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Patient Perspectives on Biosimilar Insulin

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Abstract

Given that a new wave of biosimilar insulins will likely enter the market in coming years, it is important to understand patient perspectives on these biosimilars. A survey (N = 3214) conducted by the market research company dQ&A, which maintains a 10 000-patient panel of people with type 1 or type 2 diabetes in roughly equal measure, investigated these perspectives. The survey asked whether patients would switch to a hypothetical less expensive biosimilar insulin that was approved by their provider. Approximately 66% of respondents reported that they would "definitely" or "likely" use a biosimilar insulin, while 17% reported that they were "unlikely" to use or would "definitely not use" such a product. Type 2 diabetes patients demonstrated slightly more willingness to use biosimilars than type 1 diabetes patients. Common patient concerns included whether biosimilars would be as effective as reference products (~650 respondents), whether side effect profiles would deviate from those of reference products (~220 respondents), and the design of the delivery device (~50 respondents). While cost savings associated with biosimilar insulins could increase patient uptake, especially among patients without health insurance (some recent estimates suggest that biosimilars will come at a substantial discount), patients may still need assurance that a cheaper price tag is not necessarily associated with substandard quality. Overall, the dQ&A survey indicates that the majority of patients are willing to consider biosimilar insulins, but manufacturers will need to work proactively to address and assuage patient concerns regarding efficacy, safety, drug administration, and other factors.

Keywords

biosimilar insulin, insulin therapy, insulin formulations, costs, diabetes

The expected entry of biosimilar insulin in the coming years could be a major development in diabetes care. While manufacturing and regulatory considerations will be important factors in the insulin's commercial success, patients will ultimately decide the product's fate. In this article, we explore how patients may respond to biosimilar insulin.

Patient Survey Data on Biosimilar Insulins

There are relatively little data on what patients actually think about biosimilar insulin (hereafter called biosimilars). To address that gap, the diabetes-focused market research company dQ&A conducted a survey. The company has a panel of over 10 000 patients with type 1 or type 2 diabetes; they have volunteered to provide feedback and fill out surveys on a wide range of topics in diabetes care. As part of a survey conducted in the third quarter of 2013, participants were asked the following question: "If in the future there was a less expensive 'generic' (sometimes called 'biosimilar') version of your insulin that your healthcare provider approved, would you switch?" Respondents were asked to choose from 1 of 5 responses—"definitely use," "likely to use," "unlikely to use," "definitely not use," or "I don't know." It is important to note that the survey respondent population is not representative of the overall diabetes population, as the survey population overrepresents type 1 diabetes patients.

Of the 3214 total respondents, 27% (n = 864) replied they would "definitely use" a biosimilar, and 39% (n = 1250) said they were "likely to use" a biosimilar; thus, 66% (2114) of respondents were positively disposed to the idea. Of the remaining one-third, 17% (n = 534) said they didn't know if they would be interested, while 13% (n = 424) said they would be "unlikely to use" biosimilars; only 4% (n = 142) said they would "definitely not use" biosimilars.

Subsequent analysis of type 1 patients versus type 2 patients indicated that type 2 patients expressed slightly more willingness to consider biosimilars. Most striking, 33%

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(532) of type 2 patients said they would "definitely use" biosimilars, compared to only 21% (332) of type 1 patients. This perhaps reflects the relative importance of insulin in type 1 versus type 2 therapy. While insulin is one of several medications available for type 2 diabetes, it is the sole option for type 1 diabetes. The results may also suggest greater cost sensitivity among type 2 patients, who typically have other comorbidities and medications.

Opposition to biosimilars was fairly similar in both groups. Among type 1 respondents, 15% (n = 245) said they were "unlikely to use" biosimilars, and 5% (n = 79) said they "definitely would not use" biosimilars, roughly similar to the 11% (n = 179) and 4% (n = 63) of type 2 respondents, respectively. Finally, 18% (n = 279) of type 1 respondents and 16% (n = 255) of type 2 respondents said they "did not know" whether they would use biosimilars. Taken together, these results suggest that patients are open to the idea of biosimilar insulins, provided—as the survey question presupposed—that their provider approved the biosimilar and that the costs of a biosimilar were lower than those of first-generation insulins.

Patient Questions and Concerns

The dQ&A survey also posed a series of open-ended follow-up questions, the first being, "Aside from cost, what question would you ask first about a generic insulin alternative?" The most common response was some variant of the question, "Does it work as well as my current insulin?" Respondents consistently mentioned effectiveness as a major concern; about 650 respondents mentioned some form of the word "effectiveness," with another 50 or so mentioning related terms like "reliability" or "dependability." Several respondents asked for more detail on more technical issues like absorption rate, refrigeration requirements, pen availability, and oversight of the manufacturing process. About 220 participants also asked about side effects, and respondents frequently asked for direct comparisons between such biosimilars and the specific insulin they were currently using. Sanofi's Lantus (insulin glargine), Novo Nordisk's Novolog (insulin aspart), and Novo Nordisk's Levemir (insulin detemir) were all frequently mentioned. Dozens of respondents indicated that they would only consider biosimilars if these insulins performed *exactly* the same as their current insulins.

Apart from the insulin product itself, the delivery device used with a biosimilar will have an important impact on whether patients embrace the product. About 50 respondents mentioned the delivery device as an important consideration; the most common question along these lines was some version of "Does it come in a pen?" Research by major insulin manufacturers such as Sanofi indicates that patients who are satisfied with a particular insulin delivery pen or other device are unlikely to be displaced easily.[1] While biosimilar insulins may not come in devices identical to those used by the reference products, patients will expect delivery devices to be highly functional and reliable. Patient satisfaction—as measured in other dQ&A surveys—with current insulin pens is generally high.

The second open-ended follow-up question directly addressed those who said they would "definitely not use" biosimilars or were "unlikely" to. It prompted these respondents, "You said that you would be unlikely to or definitely not use a generic insulin. Please tell us why." About 40 such respondents indicated that they considered a brand name to be a symbol of quality, effectiveness, or trustworthiness—one type 1 respondent noted, "I feel that the current manufacturers of insulin spend an enormous amount of money on research to provide the best, safest, and fastest insulin I can receive." Other respondents mentioned the proven track record of brand-name insulins—and the lack of such a record with biosimilars—as a reason they would stick with their current insulins. Another group of respondents said their brand loyalty was more a function of their current personal satisfaction with their particular insulins. As another type 1 patient who would "definitely not use" biosimilar insulin observed, "It is not Humalog. I know how my body acts with Humalog. I do not trust things I do not know when it comes to my health." Furthermore, about 25 respondents cited past bad experiences with other types of generic medication, which left them uncomfortable with the prospect of switching to biosimilar insulin. Approximately 32 additional respondents mentioned that they either do not trust generic medications in general or would not be able to trust biosimilars in particular.

In this particular survey, neither pain of injection nor risk of hypoglycemia appeared to be a major factor differentiating biosimilar insulin from other insulins, as only about 6 respondents explicitly mentioned either of these as concerns. Lifestyle change and patient independence were entirely neutral factors, as patients may have assumed that the logistics of biosimilar therapy would not be appreciably different from those of their current insulin therapy. A few respondents asked about weight-related issues, although some did so to register their frustration with the weight gain associated with their current insulins and to ask whether biosimilars might actually represent an improvement, which is somewhat unlikely given the homology between biosimilars and their reference products. Several participants also noted their allergic reactions to various insulins, which limit their current options and means they are hesitant to try an unfamiliar biosimilar insulin.

Because small variations in biosimilar manufacturing protocols (along with slight variations in the compounds themselves) have the potential to increase these insulins' immunogenicity, we believe that immunogenicity will also be a major consideration for patients, regulators, and providers. While immunogenicity will be tested as much as possible prior to regulatory approval and on an ongoing basis, it will be important to educate patients on this risk.[2]

Because of side effect concerns regarding biosimilar insulins, patient education will likely be crucial in this area. Since biosimilars are more heterogeneous than small molecule generics and may therefore vary more in side effects,

brand-specific safety education programs may be needed. The availability of clinical data that can speak directly to these issues would also be important as part of the general effort to build patient confidence in biosimilars.

Biosimilar Costs and Copays

Turning to the advantages of biosimilar insulins, reduced cost is likely to be the biggest factor favoring them compared to currently available insulins, although the actual amount is still uncertain. Recent estimates suggested biosimilars would still cost 65% to 85%[3] or 60% to 80%[2] of brand-name insulins, but more extreme estimates range from 30% to 90% of current price. The pricing could have an important direct and indirect effect on patient acceptance: direct for patients who pay for insulin out of pocket and indirect for patients on private insurance (ie, discounts could encourage payers to place a biosimilar on a preferred prescription formulary tier with lower patient copays).

Biosimilar insulin manufacturers could also attract patients through financial assistance programs. Through this route, manufacturers could provide copay assistance directly to patients.[4] Financial assistance programs would improve acceptance while also securing brand loyalty. That most major branded insulin manufacturers offer financial assistance programs might increase the need for similar programs with biosimilars, to offer a true lower cost. Regardless of which route biosimilar insulin manufacturers choose, a certain level of cost savings may need to be associated with biosimilars. It could be worthwhile in future studies to explore just how much cost drives patients to switch to biosimilars, and how much of a discount compared to the reference product is required before patients will consider such a switch.

A few participants in the dQ&A survey mentioned cost as a potential reason to be hesitant about switching. These respondents equated lower cost with diminished quality. A type 1 respondent who would "definitely not use" biosimilars wrote, "There must be a reason why the generic is less expensive. I would be concerned about quality." Another type 1 patient who was "unlikely to use" biosimilars said, "I am afraid like anything else you get what you pay for and it would not work as well. I don't like to play with my life like that." For other participants, cost was simply not a factor, as many explained that their insurance covered most or all of their current insulins. These results suggest that for some patients, discounts will need to be paired with patient and provider education confirming that the generic insulin is as good as the brand-name insulin.

Conclusion

Assuming biosimilars can secure the approval of providers, offer a cost reduction compared to currently available insulins, and perform as effectively, the majority of patients seem to be willing to consider them, according to the dQ&A survey. The cost reduction associated with biosimilars—which stand to be meaningful (though not at the level of small molecule generics)—will likely spur significant interest among patients, providers, and payers alike. However, we presume that cost advantages alone will not eliminate concerns about effectiveness and side effects. The desire of some survey respondents for any potential generic insulin to be exactly identical to their current insulin may represent a meaningful barrier to the acceptance of biosimilars, even among those who are otherwise willing to switch. It may well prove difficult for biosimilar insulins to demonstrate interchangeability with brand name insulins in clinical trials.[2] Even then, patients may be hesitant to switch from an insulin that works for them.

Ultimately, manufacturers and providers will likely need to address the concerns of potential biosimilar users. Type 1 patients rightly consider the quality of their insulin to be a matter of life and death, and the health risks of substandard insulin are only marginally less devastating to type 2 patients. Clinical data on safety and efficacy for biosimilars should speak to these concerns, but it is worth remembering that this is as much a matter of perception and psychology as it is one of biology and economics.

Declaration of Conflicting Interests

Close Concerns has ongoing business relationships with many companies in the diabetes care field. Please see www.closeconcerns.com/disclosure.php for a current list.

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