Project HealthDesign
Full Proposal Narrative
Proposal Title: ODLs Via Mobile Platforms for Youth with Obesity and Depression
Organization: San Francisco State University

Executive Summary

Observations of daily living (ODLs) for teens and young adults (youth) who are simultaneously managing obesity and depression are illuminating data to consider for their treatment and health action plans. For this project, ODLs will be collected via mobile phones, sent to a web-based platform that interprets and reports the observations in a digestible format, and delivers them to a hospital electronic health record for use by a care team of health coaches, physicians, and therapists.

The use of smart phones/PDAs as a platform for engaging youth in their care is an innovation that takes advantage of the ubiquity of these devices among this population and allows them to actively participate throughout the day and in any location. It breaks down barriers to care that exist in purely clinic-based interventions. This platform may also yield more frequent, accurate and timely data capture and communication with providers that can improve the overall decision-making among patients and providers.

The project involves the collaboration of San Francisco State University (SF State) as lead applicant, the Family Health Center (FHC) Teen and Young Adult Clinic at San Francisco General Hospital (SFGH)/University of California at San Francisco as clinical partner, and Health Analytic Services/The Carrot.com (The Carrot) as technology partner. The project focuses on youth patients served at this urban public clinic, a population that is primarily low-income and ethnically/racially diverse. The physicians who staff all services at SFGH including FHC are faculty and attendings from UCSF.

Evaluation of the project will focus on the efficacy of reported ODLs as a part of the action plan development for treatment and management of obesity and depression within the health coaching model used in the FHC. It will also assess the usefulness and feasibility of the technology for supporting the patient-care team collaboration.

Refinements have been made since the brief proposal but no major modifications were made.

Vision and Health Impact

Health Impact: Obesity is a serious health condition for teens and young adults –

one that has reached epidemic proportions (Mokdad et al., 1999). Data from the National Health and Nutrition Examination Survey (1976–1980 and 2003–2006) show that the prevalence of obesity has increased for children aged 12–19 years, from 5.0% to 17.6%, and the CDC suggests that obesity disproportionately affects teens in underprivileged populations (CDC, 2009). Obese adolescents are at risk for serious health complications and are more likely to have risk factors associated with cardiovascular disease (such as high blood pressure, high cholesterol, and Type 2 diabetes) than are other adolescents (Freedman, Mei, Srinivasan, Berenson, & Dietz, 2007). Obese children and adolescents are more likely to become obese as adults (Serdula, Ivery, Coates, Freedman, Williamson, & Byers, 1993; Whitaker, Wright, Pepe, Seidel, & Dietz, 1997).

Obesity adversely effects mental health in adolescents and young adults. In a recent study, children who were teased about being overweight were more likely to have poor body image, low self-esteem, and symptoms of depression. The study found that 26 percent of teens who were teased at school and home reported they had considered suicide, and 9 percent had attempted it (Eisenberg, Neumark-Sztainer, Story, 2003). Adolescent depression is also a risk factor for the development and persistence of obesity during adolescence – researchers found that for adolescents, grades 7-12, depressed mood at the time of interviewing predicted obesity 1 year later (Goodman & Whitaker, 2002).

The health of adolescents is a particular concern in the San Francisco Bay Area where only 30% of San Francisco 9th graders achieve all six California FITNESSGRAM standards, which include aerobic activity, body composition, abdominal strength, upper body strength and flexibility. And, among high school students in San Francisco, 19% of females and 29% of males are overweight. Overall, 31% of San Francisco public school high school students consider themselves “slightly or very overweight.” A substantial number of high school students (33% of females and 22% of males) reported feeling “sad or hopeless almost every day for two weeks or more in a row . . . during the past 12 months,” and 13% of San Francisco public high school students report having “seriously considered suicide during the past 12 months.” (Simmons, David, Larson-Fleming & Combs, 2008).

The target population for this project is diverse and will include individuals with low income and education levels, limited access to computers, and possibly unstable housing situations. Participants will be drawn both from current patients at the SFGH FHC and high school students at Downtown Continuation School, an existing partner of the FHC, who are eligible for services at SFGH. The FHC is one of the largest primary care clinics for low-income, Medicaid, and uninsured individuals and families in San Francisco. Ethnically diverse, 40% of patients are Latino/a, 29% Asian, 12% African American, and 15% White; they come from every continent and speak over 30 languages. About 1,000 of the patients are between ages 13 and 24. Other participants will be recruited from Downtown Continuation School in San Francisco, which has an ethnically diverse group of students weighted toward Latino/a (35%) and African American (33%), with over 40% of students on a free lunch program.

Vision: Our vision merges high-tech innovation for capturing ODLs with the collaborative health-coaching model of medical care. The care approach promoted by FHC sees chronic, lifestyle-driven conditions such as obesity as moving away from a directive paradigm (physicians telling patients what to do) and adopting a health-coaching model based on a shared decision-making partnership between the care team and the patient (Bennet, Colman, Perry, Bodenheimer & Chen, 2009). Shared decision-making and coaching requires data gathering from patients. This is time-consuming and because it relies on patient recall at monthly visits may not be accurate. Alternatively, gathering ODLs in near-real-time brings more detailed and accurate information about a patient's condition, which promotes better communication between patient and provider. We envision the use of mobile devices: iPhones and iPodTouches as a complement to computers to collect these ODLs:

- Daily photo food diary – picture of each meal, reasons, alternatives available
- Daily physical activity – couch time vs. active time including social activities and informal exercise, level of intensity
- Daily social networking and outreach – who, in what activities (online and in-person)
- Weekly moods – emotions through pictoral scale, coping mechanism in short text
- Custom ODL-determined based on individual action plan

Other issues such as addictions, risky sexual behavior will be addressed in clinic visits

Change in Clinical Practice and Insights for Clinical Care Team and Patients: This vision helps to address several problems with the status quo medical paradigm. First, it mitigates the short length of time available for patient encounters, usually limited to 15 minutes. This time doesn't allow for comprehensive data collection, exploration of issues, or shared decision-making. By collecting data in advance of a visit, time can be spent in meaningful discussion instead. Second, it enhances the role of youth in their own treatment and action plans. Patients collect their own information at the time activities are occurring via mobile devices in diaries and simple forms. They can view their reports at any time and discuss them at the clinical visit. Third, it enhances the collaboration in the care team by supporting regular (weekly) interdisciplinary team meetings to discuss specific patient situations that need the expertise of physicians, coaches, behavioral health professionals, and others. This strengthens the relationship between care providers and patients by facilitating communication (i.e. each has concrete expectations and strategies), and trust (i.e. the patient sees that the care team is interested in more than just their clinical symptoms).

Health coaching has also been shown to improve disease outcomes, increase self-management behavior and improve quality of life (Vale et al., 2003, Whittemore, D'Eramo Melkus, Sullivan & Grey, 2004, Engel & Lindner, 2006). The health coaching model is relevant to this proposal because youth who are struggling with obesity and depression often lack the confidence and support to follow through with major life changes and activities that help them manage their weight and mental condition. Health coaching helps individuals interpret information about themselves and participate in shared decision making surrounding the action plans that they choose to take. Further, the level of detail that they achieve about their behavior when frequently and accurately recording ODLs helps patients and care teams identify patterns of behavior, suggest clearer paths toward effective management than if the patient were simply recalling information during bi-weekly or monthly visits, and capture the success factors for and barriers to adherence to treatment and action plans. Learning that a particular activity or interaction with a specific person leads to feelings of depression or binge eating is meaningful in the co-development of an action plan as well as compliance with it (Rimmer, Roland & Yamaki, 2007). Use of mobile devices that are available throughout

the day allows for this convenient and frequent data collection.

Youth at high risk for illness associated with obesity and depression require ongoing comprehensive, primary care that starts during adolescence and continues in the same setting into young adulthood. A health-coaching model of primary care such as that used at FHC has provides consistent and uninterrupted care until they reach the age of 25. The coaching is generally conducted over 2-3 sessions held during primary care visits and empowers the patient to manage her own health by providing her the information and tools to do so. The model depends upon the patient setting her own goals, parameters of her health action plan and the coach's intervention (e.g. type of follow up, frequency if more than once between visits). This places the patient in control rather than creating dependency on the care team. The care team will use the ODL reports in conjunction with clinical information such as HbA1c, LDL cholesterol and blood pressure levels to teach the patient to create a targeted behavior-change action plan. ODL reports are a resource both the coach and patient will use to problem-solve barriers for a healthier life. And, they allow the care team to better determine particular risks and needs of the patient. The consumer applications developed in this project will be freely available beyond the project period.Our vision is that information collected from ODLs will help the patient and care team make more meaningful interventions that lead to positive behavior change.

Technical Approach, Feasibility and Viability

Technical Approach and Third Party Platform: We will use principles of user-centered design by engaging the target population throughout the project. We will create a user advisory board of 6-9 youth to participate in technical development, program design, and implementation of the program in each phase as shown in the table below. We will engage the care team in each of the phases shown in Table 1.

Phase	TABLE 1 User-centered Process
Requirements gathering	A focus group of the user advisory board will be convened at the beginning of the program to elicit input into design of the user interface, the types of data being collected, intended uses of the information, and the environmental context in which the patients act. A focus group of the care team will be convened separately to additionally understand clinical practice implications of the design.

Phase	TABLE 1 User-centered Process
Alpha prototype	A focus group of the user advisory board will view the alpha prototype and give input on specifications for mobile application and computer application
Beta version	Usability testing on their smart phones at time/location where users would typically have their phones available. An observer will capture feedback on usability, environmental challenges and barriers. A focus group will help summarize experience of the group.
Launch version	Broaden access beyond user advisory board to rest of target group, an initial online survey, mid-point will be used to collect user feedback. Workflows and ODL reports integrated into the FHC electronic health record will be reviewed by care team.
Evaluation	Final user survey and focus group regarding usability and content conducted online survey will be conducted as part of formal program evaluation.

We will partner with TheCarrot.com, an innovative technology service that offers health- and life-tracking applications for mobile devices and computers, enabling collaboration among consumers and providers. Named the best new web application at the Health 2.0 Conference in San Francisco, the site provides real-time, on-the-go access to all tracker histories, photos and journal entries, and the ability to search for nutritional information and medications. The web site offers some thirty trackers for monitoring clinical signs and symptoms, exercise, women's health, moods, medications, and nutrition.

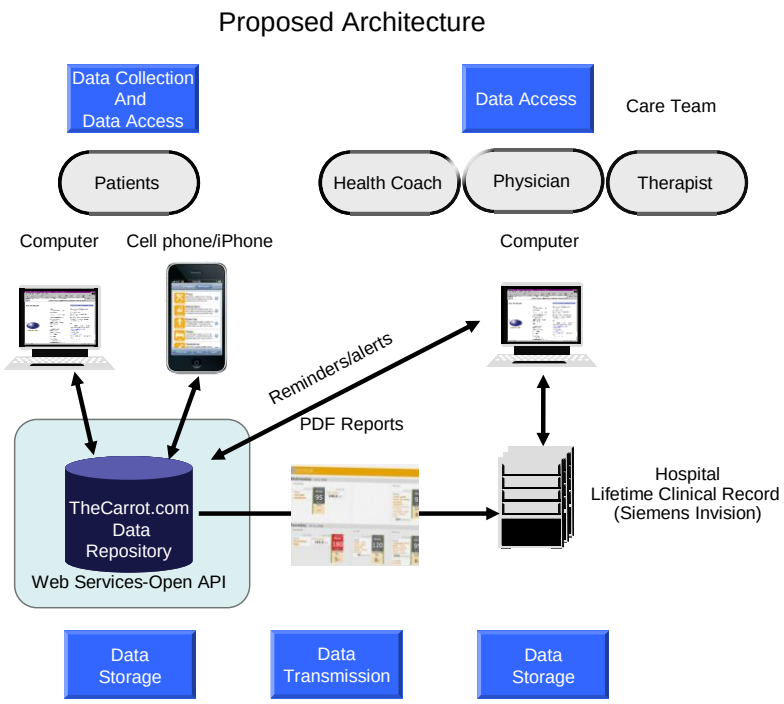
Information can be entered in a variety of formats, depending on user preference. Individuals who track their exercise patterns, for example, can choose to record the date, time, duration, location, distance and/or perceived exertion with or without accompanying photos. People tracking what they eat have instant access to nutritional information on more than 20,000 foods. They can also provide pictures of meals eaten, of food products about which they have questions from their mobile devices.

For this study, we propose to implement TheCarrot.com's health and medical tracking platform, with trackers specific to this project. These trackers will capture a) preconfigured ODLs, b) deliver feedback (e.g., alerts, changes to data requests or treatment plan) directly to patients via mobile phones, and c) integrate the ODL data reports with the hospital's Siemens Lifetime Clinical Record (LCR) system.

The major advantage of using TheCarrot.com's web platform is the entire process is

greatly simplified. TheCarrot.com provides an end to end HIPAA compliant solution from web and mobile device tracking, storage and reporting. Use of The Carrot.com builds on the widespread acceptance and use of mobile devices by youth.

The proposed architecture, as shown in Fig. 1, allows for flexible data capture via iPhone, iPodTouch, and computers that are connected via broadband, WIFI, or cell networks. This approach provides a complete feedback loop between patients and the care team.



Key factors that we believe are unique to this approach include:

1) using mobile/smart phones for data capture to complement or replace the computer, thereby increasing the likelihood that patients will enter the requested data at the appropriate time;
2) using a HIPAA compliant technology as the patient data repository and for developing a conduit to the electronic medical record;
3) reporting daily on whether patients are capturing requested data, allowing the care team to know in near-real-time about which patients are non-compliant;
4) creating a set of standardized reports from patient data, including data provided as free form notes and snapshots;
5) monitoring patient performance on a timely basis, with reports available both on a regularly scheduled and an as-needed basis;
6) delivering patient feedback in the form of reports, action plans, and reminders;
7) integration of reports into Siemens Lifetime Clinical Record.

The potential downside of an approach relying on mobile technology involves:

unavailable internet access, lost or unavailable mobile device, uncharged devices, lost or misplaced passwords which requires sending new passwords to registered e-mail addresses, and individuals unwilling to enter data in presence of peers. In order to mitigate these suboptimal conditions, patients will have access to the same capabilities via a computer for both input and access to their data through an alternative means. The study team will review data input from study participants on a regularly scheduled basis and determine which participants have failed to enter data. Participants can be contacted via e-mail, text message, or phone to obtain the missing information and/or discuss problems with use of their mobile device or computer access.

Another set of concerns relates to data privacy and security. Since we believe that ODL data belongs to the patient we propose the following steps:

1) Patients establish an account with TheCarrot.Com for access to the study portal.
2) The patient signs an agreement with Terms of Use and Privacy Policy that a) acknowledges his/her willingness to participate in the Study; b) agrees to allow TheCarrot.com to release his/her data to FHC for inclusion in their medical record; and c) grants permission to the study team to review reports and data and to contact him/her about the data on an as-needed basis.
3) The patient will be able to review the reporting schedule and receives notification of reports being sent.
4) TheCarrot.com's secure database will be accessible using a username and password, which will remain confidential. TheCarrot.com will send reports to the study team about compliance with data collection--that is, were the data received, were they complete, and were there any queries from the study participants.

Plan for Data Interpretation and Use of ODLs: ODLs will be used in real-time and retrospectively. Upon registration of the patient into the project, the coach will work with their patients to strategize achievable behavior-change goals such as nutrition, physical activity, safe sexual behavior, mental health and medication education. Action plans are specific and doable behavior modifications and can be simple, such as "I will call the smoking cessation hotline tomorrow" or "I will walk around the block two times whenever I feel sad." The goal is to create a feasible plan that the patient feels he/she can succeed at doing and in so doing improve the patient's sense of self-efficacy. The

plan will include the use of the proposed mobile platform for tracking. The ODLs serve as indicators of how those action plans are progressing and will be viewed regularly by the coach. In addition, the coach will be trained to read cumulative trending reports generated from ODLs and discuss these reports with the care team at the weekly case conferences.

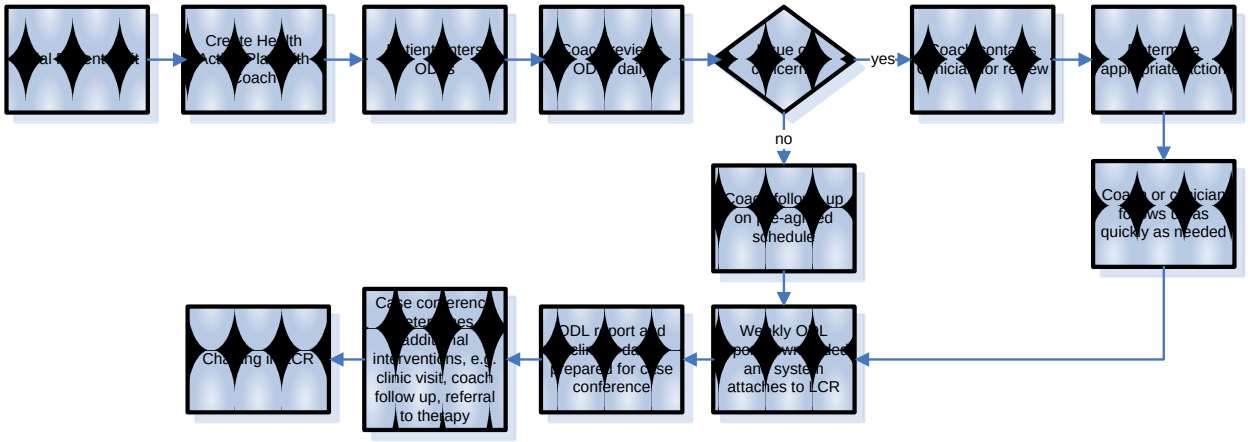
The clinical members of the care team, social worker and physicians, will develop guidelines for identifying medical or mood “red flags” and a protocol for contacting the appropriate member of the care team. For example, the coach will review each patient’s ODLs at least twice per week. However, the coach will review the depression screening tool responses within one business day. She will inform the patient’s primary care physician and the social worker about any positive depression screening results or if mood has varied significantly over the intervening time period. The notification and verification of message received will take place within one business day except if the depression screening suggests any risk of suicide in which case the notification will be done immediately. Another example is physical activity and food intake. The coach will review a cumulative trend report every two weeks and identify significant deviations in progress. She will contact the patient via agreed upon method (email, phone call, text message) within two days to discuss the issue and address challenges. The results of this intervention will be reported at the next weekly case conference. If labs or a clinic visit are indicated at the case conference then the program manager or coach will schedule it. In addition, the coach will gather feedback from the patients on usefulness of the data and relevance of the reporting format for their self-management.

Technical challenges associated with capturing, storing on a third party platform: The key technical challenge is integrating the data from The Carrot with SFGH’s Siemens LCR system since the reports from the Carrot should be a codified part of the medical record. The initial plan is for SFGH IT web development team to receive the pdf reports from The Carrot for storage in a secure server. They will insert url links to patient-specific reports in the patient record in LCR. Additional manipulation of ODL data into computable, standardized elements will be considered in the future when this project grows beyond a pilot. Currently, SFGH is considering a new system and is unable to commit to this type of integration with the LCR. All study data can also be

downloaded directly for population analysis. Most important is integration of ODL data into the clinical workflow of the care team so that it can be effectively used.

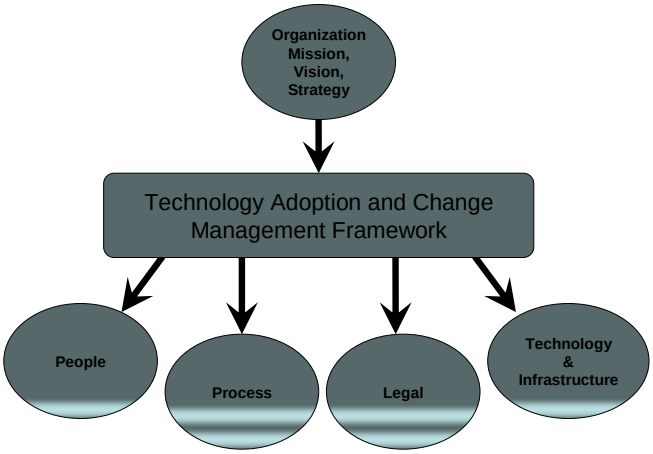
Workflow: The workflow for use of ODLs is developed out of the *"Plan for Data Interpretation and Use of ODLs*" described in p. 8-9. The initial workflow has been developed in consultation with the SFGH project manager, PI and Medical Director and will be refined with the input of the full care team to assure feasibility.

Fig. 2. Workflow



Managing Risks in Clinical Practice: With any system change, risks arise from people's attitudes and behaviors, alterations in workflow processes, introduction of technology, and challenges in the legal/regulatory environment. By identifying these risks and proactively developing strategies to mitigate them, we increase our chances for a successful outcome. We use the technology adoption and change management framework depicted to the left to plan for and address these challenges. First, in order to develop a case for change, it is necessary to understand the organization's mission, vision, and strategy. This is represented by the top circle. With this in mind, we can identify the specific benefits of our program to the organization. The teen clinic is dedicated to providing comprehensive care for teens and young adults and empower them to manage their

Fig. 3 Change Framework



health now and into adulthood. The project fits into this mission by providing an additional venue and communication channel for providers and teens to work collaboratively.

Second, we must be aware of the primary risks to successful implementation from people, process, legal and technology, represented by the four circles below the framework box. It is important to gain buy in from leadership and staff so that they see the benefit of our program as outweighing the status quo, hence be more amenable to making the needed changes for the program to be successful. We will undercover potential resistance during our design focus groups and develop a communication plan and messages targeted at clinicians, administrators, and patients. Similarly, we will map out current and new processes and workflows during the design phase and address potential issues before implementation begins as well as remain vigilant to those that arise during it. Several legal questions have already arisen which will need to be resolved. For example, do the ODLs or certain reports become a legal part of the medical record if that information remains only in the third party platform? Is there an impact on the clinician's malpractice liability if (s)he has access to the ODLs but does not review them in a certain timeframe? What is an appropriate timeframe? We will work with the legal assistance provided through Project HealthDesign to address these questions. There are also risks from new technology and infrastructure. For example, the hospital's network is highly secure. Allowing access via the internet for retrieval of data from the third party platform opens a portal that makes the network less secure. Another risk is that the pdf reports are not compatible with the LCR which is unable to store this format. We have devised an alternate strategy but this may require more work than anticipated today. (See *Technical challenges associated with capturing, storing on a third party platform*, p.9) In order to address these risks, we will include hospital IT staff and TheCarrot technical staff in our preliminary planning meetings. The leadership team for this project will have bi-weekly meetings at which we discuss these risks and assure timely resolution to maximize our potential for success.

Potential for work to lead to clinical practice change or commercialization: This work has great potential to lead to clinical practice change. The lack of timely, frequent, and accurate patient information about their lives outside the clinical visit hampers efforts to

develop realistic action plans or intervene at times when patients are most receptive. The use of mobile platforms to enable the data capture, communication, tracking and reporting is critical to the full realization of the health-coaching model of primary care. This project could lead to adaptation and wider adoption in other clinics and populations who would benefit from greater collaboration with care providers. The evaluation of this project will be critical to understanding its potential for greater impact.

The product used for this project is already available commercially through The Carrot. Disease management companies, employer wellness programs and insurance carriers have shown interest in offering The Carrot consumer applications to their members. The addition of detailed activity trackers from this project enhances their overall product offering to consumers. The company also reports that there are broader opportunities for the product with the addition of provider-focused knowledge gained in this project. For example, understanding provider uses of ODL data and appropriate report formats, clinical workflows, experience with integrating data into hospital electronic health records will help gain adoption with other provider customers.

Practice and Policy Challenges: There are several anticipated practice and policy challenges. This project includes new technology, new data, and a new workflow for the care team. Challenges may arise in managing the scope and quantity of new data available—will the patients be able to keep up with daily recording and will the care team be able to synthesize and respond to needs identified from all those data? Will this more comprehensive tracking of the patient lead to increased or decreased utilization of the clinic and how does that impact outcomes? The evaluation plan will try to answer some of these questions at checkpoints during the project so that the program can be adjusted as we go along, as well as at the end. Another practice challenge is that a number of residents will be rotating through FHC during the project necessitating significant education and training about this project. In order to address this, Dr. Mays will develop training specific to this project to be delivered to each incoming rotation, and she will oversee residents' participation in weekly case conferences. (See *Clinician Engagement* on p.13). A third challenge is the sustainability of this type of effort. Should this approach prove beneficial, will FHC be able to continue funding of health coaches and costs of maintaining subscriptions to the technology? This also raises a

policy challenge: the current reimbursement model does not compensate for care and consultation provided outside the context of clinical visits, except in a few limited cases for telemedicine and e-visits. In addition, consultations for follow up by health coaches are not separately reimbursed. We hypothesize that the efficiency of physicians and nurses in the clinic will be improved by the more frequent intervention by the health coach. And, we expect higher quality of care from the more comprehensive data being collected by the patient. Whether these benefits will yield enough cost savings or increased revenue from increased capacity is unknown.

Patient and Clinician Engagement

Engagement of patients and clinicians in this process is critical to its success, and we have planned for that engagement in a number of ways. *Patient Engagement:* The design of this project is user-centered. Initially, members from the clinical team and from the target population will form an advisory group that will help identify key ODLs that are useful and meaningful for the patient and care team. Our clinical partners have identified the ODLs that they believe will be most useful for collection on the mobile devices, and we will work with that initial list, allowing for expansion or limits as decided by our advisory group, to design the ODL collection and report strategy.

In order to encourage patient participation in the study, we plan to offer a number of incentives. First, we plan to offer a choice of: 1) an iTouch mobile device for use during the study, along with a list of free wireless access points in San Francisco, to participants who do not have access to an iPhone device already, 2) $X to offset the participant's data plan for their existing iPhone or Blackberry paid at monthly intervals, or 3) equivalent incentive for gym membership or exercise clothing or gear for controls. The user advisory board will also receive $X/focus group.

Clinician/Care Team Engagement: The core care team is composed of key personnel in this proposal. In addition, there will be 2nd year residents at the FHC during this pilot. To assure their engagement in the project, they will be trained at the rotation orientation. An expectation will be set that they recruit appropriate patients for participation, review ODL reports and participate in the case conferences regarding their patients. Dr. Mays, who oversees the residents, will be responsible for addressing issues or concerns and removing roadblocks to their participation. Dr. Hammer, as

Medical Director of FHC, will champion the project and provide support and resources to the rest of the care team. Finally, Dr. Bodenheimer and Ms. Ghorob will present the project at two FHC noon conferences, which residents and other clinicians attend. The first one will be at the start of the project and the second three months after launch to review learnings.

Clinicians' interest in, and willingness to use, information gleaned from this project: Since FHC overall is a highly-regarded teaching site for family medicine residents committed to serving vulnerable populations, there is great interest from clinicians – both faculty and residents – in this project. The information from ODL reports will be useful for clinicians who provide care to participants. The clinicians recognize that the typical 15-minute visit is too short for a primary-care clinician to handle all the problems that patients present. This project may allow clinicians more time during a visit to build relationships with patients, manage complex diagnoses, treat acute problems and address patients' agendas.

Clinical Practice Partner: The San Francisco General Hospital Family Health Center (FHC)/UCSF is the largest primary care clinic in the San Francisco Department of Public Health (DPH), caring for almost 10,000 unduplicated patients in over 43,000 outpatient visits per year. The physicians are all UCSF faculty and attendings and staff SFGH through a contract with DPH. FHC patients reflect the rich diversity of San Francisco: 39% Latino, 27% Asian, 17% White, and 13% African-American. Sixty percent speak a primary language other than English. Forty-six percent are insured under Medicaid and 27% are uninsured. Most FHC patients are San Franciscans with incomes below 200% of federal poverty level. As the largest primary clinic in the San Francisco Department of Public Health, the FHC has been a key component of the new Healthy San Francisco program, a city-wide program which provides access to care for uninsured adult residents of the city. Over 5,000 Healthy San Francisco enrollees have chosen the FHC as their Medical home, the largest number served of any other participating clinic. Because all the FHC primary care providers are family practitioners, they are ideally situated to provide continuous care to young adults who are newly enrolled in Healthy San Francisco.

The FHC serves approximately 1000 patients between ages 12 and 25. Three years

ago, it opened the Teen and Young Adult Clinic, which serves these patients in a friendly, confidential, and comfortable environment. Clinic staff and providers who work in the Teen and Young Adult Clinic are trained in adolescent health and have a particular interest in working with this population. A large majority of the teen patients have Medi-Cal, and most of the young adults are enrolled in Healthy San Francisco. Health services at the Teen and Young Adult Clinic focus on those health issues that are most important for young people from ages 12 to 25, including reproductive health and prevention of chronic disease. The clinic is able to address urgent needs as well as provide screening for and prevention of health problems.

*Management of Clinician Issues: (*See additional detail in *Clinician/Care Team Engagement*, p. 13). The residents, health coaches, and program manager are supervised by physicians. Dr. Mays will be supported by Drs. Hammer and Bodenheimer. As senior administrative and medical leaders, they have the influence and resources to address clinician issues that arise.

Evaluation Design

Our evaluation design focuses on the following major questions, which will be addressed differently in each of the two years:

- What are the most effective ways to communicate ODLs from patient to providers?
- How can care providers most effectively use the reports of ODLs in care?
- What impact does the reporting of ODLs have on health outcomes?
- What impact does the reporting of ODLs have on the communication and relationship between the patient and his/her care team?
- What does and does not work well for care team and patients in this program?
- How do cultural or economic constraints affect the capture and reporting of ODLs?
- How can this program operate sustainably once funding for the project has run out?

The first level of evaluation is user feedback, which we capture throughout the first year design process (See *Technical Approach and Third Party Platform, p. 5).* The purpose of this type of evaluation is to inform design and implementation of the program and the participants are the user advisory board and project care team. This feedback is captured during three focus groups (initial, alpha, and beta), which will be audio-taped and transcribed for analysis.

The questions answered during this phase are:

- what do clinicians and patients believe will be useful ODL data to capture?
- what report format will be most useful?
- how can the data collection and review of the reports be made feasible for patients and care team?
- does the platform meet the needs specified; does it work under varied conditions (i.e. computer and mobile device interfaces, reports are available when and where needed, etc.)?

The second level of evaluation is the program evaluation, which occurs in the second year and involves patient participants, a control group of patients, and the care team. We will recruit 50 participants to take part in the study, with a goal of maintaining at least 30 participants. We will also identify 50 members of our target population who will act as a control group. They will participate in a questionnaire tracking and provide permission to review their progress throughout the year (with small incentives such as gym passes or coupons).

Participants will take confidential structured online surveys at three points during the study (beginning, middle and end of the study). These confidential surveys will focus on participants' satisfaction with their health care, their communication and relationships with their health care providers, their feelings about their progress toward their health goals and their comfort level with the technology. The survey will consist of several questions using Likert scales and a small number of open-ended questions. The control group will also be given these surveys. In addition, the participants will attend one concluding focus group (in groups of 15-20). This focus group will target participants' satisfaction with the technology, concerns or problems with the technology, lessons learned and suggestions for improvement.

The care team will also participate in two interviews in the second year of the project: one toward the middle of implementation and one at the end. Because the sustainability of this program is a major goal of ours, we will focus our interview questions on aspects of the program that facilitate care giving and those that impede it. During these interviews, we will ask the health care team to consider issues such as time management, connection and relationship to their patients, accuracy of diagnosis,

and efficacy of the health care plans they develop with patients. We will have care team participants highlight what is working well for them and what is troubling them with their use of the reports.

In order to explore potential health outcomes, we will abstract results from medical records such as progress made in BMI, exercise program commitment, cholesterol levels, and psychological indicators of depression. We will both look at individual patient progress (which incorporates comparison with some of the other usage and satisfaction measurements described above) and as a group compared with the control group for purposes of testing the hypothesis that this type of tracking of ODLs increases patient success with their individual care plans.

The small number of participants that we propose will make it possible to do some in depth analysis of each participant's experience with using The Carrot to record and track certain aspects of their life, and with their consequent interactions with their health care providers. We may also focus on the cultural complexities that our target population experiences. This means that we may be able to obtain some meaningful and rich data that could help to inform future implementations of a program like ours in other hospitals and clinics. A sample size of 50 participants and 50 controls will also allow us to conduct basic statistical comparisons between those groups. While we expect some attrition, it is unlikely that either group would fall below 30 participants. Thus, we plan on working toward both rich, qualitative analysis of participant experience as well as simple statistical comparison to establish efficacy of the overall program.

The program evaluation data we collect from three brief participant/control group surveys, concluding patient focus group, medical records, and clinician interviews yield a variety of data along multiple measurement levels that will allow us to evaluate the themes apparent in patient and clinician use of the program and also to compare the efficacy of the program with a control group.

Analysis of the data will occur in varied ways as well. We will analyze the interview data by identifying key themes that emerge from the interview answers, and using those to explicate overall answers to our questions. Survey data will consist of Likert type and semantic differential questions and we will be able to manipulate those data differently by creating composite measurements of satisfaction, relationship status, and

participation. We will be able to look at the overall descriptives of these measurements and also compare treatment and control categories. The multiple and varied levels of measurement used in this evaluation plan substantially strengthen the credibility of the results we obtain.

Finally, the evaluation plan is feasible, given the participation and time constraints that our participants, clinical partner, and technological partner will have. Two focus groups during each year is a robust, yet not overwhelming level of participation. The brief online questionnaires will likely take participants about 15 minutes each to complete and thus should not pose much of an obstacle. Transcription and analysis of interview and other open-ended data, along with statistical analysis of questionnaire data are both familiar and feasible activities for our evaluation personnel and fit within the time constraints allotted her in our budget.

Qualifications of the Team

The team is a well-qualified, collaborative, transdisciplinary team with the necessary skills, strengths and experience to conduct this project. The table below summarizes areas of expertise and years of experience for each of the team members.

Table 2. Qualifications

	Medicine/ Health	Collaboratives/ Program Mgt	Org Behavior/ Change Mgt	Technology Devt/ Implement	Technology/ Informatics Research	Social Sciences/ Evaluation Research
SFSU						
Kim		20 years	6 years	10 years	3 years	
Sabee						7 years
SFGH/UCSF						
Bodenheimer	40 years	5 years				
Ghorob		4 years				
Mays	3 years					
Hammer	12 years	X				
TheCarrot						
Trauner				20 years		

San Francisco State University: Katherine Kim, MPH/MBA, Principal Investigator: Ms. Kim, Health Equity Institute Professor in Residence of Biology, will lead the overall collaboration and technology development effort for this project. She is also currently program director of the SF State-UCSF Cancer Center Partnership for Cancer Health Disparities. She has spent over 20 years leading teams to innovate and excel in

organizations such as University of California Office of the President, Brown & Toland Medical Group, Brigham & Women's Hospital, Alta Bates Medical Center. Her technology background includes Director of Healthcare Product Strategy at Oracle, CEO of a venture-funded startup (one of only 2% of venture funded startups led by women nationally), and leader of a technology incubator. Her research focuses on innovation and adoption in healthcare technology and service delivery, as well as the role of diversity and leadership. She has led collaborative projects such as creation of an 11-hospital collaborative to improve use of medical devices, a 7-clinic collaborative to research models of specialty care access, and is a co-chair of the State of California Health and Human Services Information Technology Workgroup (400 members) which developed California's statewide IT strategic plan. She has an MPH,MBA from UC Berkeley and BA in Biology from Harvard College.

The Health Equity Institute for Research Practice and Policy (HEI) is an SF State campus-wide effort whose mission is to advance health equity through research, practice, and policy. HEI conducts high-impact research on health disparities and interventions that lead to health equity. And, HEI collaborates with community-based organizations, health departments, foundations, and businesses, to support the effective adoption and adaptation of evidence-based approaches in "real world" settings.

Christina Sabee, PhD: Dr. Sabee will lead the evaluation and assessment of the project. She is an Assistant Professor at San Francisco State University in the Communication Studies department. Her research focuses on power and the strategic nature of interpersonal communication, especially in health care settings on communication between care providers and patients. She has published health related articles in *Health Communication, Journal of Health Communication, Patient Education and Counseling, Southern Communication Journal* and a book chapter on effective communication for genetic counselors with their patients. She has extensive experience in a variety of evaluation methodologies and in both qualitative and quantitative analysis of data as a part of her research and teaching (undergraduate and graduate levels). She earned her PhD from Northwestern University.

UCSF/San Francisco General Hospital Family Health Center: The FHC is a Federally Qualified Health Center which houses many teaching programs and has a

clinician staff of about 75 primary care nurse practitioners, residents, and faculty physicians. It is the primary ambulatory training site for the UCSF/SFGH Family and Community Medicine Residency Program. Residents and faculty provide full-scope family medicine, using a family systems model to treat and prevent illness within the context of a patient's family and community. FHC is also a core clinical site for the UCSF Family Nurse Practitioner program and UCSF medical student teaching programs. Clinical support staff is comprised of civil services employees of the City and County of San Francisco. There are 5 Health Workers, 16 Medical Assistants, 7 Registered Nurses, and 8 clerical workers. The large majority of our staff is bicultural and bilingual. The FHC is part of a network of San Francisco Department of Public Health primary care clinics. It has a steady source of funding for clinical programs with a constant stream of residents and teaching faculty from UCSF. As an academic clinic, the teaching faculty represents a stable and integral part of the clinic functions. Core faculty of the UCSF/SFGH Family and Community Medicine Residency Program provide primary care at the FHC, and most teach in the clinic as well.

Tom Bodenheimer, MD, Co-PI: Dr. Bodenheimer is a general internist who received his medical degree at Harvard and completed his residency at UCSF. He spent 32 years in primary care practice in San Francisco's Mission District – 10 years in community health centers and 22 years in private practice. He is currently Professor of Family and Community Medicine at University of California, San Francisco and a member of the Institute of Medicine. He is co-author of the books *Improving Primary Care: Strategies and Tools for a Better Practice* (McGraw-Hill, 2006), and the health policy text book *Understanding Health Policy*, 5th edition (McGraw-Hill, 2008). He has written numerous health policy articles in the *New England Journal of Medicine, JAMA,* and the *Annals of Internal Medicine*. He has trained over 50 health coaches, led collaboratives in primary care redesign for public health, and has written on health coaching and a new vision for primary care. He is currently running a collaborative aimed at improving primary care in 10 clinics.

Amireh Ghorob, MPH, Project Manager: Ms. Ghorob is the coordinator of Takin'Charge, a program designed to reduce cardiovascular risk factors by providing a medical home and health coaching for teens and young adults at the Family Health

Center's Teen and Young Adult Clinic. She is a former high school teacher and worked with the CDC to create a health tool kit for urban adolescents. Ms. Ghorob will be the project manager and coordinate implementation at the school; recruit participants; train and provide mentorship to the health coach; and facilitate weekly interdisciplinary case review meetings at the FHC.

Aisha Mays, MD, Clinic Attending: Dr. Mays is currently conducting a fellowship in adolescent medicine at the Teen Clinic in FHC. She will supervise the residents who provide medical care to the patients who participate in this project; supervise the health coach; and attend the weekly interdisciplinary case review meetings. Dr. Mays has conducted a major collaborative project at the Alameda Juvenile Justice Center, which brought multiple organizations together to address STDs in the juvenile population.

David J. Guldmann, LCSW: Mr. Guldmann has been a practicing clinical social worker for over 6 years, licensed for 3. With Kaiser Permanente, he worked full time with the child/family/adolescent outpatient psychiatry clinic, and a multi-disciplinary team of psychiatrists, case managers, psychologists, marriage and family therapists and nurses. For over a year now, he has been working at San Francisco General Hospital on a small integrative medicine program with psychiatrists and psychologists, providing brief psychotherapy to patients with chronic disease and psychosocial issues. He will provide counseling services to the patients in this project and attend the weekly interdisciplinary case review meetings.

Hali Hammer, MD, Center Director: Dr. Hammer is Medical Director of the San Francisco General Hospital Family Health Center and Urgent Care Center. She will serve as the the clinical champion and liaison to the hospital's IT department providing resources to project staff and communicating with senior management of the hospital as needed. Working within the rubric of continuous quality improvement, Dr. Hammer has participated in a number of different chronic illness collaboratives, including the California Academic Chronic Care Collaborative, the American Association of Medical Colleges Improving Chronic Illness Education Collaborative, and the California Chronic Care Learning Communities Collaborative.

Health Analytic Services/TheCarrot.com: Douglas Trauner, CEO, Technology Partner: Mr. Trauner is the CEO and a founder of Health Analytic Services, Inc. which

is the creator of TheCarrot.com, a mobile & web consumer life tracking service. He was previously responsible for business development in North and South America for Hewlett Packard's telecom software division. He was Co-founder and CFO of PM Squared, a San Francisco-based health care information technology company acquired by United Healthcare in 1998. In that capacity he developed the business plan, secured funding, managed product development. Before PM Squared, Mr. Trauner was a business analyst for San Francisco Sentry, a San Francisco-based brokerage/venture capital company. Mr. Trauner received his BS in mechanical engineering from University of California, San Diego.

Although we are a new collaborative, we will make an effective team for this project. First, both SF State and UCSF/SFGH share a commitment to the underserved and health equity. We have committed our careers to understanding and addressing the needs of these communities in accessing health services, achieving equity in quality, and improving healthcare infrastructure to serve all residents. Our organizational values are aligned. Second, the team has substantial experience in forming and managing collaboratives in healthcare and bring in-depth understanding of the challenges and promises that collaboration brings. Having experienced the highs and lows of collaborative projects, we are realistic about what can be accomplished working across organizations and disciplines. We will pay attention to the project management and communication details that form the foundation of effective collaboration. Third, we have the necessary breadth and depth of expertise and influence to accomplish the goals of the project. The team has experienced members who represent all the disciplines needed for key aspects of the project as described in the table above. In addition, senior members of the clinical and technical partners, SFGH and The Carrot.com, have dedicated time in the budget and are committed to its success. This assures that attention will be applied by these organizations on behalf of the project. Finally, we are all enthusiastic about this project. We see this as an opportunity to apply an innovative solution to an enduring problem in our health care delivery system, with potential not just for our diverse, underserved community in San Francisco, but for broader impact beyond. This fulfills the passion that drives this committed team.

Multidisciplinary Perspectives in Design: The project team represents a variety of

disciplines as shown in the qualifications of the team section. In order to harness this diversity of perspectives and produce an effective project design, we will use several approaches. Representation at the design table is necessary but not sufficient. It is a first step. The team members assigned to attend the collaborative workshops include SF State PI Kathy Kim, UCSF/SFGH Co-PI Dr. Bodenheimer or Attending Dr. Mays, and UCSF/SFGH Program Manager Amireh Ghorab, representing technical, research, clinical, and program management functions in the team. We will also conduct interviews with the medical team members and residents to obtain their input into design of the technology and the program elements impacted by it. We will build into our regular project management meetings, a standing agenda item to review and refine the design based on the input collected. The project management meetings will include the three attendees to the collaborative workshops, SF State Co-PI Christina Sabee, and The Carrot team members. Finally, at each milestone in the development of the technology, we built in checkpoints to obtain feedback from the care team and patients to assure we have incorporated the variety of constituents who have provided input.

Partner Commitment

The three partners in this project will play roles appropriate to the expertise and resources they bring. SF State has overall responsibility for the management of the collaborative, delivery of project goals and deliverables, and evaluation. SFGH is responsible for recruitment of patients to the project, overseeing the collection of ODLs by patients and review of the data by the care team, and handling of issues related to patients and the care team. SFGH's shows its commitment to this project with an in-kind contribution of 4% of Dr. Bodenheimer's time (1% charged to grant). The Carrot is responsible for development and configuration of the technology based on specifications of the SF State/SFGH design team and for its maintenance and support during the project. The roles of specific individuals on the project team are summarized in the table below. Table 3. Roles and Responsibilities (revised)

Person	Role	Responsibilities
SFSU		
Kim	Project PI (25%)	• Overall direction of project and delivery of project goals • Project management • Lead requirements gathering and design activities • Lead technology adoption and change management activities

		• Lead implementation and evaluation
Sabee	Co-investigator (5%)	• Lead focus groups • Lead mid-point and final evaluation surveys
(2) Grad Students	Research Assts. (50% paid, 50% for academic credit)	• Recruit youth for focus groups and intervention • Data collection and analysis • Assist with development of IRB materials, storyboards, evaluation tools, etc. • Project management support at SFGH and UCSF
SFGH/UCSF		
Bodenheimer	Project Co-PI (1% paid, 4% in kind)	• Co-lead direction of project and delivery of project goals • Champion for project within UCSF/SFGH administration • Resolves any organizational barriers
Ghorab	Program Manager (25% y1, 50% y2)	• Primary liaison within UCSF/SFGH for all project activities • Project management • Manage recruitment of patients • Supervise Health Coach
Mays	Attending, Teen Clinic within FHC (10%)	• Orient and supervise residents providing care • Directs weekly 1-hr care team conference
Guldmann	Psych Social Worker (5% in kind)	• Participates in weekly care team conference • Provides consultations and therapeutic interventions as needed
Hammer	Medical Director, FHC (5%)	• Liaison to hospital IT leadership and oversees assigned clinicians and staff • Medical consultation as needed
TBD	Health Coach (40% six months of y1, 50% all of y2)	• Provide coaching to patients in project (y2) • Review ODLs and checks in with patients at least once every two weeks • Daily communication with care team as needed and present selected reports at weekly care team conferences
TBD Hospital IT	Siemens LCR modifications	• Produce modifications to the LCR to accommodate ODL data and reports and make them accessible to clinicians
TheCarrot		
Trauner		• Delivering technology and implementation • Manage technical resources for development, maintenance and support for project • Resource for hospital IT staff for issues such as integration of data and access to technology.

The willingness of the partners to resolve technical, clinical, and other challenges to the project is evidenced by the senior leaders who are committed to the project. From UCSF/SFGH three senior clinicians are dedicated and budgeted to participate: Dr. Hammer, Medical Director of the Family Health Center, Dr. Mays, Director of the Teen Program, and Dr. Bodenheimer, Director of the Center for Excellence in Primary Care.

The hospital IT leadership has provided a letter of support. From The Carrot, Mr. Doug Trauner, Founder and CEO, will personally oversee this project due to its importance. Letters of support from UCSF/SFGH are included in the attachments.

Commitment to the Program

This project fits directly with key themes of the Project Health Design program. Specifically, we have assembled a team of individuals and organizations that are committed to fostering patient-centered health care, technological innovation in data capture and working with clinicians and patients to foster strong relationships. The technical design highlights separation of data from applications: patients control their own data, which are stored separately, and clinicians have access to ODL reports as they are integrated with the electronic health record. We incorporate user-centered design principles by working with an advisory group of patients and a core care team to determine the most effective technical and program design, then build in multiple evaluations and checkpoints with users during conduct of the program. We have designed initial workflows to ensure the effective integration of ODLs into clinical practice and will pay particular attention to refining and reviewing those workflows during the project. We also recognize the importance of integrating with existing technologies and leverage common platforms like the iPhone/iPod Touch for data collection while providing ODL reports through the hospital's current electronic health record for clinicians.

We look forward to working with other teams to explore how we can leverage our collective resources for improvement of all the projects. In order to foster exchange we will make available our design, project management, change management and other plans. We are committed to participating in program-wide activities. Kathy Kim and other members will attend all collaborative design workshops. Additional resources through in-kind contributions and graduate student credit courses have been budgeted for the team to successfully delivery the project and fully participate in Project HealthDesign. For SF State, total effort for the project duration is 1.2 FTEs (increased grad students to work at SFGH). For SFGH, the effort is 0.70 FTEs in year one and 1.18 FTEs in year two (increased psychiatric social worker time). TheCarrot.com staff will also dedicate time to participate in system evaluation activities.