

**Project HealthDesign
Full Proposal Narrative**
**Proposal Title: BreathEasy—A PHR for Adults Living with Asthma & Depression
or Anxiety**
Organization: RTI International

Executive Summary

Asthma is a common, chronic illness, affecting over 23 million U.S. adults (Strine et al., 2008). In addition to respiratory symptoms, individuals with asthma are also more likely to experience depression and anxiety; the lifetime incidences of depression (30.6%) and anxiety (23.5%) among persons with asthma are significantly greater than that among persons without asthma - 14.4% and 10.2%, respectively. (Strine et al., 2008). Among individuals with asthma, comorbid depression or anxiety is associated with increased asthma severity, greater risk of hospitalization, decreased asthma-related QoL, disability, and risk behaviors such as smoking compared with asthma patients without depression or anxiety (Eisner et al., 2005; Strine et al., 2008).

Individuals living with asthma and depression or anxiety face daunting challenges in managing their disease conditions on a daily basis. While each of these diseases taken separately is complex and has physical, psychological, and social consequences, the coexistence of the two conditions leads to additive, if not multiplicative impacts on quality of life (QoL). The comorbidity of asthma and depression or anxiety makes motivation to care for oneself and compliance with recommendations made by clinicians more challenging. The system will be designed to enable and support self-care, and to allow patients and providers to better understand the relationship among asthma and depression or anxiety symptoms, responses, and outcomes.

In the proposed project, *BreathEasy*, RTI and the Department of Family Medicine at Virginia Commonwealth University (VCU) propose to design a personal health record (PHR) application that builds on the latest clinical guidelines for treatment and self-monitoring for individuals with asthma. An iterative user-centered design approach will be followed with individual patient users recruited from the VCU clinics. After initial account setup at the clinicians' offices, patient users will interact with the *BreathEasy* system primarily through a smart phone, bringing the *BreathEasy* tools to them at the time and place they are most needed. Patients' spirometry results, medication use,

levels and types of physical activity, activity limitations, air pollutions, airborne allergens, smoking, subjective levels of symptoms and QoL measures will be delivered to the application through biomonitors and self report. In response to these observations of daily living (ODLs), the application will allow patients to view their data and any interactions between various measures. Clinicians will utilize a Web-based dashboard providing simple analysis and visualization tools that allow them to quickly view their patients' data, evaluate their health status, and communicate any changes in treatment or monitoring. Using the Project HealthDesign (PHD) Common Platform (CP) for Web services, RTI and VCU will develop the PHR using the open source *Android* platform for mobile devices. RTI and VCU are well-qualified to develop this application, given our extensive experience in the development of PHR tools, and the design of mobile data capture devices that interface with larger data architectures. Our ongoing successful partnership, our track record in multidisciplinary work, and our experience in collaborative design and open source development position us to be active and creative members of the PHD grantee community.

The following modifications to the study design have been made since submission of the full proposal (see **Appendix A**)

1. Comorbid diagnosis of anxiety disorder added to expand patient population
2. Added ODL related to "reason for use" of rescue medications
3. Fewer patient users recruited for the initial design focus groups and usability testing
4. All clinicians and nurses treating enrolled patients added to the evaluation phase
5. Additional possibilities for integration with the EHR have been described.

Vision and Health Impact

The present study will use a PHR in a novel manner to support adults with chronic asthma and depression or anxiety in an inner-city population. In cooperation with VCU, RTI will develop and field test a new PHR suite of tools to help patients better manage their conditions, communicate with their clinicians, and assist them in clinical decision making. The ultimate goal is to help patients and clinicians better understand factors

affecting both asthma and depression or anxiety and to produce improved health status and quality of life.

The BreathEasy system prompts patients to monitor their symptoms, use medications as prescribed and record their use, and assess their overall health status. The BreathEasy system also provides easy-to-use tools to enable users to review trends in medication use, symptom exacerbations, and functional status. The BreathEasy system also allows users to share information with their clinicians, creating a more informed partnership between patients and their clinicians and enabling them to use data collected in real time. The BreathEasy system could also provide information on association between symptoms and patient behaviors (e.g., medication adherence) and alerts for symptoms exceeding thresholds. Analysis and visualization tools will highlight symptom control over time and suggest personalized advice and interventions, potentially including alerts and reminders through the smart phone. The potential value of this information to a disadvantaged population dealing with multiple chronic diseases and the resulting improvement in disease management cannot be underestimated.

Optimal self-management of asthma includes two key components: spirometry and medication adherence. Spirometry is assessment of the volume or rate of exhaled air and reflects a patient's level of bronchoconstriction, indicating the extent to which asthma therapies are effective. Spirometry is often underused, particularly among low-income individuals (Cabana et al., 2006). Asthma medications include controller medications that prevent asthma symptoms and rescue medications that relieve symptoms. Adherence to controller medications is crucial for optimal asthma control; greater adherence is associated with decreased likelihood of asthma exacerbations (Marceau et al., 2006) and reduced need for rescue medications.

Asthma patients should record their ODLs routinely [note: the ODLs to be collected are listed in bold italics], including ***peak-flow rates, controller medication adherence, use of rescue medications, reason for using rescue medications, levels and types of physical activity (or activity limitations), and subjective levels of symptoms.*** However, patients often forget to record these values and recall (even within a few days) can be poor. Further, asthma patients with comorbid depression may be less likely to maintain adherence to asthma therapy (Smith et al., 2006) and to track ODLs.

An additional goal of the BreathEasy system is to encourage physical activity, using an **Android** activity application such as a pedometer and integrate it into the application suite. Increased physical activity and monitoring of symptoms and other behaviors will result in better control of both asthma and depression or anxiety symptoms.

In addition to use of medications and avoidance of factors that initiate asthma symptoms (e.g., **allergens, air pollution, smoking**), increased **physical activity** may also help improve the health and **QoL** of individuals with asthma (Hallstrand et al., 2000; Lucas & Platts-Mills, 2005). Physical activity is likely to be particularly important for asthma patients with depression or anxiety; all these conditions may be helped by regular, moderate physical activity (U.S. DHHS, 1996). However, having either asthma or depression decreases the likelihood that a person will engage in physical activity (Ford et al., 2003; Teychenne et al., 2008; Steger & Kashdan, 2009), and increased depression among asthma patients is associated with greater physical inactivity, activity limitations, and obesity (Strine et al., 2004, 2008). Physical activity interventions have increased relevance for low-income populations with asthma and depression. Among adults with asthma, a high level of perceived neighborhood problems (e.g., traffic, noise, trash, smells, fires) is associated with increased depressive symptoms and poorer physical functioning (Yen et al., 2006).

Technical Approach, Feasibility and Viability

To enable the BreathEasy system to be optimally effective, we envision a suite of tools that can be accessed and used via the Internet and smart phones. Using a computer at the clinicians' office, patients will set up an account in the BreathEasy system and provide initial symptom assessments and other information. Patients will then be able to track symptoms, medication use, and physical activity as well as communicate with their clinicians via the smart phone. Given the mobility, decreasing cost, and increasing capabilities and pervasiveness of smart phones, they make an ideal platform for helping patients better monitor symptoms and health behaviors. New capabilities such as global positioning system (GPS) tagging may be used, along with built-in cameras or reporting tools to help patients and clinicians understand how factors, such as the physical environment, may be associated with symptom

exacerbation. Smart phones will make an effective PHR platform that patients and clinicians will find useful and offers intrinsic incentives to the target population.

Our BreathEasy system is specifically targeted to reach individuals with asthma and depression or anxiety who reside in low-income areas and may have low education levels, limited access to computers, and unstable housing situations. We are proposing a PHR that would be accessible almost anywhere via smart phones. While low-income individuals are less likely to have internet access, the 2004 Pew Internet & American Life Project study indicated that approximately half of those without internet had a cell phone (Rainie & Keeter, 2006). In the years since the Pew study, it is expected that cell phone use has increased. To deal with lower reading skills among the target population, we will also use simple graphics for operating the smart phone interface and target and conduct reading level analysis for eighth grade reading levels for all print materials.

To ensure that the BreathEasy system meets the needs of both users and clinicians, the project will employ an iterative user-centered design approach to development and testing. The process will begin with the identification of user needs and preferences that will ultimately influence the acceptance and use of the system. This information will be gathered from focus groups held with two groups of approximately 10 patient users (n=20). The first part of these focus groups will describe the project, goals for the application, and parameters for use. During the second part we will show the users mockups of the application and discuss practical issues related to implementation and use of the BreathEasy system on a regular basis.

The project team will use information from these focus groups to develop a prototype of the BreathEasy system. After conducting internal testing of the application, the team will return to a subset of the patient user group (n=6) and ask them to test the prototype and provide feedback to enhance it. The project team will conduct user testing (i.e., cognitive and usability testing) to determine if there are any significant problems in the prototype user interface, understanding of the system, and a check to see that everything is working as planned. Based on the findings from this iteration of testing, the team will revise and update the system and conduct additional internal testing. Nurses functioning as clinical coordinators and physicians will receive in-depth, in-person training on the system, including how to use the equipment; how to set up accounts for

patients; and, how to use the system within the context of their health care delivery at the clinic. Following the training sessions, the team will conduct a 6-9 month evaluation of the prototype with approximately 35 patient users. Finally, after the evaluation period has been completed, the team will conduct open forum guided discussions with users to determine what their experience with the system was, and to determine any steps to be taken to address problems and further improve the system.

In addition to involving patient users in the development and testing process, we will ask clinicians to participate in a similar focus group discussion. The focus group will provide an orientation to concept, determine needs, and review patient system concepts and obtain feedback. Mockups to show basic ideas for the system will be presented. Clinicians' input about the usability of the tool will be collected following the prototype development and will inform any adjustments made to the system. Next, the team will conduct a 6-9 month evaluation of the prototype with all clinicians caring for the 35 patient users. Finally, after the evaluation period has been completed, the team will conduct open-ended telephone interviews with clinicians to determine what their experience with the system was, and determine any steps need to be taken to address problems and further improve the system. Clinicians' input will be valuable to the project team in helping to illuminate issues related to the integration of the BreathEasy system into the typical practices of primary care medicine. See Figure 1 for a summary of the user-centered design process.

Figure 1. Stages of Development and Testing the Prototype System

Stage	Strategies	Goals
1. Identification of user needs/ feedback on mock ups	Focus groups	<ul style="list-style-type: none"> Elicit information on participant interests, preferences, issues, and concerns regarding the use of the application Assess factors impacting the acceptance of a patient-centered technology-driven intervention Review mockups of the proposed system with users
2. Testing of systems and instruments	Cognitive and usability testing	<ul style="list-style-type: none"> Conduct cognitive testing of all data entry and questionnaire elements of the system to ensure that it is easy to understand and use for end-users Conduct usability testing to explore possible sources of error for end-users in accessing, inputting data, and using the system Specifically target obtaining feedback on acceptance of the system, identification of problem areas, how to make the system more effective
3. Evaluation	Conduct evaluation	<ul style="list-style-type: none"> Conduct a 6-9-month evaluation test of the entire PHR system with users Monitor compliance with the system, acceptance of various elements of the system, and any problems encountered by users
4. Debriefing	Open forum/ Telephone interviews	<ul style="list-style-type: none"> Obtain feedback from end-users about their reaction to the prototype Discuss possible changes and updates to the system that may need to be explored in the future

The RTI/VCU collaboration will create a dynamic and engaging intervention built upon formative research. It will utilize highly personalized messaging that responds to the user’s information and interactions with a smart phone interface (e.g., G1 or G2). Once users have established accounts using a Web portal, all interactions users have with the system will occur through the smart phone. RTI will establish a Web dashboard to give clinicians the tools to monitor patients’ ODLs using simple analysis and visualization tools, provide feedback, and interact with patients.

This BreathEasy system will stimulate innovation in the following four ways:

- use of biomonitors as a means to capture ODLs,
- use of a smart phone as the primary patient user interface,
- use of bidirectional information exchange and message prompting, and
- integration of additional Web 2.0 geo-services, such as air pollution alerts, pollen counts, nearby recreational facilities, support groups, etc.

The smart phone will provide patients direct access to the system at the time and place most convenient for them without requiring access to a PC connected to the

Internet. **Appendix B** provides a conceptual mockup of the smart phone user interface. User interface modules (breathing-related, mood, anxiety and physical activity measures) will be developed on the **Android** platform for mobile phones, chosen because it is open source and supported by multiple vendors. Integrated functionality common to smart phones such as GPS and accelerometers will be adapted for use with the system. Any external devices required by the system, such as those used in spirometry, will be modified to send data to the smart phone via serial or Bluetooth connection.

RTI will use the RWJF CP to ensure the interoperability of the various services, including access and authentication, and store the data in a secured environment in compliance with National Institute of Standards and Technology requirements. Additional features will be developed and exposed via Web services for seamless integration with the CP. RTI chose to use the CP because of the availability of the shared services, which will save programming resources and reduce costs, and also out of a desire to further contribute to the development of the publicly available CP. RTI will share additional requirements as they become available through this project.

One noteworthy characteristic of the CP is that it is not a full production service, i.e. data are not stored in an encrypted manner within the CP repository. However, as data are requested, they will be delivered encrypted via HTTPS in standard XML format. Another difference is if an alternative third-party platform was chosen, the BreathEasy system might then be hosted on their servers, thereby making it more broadly available. This difference will be mitigated because RTI plans to make all products of the project available through open-source licensing so that others could choose to implement the BreathEasy system within different environments.

Providers will access patient-level data through a secured, semantic Web dashboard. For each patient, providers will use simple analysis and visualization tools to monitor patients over time, using the ODLs to gain insights into the patients' experiences and inform prevention and treatment decisions. A mockup of the provider dashboard is shown in **Appendix C**.

The proposed strategies, methods, and system will build upon a range of existing technologies, software systems, and standards. Widely available mobile smart phone

technologies, such as **Android**, will be used as an implementation platform, ensuring compatibility across cellular providers.

RTI will use the CP to store physical activity, respiratory function, and mood in the Observation Service. Commercially available physical activity and respiratory function devices, such heart rate monitors, accelerometers, portable flow meters, and portable spirometers, will be employed for data collection. We will use the Access Control Service rules and roles functionality to control access to patient data by authorized users. **Appendix D** depicts the proposed system architecture.

Data collected from the BreathEasy system will be used to determine how information is being used within the clinical context and whether it addresses the user population's needs. We will assess whether the ODLs are providing the right kind of information and whether that information is being collected at the proper interval and is leading to appropriate action. These analyses will be ongoing during the evaluation phase in order to make adjustments to the ODLs collected, the BreathEasy system itself, or to the way in which the BreathEasy system is being used.

RTI considered several technical challenges when developing the study design. Internet access, while constantly improving, cannot be assumed, particularly in low-income areas. For this reason, we chose to provide the patient interface via smart phones, which can store collected data locally for subsequent transmission. This presents challenges as well, as not many health applications have been built using the **Android** platform. We may encounter additional security requirements or other challenges, but we will address these as needed; we do not anticipate any significant obstacles. RTI has experience programming on this platform and can draw upon the Google developer's forum and application support resources if necessary. RTI will also use our experience during PHD Round 1 in capturing ODLs from users and devices and storing them on a third-party platform. During the prototype testing phase we will present real and mockup ODLs for patients and clinicians to interpret, and will use cognitive and think-aloud approaches to evaluate their experience in interpreting them.

A further challenge is successfully integrating the ODLs into the clinical practice workflow. In initial discussions with clinician colleagues, Drs. Rothemich and Krist have found a high level of interest and motivation in accessing and using ODLs in clinical

decision making. The ODLs proposed are the exact kinds of information that would provide clinicians with a broader and deeper understanding of the patients' daily experience related to their diseases, and can only contribute to their clinical judgment. Drs. Rothemich and Krist as well as the clinical coordinators will act as champions within the VCU practices to work with clinicians in incorporating the tool into their workflow. VCU clinicians routinely access a variety of clinical applications and use laptops during their patient encounters, providing us with an ideal setting to evaluate the BreathEasy system.

Some risks are involved in implementing a software application within a clinical setting. Some relate to the difficulty of developing the application itself, but typically the real risks come from the people and their behaviors related to the system. Inadequate participation and support could thwart the ability to implement and evaluate the BreathEasy system. RTI has spent considerable time building support among those who would be stakeholders in the successful implementation of the BreathEasy system. Nurses have been recruited to serve as clinical coordinators, and physicians have been approached about participating in the study. Incentives have been planned for all participants in the use and evaluation of the BreathEasy system. In addition to Drs. Rothemich and Krist, who have significant experience researching and using health IT in clinical settings, we have designated a project coordinator who will be in regular contact with clinicians and patients. This person will provide support in many senses: answering questions, referring technical issues to the development team, escalating policy issues to the PI, and so forth.

We specifically chose the smart phone as the means to deliver our BreathEasy system to patients living in low-income areas. Although we cannot guarantee that every participant in the population would have access to a high-speed internet connection, we can virtually guarantee that each has access to the cell phone network. Following Hurricane Katrina, the epitome of suboptimal conditions, when landline telephone and internet services were down, and cell phone networks overwhelmed with the call volume, SMS messaging via cell phone was the only remaining communication technology available. Google and Google.org have made substantial investments in the past few years researching the use of smart phones and SMS as means to

communicate vital public health information during crises, including citizen reporting of suspicious deaths possibly related to influenza in SE Asia. RTI will also optimize the database environment on the back end to ensure fast, efficient communications using cellular handheld broadband access.

Providing clinicians with information about ODLs that they otherwise might not have is likely to lead to clinical practice change. So much information related to asthma, depression or anxiety, and factors influencing these conditions is not directly measurable during a clinical encounter. Giving patients a tool to collect this information, as it is occurring, and providing clinicians with tools to effectively and efficiently use the information is a tremendous improvement over patients' general recollection. We envision the BreathEasy system as being similar to mobile PACs—picture archiving and communication systems that allow radiologists to view and evaluate imagery data for patients from their cell phones. If commercialization were to happen, we could see this application being available as an applet or through the **Android** store essentially free to patients, with the viewer application sold to providers. We anticipate opportunities as the BreathEasy system is being developed to identify and expand the tools to other health conditions where capture and analysis of ODLs are critical.

We will be working with active nurse and physicians pairs who are actively engaged in the study. It is the intention of these providers to, as much as possible, seamlessly integrate the tool in the care they are providing and to test how much it supplements that care. We do not expect that the BreathEasy system will disrupt their clinic workflow or delivery of health care to any significant level.

Patient and Clinician Engagement

Setting. We propose to develop and test the PHR in two primary care practices within the Virginia Ambulatory Care Research Outcomes (ACORN) practice based research network (PBRN). Both practices are part of the Virginia Commonwealth University Health System (VCUHS). The practices, Nelson Clinic and Hayes E. Willis Health Center, are located in inner-city Richmond and primarily serve patients from a lower socioeconomic background (see **Table 1**). Hayes E. Willis Health Center is a community health center in south Richmond; Nelson Clinic is a faculty practice at the

VCU Medical Center in downtown Richmond. In 2008, Hayes E. Willis had over 11,000 patient visits; Nelson Clinic had more than 12,000. Currently, these two practices care for a total population of approximately 14,800 patients. Per a recent chart review in Nelson Clinic, we estimate 14% of the patients aged 18-50 have asthma, 11% have active depression, and 4% have both conditions. Adding anxiety as a secondary diagnoses in addition to asthma will expand the potential patient population from which to recruit user participants.

Both practices are actively engaged in implementing a common EHR that was initially implemented in the hospital and is now being deployed in the ambulatory care setting. The clinicians at both practices have a strong commitment to providing excellent care to their underserved patient populations and have embraced health information technology, with several clinicians

TABLE 1. Pooled Demographics of Patients from the Two Study Sites

Characteristic	Percentage
Gender	
Female	53%
Age	
18-34 years	26%
35-54 years	30%
Ethnicity	
Hispanic	2.3%
Race	
White	46%
African American	49%
Asian	0.3%
Education	
High school or less	18%
Income	
Below federal poverty level	16%

participating in VCUHS’s implementation team to define how the Cerner EHR will be deployed in the ambulatory care setting. VCUHS recently approved a \$~~X~~4.3M ambulatory EHR budget to design and automate the ambulatory clinics. One of the physicians at Nelson Clinic (Dr. Susan Miller) currently serves on the ambulatory rollout project as a clinical informaticist.

Practice Engagement. Clinicians from both study sites will be involved in the development of the BreathEasy system as well as the fielding and testing. Both practices are in the process of expanding and refining their current health information technology infrastructure and have expressed interest and enthusiasm for being able to participate in the creation of this system to better manage their patients with asthma and depression or anxiety (see letters of support, **Appendix F**).

Drs. Rothemich and Krist will coordinate practice engagement activities, using strategies that ACORN has employed effectively in prior studies (Krist et al., 2005). They will recruit 4-6 clinicians involved in care of the 35 patients and 4-6 nurse champions from each practice to participate in the focus groups to collaboratively

design the BreathEasy system with RTI. This group will provide input on clinical, workflow, and current EHR/PHR systems that will be used to design the BreathEasy system. Additionally, this group will participate in usability testing of the prototype. These activities will help to ensure the feasibility of successfully fielding the BreathEasy system in the study sites.

The nurses and clinicians will receive a ~~\$50X~~ gift certificate and a meal for participation in the focus group, the usability session, and for completing the follow-up survey, and the practice will receive ~~\$500X~~ reimbursement per patient participant. However, the clinicians' primary motivation for participation in the design phase of this project will be to improve the quality of care provided to their patients with asthma and depression or anxiety and to influence and improve their existing clinical workflows.

Patient Engagement. We propose to include established adult patients with both active asthma and depression or anxiety in the development, fielding, and testing of the BreathEasy system. Inclusion criteria will include age 18-50 years, having an asthma and antidepressant prescription in their electronic record or documented diagnosis of asthma and depression or asthma and anxiety, and providing informed consent. Exclusion criteria will include additional psychiatric diagnoses (e.g., schizophrenia, bipolar disorder), active suicidal ideation, or severe depression that renders the patient unable to participate in the study.

The first step in recruiting patients will be to have the informatics staff at each practice query the electronic record to identify all patients aged 18-50 years with current prescriptions for both asthma and antidepressant medication or asthma and depression or anxiety diagnoses. A nurse at each practice will function as a clinical coordinator. The clinical coordinator will review patients' records to identify patients who meet inclusion and exclusion criteria and will then call qualified patients to inquire if they are interested in participating. Patients who agree to participate will meet with the study's research coordinator to begin the informed consent process and sign consent documents. In the unlikely event that we are unable to recruit 35 patients from the two proposed clinical sites, additional practices from the ACORN PBRN that serve disadvantaged patients will be included (see ***Qualifications of the Team*** for a detailed description of additional ACORN sites).

The patients who participate in this study will receive three incentives: a \$~~25~~X gift card for participation in the focus group, the usability testing, and the follow-up open forum meeting (for a total of \$~~75~~X), an Android phone with a 1-year service plan, access to enhanced care for their asthma and depression and anxiety, and a \$~~25~~-X gift card for completion of the telephone survey at the conclusion of the evaluation phase. Given the financial status of the target population, these incentives should be sufficient to encourage participation throughout the proposed study.

To keep patients engaged during the period between the focus group and the usability testing of the prototype, and during the evaluation phase, Ms. Rita Sembajwe, proposed Project Manager, will remain in contact with patients through telephone calls, and development and distribution of a project newsletter. The newsletter will be one page in length and distributed on a monthly basis. It will update patients on the progress of the study, include interesting photos from the design workshops, and provide tips on asthma care and general mental health, and a toll-free number for patients to call if they have additional questions or concerns related to the study. In the event that health care questions are posed, they will be directed to contact their physicians directly. A message will also be sent to the clinical coordinator, alerting them that we have received a health care question and providing the patient's name to the coordinator for follow-up. The clinical coordinator and physicians will assist with input for the newsletter and provide review and approval prior to distribution. In lieu of the newsletter, we will discuss the possibility of setting up a Facebook page as a means to distribute this information.

Clinical Management. The clinician focus groups will provide a rich source of ideas on how the BreathEasy system can be integrated into clinical care, directing the final specific design of the system. At this point, though, we propose that, at a minimum, the dashboard be reviewed at each participant's clinical visits. The nursing staff and clinicians currently use wireless notebooks to access the EHR in the exam rooms, which can be used to access the dashboard as well. Other likely scenarios for use of the dashboard in clinical management of these patients include review when responding to patient telephone calls to the practice and requests for refills.

We plan to work with the VCUHS's HIT department (see letter of support) to design the BreathEasy system in a fashion that would allow for some degree of integration into the EHR. Although full integration is beyond the scope of this project, we feel that designing the BreathEasy system to allow integration at a later stage is crucial to the system's future dissemination in settings using this and other EHRs. For this project, we will be working with the EHR implementation team at VCU to discuss possibilities for some level of integration, taking into consideration the practice site capabilities and infrastructure. Some initial possibilities are list here from least ordered from least involved to most involved:

1. Providing a visible link for clinicians from the EHR to the PHR dashboard
2. Providing text templates for visit documentation to facilitate and standardize clinical actions taken after reviewing the PHR dashboard
3. Providing direct report capability from the PHR dashboard to the EHR.

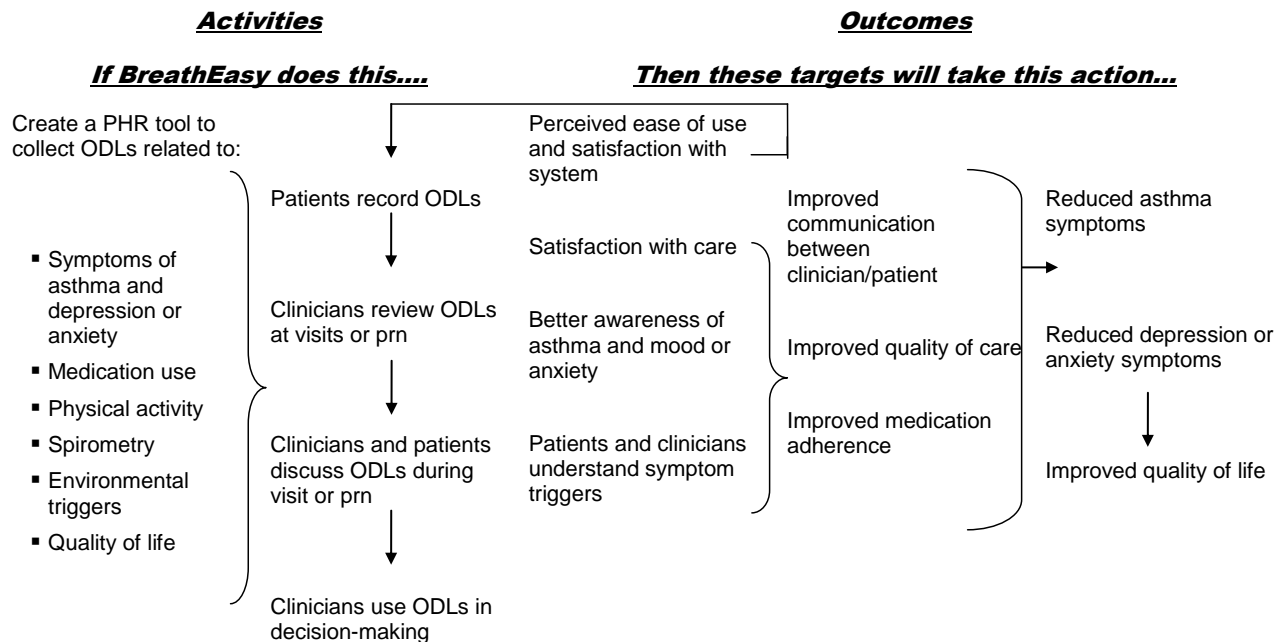
During the evaluation phase of this study, the research coordinator and site nurse champions will track study participants and prompt clinicians to use the BreathEasy system during clinical activities. Nurse champions will flag charts of study participants and assist clinicians with clinical activities prompted by the system and related to each patient's depression or anxiety and asthma care. The coordinator will give each practice a list of their participating patients and provide monthly feedback to participating clinicians on their use and their patients' use of the BreathEasy system. In general, we do not suspect that the clinical issues raised by the system will present any new difficulties for clinicians, beyond addressing the new workflow introduced by the system, as they are the same issues that clinicians are responsible for managing without the system. Collectively, we believe that the patient, practice, and clinician incentives, reminders to use the system, feedback on system use, and general system design will ensure that clinicians and patients participate in the study during both the design and evaluation phases of the project.

Evaluation Design

RTI's proposed process and outcome evaluation of the BreathEasy system is designed to assess its (1) perceived convenience and utility for managing asthma; (2) impact on patient-provider communication and information exchange; (3) impact on

improving the quality of care consistent with NHLBI guidelines (DHHS, 2007); and (4) impact on key outcomes related to asthma-related symptoms, medication adherence, and depression or anxiety (see **Figure 2**).

Figure 2. Logic Model for BreathEasy Evaluation Framework



The logic model depicts the purpose and activities (inputs) to the BreathEasy tool, the interim activities that the tool will support, and the final outputs of outcomes anticipated. We expect that creating a system to collect ODLs related to symptoms of asthma and depression or anxiety, medication use, physical activity, spirometry, environmental triggers, and quality of life will cause both patient and clinician to record ODLs. Having these ODLs available will lead clinicians to review and discuss them with patients at visits, and use them in clinical decision making. And if the tool is found to be easy to use, patients and clinicians will use it more often. This continued use of the BreathEasy system will lead to better satisfaction with care; better awareness of asthma symptoms and mood or anxiety; better understanding of triggers on the part of patients and clinicians; and, better communication between patient and clinician. All of these interim outcomes will lead to an improvement in quality of care and adherence to self-

care activities. This will lead to reduced asthma and depression or anxiety symptoms, which in turn, will lead to better quality of life.

The evaluation will target the patients (n=35) enrolled in the intervention and all their clinicians. This patient sample represents approximately 6% of adult patient population with asthma of the participating clinics and will be selected to be representative in terms of age (18-50 years), race, and gender. Although the sample is non-random, we expect the findings of the evaluation to be generalizable to the patient population from which the sample is drawn.

The RTI evaluation design will assess key measures of the tool's ease of use and utility and its impact on patient-provider communication, medication adherence quality of care, asthma symptoms, QoL and depression or anxiety. To capture these measures, we will use multiple sources of data including the focus groups with clinicians, the BreathEasy system, the CES-D10, a commonly used instrument for measurement of depression (Radloff, 1997) that has been validated in a chronic disease populations (Loring et al., 2001), see **Appendix E**, a simple measure of anxiety, and a self-administered survey at baseline and 6-9 month follow-up at the conclusion of the study (see **Table 2**).

The focus groups, usability testing, and BreathEasy system are described in fuller detail in previous sections. Here we describe the development and administration of the baseline and follow-up surveys. The provider and patient surveys will be administered at baseline approximately one month prior to the initiation of the system as part of the intervention enrollment process. The patient survey will be approximately 40 items in length, self administered and designed to take 30 minutes to complete. For patients with severely limited literacy skills, a telephone interview can be arranged to complete the survey. The provider survey will be distributed via e-mail, approximately 20 items in length and designed to be completed in 15 minutes or less. These same instruments will be administered at 6-9 months to assess change in outcomes. The patient surveys will be administered through a telephone interview with patients and the provider surveys will be administered by e-mail as in the baseline period.

Patient follow-up with low-income populations can be challenging as they may move frequently and/or fail to provide up-to-date contact information. We do not anticipate

these will be insurmountable challenges for this evaluation because the intensity of the intervention requires frequent contact between the study team and the patients.

Table 2. Evaluation Measures and Sources of Information

Measure	Usability Testing	BreathEasy system	Baseline Survey	Follow-up Survey	CES-D10	Simple Anxiety Scale
Utility						
Satisfaction with the tool	X			X		
Ease of use	X			X		
Frequency of use	X			X		
How information was used	X			X		
Communication						
Frequency of provider/patient contacts			X	X		
Duration of provider/patient contacts			X	X		
Satisfaction with provider/patient exchanges			X	X		
Quality of Care						
Routine monitoring of the severity of asthma through spirometry			X	X		
Routine adjustment of therapy to manifestations of asthma			X	X		
Content of patient education encounters			X	X		
Satisfaction with care			X	X		
Medication Adherence						
Daily use of controller medications		X	X	X		
Immunotherapy for adults with allergies			X	X		
Rescue medication use		X	X	X		
Environmental Controls			X	X		
Exposure to smoke, pollution, pets and allergens		X	X	X		
Symptoms and QoL			X	X		
Number and severity of asthma exacerbations		X	X	X		
Activities of daily living			X	X		
Mood		X			X	
Anxiety symptoms						X

Because of the small size of the sample and the lack of a control group, our primary goal for analysis is descriptive. We will produce frequency counts, proportions, means and modes on all items as appropriate and selected cross-tabulations on key

demographic variables (e.g. age, gender, race). We will use nonparametric statistical methods to assess change on individual measures from baseline to follow-up surveys.

Qualifications of the Team

For the proposed project, RTI and VCU have formed a team that has extraordinary strengths in organizational capabilities and in the skills of individuals. We propose a diverse project team representing multiple disciplines with relevant expertise and years of experience highlighted in the sketches below. Each member of the team is key to the project and contributes unique experience and skills. RTI and VCU have successfully collaborated with various team members on many projects individually, and one project jointly—an integrated PHR– EHR (www.MyPreventiveCare.org) to promote 18 U.S. Preventive Services Task Force–endorsed screening tests, counseling services, preventive medications, and immunizations. The RTI/VCU team looks forward to participating in the collaborative design workshops, and has planned for at least one member of each organization to attend all workshops. For each workshop, the team will bring capabilities in clinical medicine, informatics, user-centered design and usability, and evaluation design. Through our past involvement in RWJF programs, including PHD Round 1, we realize the tremendous benefit of cross-team sharing and collaborative design efforts, and will make ourselves available as resources for other teams and to facilitate the joint creative effort in the spirit of PHD.

Proposed Personnel – RTI International

Barbara L. Massoudi, MPH, PhD, who will serve as Project Director, is a senior research health scientist at RTI and leads the Institute’s Health Informatics Program. She has more than 20 years of experience in **epidemiology** and **health informatics**. Dr. Massoudi has participated in collaborative design efforts including a **user-centered design** approach on many projects, including Round I of the PHD grants, where she led the development of a PHR aimed at increasing physical activity among sedentary adults.

William H. Savage, MS, is a software/database developer with more than 20 years’ experience in design, implementation, testing, and deployment of innovative **software products**, **Web-based applications**, and data-warehousing solutions. His

work is performed within **collaborative teaming** environments with groups of developers, scientists, and other specialists. His current activities embrace object-oriented design and data modeling and involve technologies such as **Android** and iPhone platforms; PHP, Perl, C, and Java languages; and MySQL, Oracle, and SQL Server databases.

Murrey G. Olmsted, PhD, is a research methodologist/**psychologist** with more than 16 years of experience designing research studies, **developing instruments**, collecting data, and performing quantitative/qualitative data analyses. Dr. Olmsted led the methodological development and testing of the ActivHealth PHR Website under PHD Round I.

Elizabeth Dean, MA, is a survey methodologist at RTI with more than 10 years of experience developing and testing surveys. She has extensive experience in a variety of pretesting methods, including **cognitive testing**, questionnaire appraisal, and **usability assessment**. Ms. Dean has led instrumentation tasks for many high-profile large-scale surveys. She has managed **survey design** and data collection projects, including usability assessments of a Web-based performance management system and applications of cognitive testing methods to developing consent forms.

Lucia Rojas-Smith, DrPH, MPH, is an evaluation specialist with more than 18 years of experience in **program and technology evaluation**. She is principal investigator of the Centers for Disease Control and Prevention (CDC)-funded BioSense Evaluation, which examines the role of biosurveillance in improving and enhancing public health preparedness, situational awareness, and response to a range of public health threats. She also currently directs the qualitative evaluation of the Merck Community Asthma Network Program and is examining the implementation, translation and sustainability of **evidence-based asthma interventions** in five U.S. cities.

Rita Sembajwe, MSPH, is a public health informatics specialist with RTI's Research Computing Division. She has 7 years of combined experience in public health and IT, including firsthand experience with coalition building and strengthening of partnerships and collaborations with leading federal, private, and nonprofit organizations. She has numerous technical skills, including Web and database development, system evaluation, social marketing, and system management. As a

liaison among staff in public health and technology, standards and best practices, system interoperability, and security, Ms. Sembajwe has acquired a strong ability to organize and coordinate activities. Ms. Sembajwe recently completed a full system documentation of CDC's Pregnancy Risk Assessment and Monitoring System (PRAMS) using reverse engineering and relying on existing documents over 10 years old. Previously, Ms. Sembajwe developed the Daily Activity Reports, a CDC-wide report that highlights daily communicable illnesses of Public Health significance.

Proposed Personnel—Virginia Commonwealth University

Stephen F. Rothemich, MD, MS, is an Associate Professor of Family Medicine at VCU and co-director of ACORN. He is a former Robert Wood Johnson Foundation Generalist Physician Faculty Scholar, is a member scientist at the VCU Massey Cancer Center, and holds a master's degree in clinical research and biostatistics. He has been the lead investigator for ACORN's smoking-related research portfolio. He served as co-investigator on two previous RWJF Prescription for Health Projects and on a current AHRQ R18 focused on the development of an IPHR for prevention. As co-director of ACORN, he has intimate experience with the logistical and often unpredictable challenges of ***practice-based research***. He is an alternate panel member on the VCU Institutional Review Board and provides expertise in human research subjects regulations and HIPAA policies.

Alex H. Krist, MD MPH, is an Associate Professor of Family Medicine and Member Scientist of the VCU Massey Cancer Center. Dr. Krist joined the department faculty in 1999, with an interest in promoting the appropriate delivery of preventive care and ***empowering patients*** to make informed medical choices. He provides expertise in ***clinical informatics***, EHR use, and database architecture, ***primary care***, obtaining practice buy-in and input, and project implementation. Dr. Krist previously served as the Project Director for two RWJF Prescription for Health projects, co-funded by AHRQ. In one, he developed a health behavior change Website for patients; in the second, he developed an EMR prompt-referral system (eLinkS) to promote intensive health behavior counseling through clinician-community counselor collaboration. Dr. Krist is currently the PI of the My Preventive Care project, which gives patients direct access to the personal health information stored in the electronic record of their primary care

physician, displays tailored prevention recommendations, provides links to online educational resources, and generates patient and clinician reminders.

Virginia Ambulatory Care Outcomes Research Network (ACORN)

ACORN brings an exceptional blend of seasoned multidisciplinary investigators, more than a decade of PBRN research experience, a trusted and respected reputation among a diverse cohort of participating practices, unique dissemination opportunities, and direct access to national health care policy stakeholders. The ACORN team has been awarded nearly \$4.1 million from AHRQ, the National Cancer Institute, Health Resources and Services Administration, the Robert Wood Johnson Foundation, American Academy of Family Physicians, Massey Cancer Institute, and AD Williams Foundation. ACORN's research findings have been widely published in peer-reviewed journals and presented at national meetings (see **Appendix G** for listing of publications and presentations). ACORN maintains a robust research program that investigates strategies to improve the quality of primary care, with a focus on preventive services. The research team has significant expertise in domains (e.g., health IT, impact of practice structure and care-delivery processes on quality improvement) and methods (e.g., quantitative and qualitative analysis) that directly relate to this proposal.

ACORN was launched in 1996 and currently comprises more than 50 primary care practices serving suburban, urban, and rural communities throughout Virginia (ACORN, 2006). The practices range in size from 2 to 18 providers and operate under diverse ownership and insurance models. Approximately 265 clinicians—including family physicians, internists, pediatricians, and gynecologists—serve more than 300,000 patients of all socioeconomic classes. ACORN's research activities are designed to benefit member practices by assisting with the translation of evidence into practice in a manner that is respectful to existing practice constraints and culture as well as provide practice specific outcomes and performance information so member practices can improve and grow based on reliable and meaningful information. Many research ideas originate in ACORN's member practices and interventions are heavily informed by the expertise of practice clinicians and staff. As a result, ACORN enjoys highly productive and successful working relationships with member practices. However, these practices

face the same generalizable issues that all primary care practices face in implementing health IT interventions.

ACORN is supported by a set of skilled individuals who have expertise in ensuring the smooth, rapid, and efficient operation of research. They provide support in five important domains for success in PBRN research: (1) liaison with practices, (2) project coordination and administrative support, (3) financial administration and contract/project management, (4) database management, and (5) health IT programming.

Partner Commitment

RTI selected VCU as the clinical partner for this work for several reasons. VCU shares RTI's institutional commitment to scientifically based and ethically guided research, and the translation of research into practice. Additionally, VCU is recognized for being a leader in practice-based research and the implementation of health IT to improve quality of care (see **Appendix F**). RTI and VCU currently have a successful collaboration involving PHR research and the incorporation of patient and clinician decision support to implement preventive care guidelines, and wish to expand our collaborations around PHRs and clinical practice. For the proposed project, VCU will be responsible for identifying and recruiting patient and clinicians participants; arranging physical facilities and extending invitations for the patient and clinician focus groups; providing food and incentive payments to focus group participants; providing incentives to clinics for physician participation; providing and orientation to the tool for patients and clinicians; administering baseline data collection; and supporting and monitoring use of the tool during the evaluation phase. Drs. Rothemich and Krist have engaged stakeholders at the two clinic locations, including research directors, management, and clinical staff, as well as IT staff. Letter of support from key individuals can be found in **Appendix G**.

The RTI team is committed to resolving any technical, clinical, or other challenges that might arise during the course of the project. With substantial research experience in epidemiology, survey methodology, clinical research, and health informatics, the team is familiar with the kinds of challenges that might be expected in the project and will apply a multidisciplinary approach to problem solving. As senior members of their respective

institutions, the key staff members proposed have numerous professional contacts within the broader research community, as well as reach-back capabilities within their own institutions. These connections, coupled with their experience in health research will ensure that challenges are met with creative and timely solutions.

Commitment to the Program

The proposed project fits very well with key themes and philosophical approaches critical for PHD with regard to application development and the innovative and effective use of technologies in improving clinical practice. RTI's standard software development practices require the use of multilayered architectures with, at minimum, a database layer, a middle layer containing business rules, and a presentation layer incorporating graphical user interface best practices. This layered approach provides a primary benefit of isolating business rules, which can therefore be more easily modified since they are independent of database structures and user presentation. An additional benefit especially appealing with regard to open-source access is that system components can be more easily shared and integrated within other systems, architectures, and computing environments.

Key members of the RTI team are strong supporters, perhaps champions, of user-centered design. The proposed PI, Dr. Barbara Massoudi, frequently speaks at professional conferences about the benefits of this development approach, and is currently leading the development of a peer-reviewed publication on user-centered design approaches for public health information systems. The focus groups and iterative development process we have proposed will provide a rich source of information about users needs, desires, and preferences related to the BreathEasy system. The team believes it is critical that tools fit within the life-flow of the patients and the workflow of the providers, if they are to provide any intended benefit to the patients' health and health care. It is the intent of the team to incorporate the system into each clinical encounter the patient has during the study period as the tool will be running on the laptops the clinicians use to access the patients' EHR. Clinicians will have access to the dashboard providing an overview of the patients' ODLs at any given time. Drs. Rothemich and Krist will participate in the orientation to the BreathEasy system for clinicians and will suggest ways that it can be incorporated into the clinical workflow.

The RTI team is strongly committed to the vision and spirit of collaboration among PHD grantees. During PHD Round 1, the RTI team was an active collaborator with other grantee teams, providing consultation during and away from the workshops, particularly in the area of evaluation design for other teams. RTI team members participated in several conference panel presentations with other grantees and produced and shared the Technology Scan report early in the life of the project. RTI's proposed PI, Dr. Barbara Massoudi made visits and presentations to two grantee institutions to discuss further collaboration as follow-up to PHD Round 1.

In order to fully participate in the project, RTI has budgeted for three members of the team to attend each of the six design workshops, as well as additional travel for the focus groups, usability testing, tool orientation, and any communication opportunities that may become available. RTI staff frequently attends national conferences related to health informatics and anticipates opportunities to fulfill communication objectives associated with the PHD program. We also look forward to participating in novel communication channels such as blogging and Facebook as a means to facilitate both collaboration and exchange of ideas related to PHD.