From Evidence to Outcomes: Implementing Clinically Effective and Cost-Efficient Population-Based Interventions

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Kaiser Permanente (KP) is well recognized as an innovator and industry leader in providing cost-effective, population-based, and preventive care for its members. These same principles are reflected also in the goals and strategies of KP's National Diabetes Program. The goal of the Care Management Institute's National Diabetes Program is to provide high-quality, cost-effective, and evidence-based care to reduce morbidity and mortality in members with diabetes. However, when this goal is competing with other short-range targets and resource requests, it often becomes challenging to implement. Maintaining focus on this larger goal is especially crucial when translating evidence into practice. Although the National Diabetes Program's evidence-based guidelines cover a broad scope from prevention of diabetes to screening to self-management, these guidelines must be prioritized and translated into cost-effective programs and initiatives that lead to improved clinical outcomes.

As one of KP's oldest care management programs, the diabetes program has gone through many changes. In the process, the program has focused on a few important principles for identifying priority goals:

- Implement programs that move toward decreasing morbidity, decreasing mortality, and saving money.
- Use evidence as the foundation of the work.
- Assess program effectiveness, either by using simulation modeling or by analyzing real-world impact.
- Continually reevaluate the program, adjust it, and implement it again.

In its history, the diabetes program has undergone three cycles of change. With its successes and failures, each cycle demonstrates how following all four of these principles can ultimately lead to successful programs.

1. Expert Opinion: In the first cycle, programs were developed solely on the basis of expert opinion but with limited success.
2. Risk Stratification and Testing: In the second cycle, evidence-based medicine (EBM) was subsequently incorporated, but a lack of focus on clinical outcomes led to suboptimal results.
3. Outcomes Focus: Finally, in the third cycle, EBM was incorporated into an outcomes-focused program; modeling predicts that this will lead to an improvement in outcomes and significant cost savings for the organization.

Cycle 1: Expert Opinion Leads to an Unsuccessful Lipid Program

In the 1980s and before EBM was widely adopted, research from KP Northwest and the KP Northern California Regions suggested that cardiovascular disease was the biggest cause of morbidity and mortality in patients with diabetes. There was some evidence that lowering cholesterol (with niacin and lovastatin) decreased cardiovascular disease (CVD), and thus the logical next step was the creation of a cost-effective lipid-lowering program for all members.

This program was based on expert opinion and included the following characteristics:

- Using niacin instead of lovastatin in order to save $1000/pt/year on drug costs
- Using nurse practitioners (NPs) instead of MDs to save 50% of the cost of physician visits
- Tracking lipid values every three months to find patients who discontinued therapy (recividism was high, and no electronic medication tracking was available)
- Targeting and treating everyone who came to the doctor and requested treatment.

However, when the program was implemented, simulation modeling by Archimedes[a] revealed significant deficiencies:

- The program did not have clinically significant benefit; due to lack of risk stratification, too few events were saved, and titration of niacin was difficult.
- The program was not cost saving; "Treating those who came" resulted in treating too many low-risk patients, and the savings from use of NPs was outweighed by the costs of laboratory testing every three months.

Cycle 2: EBM is Used, but a Lack of Focus on Clinical Outcomes Results in a Risk Stratification Testing Program

In cycle 2, the focus shifted toward treating higher-risk patients. Because evidence showed that lipid and microalbumin testing could identify patients at high risk for CVD, emphasis was placed on testing lipids and microalbumin to find the highest-risk patients. An underlying assumption was that identified patients would be given appropriate treatment.

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The results were disappointing; the number of CVD events did not drop because focus was placed on intermediate outcomes instead of decreasing CVD. For example, the first identified target was lowering lipids via treatment with a statin drug. However, treating with a single drug like statin was insufficient to decrease CVD and was more expensive but no more effective than aspirin. Similarly, a focus on increased lipid and microalbumin testing led to 80% testing rates but not to a significant drop in CVD prevalence. Testing and identifying appropriate candidates did not automatically result in an increase in treatments that lower CVD prevalence. It was necessary to revisit the original goal and remodel the treatment strategy.

Cycle 3: An Evidence-Based, Outcomes-Focused Program Provides Promise for Success

In cycle 3, emphasis was shifted to creating an evidence-based program that focused on decreasing the number of CVD events. Systematic reviews of the evidence revealed that aspirin, statin drugs, and ACE-inhibitors[1-5] decreased CVD events and mortality in diabetic patients older than 40 or 55 years and in all patients with CAD. Based on this evidence, several KP regions implemented programs to increase the use of some or all of these medications in these populations. Armed with regional precedent, strong evidence, and the cost advantage of lovastatin becoming generic, the national Aspirin, Lisinopril, Lovastatin (ALL) initiative was launched in 2004 to promote use of all three medications in all patients with CAD and in diabetic patients who were older than 55 years. It appeared to be an effective and simple program to decrease mortality and CVD events in patients with CAD and in patients with diabetes.

Initial predictions for the ALL program look promising. The Archimedes model demonstrates that treating all patients with CAD and diabetic patients over age 55 years with aspirin, lisinopril, and lovastatin decreases CVD events by 71% and will lead to a cost *savings*, averaging $600 per patient per year. In addition, the STENO-II trial[5]—a multifactorial intervention aimed at treatment of diabetes and CV risk factors and which included treatment with ACE-inhibitors, aspirin, and statin drugs—led to a 50% relative risk reduction in CVD events in proteinuric diabetes patients older than 55 years.

Summary

Within three quality improvement cycles, KP has migrated from interventions based primarily on expert opinion to those driven by outcomes and clinical evidence; and from interventions with small impact and significant cost to those with large impact and significant savings. Although programs varied in effectiveness, these experiences provide important insights for each subsequent quality improvement cycle:

- Keep focus on the big goal: mortality, morbidity, and cost-effectiveness.
- Use evidence as the basis of your program.
- Make an effort to model your program and to assess real-world impact.
- Continually reevaluate, adjust, and reimplement the program. ❖

[a] Archimedes is a powerful computer simulation model which creates a "virtual world" of patients and clinicians for real clinicians to study. The model includes all the details—such as patient behaviors, risk factors and conditions—necessary for clinicians to develop best practices for treating a variety of diseases. For more information, see: Eddy DM, Schlessinger L. Archimedes: a trial-validated model of diabetes. Diabetes Care 2003 Nov;26(11):3093-101. Eddy DM, Schlessinger L. Validation of the Archimedes diabetes model. Diabetes Care 2003 Nov;26(11):3102-10.

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Self-Respect

No man who is occupied in doing a very difficult thing,
and doing it very well, ever loses his self-respect.

— George Bernard Shaw, 1856-1950, Irish playwright