

# Assessing options to increased screening for diabetic retinopathy using education, incentives, or education and incentives in a community health plan

<b>Submission date</b> 28/05/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/06/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/04/2020	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Diabetic retinopathy is a leading cause of blindness worldwide. National bodies in the United Kingdom and Australia provide guidelines on screening for diabetic retinopathy; however, no such national level screening guidelines exist in the United States. The National Committee on Quality Assurance assessed and reports on the quality of services offered by health plans in the United States, including screening for diabetic retinopathy. The purpose of this study was to increase diabetic member uptake of the retinal eye examination in compliance with NCQA HEDIS quality measures.

### Who can participate?

People insured by Sendero Health Plans who were making a claim to treat type 2 diabetes mellitus between 01/01/2017 and 31/06/2017, and who were the only household member with type 2 diabetes.

### What does the study involve?

Individuals with type 2 diabetes were assigned to one of four arms (three intervention arms and one control group) to determine if being assigned to one of these groups was associated with the individuals obtaining a medical eye exam.

### What are the possible benefits and risks of participating?

To identify what interventions are associated with obtaining a medical eye exam. In this case, we sought to determine the association

between an incentive (US\$25 gift card), education, or education plus incentive (US\$25 gift card) and obtaining the medical eye exam.

This study presented a minimal risk to the patient as this outcome of interest (medical eye exam) is a well-recognized procedure with evidence to support its use in medical practice to identify diabetic retinopathy.

Where is the study run from?  
Sendero Health Plans, Inc., Austin TX, USA.

When is the study starting and how long is it expected to run for?  
September to October 2017

Who is funding the study?  
Sendero Health Plans, Inc.

Who is the main contact?  
Dr John Litaker,  
jlitaker@litakergroup.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr John Litaker

**ORCID ID**  
<https://orcid.org/0000-0002-1867-1799>

**Contact details**  
P.O. Box 160505  
Austin, Texas  
United States of America  
78716  
1-512-804-5545  
jlitaker@litakergroup.com

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
2016F-09-05

## Study information

**Scientific Title**  
A multi-armed intervention trial to increase diabetic retinopathy screening by a community-based health insurance plan in Central Texas

**Study objectives**

H1: A person's decision to obtain a retinal eye exam is dependent of whether or not they receive any cue to action (education only or incentive only, or both education and incentive) or no cue to action (control)

H2: A person's decision to obtain a retinal eye exam is dependent of the type of cue to action received, including no cue to action, education only, incentive only, or both education and incentive

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 13/07/2017, Aspire Institutional Review Board (11491 Woodside Avenue, Santee, California 9207, USA; 619-469-0108; email@aspire-irb.com), ref: 2016F-09-05.

### **Study design**

Interventional randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Diabetic Retinopathy

### **Interventions**

The purpose of this study was to increase diabetic member uptake of the retinal eye examination in compliance with NCQA HEDIS quality measures. Specifically, we conducted a multi-armed intervention trial designed to assess member uptake of the annual retinal eye examination in one of four groups: (1) a control group with no intervention; (2) a monetary incentive group that received a \$25 gift card after completion of the examination; (3) a patient education material only group; and (4) a group that received both patient education material and a \$25 gift card after completion of the examination.

Sendero members were eligible to participate in this trial if they had a medical claim for type 2 diabetes or a medication claim used to treat

type 2 diabetes from January 1 through June 30, 2017. Excluding individuals who had already obtained a retinal eye exam through June 30, 2017 and excluding members who had ongoing, active management for ocular complications associated with diabetes mellitus, 1,648 individuals with medical claims for type 2 diabetes were identified. Of these members, 1,459 lived in a household with only one person diagnosed with diabetes. Single member households were chosen as the unit of analysis to prevent cross-contamination among additional household members who may have type 2 diabetes, but who may have been assigned to a different intervention group or to the control group.

Incentive group:

a. Outreach letter to members with diabetes offering a US\$25 gift card for completing the medical eye examination by a specific date

b. A list of Sendero providers who can perform these exams.

Education group:

- a. Outreach letter to members with diabetes to encourage them to obtain a medical eye exam by a specific date
- b. Educational material related to diabetes with a checklist of preventive care related to diabetes
- c. A list of Sendero providers who can perform these exams

#### Education and Incentive:

- a. Outreach letter to members with diabetes offering a US\$25 gift card for completing the medical eye examination by a specific date
- b. Educational material related to diabetes with a checklist of preventive related to diabetes
- c. A list of Sendero providers who can perform these exams.

Control group: No contact or information related to this clinical trial was provided to these individuals.

#### Randomization Process:

- Power analysis indicated that the control group should be twice the size of the individual intervention groups<sup>2</sup>
- Each individual was randomly assigned (using a random number generator) a number 1 through 5.
- The numbers 1 through 5 were randomly selected and assigned to the groups as follows:
  - o Control Group: Assigned groups 1 and 4 (to account for the power analysis calculation that advised the control group should have twice as many cases as the intervention groups)
  - o Incentive Only Group: Assigned group 5
  - o Education Only Group: Assigned group 3
  - o Incentive + Education Group: Assigned group 2

### Intervention Type

Behavioural

### Primary outcome(s)

Members who obtained a retinal eye exam from either an ophthalmologist or optometrist were deemed to have completed a retinal eye exam based solely on CPT codes 92004, 92012, and 92014, in accordance with US Centers for Medicare and Medicaid Services Quality Rating System technical specifications. Non-eye care providers must have also provided either a category two CPT code or a HCPCS code to indicate retinal examination occurred (2022F, 2024F, 2026F, and 3072F).

Method of Measurement: CPT codes were obtained by SQL query of medical claims processed by Sendero Health Plans, Inc. based on member identification number

Timepoint: CPT claims status was obtained based on a date of claim that occurred from September 19, 2017 to October 31, 2017 (the study period). Providers have up to 90 days to submit a claim after the date of service. In accordance with end of year activities, we ran the SQL query after March 31, 2018 to account for any claims that occurred during the September 19, 2017 - October 31, 2017 time period.

### Key secondary outcome(s)

none

### Completion date

31/10/2017

## Eligibility

### Key inclusion criteria

1. Insured by Sendero Health Plans in the IdealCare line of business during the calendar year 2017
2. Medical claim for type 2 diabetes or a medication claim used to treat type 2 diabetes mellitus from January 1 through June 30, 2017
3. Live in a household that only had one person diagnosed with type 2 diabetes mellitus

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

1454

**Key exclusion criteria**

1. Individuals who had already obtained a retinal eye exam through June 30, 2017 and excluding members who had ongoing, active management for ocular complications associated with type 2 diabetes mellitus.

**Date of first enrolment**

19/09/2017

**Date of final enrolment**

31/10/2017

**Locations****Countries of recruitment**

United States of America

**Study participating centre**

**Sendero Health Plans, Inc.**

2028 E Ben White Blvd #400

Austin

United States of America

78741

**Sponsor information**

**Organisation**

Sendero Health Plans

**ROR**

<https://ror.org/02syt4h28>

**Funder(s)****Funder type**

Charity

**Funder Name**

Sendero Health Plans, Inc.

**Results and Publications****Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to:

- This data, will de-identified, is considered personal health information
- At this time, we do not know if we are able to release the final data set due to federal privacy regulations regarding personal health information (i.e., the US Health Insurance Portability and Accountability Act of 1996)
- Individual requests for the data set are welcomed (and encouraged) and will be considered on a case by case basis
- At a minimum, any agreement to release data would be by Sendero Health Plans, Inc. and would require a signed business associate agreement outlining data protection steps, confidentiality, and how data will be used
- All decisions relating to the release of data are at the discretion of Sendero Health Plans and in compliance with applicable rules, regulations, and statute

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2020	07/04/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes