How Do Seniors Respond to 100% Cost-Sharing for Prescription Drugs?
Quality of the Evidence Underlying Opinions About the Medicare Part D Coverage Gap

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A September 2008 New York Times editorial described as “very troubling” the results of a Kaiser Family Foundation/National Opinion Research Center (KFF/NORC) study of the coverage gap in Medicare Part D.1,2 Described in the editorial as “notorious,” the gap was triggered when a beneficiary’s total drug costs exceeded $2,400, requiring the beneficiary to pay 100% of drug costs until reaching a catastrophic coverage threshold of $5,451 in total drug costs (2007 thresholds).2 In a standard prescription drug plan (PDP) for an average annual premium of $328, the beneficiary’s share of total drug cost up to the $2,400 threshold was 25% after a $265 deductible (i.e., approximately $800 of a total $2,400 drug cost). After the catastrophic coverage level was reached, the beneficiary paid about 5% of total drug cost.2

As described in the Times editorial, the findings of the KFF/NORC study certainly seemed to merit concern about how the gap affected the health of Medicare beneficiaries: “15% of the beneficiaries taking drugs in [8] categories said they stopped taking their medications when they reached the gap. Another 1% reduced their use by skipping doses, and 5% switched to another drug that was cheaper but might or might not be as effective.” The health consequences of these behaviors, the editorial opined, could be “immediate and serious” for patients with diabetes and longer-term “but still … serious” for those treated for high cholesterol or osteoporosis.1

The editorial was marred by an important inaccuracy: the beneficiaries in the KFF/NORC study certainly seemed to merit concern about how the gap affected the health of Medicare beneficiaries: “15% of the beneficiaries taking drugs in [8] categories said they stopped taking their medications when they reached the gap. Another 1% reduced their use by skipping doses, and 5% switched to another drug that was cheaper but might or might not be as effective.” The health consequences of these behaviors, the editorial opined, could be “immediate and serious” for patients with diabetes and longer-term “but still … serious” for those treated for high cholesterol or osteoporosis.1

You Can’t Assess What You Didn’t Measure: The “Problems” of Inexpensive Generic Drug Availability and Shopping for the Best Price

Like many studies of the coverage gap,3-7 the KFF/NORC study was based on analyses of beneficiaries’ pharmacy claims activity before versus after reaching the total drug expenditure thresholds specified in the standard Medicare Part D benefit. Low-income subsidy (LIS) beneficiaries were excluded using a proxy out-of-pocket cost measure. The database used by the KFF/NORC research team was based on “nationwide patient-level retail pharmacy claims data” for approximately one-half of retail pharmacy transactions in the United States; the database “[tracks] beneficiaries as they use multiple pharmacies as long as their pharmacy or [pharmacy benefits management company] is part of” the database vendor’s “panel.” However, the KFF/NORC study report transparently acknowledged important limitations: the database “does not include the entire universe of retail pharmacies or any claims filled through mail order pharmacies.”2 Additional free or low-cost medication sources, including physician samples and medications obtained through pharmaceutical manufacturer-operated assistance programs, are also not represented in a database of community pharmacy transactions. Thus, an unknown proportion of the utilization change that was interpreted as termination of drug therapy in the KFF/NORC study was false-positive discontinuation, attributable to methods of obtaining medications through a source not represented in the study database—in other words, the result of an incomplete dataset.

Database limitations of this type are becoming common as Medicare beneficiaries, like many commercial plan enrollees, increasingly turn to medication cost-savings opportunities available through a variety of sources, many of which are not represented in databases commonly used by health care researchers.8-10 Advice sources targeted to Medicare beneficiaries, such as “Savvy Senior,” ConsumerReports.org, and a Centers for Medicare & Medicaid Services (CMS) webpage entitled “five ways to lower your costs during the coverage gap,”
advise seniors to use a variety of strategies to obtain medication. These include switching to a generic or over-the-counter (OTC) alternative, ordering large (“bulk”) supplies of medications, comparison shopping to identify lowest-price sources, using mail order pharmacies, and applying for assistance through a variety of programs.9-12

A Closer Look at the KFF/NORC Study. The omission of mail order pharmacy data from the KFF/NORC database may have had a major effect on study results. For beneficiaries who changed from a community pharmacy to a mail order pharmacy to save on their drug bills after reaching the coverage gap, even perfect adherence would have been erroneously measured as discontinuation. The amount of missing data for these chronic medications is difficult to estimate but potentially substantial. The proportions of seniors who have reported turning to mail order to save money during a year in which they reached the coverage gap vary widely—for example, 11% in one national small-sample survey by the Office of Inspector General (OIG)13 and 60% in a survey conducted in a large managed care organization (MCO).14 An estimated 17% of prescriptions nationwide were filled in U.S. mail order pharmacies in 2009,15 and mail order pharmacies operating outside the United States routinely market to seniors with the message that they can “beat the ‘donut’ and extend your Medicare coverage” by discontinuation rate (20%) was for proton pump inhibitors (PPIs), a class with many inexpensive generic and OTC therapeutic alternatives.19 And, the lowest rate of discontinuation (8%) was found for anti-Alzheimer’s agents, costly drugs (annual cost approximately $1,800)22 for which there were no therapeutic alternatives.18 And, the

generic programs were included in the database, a potentially important omission because generic drugs are routinely available through these programs for $4 per month or $10-$12 for a 3-month supply.8 The 15% discontinuation rate estimated in the KFF/NORC study was not evenly distributed across drug classes, and the pattern of distribution is generally what one would expect if a portion of beneficiaries obtained generic or OTC alternatives through sources other than pharmacies represented in the study database (Table 1). That is, except for osteoporosis therapies, for which utilization generally declined during 2007 because of public concerns about the adverse effects of bisphosphonates,16-21 the percentages of patients who “stopped taking medication” in the KFF/NORC report were generally higher in therapy classes in which lower-cost generic drugs were available and widely used. The highest reported discontinuation rate (20%) was for proton pump inhibitors (PPIs), a class with many inexpensive generic and OTC therapeutic alternatives.19 And, the lowest rate of discontinuation (8%) was for anti-Alzheimer’s agents, costly drugs (annual cost approximately $1,800)22 for which there were no generic alternatives at the time of the study.

Two features of the work by KFF/NORC are especially noteworthy. First, the problem of false-positive discontinuation was probably exacerbated by a flawed methodological decision to consider only changes within the “therapy class,” which was actually a therapy subclass, in categorizing patient behaviors (Table 1). For example, a patient who switched from an angiotensin-II receptor blocker (ARB) to an ACE inhibitor or from an oral antidiabetic to insulin) were erroneously counted as discontinuations, not as switches.18

The Express Scripts Drug Trend Report notes that utilization in this class was “down due to potential side effects publicized in 2007.”18

The Express Scripts Drug Trend Report counts ACE inhibitors and ARBs in the same drug class because of therapeutic equivalence.22 Because no generic ARBs were available in 2007, the 59% figure in this class reflects 0% GDR for ARBs plus a much higher rate for ACE inhibitors.

Reflects antihyperlipidemic class, which includes mostly statins as well as other products (e.g., fenofibrate), the GDR for oral antidiabetics is likely to be considerably higher.

Generic alternatives at the time of the study.

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the study results displayed the opposite of the pattern that one
would expect from cost-related nonadherence.

Earlier Evidence that Database Details
Matter (A Lot) to Study Findings

The KFF/NORC study was perhaps not the first time that alarm
bells were sounded about drug utilization declines that in reality
may have been caused in part by missing data, not actual
medication nonadherence. A meticulous analysis by Martin et
al. (1996) took a second look at the highly publicized findings of a 1991 study by Soumerai et al. of the effects of a “cap” (limit)
of 3 prescriptions per month for Medicaid beneficiaries in New
Hampshire.24,25 The original study, an interrupted time series
analysis of Medicaid claims that compared New Hampshire
with a state that had no cap (New Jersey), found that the cap
was associated with a 30% drop in medication use for a small
subgroup of elderly patients using multiple medications for
chronic health conditions, suggesting the possibility of negative health consequences.25

In the follow-up analysis, Martin et al. assessed a similar policy change in Georgia, which in 1991 had reduced its monthly reimbursable medication cap from 6 to 5, by studying a sample of beneficiaries who had filled at least 6 prescriptions per month during the 6 months prior to the cap change. However, instead of using a dataset limited to Medicaid claims, Martin et al. matched the claims to computerized prescription dispensing data gathered directly from pharmacies, producing a more complete database. Study findings illustrated the hazards of using claims data alone to measure adherence; many drugs that would have been identified as “discontinued” because of cessation of pharmacy claims activity actually had been obtained by the beneficiaries in out-of-pocket cash transactions. As a result, a claims-based analysis would have overestimated the effects of the cap by approximately 2-fold, with a coefficient estimate suggesting a decline of 0.71 prescriptions per beneficiary per month, versus a decline of 0.34 using the more complete dataset. Additionally, for some therapy classes (e.g., central nervous system agents, antidiabetic drugs), statistically significant effects of the cap that were observed in the Medicaid claims database became nonsignificant when the complete database of dispensed medications was used. Martin et al. concluded that for accurate assessment of caps and other policy changes that limit coverage for medications, it is necessary to monitor “total prescription utilization … not simply the number and amount of reimbursement from some third party.”24

More Comprehensive Evidence About How Seniors Respond to 100% Cost Sharing

Several studies have used survey data, sometimes in combination with pharmacy claims data, to assess the responses of Medicare beneficiaries to 100% cost sharing for prescription drugs, including caps and the coverage gap. As one would expect in a series of studies of relatively new policy changes, they reflect an iterative approach, with study methodologies becoming increasingly robust and detailed over time.

Response to Caps in Medicare + Choice. In a study conducted from March through July 2002, prior to the availability of generic drug discount programs in community pharmacies, Tseng et al. (2004) surveyed Medicare + Choice beneficiaries, comparing those who had exceeded their cap of $750 or $1,200 and experienced a coverage gap of 75-180 days in 2001 (n = 665) with a comparison group of enrollees who had a higher cap of $2,000, which they had not exceeded (n = 643).26 The 2 groups were matched by average monthly total drug expenditures. A response rate of 65% was achieved using a combination of 20-minute telephone survey with mailed follow-up surveys to initial nonrespondents. Respondents were presented with a list of behaviors and asked in which of these behaviors they had engaged to save money; respondents were asked to report only behaviors attributable to medication cost.

The results of the study by Tseng et al. suggested both desirable responses to the cap and opportunities for improvement. After multivariate adjustment for a number of factors including demographics, self-reported household income, and health status, respondents with a coverage gap were more likely to report engaging in behaviors that are typically viewed as an intended goal of cost-sharing. That is, they were more likely to switch medications (adjusted predicted percentages 15% vs. 9%, respectively, \(P = 0.002\)); obtain free samples (34% vs. 27%, \(P = 0.006\)); call pharmacies to identify the best price for their medications (46% vs. 29%, \(P < 0.001\)); and obtain a senior discount (12% vs. 7%, \(P = 0.003\)). They were not more likely to use mail order (63% vs. 62%, \(P = 0.64\)) or to obtain medications outside of the United States (3% in both groups, \(P = 0.92\)).26

With respect to the association of the cap with use of health care services, results were mixed. Respondents who experienced a coverage gap were more likely than those without a coverage gap to report using less than the prescribed amount of a medication (18% vs. 10%, respectively, \(P < 0.001\)) but were not more likely to report discontinuing a drug (8% in both groups, \(P = 0.86\)) or failing to fill a new prescription (6% vs. 5%, respectively, \(P = 0.39\)). Although respondents who reached the cap were much more likely than those who had not reached the cap to report that paying for medication was somewhat or very difficult (62% vs. 37%, respectively, \(P < 0.001\)) and slightly more likely to say that they had difficulty paying for rent or other bills because of medication costs (24% vs. 18%, \(P = 0.02\)), they were not more likely to decide against getting other medical care because of drug costs (15% vs. 13%, \(P = 0.20\)).26

Educational opportunity was suggested by the finding that of the top 20 drug classes for which respondents reported decreasing medication use (i.e., using less than the prescribed amount, stopping a drug, or not starting a drug) because of...
cost, 15 had generic or OTC alternatives available at the time of the study. And, although Tseng et al. reported no generic or OTCs available in 2002 for the cyclooxygenase (COX)-2 inhibitors, the third most common drugs with reported decrease in use (n = 20, 6.2% of 323 respondents), there were in fact many inexpensive nonselective nonsteroidal anti-inflammatory therapeutic alternatives, and all but 1 of the COX-2 inhibitors were later withdrawn from the market because of cardiovascular safety concerns.

Large-Sample Survey Comparing Knowledgeable with Less Knowledgeable Beneficiaries. Hsu et al. (2008) conducted a telephone survey of community-dwelling Medicare Advantage beneficiaries in 2007 (response rate 74.9%) and reported results for a stratified sample of beneficiaries who had incurred total drug expenses high enough to trigger the coverage gap in 2006 ($2,250, n = 514) and beneficiaries with lower drug expenses (n = 526); the sample was further stratified by level of total drug expenditure in 2006. Outcomes included (a) “cost-coping behaviors” (splitting or skipping pills with doctor’s advice, switching to a less expensive drug, receiving samples, receiving help from an assistance program, borrowing a prescription medication, or using an OTC drug); (b) nonadherence (splitting or skipping pills without doctor’s advice, not filling a new prescription, not refilling an existing prescription); and (c) financial burden (borrowing money or going without a necessity to pay for medication). All outcomes were assessed separately for beneficiaries with versus without knowledge of the gap—defined as awareness that the gap existed; accurate identification of gap starting and ending dollar amounts (within margins of error); and knowledge of specific drug cost sharing requirements before, during, and after the gap. Results for the sample strata were appropriately weighted by the mathematical inverses of the selection probabilities so that outcomes for the sample represented the membership overall.

Hsu et al. found that knowledge about the gap was generally poor. For example, after weighting, only 40.1% of the beneficiaries were aware that the coverage gap existed; only about one-half were able to identify the coverage gap starting threshold within a $250 margin of error; and knowledge of specific drug cost sharing requirements before, during, and after the gap. Based on their analysis of pharmacy claims data, the OIG reported that of the 7% of Medicare Part D beneficiaries who entered the coverage gap and did not receive financial assistance with prescription drug costs in 2006, 69% decreased, whereas 29% increased, the average monthly number of drugs purchased while in the gap. Among those purchasing 1 to 8.9 unique drugs per month prior to entry into the coverage gap, the average monthly number of unique drugs purchased while in the coverage gap declined by 9%-10% (from 3.5 to 3.2 for those using 1 to 4.9 drugs and from 6.2 to 5.6 for those using 5 to 8.9 drugs). The utilization decline was steeper, from 10.1 to 8.3 (18%) for those using 9 or more drugs.

Results of the OIG survey, like those in the survey by Tseng et al., suggested a mix of desirable and undesirable behaviors. In response to the question “how did you change your...
prescription drug use after you entered the coverage gap?” with a structured list of response choices, about one-fifth (21.1%) of respondents reported using a drug less often than prescribed, 15.8% said that they discontinued a medication, 14.0% said that they did not start a new medication, and a total of 33.3% reported engaging in at least 1 of these strategies. However, 25.4% reported obtaining free drug samples, 22.8% reported comparison price shopping, and 14.9% reported receiving “at least [1] type of help in purchasing their prescription drugs” (e.g., state pharmacy assistance program, private pharmaceutical company, charitable organization). Again highlighting the risks associated with measuring the effects of coverage gaps using community pharmacy claims data, the OIG found that 11.4% of respondents reported switching to a mail order pharmacy, and 7.9% reported that they “purchased drugs outside my health plan.” Suggesting an additional educational opportunity for seniors who reach the coverage gap, 20% of respondents were potentially eligible for LIS according to their self-reported incomes (below 150% of the federal poverty limit); yet, none had LIS status (by sample design), suggesting that they had perhaps not applied to receive assistance for which they may have qualified.13

In interpreting the OIG results, it is important to note that community pharmacy discount generic programs were available for at least part of 2006 (the Walmart $4 generic program was launched in September), and 55% of those who entered the gap did so prior to the fourth quarter of the year. Additionally, the OIG survey sample was small (n = 114), making some CIIs around the estimates wide; for example, the 95% CI for the percentage of respondents who reported that they stopped taking a medication during the gap was 9.0%-22.6%. Finally, an important limitation of the OIG study was that it lacked a comparison group of seniors with comparable total drug expenditure levels but no coverage gap.13

MCO Survey Comparing Beneficiaries With Versus Without a Gap. A report by Cronk et al. (2008), which assessed medication cost-lowering strategies used by Medicare Part D beneficiaries who reached the coverage gap in 2006, was strengthened by several positive methodological features that enhanced both internal validity (accuracy of inference) and external validity (applicability to the groups in which results will be applied).14 First, it compared self-enrolled “direct pay” beneficiaries who reached the gap threshold (total drug expenditures of $2,250) in a standard Medicare Part D benefit (n = 332) with enrollees in a group retiree drug subsidy (RDS) plan who reached the same drug expenditure threshold but experienced no gap because they had a more generous benefit design (n = 290). Enrollees who had no gap because of LIS or end-stage renal disease (ESRD) status were excluded from both study groups. This cohort assignment process was more exogenous (i.e., less affected by respondent characteristics) and therefore methodologically less likely to produce confounded findings compared with other commonly used research designs (e.g., comparing beneficiaries with expenditures high enough to reach the gap vs. those with lower expenditures, or respondents with more vs. less knowledge of the gap). Second, Cronk et al. used both pharmacy claims data and survey data, a method similar to that used in the OIG report, but with a larger sample size. Third, the survey by Cronk et al. was a modified version of the questionnaire used by Tseng et al., which had previously been used in a demographically similar group. Fourth, Cronk et al. analyzed pharmacy claims for Part D beneficiaries to provide information specific to the Part D threshold, instead of the $750-$1,200 expenditure caps that had been studied by Tseng et al. 4 years earlier.14,26

Like previous surveys on medication cost-related behaviors of seniors, the survey by Cronk et al. suggested a mix of desirable and undesirable behaviors; however, results indicated more cost-related nonadherence than had been suggested previously. Among direct pay (standard benefit) enrollees, the proportions reporting using less medication than prescribed, stopping a medication, or not filling a new prescription were 29.1%, 20.1%, and 21.8%, respectively, compared with rates of 11.0%, 4.6%, and 6.1% for RDS enrollees. Use of a mail order pharmacy to save money was reported by 59.7% of direct pay and 18.0% of RDS enrollees, and switching to a different medication was reported by 32.1% of direct pay and 10.9% of RDS enrollees. In contrast to the finding by Tseng et al.26 of no significant relationship between the drug expenditure cap and seeking other (nondrug) medical care, Cronk et al. found that direct pay enrollees were more likely than RDS enrollees to report not seeking medical care because of medication costs (34.0% vs. 16.6%, respectively, P < 0.001).14

Cronk et al. also reported the results of a logistic regression analysis of predictors of nonadherence attributable to cost (defined as using less medication than prescribed, stopping a medication, or not filling a prescription for a new medication). These included younger age (odds ratio [OR] for each year=0.97, 95% CI=0.94-0.99, P=0.009); not using a second-generation antipsychotic (OR=0.30, 95% CI=0.11-0.82, P=0.019, for using an antipsychotic); poor health status (OR=0.55, 95% CI=0.34-0.89, P=0.015, for excellent, very good, or good health status); higher educational levels (OR=1.70, 95% CI=1.06-2.71, P=0.027, for high school or postsecondary education); and annual household income below $30,000 (OR=0.57, 95% CI=0.33-0.98, P=0.040, for income of $30,000 or more). Controlling for these factors and for other nonsignificant comorbidity measures, the OR for the direct pay plan was 5.21 (95% CI=2.17-12.53, P<0.001).14 Although the associations of low income and poor health status with nonadherence were as expected, the associations of antipsychotic use with better adherence and of higher educational levels with nonadherence were counterintuitive, providing an important reminder that patient adherence behaviors are complex and not always easily understood.
Several differences between the work of Tseng et al. and Cronk et al. are noteworthy. First, samples dispensed by physician offices, a major source of medication for seniors in the survey by Tseng et al. (34% and 27% for the cap and no-cap groups, respectively) were seldom used by the MCO enrollees in the survey by Cronk et al., who reported that the MCO had a policy that prohibited the dispensing of samples by its participating physicians. Second, Cronk et al. did not ask respondents about calling different pharmacies to find the best price, an important cost-saving strategy in the survey by Tseng et al. (65%) or the OIG survey (81%), which had much lower response rates (42%) than in the Cronk et al. study period (2006), when generic discount programs were first launched. Third, the work of Cronk et al. had limitations that included a much lower response rate (42%) than in the survey by Tseng et al. (65%) or the OIG survey (81%), as well as inclusion of only self-enrolled beneficiaries in the Medicare standard plan (direct pay) group; self-enrolled beneficiaries may have been more likely than RDS (group-insured) plan beneficiaries to engage in cost-saving strategies, regardless of the coverage gap.

MCO Study of Association of the Coverage Gap with Medical and Pharmacy Utilization. A study by Raebel et al. (2008), conducted in the same MCO and using a similar cohort construction method as in the Cronk et al. study, assessed changes in both pharmacy and medical care utilization from before to after reaching a coverage gap threshold of $2,250 in 2006. Raebel et al. compared self-enrolled direct-pay beneficiaries who experienced a coverage gap of at least 60 days with RDS beneficiaries who had similar drug expenditures but no coverage gap. Cohorts were matched by age, chronic disease score, and a comorbidity index, and enrollees with LIS or ESRD status were excluded from both groups.

Results suggested no clear relationship between reaching the coverage gap and medical utilization. Among the 1,237 beneficiaries who experienced any coverage gap, representing 6% of enrollees in the direct pay plan, 783 (63% of those reaching threshold, about 4% of direct pay enrollees overall) experienced a gap of at least 60 days. In both the direct pay (coverage gap) group (n = 759 after matching) and in the matched RDS cohort (n = 2,818), total office visit utilization rates were slightly lower in the post-threshold period in 2006 than in the same months in 2005 (incidence risk ratio [IRR] vs. 2005 = 0.90 in both groups), and no significant between-group differences were noted for change in emergency room use (IRR = 0.91, 95% CI = 0.71-1.16 in direct pay plan; IRR = 1.14, 95% CI = 0.96-1.35 in RDS) or hospitalization (IRR = 1.08, 95% CI = 0.88-1.33 in direct pay plan; IRR = 1.06, 95% CI = 0.93-1.21 in RDS). Medication refill adherence (defined as total days supply divided by total number of calendar days times 100) also declined slightly for both groups, but the between-group differences in the adherence reduction amounts were significant only for antihyperlipidemic agents (91.0% before gap vs. 87.3% after gap in the direct pay plan, between-group difference P = 0.031) and antihypertensives (89.8% before vs. 84.5% after gap in the direct pay plan, between-group difference P = 0.006) and not significant for beta-blockers, diuretics, or antidiabetic medications.

Raebel et al. observed that their results were different from those of a study of Medicare + Choice conducted by Hsu et al. (2006), which had compared medical and pharmacy utilization in 2003 for self-enrolled beneficiaries who had a $1,000 medication cap (n = 157,275) with employer-enrolled retirees who had “unlimited” drug benefits (n = 41,904) using a cross-sectional design with statistical controls for demographics, comorbidities, and cost-sharing levels. As Raebel et al. pointed out, the difference between their results and those of Hsu et al. could have been partly attributable to statistical power because of the enormous differences in sample size. The differences in rates of medication nonadherence (defined as percentage of days covered less than 80% in the study year for those with use of the same drug in the prior year) that were observed by Hsu et al. were small and similar to those of Raebel et al. (for no-cap vs. cap, respectively: 14.6% vs. 18.1% for antihypertensives; 26.5% vs. 31.4% for lipid-lowering drugs; 21.2% vs. 26.2% for antidiabetics). More importantly, the medical utilization differences reported by Hsu et al. were small despite statistical significance (e.g., all-cause emergency room visits 45.2 vs. 49.2 per 100 person-years; all-cause hospitalizations 38.4 vs. 39.7 per 100 person-years). An additional possible explanation is the use of a cross-sectional design in the utilization analysis by Hsu et al. in contrast to the Raebel et al. quasi-experimental analysis, which consisted of by-group comparisons of changes from comparable time periods in the previous year (e.g., for a member whose cap was reached in September 2006, Raebel et al. measured utilization change for September 2006-December 2006 vs. September 2005-December 2005).

The Multifaceted Nature of Nonadherence: Difficulties in Isolating (Let Alone Controlling) a Single Causal Agent

“What can be done about a problem that has been studied in thousands of articles and yet barely improved in decades?” This question was posed by Gellad et al. in the introduction to a 2009 Rand technical report on barriers to medication adherence, which noted that studies of the topic were “heterogeneous and of variable quality,” hampering the “ability to form policy recommendations rooted in the literature.” In their systematic review of studies of nonfinancial causes of nonadherence, Gellad et al. identified beliefs about medications, including “perceived risks of having a side effect and perceived impact and need for the medication,” as “key barriers to and facilitators of medication adherence.” Of 21 articles assessing the association between medication beliefs and adherence, 16 found “strongly positive” relationships. Qualitative interview studies, especially those conducted...
in publicly funded health care systems with little or no out-of-pocket cost, help provide in-depth understanding of the relationships between patient beliefs and nonadherence. For example, Barber et al. (2004) interviewed English patients aged 75 years or older by telephone at 2 points in time: first at 10 days (n = 239), then at 4 weeks (n = 197), following initiation of new medication for stroke, coronary heart disease, asthma, diabetes, or rheumatoid arthritis.32 At 10 days, 13 patients (5.4%) had discontinued the medication on the advice of their physician. Of the remaining 226, 67 (29.6%) reported nonadherence to the new medication, defined as missing any doses in the previous 7 days, and 18 (8.0%) had discontinued the medication without medical advice. Notably, of 208 patients still taking medication at 10 days, 138 (66.3%) reported a problem or issue with the medication, including side effects (50% of problems reported); “concerns about the medication” including “don’t believe in taking pills” and “worried about taking new medicine” (43%); and “difficulties with the practical aspects of taking the medication” (7%). After the first 10 days of therapy, only 37 patients (16.4% of the 226 whose physicians had not discontinued their medication) reported that they were “adherent, problem free, and had received sufficient information” about their medication.32

Similarly, Sale et al. (2011) reported the results of qualitative in-depth (1- to 2-hour) interviews with 21 patients aged 65 to 88 years in Ontario, Canada, who had been prescribed drugs to treat osteoporosis after sustaining a fracture within the previous 5 years.33 For 12 patients, the decision to take the medication “involved minimal contemplation … because they liked/trusted their health care provider.” However, 9 patients described the decision to take the prescribed medication as “difficult” because they “were unconvinced by their health care provider, engaged in risk-benefit analyses using other information sources, and were concerned about side effects.” Eleven of the 21 patients indicated that their decision about medication “was not permanent and that they might be persuaded to start or stop taking medication depending on a number of circumstances.”33

In a U.S. study, Fried et al. (2011) used in-person interviews with 356 community residents recruited from senior centers and an assisted living facility (mean [standard deviation] age 76 [7] years) to estimate associations of the beliefs about the benefits and risks of medication with willingness to take medication for primary prevention of cardiovascular disease.34 Fried et al. found that willingness to take medication was “relatively insensitive” to beliefs about benefits. When seniors were presented with a baseline scenario that 20 in 100 untreated patients and 14 in 100 treated patients would have a myocardial infarction (MI) during a 5-year period (i.e., 6 MIs prevented), 87.9% responded “yes” when asked if they would take a medication with “no adverse effects.” Still assuming no adverse effects, of those unwilling to take the medication (n = 33) or not sure (n = 9), only 16.7% (n = 7) expressed willingness to take the drug if the drug reduced the MI risk from 20 to 10 (i.e., 10 MIs prevented). Of those willing to take the medication (n = 313), only 13.7% (n = 43) said that they would change their minds about taking the drug if the MI risk were reduced from 10 to 7 (i.e., just 3 MIs prevented).34

In contrast, medication-taking decisions were strongly associated with concerns about adverse effects. Of the 313 who expressed willingness to take medication in the initial scenario, the proportions who remained willing to take the medication when told that it would result in daily fatigue and dizziness, daily mild to moderate nausea, and daily fuzzy or slowed thinking were 52%, 35%, and 31%, respectively. Only 3% of respondents reported willingness to take a medication with adverse effects serious enough to affect activities of daily living. Fried et al. commented on the “notable” finding that in response to the initial scenario in which respondents were told that a drug would have no adverse effects, 13 (31%) of 42 respondents who expressed either uncertainty or unwillingness to take the drug told the investigators that they did not believe that the drug would actually have no adverse effects, and 7 (17%) said that they disliked medications.34

Information about other nonfinancial factors affecting medication adherence is somewhat limited. For example, Ingersoll and Cohen (2008) conducted a systematic review of the literature on the relationship between drug regimen characteristics and adherence to treatment for multiple chronic diseases.35 They reported that of 110,218 PubMed articles identified using the search terms “adherence” or “compliance” from 1998 to 2007, only 61 examined regimen characteristics, and studies in most therapy classes “failed to use state-of-the-art methods of measuring adherence.” Despite these limitations, Ingersoll and Cohen “identified regimen complexity,” including number of daily doses, “as a likely determinant of adherence.” Still, Ingersoll and Cohen acknowledged that, with the exception of patients with human immunodeficiency virus, there are “few behavioral methods targeting improved adherence with known efficacy” in “most areas of chronic illness.” Supporting their viewpoint was a systematic review of randomized controlled trials (RCTs) of adherence-improvement interventions by Haynes et al. (2008), which found that only 39 of 81 interventions “to help patients follow prescriptions for medications for medical problems” (n = 69 trials for long-term treatments) were associated with adherence improvements, and only 25 “led to improvement in at least 1 treatment outcome.”36

In interpreting findings about the sometimes complex patient perspectives on medication, it is worth noting that some fears of potential side effects with long-term use turn out to be well-founded; the risks of newer medications are often not fully understood at the time of market launch. Well-known examples include COX-2 inhibitors,27 bisphosphonates,20 and several antidiabetic medications including rosiglitazone,37,38 sitagliptin,39,40 and exenatide.41
100% Medication Cost Sharing for Seniors: What We Know and What We Need to Know

The Rand Health Insurance Experiment, to date the most rigorously designed study of the effects of cost sharing on health outcomes, found that requiring insured enrollees to pay a portion of the cost of their care results in savings without negative effects on health outcomes. However, that study was limited to enrollees aged 64 years or younger, and its results may not have external validity for seniors. The unfortunate result is that many public policy decisions about health care benefit designs for seniors have been made based solely on observational evidence, which is suboptimally rigorous.

Even more unfortunate is the tendency of authors of observational studies to extrapolate beyond study results—or even the outcomes that were actually measured—in describing the clinical and economic consequences of various benefit designs. For example, in an observational analysis of Medicare beneficiaries in 2006, Zhang et al. (2009) found a decrease of 0.7 pharmacy claims per month paid by the health plan (0.4 generic, 0.3 brand), approximately 14%, after entry into the coverage gap. For beneficiaries with generic drug coverage in the gap, the reduction in pharmacy claims was smaller, 0.14 claims per month, which represented “the net effect of a decrease of 0.5 brand-name prescriptions and an increase of 0.36 generic prescriptions.” Without analyzing the medical utilization data that were included in their study database, Zhang et al. concluded that “on the assumption that the generic drugs taken by beneficiaries . . . were appropriately prescribed, one can assume not only that the lack of coverage in the doughnut hole had adverse health consequences but also that it could have increased costs for hospital and physician services.”

Based on the limited evidence available to date, it seems likely that a small proportion of seniors is negatively affected by 100% cost sharing. That is, they enter the coverage gap without LIS (approximately 6%-7% in the analyses by OIG and Raebel et al.).13,29 they are more likely to be nonadherent than beneficiaries who have comparable drug expenditure levels but no coverage gap (percentage point difference about 15%-20%, or about 1% of beneficiaries overall);14 the nonadherence occurs because they need medication for which there is no low-cost generic substitute (proportion unknown); and they are either unable to obtain medication from or are unaware of alternative resources, such as patient assistance programs (proportion unknown). Yet, we know little about the characteristics and behaviors of this small group of beneficiaries—and therefore we know little about how to help them obtain medication affordably—because research in the topic area has generally used incomplete data sources and/or left unanswered critically important questions. The areas of greatest need include the following: Examination of Cost-Related Behaviors by Therapy Class. Beneficiary surveys have certainly been a great improvement over claims data alone in providing information about whether the absence of a pharmacy claim represents nonadherence versus the use of a medication source not reflected in a claims database. However, surveys to date have not examined the critically important question of which therapy classes are affected by nonadherence. For example, the OIG survey and the survey by Cronk et al. both indicated that, of beneficiaries who entered the coverage gap without LIS, about 16%-20% (or about 1% of beneficiaries overall) reported stopping a prescription medication because of cost during 2006. However, the therapeutic implications—and therefore the policy implications—of these findings are uncertain without information about the discontinued prescription drug. For example, it is important to know if the discontinued drug was an antihypertensive for a patient with congestive heart failure (clearly clinically problematic), a PPI for which a patient with heartburn substituted an OTC alternative (cost-saving with probably no clinical effect), or an oral antidiabetic drug with a higher-risk cardiovascular profile for which a patient with type 2 diabetes substituted metformin available for $4 through a community pharmacy discount program (possibly clinically beneficial) in addition to cost-saving). Additionally, because of the gradual transition of many specialty injectable medications (e.g., glatiramer acetate and interferon β-1a for multiple sclerosis) from in-office administration reimbursed by Medicare Part B to Medicare Part D, depending on the Medicare intermediary in a patient’s geographic region, more information is needed about the effect of the Medicare Part D design on patients with catastrophic illnesses. Surveys that “drill down” to drug therapy class and type of cost-related response should be used to determine the circumstances in which responses to 100% cost sharing are clinically harmful, neutral, or beneficial.

High-Quality Survey Data to Assess Incentives Associated with 100% Cost-Sharing. As observed by editorialists Shrank and Choudhry, the provision in the Affordable Care Act that in 2011 discounts brand-name drugs by 50% but generic medications by only 7% is unfortunate; “by disproportionately reducing the cost of brand-name medications, the legislation creates incentives for patients to use more expensive drugs and will leave the federal government on the hook for increased medication costs during the catastrophic-coverage period” because “exposure to out-of-pocket costs [in the coverage gap] may encourage seniors to consider the cost of their medications and to seek more cost-effective options.” Shrank and Choudhry’s observations make sense in principle, and it seems clear from the limited evidence available to date that the coverage gap does encourage seniors to “shop around” for the best price—a behavior that public policy presumably should encourage. However, the question of how often this comparison price shopping actually results in identification of the lowest price is critically important because price differences among medication sources can be large. For example, Internet prices for a 90-day supply of gabapentin 400 milligrams (mg) taken 3
times daily (i.e., 270 tablets) are $69 at one pharmacy and $210 at another; and, for those with incomes less than 300% of federal poverty level (e.g., $32,670 for a single adult and $44,130 for a couple in most states), 30 $35 at RxOutreach. 31 Additionally, more detailed information is needed about the sources from which beneficiaries obtain their drugs, especially for survey respondents who report that they used a “mail order pharmacy” while in the coverage gap. The policy implications of “mail order” use vary considerably depending on the specific source—for example, health plan mail order or a reputable U.S. discount Internet pharmacy versus a foreign Internet pharmacy.

Surveys of Medicare beneficiaries, coupled with verification (e.g., pharmacy records audits) whenever possible, should be used to determine whether and from what sources patients obtain their medications in the coverage gap, as well as whether patients accessed the best price or paid more than necessary.

More Knowledge About Knowledge Gaps. Limited survey evidence available to date suggests that educational interventions may be needed in several critical areas. First, the study by the OIG suggested that up to one-fifth of Medicare beneficiaries who entered the coverage gap without LIS assistance in 2006 may have been LIS-eligible but failed to apply. 13 Second, the survey by Hsu et al. suggested that only about 40% of Medicare Part D beneficiaries were even aware that a coverage gap existed, and only a minority was able to identify key features of the gap, at least shortly after implementation of Medicare Part D. 28 Similarly, Cronk et al. found that about 22% of their respondents in 2007 “were unaware or unsure if they had an initial threshold on medication purchases.” 14 Third, the survey by Tseng et al. suggested that seniors may not always correctly identify opportunities to substitute generic medications for brand drugs, although it is possible that knowledge has improved since that study period (2002). 26 It is also possible that the extent and type of knowledge gaps may depend in part on medical condition. Bayliss et al. found that Medicare beneficiaries in 1 HMO who reached the coverage gap in 2 consecutive years (4% of the sample) were somewhat more likely than those who reached the gap in only 1 year to have 2 or more medical conditions (e.g., chronic obstructive pulmonary disease, Parkinson’s disease) for which generic drug treatment options were limited (41% vs. 32%, respectively). 52

Thus, it seems that many seniors lack knowledge of the medication resources available to them and of the coverage gap design. In addition to suggesting a need for education and outreach, these findings perhaps suggest that a different design—such as a high upfront deductible or flat coinsurance percentage that would apply to all beneficiaries except those currently excluded from cost-sharing (e.g., LIS, ESRD)—could encourage efficient drug purchasing and produce the same cost savings without confusing patients who make drug-purchasing decisions. Surveys that provide detailed information about gaps in beneficiary knowledge are needed to inform educational efforts and potential benefit design changes.

More Comprehensive Examinations of Factors Contributing to Nonadherence Under 100% Cost Sharing. To date, surveys assessing behaviors after cap or during coverage gap periods have asked only about cost-related behaviors, not about nonadherence attributable to other factors. Although this approach is consistent with the generally accepted survey research practice of reducing respondent burden to enhance response rate, it may be misguided. Previous research suggests that the causes of nonadherence are multifaceted and include adverse drug effects, beliefs about medications, and regimen complexity. As Cronk et al. observed, social desirability factors may affect the results of surveys in which beneficiaries are asked about the effects of medication costs. 15 Especially in a survey sponsored by his or her health plan, a respondent may find it considerably more comfortable to report that cost was the cause of nonadherence than to report negative beliefs about medication or fears of adverse effects; and beneficiaries are highly unlikely to report beliefs or fears if they are not asked about them directly, using appropriate survey research techniques. Analysis of the probably complex relationships between financial and nonfinancial causes of nonadherence requires a more comprehensive approach to questionnaire construction than has been used to date. Conjoint analysis (also known as discrete choice analysis), an analytic technique that permits calculation of patient preferences on multiple dimensions (e.g., price, adverse effects, efficacy), would likely be a good approach to analyzing surveys of this type. 53 Surveys intended to address financial or benefit design issues should in addition ask respondents about nonfinancial factors to assess the relative importance of a variety of causes of nonadherence and enable more effective policy approaches.

More RCTs. A number of studies, especially claims-based studies, have documented a decrease in pharmacy claims utilization upon entry into the coverage gap. 2–6 Putting aside the problem of incomplete claims data, more focus in future research should be placed on RCTs of interventions to improve both awareness of pharmacy benefit design and medication adherence. For example, it is one thing to document that beneficiary knowledge may be associated with certain behaviors; it is quite another to test whether a particular educational intervention to improve beneficiary knowledge actually results in improvement in health-related behaviors or clinical outcomes. More rigorous testing of interventions, and less documentation of associations that may have little actionable value, are needed.
Obtaining Necessary Information About the Effects of 100% Cost Sharing on Seniors: Moving Forward

Although the current information deficit about the coverage gap is not entirely unexpected because the Medicare Part D program is relatively new, reliance on claims-based analyses to inform questions that claims data cannot possibly address accurately has tended to mislead and politicize rather than produce constructive policy guidance. Moreover, pronouncements of dire health consequences without examination of medical claims data are unhelpful—not just because they are potentially inaccurate, but also because they have drawn attention away from important health policy questions that remain unaddressed. These questions are becoming especially important as optimal approaches to providing health care to seniors are the subject of an increasingly vigorous debate.

With the burgeoning number of options for seniors to access affordable medications to treat chronic illness, most observational analyses of nonadherence based solely on pharmacy claims data have become obsolete and uninformative, depending in part on the therapy class studied. Absent an RCT of the effects of various benefit designs on seniors—the ideal information source—high-quality survey data are probably the best source of information at the present time. In other words, if we want to know how health care policies affect seniors, it makes sense to ask them.

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