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The doughnut hole: it's about medication adherence

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The Medicare Prescription Drug, Improvement, and Modernization Act went into effect on January 1, 2006. Part of this act was the creation of Medicare Part D, a federal program to subsidize the costs of prescription drugs for Medicare beneficiaries. In 2006, the plan required beneficiaries whose total drug costs exceeded \$2,250 a year to pay 100% of prescription costs until they reached catastrophic coverage (and spent \$5,100 on medications out of pocket). This coverage gap is well known among Medicare beneficiaries as the “doughnut hole.” Once the patient spends \$5,100 per year in out of pocket costs, the “hole” closes and all medication expenses above that amount are covered. An exception to the coverage gap exists among beneficiaries with income below 150% of poverty level, who are eligible for the low-income subsidy (LIS). LIS pays for all or part of the monthly premium, annual deductible, and drug co-payments.

Many patients who fall in the “doughnut hole” try to save money by cutting back on their blood pressure, and cholesterol medications, increasing the risk of cardiovascular disease and suboptimal outcomes. A number of studies have demonstrated that up to 1/3 of older adults take less medication than prescribed to avoid costs, also termed cost related non-adherence.(1-3) The cost of the medication is an important predictor of cost related non adherence, regardless of whether the patient has insurance.(4)

Medication adherence behavior has been divided into 2 concepts, adherence and persistence. Although conceptually similar, adherence refers to the use of the medication as intended, whereas persistence refers to the maintenance of the medication over a period of time or duration. Medication adherence and persistence are growing concerns to clinicians and payers because of the mounting evidence that medication non-adherence is associated with worse clinical outcomes and higher costs of care, particularly among those with cardiovascular disease.(5-7)

In this issue of *Annals*, Li and colleagues (ref) sought to determine the magnitude of the impact of the Medicare “doughnut hole” on coverage for antihypertensive and lipid lowering medications. They postulated that these medications are used to treat asymptomatic cardiovascular conditions and may be prone to cost related non adherence during the

coverage gap. They studied 4 insurance groups of Medicare beneficiaries who had hypertension or hyperlipidemia. Group 1 had LIS (no out of pocket medication costs); group 2 had generic medication coverage during the gap (out of pocket brand medications costs during gap); group 3 had generic and brand coverage during the gap period (no out of pocket medication costs during gap); and group 4 had no medication coverage during the gap period, (all out of pocket medication costs during gap).

The authors found that once patients entered the doughnut hole and had to pay out of pocket (group 4) there was a decline in the number of antihypertensive or lipid lowering medication prescriptions per patient compared with similar patients who did not have a coverage gap because of LIS (group 1). This difference in coverage was associated with an increased risk of non adherence and non persistence of cardiovascular medications. The results were similar among patients at the highest risk for cardiovascular outcomes, including those with diabetes, coronary heart disease and stroke. Interestingly, the presence of a commercial insurance plan which covered generic prescriptions during the “doughnut hole” time period (group 2) did not mitigate these effects. Among patients who had a Medicare Part D plan that had generic and brand coverage (group 3) during a gap period, the risk of non adherence was similar to those with LIS (or essentially no decline in adherence). They also demonstrated that this “gap effect” or decline in the number of prescriptions did not occur for medications which treat symptoms (such as pain relievers).

While Li and colleagues studied the effects of the coverage gap on non-adherence, they did not determine the effect on patient outcomes. Many observational studies have evaluated the association between medication adherence and outcomes. Non-adherence to cardiovascular medications has been associated with increased risk of morbidity and mortality.(7) For example, non-adherence to statins in the year after hospitalization for myocardial infarction was associated with a 12% to 25% increased risk for mortality.(8, 9) Among those with coronary disease, non adherence to cardiovascular medications is common(10, 11) and associated with a 10% to 40% relative increase in risk of hospitalizations and a 50% relative increase in risk of mortality.(12)

Clinicians understand that non adherence contributes to poor blood pressure and cholesterol control. Observational studies have also demonstrated that non adherence is associated with worse clinical outcomes. So what is the solution? Li and colleagues propose a multi-factorial approach by all stakeholders including clinicians, pharmacists, health plans and government agencies. This approach should help patients identify and adopt low cost alternatives (including generics) to maintain adherence. Patients will rarely change medications to a less costly option once they are in the “doughnut hole,” rather; they often split their existing medications or just stop filling the costliest medications. This phenomenon may explain why in the study by Li et al. (ref) those patients in group 2, who had generic medication coverage, still became non adherent. If patients initiated generic medications wouldn't fewer people get into the gap?

It also is imperative that government agencies are part of the solution. While the original purpose of instituting the gap was to limit the cost of the Part D program, it has resulted in unintentional consequences.(13, 14) In fact, a recent study indicates that Medicare Part D

beneficiaries have an overall **decrease** in the use of generic medications.(15) As part of the design of the Medicare Part D program, the federal government is not permitted to negotiate prices of drugs, and as a result the Centers for Medicare and Medicaid services (CMS) does not have an established formulary.(16) Medications that appear on a preferred list for one formulary may appear as a tier 2 or 3 medication on another formulary. This variation leads to confusion among physicians, pharmacists and beneficiaries and has the potential to lead to suboptimal care. Veterans Health Administration (VHA) is allowed to negotiate drug prices and establish a formulary, and as a result VHA pays on average 56 to 63 percent of the prices paid by Medicare for medications. The VHA's national formulary covers about 59% of the top 200 drugs prescribed, while the average Medicare part D plan covers about 85% of those 200 drugs. A recent economic analysis (17) evaluated the "loss of consumer surplus" or the ability to choose among a variety of medications available on a typical Medicare plan to a formulary similar in structure to that found in VHA. The authors found that Medicare plans could reduce all costs by 40% by switching to a VHA-like formulary, and Medicare could save up to \$510 per non-LIS enrollee per year. According to a number of estimates this is an annual cost savings of between \$14 billion and \$21.9 billion per year. (17, 18) Eight out of the 10 most commonly prescribed drugs to seniors are antihypertensive and lipid lowering medications. Even small changes such as substitution of the 10 most commonly prescribed drugs within the VHA formulary or substitution of a generic whenever one is available would lead to a projected cost savings of \$5.9 billion annually.(18, 19) This cost savings should obviously not reduce the quality of care provided for patients. Performance for certain conditions including diabetes, hyperlipidemia, and hypertension among a sample of patients seen at VHA exceeded care provided for patients in a national sample who received care in the private sector.(20)

The cost of healthcare is increasing and the projected net expenditures for the Part D program from 2009 through 2018 are estimated to be \$727.3 billion. Small changes which would promote more generic prescribing and achieve a more consistent approach among the Medicare Part D plan formularies could result in not only large cost savings to Medicare but also less cost related non adherence and subsequent improvement in health of Medicare beneficiaries.

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