Strategies to improve the affordability of insulin in the USA

Global challenges regarding access to insulin have been documented in low-income and middle-income countries, but high-income countries are not exempt from these problems. In the USA, where the entire insulin supply comes from only three manufacturers, prices have risen sharply, complicating access to this essential medicine (table). In 2015, Medicare Part D—the outpatient prescription drug benefit associated with the government insurance programme for patients older than 65 years—spent more than US$43 billion for just one long-acting insulin analogue, glargine. Expenditures on glargine were the second largest of all Part D drugs that year, just after those for ledipasvir–sofosbuvir, an antiviral agent used to treat hepatitis C. That same year, Medicaid—the federal-funded and state-funded health insurance programme for people with a low income—spent more than $1.4 billion on glargine.

High insulin prices affect more than just the budgets of government health insurance programmes. For the majority of Americans who have commercial health insurance, out-of-pocket payments have been increasing at rates far above inflation for all insulin products. Many patients are forced to use less insulin than prescribed, or to go without it because they cannot afford it. In the short term, insulin cessation is the main cause of diabetic ketoacidosis. In one study, about a third of US patients who stopped taking insulin and had diabetic ketoacidosis reported that they did not have enough money to buy insulin. In the long term, poor control of diabetes can lead to serious complications, including heart disease, stroke, vision loss, kidney failure, nerve problems, and amputations.

The high prices for insulin are ironic given the intentions of the original insulin discoverers. In 1923, Frederick Banting, Charles Best, and James Collip isolated 95 years ago, the data are not definitive on whether insulin analogues being used today are safer or more effective for most patients with type 2 diabetes than human insulins used widely in the 1990s, for which the main patents have expired.

In response to this crisis, in November, 2016, the American Diabetes Association called on Congress to examine insulin costs across the entire supply chain, ranging from the manufacturers to health insurers, pharmacy benefits management companies (which set pharmaceutical formularies and manage drug costs for payers), and wholesalers. Unfortunately, reliable estimates of the proportion of price increases attributable to these entities cannot be obtained because the underlying data that drive net price calculations in the USA are confidential. The US Federal Trade Commission has been asked to investigate whether simultaneous price increases displayed in some instances by insulin manufacturers violate antitrust law. The leading insulin manufacturers have offered their own solutions to improving market access. Patients with a low income can apply for manufacturer-run programmes that provide co-pay assistance or, in some cases, free insulin. Unfortunately, some of these programmes cannot by law include patients who have coverage under Medicaid or Medicare.

Additionally, such patient assistance programmes have the paradoxical effect of increasing overall drug spending by steering patients towards more expensive products. We believe that lower insulin prices will be one step closer if patients and physicians could better understand

<table>
<thead>
<tr>
<th>Glargine* (Medicare Part D)</th>
<th>Glargine* (Medicaid)</th>
<th>Lispro† (Medicaid)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total spending in 2015, US$</td>
<td>$4,359,504,167</td>
<td>$1,435,574,715</td>
</tr>
<tr>
<td>Number of beneficiaries</td>
<td>1,673,911</td>
<td>NA</td>
</tr>
<tr>
<td>Prescription count</td>
<td>NA</td>
<td>3,651,839</td>
</tr>
<tr>
<td>Spending per Medicare benefi</td>
<td>$2,604</td>
<td>NA</td>
</tr>
<tr>
<td>Spending per Medicaid presci</td>
<td>NA</td>
<td>$299</td>
</tr>
<tr>
<td>Weighted annual % change (vs 2014)</td>
<td>15%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Data are from Centers for Medicaid and Medicare Services Drug Spending Dashboards: *NA=not applicable. †Lantus and Lantus Solostar (Sanofi-Aventis, Bridgewater, NJ, USA). Humalog (Eli Lilly and Company, Indianapolis, IN, USA).
Comment

the actual price of the drugs, and what contributes to those prices. Drug price transparency and accountability laws have been proposed in numerous states, including one enacted in Vermont in 2016.11 A similar bill, the FAIR (Fair Accountability and Innovative Research) Drug Pricing Act,12 was proposed in Congress. Many of these bills require that manufacturers of drugs with the greatest increases in price justify price hikes to a federal or state entity such as the Secretary of the Department of Health and Human Services or a state’s attorney general.

Comprehensive reporting should include information about research, development, and advertising costs, as well as how manufacturers determine launch prices, rebates, discounts, and coupon or patient assistance programmes. These transparency measures would also make data available to design future reforms. For example, if rebates were substantial contributors to insulin price changes, policy makers could enact measures to require that larger proportions of those rebates be passed to individual patients or payers. An important limitation of transparency laws is that they are unlikely to substantially reduce insulin prices in the USA by themselves. In many other high-income countries, price transparency laws operate alongside other price control mechanisms such as reference (benchmark) pricing, price caps, or cost-effectiveness evaluations.

Short of additional legislative or regulatory action, such as might be needed to improve price transparency, access to insulin products can be improved through better patient and physician education and awareness with regards to the different types of insulin available for the treatment of diabetes. Many patients with type 2 diabetes can effectively manage their disease using human insulin. Local programmes could be established using unbiased, trained clinical educators to help prescribers become more comfortable with providing human insulin. Local programmes could be established using unbiased, trained clinical educators to help prescribers become more comfortable with providing human insulin. Local programmes could be established using unbiased, trained clinical educators to help prescribers become more comfortable with providing human insulin. Local programmes could be established using unbiased, trained clinical educators to help prescribers become more comfortable with providing human insulin. Local programmes could be established using unbiased, trained clinical educators to help prescribers become more comfortable with providing human insulin.

Insulin is a vitally important medicine and should be accessible to people who require it at a price that they can afford and that does not put undue burden on the health-care system. The recommendations we outline here can serve as starting points for systemic and durable reforms that are needed to improve the affordability of insulin in the USA.

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