

Project HealthDesign Full Proposal Narrative
Proposal Title: Use of Observations of Daily Living among Low Birth Weight Infants and their Caregivers to Improve Care and Reduce Incidence of Chronic Conditions over the Lifespan
Organization: University of California, Irvine

Executive Summary

To reduce the burden of chronic illnesses over the lifespan of prematurely born infants, we propose to use observations of daily living (ODLs) to improve the care of preterm, low birth weight infants in their first few months of life. Use of **innovative mobile technology solutions to collect and report ODLs** can enable changes in clinical practices that will alert providers to early signs of health problems and strengthen support for caregivers at home. This work is particularly innovative in that we make use of ODLs about both the baby (patient) and parents or other caregivers. The proposed project will allow caregivers to record those ODLs onto a mobile phone and, in the case of some ODLs, automatically, through sensing devices. Access to baby and caregiver ODLs can assist providers in making earlier diagnoses and treatment, which can improve the health outcomes of babies and caregivers. In addition, the gathering and feeding back of parent ODLs is an exciting innovation. Parent wellbeing is often ignored in infant care. By helping parents monitor and understand the patterns of their own emotional and physical wellbeing, we believe that parents will be encouraged to better care for themselves, leading to better quality of care for the babies.

Specifically, we are developing a mobile application for parents of preterm infants, which we call FitBaby. This system runs on Smartphones and enables parents to log ODLs in an easy, portable, and convenient manner by using simple input forms that can be completed with only a single hand in a few minutes. FitBaby also supports the automatic collection of sensor-based ODL data, such as from crib pressure sensors. This system utilizes mobile phone networks and visualizations on the phone itself to allow for real-time prompting and feedback to caregivers. Additionally, the system enables the upload of data to HealthVault, through which clinicians can then access the data and communicate with patients and caregivers.

To ensure that FitBaby serves the needs of potential users of the system, we are taking a participatory design approach [3, 8, 24]. We have included clinicians—nurses, a pediatrician, and an occupational therapist—on our design team. Moving forward, we

will invite parents and other caregivers to participate in design activities. We will use focus groups, in-depth interviews, and one-on-one design sessions to finalize the features of the full FitBaby system. Specifically, we will recruit pediatricians, nurses, physician assistants, social workers, parents, and individuals within parental social and support networks to participate in interviews and design sessions as part of our design and development for the next version of FitBaby. In particular, unanswered questions still exist surrounding how frequently and in what ways clinicians might want to access patient ODL data for this population.

In the first year of this work, we will complete the design and development of the FitBaby system, which we have been iteratively designing and developing for the last year. In the second year of this work, we will deploy and evaluate the system alongside a clinical trial of a home-based assisted exercise intervention for preterm infants. We will use quantitative and qualitative methods to evaluate the utility and efficacy of the FitBaby system. Evaluation will focus on three broad categories of outcomes: *health of babies, wellbeing of caregivers, and clinical care*. We expect to see improved outcomes in all three categories for babies and parents using the FitBaby system, compared to babies and parents not using the FitBaby system. We will share personnel and resources with an existing study at UCI, in order to make this evaluation feasible.

Since the submission of our proposal, we have engaged with more providers and refined our vision of how FitBaby can affect clinical practice and improve care. A diagram depicting the full potential of this system is in Appendix C. We have also added a medical sociologist to the team. Dr. George's experience in observing and documenting clinical workflow will help us in evaluate the impact of the FitBaby system.

Vision and Health Impact

Our **vision of personal health information management** for low birth weight (LBW) babies is responsive to both the needs of the infants who are at risk for multiple chronic illnesses as well as their caregivers who are at risk for a variety of physical and mental illnesses. This vision includes the development of both a mobile application for

caregivers¹ of LBW babies and a web-based application built on the HealthVault platform for caregivers and clinicians. The goal of these applications is to assist in the transition from the Neonatal Intensive Care Unit (NICU) to home. Premature birth is associated with long-term health impairments including neurological and cognitive deficiencies, chronic lung disease, and altered growth patterns of lean, fat, and bone tissues [5, 11, 12, 21, 27]. Furthermore, in Hack *et al's* study, 64% of low birth weight (LBW) children at age eight demonstrated one or more limitations, including conditions such as asthma, cerebral palsy, impaired vision, and cognitive and social disabilities [14]. Other studies suggest that an improvement in care for these LBW infants in the early months, a critical period for growth [2, 6], is likely to reduce the incidences and burdens of their chronic conditions over the lifespan [22, 25, 26].

Improved quality and continuity of care during this critical time is essential to reducing the long-term impacts of premature birth. The proposed project will improve care for LBW children by providing a daily monitor of the child's progress to clinicians and to parents. Parents will receive the data in a visualized format, to facilitate understanding regardless of education level or fatigue. Through this mobile application, parents will also receive educational materials to support home care.

Appendix C depicts our vision for the full potential of this system. ODLs, about both babies and parents, are collected through the mobile application and shared with providers through the HealthVault system to which the data are uploaded. The data can alert providers—including pediatricians, other specialists, staff from county regional centers and the parents themselves—to early signs that a LBW baby may have a health problem (e.g., the baby is not eating or sleeping enough or is losing weight). Parent ODLs can be shared with the parents' providers, to help providers catch signs of possible mental and physical health problems that may arise for parents. In addition, alerts generated from parent ODLs notify the parents of possible concerns in their own health, such as post-partum depression [10] or lactation problems. Finally, data stored in the third-party HealthVault repository will, over the long-term, enable scientists, public health officials, and policymakers to identify trends across the population of LBW babies

¹ The terms “caregivers” and “parents” will be used interchangeably through the text for ease of reading. We recognize that in some cases, the primary caregivers will not be parents but may be other relatives, friends, or nannies. The proposed system can be used by anyone who is a caregiver to the LBW baby.

and to create new strategies and interventions for improving health outcomes for LBW babies.

This system has far-reaching potential to impact care of LBW babies and reduce the burden of chronic illnesses in the future. For this proposal, however, we focus on only a subset of the overarching potential (again, see Appendix C). This subset includes the core of the proposed system and is feasible and testable at this stage of development.

The proposed project can provide **new insights for both providers and parents**. In particular, use of baby ODLs will enable physicians to monitor patients more frequently. ODLs can allow providers to *proactively* identify and treat potential problems before they become serious, rather than react to more serious problems when the parents contact the physician. Through access to the same baby ODLs, parents may also flag issues earlier, using the data to ask questions of providers and thus, improving parent-provider communication. By tracking the progress of their babies, parents may demonstrate greater feelings of empowerment and self-efficacy—taking more responsibility for the long-term health of their children. Finally, we anticipate that linking parent ODLs (*e.g.*, stress or tiredness ratings from caregivers) with baby response will help caregivers to think about how their own wellbeing may impact their babies.

Use of ODLs for at-risk—or even healthy—newborn infants has the potential to **change clinical practice** in both pediatric medicine and post-natal maternal care. In particular, use of ODLs enables physicians to monitor patients more frequently and outside of office visits and phone calls. Clinicians will have access to ODL data through HealthVault. UCI and Children’s Healthcare of Orange County will additionally have access to the HealthVault system via hyperlink from within the Eclipysis EMR system. Thus, in essence, use of ODLs allows clinicians to be more proactive. As one pediatrician in our preliminary interviews stated, “By the time they come see me, they can be really sick.” Thus, rather than react to serious problems, pediatricians have the potential to proactively identify and treat potential problems before they become serious. Because it is generally less stressful, less time-consuming, and more effective to treat problems early, pediatricians will be able to provide better quality of care to babies and reduce the cost of care over time.

In addition to better care for at-risk infants, use of ODLs has the potential to change clinical practice in the care of new parents. Our choice of ODLs will not only enable the monitoring of infant health but also that of the primary caregiver, typically the mother. Identifying sleeping and feeding habits alongside parental support and educational activities (e.g., calling a friend or relative for help, viewing educational materials on the mobile phone) can provide insight to the parent's primary care provider or OB/GYN about the parent's health. These data have the potential for earlier identification of post-partum depression, problems with breast health, or other physical and mental illnesses directly following the birth of a child, particularly for those who are at risk.

Technical Approach, Feasibility and Viability

In this work, we use a **participatory and user-centered design approach**, in which physicians, nurses, parents, and other caregivers are explicitly included in the design team [3, 8, 24]. The clinicians contribute knowledge about both their own needs and ways to support parents at home and the parents of LBW babies, particularly those who participated in the pilot study, provide feedback on the design process from their lived experiences. These activities, along with the results from our initial pilot study using an early prototype of FitBaby, have enabled us to uncover a series of design



Figure 1: Our original FitBaby prototype, which was piloted early this year in both English and Spanish, allowed caregivers to record simple ODLs through manual input and send those data back to clinicians via the mobile phone network. The new system will automatically collect data from sensors and correlate it to the manual caregiver-entered observations.

<i>Specific ODL</i>	<i>Method of Collection</i>
Weight	Bluetooth-enabled scale
Movement	Crib sensors
Sleeping schedule	Crib Sensors and Self-report
Feeding schedule	Self-report
Baby temperament and responses to exercise intervention	
Caregiver stress and daily attitudes	

considerations for the new version of FitBaby.

During our initial pilot study, which was focused on baby ODLs, we observed the ways in which our choice of the mobile phone platform and simple interface matched parents' needs and context of use. Parents were able to interact with the device with just one hand, leaving the other free to hold the baby or perform other tasks. Also, parents universally reported appreciating the reminders delivered by the phone that encouraged them to record their daily observations to be sent to the clinicians. In fact, the reminders for documenting observations also served to remind them to conduct the health-related behavioral interventions that had been prescribed. Finally, the solution was robust in the face of challenging infrastructure capabilities. For example, occasionally, parents might be out of cell phone range, but the system simply queued up their information until they were in range again.

Using FitBaby, ODL data will be collected by both manual (diary entries completed on the mobile phone, photos and videos of the infants taken using the built-in camera) and automatic means (wireless sensors, including a crib monitor). When possible, we will make use of existing mass-produced products (e.g., scales, mobile phones) or open source toolkits (e.g., the MyExperience toolkit [9] on which we have built the FitBaby application or the Campaignr toolkit [16] from UCLA).

We will use the **third party platform, Microsoft HealthVault**, to store ODLs collected using the FitBaby system. This platform was chosen, because UCI MC already has plans to implement HealthVault in connection with our imminent installation of Sunrise Clinical Manager from Eclipsys. Data collected using the FitBaby application (e.g., from sensors, custom input forms, and so on) will be sent to HealthVault over the mobile phone network (see Appendix D). HealthVault will be configured to accept these inputs using the Microsoft HealthVault SDK. Parents and other caregivers may also

enter information into HealthVault directly using both the Smartphone interface and the web-based interface for standard PCs (see Figure 2). In this way, caregivers may leverage both the interoperable collaborative aspects of our third party platform as well as the custom premature infant dedicated features of the FitBaby system. For example, patients may explicitly message clinicians through the HealthVault connection in the UCI MC's EMR. We will make use of this feature by supporting this sort of messaging through FitBaby into HealthVault and through HealthVault directly.

Our proposed mobile system will support collection of ODLs and the **interpretation of data through the use of guidelines and decision-strategic approaches**. The system will generate *alerts* to both parents and clinicians for a variety of reasons, such as if a log entry has not been completed by a prescribed time. This feature was found to be very useful during the pilot study of FitBaby and improved the frequency of parents completing the logs. The system will reflect the ODL data back to the caregiver through simple *visualizations*. These interfaces will include *glanceable displays* [4] on the mobile phones as well as the ability to “drill down” into the data on a more traditional desktop platform. Reflecting this kind of information back to parents can enable greater feelings of self-efficacy and influence on the health of their babies [19, 20]. The system will include appropriate *educational materials*, focused on preterm infant care that parents can use at home. Families of children with chronic illness often struggle to get the information they need but experience greatly reduced stress and anxiety when they feel engaged and informed [5, 33]. Thus, in this work, we will use the mobile tools not only to collect ODL information but also to help educate caregivers about caring for their infants.

During the first year of this work, we will identify a set of appropriate alerts and visualizations for the system to provide using clinical guidelines and feedback from both caregivers and clinicians. These alerts and visualizations will be provided on both the mobile phone itself and through the HealthVault interface depending on the audience and resources available for the data. There is no single set of guidelines for newborn health. Thus, we will make use of a combination of guidelines from the American Academy of Pediatrics and the Academy of Breastfeeding Medicine. We will use the guidelines as starting points for conversations with caregivers and clinicians in the first year with regards to the appropriate thresholds that should be used for generating

alerts, how various data should be visualized, and so on. Furthermore, we will develop mechanisms by which clinicians can customize the thresholds for alerts, because, as one pediatrician in our preliminary interviews noted, “every [pediatrician] practices a little differently” and some may want to be alerted more or less frequently depending on experience, health of the particular baby, clinical expertise, and schedule.

In addition to the numerous clinical and social challenges of working with the at-risk premature infant population, there are **technical challenges** associated with the capturing of ODL data, storage on HealthVault, and interpretation of ODL data both for the parents and caregivers and for the clinicians. We will address these challenges by leveraging our technical expertise and that of our clinical partners along with our close relationships and collaborations with other research groups. In particular, we will build our solution to meet the technical specifications of the HealthVault instance to be installed at UCI MC using the Microsoft HealthVault SDK and leveraging resources from the Information Services department at UCI MC to connect these systems. Furthermore, we will build upon our own previous development experience across a variety of mobile phone hardware and software platforms and building on open source toolkits such as the MyExperience platform [9] used in our first FitBaby prototype and the Campaignr platform [16] with which we have worked as part of the Community Sensing Initiative in which we are collaborators. Finally, to ensure appropriate interpretation of ODLs for both patients and clinicians, we will make use of clinical guidelines and preferences from clinicians and caregivers as described above.

Integration of ODLs into clinical pediatric practice requires that the data be easy to capture at home as well as to access both at home and in the clinic and be useful and motivating to both the parents and the clinicians. Our approach includes a combination of *automatically* and *manually* collected data that will enable us to record a significant amount of information about infant progress without substantial burden on the families. Certainly, these data in and of themselves are interesting and may even be useful in unfiltered form to parents, caregivers, and clinicians. However, our preliminary findings indicate that a more feasible and useful strategy for incorporating these data into the clinical workflow is to provide *filtering* and *summarization* of data. Thus, we will develop innovative visualizations and reporting to caregivers and clinicians that will

enable both overview and detailed reporting on infant progress and development. In this way, clinicians can proactively and efficiently check on patient data at a distance if there is a particular concern or simply review data quickly prior to an in office or phone consultation to check for any emergent concerns. Typically, clinicians will access data via HealthVault while parents (caregivers) will more likely access data directly on the mobile phone.

Close collaboration with clinicians and information services at UCI MC will help us to **identify and mitigate threats to successful implementation** in clinical practice. During focus groups, interviews, and design sessions in the first year, we will document the real and perceived risks to implementation identified by various stakeholders. Furthermore, we will use the lessons learned from our pilot studies and from the ongoing EMR and PHR implementations at UCI MC to address these concerns rapidly.

The findings from our pilot study demonstrate the **robustness of our technical approach under sub-optimal conditions**. During our pilot study, caregivers (primarily parents and one aunt) were easily able to use FitBaby, keep it charged, and send data to our clinical partners in the NICU. We will ensure that the next generation of the FitBaby system is as robust as the version we deployed in our pilot study in terms of networking, data storage, battery life, and the abuses of day-to-day life.

Network: Our use of the cell phone network ensures that data connectivity will be nearly continuous. During our pilot study, we used the T-Mobile data network, which has 3G coverage nearly everywhere served by UCI MC, and Edge/GPRS service in those areas not served by 3G. Additionally, the FitBaby software tolerates breaks in network service by using a store and forward model for data transmission.

Data storage: The store and forward model used in FitBaby ensures that data are stored on a database local to the device and transmitted over the network. The system can also be configured to allow parents and caregivers to determine the level of sharing they would like to employ. These choices can be made at the site of the data capture (e.g., on the phone) or on the HealthVault instance itself (e.g., by providing or blocking access to all or a subset of data for certain providers or other caregivers).

Battery life: In our pilot study, the phones only needed to be charged every two to three days. We expect similar performance with the new version of FitBaby,

downgraded slightly due to the wireless connection to the sensors. The system provides alerts when the battery should be charged. We will also provide backup batteries to the parents in the event that a battery dies and cannot be recharged. Finally, in the event that the batteries do die, no data are lost. Instead, everything in the FitBaby system is written out to Flash memory to be retrieved when the system is next started.

Everyday use: We are well aware of the challenges that computing devices will encounter in everyday use in the home of a new infant. A significant motivator for choosing mobile phones as the FitBaby platform is their general level of robustness in the face of liquids, drops, and other abuse. Additionally, when possible, we will make use of commodity off-the-shelf products that are similarly robust for everyday use.

In the event that the sensors lose their connection with the mobile phone, it will generate an alert. The disconnect alerts lead users through step-by-step instructions for reconnecting. If any particular sensors cannot be reconnected, users will be instructed to continue to take manual ODLs and use the remaining connected sensors. The generation of alerts also triggers the sending of messages to the clinical IT support staff over the mobile phone network with the details of the disconnect. In the event that the mobile phone itself cannot send any messages, the users will be alerted to this problem and encouraged to phone clinical IT support to address the problem. Furthermore, an alert will be generated on the side of the clinicians any time no data have been received for a set amount of time. Finally, we will work with Information Services to develop a protocol for clinicians and parents to handle any potential problems with the FitBaby and HealthVault systems.

As mobile phones have become more prolific and their capabilities more elaborate and robust, they have also become one of the most *promising platforms for home healthcare*. The recent popularity of “iPhone apps” for health [32, 28]—including one that helps parents track the basics of life with a healthy new baby (TrixieTracker) is just one indicator of this trend. The FDA’s potential interest in classifying mobile phones as medical devices [7] is another potential indicator. Use of mobile phones and email by clinicians in our preliminary studies to “keep patients from having to come in” or “show them visually” some product or symptom that is difficult to describe otherwise is another indicator. By utilizing simple sensors and motivating data recording applications on this

ubiquitous platform and connecting these data to a third party online PHR system, we are able to change clinical practice without requiring substantial hardware investment or the discomfort of bringing unfamiliar systems into the home or clinical setting. Furthermore, we rely on primarily off the shelf hardware and are using and contributing our work back to open source software projects. Thus, the applications we develop as part of this work can easily be further modified, customized, and reproduced to create and distribute robust ODL software for this and other populations.

Throughout this work, we will seek to **identify and illuminate practice and policy challenges** associated with our approach, some of which may only be identified by deploying the system *in situ*. Regular communication with clinicians and other stakeholders through interviews, focus groups, and reports of our findings will serve as forums for discussing these issues. Using similar methods, our preliminary results have helped us already to identify and begin to address some of these challenges.

First, billing and reimbursement for time spent reviewing ODL data is a consistent concern for clinicians. For those using capitated plans in which clinicians are paid monthly for each patient, fewer visits for the same quality care is considered a benefit. However, in a fee for service model, clinicians are typically not reimbursed for telephone visits and by extension, electronic data review. Changes in policies at both private and public insurers would be required for substantial uptake of these systems.

Second, clinicians—in particular nurses—who are negative towards technology use could project that negativity onto the patients and caregivers responsible for using the technology to collect ODLs. In our pilot study, nurses trained parents to use the system at the same time as they were educating them about the assisted exercise intervention for home and other information. Some of the NICU nurses with whom we were working self-described as negative towards information technology, which resulted in some negativity towards FitBaby that we observed during training of the parents. Thus, in this work, we will develop additional training for the NICU nurses to further their own comfort levels and have a member of the study team primarily responsible for training parents to use the system, rather than only the NICU nurses. Furthermore, we will report the results not only from the pilot study but from the evaluations conducted as part of this work to demonstrate the clinical benefits to the nursing teams.

Third, interviews with social workers revealed that transitioning between the NICU and home can be particularly challenging for parents. Currently, the social workers at the NICU stop providing care for the parents at the time of discharge and community-based social workers who specialize in at-risk children may not begin their care of the family for several weeks. Thus, this particularly challenging and risk-laden time can also be a time in which parents are receiving the least support. Changes at the policy level may be required to ease the transition between NICU and community-based social workers, including the hiring of additional staff and the use of ODL data to facilitate communication between these two separate entities that both provide care to the same patients.

Patient and Clinician Engagement

To produce successful user-centered designs, we must engage a variety of stakeholders, including patients and their parents, NICU and pediatric clinicians, and social workers and others from county regional centers, at all stages of development. To this end, we have taken a participatory design approach [3, 8, 24] in which we have included clinicians—nurses, a pediatrician, and an occupational therapist—on our design team. Moving forward, we will invite parents and other professional and non-professional caregivers to participate in design activities. Specifically, in the first year, we will continue interviews with primary caregivers of infants currently in the UCI MC NICU and with parents who were previously enrolled in our pilot study of the FitBaby prototype. We will then invite a subset of those participants to join in one-on-one design sessions with our team as well as group design workshops to be held at UCI, in which a mix of parents, social workers, nurses, physician assistants, and other interested stakeholders will work together with our design team to finalize the features of the next generation of FitBaby. In particular, we will look to these teams to help select the most useful ODLs to include in FitBaby, determine the appropriate visualizations of collected data for the caregivers at home and the clinicians as well as the appropriate privacy and security settings and options to ensure comfortable use of the system and sharing of data.

In the proposed work, **patient incentives** will include a small monetary compensation to the caregivers for participating and use of the system for the length of the study. We will emphasize to caregiver volunteers that their contribution has the

potential to lead to improvements in future clinical care of babies similar to their own. And, we will ensure that the goodwill of participating supplied by the caregivers is treated with respect and empowerment from the researchers [23].

Beyond the research endeavor, this work seeks to provide **incentives** for the involvement of caregivers in the **collection of data for clinical practice**. In essence, any PHR system is a piece of groupware, for which there are well known challenges, including ensuring that those who do the work get the benefit [13]. Specifically, we will provide benefits to the caregivers who must do the data collection in three ways. First, we will provide visualizations of these data to the caregivers on the phones as well as in an online system for those caregivers with access to a PC and standard web browser. In the first year of this work, we will finalize the design of these visualizations, but examples include:

- graphs of baby weight compared to the modified growth charts for premature infants;
- graphs of diaper use and time and frequency of feeding to ensure caregivers that their babies are eating enough; and
- fun, glanceable displays [4] that give caregivers an overall sense of the progress of their child and of their own wellbeing.

Second, we will provide additional educational materials on the phones covering topics like breast feeding, appropriate colors for baby excrement at particular stages of development, and so on. These materials will be provided in both English and Spanish and in both text-based and video-based form to ensure that caregivers can engage with them in the format of their choosing. Interactive quizzes will be built into the educational materials to provide both a fun way to learn and a means for collecting further data on caregiver understanding and wellbeing.

Third, we will use the data collected through the FitBaby system to auto-populate some portions of a well-baby questionnaire that will be included in the UCI MC HealthVault instance. This questionnaire includes items from the Ages and Stages Questionnaire (ASQ)² developmental screening tool, which has a portion to be completed at home before coming to a well-baby visit, and which has recently been

² <http://www.agesandstages.com/>

mandated for use at every pediatric screening in a subset of clinics in our county through an American Academy of Pediatrics grant to Orange County. This auto-completion not only benefits caregivers who now no longer have to complete the forms manually just before a visit, but also ensures more accurate and efficient use of these data, because manually scoring the questionnaires can result in human errors in calculation and take substantial time away from clinical staff [17, 18]. In preparation for a patient visit, we anticipate clinicians may want to access these data, which they will be able to do through HealthVault.

We will employ a variety of strategies for engaging clinical practitioners throughout the design and evaluation processes. First, in year one, we will conduct focus groups with local private practice clinicians, building on early key informant interviews conducted with this same population. These group interviews will enable us to ensure that we are collecting the right ODLs—those that are useful in clinical practice and can reliably be collected at home—and that we are providing appropriate access to these data (e.g., through filters, smart summarizations, and graphical depictions of the data). Second, also in the first year, we will conduct focus groups with social workers and psychologists from UCI MC and from community centers that focus on at-risk children. Again, these group interviews will build on early key informant interviews conducted with this population during the past year. They will enable us to ensure that appropriate data recording and access can be provided through our system to these specialists. Finally, through the support of the Department of Pediatrics at UCI MC, we will conduct seminars with residents and medical students interested in pediatrics to engage them in the use of Health IT and PHR solutions as they move into practice. These sessions will also help us to understand better the concerns of young doctors and the potential barriers to adoption of these solutions in their practices.

In our preliminary work, we identified several factors motivating clinician willingness to use information gleaned from the FitBaby system. First, pediatricians need alerts to help them identify potential problems earlier. Access to ODLs can lead to earlier diagnosis and treatment, which can improve health outcomes. For example, decline in a baby's weight over a few days or pain in the mother for more than a minute at the start of breastfeeding can indicate that a baby is not latching properly or some other

challenge to feeding. An alert about this concern can ensure that action is taken quickly to restore the infant to a regular feeding schedule.

Likewise, certain symptoms in an infant may indicate an emergency situation (e.g., fever) while others are normal (e.g., hiccups). Physicians want and need alerts for emergency situations while they can use data sent to them by parents associated with non-threatening concerns to assure caregivers that hiccups, or other common symptoms, are normal and do not require a doctor's visit. In particular, for low income patients for whom transportation can be challenge and whose care is often paid in capitated plans, preventing an in-office visit can be a huge cost savings to both the provider and the caregivers.

Third, physicians want better screening and monitoring tools. Thus, auto-completion of the ASQ alongside smart summarizations of other FitBaby data within HealthVault can greatly support physicians in quickly and efficiently screening infants for any problems both in person at the well-baby visit and at a distance, when the infants are still at home. Better screening and monitoring can greatly reduce the stress and anxiety experienced by pediatricians, particularly of children at high risk for chronic illnesses. One of the pediatricians we interviewed in our preliminary work commented that being able to view a summary of ODLs for a high-risk baby would provide some "peace of mind."

Finally, as with volunteer research subjects, some comfort with or interest in technology and the notion of technological progress are likely to be motivating to clinicians getting involved in this work. The nationwide push for more HIT, including EMR and PHR, will help drive interest in these types of projects. We will watch for and capitalize on these trends in our recruitment of clinicians. Success by early adopters can then translate into more widespread clinical use over time.

We are confident that our clinical practice partner, UCI MC, can provide access to sufficient numbers of our target population. On average, UCI MC has 1440 deliveries per year with roughly 375 premature infants in the 30 bed NICU each year. UCI MC recently merged with Children's Hospital of Orange County, which admits another 650 babies per year to their 54 bed NICU. In Dr. Cooper's current study of an infant exercise intervention in the UCI NICU, we have observed a 69% enrollment rate for qualified

approached subjects. We will leverage resources from our collaborative study of an infant exercise intervention at home, again led by Dr. Cooper, to ensure that we can recruit from these populations with a similar rate of success.

Throughout this work, we will make use of the resources available to us through our association with the Institute for Clinical and Translational Science (ICTS) at UCI MC, which Dr. Cooper directs. Dr. Stan Bassin, who directs the Community Education Unit of the ICTS, has committed to supporting this effort by helping to develop community outreach workshops and educational seminars surrounding the HealthVault installation at UCI MC. Dr. Ruth Bundy, leader of the Research Operations Office for Translational Science (ROOTS), has committed to supporting this project by helping the project team obtain resources when necessary (*e.g.*, clinical space, biostatistics support, regular regulatory consultations). Finally, we already have a data safety monitoring (DSM) plan and approved IRB protocols in place for the pilot study of our first FitBaby prototype. Through these mechanisms we can provide assurance that there is no increased liability for participating physicians as well as continue to build upon our collaborative and mutually beneficial relationships with community-based clinicians.

Evaluation Design

We will use both **questionnaires** and **ethnographic interviews** to gather data about caregiver and clinician experiences. We will use these data to inform the iterative design of intervention plans and tools as well as to develop a set of theories grounded in these data [29, 30]. By conducting individual interviews with caregivers and healthcare providers at several time points, we will be able to better understand their experiences and learn what the barriers and facilitators are to caregiver use of FitBaby.

Specifically, in the second year of this work, we will evaluate the utility and efficacy of the FitBaby system by examining use of FitBaby during the data collection period and three other broad categories of outcomes: indicators for *improved health of babies*, indicators for *improved wellbeing of parents*, and indicators of *improved clinical care*. For each of these categories, we expect long-term and proximal outcomes. Long-term outcomes include reduced chronic illnesses for babies as they grow, reduced costs to the healthcare system, and improved clinical care due to better information about the patient and reduced burden of care. However, we expect to see these outcomes years

in the future and across the lifetime of the patient. Within the time period of this grant, we will focus on the short-term outcomes described below.

There are some unique challenges to working with premature babies. Because of their fragility at this stage of life, we need to ensure that babies start in and remain in reasonable health and are provided with appropriate clinical oversight for the duration of the study. To meet these challenges, we have designed an evaluation plan that assesses the utility and efficacy of FitBaby while leveraging clinical resources from ongoing studies of premature babies from the UCI MC Neonatal Intensive Care Unit (NICU). Our study design is depicted in Appendix E and described below.

Leveraging ongoing NICU studies. For the past several years, the team at UCI MC NICU, with Dr. Cooper as the PI, has been conducting research to improve the health outcomes of LBW babies. In a clinical trial starting the fall of 2010, caregivers of NICU babies will be taught home-based assisted exercises by trained nurses and will be given the FitBaby system to help log their exercise activities and record ODLs. The full inclusion and exclusion criteria can be found in Appendix A.

In our evaluation plan, the families of babies enrolled into the exercise study (half receiving the exercise intervention and half not receiving it) will all receive the FitBaby system and will be compared with families and babies not enrolled in the exercise study, who do not receive the FitBaby system. **Based on previous experience working with this population, we expect to enroll and retain approximately 40 babies per 12-month period into the FitBaby group.** We will recruit a comparison group of 40 babies who were in the NICU in the same time period as the babies in the FitBaby group. To make this study feasible with limited resources from the current proposal, we will cost-share NICU personnel and study materials with the exercise study.

Use of FitBaby system. We will monitor the use of FitBaby by the rate of completed logs per week (maximum of 7 daily logs per week). We expect to see high rates of completion in the early part of the 4-month evaluation period as parents may be intrigued by the new mobile application, lower rates in the middle part as parental interest may taper off, and higher rates in the last part of the evaluation period as parents begin to understand the benefits of the FitBaby system for their baby's care.

Expected proximal outcomes

- *Improved health of babies.* We will use nurses' observations to compare the health indicators of FitBaby and comparison babies at baseline (discharge from the NICU) and at 4 months after discharge. In particular, we expect that babies whose families used the FitBaby system will show improved health indicators at 4 months after birth compared to babies whose families did not use the FitBaby system. These indicators include the standard anthropometric measures of height, weight, and head circumference, as well as number of urgent doctor's visits and phone calls. The 40 parents in the comparison group will be recruited from families whose babies were in the UCI MC NICU in the same 12-month period but who were not enrolled in the FitBaby group. A nurse educator and research assistant will visit all families at 4 months to take the anthropometric measurements. Additionally, through chart analysis, we expect to find that babies whose parents use the FitBaby system will have fewer urgent clinic visits and phone calls than babies whose parents do not use the FitBaby system.
- *Improved wellbeing of parents.* The FitBaby system is designed to improve the overall wellbeing of parents by providing them important feedback on their LBW baby's health and on the parents' own emotional wellbeing. As such, we will use questionnaires and in-depth interviews to assess parent characteristics and parents' wellbeing at baseline, and parents' wellbeing at 4 months post-discharge. In particular, we expect that parents using the FitBaby system will report reduced parental stress, increased attachment, and improved bonding/feeding to their baby after 4 months, compared to parents who did not use the FitBaby system. Measures include the Beck Depression Inventory, the Beck Anxiety Inventory, the Parental Stress Scale [1] and NCAST-AVENUW Caregiver/Parent Child Interaction Teaching and Feeding Scales [31]. The 40 parents in the comparison group will be recruited from families whose babies were in the UCI MC NICU in the same 12-month period but who were not enrolled in the FitBaby group.

We will also conduct in-depth interviews with each of the parents in the FitBaby condition to better understand their experience of working with the system and how they believe it affected their ability to care for their child.

- *Improved clinical care.* We will administer questionnaires and conduct in-depth interviews to assess changes in clinical care. Through questionnaires administered to

each participating clinician, we expect to find that clinicians will report improved quality of care for babies and quality of interaction with parents using the FitBaby system compared to reports of quality of care for babies and quality of interaction with parents not using FitBaby. We will conduct in-depth interviews with a subset of clinicians to further explore the changes that they experienced in their clinical practice.

Analysis. We will use regression models to test the effect of the FitBaby system on health of babies, wellbeing of parents, and clinical care, as defined above. The primary predictor variable in each of these regression models will be a dummy variable indicating the presence or absence of FitBaby. We will include several control variables that may affect the outcomes but are independent of assignment into FitBaby vs. no FitBaby groups, such as baby size and weight at birth or discharge, parental stress at discharge, parental age, number of children in family, number of other caregivers, match between parents and clinicians on language, and number of years of clinician experience. For babies in the FitBaby group, we will also statistically control for the effect of some babies receiving the exercise intervention in the exercise study.

Credibility of evaluation plan. The FitBaby system is expected to produce long-term outcomes of reduced chronic illnesses for babies as they grow, reduced costs to the healthcare system, and improved clinical care due to better information about the patient and reduced burden of care. These outcomes are likely to happen years in the future and across the lifetime of the patient. There are, however, some proximal outcomes that we expect to see within the time period of this grant. These proximal outcomes are intermediate steps on the road to a lifetime of reduced chronic illness and improved clinical care. The proposed evaluation plan follows babies and parents with the FitBaby system and babies and parents without the FitBaby system for four months after discharge from the NICU. This allows us to compare the stated proximal outcomes across the two groups.

Feasibility of evaluation plan. Based on previous experience working with this population, we expect to be able to enroll and retain approximately 40 babies per 12-month period into the FitBaby group and 40 babies into the comparison group. The UCI MC NICU houses nearly 500 babies each year, 375 of them preterm. From this pool, we believe we can recruit the appropriate number of babies into the proposed study. To

make this study feasible with the resources from the current proposal, we will cost-share NICU personnel and study materials with the exercise study.

Partner Commitment

Our multidisciplinary research team includes a pediatrician, computer scientist, nurse, psychologist, and sociologist. Furthermore, our relationship with UCI MC brings additional clinical and technical partners to the project. The three NICU nurses from the current assisted exercise study along with our study team will recruit potential participants and train them on use of the system as part of their discharge activities. The UCI MC Information Services department provides numerous resources to clinicians and researchers, including research applications hosting space and help desk support for both patients and clinicians. We will work with these individuals and the technical support personnel from the ICTS to ensure that appropriate support is in place for any technical challenges patients, parents, and providers might encounter. Finally, we will recruit pediatricians for involvement in this work through our relationship with the UCIMC Department of Pediatrics and local community clinics.

The UCI MC and the ICTS have both given their support to this proposal. We are attaching letters of commitment from the Chief Information Officer of the UCI MC and from the Chair of the Department of Pediatrics at UCI MC. Although we were limited to these two letters, these individuals represent the institution's commitment to the project both clinically and technically.

Throughout our previous work, we have demonstrated a willingness to resolve clinical, technical, and other challenges, a commitment we will continue in this work. We have made use of the technical skills of our own team—including the PI, hired programmers, and graduate students—to address a number of challenges. In addition to the standard design and development challenges, this work brings the added challenge of potential for technical problems during the field trial. In our pilot study, we set up a variety of mechanisms by which parents and clinicians could communicate problems to the researchers. Few problems arose, and when they did, most could be solved over the phone. However, we still ensured that a technical team member accompanied the nurses on home visits. We will continue that practice in this work,

because not only does it ease the burden on the nurses and parents, but it also yields valuable research insights for the technical members of the team.

Clinically, the biggest challenge to this work is the fragility of the population. Our team has been working with premature infants for nearly a decade as a part of this research project. Additionally, the NICU nurses have several combined decades of experience. We will leverage their experience and our own knowledge to protect the infants and ensure that appropriate information is being shared with clinicians. As an example of our approach, during our studies of infant exercise in the NICU and the pilot home study that used FitBaby, we have been diligent in our screening of babies to determine their eligibility as well as in removing them from the study if they become ill or ineligible at any point. This diligence and care is at the core of our estimate of enrolling only 40 babies in the FitBaby trial of the nearly 400 who will be discharged from the NICU this year. This conservative rate allows us to ensure progress and the meeting of expectations while addressing the real clinical concerns of our patient population.

Finally, UCI MC has a largely lower socio-economic status population, some of whom are not literate and many who do not have English as their first language. In responding to the needs of this population, we have provided and will continue to use both English and Spanish language software and educational materials and present these materials in both text-based and video/audio based formats. Furthermore, part of the motivation for our technical solution is the finding that this population may be more likely to use mobile phones to access the Internet than traditional PCs [15]. Thus, we have been and will continue to be sensitive to and vigilant about any cultural, socio-economic, and language barriers encountered by our patient population.

Commitment to the Program

Our project fits with key themes of the Project HealthDesign program:

Separation of data from applications. We use an architectural model that ensures applications can change without disrupting the underlying data model and data can easily be transferred from system to system separate from any individual applications. Data collected by the FitBaby system is stored on the phone until such a time as it can be transferred (sometimes immediately, sometimes minutes or hours until network connectivity is achieved) to the UCI MC HealthVault instance. The data can then be

accessed through a variety of application interfaces, including custom FitBaby software, HealthVault, and eventually the Sunrise Clinical Manager EMR system at UCI MC connected to HealthVault.

User-centered design. As noted previously, we have a strongly inclusive and participatory approach to our design, development, and deployment processes, ensuring adherence to the principles of user-centered design. We are committed to including a wide variety of stakeholders—clinicians, social workers, parents, and other caregivers—through focus groups, ethnographic interviews, and design sessions.

Integration of ODLs into clinical practice. Given the high risk for premature infants and their parents to develop illness as a result of the added challenges of prematurity, improving clinical care in the first several months of life are essential for lifelong health outcomes. Through our close collaborations with community pediatricians and the UCI MC Department of Pediatrics, we will capitalize on the potential of ODLs to change clinical practice by integrating them into the standard of care for recently discharged premature infants. Demonstration of benefit for this population may open up the possibility of integrating ODLs into clinical pediatric practice for all infants.

Effective use of existing technologies. We are committed to the use of off-the-shelf commodity hardware and open source software toolkits whenever possible. This combination reduces costs for a patient population who have typically already received hundreds of thousands of dollars of care before their first birthday. Furthermore, the robust nature of these technologies reduces our technological risk to developing working solutions, even in the challenging environment of the home of a newborn.

Commitment to working with other grantee teams. We are firmly committed to working with other grantee teams, and in fact, already have established relationships with two other teams applying for funding. Portions of our team are already collaborating with Anind Dey (HCII, CMU) and his team to examine the various issues involved in mobile image-based memory augmentation. For this proposed work, we anticipate learning from and sharing our lessons learned with other grantee teams who are also seeking to monitor adult depression through ODLs.

We look forward to the opportunity to work with the other teams, and in particular, we recognize the importance of sharing our data across grantee teams. We make use

of LiquidPlannner—an online project management system—as well as wikis, list-serves, and shared servers to communicate amongst our various clinical, technical, and research collaborators. We are committed to sharing these resources or to moving our content to Project HealthDesign resources as is appropriate to ensure open design, tool, and data sharing across projects.

Participation in program-wide activities. As part of our commitment to collaborating with other grantees and to the program in general, we are committed to participating in all program-wide activities, including the collaborative design workshops, communications, and evaluation activities. We have budgeted for at least one member of the UCI team and one member of the CDU team to attend every workshop and in many cases more than one from each location. We currently conduct bi-weekly project meetings with published minutes, but we will also expand these activities to include our monthly blog entries to be shared with the program to support communication across the program. Finally, we have budgeted time to include our participation in any and all program evaluation activities and are committed to supporting the project and any quality improvement or policy efforts to emerge from it.