Seeing in 3-D: Examining the Reach of Diabetes Self-Management Support Strategies in a Public Health Care System

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Seeing in 3-D: Examining the Reach of Diabetes Self-Management Support Strategies in a Public Health Care System

Dean Schillinger, MD
Hali Hammer, MD
Frances Wang, MS
Jorge Palacios, MA
Ivonne McLean, BA
Audrey Tang, MS, NP
Sharon Youmans, DrPharm
Margaret Handley, PhD, MPH

The authors examined whether tailored self-management support (SMS) strategies reach patients in a safety net system and explored variation by language, literacy, and insurance. English-, Spanish-, and Cantonese-speaking diabetes patients were randomized to weekly automated telephone disease management (ATDM) or monthly group medical visits. The SMS programs employ distinct communication methods but share common objectives, including behavioral "action plans." Reach was measured using three complementary dimensions: (a) participation among clinics, clinicians, and patients; (b) patient representativeness; and (c) patient engagement with SMS. Participation rates were high across all levels and preferentially attracted Spanish-language speakers, uninsured, and Medicaid recipients. Although both programs engaged a significant proportion in action planning, ATDM yielded higher engagement, especially among those with limited English proficiency and limited literacy. These results provide important insights for health communication and translational research with respect to realizing the public health benefits of SMS and can inform system-level planning to reduce health disparities.

Keywords: *translational research; diabetes mellitus; disparities; health communication; literacy; chronic disease care; self-management; information technology*

Self-management is a cornerstone of chronic disease care, yet facilitating successful self-management requires supportive services (Holman & Lorig, 2004). Self-management support (SMS) is increasingly being recognized as an essential component of health

Dean Schillinger,University of California, San Francisco (UCSF) Department of Medicine, Center for Vulnerable Populations, San Francisco General Hospital. Hali Hammer, UCSF Department of Family and Community Medicine, San Francisco General Hospital. Frances Wang, Jorge Palacios, Ivonne McLean, and Audrey Tang, UCSF Department of Medicine, Center for Vulnerable Populations, San Francisco General Hospital. Sharon Youmans, UCSF School of Pharmacy, San Francisco. Margaret Handley, UCSF Department of Family and Community Medicine, San Francisco General Hospital.

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care delivery (Institute of Medicine, 2001; Fisher et al., 2005; Mensing et al., 2000). SMS encompasses a range of organized, system-level strategies that share one or more elements including individualized assessment, collaborative goal setting, skills enhancement, follow-up and support, access to resources, and continuity of clinical care (Fisher et al., 2005). SMS has been shown in efficacy studies to promote patient satisfaction, healthy behaviors, self-efficacy and coping skills, and, in some cases, improve physiologic outcomes and utilization patterns (Chodosh et al., 2005; Norris, Engelgau, & Narayan, 2001; Tsai, Morton, Mangione, & Keeler, 2005).

Providing SMS is resource intensive, requiring retraining of staff and organizational change, investing in information technology, encouraging populations to engage in SMS, and tailoring programs to diverse populations (Fiscella & Geiger, 2006; Schillinger, 2004; Wagner, Austin, & Von Korff, 1996). There is wide variation in the extent to which health systems implement SMS (Li et al., 2004; Rittenhouse & Robinson, 2006). Furthermore, traditional SMS approaches often do not reach significant and growing segments of the chronic disease population (Institute of Medicine, 2004; Shojania & Grimshaw, 2004), such as the uninsured or publicly insured, or those with communication barriers, such as limited literacy or limited English proficiency (Agency for Healthcare Research and Quality [AHRQ], 2005; Institute of Medicine, 2004; Schillinger, 2004; Schillinger, Barton, Karter, Wang, & Adler, 2006; Yach, Hawkes, Gould, & Hofman, 2004). The gap between research and practice may be particularly wide in safety net settings (Eakin, Bull, Glasgow, & Mason, 2002; Regenstein, Huang, Cummings, et al., 2005), which disproportionately care for such populations. This represents a significant limitation with respect to realizing the public health benefits of SMS (Fiscella & Shin, 2005).

To address these gaps, researchers and policy makers have called for "practical clinical trials" (Garfield et al., 2003; Glasgow, Magid, Beck, Ritzwoller, & Estabrooks, 2005; Murphy, Chapel, & Clark, 2004; Tunis, Stryer, & Clancy, 2003), i.e., studies of evidence-based, reproducible interventions across a range of settings, providers, and patients designed to enable rigorous evaluation with respect to reach and effectiveness. We report results of a practical clinical trial of SMS in a sample of safety net primary care centers. The Improving Diabetes Efforts Across Language and Literacy (IDEALL) project (Handley, Hammer, & Schillinger, 2006) implemented two SMS strategies: (a) automated telephone disease management system (ATDM) and (b) group medical visits (GMV) tailored to patients' literacy and language needs. Consistent with recommendations of translational research experts (Glasgow, Goldstein, Ockene, & Pronk, 2004; Green & Glasgow, 2006), the goal of this study is to describe the reach of these SMS strategies across three complementary dimensions: *participation* among clinics, providers, and patients; *representativeness* of patients; and patient *engagement* with (e.g., uptake of) SMS programs. Because communication barriers contribute to disparities in chronic care quality (AHRQ, 2005; Schillinger, 2004), we also explore whether engagement varied by patient literacy and language.

Address correspondence to Dean Schillinger, UCSF/San Francisco General Hospital, Building 10, 3rd Floor, 1001 Potrero Ave., San Francisco, CA 94110: e-mail: dschillinger@medsfgh.ucsf.edu.

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METHOD

Design and Setting

We implemented an effectiveness study of SMS nested within a randomized trial among diverse diabetes patients in a safety net system. The IDEALL project was a three-arm randomized trial of two diabetes SMS interventions compared to usual care. The rationale and design of the IDEALL project have been described previously (Handley, Hammer, et al., 2006). The project emanated from a strategic initiative to improve chronic disease care in the Community Health Network of San Francisco (CHNSF), the integrated delivery system of the San Francisco Department of Public Health, and from patient and practitioner experiences and recommendations described in studies of chronic care and patient-physician communication (Fernandez et al., 2004; Sarkar, Fisher, & Schillinger, 2006; Schillinger, Bindman, Stewart, Wang, & Piette, 2004; Schillinger et al., 2002; Schillinger et al., 2003; Seligman et al., 2005). The CHNSF clinics represent a subset of the UCSF (University of California, San Francisco) practice-based research network.

The SMS Adjunctive Models

Although primary and specialty care services were standard of care, there was no systematic diabetes SMS strategy at the start of the IDEALL project. We selected SMS strategies with different approaches to engaging patients and adapted them to the needs of the practices and diverse patient populations (see Figure 1). The first strategy—automated telephone disease management (ATDM)—employs technology to provide surveillance, education, and care management. Efficacy studies of ATDM linked to nurse care management reveal improvements in satisfaction, functional status, and metabolic control (Piette, Weinberger, & McPhee, 2000; Piette, Weinberger, McPhee, Mah, et al., 2000). The second—group medical visits (GMV)—employs a more interpersonal and collective approach with roots in adult educational theory and practice. This model has been shown in efficacy studies to improve functional status and reduce hospitalizations among patients with chronic disease (Clancy, Cope, Magruder, Huang, & Wolfman, 2003; Lorig et al., 2001; Sadur et al., 1999; Trento et al., 2001), and it is an increasingly common SMS strategy (Chin et al., 2004). Although distinct in their method of engaging patients, both employ approaches consistent with self-efficacy theory and share objectives characteristic of successful SMS (Fisher et al., 2005; Lorig & Holman, 2003). Both are system-level interventions that promote collaborative goal setting in the form of behavioral "action plans" (Estabrooks et al., 2005; Handley, MacGregor, et al., 2006), wherein patients set, and hopefully achieve, short-term goals to improve their self-management (Lorig, 2006). Collaborative goal setting and action planning represent a core element of SMS (Fisher et al., 2005; Glasgow, Nutting, et al., 2005). Both SMS models also provide individualized assessment, skills enhancement, health education, follow-up and support, access to community resources, and continuity of clinical care (Fisher et al., 2005) and were delivered in English, Spanish, and Cantonese, the most common languages in the CHNSF. We estimated that implementation of each model would use comparable staff resources.

ATDM and GMV models were developed with extensive input from the target population and CHNSF diabetes nurse educators. The models are summarized in Figure 1. Detailed descriptions of both interventions, clinical protocols, tracking forms, and training materials are available online (The Commonwealth Fund, 2004). Prior to implementation,

IDEALL clinical staff were trained in model protocols, motivational interviewing, and communication techniques for patients with limited literacy, and (for GMV) in group facilitation techniques.

Patients randomized to ATDM receive weekly, rotating automated (prerecorded) telephone calls in their native language for 9 months (39 weeks). Each call takes between 6 to 12 minutes to complete. Patients selected call times at enrollment and could alter preferred times or call the system toll free. Patients answering "out of range" on items, based on predetermined clinical thresholds, receive a call back from a nurse care manager, who helps patients problem-solve the issue identified in the report or any other concerns, with a focus on collaborative goal setting and action plans (see Section A in Figure 1). All care manager-patient interactions, including action plans created and achieved, are documented via a standardized ATDM record linked to the CHNSF record. As ATDM is an adjunct to care, this record also serves to communicate with the patient's physician. Enrolled participants received no incentives to respond to ATDM calls.

The GMV arm involves language-specific monthly GMVs for 9 months. GMVs involve 6 to 10 patients, are cofacilitated by a language-concordant physician and health educator, last 90 minutes, and share the same basic structure (see Section B in Figure 1). As with ATDM, the role of GMV cofacilitators includes a focus on collaborative goal setting with action plans. Because of the importance of patient activation to clinical communication (Street, Gordon, Ward, Krupat, & Kravitz, 2005), after each session cofacilitators rate the level of participation of each attendee (*little*, *some*, *full*). The cofacilitators document all interactions, including action plans created and achieved, which are integrated with CHNSF records. Bus tokens to assist with transportation and healthy snacks were provided, but there were no other incentives to encourage GMV attendance.

Population-Based Recruitment

The recruitment strategy had five components. Because CHNSF is linked via a clinical and administrative database, we first created a patient registry that was queried to identify potentially eligible patients between June 2003 and December 2004. We identified patients who were older than age 17; had ICD-9 codes consistent with type 2 diabetes; spoke English, Spanish, or Cantonese; made ≥1 primary care visit in the prior year; and had ≥1 hemoglobin A1c value (HbA1c). ICD-9 diagnoses criteria were used to exclude patients with psychotic illness or end-stage renal disease.

Second, we identified which of the nine CHNSF clinics had the largest numbers of potentially eligible patients and targeted these clinics for recruitment. Third, we used the registry to create a list of potentially eligible patients for clinicians at recruited clinics, for their confirmation and review of eligibility, as required by the Institutional Review Board (IRB). To ensure registry accuracy, this list had check-off boxes for provider exclusions (see Table 1). Receipt of a signed list denoted consent for clinician participation and approval to consider patients eligible for recruitment. These patients are referred to as "clinician-eligible" in subsequent discussions. Although ultimately we only enrolled patients with HbA1c ≥8%, lists included all patients, regardless of HbA1c, to enable clinician determination of eligibility only once.

Fourth, we applied one additional eligibility criterion related to suboptimal glycemic control, defined as having a most recent HbA1c of ≥8%, obtained by periodically updating the CHSNF database. Finally, we merged this list of clinician- and database-eligible patients with appointment databases so that patients could be approached prior to their appointments by language-concordant research assistants to explore potential

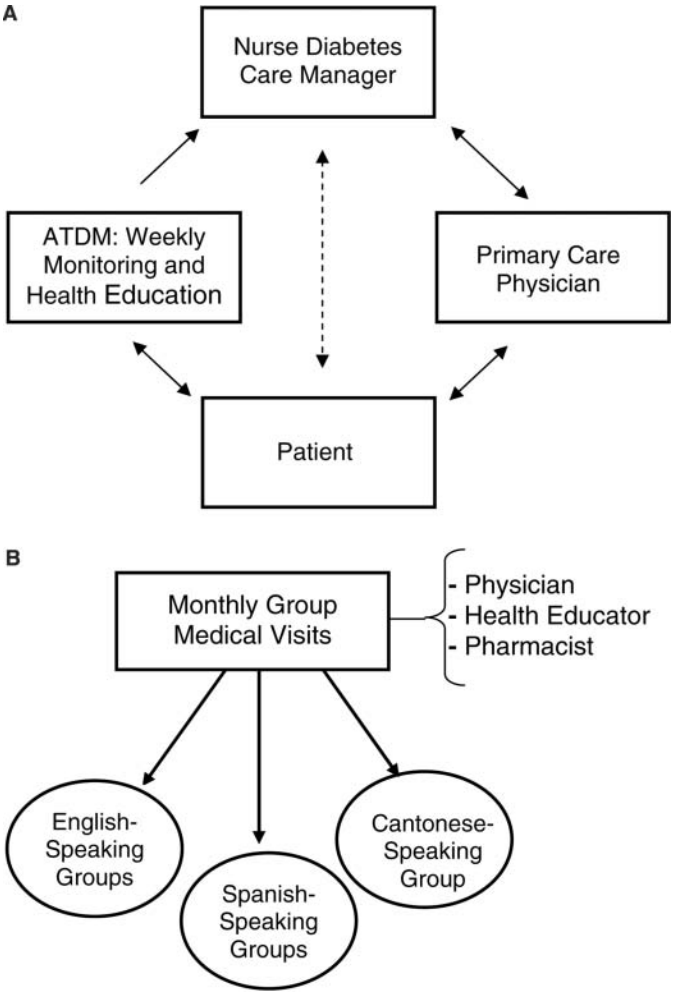

Figure 1. The IDEALL Automated Telephone Disease Management (ATDM) Model (A) and the IDEALL Group Medical Visit (GMV) Model (B).

a. The ATDM system provides weekly calls with rotating queries, in patients' native language, regarding self-care (e.g., symptoms, medication adherence, diet, physical activity, self-monitoring of blood glucose, smoking), psychosocial issues (e.g., coping, depressive symptoms), referrals for preventive services (e.g., ophthalmologist). Patients respond via touch-tone commands. Depending on the response to an individual item, patients also receive automated health education messages in the form of narratives. Patients answering "out of range" on ≥ 1 item, based on predetermined clinical thresholds, receive a call back from a language concordant nurse care manager within 24 to 72 hours. The care manager helps patients problem-solve around the issue identified in the report, or any other concerns, with a focus on collaborative goal setting with action plans.

b. The GMV model involves language-specific monthly group medical visits for 9 months. GMVs involve 6 to 10 patients, are cofacilitated by a language-concordant primary care physician and health educator, last 90 minutes, and share the same basic structure: (a) group check-in, in which participants report any problems or progress with action plans and the group facilitates problem-solving, adjustment, and/or recommitment to action plans; (b) discussion of common concerns or modeling of self-management practices; (c) social break with healthy snacks; (d) short planning session to select subsequent topics; and (e) brief, individualized care to patients with unmet medical needs by the physician, health educator, or pharmacist (to review medication regimens).

Table 1. Measures to Assess Participation in the IDEALL Project

Level	Participation Measurement	Data Source	Result
1. Health system/clinic	Proportion of CHNSF clinics participating in IDEALL among clinics approached	CHNSF data on clinics	Four of six clinics (67%), including two community and two hospital-based primary care clinics
2. Clinician	a. Proportion of clinicians participating in IDEALL among clinicians approached	CHNSF data on patients and their clinicians; IDEALL data	a. 122 of 126 eligible clinicians contacted for reviewing patient eligibility sheets completed them (97%)
	b. Proportion of clinicians with ≥1 patient enrolled in IDEALL among those with eligible patients	IDEALL data	b. 102 of 122 clinicians had one or more patient enroll in IDEALL (84%)
3. Patient	a. Proportion of database-eligible patients at the four study clinics among all nine CHNSF clinics	CHNSF data on patients with HA1c ≥8%	a. 1,307 of 2,261 database-eligible patients were affiliated with the four study clinics (58%)
	b. Proportion of clinician-eligible patients at the four study clinics, and reasons for clinician-determined ineligibility	CHNSF data on patients with no HbA1c exclusion combined with clinician eligibility criteria at the four clinics	b. 1,390 of 1,612 potentially eligible patients were clinician eligible (86%) and 222 patients were ineligible (14%) for: incorrect clinician assigned, no longer clinician, or patient moved (8%); patient too ill (4%); deceased (< 1%); does not speak study language (< 1%); and other (< 1%)
	c. Proportion of database-eligible patients approached over study period	CHNSF data on patients with HbA1c ≥8% combined with clinician-eligible patients and appointment data	c. 499 of 1,307 database-eligible patients (38%) approached in four clinics

(continued)

interest in participation and further assess for eligibility (see Table 1). Remaining eligible and interested patients were asked to attend a study enrollment visit.

Table 1. (continued)

Level	Participation Measurement	Data Source	Result
	d. Proportion of patients determined eligible and consenting and reasons for ineligibility	CHNSF data on patients with HbA1c ≥8% combined with clinician eligibility and appointment data; IDEALL patient level data	d. 339 of 499 patients approached were enrolled (68%), 70 refused (14%), and 90 were found ineligible (18%) based on self-reports: planned extended travel or move (4%), no reliable access to phone (4%), poor fluency in a study language (3%), too ill to travel to group visits (2%), visual/hearing impairment (2%), changing clinic (1%), severe mental health problems (< 1%), trouble with touch tone commands (< 1%), other (1%)

NOTE: CHNSF = Community Health Network of San Francisco; IDEALL = Improving Diabetes Efforts Across Language and Literacy.

Recruited patients attended a baseline enrollment session that included an informed consent process, physiologic measures (including HbA1c), and questionnaire. Literacy was assessed among English and Spanish speakers only with the validated, short form Test of Functional Health Literacy in Adults (s-TOFHLA), a 36-item reading comprehension test of health-related materials (Baker, Williams, Parker, Gazmararian, & Nurss, 1999). Scores of < 23 correspond to limited literacy.

Randomization

Randomization was administered using a blocked randomization strategy stratified to ensure even distribution of languages. Randomized patients were informed of their assignment at enrollment; those assigned to ATDM or GMV were told they would be contacted shortly to initiate the SMS intervention. All participants were given $15 for this baseline research visit.

Assessment of Reach

Consistent with recommendations to improve evaluation of health promotion and clinical interventions (Glasgow, Magid, et al., 2005; Handley, Hammer, et al., 2006; Tunis et al., 2003), we approached the IDEALL project using the "RE-AIM framework" (Dzewaltowski, Estabrooks, Klesges, Bull, & Glasgow, 2004; Glasgow, 2006; Glasgow

et al., 2004; Glasgow, Lichtenstein, & Marcus, 2003), which includes measurement of the reach of interventions across populations, clinicians, and practices. We developed measures to estimate reach across three complementary dimensions: participation among clinics, clinicians, and patients; representativeness of enrolled patients; and patient engagement with SMS programs.

Participation

For our first dimension of reach, we calculated participation rates using data from the CHNSF database and IDEALL registry. We created a data set of all patients who met demographic, clinical, and utilization criteria and who also had, at some point during the enrollment period, an HbA1c ≥8%. These "database-eligible" patients provide an important denominator for reach estimates, both for participation and patient representativeness (see below).

At the clinic level, we calculated the proportion of clinics that participated among clinics approached. At the clinician level, we calculated the proportion of clinicians at the recruited clinics who completed patient eligibility forms, among those with ≥1 potentially eligible patient based on CHNSF database. We also calculated the proportion of clinicians who had ≥1 patient enroll among clinicians with ≥1 database- and clinician-eligible patient.

To measure patient participation at the CHNSF population level, we first determined the number of eligible patients at participating clinics, out of all patients at the nine clinics who met study criteria, including HbA1c criterion. We further explored the inclusiveness of our selection criteria and recruitment strategy by calculating the proportion of potential participants at the study clinics deemed eligible by the clinician (and reasons for ineligibility) among eligible patients, irrespective of HbA1c criterion. We then calculated the proportion of patients approached by research assistants among those deemed eligible and the proportion that enrolled, refused, or were ineligible at interview and summarized reasons for ineligibility.

Representativeness

As a second dimension of reach, we explored the representativeness of patients who enrolled by comparing characteristics (age, sex, language, race/ethnicity, insurance, HbA1c) of enrolled participants versus three subgroups: (a) nonenrolled, database-eligible patients from the study clinics, (b) clinician- and database-eligible patients who were ineligible based on self-report, and (c) eligible patients who refused (see Table 2).

Engagement With Interventions

For our third dimension of reach, we measured engagement with SMS interventions among patients randomized to ATDM or GMV across a number of steps, concluding with successful achievement of a behavioral action plan (see Table 3; Handley, MacGregor, et al., 2006; MacGregor et al., 2006). For each SMS model, we calculated a series of engagement indices, such as (a) proportion of individuals who ever engaged in an SMS interaction (defined as responding to ≥1 ATDM call or attending ≥1 GMV), (b) proportion of SMS sessions attended among ever users, (c) proportion of these individuals

Table 2. Measures of Representativeness: Comparisons Between IDEALL-Enrolled and IDEALL-Eligible/Nonenrolled Patients

	Eligible Database Patients (N = 1,307)			Patients Approached (N = 499)				
	IDEALL Patients	Nonenrolled Patients	IDEALL Versus Nonenrolled p Value	IDEALL Patients	Ineligible Patients Based on Self-Report	Ineligible Versus IDEALL p Value	Patients Who Refused	Refused Versus IDEALL p Value
N patients	339	968		339	90		70	
Age (years): M (SD)	55.4 (11.9)	56.4 (12.8)	.2		61.9 (12.7)	< .001	60.9 (10.3)	< .001
Sex								
Female	59.0%	54.1%	.1		43.3%	.01	55.7%	.6
Language								
English	53.4%	55.5%	< .001		61.1%	.4	54.3%	.3
Spanish	35.7%	25.8%			32.2%		28.6%	
Cantonese	10.9%	18.7%			6.7%		17.1%	
Ethnic group								
Asian	22.4%	34.3%	< .001		25.6%	.2	37.1%	.1
African American	19.5%	15.5%			14.4%		17.1%	
Hispanic/Latino	47.2%	34.8%			42.2%		34.3%	
White	8.0%	11.3%			14.4%		8.6%	
Other/unknown	3.0%	4.1%			3.3%		2.9%	
HbA1c: M (SD)	9.8 (1.7)	10.0 (2.0)	.2		9.9 (1.8)	.6	9.7 (1.7)	.5
Insurance								
Medi-Cal	19.8%	18.6%	.01		23.3%	.002	14.3%	.01
Medicare	21.5%	24.0%			36.7%		38.6%	
Uninsured	50.2%	53.4%			38.9%		45.7%	
Other	8.6%	4.0%			1.1%		1.4%	

Table 3. Engagement Indices for ATDM and GMV, Overall and Stratified by Language and Literacy

Automated Telephone Disease Management (ATDM)									
	Total *N*	% of ATDM Ever Users	% of ATDM Calls Among Ever Users	Mean No. ATDM Nurse Call Backs for Ever Users	% of Those Creating ≥1 Call-Back Recipients Call-Back Recipients	Mean No. New Action Plans Created[a]	Mean No. New Plans Among Patients With ≥1 Plan[a]	% Action Plans Achieved[a]	Composite Engagement Product[b]
Total	112	93.8	57.1	10.8	88.0	5.2	2.5	42.3	22.1
English	52	92.3	53.8	9.9	86.4	5.4	2.5	40.2	20.0
Spanish	47	97.9	55.1	11.0	88.9	5.2	2.6	43.6	24.3
Cantonese	13	84.6	79.7*	14.3**	90.9	3.8*	2.0**	47.6**	22.0
Limited literacy	50	94.0	55.4	11.6	91.3	5.9	2.8	43.5	28.0
Adequate literacy	48	95.8	54.0	9.0	83.3	4.6	2.2	39.0	15.6
English									
Limited literacy	16	87.5	53.5	12.6**	92.3	7.7*	3.5**	42.0	35.5
Adequate literacy	36	94.4	61.8	8.6	83.9	4.5	2.1	38.8	14.1
Spanish									
Limited literacy	34	97.1	59.9**	11.2	90.9	5.2	2.5	44.4	25.0
Adequate literacy	12	100.0	51.2	10.3	81.8	5.1	2.4	39.3	20.7

(continued)

Table 3. (continued)

Group Medical Visit (GMV)	Total *N*	Proportion of Those Ever Attending GMV	% of GMVs Attended Among Ever Users[a]	Mean No. of GMVs Attended Among Ever Users	% of Those Creating ≥1 Action Plan Among Ever Users	Mean No. of New Action Plans Created[a]	Mean No. New Plans Among Patients With ≥1 Plan[a]	% Action Plans Achieved[a]	% Full Participation Among Ever Users[a]	Composite Engagement Product[b]
Total	112	69.6	54.0	4.8	88.5	3.2	1.6	45.3	62.7	4.8
English	51	58.8	60.0	5.4	93.3	3.7	2.1	54.1	62.3	6.4
Spanish	48	75.0*	50.8**	4.4*	80.6	2.8*	1.5**	44.0	69.6	4.0
Cantonese	13	92.3*	48.1**	4.3**	100.0	3.0**	0.7*	22.2*	42.3**	2.7
Limited literacy	56	69.6	50.9**	4.4*	82.1	2.8*	1.4*	42.2*	56.5*	3.6
Adequate literacy	42	64.3	60.9	5.5	92.6	3.7	2.3	57.4	77.0	7.6
English										
Limited literacy	18	61.1	54.5	4.9	90.9	3.3	1.9	52.8	31.5*	5.2
Adequate literacy	33	57.6	63.2	5.7	94.7	3.9	2.3	54.7	77.8	7.1
Spanish										
Limited literacy	38	73.7	49.4	4.2	78.6	2.6	1.2*	37.0*	67.8	3.0
Adequate literacy	9	88.9	55.6	5.0	87.5	3.3	2.4	65.4	75.0	9.4

NOTE: All p values are for comparisons with English speakers or patients with adequate literacy as referent groups, and all analyses control for age, sex, baseline HbA1c, and insurance status.
a. These analyses also account for within-patient clustering using GEE.
b. The composite engagement product is a unitless metric calculated as = (the proportion of individuals who ever engaged in an IDEALL SMS session) x (mean number of sessions attended) x (proportion of individuals, among those who ever participated in a session, who created at least one action plan) x (mean action plans achieved).
*$p \leq .05$. **$p \leq .10$.

that created ≥1 action plan, and (d) mean number of action plans created and achieved based on self-report. For ATDM, we calculated the mean number of nurse call-backs among ever users, an indicator of intensity of ATDM use and SMS needs. For GMV, we calculated the mean number of GMVs attended among ever users and the proportion of patient sessions in which cofacilitators rated patients as having "full" participation, an indicator of patient activation (Street et al., 2005).

Finally, we combined a subset of engagement indices to create a SMS composite engagement product (Glasgow, Nelson, Strycker, & King, 2006). This unit-less value represents a more comprehensive metric of reach among enrolled patients. For ATDM and GMV, we separately calculated the engagement product as: Proportion of Those Who Ever Engaged in SMS × Mean Number of Sessions Attended Among Ever Users × Proportion of Ever Users Who Created ≥1 Action Plan × Mean Number of Action Plans Achieved.

Analyses

For representativeness analyses, we compared enrolled participants to other groups using chi-square or Fisher's exact tests. For engagement, the patient was the unit of analysis. We did not perform statistical testing for differences in engagement between ATDM and GMV insofar as the distinct structures and frequency of patient interactions in each SMS model prevent drawing parallel statistical inferences. Rather, these indices were used to understand the relative strengths and limitations of the SMS programs (Glasgow et al., 2006). However, within each SMS strategy, we explored differences in each engagement index by language and literacy level. We created multivariate models for ATDM and GMV for both language and literacy adjusting for age, sex, insurance, and baseline HbA1c. Because of potential interactions between language and literacy, for each SMS program we generated engagement indices stratified by language and, among English and Spanish speakers, by literacy level.

Depending on the nature of the engagement index, we used logistic regression or general linear models. For engagement indices correlated within patient, we used generalized estimating equations. For enrolled patients who died during the intervention (3 in ATDM and 3 in GMV), we limited observation to the period between SMS initiation and date of death.

RESULTS

Participation

Table 1 shows extent of participation across clinic, clinician, and patient levels. Because 6 of 9 CHNSF clinics cared for the majority of patients with diabetes, we approached these clinics for potential participation, and 4 (67%) agreed. The two that did not participate could not conform to the study design: one (with a large Cantonese-speaking population) was running group educational sessions and was only interested in ATDM; the other was interested in both SMS strategies but was uncomfortable with randomization. Nearly all clinicians (97%) from the four clinics completed eligibility forms and agreed to expose patients to one or more SMS program. Of these, most (84%) had ≥1 enrolled patient.

Most CHNSF database-eligible patients (1,307 of 2,261 with HbA1c ≥8%; 58%) attended the four participating clinics. Clinician review of eligibility (as determined by

CHNSF data without HbA1c criterion) resulted in exclusion of 222 of 1,612 patients (14%). The majority of exclusions at this level were because of incorrect clinician assignment. During 18 months of recruitment, more than one third of database-eligible patients from the four clinics were approached (499 of 1,307, or 38%), and 70 of these (14%) refused. Patient interviews resulted in exclusion of 90 additional patients (18%; see Table 1), including 4% reporting not having reliable access to a phone and 2% reporting being too ill to travel to group visits.

Representativeness

Enrolled patients (n = 339) appeared to be representative of nonenrolled, database-eligible patients from the four clinics (n = 968) with respect to age, sex, and HbA1c (see Table 2), but were more likely to be Spanish-speaking, Hispanic, or African American, and to be uninsured or have Medi-Cal, but less likely to be Cantonese speaking or have Medicare. Enrolled patients differed from approached patients who reported exclusion criteria (n = 90) only in terms of age (55.4 vs. 61.9 years, $p < .01$), sex, and insurance (uninsured: 50.2% vs. 38.9%; Medicare: 21.5% vs. 36.7%, $p < .001$). Enrolled patients were more likely than patients who refused (n = 70) to be uninsured or have Medi-Cal ($p < .001$).

Engagement With SMS

In ATDM (n = 112), engagement levels were high overall (see Table 3). The percentage of individuals responding to ≥1 ATDM call was 93.8%, with no significant differences by language and literacy. Among ATDM calls (N = 4,106) to ever users, 56.6% were responded to, with higher rates among Cantonese compared to English (79.7% vs. 53.8%, $p < .01$) and Spanish speakers with limited versus adequate literacy (59.9% vs. 51.2%, $p = .09$). Among ever users, there were 10.8 mean nurse call-backs (SD = 6.5), with more triggered call-backs among Cantonese speakers (14.3 vs. 10.0, $p = .06$) and English speakers with limited literacy (12.6 vs. 8.6, $p = .10$). Among patients with ≥1 nurse call-back, the proportion that generated ≥1 action plan was high (88.0%), with similar levels across language and literacy. Among English speakers, those with limited literacy were more likely to both generate ($p = .03$) and report success with ($p = .06$) action plans. The ATDM composite engagement product was 22.2, with higher products among those with limited English proficiency and those with limited literacy in both English and Spanish.

In GMV (n = 112), engagement levels were more modest, with language- and literacy-related patterns in ATDM being reversed for many indices (see Table 3). The percentage of individuals that attended ≥1 GMV was moderate (69.6%), with higher rates among Cantonese (92.3%, $p = .02$) and Spanish speakers (75.0%, $p = .02$). Among GMV patient sessions (n = 1,008) for ever users, 53.1% were attended, with lower attendance among individuals with limited versus adequate literacy (50.9% vs. 60.9%, $p = .10$). Among ever users, there was lower GMV attendance for Spanish speakers ($p = .04$) and for limited versus adequate literacy ($p = .04$). Among patients who attended ≥1 GMV, the proportion that generated ≥1 action plan was high (88.5%), with similar levels across language and literacy. Patients with limited English proficiency and literacy were less likely than English speakers and those with adequate literacy to generate action plans ($p < .10$) and report success with them ($p < .10$). The proportion of sessions in which cofacilitators rated patients as participating fully was lower for Cantonese compared to English (42.3% vs. 62.3%,

$p = .10$) and for limited literacy among English speakers (31.5% vs. 77.8%, $p < .01$). The GMV composite engagement product for GMV was 4.8, with lower products for both those with limited English proficiency and those with limited literacy in both English and Spanish.

DISCUSSION

Although efficacy studies have demonstrated the benefit of a range of SMS strategies—even among selected vulnerable populations (Dewalt et al., 2006; Philis-Tsimikas et al., 2004; Rothman et al., 2004)—there is little translational research on SMS implementation to guide health system planners and little research on the reach of such programs with respect to diverse clinics, providers, and populations in safety net systems (Eakin et al., 2002; Lemon, Zapka, Estabrook, & Benjamin, 2006).

We describe an effectiveness study to measure the extent to which diabetes SMS strategies reach diverse patients in a safety net system. We selected two evidence-based SMS models that shared objectives characteristic of successful SMS yet differed in their method of engaging patients. Participation rates in SMS were high across clinic, clinician, and patient levels, and the programs preferentially attracted Spanish speakers, the uninsured, and Medicaid recipients, groups often underrepresented in SMS research. We believe that the population-based recruitment strategy, coupled with the adjunctive and tailored models of intervention delivery, resulted in high uptake of SMS, with both programs engaging a significant proportion of participants in an activity central to self-management: collaborative goal setting and action planning. That we achieved these results using an adjunctive model of care is especially promising in light of research suggesting the infeasibility of clinicians' conducting collaborative goal setting in routine visits (Handley, MacGregor, 2006; MacGregor et al., 2006).

Notably, the programs generated different degrees of engagement, with ATDM yielding higher engagement, especially among those with communication barriers. When combined with our finding that 96% of potential participants in this safety net setting reported reliable access to a phone, this suggests that this form of SMS is particularly accessible to vulnerable populations (Fiscella & Shin, 2005). In contrast, GMV yielded more modest levels of engagement, particularly among those with communication barriers. There are a number of possible explanations for the variation in engagement by language and literacy. The proactive nature of ATDM presents an exception to the dynamics of clinical interactions, which often require an "activated" patient to initiate communication about self-management goals and barriers (Fernandez et al., 2004; Schillinger et al., 2004; Street et al., 2005; Hofer, Zemencuk, & Hayward, 2004). Neither the communication training of cofacilitators nor the participatory approach of GMVs sufficiently altered these patterns. The hierarchical logic of ATDM (i.e., its capacity to trigger telephonic information or a nurse call-back contingent on patient responses) may have preferentially engaged those with greater communication or SMS needs. Similar findings have been reported with interactive educational strategies in asthma (Paasche-Orlow et al., 2005). Furthermore, ATDM may have preferentially appealed to those with communication barriers, either because of unmeasured factors (health status or transportation problems) or because of a willingness to engage in technologic solutions to bridge the communication divide (Piette, McPhee, Weinberger, Mah, & Kraemer, 1999). Although engagement results may have differed had patients been able to select an SMS program, a study of patient preferences for SMS support our findings (Regenstein, Huang, Schillinger, et al., 2005).

Our study has a number of limitations common to effectiveness research. First, results must be interpreted within the context of the IRB-approved recruitment protocol. As discussed in a companion paper (Handley, Hammer, & Schillinger, 2006), our findings may not precisely reflect the extent of reach were this to have been implemented as a system-level SMS initiative. The requirement to recruit research participants attending a clinic visit may have conservatively biased participation and representativeness results. Conversely, recruiting active clinic users may have led to overestimation of real-life engagement. Second, because the SMS strategies were developed and implemented in a manner sensitive to the local context (Green & Glasgow, 2006), it is not clear how generalizable our results are. Third, although we report composite engagement products for ATDM and GMV, the unique structures and differing periodicity of SMS interactions make direct comparisons problematic. Fourth, the small sample sizes of subgroups introduces the likelihood of Type I error with respect to stratified results. Fifth, we only examined the reach of two SMS strategies and cannot report on their relative merits compared to other strategies, such as the use of lay health educators (Philis-Tsimikas et al., 2004) or how reach estimates may have been affected had we combined the two strategies. Finally, we focused on action plans as a metric of engagement. Although supported by behavioral theory and the SMS literature (Estabrooks et al., 2005; Holman & Lorig, 2004; Lorig, 2006), engagement findings may have differed had we used other indicators and should be interpreted as providing a sketch rather than a complete picture. Future analyses of patient-centered physiologic and use-related outcomes, including cost-effectiveness and relative resource utilization, will enable more complete characterization of intervention components most useful to health system planning.

In summary, we implemented an effectiveness study of SMS nested within a randomized trial among diverse diabetes patients in a safety net system. We measured the reach of two diabetes SMS strategies—ATDM and GMV— using three complementary dimensions of reach. Although both programs engaged a significant proportion of participants in behavioral action planning, ATDM yielded higher engagement, especially among those with limited English proficiency and limited literacy. We believe that this study provides important insights for health communication and translational research, expands the generalizability of chronic disease management research, and can inform planning with respect to system-level strategies to reduce disparities in chronic disease care (Institute of Medicine, 2003, 2004).

Implications for Practice

Self-management is a cornerstone of chronic disease care, yet facilitating successful self-management requires supportive services. Traditional SMS approaches often do not reach large segments of the chronic disease population, which represents a significant limitation with respect to realizing the public health benefits of SMS. This gap is often particularly wide for safety net settings that disproportionately care for disadvantaged populations, consistent with the inverse care law, which states that the availability and quality of health care tends to vary inversely with need among the populations served (Tudor-Hart, 1971).

In this effectiveness study, we found that socioeconomically vulnerable and ethnically and linguistically diverse patients in a public sector, safety net delivery system appear interested in receiving diabetes SMS as adjuncts to care. By adapting evidence-based models of SMS to the needs of hard-to-reach populations, the SMS strategies we implemented were able to reach a large proportion of the eligible population—including a disproportionate share of minorities, non-English speakers, the uninsured, and those

on Medicaid—and to engage them in behavioral action planning. When comparing the two forms of SMS, we found that the ATDM model not only reached a greater proportion of the target population than the group medical visit model, but it also yielded particularly high rates of engagement for those with limited literacy and limited English proficiency. For health system planners and practitioners in health education and health promotion, this suggests that the relative accessibility and targeting of the ATDM technology, combined with its proactive nature and hierarchical logic, can provide a strategy to reverse the inverse care law and reduce health care disparities.

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