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The rising cost of diabetes care in the USA

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Medical care for people with diabetes has become increasingly expensive. In the USA, the total cost of diagnosed diabetes in 2012 was an estimated \$245 billion, up by 21% from 2007.¹ Although some of the increase is due to the growing number of people with diabetes and the rising prices of medical goods and services, not all of the increase can be attributed to these factors alone. The excess medical spending associated with caring for a patient with diabetes, compared with that for a patient without diabetes nearly doubled from 1987 to 2011,² suggesting that diabetes itself has become a more costly disease.

More than half of the increase is due to the rising costs of prescription drugs.² During the past two decades, the number of classes of glucose-lowering drugs increased from only three available in 1995 (insulin, metformin, and sulfonylureas) to 12 available by 2013. Many of these newer classes of drugs have appealing profiles. For example, dipeptidyl peptidase-4 inhibitors pose a minimal risk for hypoglycaemia, and glucagon-like peptide-1 receptor agonists are associated with weight loss. Additionally, several new insulin formulations have unique pharmacokinetic profiles, such as rapid-acting insulin analogs, which can be timed directly before meals. These newer drugs have been rapidly incorporated into clinical practice because of their efficacy in lowering glucose levels, improved side-effect profiles, and greater convenience of use, along with aggressive marketing efforts.³ But given that the prices of these newer drugs are sometimes 100 times greater than that of the available older diabetes drugs, do their costs justify the benefits?

Few data exist about the benefits of these new agents on long-term clinical outcomes. New diabetes drugs in the USA are approved by the Food and Drug Administration (FDA) after showing glucose-lowering efficacy and short-term safety. Additionally, since 2008, the FDA has required evidence that these agents do not lead to an unacceptable increase in cardiovascular risk.⁴ As a result, available data are predominantly focused on the glucose-lowering efficacy and short-term cardiovascular effects of diabetes drugs. Only a few studies are head-to-head comparisons or long-term clinical trials that assess the effect of these agents on the risk for diabetes complications.

One indirect way to gauge the value of new diabetes drugs is to examine what has happened to the health of patients with diabetes as the new drugs became incorporated into practice. More effective drug options should have enabled physicians to find suitable combinations of

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drugs that optimise glycaemic control while minimising side-effects, theoretically leading to better glycaemic control over time. Findings from a nationally representative study⁵ showed that about 8% more patients had excellent glycaemic control ($\text{HbA}_{1c} < 7.0\%$ [53 mmol/mol]) during 2007–10 than during 1999–2002. However, approximately a third of patients in 2007–10 had still not met individualised targets for glycaemic control.⁵ In fact, younger adults (aged 18 to 44 years) with established diabetic complications experienced no improvements in glycaemic control over this period.⁵

Therefore, despite the many drugs available for lowering blood glucose concentrations, only modest improvements in glycaemic control have been noted at the population level so far. However, although gains in glycaemic control have been somewhat underwhelming, rates of both macrovascular and microvascular complications have fallen over the past two decades.⁶ In particular, rates of acute myocardial infarction have decreased by as much as two-thirds, with less striking decreases in rates of microvascular complications, such as renal disease.⁶ Although these findings represent encouraging progress, how much of the decrease in the rates of diabetes complications is attributable to improved glucose-lowering per se is uncertain. Many other factors have probably contributed to the decreased rates of macrovascular disease, including improvements in the diagnosis and treatment of hypertension, the widespread use of statins, the fall in smoking rates, and a greater emphasis on timely interventions for acute vascular events.⁷ Similarly, decreases in microvascular complications might partly reflect advances in blood-pressure management and the use of angiotensin-converting-enzyme inhibitors.

Although the rates of most complications related to diabetes have decreased, the rates of hospital admissions for hypoglycaemia have increased⁸. In fact, admissions for hypoglycaemia—a complication of treatment—are now far more common than for hyperglycaemia—a complication of the disease.⁸ Patients aged 75 years or older with several comorbidities and cognitive impairments seem to be at the greatest risk for hypoglycemia.⁸

So far, healthcare spending has outpaced the modest improvements in diabetes outcomes. Similarly, medical expenditures for cardiovascular and cancer drugs have also greatly increased. In response, the American College of Cardiology, the American Heart Association, and the American Society of Clinical Oncology have created frameworks to determine the value of a prescription medicine by assessing its clinical efficacy, the magnitude of its benefit, any adverse or beneficial side-effects, and its cost.⁹ This information can help patients, physicians, policy-makers, and insurers make more educated choices about the drugs they use, prescribe, and cover. The US Institute for Clinical and Economic Review and DrugAbacus have initiatives that actually calculate drug prices that would be commensurate with the drug's value.¹⁰ Drugs with few benefits to patients are priced lower, and those with significant benefits are priced higher. In the USA, drug prices are exclusively determined by the manufacturers and are not controlled by the government; therefore, various incentives might be needed to reward drug manufacturers who price their products on the basis of their value.

To apply these efforts to diabetes drugs and curb associated spending, robust data for the comparative effectiveness of available and emerging drugs, and how these drugs influence patient outcomes, are needed. Data on clinical outcomes could then be used to determine the value of newer drugs and to estimate prices that would be commensurate with their benefits, helping to direct healthcare spending towards the most effective interventions. Faced with the reality of increasing expenditures, we need to find innovative ways to provide quality diabetes care more cost-effectively. The health of the growing number of patients with diabetes must be improved, but the sustainability of the health-care system as a whole must also be preserved.

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