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ORIGINAL RESEARCH ARTICLE

Biological Medicines, Biosimilars and Their Automatic Substitution: Concerns, Knowledge and Information Needs of People with Diabetes

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Abstract

Background Automatic substitution of biological medicines was introduced in Finnish community pharmacies in 2024, including glargine insulins in 2025. Patient views on this policy have mainly been studied with other patients than people with diabetes (PwD). Unlike other biological medicines, insulin has a narrow therapeutic window, carries risk of hypoglycemia and hyperglycemia, and requires patient-directed dose adjustments. Therefore, it is essential to explore the views of PwD regarding automatic substitution.

Objectives To investigate the concerns of insulin-treated PwD regarding the automatic substitution of insulins, their knowledge and information needs related to biological medicines, biosimilars, and automatic substitution, and the factors associated with this knowledge.

Methods An electronic survey was conducted in May 2024. Chi-squared test and binary logistic regression were used to examine the association between participant characteristics and outcome variables.

Results Among the 459 participants, 62% expressed concerns about whether the substituted insulin would be as good as the insulin previously used and about the expertise of pharmacists (47%) and physicians (46%). Awareness of biological medicines (67%) exceeded awareness of automatic substitution (45%) and biosimilars (38%), although 63% correctly identified the definition of a biosimilar. Inferior knowledge was associated with higher HbA1c, fewer comorbidities, shorter long-acting insulin use, male gender, age over 70, and use of long-acting insulin as part of multiple daily injections. Over half (55%) reported needing more information.

Conclusions Awareness of biosimilars and automatic substitution of biological medicines was limited among PwD. These findings underscore the importance of targeted communication and education to ensure medically safe substitutions.

Key Points

People with diabetes are concerned about the similarity of biosimilars to their original products.

People with diabetes question the expertise of healthcare professionals in managing automatic substitution of insulins.

Awareness of biosimilars and automatic substitution is limited. Consequently, certain patient groups may require targeted information and support.

1 Introduction

Biological medicines, including insulins, are produced by living organisms [1]. Compared with small-molecule chemical medicines, they possess larger and more complex molecular structures. Owing to the manufacturing process of biological medicines, the final product may vary somewhat between its different batches. A biosimilar contains the same protein and protein folding and has the same dosage and route of administration as the original biological reference medicine. In comparability studies, a biosimilar is required to demonstrate a high similarity to the reference product in safety, quality, and efficacy.

The increasing use of biological medicines for many common diseases, such as diabetes, rheumatoid arthritis, and cancer, has improved treatment outcomes but also increased medicine costs [2]. In the European Union (EU),

Extended author information available on the last page of the article

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the utilization of biological medicines accounts for 40% of total medicine costs [3]. Owing to lower development costs, biosimilars are generally more affordable than the reference products [1]. To increase price competition and reduce the cost of biological medicines, several European countries have implemented a range of policy decisions including price link policies, tendering, and reference price systems [4]. Additionally, prescribers have been advised or required to prescribe or switch to lower cost biosimilars. Automatic substitution of small-molecule medicines, i.e. generic substitution, is common throughout Europe, reducing costs for medicine users and society [4, 5]. However, substitution of biological medicines at the pharmacy level where the pharmacy makes the change without consulting the prescriber, i.e. automatic substitution, is a practice that has been adopted only in a limited number of countries [4].

In the EU, the European Medicines Agency (EMA) centrally approves the majority of biological medicines [1]. Biosimilars approved in the EU can be used interchangeably; nevertheless, individual member states determine their legislation if switching under the control of the prescriber or substitution at the pharmacy level are permitted [6]. In the USA, the Food and Drug Administration (FDA) approves biosimilars as interchangeable, if they meet certain additional requirements [7]. Depending on the state's specific pharmacy legislation, a pharmacist may substitute an interchangeable biosimilar for its reference product. EMA has approved biosimilars of insulin glargine, insulin lispro, and insulin aspart [8]. The FDA has approved two insulin glargine biosimilars as interchangeable insulins [9].

In Finland, it has been mandatory for prescribers to prescribe the least expensive biological medicine since 2017 [10]. To enhance the uptake of biosimilars, the automatic substitution of all biological medicines, except those prescribed for patients under the age of 18 and short-acting insulins, in community pharmacies gradually started in 2024 [11]. Automatic substitution of long-acting insulins started in 2025.

To our knowledge, few studies exist on the views of people with diabetes (PwD) on biosimilars and insulin switching by physicians and substitution in pharmacies [12–14]. More research exists on people with other diseases, such as psoriasis, rheumatoid arthritis, ankylosing spondylitis, cancer, and inflammatory bowel disease [15–20]. Based on the previous research, all people with diseases treated with biological medicines are not aware of what a biosimilar is [14, 16–18]; biosimilars are confused with generic medicines [17], and people are unaware of whether they are taking a biosimilar or an original biological medicine [21]. According to previous studies, patient support for the substitution of biological medicines at the pharmacy level has been limited [12, 14]. Moreover, patients consider switching to a different biological medicine to be riskier than switching to generic medications [22]. PwD have expressed a need for information on the differences and similarities between biosimilars and original biological medicines [12]. Furthermore, additional information is needed on the efficacy and adverse effects of biosimilar insulins [12, 13] and the use of different delivery devices [13]. Unlike other biological medicines, insulin has a narrow therapeutic window and carries a risk of both hypoglycemia and hyperglycemia. It also requires patient-directed dose adjustments. Therefore, insulin users may have different views and concerns about biosimilars and automatic substitution of biological medicines than other biological medicine users. Studies with a patient perspective in this patient group are imperative to ensure safe substitutions, and to avoid known risks, such as nonadherence [23] and nocebo effect [24]. The automatic substitution of insulins has the potential to cause confusion and dosing errors which might be life-threatening for PwD.

This study aims to investigate the concerns of insulin-treated PwD regarding automatic substitution of insulins. In addition, we explore the knowledge and information needs of PwD regarding biological medicines, biosimilars, and their automatic substitution. Furthermore, we study the association of sociodemographic and health-related variables, including the type of diabetes, with long-acting insulin users' knowledge on biological medicines, biosimilars, and their automatic substitution.

2 Methods

2.1 Study Context

The automatic substitution of insulins started in Finland in April 2025, currently concerning only insulin glargine [11]. Short-acting insulins will not be included in the automatic substitution to avoid confusion between short- and long-acting insulins [25]. The substitution can be conducted for the first time the biological medicine is dispensed and after 6 months of continuous use. The prescriber can deny substitution for medical or therapeutic reasons. Moreover, patients may choose to decline the proposed substitution. In such cases, they are required to pay the price difference between the prescribed biological medicine dispensed and the reference price of equivalent reimbursable biological medicine. In pharmacies, pharmacists must provide pharmaceutical and delivery device counseling to ensure the correct and safe use of dispensed medicines [11]. Nurses in primary and secondary healthcare provide guidance on insulin injection techniques.

2.2 Questionnaire

A cross-sectional online survey was conducted in spring 2024, i.e., 1 year prior to the initiation of the automatic substitution of insulins. The questionnaire was designed on the

basis of previous studies [15, 26–31] and the expertise of the research group, including a patient expert (T.Z.). In addition, a pilot survey was conducted ($n = 55$). Based on the pilot study, minor changes were made to the questionnaire. The responses to the pilot study were not included in the final study data.

The questionnaire contained a total of 40 structured and 6 open-ended questions. The questionnaire included six sections: (1) Background information, (2) Biological medicines and biosimilars, (3) Automatic substitution of biological medicines (including insulins), (4) Information needs on biological medicines (including insulins), biosimilars and their automatic substitution, (5) Counseling of PwD in healthcare and pharmacies, and (6) Views on the use of medicines. Supplementary Information 1 introduces sections 1, 2, 3, and 4 analyzed in this study. Information about biological medicines, biosimilars, and their automatic substitution was given to participants in the questionnaire.

2.3 Data Collection

The data were collected between 15 April and 5 May 2024. The survey was targeted at over 18-year-old PwDs using insulin. The participants were recruited through a research newsletter and other communications sent to the loyal customers of University Pharmacy as well as through the communication channels of the Finnish Diabetes Association. In addition, invitation letters were distributed through 17 outlets of University Pharmacy and 10 private pharmacies located in different parts of Finland to customers purchasing insulin. Based on the sample size calculation, a target sample size of 384 was set.

2.4 Outcome Variables

A multiple-choice question was used to assess participants' concerns about the automatic substitution of insulins (Supplementary Information 1: question 21). Participants' awareness of biological medicines was measured with questions: "Have you heard about biological medicines/biosimilars/automatic substitution of biological medicines before this study?" (Supplementary Information 1: questions 14, 16 and 18) and "Did you know before this survey that insulin is a biological medicine?" (Supplementary Information 1: question 15). In addition, one question measured if the participant knew the exact meaning of the term biosimilar (Supplementary Information 1: question 17). The common term "knowledge" is used in this article to describe both knowledge and awareness. Furthermore, participants were asked if they need more information about biological medicines and their automatic substitution (Supplementary Information 1: question 19). Those responding that they need more information were presented with a multiple-choice question about what kind of information they need (Supplementary Information 1: question 20).

2.5 Data Analysis

Diabetes types were categorized into two groups: "T1D" and "T2D or other types of diabetes." Later in the article, the term "T2D or other types of diabetes" is referred to as "T2D." Year of birth was converted into age and classified into five categories: under 40, 40–49, 50–59, 60–69 and 70 years or over. The participants' geographical treatment area was categorized into five areas: Southern, Inland, Western, Eastern and Northern Finland. Household monthly net incomes were combined into five categories: under 2000€, 2001–3000€, 3001–4000€, 4001–5000€, and over 5000€. The time since diabetes diagnosis was combined into three categories: < 5, 6–20, and > 20 years ago. Chronic diseases other than diabetes were converted into a sum of diseases and classified into two categories: 0–3 and ≥ 4 other diseases. Usage of long-acting insulin was classified into categories "Long-acting insulin as an emergency treatment for pump therapy" and "Long-acting insulin as part of multiple daily insulin injections (MDI)." The length of use of the current long-acting insulin was classified into four categories: < 1, 1–5, 6–10 and > 10 years.

The data were analyzed using IBM SPSS Statistics for Windows, Version 29.0.2 (SPSS, Inc., Chicago, IL, USA). Responses to the structured questions were analyzed using descriptive statistical methods (frequences, percentages, means, standard deviations (SD)). The Chi-squared test was used to investigate possible differences between people with T1D and T2D. Multivariable binary logistic regression was used to examine the association between age, gender, diabetes type, highest education, geographical treatment area, household monthly net income, time since diagnosis of diabetes, last measured HbA1c value, number of chronic diseases other than diabetes, length of use of the current long-acting insulin, pump therapy/injectable insulin, and other medicines for diabetes and the knowledge of automatic substitution of biological medicines (Model 1), biosimilars (Model 2), biological medicines (Model 3), the term biosimilar (Model 4), and insulin as a biological medicine (Model 5). "I don't know" answers were excluded from the logistic regression analysis in questions which measured the awareness of biological medicines ($n = 37$), biosimilars ($n = 54$), and automatic substitution of biological medicines ($n = 17$) to have binary outcome variables. The question measuring knowledge of the definition of biosimilar was made binary by recoding response options into two categories: right and wrong. Supplementary Information 2 introduces background variables according to the knowledge of participants; in addition, missing categories of background variables in the binary logistic regression are labeled. The logistic regression

model was first conducted separately among people with T1D and T2D, but differences were minor. Consequently, diabetes type was used as a background variable.

The results of the logistic regression are presented in odds ratios (OR) and 95% confidence intervals (CI). A statistical significance level of < 0.05 was set.

3 Results

3.1 Study Population

A total of 547 responses were received to the questionnaire. One of the participants was under the age of 18, 63 did not report insulin treatment for diabetes, 12 did not have diabetes, and 12 did not provide informed consent. Thus, the final size of the study population was 459. Of the participants, 67% were female (Table 1). A total of 57% of the participants had T1D, while 43% were categorized as having T2D. The mean age of the participants was 57 years (SD 15, range 20–87). Half (49%) of the participants' geographical treatment area was Southern Finland. Compared with data from the National Diabetes Registry, proportion of the respondents from Southern Finland was slightly overrepresented, while Western Finland was underrepresented [32]. Furthermore, the age distribution of participants with T1D in this study was older than generally in Finland. However, the age distribution of people with T2D aligned with the National Diabetes Registry. In both T1D and T2D, females were overrepresented.

3.2 Concerns

More than half (62%) of the participants were concerned about whether insulin substituted in the pharmacy is as good for them as their previous insulin (Fig. 1). Moreover, the expertise of pharmacists (47%) and physicians (46%) in the automatic substitution raised concerns. People with T1D had more concerns about the automatic substitution of injectable insulins than people with T2D as they were statistically significantly more concerned about the substituted insulin being as good for them as the previous one (T1D 68% versus T2D 54%), the expertise of pharmacists to implement automatic substitution (56% versus 35%), the adaptation of insulin ampoules to reusable or memory pens (30% versus 9%), the differentiation between short-acting and long-acting insulins (20% versus 8%), and the environmental impact (15% versus 8%).

3.3 Knowledge

Over half of the participants had heard about biological medicines (67%) and knew that insulin is a biological medicine (62%) before the survey (Fig. 2). In contrast, less than half of the participants had heard about biosimilars (38%) or the automatic substitution of biological medicines (45%). For the question about the definition of biosimilar, 63% recognized the right answer. In all questions about knowledge, people with T1D had statistically significantly higher knowledge than people with T2D. However, when logistic regression was executed, the difference between these groups was not statistically significant (Table 2, Supplementary Information 3).

Participants with HbA1c 64–70 mmol/mol tended to have inferior knowledge of the automatic substitution of biological medicines (model 1) and biosimilars (model 2) in comparison to those with HbA1c levels below 53 mmol/mol (Table 2). Furthermore, fewer than four comorbidities and current long-acting insulin use for less than 1 year were associated with worse knowledge compared with comorbidities of four or more and over 10 years of use of current long-acting insulin. Men tended to have less knowledge about the automatic substitution of biological medicines (model 1) compared with women. Participants aged over 70 years and using long-acting insulin as part of MDI demonstrated lower levels of knowledge regarding biosimilars (Model 2) compared with participants aged 40–69 years and those using long-acting insulin as an emergency treatment for pump therapy. Similar outcomes were observed in other models (Supplementary Information 3).

3.4 Information Needs

More information about biological medicines and their substitution was needed by 55% of the participants (Table 3). Most of them expressed a need for further information about equivalence (84%) and differences (72%) between original biological medicines and biosimilars as well as differences between the substituted and previously used biological medicine (72%). Additionally, the participants expressed greater interest in the personal financial implications (67%) of the automatic substitution than in the societal costs (33%). A chi-squared test revealed some statistically significant differences in information needs between T1D and T2D. For instance, people with T1D needed more information about equivalence (T1D 91% versus T2D 76%) and differences (81% versus 60%) between biological medicines and biosimilars. In contrast, people with T2D had a greater need for information about the definition of biosimilars (53%) and biological medicines (52%) than people with T1D (41% and 34%, respectively).

Table 1 Characteristics and medicine use of participants ($n = 459$) according to type of diabetes.

	T1D ($n = 262$) % (n)	T2D ($n = 197$) % (n)	Total ($n = 459$) % (n)
*Age (years)**			
< 40	23.3 (61)	2.0 (4)	14.2 (65)
40–49	23.7 (62)	3.6 (7)	15.0 (69)
50–59	21.4 (56)	17.3 (34)	19.6 (90)
60–69	20.6 (54)	40.6 (80)	29.2 (134)
≥ 70	11.1 (29)	36.5 (72)	22.0 (101)
*Gender**			
Female	72.5 (190)	58.9 (116)	66.7 (306)
Male	25.2 (66)	40.6 (80)	31.8 (146)
Other	1.5 (4)	0.5 (1)	1.1 (5)
I don't want to answer	0.8 (2)	0.0 (0)	0.4 (2)
*Highest education**			
Comprehensive school	5.7 (15)	11.2 (22)	8.1 (37)
High school	6.5 (17)	5.1 (10)	5.9 (27)
Vocational school	39.3 (103)	51.3 (101)	44.4 (204)
University of applied sciences	18.7 (49)	12.2 (24)	15.9 (73)
University	29.0 (76)	19.8 (39)	25.1 (115)
Other	0.8 (2)	0.5 (1)	0.7 (3)
Geographical treatment area			
Southern Finland	46.9 (123)	51.8 (102)	49.0 (225)
Inland Finland	16.4 (43)	10.2 (20)	13.7 (63)
Western Finland	14.5 (38)	12.7 (25)	13.7 (63)
Eastern Finland	12.6 (33)	12.2 (24)	12.4 (57)
Northern Finland	9.2 (24)	12.7 (25)	10.7 (49)
I don't know	0.4 (1)	0.5 (1)	0.4 (2)
Household net income per month (€)			
< 2000	24.0 (63)	27.4 (54)	25.5 (117)
2001–3000	14.9 (39)	22.8 (45)	18.3 (84)
3001–4000	19.1 (50)	18.8 (37)	19.0 (87)
4001–5000	12.2 (32)	12.7 (25)	12.4 (57)
> 5000	16.8 (44)	11.7 (23)	14.6 (67)
I don't want to answer	9.5 (25)	4.6 (9)	7.4 (34)
I don't know	3.4 (9)	2.0 (4)	2.8 (13)
*When diabetes was diagnosed**			
< 5 years ago	8.0 (21)	15.2 (30)	11.1 (51)
6–20 years ago	32.1 (84)	51.3 (101)	40.3 (185)
> 20 years ago	59.9 (157)	33.5 (66)	48.6 (223)
*Last measured HbA1c (mmol/mol)**			
< 53	24.8 (65)	18.8 (37)	22.2 (102)
53–63	39.7 (104)	36.0 (71)	38.1 (175)
64–70	15.3 (40)	17.8 (35)	16.3 (75)
> 70	6.9 (18)	4.1 (8)	5.7 (26)
Not measured in the last 2 years	0.8 (2)	2.5 (5)	1.5 (7)
I don't know or remember	12.6 (33)	20.8 (41)	16.1 (74)
*Number of chronic diseases other than diabetes**			
0–3	76.3 (200)	65.5 (129)	71.7 (329)
≥ 4	23.7 (62)	34.5 (68)	28.3 (130)
*Pump therapy/injectable insulin**			
Long-acting insulin as an emergency treatment for pump therapy	24.4 (64)	0.0 (0)	13.9 (64)

Table 1 (continued)

	T1D (n = 262) % (n)	T2D (n = 197) % (n)	Total (n = 459) % (n)
Long-acting insulin as part of MDI	74.4 (195)	99.5 (196)	85.2 (391)
I don't use long-acting insulin	1.1 (3)	0.5 (1)	0.9 (4)
How long has used current long-acting insulin (n = 455)/***	*n = 259*	*n = 196*	*n = 455*
< 1 year	7.7 (20)	14.8 (29)	10.8 (49)
1–5 years	37.5 (97)	40.8 (80)	38.9 (177)
6–10 years	27.0 (70)	21.4 (42)	24.6 (112)
> 10 years	27.8 (72)	23.0 (45)	25.7 (117)
Do you use other medicines for diabetes besides long-acting insulin			
Yes	92.7 (243)	93.4 (184)	93.0 (427)
No	7.3 (19)	6.6 (13)	7.0 (32)
*Other medicines in use for diabetes (n = 427)****	*n = 234*	*n = 184*	*n = 427*
Short-acting insulin*	96.7 (235)	29.9 (55)	67.9 (290)
Tablet*	15.6 (38)	87.0 (160)	46.4 (198)
Injectable medicine (no insulin)*	3.7 (9)	34.2 (63)	16.9 (72)
Don't know or remember	0.4 (1)	0.5 (1)	0.5 (2)
Some other medicine (no open answer given)	0.4 (1)	0.5 (1)	0.5 (2)

T1D type 1 diabetes, *T2D* type 2 diabetes, *MDI* multiple daily injections

*The differences in characteristics between people with T1D and T2D were tested using Chi-squared test. Statistically significant differences (p-value <0.05) are marked with *

**Question only for participants who reported using long-acting insulin

***Question only for participants who reported using other medicines for diabetes besides long-acting insulin. Participants may have chosen several alternatives

4 Discussion

This study showed that over half of PwD expressed concerns about whether a biosimilar insulin is as good for them as the insulin they have been using. Over half of the participants had heard of biological medicines and knew that insulin is a biological medicine. However, biosimilars and automatic substitution of biological medicines were more unfamiliar to them. These findings align with previous studies conducted in other patient groups [14, 16–18]. Additionally, characteristics of participants associated with inferior knowledge were identified. These characteristics included higher HbA1c levels, fewer comorbidities, shorter long-acting insulin use, male gender, age over 70, and use of long-acting insulin as part of MDI. Especially people with T1D had information needs regarding the equivalence and differences between original biological medicines and biosimilars.

4.1 Concerns and Information Needs of PwD

The most common concern among participants was whether the substituted medicine is as good as the previous one for the individual, which highlights the specific nature of diabetes as a disease. Furthermore, participants expressed information needs on the equivalence and similarity of biological medicines and biosimilars, which is consistent with the results of a previous study conducted among PwD in Finland [12]. PwD adjust insulin treatment daily according to meals and physical activity [33]. While biosimilars have been demonstrated to be as effective and safe as their reference products [34], even minor variations can raise concerns among insulin users that their treatment balance may be disturbed. The present study demonstrated that people with T1D have more concerns and information needs compared with those with T2D. The life-sustaining nature of insulin indicates that automatic substitution can have a significant impact on the daily lives of people with T1D.

In this study, participants were concerned about the expertise of pharmacists and physicians in automatic substitution of insulins, despite PwD generally reporting high trust in HCPs in diabetes care [35, 36]. When the automatic substitution is introduced, consistent, regularly repeated and patient-centered messaging in both healthcare units and pharmacies regarding the safety of biosimilars and the principles of automatic substitution could be an effective tool for alleviating patients´ concerns and information needs [36]. In order for patients to rely on HCPs guidance, HCPs need adequate skills not only in insulin treatment and the automatic substitution of biological medicines, but also in effective communication. HCPs have reported that they need more information and training on biosimilars [37, 38]. Furthermore, communication training should include

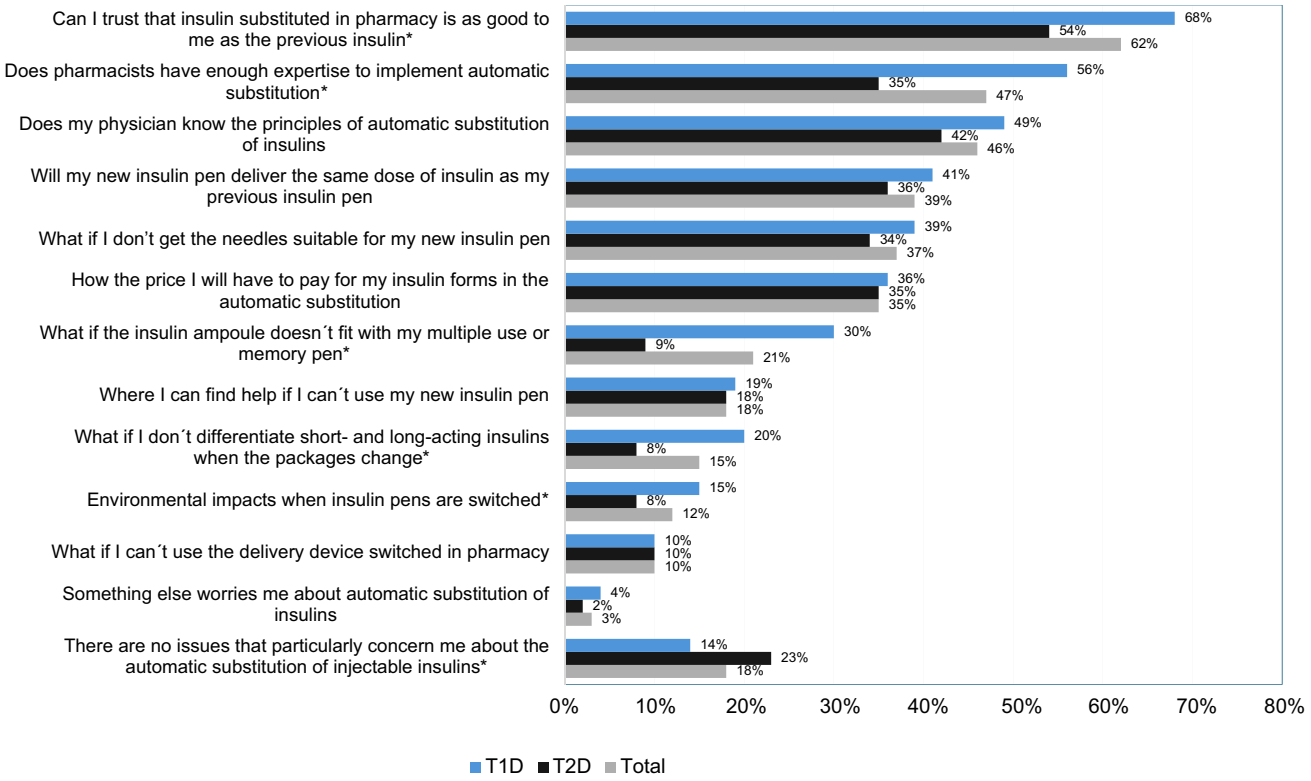

Fig. 1 Concerns of participants about the automatic substitution of injectable insulins ($n = 459$). *T1D* Type 1 diabetes, *T2D* Type 2 diabetes. *Statistically significant p-value (< 0.05) in Chi-squared test between people with T1D and T2D

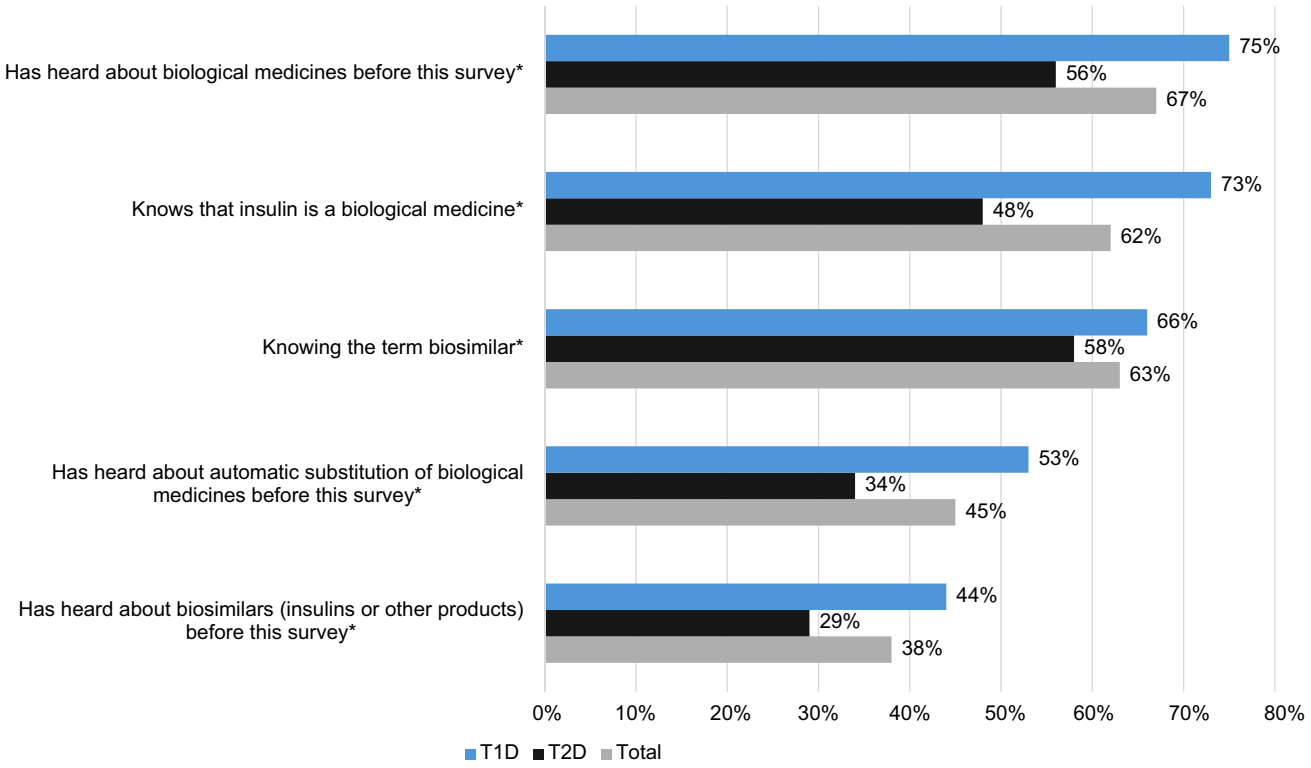

Fig. 2 Knowledge of participants on biological medicines, biosimilars, and automatic substitution ($n = 459$). *T1D* Type 1 diabetes, *T2D* Type 2 diabetes. *Statistically significant p-value (< 0.05) in Chi-squared test between people with T1D and T2D.

Table 2 Logistic regression models on the awareness of the automatic substitution of biological medicines and biosimilars ($n = 459$)

Characteristics	Had heard about the automatic substitution of biological medicines before the survey ($n = 442$) Model 1 OR (95% CI)	Had heard about biosimilars (insulins or other products) before the survey ($n = 405$) Model 2 OR (95% CI)
Age (years)		
≥ 70	1.00	1.00
60-69	1.73 (0.86–3.49)	3.12 (1.47–6.61)*
50-59	1.72 (0.77–3.88)	4.00 (1.72–9.27)*
40-49	1.18 (0.47–3.00)	3.32 (1.27–8.70)*
< 40	0.65 (0.22–1.90)	2.85 (0.94–8.61)
Gender		
Female	1.00	1.00
Male	0.45 (0.26–0.78)*	1.09 (0.63–1.90)
Diabetes type		
Type 1	1.00	1.00
Type 2	1.03 (0.41–2.53)	0.73 (0.29–1.87)
Highest education		
University	1.00	1.00
University of applied sciences	0.93 (0.43–2.04)	0.63 (0.28–1.42)
Vocational school	0.65 (0.33–1.26)	0.66 (0.33–1.33)
High school	0.30 (0.09–1.05)	0.35 (0.09–1.43)
Comprehensive school	0.78 (0.28–2.18)	1.21 (0.42–3.48)
Geographical treatment area		
Southern Finland	1.00	1.00
Inland Finland	1.71 (0.80–3.66)	1.34 (0.61–2.91)
Western Finland	1.95 (0.92–4.13)	1.89 (0.90–3.99)
Eastern Finland	1.62 (0.77–3.40)	1.72 (0.81–3.66)
Northern Finland	0.44 (0.17–1.12)	1.47 (0.60–3.56)
Household net income per month (€)		
< 2000	1.00	1.00
2001–3000	1.20 (0.58–2.47)	1.04 (0.48–2.25)
3001–4000	1.71 (0.81–3.61)	1.02 (0.48–2.15)
4001–5000	2.39 (0.99–5.77)	1.77 (0.73–4.32)
> 5000	1.58 (0.70–3.59)	1.09 (0.47–2.53)
When diabetes was diagnosed		
> 20 years ago	1.00	1.00
6–20 years ago	0.83 (0.47–1.47)	0.99 (0.55–1.78)
< 5 years ago	0.91 (0.36–2.31)	0.62 (0.24–1.63)
Last measured HbA1c (mmol/mol)		
< 53	1.00	1.00
53–63	0.66 (0.35–1.25)	0.81 (0.43–1.52)
64–70	0.42 (0.18–0.95)*	0.36 (0.15–0.84)*
> 70	0.95 (0.32–2.80)	0.55 (0.17–1.77)
I don't know or remember	0.09 (0.04–0.25)*	0.35 (0.14–0.85)*
Number of chronic diseases other than diabetes		
0–3	1.00	1.00
≥ 4	1.95 (1.10–3.49)*	2.63 (1.44–4.79)*
*How long has used current long-acting insulin***		
> 10 years	1.00	1.00
6–10 years	0.66 (0.33–1.33)	0.64 (0.31–1.30)

Table 2 (continued)

Characteristics	Had heard about the automatic substitution of biological medicines before the survey ($n = 442$) Model 1 OR (95% CI)	Had heard about biosimilars (insulins or other products) before the survey ($n = 405$) Model 2 OR (95% CI)
1–5 years	0.98 (0.50–1.92)	0.70 (0.35–1.38)
< 1 year	0.35 (0.13–0.92)*	0.27 (0.10–0.73)*
Pump therapy/injectable insulin		
Long-acting insulin as part of MDI	1.00	1.00
Long-acting insulin as an emergency treatment for pump therapy	2.29 (0.96–5.46)	2.52 (1.08–5.87)*
*Other medicines for diabetes***		
Short-acting insulin	1.17 (0.53–2.58)	0.83 (0.36–1.91)
Tablet	0.59 (0.28–1.23)	1.01 (0.49–2.12)
Injectable medicine (no insulin)	1.06 (0.51–2.21)	0.68 (0.32–1.44)

OR odds ratio, *CI* confidence interval, *MDI* multiple daily injections

*Significance $p < 0.05$

**Question only for participants who reported using long-acting insulin ($n = 455$)

***Question only for participants who reported using other medicines for diabetes besides long-acting insulin ($n = 427$), participants may have chosen several alternatives. The reference is No

effective communication strategies for building patients' trust [36, 39]. Various stakeholders, including the government, employers, patient and professional associations, and pharmaceutical companies, could provide HCPs with communication training and information on insulin treatment and automatic substitution. In Finland, for instance, the government introduced guidance on the operational process of automatic substitution of biological medicines in 2025 [40], and pharmaceutical companies have provided instructional videos on administering biological medicines that can be used during patient counselling in pharmacies [41].

4.2 Knowledge about Biological Medicines and PwD Especially Needing Information

Despite the fact that over half of the participants in this study had heard about biological medicines before the study, only under a quartile reported that they have sufficient knowledge regarding biological medicines and their substitution. Thus, it is clear that PwD were not adequately informed about the upcoming change a year prior to its initiation in Finland. Unfamiliarity with the concept of biosimilar found in this study is consistent with the results of previous studies from other patient groups [15, 16, 18]. A review of patient perceptions of biosimilars among people with rheumatic diseases, psoriasis, inflammatory bowel disease, inflammatory joint disease, cancer, and diabetes shows that the knowledge of biosimilars varies between 6 and 51% [24]. Furthermore, the same review identified that previous use of biological medicines, more hospital appointments, and membership in a patient association were associated with better knowledge of biosimilars. In this study, PwD who were identified as needing further information were those with higher HbA1c levels, less comorbidities, shorter use of the current long-acting insulin, males, those aged over 70 years, and those using long-acting insulin as part of MDI. Although people with T1D did not have inferior knowledge compared with those with T2D in the logistic regression models, they reported more concerns and information needs. This suggests that they should also be carefully considered when providing counseling. Among characteristics related to better knowledge in this study, good glycemic control and insulin pump utilization may reflect better awareness of matters related to the insulin treatment, including biosimilars. Patient counseling in pharmacies should be tailored to patients' individual needs and focus particularly on those who need information the most [42] Furthermore, special attention should be paid to counseling on high-risk medications [42], including insulins [43]. In fact, individualized counseling has been proven to improve treatment adherence and clinical outcomes of PwD [44]. This study provides HCPs with valuable information about PwD who require the most information about biological medicines, biosimilars, and their automatic substitution. These results can assist HCPs to effectively allocate resources to patients who need the most support. However, patients should be informed not only by HCPs, but also nationally by, for example, the government and patient associations.

Table 3 Information needs of participants on biological medicines and their automatic substitution ($n = 459$).

	T1D ($n = 262$) % (n)	T2D ($n = 197$) % (n)	Total ($n = 459$) % (n)
Do you think that you need more information about biological medicines and their substitution?			
I need more information about biological medicines (including insulins) and their substitution.	54.6 (143)	56.3 (111)	55.3 (254)
I have enough information about biological medicines and their substitution.	22.9 (60)	20.8 (41)	22.0 (101)
I don't know	22.5 (59)	22.8 (45)	22.7 (104)
*What kind of information do you think you need more? (n = 254)***	*n = 143*	*n = 111*	*n = 254*
Equivalence between an original biological medicine and its biosimilar (for example efficacy and possible adverse effects)*	90.9 (130)	75.7 (84)	84.3 (214)
The differences between the substituted biological medicine and the biological medicine I am currently using*	82.5 (118)	59.5 (66)	72.4 (184)
The differences between an original biological medicine and its biosimilar (for example differences in composition)*	81.1 (116)	59.5 (66)	71.7 (182)
Total price of the medicine for myself	63.6 (91)	71.2 (79)	66.9 (170)
Is my biological medicine one of the medicines that can be substituted at the pharmacy	67.8 (97)	57.7 (64)	63.4 (161)
Storage	57.3 (82)	64.9 (72)	60.6 (154)
Is the medicine I use an original biological medicine or a biosimilar	61.5 (88)	51.4 (57)	57.1 (145)
What is the price difference between the different products of the biological medicine I use	60.1 (86)	50.5 (56)	55.9 (142)
Do I get the same biological medicine from the pharmacy next time*	62.2 (89)	41.4 (46)	53.1 (135)
Do I have the possibility to refuse automatic substitution of a biological medicine*	63.6 (91)	38.7 (43)	52.8 (134)
How often can a biological medicine be changed at the pharmacy*	61.5 (88)	38.7 (43)	51.6 (131)
The differences between my existing delivery device and a new delivery device	53.8 (77)	43.2 (48)	49.2 (125)
Is the medicine I use a biological medicine or a conventional chemical medicine	46.2 (66)	50.5 (56)	48.0 (122)
Has the physician banned the substitution of my biological medicine*	53.8 (77)	36.9 (41)	46.5 (118)
What is a biosimilar*	40.6 (58)	53.2 (59)	46.1 (117)
Country of a medicine's manufacturer	39.2 (56)	48.6 (54)	43.3 (110)
What is a biological medicine*	33.6 (48)	52.3 (58)	41.7 (106)
Medicine costs for the society	32.2 (46)	33.3 (37)	32.7 (83)
Environmental impacts of biological medicines	29.4 (42)	27.9 (31)	28.7 (73)
The appearance of the medicine	19.6 (28)	11.7 (13)	16.1 (41)
Some other information	1.4 (2)	4.5 (5)	2.8 (7)

T1D type 1 diabetes, *T2D* type 2 diabetes

*Statistically significant difference ($p < 0.05$ in chi-squared test) between people with T1D and T2D.

**The question is asked only if a participant has reported a need for information about biological medicines and their substitution ($n = 254$). Participants may have chosen several alternatives

4.3 Strengths and Limitations

This study reached its target number of participants. However, people who were particularly interested in the topic in question or more engaged in their treatment may be overrepresented. This could make the results seem more favorable than they are for all Finnish PwD. Participation required internet access and the ability to utilize electronic devices, which may have contributed to selection bias. Additionally, the research group is unaware of how consistently pharmacies distributed the survey invitations. Despite these limitations, the respondents were obtained from all areas of Finland, of all age groups, both types of diabetes, and both genders. The representativeness of the data warrants generalizing the results to Finnish PwD [32]. The strength of this study was that the topic is very current in Finland, as the automatic substitution of biological medicines recently began. Furthermore, other countries planning to implement automatic substitution of biological medicines may utilize the findings of this study. The data collected in this study will provide a baseline for future research, as it is collected before the implementation of the automatic substitution.

Insulin use was self-reported without any specific operationalization of dosage. There is a small risk that a respondent may have incorrectly identified themselves as an insulin user. However, the answers to the questions "What basic

insulin, i.e., long-acting insulin, do you use?" and "What other medicines do you use for diabetes other than basic insulin?" were carefully investigated to mitigate the possibility of analyzing the responses of noninsulin users. Question measuring awareness of insulin as a biologic medicine ("Did you know before this survey that insulin is a biological medicine?") may have been leading for respondents, resulting in too positive results on awareness. This question format was chosen because, based on earlier studies [14, 16–18, 21], there was a need to provide background information on biological medicines, biosimilars, and automatic substitution within the survey.

5 Conclusions

The automatic substitution raises concerns, especially among people with T1D. PwD need more information about biological medicines, biosimilars, and their automatic substitution. This study identified specific patient groups requiring further information. Furthermore, the present study recognized information needs of PwD on the equivalence and similarity of biological medicines. The primary information needs and concerns addressed in this study can be managed through medication counseling and communication. Improved communication strategies are essential to ensure that patients understand the implications of automatic substitution. Adequate training for HCPs is essential to address patient concerns and provide them with comprehensive information about the equivalence and differences between original biological medicines and biosimilars. Furthermore, the findings of this study can assist healthcare and HCPs in effective allocation of resources, ensuring that those in need of support receive the necessary counseling and guidance.

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Declarations

Conflict of Interest The authors have no competing interests to declare that are relevant to the content of this article.

Ethics Approval and Consent to Participate The study was conducted in accordance with the ethical principles of research in the human sciences in Finland and did not require ethical approval [45]. Participants were asked for informed consent before answering the survey. Privacy legislation [46, 47] was followed when handling the data.

Consent for Publication Not applicable.

Availability of Data and Materials The data generated or analyzed in the current study are not publicly available due to the sensitivity of the data; however, anonymized data are available from the corresponding author upon reasonable request for academic purposes.

Author Contributions MK: Conceptualization, Formal analysis, Investigation, Methodology, Writing—original draft; KL: Supervision, Conceptualization, Methodology, Writing—review & editing; SM: Supervision, Conceptualization, Methodology, Writing- review & editing; EP: Conceptualization, Methodology, Writing—review & editing; SK: Conceptualization, Methodology, Writing—review & editing; EA: Formal analysis, Writing—review & editing; TZ: Methodology, Writing—review & editing; KH-A: Supervision, Conceptualization, Methodology, Writing—review & editing

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