



Impact of the 2013 National Rollout of CMS Competitive Bidding Program: The Disruption Continues

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OBJECTIVE

Use of glucose monitoring is essential to the safety of individuals with insulin-treated diabetes. In 2011, the Centers for Medicare & Medicaid Services (CMS) implemented the Medicare Competitive Bidding Program (CBP) in nine test markets. This resulted in a substantial disruption of beneficiary access to self-monitoring of blood glucose (SMBG) supplies and significant increases in the percentage of beneficiaries with either reduced or no acquisition of supplies. These reductions were significantly associated with increased mortality, hospitalizations, and costs. The CBP was implemented nationally in July 2013. We evaluated the impact of this rollout to determine if the adverse outcomes seen in 2011 persisted.

RESEARCH DESIGN AND METHODS

This longitudinal study followed 529,627 insulin-treated beneficiaries from 2009 through 2013 to assess changes in beneficiary acquisition of testing supplies in the initial nine test markets (TEST, $n = 43,939$) and beneficiaries not affected by the 2011 rollout (NONTTEST, $n = 485,688$). All Medicare beneficiary records for analysis were obtained from CMS.

RESULTS

The percentages of beneficiaries with partial/no SMBG acquisition were significantly higher in both the TEST (37.4%) and NONTTEST (37.6%) groups after the first 6 months of the national CBP rollout, showing increases of 48.1% and 60.0%, respectively (both $P < 0.0001$). The percentage of beneficiaries with no record for SMBG acquisition increased from 54.1% in January 2013 to 62.5% by December 2013.

CONCLUSIONS

Disruption of beneficiary access to their prescribed SMBG supplies has persisted and worsened. Diabetes testing supplies should be excluded from the CBP until transparent, science-based methodologies for safety monitoring are adopted and implemented.

Self-monitoring of blood glucose (SMBG) is a key component of diabetes self-management among individuals treated with insulin, particularly for those on intensive insulin therapy (1). Frequent SMBG is especially important in elderly insulin-treated patients due to their increased risk of severe or fatal hypoglycemia (2–5).

In January 2011, the Centers for Medicare & Medicaid Services (CMS) initiated a test of a Competitive Bidding Program (CBP) in nine test markets, which included ~444,000 fee-for-service Medicare Part D beneficiaries with insulin-treated diabetes. Payment rates were reduced from \$34 to \$14 per vial of 50 SMBG test strips. Importantly, only

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SMBG supplies obtained through mail-order channels were impacted in the test implementation of the CBP; supplies obtained through retail channels were exempted from the first round of the program. CMS subsequently reported in April 2012 that no disruption of access to diabetes testing supplies occurred and that no negative health consequences to beneficiaries were observed as a result of the program (6). CMS expanded the program nationwide in July 2013. In the expanded program, reimbursement for test strips was further reduced to \$10.41 per bottle of 50 strips when acquired through both mail-order and retail channels, and the number of mail-order distributors was reduced from 891 to 21.

In March 2016, we reported findings from a retrospective, longitudinal study that assessed the impact of the 2011 CBP rollout on insulin-treated beneficiaries in the nine test markets compared with matched beneficiaries in the remaining Medicare markets (7). In both cohorts, we found that reduced or no acquisition of SMBG supplies was negatively associated with survival ($P < 0.0001$). Moreover, compared with the matched beneficiary control group, the data showed that among beneficiaries who obtained insulin as prescribed, shifting from full acquisition of SMBG supplies to partial or no acquisition was associated with increased mortality and higher in-patient admissions and associated costs. A notable change in obtaining SMBG supplies from the mail-order to retail channels was also observed in test market beneficiaries but not the non-test market beneficiaries.

Our results demonstrated that the program was significantly associated with a negative impact on obtaining SMBG supplies, leading to several significant, unintended consequences. Nevertheless, CMS elected to initiate the program nationwide and subsequently reported that its “health status monitoring tool has not detected any changes in health measures attributable to the CBP” (8).

In our initial report, we hypothesized that the national program rollout in 2013 would result in even greater disruption of SMBG supply acquisition due to further reductions in the number of mail-order distributors, lower reimbursement rates (which would limit beneficiary choice to lower-quality SMBG systems), and expansion of the program to include both mail-order and retail channels. To

test our hypothesis, we expanded our longitudinal analysis to assess the impact of the program on insulin-treated beneficiaries during the first 6 months of the national program rollout.

RESEARCH DESIGN AND METHODS

In this 4-year, retrospective, longitudinal study, we assessed the impact of competitive bidding during the first 6 months of the national program implementation among Medicare beneficiaries who treated their diabetes using insulin within the nine test markets and nontest markets, which represent the rest of the country. For our analysis, we obtained the CMS data set used to assess impact and outcomes. Our goal was to determine whether access to SMBG supplies changed in the year after the July 2013 national rollout of the program and, if so, assess the behavioral and health outcomes resulting from the potential impact on obtaining supplies.

In this presentation, we use “access” to describe the beneficiary’s pattern for obtaining glucose test strips. Access was defined as the rate of each beneficiary’s acquisition of insulin and SMBG supplies and benchmarked against the amount of testing strips prescribed by their health care provider. For insulin-treated beneficiaries, Medicare reimburses for the acquisition of three strips per day. Based on that reimbursement schedule, full acquisition of SMBG supplies is defined here as the purchase of diabetes testing strips so that from the date of the first purchase, the beneficiary continued to acquire testing supplies to use three strips per day $>80\%$ of the year. Any beneficiary who scored 80% or higher on this proportional days covered (PDC) scale was considered “full SMBG” acquisition; any beneficiary who scored $<80\%$ was defined as “partial/no SMBG” acquisition.

Outcome Measures

The primary outcome measure was change in number/percentage of Medicare beneficiaries with full insulin and partial/no SMBG acquisition after implementation of the July 2013 program national rollout. Secondary outcomes included number/percentage of beneficiaries with changes in patterns of obtaining strips. This included full insulin and full SMBG acquisition, full insulin and partial/no SMBG acquisition, partial/no insulin and full SMBG acquisition, and partial/no insulin and partial/no SMBG acquisition.

Change in percentage of beneficiaries with Part D record for insulin but no durable medical equipment (DME) record for SMBG supplies was also assessed.

Data Source

The data for our analyses were the Medicare Beneficiary Annual Summary Files 2009–2010 and the Medicare Master Beneficiary Summary File: Base Segment, Chronic Conditions Segment, and the Cost and Utilization Segment 2011–2013 (Supplementary Data).

Study Population

The study population was Medicare beneficiaries with a diagnosis of diabetes and a record of insulin treatment in 2009 ($n = 529,627$). This study population was separated into two groups, TEST and NONTEST, for analysis. The TEST group included all insulin-treated beneficiaries who resided in the nine CBP markets (TEST, $n = 43,939$) in 2009. The NONTEST cohort included all other insulin-treated beneficiaries ($n = 485,688$). Among the types of insulin used, CMS records showed that 349,200 (65.9%) of beneficiaries were treated with short- or rapid-acting insulin (including premixed insulins) with or without long-acting or NPH insulin, whereas 180,427 (34.1%) were treated with long-acting or NPH insulin only.

Analysis

As described in our previous report (7), the TEST and NONTEST beneficiaries were further categorized into two groups: beneficiaries whose records showed full insulin acquisition and either full insulin and full SMBG acquisition and full insulin and partial/no SMBG acquisition (Table 1). A beneficiary was characterized as full or partial acquisition of insulin based upon the PDC model. PDC for insulin was calculated based on the fill dates and days of supply for each prescription filled in the Medicare Part D event file. The numerator was the total number of days covered by the medication fills during the measurement period; the patient-level denominator was the number of days between the first fill and the end of the study period or death. According to the time-array method used by Leslie (9), we calculated the PDC of insulin for each year from 2009 through December 2013.

We then followed these clusters within the TEST and NONTEST groups from 2009 through December 2013 to determine whether beneficiaries remained in one cluster or migrated to the other. This allowed us

Table 1—Demographic characteristics (7)

Variable	Full Cohort			
	TEST		NONTTEST	
	Full SMBG (n = 14,179)	Partial SMBG (n = 17,411)	Full SMBG (n = 130,298)	Partial SMBG (n = 200,511)
Age (years), mean ± SD	75.0 ± 7.0	76.5 ± 7.7	74.3 ± 6.6	76.3 ± 7.7
Sex, n (%)				
Male	4,969 (35.0)	6,278 (36.1)	47,173 (36.2)	72,640 (36.2)
Female	9,210 (65.0)	11,133 (63.9)	83,125 (63.8)	127,871 (63.8)
Race or ethnicity, n (%)				
White	9,077 (64.0)	11,462 (65.8)	106,089 (81.4)	153,914 (76.8)
Black	1,685 (11.9)	2,879 (16.5)	15,471 (11.9)	28,229 (14.1)
Hispanic	2,997 (21.1)	2,485 (14.3)	4,108 (3.2)	7,303 (3.6)
Other	401 (2.8)	562 (3.2)	4,491 (3.4)	10,807 (5.4)
Unknown	19 (0.1)	23 (0.1)	139 (0.1)	258 (0.1)
Medical conditions, n (%)				
Acute myocardial infarction	398 (2.8)	463 (2.7)	3,801 (2.9)	5,199 (2.6)
Atrial fibrillation	1,661 (11.7)	2,149 (12.3)	17,499 (13.4)	25,730 (12.8)
Chronic kidney disease	6,032 (42.5)	7,405 (42.5)	58,407 (44.8)	83,911 (41.9)
Chronic obstructive pulmonary disease	4,717 (33.3)	4,802 (27.6)	27,248 (20.9)	37,152 (18.5)
Heart failure	6,823 (48.1)	8,648 (49.7)	59,623 (45.8)	94,659 (47.2)
Ischemic heart disease	10,186 (71.8)	11,347 (65.2)	83,378 (64.0)	118,554 (59.1)
Stroke or transient ischemic attack	1,292 (9.1)	2,322 (13.3)	9,776 (7.5)	21,815 (10.9)
Any cancer	1,022 (7.2)	1,139 (6.5)	9,455 (7.3)	12,327 (6.2)

to identify any patterns in mortality, inpatient admissions, and costs associated with migration changes. Of interest were changes that occurred between January 2012 and December 2013, which included the first 6 months after the national program rollout. Analyses were performed to determine whether acquisition of insulin and SMBG supplies was associated with these results.

In both groups (TEST and NONTTEST), differences between January 2012 and December 2013 were calculated and tested with χ^2 tests. We used logistic regression models with outcome of SMBG supply acquisition for insulin-treated beneficiaries. The outcome event counts, including migration patterns, mortality rates, inpatient admissions, and medical costs, were compared. Because of the imbalance in the number of beneficiaries in the TEST versus NONTTEST populations, absolute percentages were used to describe beneficiary characteristics (e.g., partial/no SMBG), whereas relative percentages were used to describe changes in characteristics. Because we were looking at actual patient records, use of 95% CIs or SDs was not required.

RESULTS

Changes in Insulin and SMBG Acquisition

Full Insulin and Full SMBG Acquisition

Within the full study cohort (TEST and NONTTEST), the number/percentage of

beneficiaries with full insulin and full SMBG acquisition increased from 71,576 (29.0%) in January 2013 to 75,657 (31.2%) after the national program implementation, a slight but statistically significant increase of 4,099 (7.9%) ($P < 0.0001$). The percentage of TEST and NONTTEST beneficiaries with full insulin and full SMBG acquisition remained relatively stable before and after the national program implementation (Table 2 and Fig. 1A).

Full Insulin and Partial/No SMBG Acquisition

Within the full study cohort, the number/percentage of beneficiaries with full insulin and partial/no SMBG acquisition increased from 58,339 (23.6%) in January 2013 to 90,923 (37.5%) after the national rollout, an increase of 32,584 (59.0%) ($P < 0.0001$). The percentage of full insulin and partial/no SMBG beneficiaries in the TEST group remained relatively stable prior to 2011, increased significantly ($P < 0.0001$) after the CBP pilot implementation, and decreased slightly by January 2013 but then increased significantly ($P < 0.0001$) during the first 6 months of the July 2013 national implementation of the program. The percentage of NONTTEST beneficiaries with full insulin acquisition and partial/no SMBG acquisition remained stable from 2010 to 2013 but increased significantly ($P < 0.0001$) after the national implementation (Table 2 and Fig. 1B).

Partial/No Insulin and Full SMBG Acquisition

Within the full study cohort, the number/percentage of beneficiaries with partial/no insulin and full SMBG acquisition decreased from 58,102 (23.5%) in January 2013 to 28,319 (11.7%) after the national program implementation, a decrease of 29,783 (50.3%) ($P < 0.0001$). The percentage of TEST beneficiaries with partial/no insulin and full SMBG acquisition remained stable prior to January 2013 but decreased significantly ($P < 0.0001$) after the national program implementation. The percentage of beneficiaries in the NONTTEST group with partial/no insulin and full SMBG acquisition also remained stable from 2010 to 2013 but decreased significantly ($P < 0.0001$) after the national program implementation (Table 2 and Fig. 1C).

Partial/No Insulin and Partial/No SMBG Acquisition

Within the full study cohort, the number/percentage of beneficiaries with partial/no insulin and partial/no SMBG acquisition decreased significantly ($P < 0.0001$), by 18.4%, from 59,121 (23.9%) in January 2013 to 47,285 (19.5%) after the national rollout. The percentage of TEST beneficiaries with partial/no insulin and partial/no SMBG acquisition remained stable prior to the national program but decreased significantly ($P < 0.0001$) to 18.3%

Table 2—Changes in SMBG acquisition from January 2010 to January 2014

Acquisition group	January 2010	January 2011	January 2012	January 2013	January 2014
Full and full					
TEST	14,179 (32.3)	10,864 (32.2)	6,567 (28.7)	5,746 (31.1)	5,897 (32.9)
NONTEST	130,298 (26.8)	104,939 (27.6)	81,092 (28.2)	65,830 (28.8)	69,778 (31.1)
Full and partial/no					
TEST	9,193 (20.9)	7,465 (22.1)	6,216 (27.2)	4,659 (25.2)	6,708 (37.4)
NONTEST	101,746 (21.0)	84,935 (22.3)	65,329 (22.7)	53,680 (23.5)	84,215 (37.6)
Partial/no and full					
TEST	9,972 (22.7)	7,254 (21.5)	4,266 (18.7)	3,796 (20.6)	2,052 (11.4)
NONTEST	114,382 (23.6)	85,997 (22.6)	69,704 (24.2)	54,306 (23.8)	26,267 (11.7)
Partial/no and partial/no					
TEST	10,595 (24.1)	8,207 (24.3)	5,822 (25.5)	4,266 (23.1)	3,282 (18.3)
NONTEST	139,262 (28.7)	105,033 (27.6)	71,832 (25.0)	54,855 (24.0)	44,003 (19.6)

Data are presented as *n* (%). Full and full = full insulin and full SMBG; full and partial/no = full insulin and partial/no SMBG; partial/no and full = partial/no insulin and full SMBG; partial/no and partial/no = partial/no insulin and partial/no SMBG. Boldface numbers indicate notable percentage changes in each beneficiary category.

(*n* = 3,282) after the rollout. The percentage of beneficiaries in the NONTEST group with partial/no insulin and partial/no SMBG acquisition decreased year to year prior to the national rollout but decreased significantly ($P < 0.0001$) to 19.6% (*n* = 44,003) after the national program rollout, an 18.2% decrease ($P < 0.0001$) (Table 2 and Fig. 1D).

Change in Insulin-Treated Beneficiaries With No DME Record for SMBG Supplies
Among all beneficiaries with a record of insulin acquisition within the study cohort, the percentage of beneficiaries with no DME record for SMBG acquisition increased from 54.1% in January 2013 to 62.5% by January 2014.

CONCLUSIONS

As reported in our earlier analysis, the 2011 test rollout of the CMS CBP in nine markets was associated with significant changes among insulin-treated Medicare beneficiaries obtaining SMBG supplies as prescribed by their providers (7). These reductions were associated with increased deaths, in-patient hospitalizations, and associated costs (7). Findings from our current retrospective, longitudinal analysis of the same CMS data set confirm our hypothesis that the national program rollout in 2013 would result in an even greater reduction of obtaining SMBG supplies as prescribed.

Like our earlier findings, we observed a significant increase in the percentage of beneficiaries in both the TEST and NONTEST groups who migrated from full SMBG to partial/no SMBG acquisition during the first 6 months of the national program implementation. Although we expected

to see disruption in the NONTEST beneficiaries, who were not impacted by the CBP test rollout in 2011, it was concerning that the TEST group beneficiaries were also impacted with regard to obtaining needed supplies in 2013 despite their previous exposure to the program and the opportunity to adapt to the new changes in strip acquisition.

Of great concern is the significant decrease (−50.3%) in the percentage of beneficiaries with partial/no insulin and full SMBG acquisition and partial/no insulin and partial/no SMBG (−18.4%). Given that the percentage of beneficiaries with full insulin and full SMBG acquisition increased by only 7.9% (from 71,576 to 75,675 beneficiaries), compared with the 59% increase in beneficiaries with full insulin and partial/no SMBG (from 58,339 to 90,923), we now have a large percentage of our cohort calculating their insulin dosages with inadequate (or no) SMBG to guide their therapy decisions.

Although it is not possible to identify the specific reason(s) for the disruption in access to SMBG supplies from the CMS data set, several factors may explain the migration to full insulin and partial/no SMBG. First, the national rollout was expanded to include both mail-order and retail outlets. As a result, beneficiaries could purchase their prescribed SMBG supplies from retail outlets and mail-order suppliers that accepted Medicare assignment. However, outlets that did not accept assignment forced patients to pay higher out-of-pocket costs. As shown in Fig. 1B, disruption in access to SMBG supplies was mitigated among TEST group beneficiaries in 2012 when the retail

option was still available. Second, many beneficiaries who continued to acquire their supplies through mail-order channels were burdened to find new suppliers. In 2011, there were 891 unique mail-order suppliers of SMBG supplies. In 2013, the number of mail-order suppliers decreased to 21; this number eventually shrank to 15 due to business failures and noncompliance.

Fewer choices and limited access to the SMBG supplies most commonly used prior to implementation of the program may also help to explain our findings. In a recent survey by the American Association of Diabetes Educators, beneficiaries who chose to obtain their diabetes testing supplies through mail-order suppliers were “effectively being made to either switch to different testing systems or purchase supplies through non-mail-order settings” (10). Moreover, the survey found that the information available from suppliers themselves was inconsistent and may be further complicating the beneficiary’s ability to find appropriate testing systems.

When exploring the link between competitive bidding and the increased mortality and hospitalizations observed in our earlier study, one must also consider the potential impact of the accuracy of many of the SMBG systems provided to beneficiaries. Because SMBG data are used in insulin dosing decision making, obtaining accurate glucose data is critical. As reported by Breton and Kovatchev (11), inaccurate glucose information can lead to severe consequences, either by failing to detect hypoglycemia or by prompting patients to overcorrect with insulin based on an erroneous hyperglycemia result (11). Several studies revealed significant inaccuracy and lot-to-lot variability in up

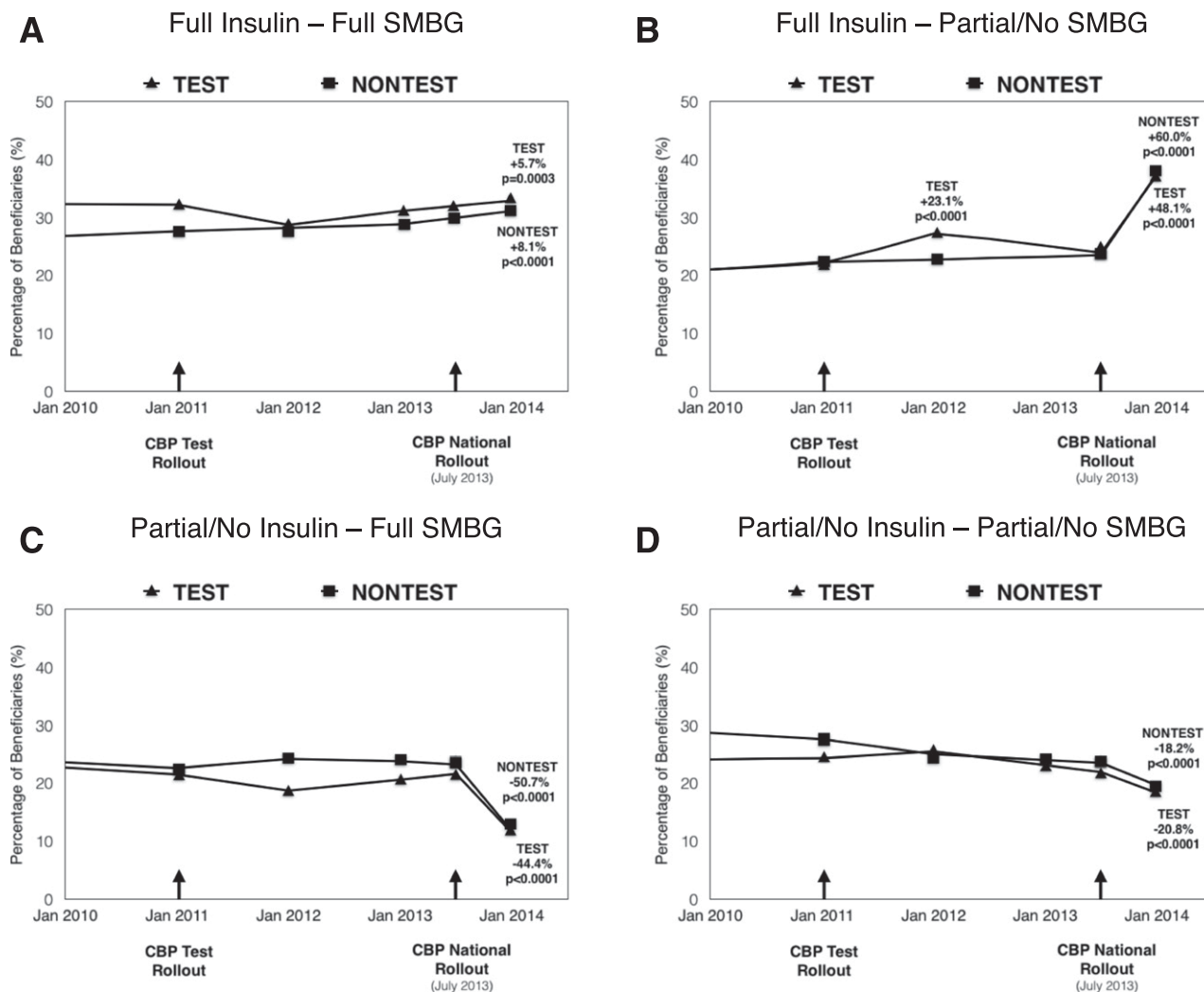


Figure 1—Changes in beneficiary acquisition of insulin and SMBG supplies. The percentage of TEST and NONTEST beneficiaries with full insulin and full SMBG acquisition remained relatively stable before and after the national program implementation (A). The percentage of NONTEST beneficiaries with full insulin acquisition and partial/no SMBG acquisition remained stable from 2010 to 2013 but increased significantly ($P < 0.0001$) after the national implementation (B). The percentage of beneficiaries in the NONTEST group with partial/no insulin and full SMBG acquisition also remained stable from 2010 to 2013 but decreased significantly ($P < 0.0001$) after the national program implementation (C). The percentage of beneficiaries in the NONTEST group with partial/no insulin and partial/no SMBG acquisition decreased year-to-year before the national rollout but decreased significantly ($P < 0.0001$) to 19.6% ($n = 44,003$) after the national program rollout, an 18.2% decrease ($P < 0.0001$) (D). ↑ indicates the test launch of CBP in 2011 and national launch in July 2013.

to 45% of the SMBG systems currently marketed (12–15). Most recently, Klonoff et al. (16) reported findings from a post-marketing surveillance study that assessed the accuracy of 18 blood glucose monitoring systems marketed in the U.S. across a wide range of blood glucose levels in the hands of trained professionals. Twelve systems failed to meet the study’s accuracy criteria, two of which were found to less accurately account for 43.5% of the Medicare market (17). Because many Medicare mail-order suppliers offer only these products through the CBP, beneficiaries may have to rely on a meter of less accuracy. One must also consider the potential impact of less accurate meters on individuals using continuous glucose

monitoring (CGM) to guide their self-management. In 2017, CMS approved CGM for patients with type 1 and type 2 diabetes receiving multiple daily injections (18). Use of less accurate blood glucose meters to calibrate these devices may result in inaccurate CGM readings.

It remains unclear as to why the U.S. Food and Drug Administration (FDA) has not regulated the marketing of less accurate SMBG systems more aggressively. It is possible that some companies have simply failed to maintain adequate quality standards in their manufacturing processes over time. Unfortunately, the FDA has neither the resources nor ability to effectively monitor offshore manufacturers (19). Another explanation is that

offshore manufacturers may be falsifying their supporting data when filing for FDA 510(k) clearance. Currently, the agency does not conduct independent evaluations of SMBG devices and must rely on the accuracy of data generated and submitted by manufacturers. Although the FDA is working to strengthen its postmarket surveillance processes, the agency acknowledges that fraudulent system performance data are a significant concern (19).

An additional concern is the limit of three strips per day for patients on insulin by the Medicare coverage policy. This is in stark contrast to the American Association of Clinical Endocrinologists, which recommends more frequent testing among insulin-treated patients. The CBP program

also potentially challenges the clinical standard of care by limiting product offerings; in some cases, only one brand is made available, thus forcing the patient to switch to unfamiliar systems without any counseling or coaching. Self-monitoring must be individualized to meet the specific needs of each patient, and glucose monitoring systems should be selected based on their ability to achieve that goal.

Several limitations of our analysis are noteworthy. As noted above, it is not possible to identify the specific reason(s) for the disruption in access to SMBG supplies from the CMS data set. In addition, it was not possible to link outcomes with actual utilization of SMBG because the CMS data only provided information about SMBG supply acquisition by beneficiaries. Also, because the program was implemented nationally, we no longer had a control group for comparison. The significant changes in SMBG acquisition, however, suggest a strong association between the national implementation of the CBP and glucose strip utilization. Additionally, the data provided by CMS did not indicate the specific cause(s) of the increased hospitalizations observed. Moreover, the records provided by CMS provided limited information regarding the socioeconomic or educational characteristics of the beneficiaries.

Nevertheless, our findings demonstrate that access to diabetes testing supplies was significantly altered by the national CBP rollout in July 2013. Based on our earlier analysis (7), we know that this disruption of access is associated with reductions in the number of insulin-treated Medicare beneficiaries who are acquiring their prescribed diabetes supplies and is associated with increased mortality, hospitalizations, and associated costs. Moreover, we expect the disruption to continue among insulin-treated diabetes beneficiaries with further reductions in the reimbursement price (from \$10.41 to \$8.19) and even fewer mail-order suppliers (from 21 to 9), effective July 2016.

It is important to note that our analysis included only those Medicare beneficiaries who were enrolled in 2009. Since that time, hundreds of thousands more beneficiaries with insulin-treated diabetes have enrolled in Medicare. Thus, our findings may not reflect the full magnitude of the adverse impact of CBP that is now occurring among all insulin-treated Medicare

beneficiaries. This is particularly alarming given that CMS has made no apparent changes in safety monitoring protocols or reporting, which were criticized in a 2015 report by the National Minority Quality Forum (20).

Given CMS's failure to provide effective oversight and safeguard beneficiaries against harm, and the FDA's inability to ensure beneficiary access to accurate and reliable SMBG products, it is our view that diabetes testing supplies should be excluded from the CBP until transparent, science-based methodologies for monitoring beneficiary safety and ensuring SMBG accuracy are adopted.

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Author Contributions. G.A.P. and L.X. developed the study protocol, provided statistical analysis, and contributed to data interpretation. I.B.H., C.G.P., B.T.T., and D.G.M. contributed to data interpretation and wrote the manuscript. All authors reviewed the manuscript and accept responsibility for the contents of this report. G.A.P. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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