

Bundling 2 low-cost heart drugs prevents heart attack and stroke in large, diverse population

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A program that bundled two generic, low-cost drugs - a cholesterol-lowering statin and a blood pressure-lowering drug - and gave daily doses to 68,560 people with diabetes or heart disease for two years is estimated to have prevented 1,271 heart attacks and strokes in the first year following the study period, according to a Kaiser Permanente study published online in the *American Journal of Managed Care*.

Kaiser Permanente developed the ALL initiative (Aspirin, Lisinopril and Lipid-Lowering Medication) in 2003 to reduce heart attacks and strokes by aggressively enrolling patients with heart disease or patients over 55 with diabetes in a therapeutic program that included the use of a triad of medications: low-dose aspirin, lovastatin and lisinopril.

The three-year clinical observational study found that offering 40 milligrams of lovastatin and 20 milligrams of lisinopril daily for two years to people not already on both drugs reduced their risk of hospitalization for [heart attack](#) or stroke the following year by more than 60 percent. Aspirin was not part of the study because it was over-the-counter and its use could not be measured through pharmacy records. However, it was separately estimated that 75 percent of study participants were already taking aspirin. The study was conducted by Kaiser Permanente's Care Management Institute in Oakland, Calif., which synthesizes knowledge on the best clinical practices to develop evidence-based care programs at Kaiser Permanente.

While previous research and clinical trials have shown that statins and angiotensin-converting enzyme inhibitors / angiotensin receptor blockers (ACE-I/ARB) individually reduce heart attacks and strokes, this is the first study to evaluate whether a consistent process could be developed to deliver the combined drugs to large numbers of people with diabetes and/or heart disease in realistic settings across a health care delivery system. It is also the first study to evaluate how dramatically this program would affect clinical outcomes and hospitalization rates for heart attack and stroke.

The study followed 170,024 ethnically diverse Kaiser Permanente members in California with heart disease and/or diabetes for two years during the medication phase and for one year during the outcome monitoring phase. The study cohort was broken into three groups: 21,292 members in the high-exposure group who took the bundled drugs more than half of the time in 2004 and 2005 based on their prescription refill habits; a low-exposure group of 47,268 people who took the drug bundle less than half of the time during 2004 and 2005 based on their prescription refill habits, and a no-exposure group of 101,464 people who either took neither or just one type of the two tracked drugs during 2004 and 2005.

The researchers found that among the study population as a whole, there were 21 heart attacks and strokes per 1,000 people in 2006. Among the 47,268 people in the group that had low exposure to the drugs, there were 726 fewer heart attacks and strokes than in the no exposure group, equivalent to a reduction of 15 heart attacks and strokes per 1,000 people. Among the 21,292 people in the high- exposure group, there were 545 fewer heart attacks and strokes, equivalent to a reduction of 26 heart attacks and strokes per 1,000 people. The study estimated this effect to be a 60 percent savings of these events.

"Heart disease is the number one killer in the United States, and 23

million Americans have diabetes. This is a proven program that can be applied in many settings to reduce heart attacks and strokes, and at the same time decrease the cost of care for those events," said the study's lead author, R. James Dudl, MD, the diabetes clinical lead at Kaiser Permanente's Care Management Institute.

These findings validate the forecasts of the Archimedes Model. The Archimedes Model simulated the pathophysiology, treatments, and outcomes of coronary artery disease and diabetes and its complications at the individual level and aggregated the results to project population-level effects. The model forecasted that "bundled" cardioprotective medications aspirin, lisinopril, and lovastatin would reduce the risk of heart attack and stroke in a high-risk population by 71 percent. In 2002 Kaiser Permanente researchers used the Archimedes Model to project the effects of offering the combined pharmacotherapy and to develop a simple, inexpensive method for delivering it.

The Kaiser Permanente researchers conducted this observational study of its drug-bundling program as a clinical execution of the Archimedes modeling because the simulation model outcomes looked so promising, researchers said.

"The program's results confirm the Archimedes Model's predictions that these treatments can save lives and reduce health care costs," said David Eddy, MD, Ph.D., founder and chief medical officer emeritus of Archimedes, Inc.

Currently more than 256,000 Kaiser Permanente members in Hawaii, California, Oregon, Washington, Colorado, Ohio, Georgia, Maryland, Virginia, and Washington, D.C. are participating in the drug medication bundle program. Clinicians use Kaiser Permanente HealthConnect®, the world's largest civilian electronic health records system, to find high-risk patients not already on the medications and use the health provider's

integrated delivery system to reach out to eligible members at every point of care.

As an example of how this program can be widely implemented in diverse populations and health care settings, this initiative has also been applied in community health centers through Kaiser Permanente's community benefit program. In underserved populations with varying levels of health literacy, the number of patients taking the bundle increased fourfold within a 12-month period.

"We have long known from clinical trials that aspirin, cholesterol-lowering therapies such as statins, and ACE inhibitors such as lisinopril reduce the risk of future heart attacks and strokes in patients who have had a prior cardiovascular event or who have diabetes. Our primary goal here was to increase the use of the drugs," said study co-author Jim Bellows, Ph.D., Kaiser Permanente Care Management Institute's director of the Center for Evaluation and Innovation. Bellows helped develop the evaluation of the program to bundle and deliver the two medications.

Source: Kaiser Permanente ([news](#) : [web](#))

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