Association Between High Deductible Health Plans and Cost-Related Non-adherence to Medications Among Americans with Diabetes: an Observational Study



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BACKGROUND: For people with diabetes, adherence to prescribed medications is essential. However, the rising prevalence of high-deductible health plans (HDHPs), and prices of diabetes medications such as insulin, could deter adherence.

OBJECTIVE: To assess the impact of HDHP on costrelated medication non-adherence (CRN) among nonelderly adults with diabetes in the US.

DESIGN: Repeated cross-sectional survey.

SETTING: National Health Interview Survey, 2011–2018. **PARTICIPANTS:** A total of 7469 privately insured adults ages 18-64 with diabetes who were prescribed medications and enrolled in a HDHP or a traditional commercial health plan (TCP).

MAIN MEASURES: Self-reported measures of CRN were compared between enrollees in HDHPs and TCPs overall and among the subset using insulin. Analyses were adjusted for demographic and clinical characteristics using multivariable linear regression models.

KEY RESULTS: HDHP enrollees were more likely than TCP enrollees to not fill a prescription (13.4% vs 9.9%; adjusted percentage point difference (AD) 3.4 [95% CI 1.5 to 5.4]); skip medication doses (11.4% vs 8.5%; AD 2.8 [CI 1.0 to 4.7]); take less medication (11.1% vs 8.8%; AD 2.3 [CI 0.5 to 4.0]); delay filling a prescription to save money (14.4% vs 10.8%; AD 3.0 [CI 1.1 to 4.9]); and to have any form of CRN (20.4% vs 15.5%; AD 4.4 [CI 2.2 to 6.7]). Among those taking insulin, HDHP enrollees were more likely to have any CRN (25.1% vs 18.9%; AD 5.9 [CI 1.1 to

CONCLUSION: HDHPs are associated with greater CRN among people with diabetes, particularly those prescribed insulin. For people with diabetes, enrollment in non-HDHPs might reduce CRN to prescribed medications.

KEY WORDS: insurance; cost; diabetes.

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INTRODUCTION

Adherence to hypoglycemic medications for people with diabetes is essential for maintaining glycemic control, ¹⁻⁴ reducing hospitalizations, 5-7 and preventing long-term complications.^{3,8} Out-of-pocket costs for prescribed medications are strongly associated with patients taking less medication than prescribed. 9-11 Such cost-related medication non-adherence (CRN) is common among patients with diabetes, ^{3,12–15} particularly those with low incomes. 14,16,17 Prices for hypoglycemic medications, especially insulin, have been increasing substantially in recent years. 18-20 Between 2002 and 2013, for example, the mean price of insulin rose by over 200%. This price increase has resulted in a substantial rise in out-ofpocket costs for medications to treat diabetes.²¹

High deductible health plans (HDHPs), which can substantially increase out-of-pocket costs, are increasingly common.²² These plans require potential out-ofpocket spending of \$1000 to \$7000 per person annually for non-preventive care. For commercially insured patients with diabetes, HDHP enrollment has been associated with increased out-of-pocket medical expenditures²³⁻²⁶ and reductions in receipt of some forms of outpatient care among lower income individuals, including primary care and specialty visits.¹⁶ Additionally, HDHPs are associated with delays in seeking treatment for macrovascular complications of diabetes,²⁷ and with CRN and forgone care among those with other chronic illnesses.^{28,29} However, to date, no studies have quantified the effect of HDHP enrollment on CRN among patients with diabetes in the US.

We analyzed nationally representative data on non-elderly adults with diabetes enrolled in private health plans to assess (1) the association between HDHP enrollment and multiple measures of CRN among those taking any prescribed medication and the subset taking insulin; (2) the effect of income level on this association; and (3) the relationship between CRN and the risk of experiencing two adverse outcomes, emergency department visits and hospitalizations.

METHODS

Data Source and Study Population

We analyzed the National Health Interview Survey (NHIS) from 2011 to 2018. This is a cross-sectional, household interview survey of a nationally representative sample of the non-institutionalized US population. The NHIS uses a complex, multistage area probability sample design. The NHIS is conducted annually by the National Center for Health Statistics through in-person interviews with approximately 35,000 families. All family members are invited to participate, and only one adult in each family is randomly selected to complete a more extensive interview. Details of the structure, sampling frame, and survey items have been published previously. The total household response rate for the NHIS during the study years ranged from 82.0% in 2011 to 64.2% in 2018.

The study sample included non-elderly adults (ages 18–64) who reported having a diagnosis of diabetes (an affirmative response to the question: "Have you ever been told by a doctor or other health professional that you have diabetes or sugar diabetes?") and being enrolled in a commercial health insurance plan. We excluded from the study sample individuals with a commercial plan if they also had any other form of insurance (Medicaid, Medicare, Veterans' Administration coverage, etc.). Respondents who were 65 years of age or older, and therefore eligible for Medicare, were also excluded. We also excluded the small number of respondents that had missing data for any outcome of the study.

Study Variables

Respondents in the NHIS were deemed to have a HDHP if they indicated that their commercial health plan had an annual individual deductible of \$1300 per year or more or a family deductible of \$2400 per year or more during the years 2011– 2014 and \$2600 per year or more during the years 2015–2018. Respondents were considered to have a traditional commercial health plan (TCP) if their annual individual deductible was less than these values. Cost-related medication non-adherence (CRN) was assessed using responses to four survey questions. Participants were asked if, in the last 12 months, they (1) could not afford prescription medications; (2) skipped medication doses to save money; (3) took less medicine to save money; or (4) delayed filling a prescription for a medication to save money. In addition, we constructed a composite measure for which experiencing any CRN was defined as answering "yes" to at least one of these individual items. CRN has been linked to adverse outcomes in patients with diabetes³¹ but not in a nationally representative sample. Thus to assess the importance of CRN as an outcome in this population, we also examined two potential adverse consequences of CRN: (1) having 1 or more emergency department visits in the last 12 months (this includes emergency room visits that resulted in a hospital admission); and (2) having 1 or more hospitalizations. We considered respondents to be insulin users if they

answered affirmatively to the question "Insulin can be taken by shot or pump. Are you now taking insulin?"

We obtained information on self-reported health status (those with excellent, very good, or good health were categorized as "good" while those with fair or poor health were categorized as "poor") and the presence of health limitations (physical, mental, or emotional problem requiring the help of other persons with personal care needs). NHIS also assesses the presence of the following set of common chronic medical conditions: diabetes, hypertension, cardiovascular disease (with questions about coronary heart disease, angina, myocardial infarction, and other heart disease), chronic obstructive pulmonary disease (with questions about chronic bronchitis, emphysema, and, from 2012 onward, COPD), stroke, and kidney disease. We also obtained information on the following demographic variables and treated them analytically as indicated in parentheses: age (continuous), race (Hispanic, white, black, Asian, or other), family size (1, 2, 3, 4, or more), marital status (currently married vs not married), health status (good or poor), education status (less than high-school, high-school degree, college degree, postgraduate degree), employment status (employed or not), and annual family income: lowestincome (\$0-\$34,999), low-income (\$35,000-\$74,999), middle-income (\$75,000-\$99,999), and high-income (\$100,000 or more).

Analyses

We compared baseline characteristics of the study population between respondents enrolled in a HDHP and those enrolled in a TCP. We then examined the relationship between HDHP enrollment (vs TCP enrollment) and CRN among the entire cohort ("all diabetics") and the subset of those taking insulin ("insulin users"). For all diabetics and for insulin users, we calculated the proportion of individuals in both HDHPs and TCPs that reported experiencing each of the four individual CRN measures and the composite, "any CRN" measure. We then examined the association of HDHP status with CRN by estimating the adjusted percentage point difference between HDHP enrollees and TCP enrollees for each CRN outcome measure using multiple linear probability regression models that included terms for the presence of each chronic medical condition, age, sex, family size, race/ethnicity, marital status, health status, presence of a functional limitation, education level, income group, and employment status.

In order to assess the effect of income on the relationship between HDHP enrollment and CRN, we stratified the study sample by income group and replicated the above analysis for any CRN outcome, except that for these models, we excluded the term for income.

We also examined the relationship between experiencing any CRN and having an emergency room visit (1 or more) or hospitalization (1 or more) in the last year by estimating the adjusted percentage point difference for each outcome between those with and without CRN using the same modelling approach as described above. In addition, because the association between CRN and these outcomes could be influenced by enrollment in a HDHP (vs a TCP), in a sensitivity analysis, we additionally controlled for enrollment in a HDHP. This did not alter any of our findings and thus we do not report these analyses further.

Although our study population was comprised entirely of people with diabetes, the CRN questions were not specific to diabetes medications. To assess the extent to which CRN to non-diabetic medications influenced our results, we conducted 2 additional sensitivity analyses in which we excluded those respondents who reported having any chronic condition other than diabetes. We replicated the analyses of the association between HDHP and CRN and the association between CRN and emergency department visits and hospitalizations described above, including only people with diabetes but no other chronic condition.

For all analyses, we applied survey weights provided by NHIS in order to produce nationally representative estimates. Statistical significance was assigned at the p<0.05 level. Categorical variables were analyzed using chi-square tests of independence. We used STATA (version 15.1) for all analyses. The Cambridge Health Alliance Internal Review Board deemed this study exempt from human subjects review.

RESULTS

Sample

The Supplement Figure illustrates how our study population was formed. The final study population included 7469 adults, 2691 with a HDHP, and 4778 with a TCP.

Demographics

We found that HDHP enrollees and TCP enrollees did not differ with respect to age, sex, family size, marital status, health status, and family income (Table 1). However, HDHP enrollees were more likely than TCP enrollees to identify as white (69.7% vs 62.9%, p<0.01), be employed (83.0% vs 79.3%, p<0.01), have a college education (21.3% vs 18.2%, p<0.01), and report a functional limitation (53.5% vs 49.9%, p<0.05).

Association Between HDHP Enrollment and Cost-Related Medication Non-adherence

HDHP enrollees were more likely than TCP enrollees to be unable to afford a prescription medication (13.4% vs 9.9%; AD 3.4 [95% CI 1.5 to 5.4]); to skip a medication to save money (11.4% vs 8.5%; AD 2.8 [CI 1.0 to 4.7]); take less

Table 1 Characteristics of the Study Population Stratified by Health Plan Type: High-Deductible Health Plan (HDHP) vs Traditional Commercial Health Plan (TCP)

| | TCP (Unweighted n=4778) Weighted % | HDHP (Unweighted n =2691) Weighted $\%$ | P-value 0.23 | |
|--|---------------------------------------|---|---------------------|--|
| Age, mean (SE) | 51.7 +/- 0.2 | 51.3 +/- 0.3 | | |
| Female | 47.4 | 49.7 | 0.13 | |
| Race | | | < 0.01 | |
| Hispanic | 14.1 | 11.8 | | |
| White | 62.9 | 69.7 | | |
| Black | 14.5 | 12.0 | | |
| Asian | 7.1 | 5.7 | | |
| Other | 1.5 | 0.9 | | |
| Family size | | | 0.79 | |
| 1 | 15.3 | 16.2 | | |
| 2 | 40.1 | 39.3 | | |
| 2 3 | 19.2 | 18.6 | | |
| 4+ | 25.4 | 25.9 | | |
| Married | 68.3 | 67.7 | 0.69 | |
| Health status | 00.0 | · · · · | 0.54 | |
| Good/better | 76.4 | 77.2 | | |
| Fair/worse | 23.6 | 22.8 | | |
| Employed | 79.3 | 83.0 | < 0.01 | |
| Education | 17.5 | 03.0 | < 0.01 | |
| Less than high school | 9.0 | 6.2 | 40.01 | |
| High school/some college | 61.1 | 61.1 | | |
| College degree | 18.2 | 21.3 | | |
| Postgraduate degree | 11.7 | 11.4 | | |
| Any functional limitation ^a | 49.9 | 53.5 | 0.03 | |
| Family income | 19.5 | 55.5 | 0.31 | |
| \$0–\$34.999 | 14.4 | 12.4 | 0.51 | |
| \$35,000-\$74,999 | 35.9 | 36.2 | | |
| \$75,000 \$74,777 | 17.0 | 18.1 | | |
| \$100,000 and up | 32.7 | 33.3 | | |
| Any chronic disease ^b | 34.1 | 35.3 | 0.45 | |
| This childre disease | J7.1 | JJ.J | 0.73 | |

Abbreviations: TCP, traditional commercial health plan; HDHP, high-deductible health plan

^aAny limitation in walking, climbing, standing, sitting, stooping/bending, reaching overhead, grasping small objects, carrying/lifting, going out to participate in events, going out to participate in social activities, or relaxing at home

^bHaving one or more of the following chronic health conditions: cardiovascular disease, chronic obstructive pulmonary disease, stroke, chronic kidney disease, or chronic liver disease

| Category of cost-related non-adherence (CRN) | Plan type | | Unadjusted difference between TCP and HDHP | | Adjusted* difference between TCP and HDHP | |
|--|-----------|---------------|--|---------|---|---------|
| | TCP % | HDHP % | Percentage points | P-value | Percentage points (95% CI) | P-value |
| | | All diabetics | (n=7469) | | | |
| Couldn't afford prescription medicine | 9.9 | 13.4 | 3.5 | < 0.001 | 3.4 (1.5 to 5.4) | < 0.01 |
| Skipped medication to save money | 8.5 | 11.4 | 2.9 | < 0.01 | 2.8 (1.0 to 4.7) | < 0.01 |
| Took less medicine to save money | 8.8 | 11.1 | 2.3 | < 0.01 | 2.3 (0.5 to 4.0) | 0.01 |
| Delayed filling script to save money | 10.8 | 14.4 | 3.6 | < 0.001 | 3.0 (1.1 to 4.9) | < 0.01 |
| Any CRN | 15.5 | 20.4 | 4.9 | < 0.001 | 4.4 (2.2 to 6.7) | < 0.001 |
| · | | Insulin users | (n=1772) | | | |
| Couldn't afford prescription medicine | 13.3 | 16.4 | 3.1 | 0.13 | 3.7 (-0.4 to 7.7) | 0.08 |
| Skipped medication to save money | 11.0 | 15.5 | 4.5 | 0.03 | 4.1 (-0.2 to 8.4) | 0.06 |
| Took less medicine to save money | 11.2 | 14.5 | 3.3 | 0.10 | 2.9 (-1.2 to 7.0) | 0.17 |
| Delayed filling script to save money | 13.7 | 17.7 | 4.0 | 0.06 | 3.5 (-0.7 to 7.8) | 0.10 |
| Any CRN | 18.9 | 25.1 | 6.2 | 0.01 | 5.9 (1.1 to 10.8) | 0.02 |

Abbreviations: TCP, traditional commercial health plan; HDHP, high-deductible health plan; CRN, cost-related medication non-adherence *Adjusted for age (continuous), sex (male/female), family size (1, 2, 3, or 4+), race (Hispanic, non-Hispanic white, non-Hispanic black, non-Hispanic Asian, all other non-Hispanic), marital status (married/not married), health status (good or better vs fair or worse), any functional limitation (yes/no), education (less than high school, high school degree/some college, college degree, postgraduate degree), income group (\$0 to \$34,999; \$35,000 to \$74,999; \$75,000 to \$99,999; \$100,000+), employment status (employed vs not employed), and presence of chronic diseases (cardiovascular disease, chronic obstructive pulmonary disease, stroke, chronic kidney disease or chronic liver disease)

medication (11.1% vs 8.8%; AD 2.3 [CI 0.5 to 4.0]); and delay filling a prescription (14.4% vs 10.8%; AD 3.0 [CI 1.1 to 4.9]) (Table 2). HDHP enrollees were also more likely to have any CRN (20.4% vs 15.5%; AD 4.4 [CI 2.2 to 6.7], a 28% relative increase). Among insulin users, HDHP enrollees were more likely than TCP enrollees to have any CRN (25.1% vs 18.9%; AD 5.9% [CI 1.1 to 10.8], a 31% relative increase). While the point estimates for proportions of enrollees experiencing each of the remaining individual CRN measures were higher for HDHP enrollees, they did not achieve statistical significance.

In analyses stratified by income level, we found that the proportion of respondents having any CRN was substantially greater among lower income compared with higher income respondents, with approximately one-third of those in HDHPs and TCPs in the lowest-income group reporting any CRN, for the overall and insulin user sub-population (Table 3). The magnitude of the point estimates for differences between HDHP enrollees and TCP enrollees was small and nonsignificant for the lowest income group and larger for the remaining 3 income groups among all people with diabetes and the insulin user groups. Among all diabetics, HDHP enrollees were more likely than TCP enrollees to have any CRN in the low-income group (26.1% vs 19.7%; AD 5.4 [CI 1.5 to 9.3]) and high-income group (10.7% vs 6.1%; AD 4.5 [CI 1.1 to 8.0]). No statistically significant difference was observed for the remaining income categories. Among insulin users, we observed a similar pattern.

Association of Cost-Related Medication Nonadherence with Emergency Department Visits and Hospitalizations

Among all diabetics, those reporting any CRN were more likely to have 1 or more emergency department visits

(34.1% vs 20.6%; AD 5.5 [CI 2.1 to 8.9]) but not hospitalizations (Table 4). Among insulin users, those reporting any CRN were also more likely to have 1 or more emergency department visits (43.7% vs 24.6%; AD 11.2 [CI 4.4 to 18.1]) but not hospitalizations.

Sensitivity Analyses

When we replicated our analysis of the association between HDHP status and any CRN excluding those with chronic diseases other than diabetes, the point estimates for adjusted differences were comparable to the main analyses, although the difference for insulin users was no longer statistically significant (Supplement Table 1). When we replicated our analysis on the association of any CRN with emergency department visits and hospitalizations, the adjusted differences were again comparable and maintained the same pattern of statistical significance (Supplement Table 2).

DISCUSSION

In this nationally representative observational study of commercially insured non-elderly adults with diabetes, we found that enrollment in a HDHP was associated with greater CRN, with larger effects among insulin users. We also observed that among the lowest income group, approximately one-third of all diabetic patients and the insulin using subgroup experienced CRN. Differences in CRN were not observed in the lowest income group but were seen among the low-, middle-, and high-income groups, although for several comparisons, statistical significance was not reached. Finally, we found that CRN was associated with greater emergency department utilization, but not hospital utilization.

Table 3 Association Between HDHP Status and Any Cost-Related Medication Non-adherence According to Income Group

| Annual income group | Any Cost-Related Medication Non-adherence | | | | | | | |
|--|---|-----------|---------------------------------------|---------|---|---------|--|--|
| | Plan type | | Unadjusted difference TCP and HDHP | between | Adjusted* difference between TCP and HDHP | | | |
| | TCP % | HDHP % | Percentage points | P-value | Percentage points (95% CI) | P-value | | |
| | , | | All diabetics (n=7060) | | | | | |
| Lowest income: (n=1353) (\$0 to \$34,999) | 31.9 | 36.2 | 4.3 | 0.24 | 1.9 (-5.2 to 8.9) | 0.60 | | |
| Low income: (n=2791) (\$35,000 to \$74,999) | 19.7 | 26.1 | 6.4 | < 0.01 | 5.4 (1.5 to 9.3) | 0.006 | | |
| Middle income: (n=1117) (\$75,000 to \$99,999) | 12.7 | 16.3 | 3.6 | 0.25 | 3.9 (-1.2 to 8.9) | 0.13 | | |
| High income: (n=1799) (\$100,000 and over) | 6.1 | 10.7 | 4.6 | 0.01 | 4.5 (1.1 to 8.0) | 0.01 | | |
| (, , , , , , , , , , , , , , , , , , , | | | Insulin users (n=1202) | | | | | |
| Lowest income (n=345) (\$0 to \$34,999) | 32.5 | 38.8 | 6.3 | 0.39 | 1.1 (-14.5 to 16.7) | 0.89 | | |
| Low income (n=675) (\$35,000 to \$74,999) | 22.8 | 33.6 | 10.8 | 0.01 | 9.1 (0.9 to 17.3) | 0.03 | | |
| Middle income (n=260) (\$75,000 to \$99,999) | 17.7 | 21.8 | 4.1 | 0.49 | 7.8 (-3.1 to 18.7) | 0.16 | | |
| High income (n=397) (\$100,000 and over) | 9.3 | 13.4 | 4.1 | 0.28 | 6.2 (-1.0 to 13.5) | 0.09 | | |

Abbreviations: TCP, traditional commercial health plan; HDHP, high-deductible health plan; CRN, cost-related medication non-adherence *Adjusted for age (continuous), sex (male/female), family size (1, 2, 3, or 4+), race (Hispanic, non-Hispanic white, non-Hispanic black, non-Hispanic Asian, all other non-Hispanic), marital status (married/not married), health status (good or better vs fair or worse), any functional limitation (yes/no), education (less than high school, high school degree/some college, college degree, postgraduate degree), employment status (employed vs not employed), and presence of chronic diseases (cardiovascular disease, chronic obstructive pulmonary disease, stroke, chronic kidney disease or chronic liver disease)

Prior literature has documented that HDHP enrollment is associated with decreased^{5,16,23} or delayed²⁷ utilization of several forms of care in people with diabetes, but that being switched to a HDHP (with a health savings account) which covers medications such as insulin before deductibles are met, decreases out-of-pocket costs.³² However, little has been known about the association of HDHP enrollment and CRN to medications among patients with diabetes.^{1,2,4,7,17,33} Two prior studies have demonstrated that a switch to a HDHP was associated with a modest decline in hypoglycemic medication use,^{34,35} but both were conducted in a single health plan or employer over a decade ago, prior to the recent rapid rises in cost of hypoglycemic medications. Our study is the only one

we are aware of that examines the association of HDHP enrollment with CRN among diabetic patients in a contemporary, nationally representative sample. It also documents that the increased rate of CRN among HDHP compared with TCP enrollees is sizeable — 28% greater among all diabetic patients and 31% greater among insulin users.

High-deductible health plans, by design, expose patients to high out-of-pocket costs for care. 9,13,24,25 Until the insurance plan deductible is reached in any given year, some may be unable to afford these out-of-pocket costs and may instead skip medication doses, take less medication than prescribed, or delay filling a prescription. We were not able to directly study the impact of medication prices; however, it seems likely

Table 4 Emergency Department Visits and Hospitalizations among Diabetic People with and without Cost-Related Non-Adherence

| | Respondents reporting any CRN | | Unadjusted difference between any CRN and no CRN | | Adjusted* difference between any CRN and no CRN | |
|----------------------------------|-------------------------------------|----------|--|---------|---|---------|
| | No % | Yes % | Percentage points | p-value | Percentage points (95% CI) | P-value |
| | | , | All diabetics | | | |
| 1 or $>$ ED visits (n=7465) | 20.6 | 34.1 | 13.5 | < 0.001 | 5.5 (2.1 to 8.9) | < 0.01 |
| 1 or > hospitalizations (n=7465) | 11.7 | 18.1 | 6.4 | < 0.001 | 1.1 (-1.8 to 3.9) | 0.47 |
| • | | | Insulin users | | | |
| 1 or $>$ ED visits (n=1768) | 24.6 | 43.7 | 19.1 | < 0.001 | 11.2 (4.4 to 18.1) | 0.001 |
| 1 or > hospitalizations (n=1772) | 16.3 | 27.0 | 10.7 | < 0.001 | 5.0 (-0.6 to 10.7) | 0.08 |

^{*}Adjusted for age (continuous), sex (male/female), family size (1, 2, 3, or 4+) race (Hispanic, non-Hispanic white, non-Hispanic black, non-Hispanic Asian, all other non-Hispanic), marital status (married/not married), health status (good or better vs fair or worse), any functional limitation (yes/no), education (less than high school, high school degree/some college, college degree, postgraduate degree), income group (\$0 to \$34,999; \$35,000 to \$74,999; \$75,000 to \$99,999; \$100,000+), employment status (employed vs not employed), and presence of chronic diseases (cardiovascular disease, chronic obstructive pulmonary disease, stroke, chronic kidney disease or chronic liver disease)

that cost increases of newer oral hypoglycemic agents and insulin, ¹⁸ as well as the concurrent general rise in out-of-pocket expenditures for these medications, ^{21,36} particularly in HDHPs tied to health savings accounts, ³⁷ also play a role in the CRN we observed. Our finding that HDHP-related CRN was generally greater among insulin users is consistent with these patients' higher costs for medications and other care. This is particularly concerning given the potential clinical consequences of non-adherence to insulin compared with oral agents, such as diabetic ketoacidosis.

Our finding that income level dramatically affects CRN rates among both HDHP enrollees and TCP enrollees, and that a full third of patients in the lowest-income group report CRN, underscores the substantial financial barriers currently faced by commercially insured patients with diabetes. Differences in CRN between HDHP enrollees and TCP enrollees were observed in income groups above the lowest income category. These findings show that exposure to high out-of-pocket costs of medical care may adversely affect those with middle or even relatively high incomes.

Among patients with diabetes, medication non-adherence (from any cause) has been associated with a range of adverse outcomes, including an increase in hospitalizations, ^{5–7} and CRN has been associated with worse glycemic control and physical functioning in studies conducted within single health insurers or managed care organizations. In our national sample of patients with diabetes, we found that experiencing any CRN was associated with an elevated risk of having an emergency department visit; this adds additional support for the use of CRN as a clinically relevant outcome among people with diabetes. In contrast to prior studies, we found no increase in rates of hospitalization associated with HDHP enrollment in adjusted analyses, although the reasons for this are not clear.

Our study has several limitations. First, the NHIS deductible variable is binary — high vs low or no deductible — and the actual numerical values were unknown. Consequently, we were unable to assess how actual differences in deductible levels in the two plan types are related to CRN. Second, we do not know the duration of insurance coverage of respondents at the time of the survey interview; therefore, some respondents with newly acquired insurance could have answered CRN questions referring to a time when they did not have their current coverage. Third, we did not have information about the time course or severity of the diabetes diagnosis, both of which could affect perceptions about the urgency of adherence to diabetes medications and, if this differed by HDHP status, may have affected our results. Fourth, our outcomes were selfreported and are therefore subject to potential recall error, although it seems unlikely that there would be a differential effect by HDHP status. Fifth, our CRN questions were not specific to diabetes medications. However, in our sensitivity analysis, we obtained very similar results when patients with other chronic conditions were excluded, suggesting that the CRN we observed related to medications for diabetes. Sixth, this was an observational study; thus, we cannot definitively

establish that the associations we observed were causal. We were able to control for a wide range of potential demographic and clinical confounders but residual confounding by unobserved factors remains a possibility.

Our findings have several implications. First, clinicians should be cognizant that inadequacies in insurance coverage could lead to CRN among their patients with diabetes, particularly among insulin users and those with low incomes. Second, to improve CRN, policy makers should enact reforms to control rapidly escalating prices of diabetes medications, particularly insulin. Potential tools include patent reform, ensuring timely generic drug availability, expanding opportunities for government entities to negotiate prices with pharmaceutical companies,³⁸ and expanding a recent IRS rule allowing HDHPs with a health savings account to cover medications such as insulin before deductibles are met³⁹ to other types of HDHPs. Finally, the public should be aware that policies that expand the use of HDHPs could harm patients with diabetes, while policies that reduce financial barriers to care could improve access and adherence to needed medications for patients with this condition.

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