

***Grant Final Report***

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**Implementation Outcomes of a Health IT Program for  
Vulnerable Diabetes Patients**

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# Structured Abstract

**Purpose:** To examine the fidelity of implementation of SMART Steps so as to better inform tailoring of health IT interventions, particularly those focused on diverse populations and multiple languages.

**Scope:** We conducted a fidelity assessment of implementation of the SMARTSteps Program, a health-IT Automated Telephone Self-Management Support Program (ATSM) among 252 patients with type 2 diabetes in San Francisco, in partnership with a regional Medi-Cal Managed Care Plan, the San Francisco Health Plan (SFHP) between 2009 and 2011.

**Methods:** Fidelity analysis focused on: two areas: health systems integration and moderating factors affecting fidelity of implementation. Health system factors include: population-based data linkage to determine patient eligibility; electronic exchange of health information to deliver the intervention to patients; electronic integration of health information to identify patients requiring a health coach call-back or a call-back for a medication or lab trigger. Moderating factors include: representativeness of participants (reach), quality of intervention delivery in health coach call-backs (responsiveness), and consistency of delivery over time.

**Results:** Fidelity to health systems integration was high. Eligibility data linkages were successful, with 76% of potential participants determined eligible. Most patients (96%) received correctly sequenced ATSM calls and the majority (70%) of calls requiring a call back, received one by a health coach. The participants well-represented the target SFHP population, although there were some differences. There was a high level of variation in call backs by type of patient problem and by study language, which warrants consideration for implementing health IT interventions in diverse populations.

**Key Words:** health IT; diabetes; self-management support; health communication

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# Final Report

## Purpose

We conducted a fidelity assessment of implementation processes for the SMARTSteps Program, an Automated Telephone Self-Management Support Program (ATSM) implemented for patients with type 2 diabetes in San Francisco in partnership with a regional Medi-Cal Managed Care Plan, the San Francisco Health Plan (SFHP). SMARTSteps previously received funding from an R18 from AHRQ (R18HS017261, I Schillinger, D) which serves as the parent grant for this R03. The purpose of the R03-funded research was to examine the fidelity of implementation of SMART Steps so as to better inform tailoring of health IT interventions, particularly those focused on diverse populations and multiple languages.

Areas of focus include: (1) Population-based data linkage to determine SMARTSteps patient eligibility; (2) Electronic exchange of health information to deliver ATSM queries to SMARTSteps-enrolled patients; (3) Electronic integration of health information to identify SMARTSteps patients requiring a health coach call-back for an ATSM trigger; and (4) Electronic integration of SFHP data to identify patients requiring a call-back for a medication or lab trigger.

We also examined potentially moderating factors relevant to the intervention implementation including: representativeness of participants (reach), quality of intervention delivery in health coach call-backs (responsiveness), and consistency of delivery of the intervention over time. The Specific Aims are:

- **Specific Aim 1a:** Estimate the proportion of patients identified as SMARTSteps-eligible who were ineligible, and describe reasons for ineligibility. (Population- based data linkage to form target sample).
- **Specific Aim 1b:** Determine if SMARTSteps patients received ATSM calls with intended frequency (weekly), content (questions/language), and duration (27 weeks). (Fidelity of ATSM call delivery).
- **Specific Aim 1c:** Estimate the frequency with which electronic exchange for out-of-range triggers (from ATSM and SFHP clinical registry/pharmacy claims) resulted in a documented call-back, in a sample of patients stratified by language. (Integration of Electronic Exchange for Care Management).
- **Specific Aim 2a:** Compare SMARTSteps-enrolled to -eligible patients for clinic, age, language, sex, HA1c, insulin use, BP, cholesterol, and prior medication non-adherence. (Representativeness).
- **Specific Aim 2b:** Describe the quality of intervention delivery from health coach call-backs, including frequency of supplemental self-management support, call duration,

adherence to protocols, and creation of patient action plans, for a diverse sample of patient triggers. (Responsiveness)

- **Specific Aim 2c:** Over the course of SMARTSteps implementation, identify differences in average length of call-backs, proportion of call-backs made for triggers, and whether wait-list patients (vs. exposed) had differential ATSM engagement. (Consistency of delivery over time)
- **Specific Aim 3:** Summarize fidelity assessment findings, adaptations and implications for real world ATSM implementation and related health IT interventions into a guide, with SFHP partnership.

## Scope

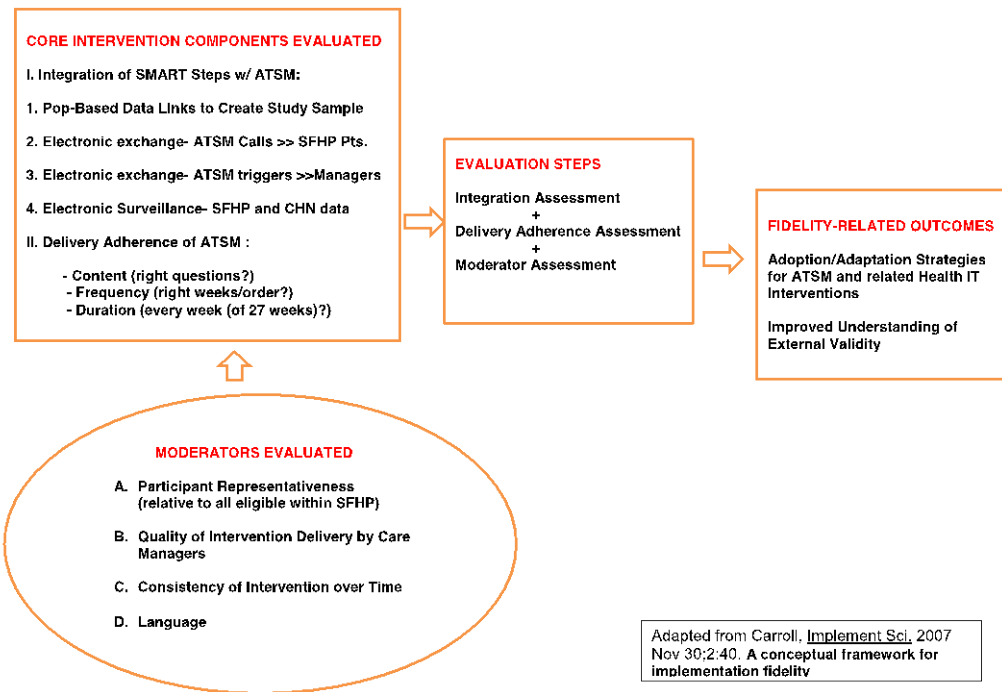
### Background

One of the primary components of implementation research is evaluation of the effectiveness of interventions deployed in real world settings. To examine this in more detail within our Health IT program for patients with diabetes, we conducted a fidelity analysis of SmartSteps implementation using data primarily collected within our parent AHRQ-funded R18 grant. Guided by an implementation fidelity evaluation framework proposed by Carroll et al (2007), we utilized methods for determining intervention *fidelity to core components* while also describing moderating factors affecting implementation. The importance of separating implementation fidelity measurement from the influence of moderating factors is depicted in the adapted version of the Conceptual Framework for Implementation Fidelity of SmartSteps (Figure 1).

### Context and Setting

Patients with limited health literacy and limited English proficiency experience suboptimal diabetes care experiences and health outcomes. We have developed a diabetes automated telephone self-management support (ATSM)/ health coaching intervention and have found it to be efficacious in improving diabetes outcomes, (Schillinger et al 2008, Schillinger et al 2009, Handley et al 2010). With ATSM, patients receive weekly automated calls (<5 min.) at home and respond to the call queries via touch-tone commands. Patients who answer ‘out of range’ on a query, referred to as ‘triggers’ (based on predetermined thresholds, such as reporting high level of depressive symptoms), receive an immediate brief automated health narrative that encourages goal setting (behavioral action plans). Patients with triggers also potentially receive a call-back by a health coach to directly engage patients in setting goals and developing an action plan to improve their overall health, focusing on behaviors related to call triggers. The previous success of the ATSM program led to a new request for its adaptation for implementation by a nonprofit government-sponsored managed care plan, the SFHP.

**Figure 1. Conceptual framework for Smart Steps implementation fidelity assessment**



## SMARTSteps

In the R18 project, SMARTSteps participants were assigned by SFHP through language-stratified randomization to one of four intervention statuses: SMARTSteps-ONLY, SMARTSteps-PLUS, waitlist for SMARTSteps-ONLY, or waitlist for SMARTSteps-PLUS (Ratanawongsa et al, 2012).

**SMARTSteps-ONLY.** this ATSM system was developed to provide 27 weeks of 8-12 minute weekly calls in English, Cantonese, or Spanish at a day and time convenient for participants as described for ATSM above. “Out-of-range” response triggered callback protocols for contacting patients within 3 days by a language-concordant SFHP health coach who provided education. The health coach were also instructed to engage with patients in collaborative goal-setting to form patient-centered action plans if patients were interested in goal setting, a core process for self-management support by which patients set short-term goals to improve their self-management. SFHP used lay health coaches who received basic training in behavior change counseling and supervision by an SFHP registered nurse UCSF physicians assisted with health coach trainings– involving small group discussion and role playing – to practice implementation of written protocols and scripts to respond to potential ATSM call triggers. As part of follow-up to callbacks, SFHP health coaches contacted primary care clinics by email, fax, and phone using standardized templates for patients with pre-specified potential safety concerns (such as a new medical symptom) or access concerns (such as need for refills or appointments).

**SMARTSteps-PLUS.** An additional goal of the SMARTSteps-PLUS intervention was to augment ATSM by enabling health coaches to detect and intervene with participants whose

medication treatment was suboptimal, due to non-adherence or potential need for medication intensification. This arm received the ATSM intervention described above, as well as medication activation and intensification coaching triggered by self-reported non-adherence on ATSM responses, refill non-adherence by pharmacy claims, or suboptimal achievement of cardiometabolic treatment goals. SFHP queried pharmacy claims and clinical registry data (referred to as the i2i diabetes registry/ Lifetime Clinical Record or LCR registry compiled within the CHNSF, the community clinic consortium of safety net clinics in San Francisco) monthly to provide health coaches with a list of participants to be called.

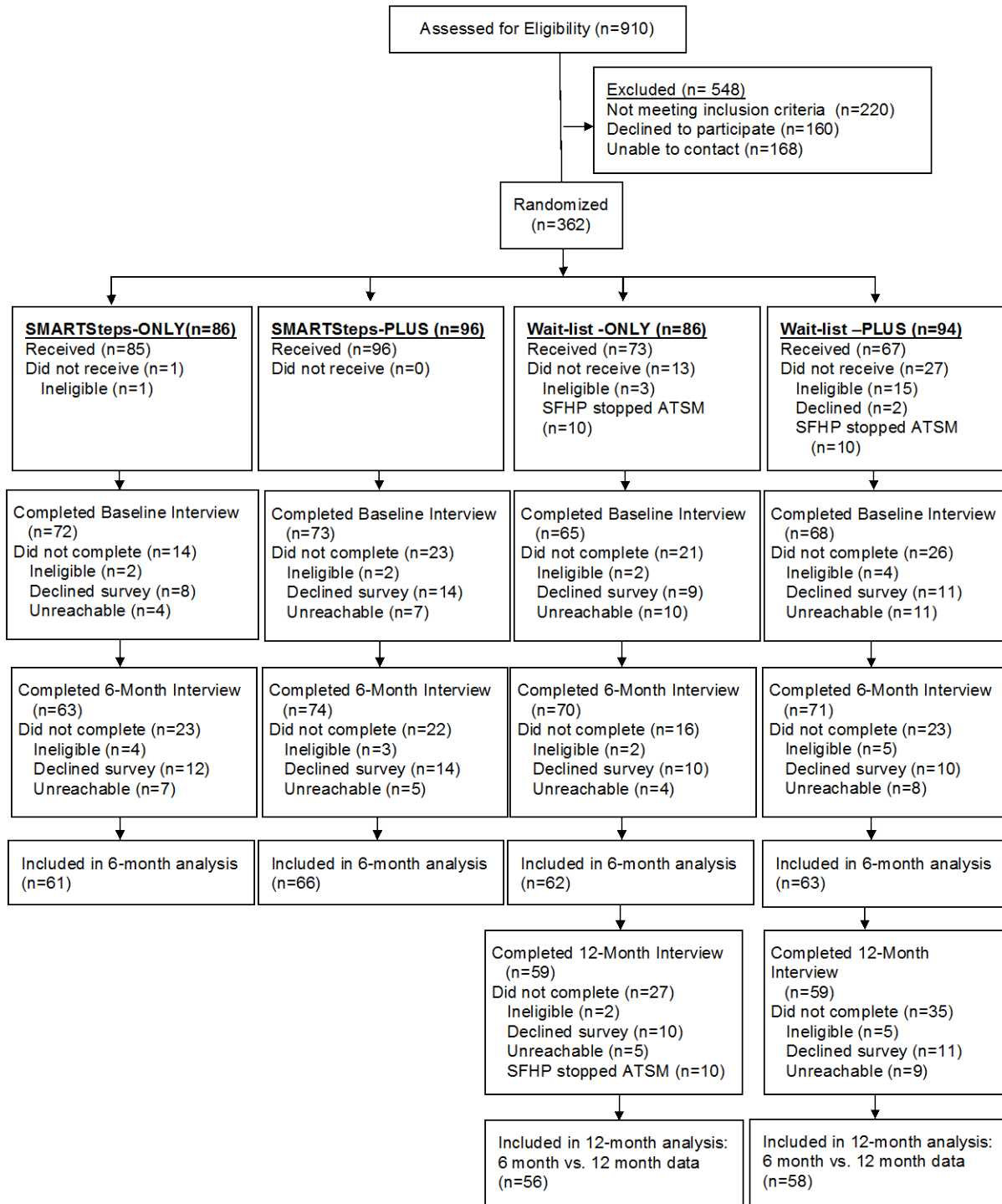
**Waitlist Control.** Those randomized to the waitlist received usual care through their clinics, as well as all existing SFHP benefits (reminders and incentives for receipt of recommended health services, including laboratory testing, eye and foot examination, and influenza vaccination). After the 6-month waitlist period, participants crossed over to begin SMARTSteps-ONLY or SMARTSteps-PLUS, as randomized initially.

SMARTSteps was offered to members with diabetes who spoke English, Spanish, or Cantonese and received care at 4 publicly-funded clinics. Outcomes included 6-month changes in quality of life (SF-12 scores), self-management behaviors, patient-centered processes of care, and cardiometabolic outcomes. Two papers summarizing the design and the details of the current intervention and study arms have been published (Handley, 2011; Ratanawongsa 2012).

## Participants and SMARTSteps Outcomes

Figure 2 depicts the CONSORT flow diagram for SMARTSteps enrollment. Although most of the fidelity analysis concerns the top section of this figure, the participation in follow-up surveys is also included for reference. Among those randomized, 252 participants (70%) completed both a baseline and 6-month follow-up interview. The mean age of participants was 55.7 years, 74% were women, and 84% reported annual incomes  $\leq$ \$30,000. One-quarter (23%) of participants were Latino, 62% Asian, and 8% African-American; 86% were born outside the U.S. Most reported limited English proficiency (69%), with 19% identifying as Spanish-speaking and 55% Cantonese-speaking. The average number of years with diabetes was 7.0, and the mean HbA1c was 7.7%. Among the 151 intervention participants who received all 27 weeks of calls, 85% completed at least one call. Those randomized to immediate intervention completed a median of 20 calls (interquartile range 5-25). Overall results from the SMARTSteps program are described in a separate paper (Ratanawongsa et al, under review). Compared to waitlist, intervention participants had greater 6-month improvements in improved overall diabetes self-care behaviors (ES 0.29,  $p < 0.01$ ) and SF-12 physical scores (standardized effect size [ES] 0.25,  $p = 0.03$ ); changes in other patient-centered and cardiometabolic outcomes did not differ. We were able to evaluate several fidelity measures regarding ATSM within this context of high engagement with the intervention by SFHP enrollees.

**Figure 2. SMARTSteps CONSORT diagram**



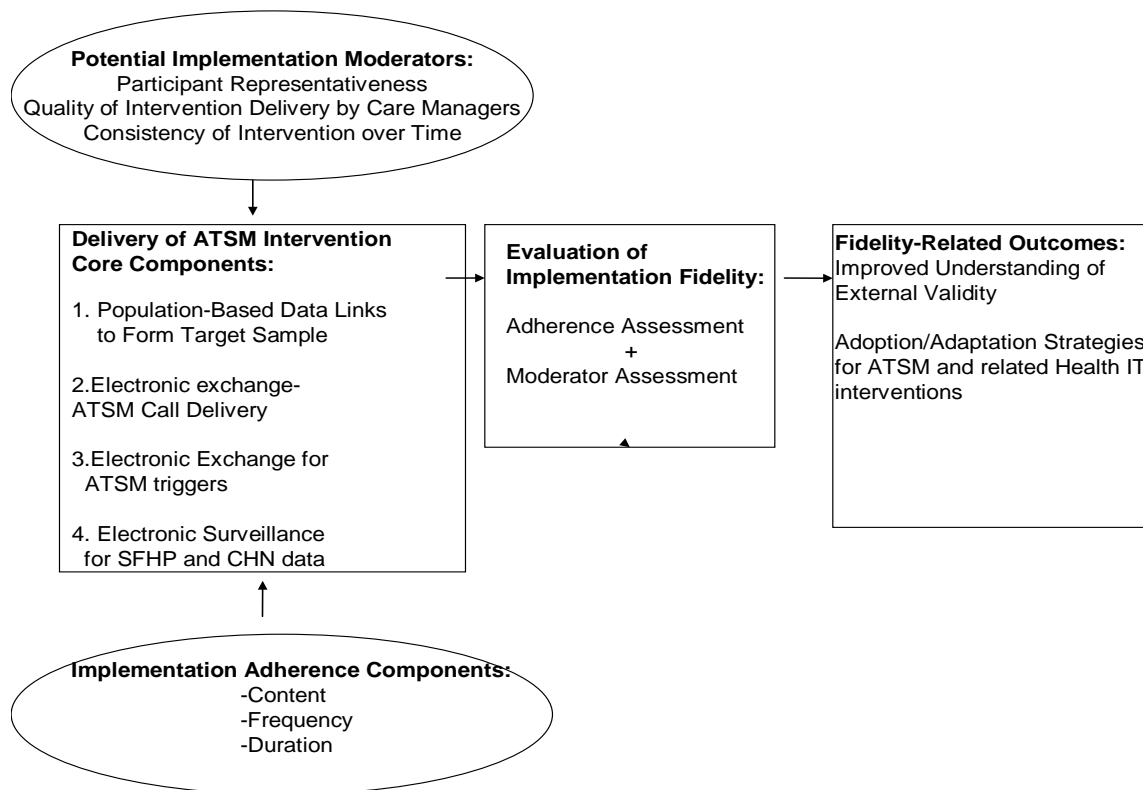
**Note:** Ineligible defined as non-SFHP member, non-diabetic, inappropriate clinic or language, health reason or death (2). Declined survey included declined intervention (1), declined survey, or survey incompleting. Unreachable designated after 15 call attempts.

# Methods

## Study Design

The fidelity study included analysis of existing data collected electronically in the ATSM daily and weekly reports and SFHP SMARTSteps health coaching system. The implementation fidelity evaluation methodology consisted of an adapted version of the Implementation Fidelity Conceptual Framework developed for the evaluation of implementation fidelity for complex interventions, such as SMARTSteps (Figure 3).

Figure 3. Conceptual framework for evaluating implementation fidelity for SMARTSteps



## Measures

In the conceptual framework depicted in Figure 3, there are *Core Components* of the SMARTSteps intervention delivery that are impacted by *implementation adherence factors* (e.g. ATSM call content, call frequency, care managers call-backs for triggers), and also by *potential moderating factors* (e.g. participant representativeness characteristics); and consistency over time of delivery of the core components.



**Measures for Core Components.** The core components of the SMARTSteps intervention delivery were identified to be in the areas of: (1) Integration of ATSM and SmartSteps and (2) Delivery Adherence of ATSM calls to patients. The measures for each of these are summarized in the following Tables 1 and 2.

**Table 1. Measures related to integration of ATSM and SMARTSteps**

| <b>Core Component</b>   | <b>Data Source</b>   | <b>Aim/Measure Used</b>   |
|---|--|---|
| I. Integration- of SMART Steps w/ATSM.  | SFHP active members database, i2i diabetes registry. Mismatches were manually examined using a third source of data, the CHNSF Lifetime Clinical Record (LCR).   | Specific Aim 1a: Estimate the proportion of patients identified as SMARTSteps-eligible who were ineligible, and describe reasons for ineligibility.   |
| II. Electronic exchange- SFHP data plus ATSM system data, such that enrolled patients received programmed ATSM calls. | ATSM reports for enrolled patients.  | Specific Aim 1b. Estimate proportion of enrolled SMARTSteps patients who received ATSM calls with intended frequency (weekly), content (questions/language), and duration (27 weeks).             |
| III. Electronic exchange- ATSM triggers >>SFHP-ATSM health coaching database for care Management.                     | WACAY database (created for SMARTSteps health coaches to record call data), linking SFHP member data, ATSM data, pharmacy claims data, and LCR-derived lab data. | Specific Aim 1c Estimate the frequency with which electronic exchange for out-of-range triggers resulted in a documented call-back, in a sample of patients stratified by language.               |
| IV. Electronic surveillance of SFHP and CHN data on patients to keep patient characteristics up to date.              | WACAY database.  | How often was the WACAY database updated from the following sources?: Pharmacy claims, SFHP members, LCR patient labs and demographics and was data integrated for SMARTSteps PLUS patient calls? |

**Table 2. Measures related to delivery adherence of ATSM**

|   | <b>Data Source</b> | <b>Aim/Measure Used</b>   |
|---|--------------------|---|
| ATSM content (did patients get the correct calls and questions?).   | ATSM reports       | Aim 1b: Proportion of patients receiving correct calls, based on matching weekly call templates (number of Qs, skip patterns) with ATSM weekly reports on patients and also on individual patient-generated ATSM reports. |
| Frequency of calls (did patients get the correct number of calls over the intervention period?).          | ATSM reports       | Aim 1b: Proportion of patients who received consecutive weeks of calls based on templates and dates of calls.   |
| Call duration (did patients receive the correct sequence of weeks over the 24 week intervention period?). | ATSM reports       | Aim 1b: Proportion of patients who received correct sequence of weeks of calls based on templates and dates of calls.   |

**Measures for Moderating Factors.** Potentially moderating factors of implementation that were measured included participant representativeness, responsiveness, and quality of delivery of intervention components by health coaches. The project also included key informant interviews with Smart Steps staff to provide context for the results and to guide recommendations for similar programs.

**Table 3. Measures related to moderating factors**

| <b>Moderating Component</b>   | <b>Data Source</b>     | <b>Aim/Measure</b>   |
|---|------------------------|--|
| A. Representativeness of enrolled in SMARTSteps.                                | WACAY data.            | Specific Aim 2a: Proportions and means for SMARTSteps-enrolled to -eligible patients for demographics and measures of cardio-metabolic control   |
| B. Responsiveness of health coaches to SmartSteps patients.                     | WACAY data, ATSM data. | Specific Aim 2b: Descriptive statistics for call duration, adherence to call back protocols, and creation of patient action plans among patients with first time trigger of an urgent trigger topic*.                                      |
| C. Consistency of delivery of ATSM calls and health coach call backs over time. | WACAY data, ATSM data. | Specific Aim 2c: Estimate differences in average length of call-backs, proportion of call-backs made for triggers, and whether wait-list patients (vs. not) had differential ATSM engagement.  |
| D. Consistency of delivery of ATSM calls and call backs by language.            | WACAY data, ATSM data. | Specific Aim 2c: Did SMARTSteps implementation, identify differences in engagement with ATSM or for the average length of health coach call-backs, proportion of call-backs made for triggers for English, Spanish and Cantonese patients. |

\*Urgent first triggers defined as the first time a patient triggered for any of the following: Low blood sugar (<50), high blood sugar (>300), not taking diabetes medications (3 or more days), not taking insulin (3 or more days), not taking blood pressure medications (3 or more days), reported a foot problem (sores, peeling or cracking skin, or not checking feet), feeling sad or blue most of the time or always in the last 7 days. We focused on the first urgent trigger as an indicator of coaching call back fidelity as these call-backs were categorized by the health coach protocol as high priority calls, requiring callback within 3 days.

## Results

### Fidelity Results Related to Electronic Exchange of Data in Smart Steps

Table 4 provides a summary of key findings for Specific Aim1 which focuses on the electronic exchange of data, organized by fidelity question asked. Discussion of the expanded Results for this Aim follows the table.

**Table 4. Key findings for electronic exchange related measures – Specific Aim 1**

| <b>Core Component</b>  | <b>Health IT Area/Specific Aim</b>                            | <b>Fidelity Question</b>   | <b>Results</b>   |
|--|---|--|--|
| I. Integration of SMART Steps w/ ATSM  | Population- based data linkage to form target sample.         | Does linking health plan members with clinic-based registries correctly identify linguistically diverse patient with diabetes who would benefit from health plan initiated health IT intervention? | Of the 910 patients initially identified as eligible, 220 did not meet eligibility requirements (24%). Differences between enrolled and non-enrolled participants for patient characteristics are in the Table below (Table 2, Ratanawongsa et al 2012)<br><br><b>Conclusion: Eligibility data linkages were successful.</b>   |
| II. Electronic exchange- SFHP pts. data>>ATSM system   | Fidelity of ATSM call delivery over 27 weeks of intervention. | Fidelity Q: Can a health plan member database be integrated with an automated ATSM system to activate ATSM calls to enrolled patients (at time of enrolment, and for preferred day/time/language)? | There were 362 participants: All were uploaded, activated and received calls from the ATSM system. 13 patients (3.6%) had a week of calls delivered outside of the protocol.<br><br><b>Conclusion: There was a high level of ATSM call delivery/integration in SFHP data systems.</b>  |
| III. Electronic exchange- ATSM triggers >>SFHP- ATSM health coaching database for care management        | Fidelity of WACAY integration with ATSM data                  | Fidelity Q: Can automated ATSM calls be integrated into a health plan member database so as to have patient trigger data responded to by health coaches?   | Of the 298 patients completing one or more ATSM calls, 221 had at least 1 ATSM trigger that would generate a coaching call-back. Of these patients, 212 had at least one coaching call back (96.0%).<br><br>This represented 1,980 coaching call backs with records in the WACAY database, including 1,403 with a person contact described (70%), and 577 (30%) with a note indicating that either:(a). no contact was made, or (b) a message was left or (c) an action was made on behalf of patient (e.g. referral).<br><br><b>Conclusion: SFHP WACAY data integrated ATSM call triggers. SFHP care managers generated coaching callbacks for the vast majority of patients and triggers. But there was some variation by language (see text).</b> |
| IV. Electronic surveillance of SFHP and CHN data on patients to keep patient characteristics up to date. |   |  | Data was uploaded monthly into WACAY, but did take considerable time for organizing the data from all the sources prior to uploading.<br><br><b>Conclusion: Regular updates were routinized, but were time-consuming to verify.</b>  |

## **Additional Results: Aim 1**

### **Adherence to the ATSM Call Delivery and Variation by Language and Study Period.**

Adherence to the ATSM call delivery uploads for patients was very high (96.4%). For the 13 patients with an error, 5 patients received 26/27 weeks; 5 received an extra week (28 weeks). These were duration errors. 3 patients had a skipped week, with blank data in the report (this was considered a frequency error). No other irregularities in the calls were noted. Of the 13 patients with irregularities, there were no noticeable differences by language (7 errors were for English speaking patient, and 3 each were among Spanish and Cantonese-speaking patients). There were also no differences by study arm: 7 were in PLUS, 1 in SmartStepsONLY, 2 in WAIT LIST PLUS, and 3 in WAIT LIST ONLY.

**Adherence to ATSM Integration into Database and Triggered Data Call Backs by Language.** Of the 1,980 total ATSM triggers, 1973 had information on language. Of these triggers, 1264 (64.1%) were among 155 Cantonese speaking patients, 433 were among the 85 English speakers (22.0%), and 276 (14.0%) were among the 53 Spanish speakers who completed at least 1 ATSM call. The proportion of triggers with a documented call-back by health coaches were similar for English and Spanish speakers (65.1% and 64.5%) respectively, but higher among Cantonese speaking patients, with 74.5% of triggers resulting in a health coach call back. There were more total call backs per patient among the Cantonese speakers, with 9.4 triggers per patient receiving a call back (1264 triggers/135 Cantonese patients with call backs), compared with 6.0 per patient for Spanish speakers (276 triggers/46 Spanish patients with call backs), and 6.8 per patient for English speakers (433 triggers/64 English patients with call backs).

## **Summary of Findings and Discussion: Aim 1 Results**

- The fidelity of implementation of core components related to electronic exchange was very high across most of the data systems included in SMARTSteps.

The integration of data systems allowed for diverse patients to be enrolled in SMARTSteps and to receive the ATSM intervention components that relied on electronic integration of data systems or exchange of data, with few discrepancies by language or study arm.

- There were some differences by language related to health coach call back frequencies.

These could be related to both patient factors (potential ease/difficulty in reaching some patients vs. others) as well as factors related to health coach staffing and ability to follow up on large volume of triggers on a consistent basis. These are discussed more under Aim 2.

## **Results Describing Moderating Factors (Aim 2)**

**Representativeness.** Table 5 provides a comparison of SMARTSteps-enrolled to those patients that either declined or were not contacted for demographic (age, language, sex, race/ethnicity, insurance class) and cardiometabolic indicators (HAlc, blood pressure, and low

density lipoprotein). Compared with the members who declined, SMARTSteps participants were younger; more likely to be women, Hispanic /Latino, and non-English-speaking; and less likely to be white/Caucasian. Compared with non-contacted members, SMARTSteps participants had lower LDL values and were more likely to be non-English speaking and to have Healthy Workers insurance.

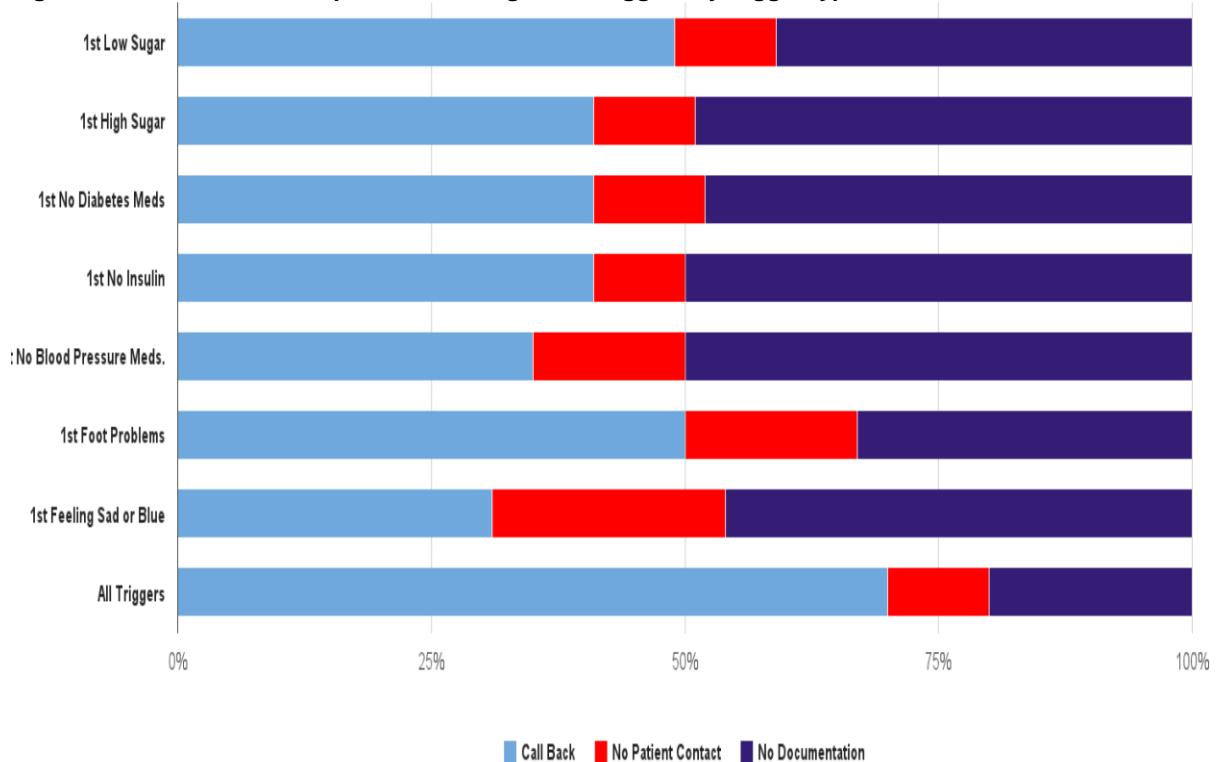
Three-quarters of the target sample met eligibility criteria for SmartSteps enrollment. Among 910 persons initially assessed for eligibility, 220 (24%) did not meet inclusion criteria. Thirty-eight percent of these exclusions were for discontinuous SFHP membership (n=84), 31% for not having type 2 diabetes (n=69), 21% for non-study clinic (n=49), and 9% for non-study language or other reasons (n=18). 168 of the 910 (18%) could not be contacted, and 160 (18%) declined to participate. Compared with the members who declined, SMARTSteps participants were younger; more likely to be women, Hispanic / Latino, and non-English-speaking; and less likely to be white/Caucasian. Below is a description of the SmartSteps enrolled versus declined and not contacted patients from our recent publication of the SmartSteps trial design (Ratanawongsa et al, 2012).

**Table 5. Baseline characteristics in a quasi-experimental evaluation trial of a language-concordant automated telephone diabetes self-management health plan intervention**

| Characteristic                          | Enrolled (N=362) | Declined (N=160) | p-value* | Non-Contacted (N=168) | p-value* |
|---|------------------|------------------|----------|-----------------------|----------|
| Age in years, mean +/- SD               | 54.8 (8.4)       | 56.2 (9.2)       | 0.03     | 54.5 (10.9)           | 0.93     |
| Female, n (%)                           | 258 (71.3)       | 98 (61.3)        | 0.02     | 111 (66.1)            | 0.23     |
| Race/ethnicity, n (%)                   |                  |                  | <0.01†   |                       | 0.10†    |
| Asian                                   | 212 (58.6)       | 97 (60.6)        |          | 84 (50.0)             |          |
| Black / African-American                | 25 (6.9)         | 9 (5.6)          |          | 18 (10.7)             |          |
| White / Caucasian                       | 34 (9.4)         | 31 (19.4)        |          | 20 (11.9)             |          |
| Latino / Hispanic                       | 81 (22.4)        | 16 (10.0)        |          | 38 (22.6)             |          |
| Native American / Eskimo                | 1 (0.3)          | 0 (0.0)          |          | 2 (1.2)               |          |
| Hawaiian / Pacific Islander             | 3 (0.8)          | 0 (0.0)          |          | 0 (0.0)               |          |
| Other                                   | 5 (1.4)          | 6 (3.8)          |          | 5 (3.0)               |          |
| Unknown                                 | 1 (0.3)          | 1 (0.6)          |          | 1 (0.6)               |          |
| Language, n (%)                         |                  |                  | <0.01    |                       | <0.01    |
| English                                 | 121 (33.4)       | 81 (50.6)        |          | 95 (56.5)             |          |
| Spanish                                 | 61 (16.9)        | 6 (3.8)          |          | 22 (13.1)             |          |
| Cantonese                               | 180 (49.7)       | 73 (45.6)        |          | 51 (30.4)             |          |
| Financial Class – Insurance Type, n (%) |                  |                  | 0.83‡    |                       | 0.04‡    |
| Healthy Worker                          | 255 (70.6)       | 112 (70.0)       |          | 95 (56.5)             |          |
| Medicaid                                | 82 (22.7)        | 35 (21.9)        |          | 53 (31.6)             |          |
| Medicare                                | 16 (4.4)         | 9 (5.6)          |          | 10 (6.0)              |          |
| Healthy San Francisco                   | 5 (1.4)          | 2 (1.3)          |          | 6 (3.6)               |          |
| Uninsured                               | 3 (0.8)          | 1 (0.6)          |          | 3 (1.8)               |          |
| Commercial                              | 0 (0.0)          | 1 (0.6)          |          | 1 (0.6)               |          |
| Healthy Kids                            | 1 (0.3)          | 0 (0.0)          |          | 0 (0.0)               |          |
| Cardiometabolic Indicators, mean +/- SD |                  |                  |          |                       |          |
| Hemoglobin A1c                          | 7.7 (1.6)        | 7.6 (1.5)        | 0.09     | 7.9 (1.9)             | 0.82     |
| Systolic blood pressure                 | 128.6 (17.6)     | 128.8 (16.7)     | 0.80     | 131.6 (19.2)          | 0.38     |
| Diastolic blood pressure                | 74.7 (11.2)      | 75.2 (11.0)      | 0.48     | 75.6 (10.2)           | 0.31     |
| Low-density lipoprotein                 | 95.0 (30.6)      | 95.0 (34.3)      | 0.99     | 105.2 (34.0)          | <0.01    |

**Responsiveness of Health Coaches to SmartSteps Patients.** The percentages of health coach call-backs to patients for the seven first urgent trigger topics we selected were lower than the overall call back percentage across all triggers (70%, 1403/1980), ranging from 30.8% of patients with first trigger for feeling sad or blue most of the time, to 50.0% among patients reporting foot problems. Similar percentages were identified for patients with medication-related call-backs and low or high blood sugar values. These percentages are shown below in Figure 4.

**Figure 4. Percent of follow-up for self-management triggers by trigger type**



The medium dark bars (middle of stacked bar) indicate patients who could not be reached or contacted by the health coaches for the first urgent trigger, the light bars (left side of stacked bar) are the contacted patients, and the dark (right side of stacked bar) are the triggers for which there is no documentation of a care manager call back/contact for the trigger. For reference, the bottom bar is for all triggers combined, not just first urgent triggers.

For SMARTSteps patients who did receive call-backs for these seven urgent trigger topics, the mean number of minutes for the calls indicated that health coaches spent an average of about 9 minutes on the phone with patients covering the trigger. There were no differences in the number of minutes across these trigger sub-groups. Also, the call-backs turnaround time for these urgent triggers was around 3-4 days, with little variation by type of urgent trigger, which was consistent with the SMARTSteps protocols. Most (>76%) of these call-backs had documentation that appropriate trigger-specific education was provided on the call. For low blood sugar triggers, 80% had documentation that education was provided. The top topics of education noted in the database were: glucose monitoring education provided (48.6% of these calls), hypoglycemia symptoms discussed (12.9% of calls), and medication review (47.1%).

Similarly, these same topics were reviewed in the calls for patients with high sugar triggers. Most of these 76.1% received education as noted in the WACAY database, with 45.7% receiving education for glucose monitoring, 23.9% for hyperglycemia symptoms, and 50% for review of medications. For patients reporting not taking their medications (diabetes, insulin, blood pressure), similarly, the mean duration of calls was between 7.8 and 9.1 minutes and the number of days to receive a call back was between 3 and 4 days. Topics on the call covered medication review, glucose monitoring, and symptoms of hypo and hyperglycemia. Patients triggering for foot problems had similar values for duration of calls and days to receive call back, with 100% of call database notes indicating that foot problems were discussed. For patients with depression-related triggers, 100% of call database notes indicated that depression was discussed. We also examined the Action Plans created among patients with urgent triggers and our results suggest that about one-third of the call backs for these first urgent triggers resulted in an Action Plan, ranging from 14% for patients not taking blood pressure medications to 44% for patients not taking insulin as prescribed.

In a separate analysis of SMARTSteps patients who were in the PLUS arm and intended to receive call backs for medication review and possible medication intensification discussions (n=303), 68% got a call-back from health coaches, with a higher proportion among Spanish (80.0%) and Cantonese-speaking patients (79.5%) than for English speaking patients (42.4%). The average length of these calls was 5.6 minutes, ranging from 3.3 minutes for Spanish calls and 6.3 and 6.1 minutes for English and Cantonese calls respectively.

**Consistency of Delivery of Call Backs across Study Languages and Treatment Arm for First Urgent Trigger.** The review of consistency across the three study languages and for treatment arm for first urgent triggers focused on the following 4 trigger topics which covered some of the topics with lower call-back percentages in the Figure 4 above (first blood pressure medication trigger, n=35 total first triggers with call back data, and first feeling sad or blue trigger, n=26 total first triggers with call back data). Additionally, two urgent triggers with larger total volume of triggers were selected to examine language differences, including first foot problems (n=88 with data on first trigger) and first low sugar (n=144 with data on first triggers). Table 6 summarizes the percent of these calls by language that had a coaching call back the mean number of days for the call-back and the number of minutes reported in the WACAY database. Table 7 summarizes these same trigger data for treatment arm.

**Table 6. Health coach call-back details for urgent first triggers by language**

|   | Overall       | English         | Spanish         | Cantonese       |
|---|---------------|-----------------|-----------------|-----------------|
| <b>First not taking BP medication trigger</b> | N=35 triggers | N=11            | N=8             | N=16            |
| Engaged through call back                     | 36.4%         | 36.4% call back | 50.0% call back | 37.5% call back |
| Duration of call                              | 7.4 minutes   | 6.3 minutes     | 3.5 minutes     | 10.8 minutes    |
| Days elapsed before call back                 | 3.7 days      | 3.3 days        | 3.3 days        | 4.3 days        |
| <b>First sad or blue most of the time</b>     | N=26 triggers | N=12            | N=5             | N=9             |
| Engaged through call back                     | 42.3%         | 33.3% call back | 20.0% call back | 11.1% call back |
| Duration of call                              | 10.6 minutes  | 7.7 minutes     | missing         | 12.4 minutes    |
| Days elapsed before call back                 | 3.5 days      | 5.0 days        | missing         | 2.6 days        |
| <b>First foot problem</b>                     | N=88 triggers | N=25            | N=12            | N=51            |
| Engaged through call back                     | 50.0 %        | 44.0% call back | 50.0% call back | 52.9% call back |

|   | Overall         | English         | Spanish         | Cantonese       |
|---|-----------------|-----------------|-----------------|-----------------|
| Duration of call                            | 9.4 minutes     | 9.9 minutes     | 7.4 minutes     | 9.5 minutes     |
| Days elapsed before call back               | 3.2 days        | 3.6 days        | 3.2 days        | 3.0 days        |
| <b>First low blood sugar value (&lt;50)</b> | N=144 triggers  | N=26            | N=27            | N=91            |
| Engaged through call back                   | 48.6% call back | 53.8% call back | 55.7% call back | 45.0% call back |
| Duration of call                            | 9.3 minutes     | 9.6 minutes     | 8.0 minutes     | 9.5 minutes     |
| Days elapsed before call back               | 3.3 days        | 3.4 days        | 3.7 days        | 3.1 days        |

**Table 7. Health coach call-back details for urgent first triggers by treatment arm**

|   | All Groups      | ATSM-PLUS        | ATSM-ONLY       | WAITLIST        |
|---|-----------------|------------------|-----------------|-----------------|
| <b>First not taking BP medication trigger</b> | N= 35 triggers  | N=14             | N=8             | N=13            |
| Engaged through call back                     | 40.0%           | 57.1% call back  | 25.0% call back | 30.7% call back |
| Duration of call                              | 7.4 minutes     | 8.8 minutes      | 9.5 minutes     | 3.8 minutes     |
| Days elapsed before call back                 | 3.7 days        | 3.1 days         | 4.5 days        | 4.5 days        |
| <b>First sad or blue most of the time</b>     | N= 26 triggers  | N=11             | N=6             | N=9             |
| Engaged through call back                     | 42.3%           | 45.4% call back  | 33.3% call back | 44.4% call back |
| Duration of call                              | 10.6 minutes    | 13.0 minutes     | 8.0 minutes     | 8.3 minutes     |
| Days elapsed before call back                 | 3.5 days        | 1.4 days         | 7.0 da          | 5.3 days        |
| <b>First foot problem</b>                     | N= 88 triggers  | N=29             | N=23            | N=36            |
| Engaged through call back                     | 50.0%           | 62.0 % call back | 47.8% call back | 41.6% call back |
| Duration of call                              | 9.4 minutes     | 10.3 minutes     | 10.3 minutes    | 7.6 minutes     |
| Days elapsed before call back                 | 3.2 days        | 3.0 days         | 3.6 days        | 3.1 days        |
| <b>First low blood sugar value (&lt;50)</b>   | N= 144 triggers | N=48             | N=38            | N=58            |
| Engaged through call back                     | 48.6% call back | 39.5% call back  | 50.0% call back | 55.2% call back |
| Duration of call                              | 9.3 minutes     | 9.3 minutes      | 10.0 minutes    | 8.9 minutes     |
| Days elapsed before call back                 | 3.3 days        | 3.9 days         | 3.3 days        | 2.8 days        |

## Summary of Findings and Discussion: Aim 2 Results

- **The recruitment strategy resulted in identifying a moderately representative sample for SMARTSteps for important variables, such as age, sex, race/ethnicity, and most cardiometabolic indicators.** However, important differences for enrolled patients existed for cholesterol control, insurance and language, although SFHP was interested in over-recruiting Cantonese speakers.
- **There were important variations identified for some of the potential moderating factors affecting implementation adherence to core components of SMARTSteps.**



**1. Variation in Health Coach Call Backs by Type of Trigger.** For example, the data in Figure 4 suggest that some of the urgent triggers had fewer health coach call backs. It is possible that for the first urgent trigger patients, it was more difficult to reach these patients than patients who may have triggered for less urgent topics, such as not exercising, requesting a call back, unhealthy eating, or having difficulty scheduling clinic visits, or that health coaches were less comfortable making calls for counseling on behavior topics they found to be outside of their area of comfort. It is also possible that these first triggers occurred early on in the intervention and that after the participant had been involved/were more familiar with SMARTSteps, they were less difficult to contact. However, the large volume of call back data that is missing, with no documentation, does not allow for a detailed interpretation of the overall patterns of call backs and suggests that documentation of triggered call-related activities was often limited. This may be due, in part, to the turnover of health coaches during the time of the SMARTSteps project. This may have contributed to health coaches being more comfortable with some trigger topics than others. It is also possible that since there's a difference in the required timeframe for urgent vs. non-urgent callbacks (urgent calls were required to be called back within 1-3 days) it is possible that health coaches had more time to contact people for other triggers and tried more often over a longer time period.

**2. Variation in Health Coach Call Backs by Language.** There was little variation by language in call-back details for first not taking blood pressure medications, but greater variation for the depression urgent trigger, with lower call backs for Spanish and Cantonese. As well, there were differences in the days elapsed for call backs with shorter time for Cantonese and longer for Spanish. It is possible that health coaches felt inadequately trained in cultural competency around depression.

**3. Variation in Health Coach Call Backs by Treatment Arm.** There were some important differences suggested by the data on treatment arm, in general suggesting that the ATSM-PLUS call backs were more frequent than other treatment groups (except for low blood sugar value), and that wait list patients call duration was slightly lower than other treatment arms for these selected triggers.

### **Aim 3**

Working with the UCSF Telemedicine Group, we prepared a series of logic templates and a demonstration call in number for the ATSM program, based on the work we did with SFHP. These templates have since been used for a new implementation project for SMARTSteps in a primary care clinic in the CHNSF safety net clinic system, which is underway at General Medicine Clinic at San Francisco General Hospital with care management by diabetes educators. We also have developed week-by-week counseling guides for health coaches. There are several recommendations we have for moving forward that relate to improving the coaching database and incorporating fidelity feedback earlier on so as to improve protocols and coaching trainings:

1. Build the WACAY management database screens in a way that facilitates the call, not just the data collection.

2. Using this fidelity data about differences in language as a “what do you make of this” reflection exercise for cultural competency training of health coaches. It is possible that some of the differences we identified may relate to the health coach turnover, but also some of the potential discomfort in discussing topics like depression may relate to cultural stigma.
3. Solicit health coach feedback in the tailoring of the care manager guides to figure out where they felt uncomfortable with the language and provide adjustments/updates based on the actual coaches working on the project. One might consider adding phrases in all languages so that it doesn’t just facilitate the English coaching (all the sample questions were in English so this may have made it harder to conduct the non-English calls).
4. Use fidelity analyses early in project and then with regularity to figure out where protocols were faltering and provide corrective feedback to health coaches or IS people helping them.

## Limitations

In the SMARTSteps project there were two important limitations that affected this fidelity analysis, but are applicable to many real-world implementation projects. The first is that the health plan had considerable staff turnover during the time we conducted the implementation and evaluation (7 staff and 2 supervisors total). There was turnover in leadership, health coaches, and nurse coordinators about every 3-6 months. This had a large impact on the requirements for re-training staff, lag times of completing protocols and for consistency of notes over time. Nonetheless, SFHP was very committed to seeing through the SMARTSteps project at as high a level of delivery as possible, which shows in the overall high rates of coaching delivery. A second limitation is that the WACAY database was not extensively detailed and as described below, did not facilitate use by health coaches during the calls. As a result, many fields had to be entered after calls were completed, and there was a fair amount of missing data. Additionally, because we only had the reported data in the database, we could not complete a more in-depth qualitative analysis of calls, compared to if we had been able to audio-record some of the health coaching calls.

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## **List of Publications and Products**

We have papers directly related to fidelity analysis results underway. The first of these is a paper focusing on Aim 2. The second would focus more on the role of fidelity analyses for Aim 1 types of processes in the implementation of health IT interventions that work with registries and panel management types of self-management support programs. Papers 4-6 above were produced during the grant period related to the R18 and R03.