BMJ Open Cross-sectional patient survey of biological medicine users in Finland to investigate the types of guidance needed by patients in order to carry out their treatment successfully

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ABSTRACT

Background The use of new biological medicines as standard treatment is expected to increase substantially and cover new therapeutic indications in the near future. Interchange of biological medicines in pharmacies increases the need for patient guidance. **Objectives** The study aims to gain a patient perspective on biological medicine users' needs and wishes regarding patient guidance by exploring what kind of information patients wish to receive and to further investigate the potential differences in needs between originator biological medicine users and biosimilar users.

Design A cross-sectional patient survey. Setting Anonymous electronic patient survey was conducted in 88 community pharmacies and via two patient organisations in Finland in 2022.

Participants Users of originators and biosimilars of adalimumab, etanercept, filgrastim and pegfilgrastim. Results The majority of the 199 respondents had received instructions from a nurse or a public health nurse on how to use their self-injected medicine. According to the patients, the main factors affecting treatment persistence, apart from treatment effectiveness, were few adverse effects, access to treatment support and an easy-to-use administration device. At treatment initiation, the optimal types of guidance were face-to-face instruction, handson practice with injecting the medicine, using the administration device and information on adverse effects. Even though 79% of respondents indicated that they would not have wanted more instruction on using their self-injected medicine, these respondents also expressed that, at the time of treatment initiation, additional information or help would have been needed concerning adverse effects, biosimilars, and biological medicines in general. In general, biosimilar users were more concerned about adverse effects than users of originator products.

Conclusion Patients consider information about adverse effects an important part of patient guidance when starting and maintaining self-administered biological therapy. The results highlight the importance of ensuring that up-to-date evidence-based information is readily available to patients from reliable sources.

- STRENGTHS AND LIMITATIONS OF THIS STUDY

 Participants were recruited via pharmacies and patient organisations, and the study managed to capture a diverse patient population from all over Finland.

 Even though the data were collected during the COVID-19 pandemic in the summer and autumn of 2022, the desired number of respondents was reached.

 At the time of the data collection, interchange of biological medicines in pharmacies was not yet possible; thus, the results of this study can be considered as baseline information concerning the level of patient guidance needed for these products.

 INTRODUCTION

 The introduction of biological medicines has significantly improved the effectiveness of the treatment of many command diseases.

has significantly improved the effectiveness of the treatment of many common diseases such as autoimmune diseases and cancers.¹ The development of new biological medi- ≥ cines is a very active field of research, and the use of these medicines is expected to expand substantially and cover new therapeutic indications. In 2022, about 30% of new medicines approved by the US Food and Drug Administration (FDA) were biological medicines.² In 2023, the estimated global market for biological medicines was over 300 billion USD and is expected to double within a decade.³

Biological medicines are proteins produced in or derived from living cells or organisms of human, animal or microbial origin. Due to the complex production process, the production costs of biological medicines are significantly higher than those of chemically manufactured small-molecule agents. In general, when the patent of an originator biological medicine expires, biosimilars can be granted marketing authorisations and introduced to the market. Biosimilars resemble the originator biological medicines, and while their



structure, biological activity, efficacy, safety and immunogenicity profile have been proven to be highly similar to those of the reference product, biosimilars are more affordable.

The Heads of Medicines Agencies and European Medicines Agency (EMA) consider that biosimilars approved in the EU are interchangeable.⁵ In Finland—as in some other countries—switching between different biological medicines has previously required a doctor's prescription, but in order to restrain increasing healthcare costs, the Finnish Government has approved an amendment to the Finnish Medicines Decree in 2023 that will gradually allow interchange in pharmacies from 2024 onwards. However, according to a recently published cross-sectional patient survey, only about 40% of Finnish patients using biological medicines would allow pharmacy interchange for their biological medicine with a lower-cost product (ie, allow the pharmacist to switch a more expensive biological medicine to a more affordable alternative, most commonly from originator to biosimilar). The most common obstacle to interchange in pharmacies, from the patients' perspective, was that the patients wanted to keep the product their doctor had initially prescribed.

Price is thought to be a key influencing factor in the choice of a specific biological product, but the findings of the recent survey indicate that many patients still use more expensive originators as prescribed by their doctors. Now that interchange is proposed in pharmacies, it is important to ensure that adequate guidance about biosimilars and biological medicines, in general, is readily available to improve patient confidence towards substitution without a new prescription and, thus, to achieve the desired reduction in healthcare costs. (In the present publication, interchange refers to an action taken by a pharmacist, while substitution refers to an action with a written prescription by a doctor.) Proper guidance by healthcare professionals is necessary to ensure patient compliance and effective and safe treatment.

Scientific literature about the substitution of biological medicines is scarce, ^{79–12} and there is a demand for research on the need for patient guidance from the patients' point of view. A recent publication from New Zealand highlights that patient support programmes run by patient organisations would help adalimumab-treated patients during the substitution of biosimilars. 12 At the European level, Finland is a pioneering country in terms of biosimilar use, supporting the interchange of biosimilars under the supervision of a healthcare professional since 2015, 13 but the safe and efficient implementation of the recent legislation⁶ requires new research. In 2019, Tolonen et al discussed that patient counselling provided by pharmacists is important in ensuring medication safety in connection with the substitution of biological medicines and that there is a particular need for studies exploring patients' views of interchange in pharmacies. ¹⁴ The purpose of this present study was to address this gap and to investigate what kind of information and guidance patients need and wish in order to carry out their treatment successfully. In

addition, this study aimed to explore patients' opinions and experiences regarding the quality and information content of the patient guidance they had already received regarding their biological medication. Furthermore, the aim was to understand the potential differences between the needs and wishes of originator biological medicine users and those of biosimilar users.

METHODS

This cross-sectional study was conducted as an anonymous patient survey of adults (aged 18 years or older) receiving continuous therapy with self-injected biological medicines for which biosimilars were available (adalimumab, etanercept, pegfilgrastim or filgrastim).

In total, 157 pharmacies were enrolled for data collection, covering approximately 20% of all Finnish community pharmacies. Data were received from 88 community pharmacies across Finland and via two national patient organisations (the Finnish Rheumatism Association and the IBD and Other Intestinal Diseases Association) during a 6 month period in the summer and autumn of 2022. In the pharmacies, customers purchasing originators or biosimilars of adalimumab, etanercept, pegfilgrastim or filgrastim were invited to participate in the survey. The patient organisations invited their members via social media platforms. The invitation addressed to patients included information about the data collection, privacy and purpose of the study (see also the section Ethics of the study). Patients were instructed to participate in the survey only once.

The survey was completely customised for the purposes of this study. The content and intelligibility of the questionnaire were assessed by a few biological medicine users and pharmacists before launching the survey (see also the section Patient and public involvement). The final electronic questionnaire, available in Finnish, Swedish and English, included 25 semistructured questions with several subquestions (see online supplemental material 1). Part of the results have been published previously by Pölkki and Prami. In this article, in order to cover the study aims, the analyses address the following topics: (1) demographic characteristics, (2) biological therapy and (3) experiences and opinions about the patient guidance received and preferences regarding optimal guidance.

Statistics

No specific sample size calculation was performed as general to the size of the size of

the aim was to invite all patients fulfilling the inclusion & criteria during the 6 month data collection period. Prior to conducting analyses, the data were checked for duplicates.

Analyses were conducted with the statistical software R Studio, V. 4.2.2 (for Windows). Categorical variables were reported as percentages of given responses. Continuous variables were reported as medians with lower and upper quartiles (Q1, Q3), means and ranges (minimum and maximum values). Due to the voluntary nature of the data

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collection and the fact that respondents could skip questions and stop answering, the number of responses varied between questions; the results are, therefore, presented as question-specific distributions. In those analyses that compared distributions among biosimilar users versus users of originator products, the brand name of the medicine currently in use, as reported by the respondent, was used as a background variable.

Ethics of the study

Participation as well as data collection and storage methods followed the European Union (EU) General Data Protection Regulation (GDPR) and local guidelines. ¹⁵ Before data collection, Oriola provided a data protection impact assessment based on the EU GDPR, including a risk assessment concerning the study database.

The survey was anonymous, and participation was voluntary. Participants were able to skip questions and withdraw their answers at any time, and they were informed of this possibility. Data collection was based on the informed consent of each respondent; thus, the legal grounds for data collection and use included both informed consent and scientific research. A privacy statement was available for the participants during the study in Finnish, Swedish and English. To protect respondents' privacy, no exact results were reported for options selected by fewer than five respondents.

According to local legislation, an external ethical review was not needed for a voluntary anonymous survey of adults (see also the section Ethics approval).

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research. To evaluate the comprehensiveness of the questions and response options, and the comprehensibility of the survey, it was assessed by a few biological medicine users and pharmacists. Also, the time required to participate in the research was assessed during this phase.

In addition to community pharmacies, the patient survey was advertised by two patient organisations. After the scientific publication phase of the study, the authors will inform the participants involved in the recruitment of respondents, and they can further share the vernacular information with their customers.

RESULTS

Patient characteristics and biological therapy

A total of 199 patients using a biological product responded to the survey. For 60% of the respondents, the current biological medicine was their first. Half of the respondents (50%) had used a biological product for 3 years or more. All respondents injected their medicine themselves. The median age of the respondents was 50 years (mean=49.8; range=20–83; Q1=40; Q3=61), and 69% of respondents were female (table 1).

Table 1 Characteristics of the respondents			
Variable	Definition	Proportion (N)	
Gender (n=197)	Female	69% (136)	
	Male	31% (61)	
Type of biological medicine* (n=188)	Biosimilar	66% (124)	
	Originator	34% (64)	
Medicine* (n=188)	Adalimumab	64% (120)	
	Etanercept	26% (49)	
	Filgrastim/pegfilgrastim	10% (19)	
Brand name* (n=188)	Humira	21% (40)	
	Hyrimoz	13% (24)	
	Hulio	12% (23)	
	Amgevita	11% (21)	
	Erelzi	11% (21)	
	Enbrel	10% (19)	
	Benepali	4% (8)	
	Zarzio	3% (6)	
	Fulphila	NA (<5)†	
	Idacio	NA (<5)†	
	Nepexto	NA (<5)†	
	Neulasta	NA (<5)†	
	Pelgraz	NA (<5)†	
	Ratiograstim	NA (<5)†	
	Yuflyma	NA (<5)†	
	Ziextenzo	NA (<5)†	
Therapeutic indication‡ (n=179)	Rheumatoid arthritis	32% (57)	
	Crohn's disease	22% (40)	
	Ankylosing spondylitis	15% (27)	
	Ulcerative colitis	13% (23)	
	Psoriatic arthritis	9% (16)	
	Other	9% (16)	

This table excludes results with N=0.

In 65% of the cases, the prescribing doctor had made the decision about the medication alone, and in 24% of the cases, the decision was based on a discussion of several options where the respondent had made the final choice. The most common drugs were adalimumab and etanercept (64% and 26%, respectively; table 1). Humira (the adalimumab originator) was the most common single brand in use (21%). Of the 179 adalimumab and etanercept users, 32% had been prescribed for the treatment

^{*}Based on self-reported product name.

[†]To protect respondents' privacy, exact results are not reported if N<5.

[‡]The question was presented to adalimumab and etanercept users only.

NA, not applicable.

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Table 2 Concurrent chronic conditions (other than the indication of the biological medicine) and other concomitantly used medication

Variable	Definition	Proportion (N)
Medical condition (n=190)	None	30% (59)
	Cardiovascular diseases	17% (34)
	Respiratory condition	17% (34)
	Condition involving the musculoskeletal system	15% (29)
	Skin condition	11% (22)
	Neurological condition	11% (21)
	Condition involving the gastrointestinal tract	9% (17)
	Cancer	8% (16)
	Other	8% (16)
	Mental health problem	7% (14)
	Diabetes	4% (8)
	I do not want to answer	3% (6)
	Cerebrovascular disorder	NA (<5)*
Medication (n=194)	Painkillers	38% (75)
	Cardiovascular medication	29% (57)
	No other medication	18% (35)
	Respiratory medication	16% (31)
	Medicines affecting the gastrointestinal tract	15% (29)
	Other medication	11% (21)
	Medicines involving the central nervous system	7% (13)
	Medicines affecting blood coagulation	7% (13)
	Cancer medication	6% (11)
	I do not want to answer	6% (11)
	Diabetes medication	4% (8)

NA, not applicable.

for rheumatoid arthritis, 22% for Crohn's disease, 15% for ankylosing spondylitis and 13% for ulcerative colitis (table 1).

About one-third (30%) of all respondents had no chronic medical conditions except for the one that their biological medication was indicated for, 18% had a cardio-vascular condition, 17% had a respiratory condition and 15% had a condition involving the musculoskeletal system (table 2). When asked about other medicines used concomitantly with the biological medication, 38% of the respondents reported they currently used painkillers,

cardiovascular medication was used by 29%, respiratory medication by 16% and medicines affecting the gastro-intestinal tract by 15%, while 18% of the respondents reported no other use of medication (table 2).

According to the respondents, the most important factors affecting treatment persistence—in addition to treatment efficacy—were the following: (1) low adverse effects (58%), (2) access to treatment support (54%), and (3) an easy-to-use administration device (48%) (figure 1A). In the group of biosimilar users only, having access to help in matters related to the treatment, if needed, was the most important factor along with treatment efficacy (figure 1B).

Needs and wishes regarding patient guidance

Almost all respondents felt that they had received sufficient written or verbal instructions for carrying out their self-administered therapy (95%) and were very or quite satisfied with the level of instruction (97%). In total, 73% had received a practical face-to-face introduction on how to inject the medicine or use the administration device. Instruction on methods of administration was most commonly given by a nurse or a public health nurse (86%), less often by a doctor (36%) or a pharmacist (21%). Some respondents (29%) reported self-studying the topic, using, for example, the package leaflet as a source of information. The most important instruction was received from the nurse or public health nurse (79%) or the doctor (13%).

Originator users were more often instructed by a doctor than biosimilar users (46% vs 32% of originator and biosimilar users, respectively, had received instructions from a doctor and 79% vs 90% from a nurse). Originator users had also more often received the most important instructions from a doctor (22% vs 8% of originator and biosimilar users, respectively, had received the most important instructions from a doctor and 69% vs 86% from a nurse).

When asking about optimal instruction at treatment initiation, the most important guidance, according to 89% of the respondents, was a face-to-face introduction and practical instruction on how to inject the medicine and use the administration device (figure 2). This was followed by information on adverse effects (49%), instruction on choosing the injection site (48%), and advice on storing and transporting the medicine (40%). Originator users wished to receive instructions on choosing the injection site more often than biosimilar users (54% vs 46%, respectively), and biosimilar users considered information about adverse effects somewhat more important than originator users (52% vs 44%, respectively).

Biosimilar users needed information about adverse effects more often than originator users (49% vs 35%, respectively) (figure 3), while originator users wished for more information about drug disposal more often than biosimilar users. When the respondents were asked if they would have wanted more instruction on their self-injected medication, 79% answered 'no'. However, the

^{*}To protect respondents' privacy, exact results are not reported if N<5.

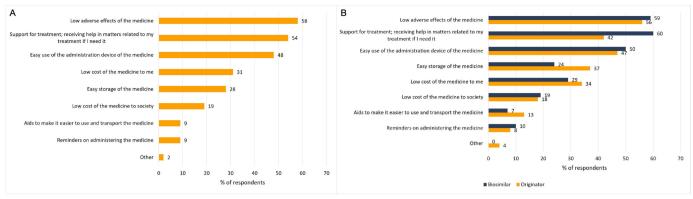


Figure 1 (A) and (B) Along with treatment efficacy, the most important factors that would have facilitated the introduction and maintenance of a new biological treatment ((A) n=199; (B) n=186; the type of medicine was a background variable based on self-reported product names).

participants further responded that additional information or help would have been needed at the time of treatment initiation regarding the following topics: (1) information about adverse effects (37%), (2) information about biosimilars (20%), and (3) information about biological medicines in general (19%).

DISCUSSION

In this Finnish cross-sectional patient survey, information about adverse effects as a key aspect of successful patient guidance emerged as an important topic among patients using biological medicines, of whom two-thirds were biosimilar users and one-third were originator users. In general, 80% of respondents were very satisfied regarding the level of instruction they had received, and about the same number felt they would not have needed more information about the use of their self-injected medicine. However, when respondents were asked more specifically about their needs for more information with a structured topic list, the most common answer was information about adverse effects. This result was particularly prominent in the biosimilar users' group. Furthermore, this study showed that face-to-face guidance was considered the optimal form of instruction and that patients preferred this type of guidance, especially with regard to practising injecting their medicine or using their administration device.

The Finnish Parliament's requirement to strengthen guidance and advice, especially concerning the use of administrative devices, ⁶ is in line with patients' wishes. On the other hand, self-study materials such as videos, web page tutorials or other digital tools were not regarded as optimal methods by the patients. Every package of medication includes a package leaflet, but not many

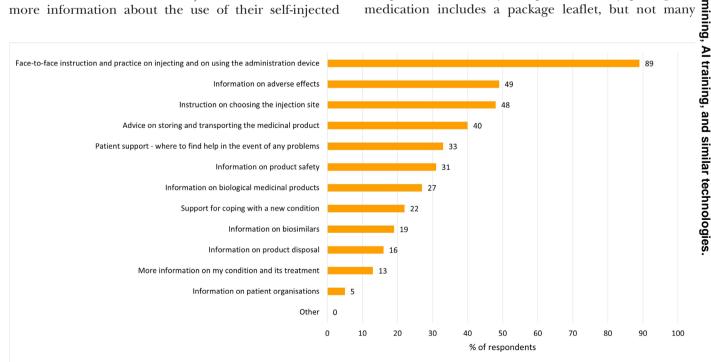


Figure 2 The type of guidance/information that was rated as the most important/optimal when starting the use of a biological product (n=197).

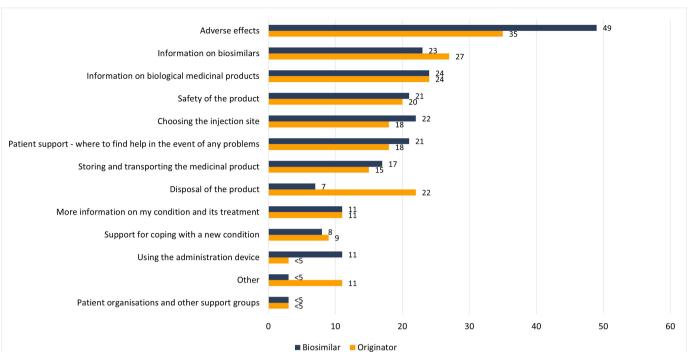


Figure 3 Topics on which more information or help would have been needed when initiating biological treatment (n=155) (the type of medicine was a background variable based on self-reported product names).

respondents have read this. However, even though selfstudy materials were not a preferred source of information, they might still provide valuable support later when users take their medication independently. According to the Finnish Medicines Decree, 16 healthcare professionals must ensure that the user of the medicine receives the necessary information to carry out the treatment independently. Differences between the administration devices of different manufacturers and the practical aspects of their use may raise questions at the time of the interchange of biological medicines in pharmacies. Adalimumab users have named the injection experience as an important component of patient satisfaction in comfortable substitution to a biosimilar. 11 The gradually introduced interchange creates new tasks and communication needs, which particularly affect community pharmacists counselling the patients. 14 Even if patients prefer faceto-face guidance, virtual consultation might nevertheless be helpful for sharing information between different healthcare professionals.¹⁷ In every case, it is important that information is easily available from a reliable source. Clear communication optimises perception with a new treatment. 10

According to the patients in this study, the most important instruction on the treatment was provided by a nurse or a public health nurse. However, it appeared that originator users were more often instructed by and had also more often received the most important instructions from a doctor than biosimilar users. In our previous study, we found that the earlier the initiation of respondents' biological therapy had occurred, the more likely it was that an originator product had been used.⁷

These findings may further indicate that the initiation of new (originator) medication was previously more often carried out by doctors and that more recently changes in healthcare resourcing have resulted in the introduction responsibility (presumably more often than that of biosimilar medication) being delegated to nurses. The same phenomenon may explain two other observations made in this study: the originator users lacked information about medicine disposal more often than biosimilar users (figure 3), and they more often reported that, in addition to treatment efficacy, easy storage was one of the most important factors that facilitated new treatment. Perhaps disposal and storage topics have been more thoroughly considered for biosimilars that have been introduced on the market more recently.

EMA does not assess or make recommendations on interchangeability, and interchangeability is driven by national policies in the EU countries. In the USA, subject to local state policies, an interchangeable biological product evaluated by the FDA may be substituted by a pharmacist.¹⁸ Even though some experience of substitution of biological medicines had been gained in some countries, there had been no reported studies on the type of informational content that community pharmacists should provide to patients and their caregivers about biological medicines¹⁴ before the present cross-sectional survey was conducted in 2022. At the time of the data collection, substitution between different biological products was only possible with a doctor's prescription in Finland. The implementation of Finnish legislation on the interchange of biological medicines in pharmacies gradually started in early 2024.6



Overall, considerable interest in biosimilar development within the pharmaceutical industry and the simultaneous changes in biosimilar regulations have led to a growing biosimilar market.¹⁹ To increase the benefits of biosimilars' more reasonable prices, interchange in pharmacies has been presumed to be an effective way to reduce fast-growing healthcare costs.²⁰ Previously, the price was thought to play an important role in increasing patients' access to biological treatment in connection with the introduction of biosimilars.⁸ However, in this Finnish setting, a low cost to patients was considered important by just 31% and a low cost to society by only 19% of the patient respondents (figure 1A). Originator users highlighted the importance of a low price to the patient more often than biosimilar users (figure 1B). This may reflect the fact that their treatment costs more, even if the cost is usually covered by society.

While interchange in pharmacies can provide many advantages, there are also certain concerns that require careful consideration. One of these is that patients wish to use the biological product that their doctor has prescribed. Substitution may risk treatment success if patients do not trust the medicine proposed to them in the pharmacy. Such patients may have negative expectations of unfamiliar products or may fear adverse effects. Adoption of nocebo-reducing strategies to avoid these negative expectations is recommended.²¹ Healthcare professionals confident in their knowledge of biosimilars may help reduce the risk of nocebo effects and improve patients' adherence to biosimilars. At treatment initiation, it is important to provide sufficient information about the underlying rationale and safe treatment implementation, based on up-to-date information and in accordance with the latest research. According to recent research on the biosimilar landscape, progress has been made so far, but an increased global market penetration of biosimilars is important to allow biosimilars to impact patient outcomes.1

Loss of efficacy and adverse effects of biosimilars are common concerns for patients, 11 which were further confirmed in the present study. Information about adverse effects is essential, and it may further affect treatment compliance. Even though such information is desired, one should avoid transferring unnecessary concerns to patients, as these could generate negative attitudes towards their medication and potentially affect compliance.²² On the other hand, the lack of necessary information can cause uncertainty in itself. Above all, it is important to ensure that the evidence-based information patients need is readily available and, most importantly, provided by trusted sources by healthcare professionals.

To successfully implement the interchange in pharmacies, it is essential that pharmacists have access to the necessary information for both themselves and their patients. According to a semistructured interview study, the interchange is associated with risks that should be managed before introducing the procedure.¹⁴ This study focused on medication safety and issues that must

be considered to create an appropriate model for the interchange of biological products. After a total of 32 interviews with 62 stakeholders (mainly community pharmacists), six major risk themes were identified, of which two were 'the patient does not receive substitution-related advice from the pharmacy' and 'the patient is distracted by the support material he/she receives'.

In our present cross-sectional patient survey, 21% of respondents mentioned pharmacies as a source of information about biological medication, but only a few individual respondents mentioned pharmacies as a point of contact for the most important instructions. This may be due to the chronological order of the treatment chain, in which the pharmacy is usually visited last. Nevertheless, patients are likely to meet pharmacists more frequently for the macists will, therefore, need tools for future encountered by attitudes or uncertainty. The patients' need for information was similar regardless of whether they had started using biological medicines in the previous 12 months or of had been using them for several years. This further highlights the fact that, in each patient contact, pharmacists and other healthcare professionals should keep in mind that even an experienced biological medicine user may enced or want more information about their medication. In addition to emphasising the importance of practical training and detailed information regarding administration, the results of this study indicate that patients need more information about the adverse effects but also about displayment of the study.

Strengths and limitations of the study

Although this patient survey was conducted during the COVID-19 pandemic in 2022, the targeted number of respondents was achieved, and it represents 1% of adult adalimumab, etanercept, filgrastim and/or pegfil adult adalimumab, etanercept, fi

Patient recruitment was carried out via two distinct sources (in pharmacies and via patient organisations) to reduce the effect of selection bias. Potential recall bias should also be considered when interpreting the results. Results regarding the early stages of a long-term treatment may be biased, and the findings may reflect the respondents' current wishes and needs rather than those they considered relevant at the time of treatment initiation. Nevertheless, the cross-sectional results show that patients are currently reporting that they have not received some of the required information, although it remains unclear whether the information was not provided at all or whether it was provided but not remembered. This survey highlights the need for guidance preferred by the patients themselves, and as this study was executed before biological medicines could be interchanged in pharmacies, the present results can be seen as baseline information for future projects.

CONCLUSION

Patients consider information about adverse effects to be an important part of patient guidance when starting self-administered biological therapy. Regarding the interchange in pharmacies permitted by new legislation in Finland, pharmacists must adopt a stronger role as patient instructors. This requires up-to-date evidence-based information that not only focuses on the details of different products but also contains more general information as patients wish to develop an understanding of their medication. This will further have the potential to enhance treatment compliance and decrease costs to society.

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Contributors MP and TP made significant contribution to the work reported, whether in the conception, study design, execution, acquisition of data, analysis, interpretation or in all of these areas. They took part in drafting, revising or critically reviewing the article; gave their final approval for the version to be published; agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work. TP is the guarantor of the study.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The study was conducted in accordance with national and EU requirements to ensure the well-being and rights of the participants. In addition, the survey was conducted following the guidelines of the Finnish National Board on Research Integrity. Before data collection, Oriola provided an EU GDPR-based data protection impact assessment with a risk assessment concerning the study database. According to local legislation, an external ethical review was not needed

for a voluntary anonymous survey. Data collection was based on the individual consent of each respondent; thus, the legal grounds for data collection and use included both informed consent and scientific research. A privacy statement was available for the participants during the study in Finnish, Swedish and English.

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Data availability statement No data are available. The survey data were collected for this research project only. The data are not shared.

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