured with the Asthma Numeracy Questionnaire (ANQ), a 4-item questionnaire of numerical concepts (arithmetic, percentage) specific for asthma that we developed and validated.⁴³ Reading comprehension is assessed using the Short Test of Functional Health Literacy in Adults (S-TOFHLA).⁴⁴ The third literacy measure is the baseline score of the eHEALS. Other moderators include depressive symptoms measured by the Center for Epidemiologic Studies Depression Scale, a validated 20-item scale.⁴⁵ Convenience of internet access will be assessed by asking how the participant would most conveniently access the internet: a) at home or work, b) through a nearby friend or family member, c) nearby library or public facility, d) by smartphone only, or e) no access other than at the health center or distant community establishment.

Data management

REDCap (Research Electronic Data Capture) is a secure web-based application for data entry and management. It employs electronic data capture using electronic case report forms, real-time data validation, integrity checks, and ensuring data quality.⁴⁶ REDCap (<http://www.project-redcap.org/>) allows data attribution and audit capabilities, data storage and backup, and export functions.⁴⁶

Analysis plan

Testing within-group effects over the time of the study will allow us to assess the effect of each intervention. The within-group change in the PT group will allow measurement of PT alone. Subtracting any change over time in the PT+HV group from the PT group will allow estimate of the additional effect of home visits. To test the within group and across group effects of the interventions on outcomes we will implement mixed effects

models (using restricted maximum likelihood and adaptive quadrature) and marginal models (using generalized estimating equations (GEE)) as a unified approach for the analysis of the longitudinal data with baseline randomization. For within-group outcomes, these models use all available data to estimate changes over time. Both the mixed effects and marginal models can be used for continuous, binary, and count outcomes using linear, logistic, and log linear models that can compare changes over time in the outcomes of asthma control, quality of life, ED visits, hospitalizations over one year.⁴⁷ By including group-by-time interaction terms, these models can then be adapted to compare improvement over time between the patient portal plus home visit group and the portal only group. Each type of model has its strengths and weaknesses. While the GEE method benefits from simplicity and robustness, it requires stronger assumptions about dropout (dropout completely at random). Planned analyses will consider the effects of both dropout and nonadherence (failure to use the Portal, for example) as sensitivity analyses.

Statistical power

Estimating power for longitudinal data can be a challenge because these designs must account for the added power of following individuals over time. To estimate power of our somewhat complex design, we resorted to statistical simulations, implemented in Stata v 13 (StataCorp, College Station, TX), in which we varied the correlations of outcome within individual over time. Using the asthma control measure as an example, we estimated using simulations that power of a balanced design with 300 evaluable subjects was adequate (from 0.82 to 0.87) to detect a difference between groups of 1/3 of a standard deviation of asthma control. According to Juniper's work on asthma control, this detectable difference is less than

the minimally important clinical difference. Additional simulations, for effect modification, suggested good power (0.9) to demonstrate a greater improvement among low literacy patients with home visitors. As for mediation effects, we found adequate power (0.82) to demonstrate greater frequency of keeping four appointments (86% of patients keeping more than one-half of their appointments as contrasted with only 70%) in home visitor compared to portal only patients. For this last calculation we used PASS v. 11 (NCSS, LLC Kaysville, Utah, USA. www.ncss.com).

Trial monitoring

An external Data Safety Monitoring Board reviews progress and data every six months and monitors adverse events and serious adverse events (unexpected ED visits and hospitalizations). Because patients have moderate or severe asthma, it is expected that ED visits and hospitalizations for these and patients' co-morbid conditions will occur.

Engagement

Especially for chronic diseases, such as asthma that require constant and careful attention by patients, participation by patient representative groups in study design and monitoring takes on added importance. To engage the expertise and insights of patients and their families, their healthcare providers, and health system administrators who must enroll patients in the portal and implement Meaningful Use, we recruited members not otherwise engaged in research from these stakeholder groups to our study research team. For example, the interventions were developed from pilot projects and focus groups with patients and clinicians. Members of the Community Asthma Prevention Program have contributed to our project design and monitoring. We regularly visit practices and communicate with clinician representatives of these practices.

Additionally, we have built a Community Advisory Board of patients and family members of patients who meet quarterly to comment on the project's progress and offer suggestions.

RESULTS

We describe the experiences implementing the study and the baseline data of the first 150 participants, recruited over the first 8 recruitment months (Table 3). Our cohort is from a population with the highest morbidity for asthma: adults (mean age 49), female (87%), African American (80%), Latino (16%). Morbidity is evidenced by the high rate of self-reported ED visits and hospitalizations for asthma in the year before enrollment, and the prevalent comorbidities. This important high risk group differs in both personal and environmental characteristics from patients commonly recruited for clinic-based studies. To date, one participant has withdrawn and four were discharged from the project for their inability to adhere to study procedures.

Approximately half (81) had a computer or computer cell phone in the home. Some participants who reported they had a computer considered their cell phones to be computers. Of the 81 participants, 63 reported internet access at home. 103 (69%) had an email address. 69 (46%) had heard of a patient portal. Approximately, 86% of participants from the UPHS practices had never used the portal prior to enrollment.

CHWs have made more than 100 home visits. They found some participants could not walk independently, struggle with stairs for the subway and buses and otherwise have difficulty getting to clinic appointments. Home visits required that CHWs drive into neighborhoods with abandoned homes (figure 2a, b). CHWs found some participants living as tenants in homes poorly maintained by the owners, sometimes having poor ventilation, and, on one occasion,

fierce dogs. In several of the homes the gas or electricity was about to be or had been shut off. CHWs report challenges in making home visits owing to dangerous neighborhoods, even during the daylight hours. CHWs have arranged visits that were cancelled at the last minute or the participant was not home when the CHW arrived. On one occasion CHWs driving to a home visit found themselves in the middle of an active crime scene.

The biggest challenge for CHWs is scheduling appointments. Phone numbers frequently change or phones are temporarily or permanently disconnected. The former happens more frequently at the end of the month when purchased phone time is used up. The CHWs have learned to schedule visits as much as possible at the beginning of the month.

When demonstrating the use of the portal to patients, CHWs found that several participants could not learn to log on. Some of these were unable to read, as evident by inability to find the login portion of the screen. We found that some participants young and old had difficulty reading, while many older participants had never used a computer. Some participants called in family members to help them with the computer exercise. Some participants strongly preferred calling the medical practice to using the portal as they were recognized on the telephone by the staff and received a warm response. No participant went to a library to use a computer and participants frequently noted that neighborhood libraries had been closed. There was distrust of using a public computer. Participants also frequently expressed concern about privacy of health information in using a computer even at home.

Nevertheless, these adult participants generally appreciated the home visits and found the features of the portal potentially useful. They liked the options of requesting refills and making appointments but without a computer most, particularly the older participants, could not take advantage of it.

DISCUSSION

This trial of the impact of an electronic patient portal on asthma-related outcomes is timely and innovative. Unlike our previous experience with CHWs this study focuses on improving asthma outcomes in adults rather than children and on encouraging communication through the portal. The current project examines physician and patient use of information technology which has become a popular approach for improving physician-patient communication and the quality of care for chronic conditions. It studies the benefits of portal use and will allow determination of portal modifications to improve patient-provider communication and ultimately health outcomes. The setting is real, patients are recruited from clinics, and ongoing care proceeds through the same clinics at which ongoing care is delivered. While the intervention is real-world, and pragmatic, the study design, a formal randomized study, benefits from the strengths of randomization and repeated measures over time of the individual subjects. As such the study is more powerful and less subject to bias than would be the more common designs such as an observational time-series or pre-post studies. Because we can follow individuals, our study will allow for collection of extensive qualitative data on barriers that face individuals in their attempt to use the portal and/or to engage the CHW. Addressing long-standing health disparities is critical for improving the health of large groups of patients. This research will therefore address implementation, the study of adoption of interventions to the real world.^{16, 17}

Our findings, regardless of the direction or size of the estimated effect, will be valuable because a population of high asthma morbidity and low-income is not likely to enjoy easy access to or use of electronic patient portals. The ongoing trial compares two interventions and their

possible synergy to improve access and communication, critical aspects of self-management for patients with significant asthma and chronic diseases that could also possibly be synergistic. The interventions consider literacy and language barriers. Because treatment allocation is randomized, the design benefits from baseline balance on observed and unobserved patient characteristics. Randomized assignment also supports adjustment for nonadherence to the study protocol. The longitudinal design enhances statistical power to detect important changes. Finally, there is an effort to engage patients and their families as well as other stakeholders, not only in designing the project, but as it unfolds.

Home visits by CHWs allow understanding of patients' context and barriers to achieving health and to better understanding how the portal can help with achieving health or should be modified to better attain this goal. Asthma, a common and chronic disease influenced by the environment both physical and social, and often accompanied by comorbidities, creates a disease management paradigm generalizable to other chronic diseases.

By design the study is limited. Without a control group of patients who have no access to the Portal, a group that cannot be formed in practice, we must rely solely on longitudinal contrasts to estimate the effect of the portal alone. Sustainability of our interventions must also await follow-up studies, because our 36 months project cannot estimate more than short term effects. Nevertheless, if this trial is successful it will establish the feasibility of a longer trial in which effectiveness could be validated and cost-effectiveness estimated.

In conclusion, this trial examines the ability of a diverse but resource-limited population to use and benefit from the electronic health record and particularly its patient portal. In particular the project assesses the benefits of both the portal and home visits by CHW to access health care and communication. The study will suggest possible changes in portal format to

become more accessible to patients with chronic conditions, and the elements of the home visit that might help these patients. Our experiences to date already illustrate the importance of the contributions of CHWs in describing the social context of these patients, not usually enrolled in studies, and the challenges that CHWs encounter in visiting participants in their home neighborhoods.

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DISCLAIMER:

All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors or Methodology Committee.

Table 1. Activities and Data Collection (DC) for PT+HV and PT Groups

Time	PT+HV	PT
DC- Week 0	Participant meets with a member of the research team for consent, enrollment, randomization, and baseline data collection. This data collector is not the CHW who provides PP1, PP2 or HVs (if participant is randomized to HV).	
PP1 (within 2 weeks of enrollment)	A CHW demonstrates accessing internet if necessary, ensures patient's internet access and request for an activation code for PP, and demonstrates use of PP with a "test" patient. Participants are shown how to complete 7 tasks and how to ask for on-line help and to read FAQs.	
PP2 (within 2 weeks of enrollment)	Patient activates their PP and goes through exercises with the same CHW, using the PP to obtain and ask for information (the 7 tasks demonstrated at PP1). Participants are again shown how to ask for help & to read FAQs. They are given a printed card with a phone number for the Help Line. They are shown how to access medical information through the PP.	
HV1 (within 2-4 weeks of enrollment)	Re-Introductions & conversation- CHW is the same CHW who supervised PP1 and PP2. CHW meets patient and family and asks how they are doing. Care Coordination. The CHW • asks patient to produce medications and explain doses • asks about smokers in home and offers a QUIT number if needed • reviews participant's baseline environmental survey • asks where emergency medical information is kept, emergency telephone numbers • assists as needed as patient drafts an asthma action plan for review/revision by patient's asthma care provider • asks when next appointment with asthma doctor is & assists with scheduling if necessary • asks about refills needed • asks about patient Care Coordination goals CHW reviews use of PP and how to access it and the internet including access to health information resources • CHW shows how to access asthma education materials with the PP	Email/phone to patient encouraging sign in to PP.
HV2 (between weeks 4-7)	CHW inquires how patient and family are doing. THEN CHW and participant: • review Action Plan and care coordination goals, medications, refills, appointments etc They review use of tablet and PP • Problems with use • Complete at least 2 tasks with PP • CHW demonstrates how to "google" for information	Email/phone to patient encouraging sign in to PP.
HV3 (between weeks 6-11)	CHW inquires how patient and family are doing Review care coordination, action plan, goals, medications, and relevant community resources Review use of tablet and PP- • Problems with use addressed • Complete at least 2 tasks with PP • Show how to email if not known already	Email/phone to patient encouraging sign in to PP.
DC-week 12	Participant called by a member of the research team for data collection.	
HV4 (between weeks 23-27)	CHW inquires how patient and family are doing Review care coordination, action plan, goals, medications, and relevant community resources Review use of tablet and PP • Problems with use addressed • Review how to "google", email, and how to get weather and latest news on the internet	Email/phone to patient encouraging sign in to PP.
DC – week 28	Participant meets with a data collector for data collection which includes spirometry	
DC-week 36	Participant called by a member of the research team for data collection.	
DC week 48-50	Participant meets with a data collector for data collection which includes spirometry	
DC every 12 weeks	Participant called by a member of the research team for data collection.	

CHW= community health worker, DC= data collection, PP= patient portal, PT= patient portal training, PT+HV= patient portal training plus home visits, HV1= first home visit, etc

Table 2. Summary of Data Collection

Measure	At enrollment	Quarterly*	12 months & final
Outcomes			
Asthma control	X	X	X
Asthma-related quality of life	X	X	X
ED visits for asthma or any cause	X	X	X
FEV1	X	X	X
Prednisone bursts+	X	X	X
Hospitalizations for asthma or any cause	X	X	X
Mediators			
Appointments kept with asthma doctor	X	X	X
Use of patient portal	X	X	X
eHealth Literacy Scale	X		X
Moderators (Baseline)			
Sociodemographics	X		
Computer at home	X		
Convenience of internet access	X		
Educational attainment	X		
Health literacy –S-TOFHLA, ANQ, eHealth Literacy Scale	X		
Comorbidities	X		
Depressive thoughts	X		
Primary language	X		

*Quarterly data collection occurs at months 3, 6, 9, and 12 and every 3 months after month 12 until the end of the study.

** We collect outcomes quarterly, at 12 months, and every 3 months until the study ends. Final visit is the final visit of data collection that occurs after the 12 month collection.

+Prednisone bursts are defined as a new prescription or an increase in dose of prednisone.

Table 3. Baseline characteristics of the first 150 adults with moderate of severe asthma, 75 assigned to each Group, expressed as frequency (percent) for discrete and mean ($\pm$ SD) for continuous variables.

Characteristic	Total N=150	Group A N=75	Group B N=75
Sociodemographics			
Age (years)	49 $\pm$ 12	49 $\pm$ 10	49 $\pm$ 14
Sex			
Female	131 (87%)	66 (88%)	65 (87%)
Race			
Black/African American	120 (80%)	61 (81%)	59 (79%)
White	9 (6%)	5 (7%)	4 (5%)
Other	1 (1%)	0 (0%)	1 (1%)
Declined to answer	20 (13%)	9 (12%)	11 (15%)
Ethnicity: Hispanic/Latino	24 (16%)	12 (16%)	12 (16%)
Household income			
< \$30,000/year	109 (72%)	53 (70%)	56 (75%)
\$30,000 - \$49,999/year	9 (6%)	3 (4%)	6 (8%)
\$50,000 to \$99,999	4 (3%)	2 (3%)	2 (3%)
\$100,000 or more	1 (1%)	1 (1%)	0 (0%)
Declined to answer	27 (18%)	16 (21%)	11 (15%)
Educational attainment (highest level achieved)			
8 th grade or less	10 (7%)	5 (7%)	5 (7%)
Some high school	38 (25%)	16 (21%)	22 (29%)
High school graduate	53 (35%)	30 (40%)	23 (31%)
Some college or trade school	34 (23%)	17 (23%)	17 (23%)
College graduate	15 (10%)	7 (9%)	8 (11%)
Literacy			
S-TOFHLA	26 $\pm$ 13	25 $\pm$ 13	26 $\pm$ 13
Minimum, maximum	0, 36	0, 36	0, 36

Asthma Numeracy (ANQ) (number of items correct)			
0	59 (39%)	29 (39%)	30 (40%)
1	32 (21%)	15 (20%)	17 (23%)
2	24 (16%)	15 (20%)	9 (12%)
3	20 (13%)	7 (9%)	13 (17%)
4	15 (10%)	9 (12%)	6 (8%)
eHEALS	24 $\pm$ 9	23 $\pm$ 10	25 $\pm$ 9
Minimum, maximum	8, 40	8, 40	8, 40
Asthma severity at baseline			
FEV1 (percent predicted)	69 $\pm$ 23	67 $\pm$ 23	71 $\pm$ 24
Minimum, maximum	21, 118	28, 99	21, 118
# with $\geq$ 1 ED visit for asthma in past year	128 (85%)	63 (84%)	65 (87%)
# with $\geq$ 1 hospitalization for asthma in past year	84 (56%)	41 (55%)	43 (57%)
Asthma-related quality of life	3.5 $\pm$ 1.4	3.4 $\pm$ 1.4	3.6 $\pm$ 1.4
Minimum, maximum	1.1, 6.8	1.1, 6.8	1.0, 6.3
Asthma control	3.0 $\pm$ 1.1	2.9 $\pm$ 1.1	3.0 $\pm$ 1.0
Minimum, maximum	0.7, 6.0	0.1, 5.1	0.7, 5.1
Co-morbidities			
Hypertension	91 (61%)	50 (67%)	41 (55%)
Diabetes	46 (31%)	22 (29%)	24 (32%)
BMI	35 $\pm$ 9	35 $\pm$ 10	36 $\pm$ 9
Ever smoked in the past	90 (60%)	48 (64%)	42 (56%)
Current smoker	49 (33%)	29 (39%)	20 (27%)
Computer at home	81 (54%)	39 (52%)	42 (56%)

ANQ= Asthma Numeracy Questionnaire,⁴³ S-TOFHLA = Short Test of Functional Health Literacy in Adults,⁴⁴

eHEALS= eHealth Literacy Scale⁴⁰

*Note: A likelihood test of overall differences across all baseline factors between the two groups confirms success of randomization. (chisq= 34.4 df=31, p=0.31)

**Several factors were less than complete at baseline owing to delays in data acquisition.: BMI n=124, nA=62, nB=62; eHEALS n=148, nA=75, nB=73; FEV1 n=67, nA=27, nB=40 ; S=TOFLA n=141, nA=72, nB=69.

LEGENDS

Figure 1. Schematic of participants' appointments with research staff.

Figure 2. Google Streetview images of the homes and neighborhood of two participants. These are typical of the neighborhoods of participants. CHWs could not take photographs of the neighborhoods for fear of drawing attention to themselves. **Figure 2a.** Some participants lived next to abandoned properties. 2015 Google. Google Earth. Image date: October 2014. **Figure 2b.** Home of another participant. 2015 Google. Google Earth. Image Capture: September 2014.



Figure 2a.



Figure 2b.

REFERENCES

1. Akinbami LJ, Moorman JE, Bailey C, Zahran HS, King M, Johnson CA, et al. Trends in asthma prevalence, health care use, and mortality in the United States, 2001-2010. NCHS Data Brief 2012;1-8.
2. Expert Panel Report 3: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Institutes of Health: National Heart, Lung, and Blood Institute, 2007.
3. Asthma and African Americans. Office of Minority Health; 2013.] Available from <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=15>.
4. Asthma and Hispanic Americans. Office of Minority Health; 2013.] Available from <http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=60>.
5. Schiller JS, Lucas JW, Ward BW, Peregoy JA. Summary health statistics for U.S. adults: National Health Interview Survey, 2010. Vital Health Stat 10 2012;1-207.
6. Smedley BD, Stith AY, Nelson AR. Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care. Washington, D.C. : Institute of Medicine. The National Academies Press; 2003.
7. American Recovery and Reinvestment Act of 2009. Washington, DC; 2009.] Available from http://www.recovery.gov/arra/About/Pages/The_Act.aspx.
8. Marcotte L, Seidman J, Trudel K, Berwick DM, Blumenthal D, Mostashari F, et al. Achieving meaningful use of health information technology: a guide for physicians to the EHR incentive programs. Arch Intern Med 2012; 172:731-6.
9. Seidman J, Wolf MS. The role of health literacy in health information technology. In: Press TNA, editor. Innovations in Health Literacy Research. Washington, D.C.: The National Academies Press; 2011. p. 23-32.
10. Goel MS, Brown TL, Williams A, Cooper AJ, Hasnain-Wynia R, Baker DW. Patient reported barriers to enrolling in a patient portal. J Am Med Inform Assoc 2011; 18 Suppl 1:i8-12.
11. Goel MS, Brown TL, Williams A, Hasnain-Wynia R, Thompson JA, Baker DW. Disparities in enrollment and use of an electronic patient portal. J Gen Intern Med 2011; 26:1112-6.
12. Shah M, Kaselitz E, Heisler M. The role of community health workers in diabetes: update on current literature. Curr Diab Rep 2013; 13:163-71.
13. Singh P, Chokshi DA. Community health workers--a local solution to a global problem. N Engl J Med 2013; 369:894-6.

14. Neta G, Glasgow RE, Carpenter CR, Grimshaw JM, Rabin BA, Fernandez ME, et al. A Framework for Enhancing the Value of Research for Dissemination and Implementation. *Am J Public Health* 2015; 105:49-57.
15. Rothman K, Greenland S. *Modern Epidemiology*. Philadelphia: Lippincott Williams and Wilkins; 1998.
16. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* 1999; 89:1322-7.
17. Glasgow RE, Vinson C, Chambers D, Khoury MJ, Kaplan RM, Hunter C. National Institutes of Health approaches to dissemination and implementation science: current and future directions. *Am J Public Health* 2012; 102:1274-81.
18. Rand CS, Butz A. Psychosocial and behavioral risk factors in asthma management. *Sem Resp Crit Care Med* 1998; 19:603-11.
19. Seidman J, Wolf MS. The role of health literacy in health information technology. In: *Innovations in Health Literacy*. . Washington, D.C.: The National Academies Press; 2011. p. 23-32.
20. Krieger JW, Takaro TK, Song L, Weaver M. The Seattle-King County Healthy Homes Project: a randomized, controlled trial of a community health worker intervention to decrease exposure to indoor asthma triggers. *Am J Public Health* 2005; 95:652-9.
21. Black HL, Gonzalez R, Priolo C, Schapira M, Sonnad SS, Hanson CWI, et al. True Meaningful Use: Technology meets both patient and provider needs. *Am J Managed Care* 2015; 21:e329-e37.
22. Black HL, Gonzalez R, Priolo C, Schapira M, Sonnad SS, Hanson CWI, et al. True "Meaningful Use": Technology Meets Both Patient and Provider Needs. *Am J Manag Care* 2015; in press:In press.
23. Bryant-Stephens T, Kurian C, Guo R, Zhao H. Impact of a household environmental intervention delivered by lay health workers on asthma symptom control in urban, disadvantaged children with asthma. *Am J Public Health* 2009; 99 Suppl 3:S657-65.
24. Apter AJ, Wan F, Reisine S, Bogen DK, Rand C, Bender B, et al. Feasibility, acceptability and preliminary effectiveness of patient advocates for improving asthma outcomes in adults. *J Asthma* 2013; 50:850-60.
25. Peretz PJ, Matiz LA, Findley S, Lizardo M, Evans D, McCord M. Community health workers as drivers of a successful community-based disease management initiative. *Am J Public Health* 2012; 102:1443-6.
26. Krieger JW, Philby ML, Brooks MZ. Better home visits for asthma lessons learned from the Seattle-King County Asthma Program. *Am J Prev Med* 2011; 41:S48-51.

27. Research Electronic Data Capture. 2015.] Available from <http://project-redcap.org/>.
28. Black HL, Priolo C, Akinyemi D, Gonzalez R, Jackson DS, Garcia L, et al. Clearing clinical barriers: enhancing social support using a patient navigator for asthma care. *J Asthma* 2010; 47:913-9.
29. Asthma Action Plan. American Lung Association; 2015.] Available from <http://www.lung.org/associations/states/colorado/asthma/asthma-action-plan.html>.
30. Busse WW, Morgan WJ, Taggart V, Togias A. Asthma outcomes workshop: overview. *J Allergy Clin Immunol* 2012; 129:S1-8.
31. Juniper EF, O'Byrne PM, Roberts JN. Measuring asthma control in group studies: do we need airway calibre and rescue beta2-agonist use? *Respir Med* 2001; 95:319-23.
32. Juniper EF, O'Byrne PM, Ferrie PJ, King DR, Roberts JN. Measuring asthma control. Clinic questionnaire or daily diary? *Am J Respir Crit Care Med* 2000; 162:1330-4.
33. Juniper EF, O'Byrne PM, Guyatt GH, Ferrie PJ, King DR. Development and validation of a questionnaire to measure asthma control. *Eur Respir J* 1999; 14:902-7.
34. Juniper EF, Bousquet J, Abetz L, Bateman ED. Identifying 'well-controlled' and 'not well-controlled' asthma using the Asthma Control Questionnaire. *Respir Med* 2006; 100:616-21.
35. Juniper EF, Guyatt GH, Cox FM, Ferrie PJ, King DR. Development and validation of the Mini Asthma Quality of Life Questionnaire. *Eur Respir J* 1999; 14:32-8.
36. Juniper EF, Buist AS, Cox FM, Ferrie PJ, King DR. Validation of a standardized version of the Asthma Quality of Life Questionnaire. *Chest* 1999; 115:1265-70.
37. Juniper EF, Guyatt GH, Willan A, Griffith LE. Determining a minimal important change in a disease-specific Quality of Life Questionnaire. *J Clin Epidemiol* 1994; 47:81-7.
38. Leidy KN, Chan KS, Coughlin C. Is the asthma quality of life questionnaire a useful measure for low-income asthmatics? *Am J Respir Crit Care Med* 1998; 158:1082-90.
39. Standardization of Spirometry, 1994 Update. *Am J Respir Crit Care Med* 1995; 152:1107-36.
40. Norman CD, Skinner HA. eHEALS: The eHealth Literacy Scale. *J Med Internet Res* 2006; 8:e27.
41. Knapp C, Madden V, Wang H, Sloyer P, Shenkman E. Internet use and eHealth literacy of low-income parents whose children have special health care needs. *J Med Internet Res* 2011; 13:e75.

42. Holmbeck GN. Toward terminological, conceptual, and statistical clarity in the study of mediators and moderators: examples from the child-clinical and pediatric psychology literatures. *J Consulting and Clinical Psychology* 1997; 65:599-610.
43. Apter AJ, Cheng J, Small D, Bennett IM, Albert C, Fein DG, et al. Asthma numeracy skill and health literacy. *J Asthma* 2006; 43:705-10.
44. Baker DW, Williams MV, Parker RM, Gazmararian JA, Nurss J. Development of a brief test to measure functional health literacy. *Patient Educ Couns* 1999; 38:33-42.
45. Radloff LS. The CES-D Scale: a self-report depression scale for research in the general population. *Applied Psychological Measurement* 1977; 1:385-401.
46. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009; 42:377-81.
47. Fitzmaurice GM, Laird NM, J.H. W. *Applied Longitudinal Analysis*, 2nd Edition. Hoboken, NJ: John Wiley & Sons; 2011.

