

Economic Implications of Type 2 Diabetes Management

Carrie McAdam Marx, PhD, RPh

Diabetes mellitus (DM) is a term used to describe a group of metabolic diseases of multiple etiologies. The condition results from defects in insulin secretion, insulin action, or both, and is characterized by hyperglycemia with disturbances of carbohydrate, fat, and protein metabolism.^{1,2} DM affects over 25 million people in the United States, representing 8.3% of the population, according to data generated by the Centers for Disease Control and Prevention (CDC) in 2010.³ Of the 25 million people with DM, more than one-fourth (7.0 million) were undiagnosed³ and 90% to 95% of the patients with DM had type 2 DM, a form of DM associated with a continuum ranging from insulin resistance with relative insulin deficiency to a predominantly insulin secretory defect with or without insulin resistance.^{1,2} The CDC data also indicated that DM was the leading cause of kidney failure, lower-limb amputations, and new cases of blindness, and was the seventh-leading cause of death in the United States.³

These data are certainly troubling and become even more unsettling when viewed in light of the steadily increasing prevalence of DM in the United States (Figure 1).^{4,5} The crude prevalence of diagnosed DM has risen from 2.7% in 1980 to 6.9% in 2010⁴ and is predicted to increase to 8.5% by the year 2031.⁵ The rise in the prevalence is due to increases in life expectancy and in DM incidence, which in turn is partially driven by the increase in the rate of obesity in the United States.⁶ This dynamic further complicates DM, as obesity and DM are independently associated with poor outcomes directly or through other comorbidities, such as hypertension.⁷ Thus, it is not surprising that the rise in DM prevalence has translated into a disproportionate increase in the health and economic burden associated with DM.

Costs of DM in the United States

The American Diabetes Association (ADA) has published periodic reports regarding the costs of DM in the United States. These reports have shown a dramatic increase in costs attributable to DM over the past 15 years. In 1997, the total estimated cost of DM was \$98 billion (Figure 2A).⁸ These costs increased to \$174 billion in 2007 and \$245 billion in 2012 (not adjusted for inflation).^{9,10} Direct healthcare cost related to DM, a primary driver of the cost increase, rose from \$44 billion in 1997 to \$116 billion in 2007 and \$176 billion in 2012 (not adjusted for inflation).⁸⁻¹⁰ On a

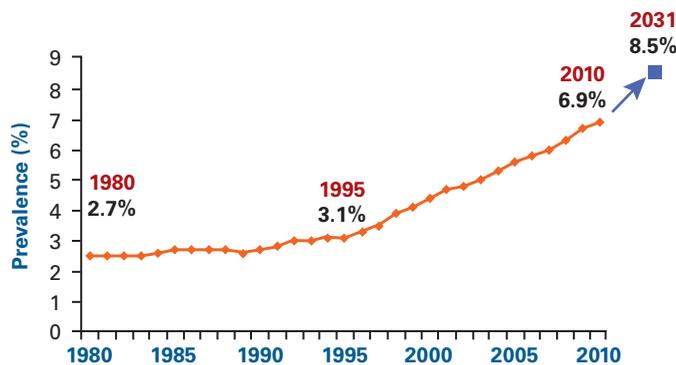
Abstract

Diabetes mellitus (DM) is a complex and progressive disease associated with significant morbidity and mortality. Both the prevalence and economic burden associated with DM have been steadily increasing and are projected to continue to increase. A series of cost reports published by the American Diabetes Association (ADA) between 1997 and 2012 have suggested that direct medical costs are the primary cost driver in DM. Direct costs have increased over 5-fold during this time frame, from \$44 billion to \$176 billion annually, likely due to both the increased prevalence of DM and increased costs of providing DM-related care. Trends in anti-diabetic medication usage as reported by Centers for Disease Control data from 1997 to 2011 have found that the proportion of diagnosed patients treated for DM has remained fairly stable. However, there has been an increase in the use of oral agents alone, a decrease in patients on insulin only, and a relatively small increase in the percentage of patients using both insulin and oral agents, suggesting stagnation regarding the uptake of insulin use. In parallel, the ADA cost and utilization data suggest that use of medications to treat DM-related comorbidities and complications has risen, which contributes to the risk of medication errors, avoidable adverse drug events, and noncompliance. These data highlight a few of the challenges involved in managing a population of patients with DM. A comprehensive assessment of unmet needs for the population with DM is essential for effective population management. An approach that strives to identify and reduce barriers to patients receiving optimal care and being active participants in their DM management will facilitate systemwide efforts to improve DM outcomes.

(*Am J Manag Care. 2013;19:S143-S148*)

For author information and disclosures, see end of text.

■ **Figure 1.** Crude Prevalence of Diagnosed Diabetes in the United States^{4,5}



The crude prevalence of diagnosed diabetes mellitus rose by 4.2% from 1980 to 2010 (from 2.7% to 6.9%), and is predicted to increase to 8.5% by the year 2031.

per patient basis, direct costs to treat DM rose from \$11,744 in 2007, of which \$6649 was attributed to DM, to \$13,700 in 2012, of which \$7900 was attributable to DM, which averaged approximately 2.3 times higher than those without DM. While also higher, indirect medical expenditures attributable to DM rose moderately from \$54.1 billion in 1997 to \$58 billion in 2007 and \$69 billion in 2012 (not adjusted for inflation) (Figure 2A).⁸⁻¹⁰

In addition to overall costs, the distribution of DM-related medical costs has changed since 1997, when direct costs comprised \$7.7 billion specifically for the care of DM, \$11.8 billion in association with increased prevalence of DM-related chronic complications, and \$24.6 billion due to increased prevalence of general medical conditions (Figure 2B).⁸ By 2007, direct DM costs accounted for \$27 billion of direct costs, \$58 billion to treat DM-related chronic complications, and \$31 billion in excess general medical costs (Figure 2B).⁹ This represents a notable increase in costs related to complications and comorbidities associated with DM. While these data were not provided for 2012, costs provided for specific sites of service suggest that factors other than hyperglycemia and acute DM care continue to drive costs in DM.¹⁰

Cost and resource use associated with specific locations of service have also been in flux since 1997. Inpatient care accounted for the majority (62%) of direct costs in 1997, followed by outpatient services (25%) and nursing home care (13%).⁸ These expenditures reflect 13,872,146 hospital inpatient days, 30,270,663 office-based physician visits, and 48,564,116 retail prescriptions (Figure 2C).⁸ In 2007, half (50%) of the medical expenditures attributed to DM were for hospital inpatient care, DM medication and supplies accounted for 12%, retail prescriptions to treat complications of DM accounted for 11%, and physician office visits accounted for 9%.⁹ These expenditures reflect

24,262,000 hospital inpatient days, 64,713,000 office-based physician visits, and 175,317,000 retail prescriptions (Figure 2C).⁹ The latest figures (2012) show that hospital inpatient care continues to represent a smaller share of DM costs, decreasing to 43% of DM costs and 26,383,000 inpatient days; a total of 28,150,000 office-based physician visits accounted for 9% of costs; while medications, including DM drugs, increased to 28% of expenditures, with utilization more than doubling since 2007.¹⁰ These data

show a continuing shift in the care and cost of care from the inpatient setting to the ambulatory care setting, and reflect an increase in the use of medications to treat DM-related comorbidities.

The other component of DM costs is indirect costs related to lost productivity and premature mortality. In 1997, indirect costs were \$54 billion, including \$37 billion from lost productivity and disability and \$17 billion from premature mortality.⁸ Indirect costs in 2007 were just over \$58 billion and included \$31 billion attributable to reduced productivity and disease-related disability, and \$27 billion in lost productivity due to early mortality.⁹ In 2012, indirect DM costs were \$69 billion including \$50 billion attributed to reduced productivity and disability and \$19 billion attributed to mortality-related productivity loss.¹⁰ When adjusted for inflation, indirect costs represented a 3% increase.¹⁰

In summary, data compiled over time suggest a trend whereby indirect costs have been relatively stable while medical costs increased 5-fold between 1997 and 2012, from \$44 billion to \$176 billion (not adjusted for inflation).⁸⁻¹⁰ Like the case for DM prevalence over time, this cost trend is expected to continue. An actuarial projection issued by the Institute for Alternative Futures in 2011 estimated that the total cost of DM will reach \$514 billion in 2025 (in 2010 dollars) (Figure 2A).¹¹ This figure includes a projected \$361 billion in excess medical expenditures and \$154 billion in reduced national productivity (Figure 2A).¹¹

Trends in Anti-Diabetic Utilization

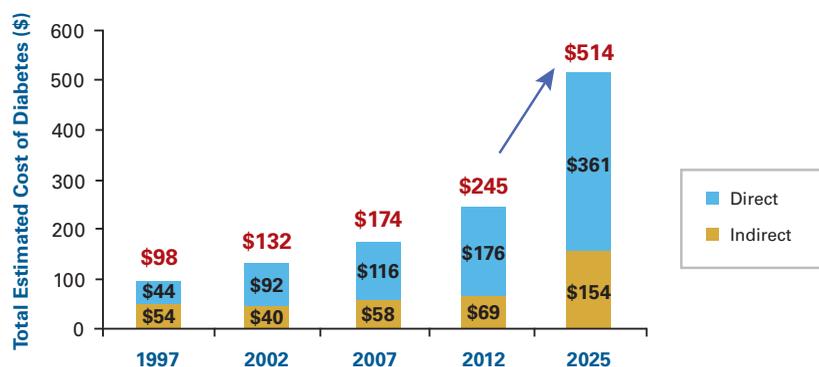
The CDC has reported age-adjusted anti-diabetic medication use from 1997 through 2011 (Figure 3).¹² During that time period, the percentages of adults 18 years or older with diagnosed DM receiving treatment with oral agents and/or insulin has remained relatively stable at approximately

80%. By type of therapy, the percentage of patients who reported taking oral agents increased until 2001 then remained unchanged afterward, while the percentage of those taking insulin only decreased until 2007 and then remained unchanged. By 2011, the percentage of patients who reported taking oral agents only was 3 times higher than those who reported using insulin only (50.3% vs 17.8%), and the percentage of patients taking both insulin and oral agents increased slightly. Between the small increase in the percentage of patients on both oral agents and insulin, and the decrease in patients on insulin only, the data would seem to suggest stagnation regarding the uptake in insulin use.¹² Numerous studies have documented patient and provider barriers to initiating insulin^{13,14} and such reluctance and delays in initiating insulin therapy may be contributing to less than optimal DM control in the United States.¹⁵

Medication Errors

Pharmacotherapy is a key component of managing hyperglycemia due to DM; thus most patients with DM have at least some risk for experiencing a medication error. The Institute of Medicine (IOM) defines a medication error as any error occurring during the medication-use process.¹⁶ These errors include incorrect doses of medicines prescribed, administered, or taken; failure to give or take a medication; and avoidable adverse drug events (ADEs). A study published in 1995 indicated that hospitalized patients are subject to 0.3 prescribing errors per day¹⁷; another study published in

Figure 2A. Diabetes Cost Trends (in Billions)^{8-11,34}



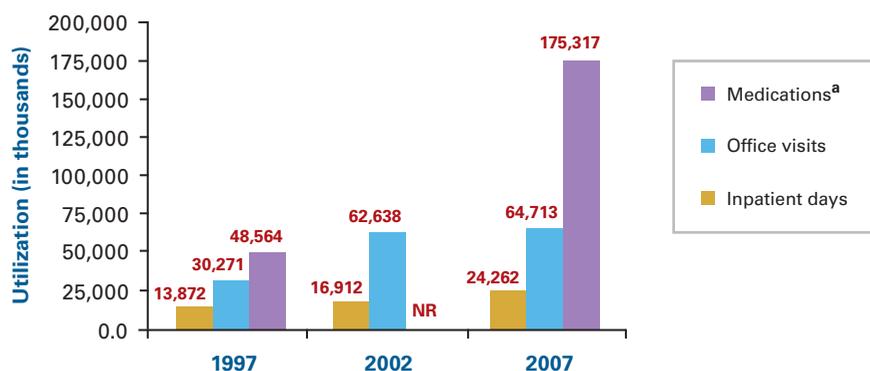
The total estimated cost of diabetes mellitus has increased from 1997 to 2012, and is estimated to reach \$514 billion in 2025. Direct healthcare costs increased more dramatically than indirect costs from 1997 to 2012.

Figure 2B. Diabetes Direct Costs (in Billions)^{8,9,34}



The distribution of diabetes mellitus-related medical costs has changed between 1997 and 2007, reflecting a notable increase in costs related to complications and comorbidities associated with diabetes mellitus.

Figure 2C. Healthcare Resource Utilization^{8,9,34}

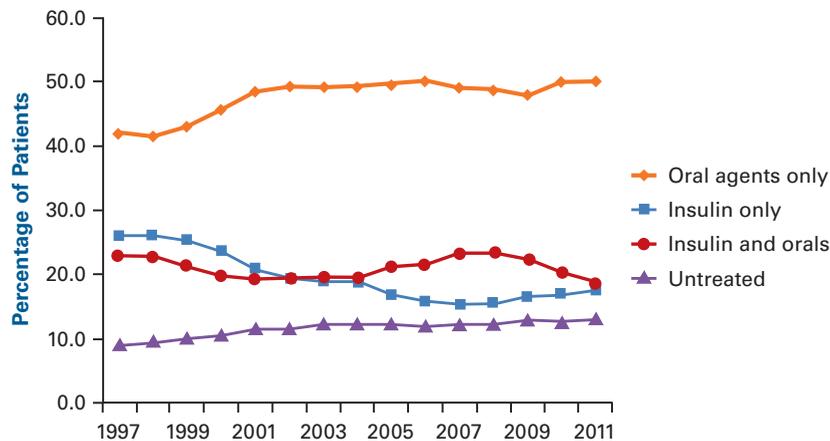


NR indicates not reported.

^aA change in the method for reporting medication utilization accounts for a portion of the increase from 1997 to 2008; includes nondiabetes medications, oral antidiabetic agents, insulin, and supplies.

Cost and resource use associated with specific locations of service has changed from 1997 to 2007, showing a continuing shift in the care and cost of care from the inpatient setting to the ambulatory care setting, and reflecting an increase in the use of medications to treat diabetes mellitus-related comorbidities.

■ **Figure 3. Trends of Medication Utilization**¹²



Changes in age-adjusted anti-diabetic medication use from 1997 through 2011 indicated that treatment with oral agents and/or insulin has remained relatively stable, that the percentage of patients who reported taking oral agents increased until 2001 then remained unchanged afterward, and that the percentage of those taking insulin only decreased until 2007 and then remained unchanged. These data suggest stagnation regarding the uptake of insulin use.

2002 observed an administration error rate of 11%.¹⁸ In addition to dosing and administration errors, the IOM estimates that 1.5 million preventable ADEs occur each year in the United States.¹⁶

In a study of a voluntary electronic medication error reporting system, glucose-lowering medications accounted for 3.5% of reported inpatient medication errors¹⁹ and 10.9% of preventable ADEs.²⁰ In a study published in 2008, insulin accounted for approximately 80% of the medication errors associated with anti-diabetic agents overall while sulfonylureas were associated with the majority (51.8%) of errors reported for oral anti-diabetic agents.¹⁹ When considering that most DM care occurs outside of the hospital (where it is not as standardized and as well documented as in an institution), and taking into account medication nonadherence rates (estimated to range from 15% to 39% in the DM population), medication error rates in outpatient settings may potentially be higher than the reported rates for hospitalized patients.²¹

One factor that increases the risk of medication errors for patients with DM is that many of these patients also receive treatment for DM-related complications and comorbidities.^{22,23} The risk for medication errors increases with the presence of comorbidities and associated drug therapy.²² Several other factors are thought to contribute to medication errors in patients with DM, including use of insulin, which is associated with administration errors as well as adverse effects, namely hypoglycemia.^{24,25} Between 2003 and 2006, 25.6% of patients with DM were on insulin therapy, putting

them at elevated risk of medication errors.¹⁵ Lastly, a considerable proportion of patients with DM are not adherent to anti-diabetic medications, a factor that is influenced by pill burden as well as concerns regarding the side effects of insulin and oral agents, including hypoglycemia, weight gain, and GI discomfort.²⁶ Ultimately, medication errors, including nonadherence, can lead to poor patient outcomes and unnecessary healthcare costs. Therefore, efforts to reduce medication error risk factors across a DM population, such as monitoring for nonadherence and patient medication counseling, should be an area of focus in DM population management.²⁷

Evaluating Unmet Needs in Population-Based Management

The increasing health and economic burden of DM, accompanied by the risk of medication errors, including avoidable adverse events and poor adherence, make DM a top concern for payers and providers managing a population of DM patients. Given the progressive nature of DM, managing patients with DM entails much more than addressing hyperglycemia. Thus, the evaluation of unmet needs in this population must be comprehensive and assessed from multiple perspectives.

This gap analysis can begin with an assessment of quality data, which can be used to identify differences between ideal DM management targets and what is occurring in the population. A key aspect of this assessment is to evaluate how well the population is being managed across all relevant comorbid conditions and complications—or how well patients with DM are managed overall as opposed to focusing only on how well DM is managed. Thus, the evaluation should consider whether all conditions that affect outcomes in patients with DM, such as dyslipidemia and hypertension, are being well managed. Population-based indicators of DM management, including clinical and economic measures put forth by the National Committee for Quality Assurance, go a long way toward helping a health plan, employer, or provider assess these aspects of DM population management.^{28,29}

While reasonably comprehensive, such measures are not necessarily designed to help determine how well patients in the population are living with DM. Thus, the third area of

analysis in the population needs assessment should be to evaluate overall patient functionality and satisfaction, including quality of life (QoL), disability, and productivity. In other words, efforts should be undertaken to determine if patients with DM are living full and productive lives. This aspect should be of particular concern to employers, as a greater number of patients with DM are of pre-retirement age.

There are several interconnected aspects of identifying unmet needs in the population-based management of DM. For example, DM is associated with numerous comorbidities including hypertension and dyslipidemia.³ Therefore, a series of interconnected questions needs to be addressed for all conditions and complications, with an overarching evaluation of humanistic outcomes. The **Table** lists quality indicators as a function of process measures, clinical outcomes, and economic outcomes, and lists indicators for the management of hypertension and dyslipidemia in addition to DM-specific measures, as well as humanistic measures for assessing QoL and satisfaction.^{28,29}

Once gaps are identified, the next step is to identify likely barriers to achieving DM population management targets. Population-level barriers can be assessed from several perspectives, including the delivery system and the patient. While each organization and population will vary in terms of unmet needs, innovations in healthcare delivery and benefit design are being undertaken in an effort to improve DM population management by reducing barriers to optimal care and outcomes. For instance, a patient-centered medical home model of primary care delivery takes a coordinated, preventive, and patient-focused versus disease-centered approach to patient care to improve efficiency of care and increase patient engagement.³⁰ Further, employers and third-party payers are implementing benefit designs to reduce barriers or create incentives to engage patients in the active management of their health. Incentives may include reduced or eliminated copays for medications for DM and related comorbidities to improve compliance (eg, reduced copays for retinal eye exams).³¹⁻³³

Summary

DM is placing a large and growing health and economic burden on patients and the healthcare system. This burden

■ **Table.** Population-Based Indicators of Diabetes Management^{28,29}

Process	A1C measures Eye and foot exams LDL-C screening Medical attention for nephropathy Discharge planning; transitions of care
Outcomes—economic	Relative resource use for diabetes Cost of care for diabetes Cost of care for patients with diabetes
Outcomes—clinical	A1C >9.0%, <8.0%, <7.0% LDL-C <100 mg/dL Blood pressure <140/80 or <140/90 mm Hg Adherence to diabetes-related medications Diabetes long-term/short-term complications admission rate Readmission rates
Outcomes—humanistic	Patient satisfaction Disability/functioning Quality of life

A1C indicates glycated hemoglobin; LDL-C, low-density lipoprotein cholesterol.

will continue to grow, as the prevalence and economic costs of DM are expected to increase substantially over the next 15 years. Furthermore, the complexities of treating DM and related conditions may put patients at higher risk of medical errors, including nonadherence and avoidable ADEs. Therefore, comprehensive assessment of unmet needs and barriers to optimal outcomes in DM is essential for effective population management, both today and in the future.

Author affiliation: Department of Pharmacotherapy, Pharmacotherapy Outcomes Research Center, University of Utah, Salt Lake City, UT.

Funding source: This activity is supported by an educational grant from Amylin Pharmaceuticals.

Author disclosure: Dr Marx reports consultancy/advisory board membership with GlaxoSmithKline and Novo Nordisk; she also reports receiving a research grant from Bristol-Myers Squibb.

Authorship information: Concept and design; acquisition of data; analysis and interpretation of data; drafting of the manuscript; and critical revision of the manuscript for important intellectual content.

Address correspondence to: E-mail: carrie.mcadam-marx@pharm.utah.edu.

REFERENCES

1. Alberti KG, Zimmet PZ. Definition, diagnosis and classification of diabetes mellitus and its complications: part 1: diagnosis and classification of diabetes mellitus provisional report of a WHO consultation. *Diabet Med*. 1998;15(7):539-553.
2. American Diabetes Association. Diagnosis and classification of diabetes mellitus. *Diabetes Care*. 2010;33(suppl 1):S62-S69.
3. Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2011.
4. Centers for Disease Control and Prevention. Centers for Disease Control and Prevention. Diabetes Data & Trends. www.cdc.gov/diabetes/statistics/prev/national/figage.htm. Accessed March 27, 2013.

Reports

5. Fitch K, Iwasaki K, Pyenson B; Milliman, Inc. Improved Management Can Help Reduce the Economic Burden of Type 2 Diabetes: A 20-Year Actuarial Projection. www.publications.milliman.com/publications/health-published/pdfs/improved-management-can-help.pdf. Accessed March 27, 2013.
6. Gregg EW, Kirtland KA, Cadwell BL, et al. Estimated county-level prevalence of diabetes and obesity—United States 2007. *MMWR*. 2009;58(45):1259-1262.
7. American Diabetes Association. Standards of medical care in diabetes—2013. *Diabetes Care*. 2013;36(suppl 1):S11-S66.
8. American Diabetes Association. Economic consequences of diabetes mellitus in the U.S. in 1997. *Diabetes Care*. 1998;21(2):296-309.
9. American Diabetes Association. Economic costs of diabetes in the U.S. in 2007. *Diabetes Care*. 2008;31(3):596-615.
10. American Diabetes Association. Economic costs of diabetes in the U.S. in 2012. *Diabetes Care*. 2013;36(4):1033-1046.
11. Institute for Alternative Futures. Diabetes 2025: United States Overall Briefing Paper. www.altfutures.com/diabetes2025. Published 2011. Accessed March 27, 2013.
12. Centers for Disease Control and Prevention. Centers for Disease Control and Prevention. Diabetes Data & Trends. www.cdc.gov/diabetes/statistics/meduse/fig2.htm. Accessed March 27, 2013.
13. Peyrot M, Rubin RR, Lauritzen T, et al. Resistance to insulin therapy among patients and providers: results of the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) study. *Diabetes Care*. 2005;28(11):2673-2679.
14. Nam S, Chesla C, Stotts NA, Kroon L, Janson SL. Factors associated with psychological insulin resistance in individuals with type 2 diabetes. *Diabetes Care*. 2010;33(8):1747-1749.
15. Cheung BM, Ong KL, Cherny SS, Sham PC, Tso AW, Lam KS. Diabetes prevalence and therapeutic target achievement in the United States, 1999 to 2006. *Am J Med*. 2009;122(5):443-453.
16. Institute of Medicine. Preventing medication errors. In: Aspden P, Wolcott J, Bootman L, Cronenwett L, eds. Washington, DC: National Academies Press; 2006.
17. Bates DW, Boyle DL, Vander Vliet MB, Schneider J, Leape L. Relationship between medication errors and adverse drug events. *J Gen Intern Med*. 1995;10(4):100-205.
18. Barker KN, Flynn EA, Pepper GA, Bates DW, Mikeal RL. Medication errors observed in 36 health care facilities. *Arch Intern Med*. 2002;162(16):1897-1903.
19. Amori RE, Pittas AG, Siegel RD, et al. Inpatient medical errors involving glucose-lowering medications and their impact on patients: review of 2,598 incidents from a voluntary electronic error-reporting database. *Endocr Pract*. 2008;14(5):535-542.
20. Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA*. 2003;289(9):1107-1116.
21. Cramer JA. A systematic review of adherence with medications for diabetes. *Diabetes Care*. 2004;27(5):1218-1224.
22. Field TS, Gurwitz JH, Harrold LR, et al. Risk factors for adverse drug events among older adults in the ambulatory setting. *J Am Geriatr Soc*. 2004;52(8):1349-1354.
23. Gandhi TK, Weingart SN, Borus J, et al. Adverse drug events in ambulatory care. *N Engl J Med*. 2003;348(16):1556-1564.
24. Hellman R. A systems approach to reducing errors in insulin therapy in the inpatient setting. *Endocr Pract*. 2004;10(suppl 2):100-108.
25. Armor B, Hall M. Insulin and medication errors. *Pharmacy Times Diabetes Issue*. 2009;75(10):24-25.
26. Farmer A, Kinmonth AL, Sutton S. Measuring beliefs about taking hypoglycaemic medication among people with Type 2 diabetes. *Diabet Med*. 2006;23(3):265-270.
27. Grissinger MC, Globus NJ, Fricker MP Jr. The role of managed care pharmacy in reducing medication errors. *J Manag Care Pharm*. 2003;9(1):62-65.
28. National Committee for Quality Assurance. The State of Health Care Quality. http://www.ncqa.org/portals/0/state_of_health_care/2010/sohc_2010_full2.pdf. Accessed March 27, 2013.
29. O'Connor PJ, Bodkin NL, Fradkin J, et al. Diabetes performance measures: current status and future directions. *Diabetes Care*. 2011;34(7):1651-1659.
30. Bojadziewski T, Gabbay RA. Patient-centered medical home and diabetes. *Diabetes Care*. 2011;34(4):1047-1053.
31. Gibson TB, Mahoney J, Ranghell K, Cherney BJ, McElwee N. Value-based insurance plus disease management increased medication use and produced savings. *Health Aff (Millwood)*. 2011;30(1):100-108.
32. Tzeel AL. Diabetes benefit management: evolving strategies for payers. *Am J Manag Care*. 2011;17(suppl 14):S384-S390.
33. Fendrick AM. Value-based insurance design for diabetes mellitus: approaches to optimal pharmacoeconomic implementation. *Am J Manag Care*. 2010;16(suppl 11):S314-S322.
34. Hogan P, Dall T, Nikolov P; American Diabetes Association. Economic costs of diabetes in the US in 2002. *Diabetes Care*. 2003;26(3):917-932.