

# Recruitment of Medicaid and Dual-enrolled Medicare Beneficiaries With Diabetes Mellitus Into a Randomized Controlled Trial

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**Objective:** To document the recruitment of Medicaid and dual-enrolled Medicare beneficiaries with diabetes mellitus into a randomized clinical trial.

**Study Design:** Randomized controlled trial with 1-year follow-up.

**Methods:** A total of 2242 Medicaid or dual-enrolled Medicare beneficiaries with diabetes residing in King County, Washington, were recruited by direct mail for a clinical trial of diabetes self-care management. Washington State Medicaid program databases were used to identify the target population who received recruitment packets from the program director. Individuals who did not return a participation refusal letter were telephoned to determine study eligibility. Subjects were screened during a study visit, and written informed consent was obtained. Enrolled subjects were randomized to a self-care intervention group or a usual care group.

**Results:** Of 2242 recruitment packets sent, we were unable to contact 40% of the target population, despite the fact that packets were sent to the same mailing addresses used for monthly Medicaid check distributions. The primary recruitment challenges were missing telephone contact information and a lack of interpreters speaking needed dialects. Of the 146 subjects enrolled, 71% were nonwhite, 28% were non-English speaking, 69% were women, and the mean age was 59.8 years.

**Conclusions:** Research in Medicaid and Medicare populations is possible but requires additional time, energy, and resources. The finding that 40% of the Medicaid population could not be contacted suggests that Medicaid may want to revisit their contact information procedures to facilitate case management and other programs.

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Diabetes mellitus is a major public health problem, accounting for nearly 20% of annual US healthcare costs.<sup>1</sup> Diabetes is more prevalent among individuals with limited means and in certain ethnic minority groups. Among adult Medicaid recipients, 17% to 25% have diabetes, as do 24% of the population dual enrolled in Medicaid and Medicare.<sup>2-4</sup> The optimal control of chronic diseases, such as diabetes, relies on healthcare providers and their teaching and support of patients' self-care management. Unfortunately, this strategy has not been widely adopted. Several randomized controlled trials of diabetes self-management programs have been tested in largely affluent white older women and have demonstrated reduced healthcare utilization and costs.<sup>5-8</sup> One program, the

Health Enhancement Program, showed an increase in self-care practices for chronic conditions but was conducted in a nondiabetic affluent older population.<sup>9,10</sup> Several diabetes self-management programs have been attempted in low-income, minority, and aged populations, but none were conducted in Medicaid or dual-enrolled Medicare populations.<sup>11</sup>

The objective of our study was to test a diabetes health enhancement program in an underserved population, namely, Medicaid and dual-enrolled Medicare beneficiaries with diabetes. Beneficiaries eligible under Medicaid (eg, the poor or indigent) or dually enrolled in Medicare (eligible for Medicaid and Medicare, such as the indigent and disabled) have a unique profile that is different from that of typical research participants. This article reports the recruitment challenges and success in targeting a Medicaid and dual-enrolled Medicare population.

## METHODS

### Study Setting

Individuals with diabetes enrolled in Medicaid or dually enrolled in Medicaid and Medicare residing in King County, Washington, during fiscal years 2000 and 2001 were recruited. The Washington State Institutional Review Board approved this research.

### Recruitment

Because Medicaid and Medicare protected health information is confidential, the recruitment process was divided into 2 steps, the first under the jurisdiction of

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## METHODS

the Washington State Medical Assistance Administration (MAA) and the second under the clinical trial staff. The initial eligibility screening and first subject contact were done by the MAA. The MAA used Washington State databases to identify potential subjects for the trial. The inclusion criteria were coverage under Medicaid or dual enrollment in Medicaid and Medicare for at least 1 year, a diagnosis of type 1 or type 2 diabetes for at least 1 year ( $\geq 1$  inpatient or  $\geq 2$  outpatient visits with *International Classification of Diseases, Ninth Revision, Clinical Modification* codes 250.00-250.93) or prescriptions for insulin or oral hyperglycemic medications),<sup>12</sup> aged 40 to 85 years (an age range with frequent diabetes-related complications), and residence in King County. The top 10% and bottom 10% (by reimbursements) were excluded from the potential pool of participants, as we were unlikely to change their healthcare costs.

From August 2001 to July 2002, the MAA mailed 2242 study recruitment packets to our target population. The recruitment packet included a study invitation letter, a study description flyer, an informed consent form, and a self-addressed stamped participation refusal letter. The study invitation letter was signed by the director of the MAA and described the collaboration between the MAA and the University of Washington for this clinical trial. The letter also explained that Medicaid or Medicare benefits would not be affected by volunteering for the clinical trial. Beneficiaries had 3 weeks in which to mail the MAA a letter declining participation. When no refusal letter was received, the MAA released contact information to the clinical trial staff. Invalid addresses were checked by the MAA against another Medicaid database, the Automated Client Enrollment System, for more current information. Study materials were resent to the corrected addresses.

The second recruitment step was performed by the clinical trial staff. Once a list of potential participants was received from the MAA, subjects were telephoned to explain the trial and answer any questions. Beneficiaries with no listed telephone number were sent a letter requesting that they telephone the clinical trial staff with contact information. Searches for invalid or missing telephone numbers were performed using telephone and Internet directories. Transportation assistance was provided, as needed.

Eligibility was confirmed during the first scheduled clinic visit, verifying aged 40 to 85 years, geographic proximity to the trial site, and the subject's established relationship with a fee-for-service primary care provider (to capture complete healthcare use and cost data). Exclusion criteria included kidney disease (serum creatinine level,  $>2.5$  mg/dL [ $>221$   $\mu\text{mol/L}$ ]; or dialysis),

other serious illness that would preclude 1-year participation (dementia, terminal illness, or organ transplantation), pregnancy, or inability to give informed consent. Written informed consent was obtained from each participant. A blood sample was taken for serum creatinine measurement. Participants were then randomized to a self-care intervention group or a usual care group.

Special efforts were made for the non-English-speaking participants. The MAA collects data on the primary language spoken and assigns 1 of 34 language codes. The study invitation letter and informed consent form were translated into the 15 most common non-English languages. Language-specific recruitment packets were sent. If the MAA list indicated that a subject's primary language was not English, an interpreter for the appropriate language was present when the clinical trial staff called the beneficiary about the study and for all trial visits. Ethnicity was defined by the code indicating the primary language spoken, as identified in the MAA database.

### Enrollment Survey

At enrollment, among the baseline data collected, participants were asked the following 3 questions to assess their motivation for enrolling in the trial: (1) "What is your worst problem with diabetes healthcare resources?" (2) "What is your biggest problem in controlling your diabetes?" (3) "Who is chiefly responsible for your diabetes care?"

### Statistical Analysis

Differences in groups by ethnic status and language were analyzed with the  $\chi^2$  test or Fisher exact test for dichotomous variables. Continuous variables were analyzed using the *t* test for parametric data or Wilcoxon rank sum test for nonparametric data.

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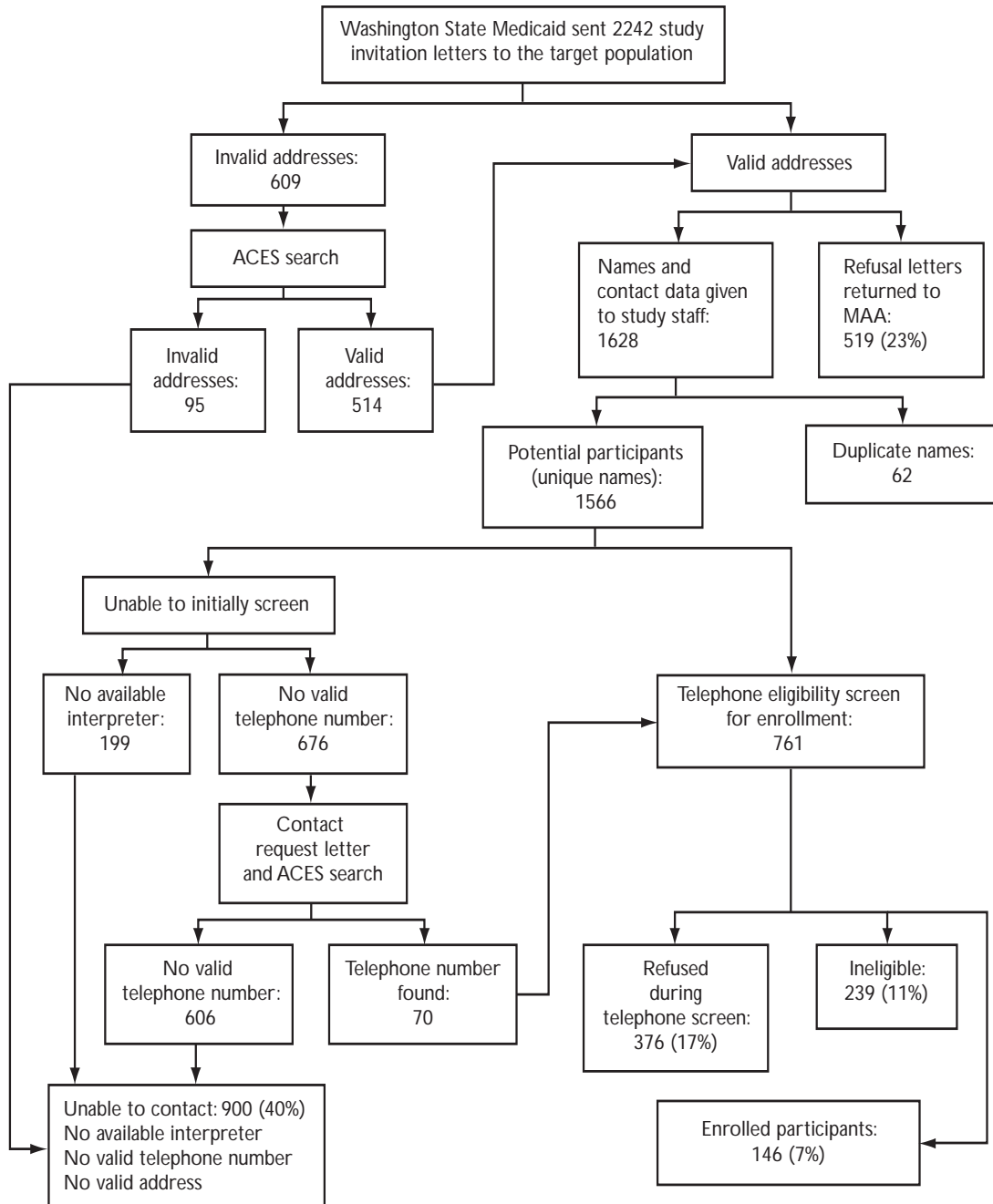
## RESULTS

### Recruitment

The results of the recruitment process are shown in the **Figure**. The MAA mailed 2242 recruitment packets to the target population. After initial screening, the MAA sent the clinical trial staff 1566 unique names of potential participants. The clinical trial staff attempted to call all participants, but no valid telephone contact information was available for 676 individuals. Mailing of letters requesting current contact information and repeated searches of Medicaid's Automated Client Enrollment System databases were done to search for valid telephone numbers. Of the initial pool of 2242 potential participants, 900 (40%) could not be contacted, 895 (40%) refused participation, 67 (3%) were duplicates, 239 (11%)

## Recruiting Beneficiaries With Diabetes Into an RCT

**Figure.** Recruitment of the Medicaid and Dual-enrolled Medicare Beneficiary Sample With Diabetes in Washington State



ACES indicates Automated Client Enrollment System; MAA, Medical Assistance Administration.

were ineligible, and 146 (7%) were enrolled in the trial. Reasons for ineligibility included major illness precluding trial participation (25%), residence outside of King County (12%), lack of current enrollment in a Medicaid fee-for-service program (11%), absence of a primary care

physician (10%), end-stage renal disease (8%), severe mental illness (7%), death (7%), age outside of the range (6%), denial of having diabetes (5%), and others (9%).

Study participants were drawn from a target population representing many ethnic groups. Of the 1566

## METHODS

**Table 1.** Enrollment Outcomes of Potential Participants by Primary Language Spoken\*

Primary Language <sup>†</sup>	Not Enrolled (n = 1420)	Enrolled		Total (n = 1566)
		Medicaid (n = 85)	Dual-enrolled Medicare (n = 61)	
English	914 (64)	55 (65) <sup>‡</sup>	50 (82)	1019
Asian	299 (21) <sup>‡</sup>	14 (16)	10 (16)	323
European	86 (6)	12 (14)	1 (2)	99
Other	121 (9)	4 (5)	0	125

\*Data are given as number (percentage).

<sup>†</sup>Asian languages included Cambodian, Chinese, Hindi, Hmong, Japanese, Korean, Laotian, Mien, Pakistani, Punjabi, Thai, and Vietnamese. European languages included Romanian, Russian, Spanish, and Ukrainian. Other languages included Amharic, Farsi, Kurdish, Persian, Somali, Tigrigna, Ilocano, Pilipino, Polynesian, Samoan, and Tagalog.

<sup>‡</sup> $P < .05$ ,  $\chi^2$  test.

potential participants, 1019 (65%) were English speaking and 547 (35%) were non-English speaking. There were 29 of the 34 possible non-English-speaking groups represented in our sample that required interpreters. The MAA could not supply interpreters for all the different languages, resulting in 157 individuals who could not be contacted because of unavailable interpreters, as well as 42 whose primary language code was “other.” As shown in **Table 1**, there were significant differences in recruitment by the major primary language groups ( $\chi^2_6 = 21.1$ ,  $P = .002$ ). Significantly fewer Asians (16%) enrolled in our trial. Enrolled Medicaid participants were more ethnically diverse than the dual-enrolled Medicare group. Significantly more Medicaid participants did not speak English (36%) compared with the dual-enrolled Medicare group (18%) ( $\chi^2_1 = 10.5$ ,  $P = .01$ ).

Of the 146 participants who enrolled in the trial, 101 (69%) were women, the mean  $\pm$  SD age was  $59.8 \pm 9.9$  years, and 41 (28%) did not speak English. From self-reported race data collected during enrollment interviews, 29% were white, 28% African American, 19% Asian, 8% Native American, and 17% “other.” Of the 146 participants, 85 (58%) were enrolled in Medicaid only, and 61 (42%) were dually enrolled in Medicaid and Medicare.

### Enrollment Motivation

We used baseline data to analyze the motivations for enrolling in our randomized clinical trial (**Table 2**). Major enrollment motivators included perceived increased access to healthcare resources, additional diabetes self-care skills instruction, and diabetes educational material in the participant’s native language. Overall, 37% of the participants reported that their pri-

mary problem with their diabetes control was lack of time with their health-care providers. Subjects believed that, by enrolling in a clinical trial, they would receive more individualized healthcare and diabetes education from the trial nurses. Only those randomized to the self-care intervention group would be offered participation in weekly support groups, additional clinic visits with the study nurse or social worker, and increased telephone visits.

For the non-English-speaking subjects, the most common problems were lack of diabetes educational material in their language, difficulties with their self-care, family obligations, and lack of money. Because the intervention arm would be provided with food pyramids, diet information, serving-size calculations, carbohydrate and calorie contents of various cultural foods in the participant’s appropriate language, and interpreters during all trial visits, access to these resources was a major motivator to enroll.

This trial focused on developing an individual’s diabetes self-care skills. Therefore, the participants were asked who they thought had chief responsibility for their diabetes care. Most English-speaking subjects (74%) believed that they were responsible for their self-care. Asians indicated that fate or God (45%,  $P < .001$ ) was chiefly responsible for their diabetes care. Europeans placed the responsibility more frequently on their physicians (69%,  $P < .001$ ) compared with the English-speaking group (17%).

## DISCUSSION

Recruitment is a challenge for most clinical trials. The most striking recruitment finding in our trial is that, despite mailings and repeated telephone calls to Medicaid beneficiaries receiving monthly financial support from the MAA, we were unable to make contact with 900 individuals (40%). Addresses for Medicaid beneficiaries changed frequently and necessitated repeated searches for valid data. Medicaid does not require a telephone number as contact information, and many Medicaid beneficiaries did not provide this information.

We successfully enrolled an ethnically diverse group of beneficiaries with diabetes. King County, which includes the city of Seattle, comprises white (75.7%), Asian (10.8%), Hispanic (5.5%), African American (5.4%), Native American (0.9%), and Pacific Islander (0.5%) ethnic groups.<sup>13</sup> Ethnicity has been found to influence healthcare utilization and involves differences in effective approaches for recruitment and participation in clinical trials.<sup>14-16</sup> In our trial, interpreter services were limited to major language groups, so some ethnic groups were excluded from screening. More than one third (35%) of the potential subjects who were recruited could not speak English, even though they had been in the United

States for at least 1 year. Interpreters were necessary for the initial telephone contact, because non-English-speaking persons typically hung up if an English-speaking person called without an interpreter to explain the purpose of the call. Enrollment of ethnically diverse subjects requires additional time during trial contacts (visits and telephone calls) when interpreters are used.

The reasons why subjects enroll in clinical trials are important to consider when designing an effective recruitment strategy. In our trial, motivations to enroll included perceived increased exposure to healthcare providers and diabetes educational material, along with the opportunity for individualized diabetes care plans. For non-English-speaking subjects, the availability of an interpreter and language-appropriate educational material was appealing. Reports of clinical trials rarely provide reasons why subjects enroll in the trials. One trial examined the reasons why older people participate in clinical trials and found that anticipated personal benefits and ongoing health monitoring were the strongest motivators.<sup>17</sup>

The strengths of our study include the collaboration of multiple agencies, a balance of Medicaid and dual-

enrolled Medicare beneficiaries, and an ethnically diverse study population from one defined geographic area. We were able to document the target population, potential participants, eligible participants, and enrolled participants, as recommended in the Consolidated Standards of Reporting Trials.<sup>18</sup> Of subjects who enroll in clinical trials, most are typically young well-educated white women.<sup>19,20</sup> One study<sup>19</sup> using mail and telephone interventions for weight control attracted mostly well-educated younger women. Typical diabetes self-management programs have recruited largely affluent, white subjects into their studies.<sup>5-10</sup> Although our enrollment rate of 7% seems low, studies<sup>21-24</sup> using mass mailings for recruitment typically only enroll participants from 1% to 7% of the letters sent.

The major recruitment limitation was the inability to contact 40% of our potential participants. Therefore, how representative our trial population is of the total Washington State Medicaid and dual-enrolled Medicare population with diabetes is not known. Of the 2 major recruitment challenges in our study, the lack of contact information reflected the Medicaid population as a whole, and the lack of an available interpreter reflected

**Table 2.** Enrollment Motivation by the Self Identified Ethnic Groups of Participants

Question	English (n = 86)	Asian* (n = 29)	European* (n = 16)
<b>What is your worst problem with diabetes healthcare resources?</b>			
Lack of time with physician or provider	41 (48)	7 (24) <sup>†</sup>	1 (6) <sup>†</sup>
Lack of educational material in my language	0	10 (35) <sup>†</sup>	9 (56) <sup>†</sup>
Lack of resources in my language	3 (4)	9 (31) <sup>†</sup>	0
Medications	2 (2)	0	0
Other	7 (8)	0	0
No problems	33 (38)	3 (10) <sup>†</sup>	6 (38)
<b>What is your biggest problem in controlling your diabetes?</b>			
Nutrition	45 (52)	5 (17) <sup>†</sup>	3 (19) <sup>†</sup>
Self-monitoring	12 (14)	3 (10)	2 (13)
Lack of money	12 (14)	4 (14)	8 (50) <sup>†</sup>
Exercise	7 (8)	2 (7)	1 (6)
Family obligations	1 (1)	11 (38) <sup>†</sup>	0
Stress	3 (4)	1 (3)	0
Other	3 (4)	2 (7)	1 (6)
No problems	3 (4)	1 (3)	1 (6)
<b>Who is chiefly responsible for your diabetes care?</b>			
Myself	64 (74)	10 (35) <sup>†</sup>	3 (19) <sup>†</sup>
My physician	15 (17)	3 (10)	11 (69) <sup>†</sup>
My family	0	3 (10)	1(6)
Fate or God	7 (8)	13 (45) <sup>†</sup>	1(6)

\*Data are given as number (percentage). The sample excludes 15 different groups.  
<sup>†</sup>P < .05 compared with the English-speaking group,  $\chi^2$  test or Fisher exact test.

## METHODS

the ethnic diversity in our Medicaid and dual-enrolled Medicare population. As already noted, Medicaid does not require a telephone number as part of the contact information for beneficiaries. Many clients may not be able to afford telephone service, or they may have non-published telephone numbers or cell phone service. If Medicaid required a telephone number and 2 contact persons (family members or friends with telephone numbers), the likelihood of maintaining contact with these individuals would be higher. Medicaid may want to revisit their contact procedures to facilitate case management and other programs. Two beneficial programs (transportation assistance and interpreters) that Medicaid provides were useful for recruiting subjects into our clinical trial. Transportation assistance was used by 67% of the enrolled subjects, and interpreters were required for 31%. Washington is one of the few states where Medicaid covers interpreters to be present during medical clinic visits. In states where the Medicaid population is ethnically diverse, similar programs would be useful.

For studies recruiting Medicaid or dual-enrolled Medicare participants, contact information may be lacking for many potential participants, and extra resources may be required, such as study staff time and transportation assistance. If the study will be drawing from an ethnically diverse population, specially adapted materials and interpreters may be needed. Our study found that, despite significant challenges, it is possible to recruit Medicaid and Medicare participants into a clinical trial.

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