The bare essentials: ensuring affordable access to insulin

The cost and availability of insulin is a growing concern and an issue of worldwide importance. The skyrocketing list prices of insulin—along with those of certain other drugs and medical products—in the USA became a major political issue last year. More recently, in January, 2017, a lawsuit was filed in a federal court in Massachusetts alleging that the three pharmaceutical companies that control the insulin market in the USA and worldwide (Eli Lilly, Novo Nordisk, and Sanofi) have been raising list prices to exploit the drug-pricing system to benefit themselves and pharmacy benefit managers, which are the go-betweens that receive a cut of rebates paid to insurers. This process has led to increasing out-of-pocket costs for patients.

In the same month, the American Diabetes Association (ADA) launched a new online platform to advocate for insulin affordability, as part of the ongoing Stand Up for Affordable Insulin initiative. The website includes a petition calling for improved transparency throughout the insulin supply chain and demanding action from Congress. In a Comment in The Lancet Diabetes & Endocrinology, Jing Luo and colleagues echo the ADA’s call for greater transparency, while noting that other measures will also be needed to increase affordability.

Although some factors affecting insulin costs in the USA relate to the opaque private sector-based health system, others have global relevance, particularly with respect to the choice of insulin products available. In this regard, a recent application submitted to WHO to add longacting analogue insulins (glargine and detemir) to the organisation’s Model List of Essential Medicines is a cause for concern.

This is not the first time that adding analogue insulins to the essential medicines list has been proposed. In 2011, WHO’s 17th Expert Committee on the Selection and Use of Essential Medicines concluded that there was “no evidence of a clinically significant difference in most outcomes” for analogues compared with human insulin. In the new submission, the authors refer to new evidence, summarised in a 2014 systematic review and meta-analysis. However, the proposal mainly serves to underline the marginal benefits of longacting analogues.

In view of the substantially higher costs of insulin analogues, their addition to the WHO model list has several potential negative implications. The first potential issue relates to fund allocation. In the USA and other high-income countries, analogues have gradually come to dominate the market, despite little evidence of substantial benefit compared with cheaper recombinant human insulin. In lower-income countries, this process is less advanced, and human insulin is still commonly used. If countries that provide insulin to patients for free decide to stock more expensive analogue insulins, higher budgets will need to be allocated for procurement of the drugs, which might be redirected from budgets for other health problems. Worse still, if budget allocation remains the same, many more patients could lose access. Where patients pay out of pocket, higher prices could make insulin much less affordable.

A second consideration is the potential effects on the market and supply chain. David Beran and colleagues have postulated that market domination by three major companies might restrict price competition and enable shaping of the market, particularly through increasing the market share of analogues. If analogues are added to the WHO model list, there could be a risk that—unless some binding agreement is put in place—industry would begin to cut back or phase out production of cheaper human insulin, further restricting the availability of affordable insulin worldwide.

A possible counter argument in favour of the proposal would be that adding insulin analogues to the WHO model list could lead to reductions in price. However, in the absence of a strong global civil society campaign to drive down prices or a central purchasing mechanism (as in the case of antiretroviral drugs for HIV), the tightly controlled insulin market might not be amenable to this approach. Additionally, regulatory issues and other barriers have so far prevented generic or biosimilar insulin from having much of an effect on prices.

This year marks the 40th anniversary of the WHO essential medicines list—over those 40 years it has grown and changed, responding to advances in drug development, public health needs, and civil society engagement. But at its core, the list is still based on effective prioritisation of the health-care needs of the population. Access to human insulin is still despairingly low for many populations worldwide, and adding more expensive analogues to the list is unlikely to improve this situation. ■

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