Grant Final Report

Grant ID: R18HS17031

Feedback of Intensifying Treatment (FIT) Data to Reduce Cardiovascular Disease

Inclusive Dates: 09/01/07 - 08/31/10

Principal Investigator:
Joe V. Selby, MD, MPH

Team Members:
Julie A. Schmittdiel, PhD
John Hsu, MD, MBA, MSCE
Bruce Fireman, MA
Marc Jaffe, MD

Performing Organization:
Kaiser Foundation Research Institute, a Division of Kaiser Foundation Hospitals

Project Officer:
Amy Helwig

Submitted to:
The Agency for Healthcare Research and Quality (AHRQ)
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Abstract

Purpose: The Intensification and Feedback of Outcomes (INFO) to Reduce Cardiovascular Disease" Study seeks to determine whether information on the need for treatment intensification in patients at high risk for CVD, when provided to population care management staff through health IT platforms, can improve quality and outcomes of care.

Scope: INFO was a cluster randomized control trial that took place within 9 medical facilities at Kaiser Permanente Northern California (KPNC), in a population of more than 65,000 patients at high risk for CVD.

Methods: The study's six-month intervention, which occurred between July 1, 2008 and January 8, 2009, incorporated new patient-level information on the need for treatment intensification into the population management software (Panel Management Tool or PMT) used by population care management outreach staff at the facilities.

Results: Adjusted treatment intensification rates for patients with elevated SBP and LDL levels differed somewhat in favor of the intervention facilities, proportions of patients who were in control of risk factor values were similar (or slightly favored the control sites) at the end of the follow-up period. Modified INFO-type flags for the need for treatment intensification, as well as denoting patient medication adherence, are now in use across the KPNC region.

Key Words: health IT; treatment intensification; clinical inertia; practice-based implementation research

Final Report

Purpose

The "Intensification and Feedback of Outcomes (INFO) to Reduce Cardiovascular Disease" Study addressed the following Specific Aims:

> **Changes in Treatment Intensification and in Physiologic Outcome Levels:** Evaluate the effectiveness of feeding back information on the need for treatment intensification to PHASE program staff for improving rates of treatment intensification and for reducing levels of poorly controlled SBP, LDL-c, and A1c.
>
> **Program Efficiency in Changing Physiologic Outcomes:** Evaluate the impact of the intervention, compared to current population management practice, on total numbers of patient contacts, outpatient visits, and costs of care in relation to improvements in risk factor control.
>
> **Work Force Acceptance:** Evaluate the effect of this innovation on physician and staff perceptions of the value (effectiveness and efficiency) of the population management program for high risk patients.

Scope

INFO is a cluster randomized trial involving 9 medical facilities of Kaiser Permanente Northern California (KP) and more than 65,000 patients from a pre-defined population at high risk for cardiovascular disease (CVD) called PHASE (Preventing Heart Attacks and Strokes Every day). The PHASE population management program uses nurses, clinical pharmacists and medical assistants in each facility to support primary care in managing CVD risk factors for high risk patients. The study's six-month intervention, which occurred between July 1, 2008 and January 8, 2009, incorporated new patient-level information on the need for treatment intensification into the population management software (Panel Management Tool or PMT) currently used by PHASE staff. Using data available through KP's electronic health record, the study's researchers and programmer/analysts identified PHASE patients in need of treatment intensification for systolic blood pressure (SBP), LDL-cholesterol (LDL-c) or hemoglobin A1c (A1c), if diabetic. This information was provided to the intervention facilities through the PMT, and was focused on patients who were in good adherence to their current medication regimens (as determined through pharmacy databases), since these patients were considered to be the best candidates for treatment intensification.

Methods

A total of five sites were randomized to the intervention arm in the first year of the study. One of the sites experienced personnel changes which prohibited them from fully participating in the intervention, leaving four intervention centers in KP. The four centers randomized to the control arm continued their usual PHASE activities during the intervention period. Patients identified as candidates for treatment intensification were prioritized in the PMT database based on the expected clinical benefit of CVD risk factor improvement as follows:

1. SBP > 140
2. LDL-c > 130
3. A1c > 9
4. SBP > 130
5. LDL-c > 100
6. A1c > 8

The six-month follow-up period for the intervention ended on July 8, 2009.

Results

The data analysis from the study has been completed. While participation in the study was randomized at the site level, some patient characteristics such as race/ethnicity were not balanced between the intervention and control sites. Multivariate analyses which controlled for these patient-level differences were used to assess whether treatment intensification and control rates differed between the patient and control arms. While adjusted treatment intensification rates for patients with elevated SBP (Priority 1) and LDL (Priority 2) levels differed somewhat in favor of the intervention facilities, proportions of patients who were in control of risk factor values were similar (or slightly favored the control sites) at the end of the follow-up period. Because the intervention overall had minimal impact on outcomes, a full cost-benefit analyses of the intervention was not undertaken.

Table 1. Patient Characteristics

	Study	Control	Overall	P-value
N	16,584	13,423	30,007	
Mean Age	61	60	60	<.0001
% Female	49.9	51.8	50.8	<.0001
Race/Ethnicity				
% Asian/PI	9.0	12.3	10.5	<.0001
% Black	6.1	16.2	10.6	<.0001
% Hispanic	9.8	12.6	11.0	<.0001
% Native American	1.3	1.3	1.3	0.97
% White	62.0	44.4	54.1	<.0001

	Study	Control	Overall	P-value
% Missing Race	8.9	11.0	9.9	<.0001
Comorbidities				
Mean Number of Comorbidities*	1.23	1.25	1.24	0.01
Has Diabetes (%)	77.5	80.4	78.8	<.0001
Current Smoker (%)	8.9	9.0	9.0	0.77
Mean Risk Factor Values at Baseline**				
Systolic Blood Pressure	131	132	132	0.18
A1c	7.3	7.3	7.3	0.13
LDL	100	98	99	<.0001
Risk Factor Control at Baseline (%)				
SBP<140	74.6	73.2	74.0	0.01
SBP<130	48.3	48.1	48.2	0.68
LDL<130	82.8	84.2	83.4	<.0001
LDL<100	55.4	57.7	56.4	<.0001
A1c<9	87.2	86.5	86.9	0.09
A1c<7	49.7	49.0	49.4	0.27
Mean Number of Medication Classes at Baseline				
Blood Pressure Medications	1.74	1.82	1.77	<.0001
Diabetes Medications	0.95	0.99	0.97	<.0001
Dyslipidemia Medications	0.70	0.70	0.70	0.35
On Max Med Therapy at Baseline (%)				
Simvastatin/Atorvastatin 80mg	12.3	13.8	13.0	<.0001
3 or more Blood Pressure Meds	27.8	31.0	29.2	<.0001
Insulin, if has diabetes	20.0	20.5	20.2	0.38
Mean Number of Primary Care Visits***				
During 6 Months Prior to Intervention	2.85	3.36	3.08	<.0001
Visit Type = Blood Pressure Check	0.21	0.18	0.19	<.0001
During 6 Months Since First Eligible	2.97	3.53	3.23	<.0001
Visit Type = Blood Pressure Check	0.29	0.27	0.28	0.05

* Comorbidity count based on whether patient is flagged in the Population Management Tool as being in these populations: abdominal aortic aneurism, coronary artery disease, chronic kidney disease, diabetes, peripheral artery disease, and stroke.
** 99% had a baseline blood pressure, 96% had a baseline LDL, and 82% had a baseline A1c.
*** Includes visits to these departments: Family Practice, General Medicine, and Internal Medicine.

Table 2. Treatment intensification rates (adjusted) within 3 months[‡]

	Control		Study		
Priority Category	Number in Priority Category	% Intensified	Number in Priority Category	% Intensified	P-Value
1: SBP ≥ 140	2,905	30.6	3,080	34.1	<.0001
2: LDL ≥ 130	1,789	22.7	2,431	28.0	<.0001
3: A1c ≥ 9%	1,059	28.8	1,318	29.5	0.70
4: SBP ≥ 130[†]	3,583	22.0	3,878	22.9	0.34
5: LDL 100-129	3,526	19.1	4,876	20.5	0.12
6. A1c 7-8.9%	3,007	26.9	3,750	26.3	0.57

[‡] Reference date is the first time a patient meets the criteria for the priority category.
Definition of treatment intensification: a) increase in the number of drug classes; b) increase in daily dosage of an ongoing medication; c) switch to a medication in the same class with an increase in bioequivalent dose category (low/med/high).

Table 3. Proportions in control* of cardiovascular disease risk factors (adjusted)

		Control		Study		
Priority Category	Definition of Control	Number in Priority Category	% in Control	Number in Priority Category	% in Control	P-Value
1: SBP ≥ 140	<140	2,905	60.0	3,080	59.9	0.94
2: LDL ≥ 130	<130	1,789	44.8	2,431	41.3	0.02
3: A1c ≥ 9%	<9	1,059	48.2	1,318	44.6	0.08
4: SBP ≥ 130	<130	3,583	51.1	3,878	46.4	<.0001
5: LDL 100-129	<100	3,526	44.3	4,876	43.0	0.21
6. A1c 7-8.9%	<7	3,007	26.3	3,750	24.5	0.09

*Control based on most recent systolic blood pressure, A1c, and LDL as of the last day of follow-up (July 8, 2009). Patients without a measurement or test since meeting the criteria for the priority category are considered to be out of control.

This intervention study was designed and implemented in close collaboration with PHASE leaders and staff and integrated into the ongoing program at intervention sites. Our qualitative assessment of the intervention showed that study facilities would be more willing to use INFO-type variables in population outreach, and that their use would be more effective, if treatment intensification flags were created in a more timely fashion and if patient-level adherence data were also provided. The study team worked closely with operational leaders to update these flags accordingly, and as of July 31, 2009, all KP facilities within the region have had access to updated adherence and treatment intensification flags on all PHASE patients to use toward improving their CVD risk factor management programs. In the fall of 2009 and early 2010, the study team hosted a series of Webinars designed to train population care management teams at KPNC facilities in using these variables. A follow-up survey of facilities and operational leaders suggests that a small but growing number of facilities have used these INFO-inspired flags in their operations, and that this use is likely to increase as KP places more of an emphasis on improving medication adherence as a PHASE program goal.

List of Publications and Products

Dr. Selby is currently writing a manuscript which summarizes the study's translational research methods and findings.