Soaring insulin prices have patients terrified and pharmacists scrambling

The numbers are staggering. According to the American Diabetes Association (ADA), 7.5 million Americans rely on insulin—including 1.5 million with type 1 diabetes—but the average cost of insulin tripled between 2002 and 2013 and continues to surge. A June 2018 study by UpWell Health found that 45% of Americans with diabetes sometimes forgo care due to cost. Manufacturers offer coupons, but insured patients aren't eligible for them, and busy pharmacies might not have time to seek them out. How can we control the insulin price crisis?

Twisted path to the patient

"The insulin supply chain is complex, and while it is unclear precisely how the dollars flow through the chain, it is clear the current pricing and rebate system encourages high list prices," said William T. Cefalu, MD, chief scientific, medical, and mission officer at ADA. "Unfortunately, people with diabetes are harmed with high list prices and high out-of-pocket costs."

In May 2018, ADA released a white paper, Insulin Access and Affordability Working Group: Conclusions and Recommendations, the product of meetings with representatives of pharmaceutical manufacturers, wholesalers, PBMs, pharmacies, pharmacists, distributors, health plans, employers, and people with diabetes and their caregivers. The major finding was that "additional transparency is needed throughout the supply chain to identify changes that will lead to long-term improvement in insulin affordability," Cefalu said.

Meanwhile, insulin utilization has trended toward the higher-priced human analog insulins, although even the price of human insulins has increased. Still, the white paper stated, "human insulins are available at the pharmacy for $25 to $100 per vial compared with human insulin analogs at $174 to $300 per vial."

"Providers, pharmacies, and health plans should discuss the cost of insulin preparations with people with diabetes to help them understand the advantages, disadvantages, and financial implications of potential insulin preparations," Cefalu said. "This could mean that human insulin may be appropriate for some appropriately selected patients instead of analog insulin; however, this must be considered based on each individual's diabetes needs, in consultation with the physician and based on current clinical evidence."

The white paper also recommended that list price for insulins should more closely reflect net price, and rebates based on list price should be minimized. Until the system changes, the white paper stated that PBMs and payers should use rebates to lower the costs of insulin for people with diabetes at the point of sale.

"The conclusions and recommendations of the working group are only a starting point. Beginning with increased transparency within the insulin supply chain, every stakeholder must work together toward a common goal—[to] ensure affordable insulin is within reach for all who need it," Cefalu said.

On the frontlines

Karen Sando, PharmD, is an ambulatory care pharmacist and associate professor and assistant dean at Nova Southeastern College of Pharmacy in Davie, FL. She's also lived with type 1 diabetes since age 8.

"I see the list prices for my insulin when I go and pick it up. I probably couldn't afford to pay that out of pocket every month even with the good salary that I make now," Sando said. "For anyone, let alone a patient who's struggling to put food on the table, a copay over $500 for something that you need to sustain your life is a little scary."

In a prior faculty position, she said, "I was at a primary care clinic doing direct patient management for diabetes along with my physicians, and there was rarely a day that went by where a patient didn't come to the front desk or call telling me they couldn't afford their insulin. My students, my residents, and I were constantly trying to think outside the box of how to get people access to their medication."

The first step was determining the preferred agent on a patient's health care plan. If it wasn't, they'd work with the physician to select something on the formulary. "From there it got a little more complicated," Sando said.

Some low-income Medicare Part D patients are eligible for a subsidy through the Extra Help program. Even for those who don't qualify, applying to Extra Help is a necessary step because "to get patient manufacturer assistance through the various manufacturers that might produce insulin, you have to send the denial letter as proof that we've made attempts to get them more affordable insulin," she said.

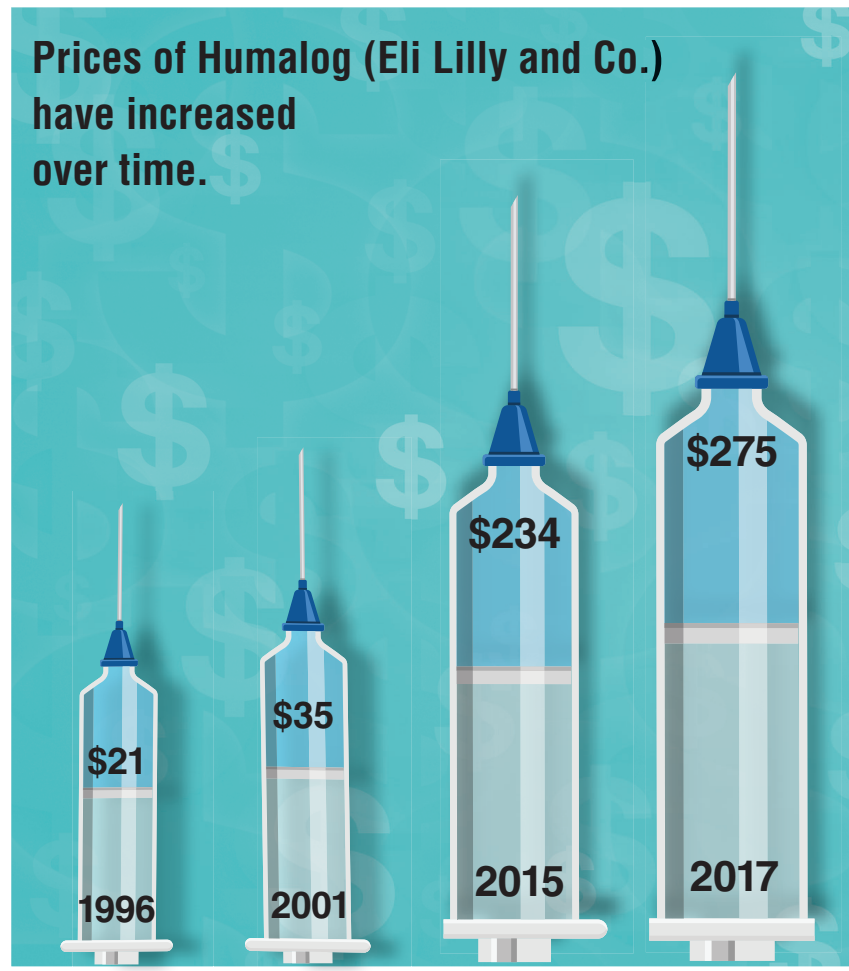
> "What we find a lot of times is people scrimp or miss doses until they get their next paycheck."

Once those options were exhausted, "we kept stock samples in the office to tide patients over until they could meet their out-of-pocket deductibles, and their insulin was their regular copay," she said. The county Department of Health would provide insulin at reduced cost to patients at a certain level of the federal poverty line. "But it was only for NPH & R," she said.

"The older insulins are effective. However, I recommend pharmacists caution their patients, if they switch to NPH or some combination of NPH and regular, to monitor their blood sugars closely over the next 2 weeks to make sure that their blood sugars remain stable," she added. "You have to be very careful overnight. I usually advise my patients to check their blood sugar before they go to bed, and if

they're less than 100, they can consider eating a snack."

Moving to a cheaper insulin won't completely relieve cost issues. "NPH is shorter acting, so somebody might go from doing one shot of a Lantus or Levemir to two shots a day. It's going to be less expensive out of pocket, but costs get shifted if they have to do more injections."



Lawmakers take action

More than 20 states are considering legislation targeting high insulin prices.

Nevada Sen. Yvanna Cancela sponsored one of the strictest drug pricing transparency laws in the country—despite fierce opposition from lobbyists, who complained that the bill singles out manufacturers without enough scrutiny on PBMs. The bill was initially vetoed by Gov. Brian Sandoval but was signed when it was packaged with another bill that does call for more PBM transparency.

Cancela's bill requires diabetes drug companies to disclose information about the costs of manufacturing and marketing—as well as the rebates they provide—if the price of their products has increased at a rate faster than inflation as measured by the medical consumer price index. The other piece of the new law requires PBMs to disclose the rebates they negotiate and which rebates they keep for themselves.

"Policy makers need unbiased data to make decisions that benefit patients. Without transparency, it's difficult to understand just how drug pricing works," Cancela said. "This legislation will equip policy makers and patients with the necessary data to ask questions and understand drug costs."

Cancela believes the new law is about more than just affordability. "I'm hopeful that this information will help patients be better advocates for themselves with manufacturers and policy makers," she said.

ADA's Cefalu testified before the U.S. Senate Special Committee on Aging on May 8, 2018. "The Special Committee was concerned by the complexity of the supply chain and vowed to address the issue," Cefalu said of his testimony. "We continue to have substantive conversations with congressional leaders as well as state lawmakers and look forward to working together to develop viable, long-term solutions."

Talking to patients

Sando has noticed a correlation between inability to pay for insulin and poor adherence. "If you have a patient who's coming to your community pharmacy and you're looking at their refill history and noticing they are filling it consistently late, it might be worthwhile to open up a conversation," she said.

"Ask new patients, 'Are there times when you skipped your insulin because you can't afford it?' Because what we find a lot of times is people scrimp or miss doses until they get their next paycheck," Sando said.

Though the uninsured population is often discussed in this context, Sando also worries about underinsurance—patients covered by Medicare Part D or commercial insurance but who have high deductibles or out-of-pocket costs that threaten access. Sando said some Part D patients select plans without realizing the implications for insulin. "Around open enrollment, pharmacists can make sure patients think about the total cost that they're going to have to pay out of pocket, not just their monthly premium."

"Pharmacists are the last person a patient sees before being left on their own with the medicine they've been prescribed. They play a key role in making sure patients understand their medications," Cancela said. "I believe pharmacists are essential in understanding how the high costs of drugs impact the way patients choose the medicines they ultimately purchase."

Rachel Balick, reporter