

Patient and Educator Attitudes Toward Biosimilar Insulin

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Abstract

Only 26% of people with diabetes in the US use insulin, even though 44% have A1c levels over 7%. Cost represents one barrier to insulin use, and biosimilar insulin (BI) offers potential savings. A regulatory pathway for biosimilar drugs was created in 2010, and several preparations are in development. This study's purpose was to assess the openness of diabetes patients and certified diabetes educators (CDEs) to BI.

In mid-2011 we surveyed a panel of subscribers to a diabetes patient newsletter (diaTribe) and a panel of US CDEs about their willingness to use or recommend BI, respectively. A total of 1,637 insulin users (65% type 1, median age 49 yrs, 62% female, median household income \$25,000-\$49,999, 67% bachelor's degree or higher, 81% private health insurance) and 415 educators (52% outpatient hospital setting, 28% private office, mean 21 patients per week) responded to the survey. Both surveys specified that BI would be priced favorably relative to current insulins; patients were to assume healthcare provider approval.

Most patients said they would "definitely" (30%) or "likely" (37%) use BI, while only 17% said "unlikely" or "definitely not." Answers of "definitely" were more common among patients currently using NPH (46%, n=26) or premixed insulin (41%, n=36) than rapid-acting analogs (28%, n=341); "definitely" answers were also more common among those with type 2 diabetes (38%, n=213) than adults (29%, n=256) or children (13%, n=26) with type 1 diabetes. Most CDEs said they would "definitely" (41%) or "likely" (42%) recommend BI, with only 5% saying "unlikely" or "definitely not." In open-ended follow-up questions, however, vast majorities of both groups stressed that BI must be identical to current insulin in safety, efficacy, action profile, and/or quality. Thus the study's results are contingent on these factors.

We conclude there is significant interest in the future use of BI among patients and CDEs that could result in major transformation in insulin usage in the US.

Introduction

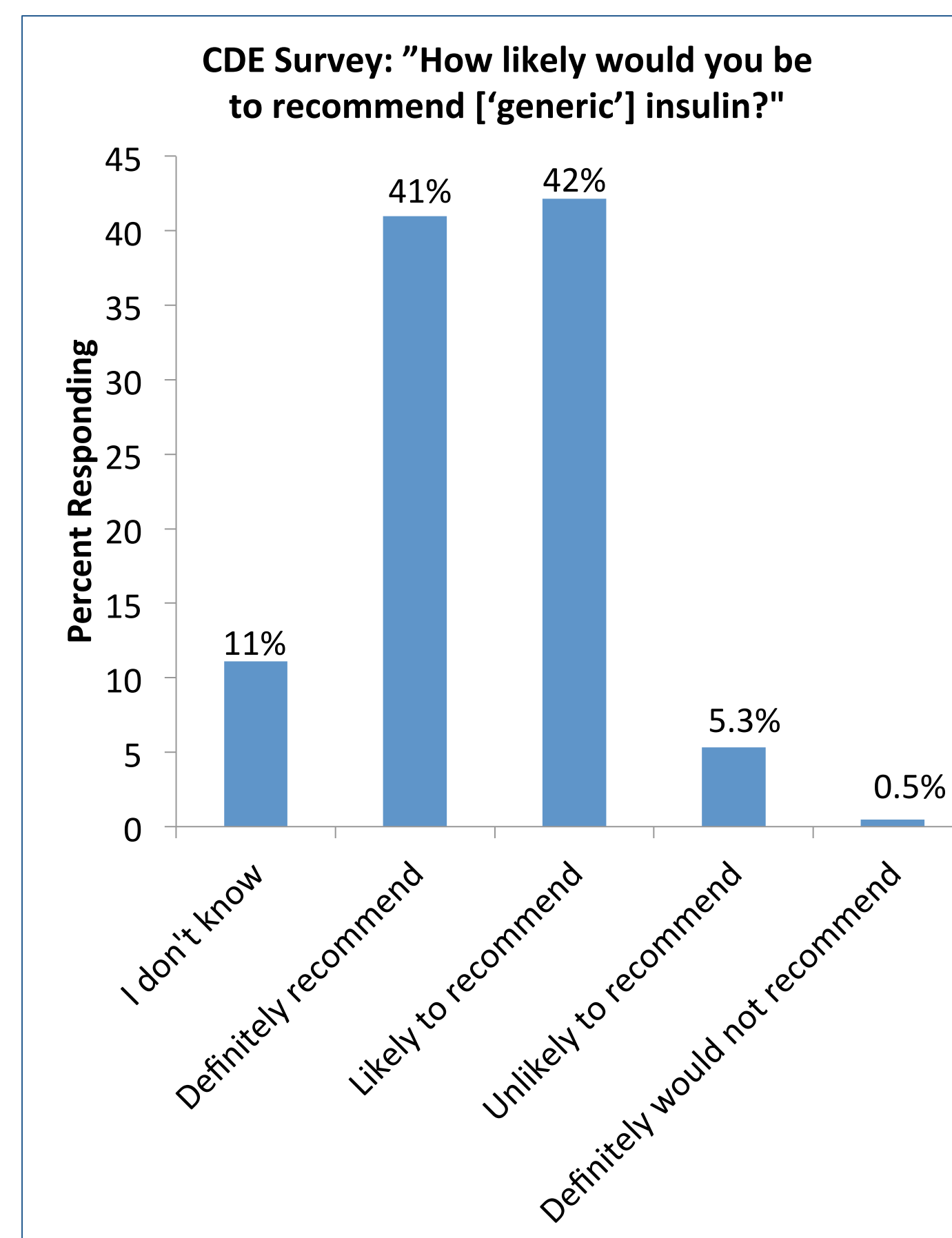
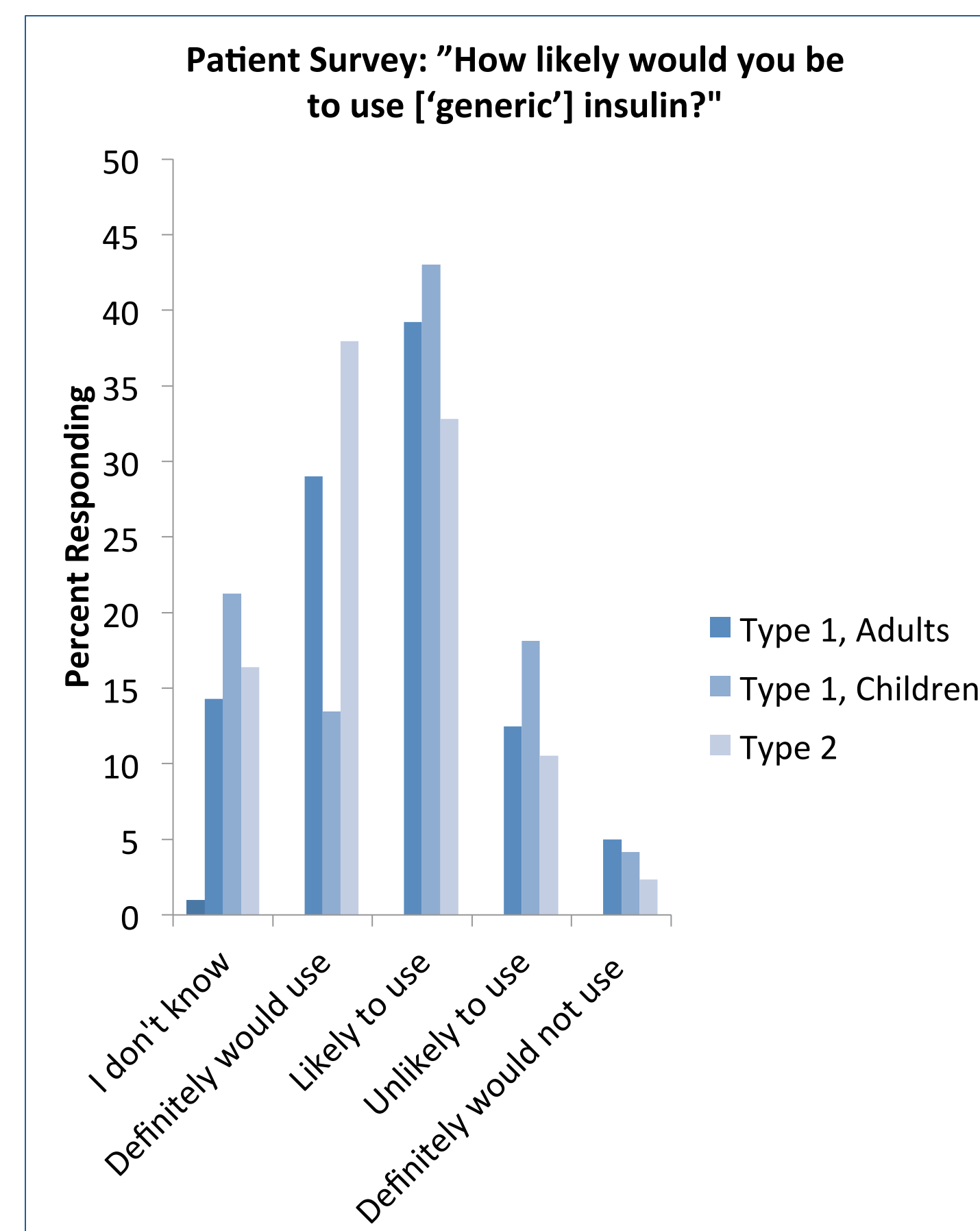
- As patents on top-selling insulin analogs expire in the next five years, including those on top-selling analog insulin glargine, biosimilars have significant potential to decrease diabetes treatment costs and increase the accessibility of insulin.
- Biosimilars are nearly identical versions of the original insulin product, though they may vary slightly in their molecular characteristics and clinical profiles due to different manufacturing techniques. Even with more defined regulatory standards, biosimilars' inherent complexity and slightly modified clinical profiles raise questions about their safety and reliability, posing an initial trust barrier to widespread patient and provider adoption.
- In order to further explore patient and certified diabetes educator (CDE) openness to biosimilars, we conducted a survey of a panel of subscribers to a diabetes patient newsletter and a panel of US CDEs.

Methods

- In mid-2011, a panel of 4,883 subscribers to a diabetes patient newsletter (*diaTribe*) and a panel of 2,503 US CDEs were surveyed about their thoughts and experiences on a variety of diabetes-related topics, including their willingness to use or recommend biosimilar insulin, respectively. Insulin-using patient respondents included 1,637 adults and children (65% response rate; children's answers were provided by their parents). The demographics of these patients were as follows: 65% type 1, median age 49 yrs, 62% female, median household income \$25,000-\$49,999, 67% bachelor's degree or higher, 81% private health insurance. A total of 415 US educators (response rate 17%; 52% outpatient hospital setting, 28% private office, mean 21 patients per week) responded to the CDE survey. Both surveys specified that biosimilars would be priced favorably relative to current insulins; patients were to assume healthcare provider approval.

Results

- Overall, patients appear to be quite interested in using biosimilar insulin, and people with type 2 diabetes appear more open than those who have (or have children with) type 1 diabetes. Of the 1,637 patients with diabetes who responded to the question on whether they would use "a less-expensive generic version of their insulin (a biosimilar)" if it were available and their healthcare provider had approved it, 30% (n=495) said they definitely would and 37% (n=613) said they likely would. Only 16% (n=269) said that they would be "unlikely" to use a generic insulin or that they definitely would not.
- Type 2 diabetes patients appear to be more willing than type 1 patients to switch to generic insulin. Among those with type 2 diabetes, 38% (n=213) said that they would "definitely" switch to generic insulin. By contrast, only 29% (n=256) of adults and 14% (n=26) of children with type 1 diabetes answered "definitely."
- Diabetes educators appear to be positive about recommending biosimilar insulin to their patients. A panel of 415 US CDEs was asked how likely they would be to recommend "a less expensive 'generic' (sometimes called 'biosimilar') versions of insulin analogs" if one were available in the future. Forty-one percent (n=170) said they would definitely recommend the biosimilar, and 42% (n=175) stated that they would likely recommend. Under 6% (n = 24) said that they were unlikely to, or definitely would not, recommend generic insulin.



- Patients' willingness to use generic insulin appears to be related to the main type of insulin they are taking most often. Answers of "definitely" were most common among patients currently using NPH (46%, n=26) or premixed insulin (41%, n=36). Those taking rapid-acting analogs gave the lowest rate of "definitely" answers (28%, n=341).

	Insulin groups					
	Rapid acting	Basal	Premixed	Regular	NPH	Other
Yes, I would definitely use a generic insulin	27.61%	36.36%	41.38%	37.84%	45.61%	25.00%
Yes, I would likely use a generic insulin	38.54%	34.93%	33.33%	24.32%	33.33%	41.67%
No, it is unlikely that I would use a generic insulin	13.28%	11.00%	10.34%	8.11%	8.77%	8.33%
No, I would definitely not use a generic insulin	4.62%	0.48%	5.75%	5.41%	1.75%	0.00%
I don't know	15.95%	17.22%	9.20%	24.32%	10.53%	25.00%

Boxes highlighted in blue statistically significantly different from one or more of the other boxes in the row, with 95% confidence.

Although patients overall showed significant interest in biosimilars, a range of people gave open-ended responses explaining why they would be unlikely to switch to generic insulin:

- "I am comfortable with my brand and my insurance covers 100%."
- "Formulation has a big impact of effectiveness. Generics aren't the same formulation, they are similar. Therefore the results often aren't the same. Also, human testing isn't as rigorous and the safety profile isn't as robust."
- "Reliability issues."
- "Why change something that works well for me and my insurance covers me 100%."
- "I am afraid it will not be effective."
- "Don't know enough about it."
- "Don't know whether it would work as well or if there are other things in the formulation that could cause unforeseen side effects."
- "I trust the name brand more. I don't know who makes the generic one."
- "I have had problems with other 'biosimilar' medications and given how closely my continued ability to live is tied to my ability to control my insulin intake/behavior, I'm unlikely to want to gamble on a 'generic'."
- "If the cost does not change, and the insulin works the same, I have no reason to change."
- "Because I don't believe it is really the same."

Representative open-ended questions submitted by patients about generic insulin:

- "Does it work exactly the same? Is the quality exactly the same?"
- "Is it as predictable/effective?"
- "Will it give me the same results as the version I currently use?"
- "How can we know that it works as effectively or doesn't have unforeseen side effects?"
- "I would ask my Doctor what he thought of the insulin and if he would recommend it."
- "What differences are there from the brand name?"
- "Is the formula for the generic insulin an exact duplication of the brand specific insulin? If not, what are the differences and how could the differences impact the management of my diabetes?"
- "Are production values consistent? Is it truly equal to the brand insulin it would replace?"

Discussion

- Patients' and CDEs' openness to biosimilar insulins seems to hinge largely on lower cost and equivalent performance compared to current insulin products. Additionally, patients assumed that their healthcare provider(s) had approved their use of the biosimilar product – a complex question likely contingent on many regulatory, commercial, and clinical factors.
- Mainstream knowledge of biosimilar insulins is limited, so new developments and media coverage could change attitudes on biosimilars even before any products become available.
- Private insurance was significantly more prevalent, and household income significantly higher, among patients with type 1 diabetes than type 2 diabetes, perhaps influencing attitudes toward biosimilar insulins. As suggested by some open-ended responses, those with more healthcare spending power may be less inclined to switch to a less-expensive insulin.
- Our current study was limited by its enrollment of subscribers to a diabetes patient newsletter, whose choice to subscribe may indicate an atypical level of motivation or diabetes knowledge. Also, the majority are Caucasian. Thus, the generalizability of these findings to the larger diabetes population is unknown.

Summary

- We found that the majority of patients and CDEs are interested in using biosimilar insulins.
- Patients' willingness to take BI varied in relation to what type of insulin regimen they were currently using and whether they had type 1 or type 2 diabetes. Relatively greater percentages of NPH and premixed insulin users said they would "definitely" use a generic insulin if it became available. Type 2 diabetes patients were more interested in generic insulin than type 1 diabetes patients.

Acknowledgements: Many thanks to Close Concerns, Inc., a healthcare information company focused on diabetes and obesity, and dQ&A, a diabetes-focused market research firm, both based in San Francisco, CA, for providing funding for this research project.