
Pharmacists' perceptions about knowledge of biologic medicines and their interchangeability and pharmacist-led substitution – A pilot survey of Finnish community pharmacists

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Abstract

Introduction: Use of biologic medicines is increasing rapidly. Biologic medicines are often considerably more expensive in comparison to traditional synthetic medicines. Yet, the price competition is limited among these medicines. With the introduction of biosimilars and price competition, it is possible to achieve savings – provided that these medicines are made available and adapted into the use. The aim of this study was to explore Finnish pharmacists' perceptions about biologic medicines and the interchangeability and pharmacist-led substitution of these medicines. Additionally, the knowledge of biologic medicines and confidence to dispense them were explored.

Methods: The data was collected with an electronic questionnaire for Finnish community pharmacists in the autumn 2019. The study acted as a pilot study for an international research collaboration project. Results were analysed using frequencies, cross-tabulation, and chi-square test.

Key findings: Altogether, 168 questionnaires were analysed. Sixty-one percent of the respondents knew that a biosimilar is a similar copy of a biologic medicine. A quarter (25%) reported feeling sufficiently informed about biosimilars in general. Seventy-four percent of the pharmacists preferred dispensing biosimilars when they have the lowest price. However, 35% of the respondents felt uncomfortable to substitute originator with a biosimilar if pharmacist-led substitution would be possible. Many respondents deemed that substitution on treatment initiation (42%) or during a patient's treatment course (38%) should be a prescriber decision.

Conclusions: According to this study, most Finnish pharmacists have a reasonable level of knowledge about biologic medicines. However, they do not feel sufficiently informed about biosimilars. Pharmacists are not necessarily ready, given their current state of knowledge, to substitute biologic medicines without consulting a physician, and thus additional training is needed.

Keywords: biologic medicines, biosimilars, pharmacists, perception, knowledge, survey, interchangeability, substitution

Introduction

The use of biologic medicines is increasing, as with their use, we may accomplish better results in patient care for selected patient populations (Hämeen-Anttila *et al.* 2018). The reverse side comes with the costs. New high-priced medicines are challenging public health care systems worldwide, and biologic medicines have a major impact on this (World Health Organization, WHO 2021). Biologic medicines are medicinal products that contain a biological active substance and are either produced by or derived from a biological source (European Commission 2013). The use of biologic medicines is increasing in multiple therapeutic areas and thus have a significant impact on healthcare costs (Blackstone and Fuhr 2013, IQVIA 2021).

A biosimilar is a biologic medicine that is a similar copy to an already approved *originator biologic medicine, or reference medicine*, of which patent has expired (European Commission 2013). Biosimilars and originator medicines have equal safety, quality and efficacy and so they are interchangeable (Kurki *et al.* 2017). As the development of biosimilars is largely based on the clinical research data and use of the originator, they can be launched to the market at a cheaper price, leading to price competition between biologic medicines and consequently to potential savings in healthcare costs (European Commission 2013, IQVIA 2021). The aim of the uptake of biosimilars is to create and maintain price competition between the originators and biosimilars, and thus, to promote the use of the most inexpensive biologic product. Although the common aim, to restrain the increase of medical costs, is internationally recognised, national research is needed, as the definitions and standards vary from country to another (Afzali *et al.* 2021).

The use and uptake of biological medicines in Finland

Biologic medicines strongly contribute to the medical costs in Finland. In 2018, the ten best-selling medicines (measured in wholesale prices) included seven biologic medicines, costing in total more than EUR 199 million of the total of EUR 4.11 billion used for the

ten best-selling medicines (Finnish Medicines Agency and Social Insurance Institution of Finland 2019). Since 2017, physicians have been required to prescribe a biologic medicine alternative that has the lowest price and the prescriptions diverging from this requirement must be medically justified (Decree of the Ministry of Social Affairs and Health on prescribing medicine 1088/2010). Nonetheless, in outpatient care the use of biosimilars has been modest compared to the use of originator biologic medicines (Sarnola *et al.* 2019). For now, in Finland, pharmacist-led substitution, meaning a switch from a biologic medicine to another by a community pharmacist without consulting a physician, does not apply to biologic medicines, as it is not politically mandated or conducted in practice in Finland (Finnish Medicines Agency 2021a–b). However, substituting can be done for parallel import or parallel distribution products.

Pharmacists' role in enhancing the uptake of biosimilars

Pharmacists provide accurate information and ensure the safe and proper use of biologic medicines. International studies report various results on the pharmacists' knowledge of and attitudes towards these medicines (e.g. Adé *et al.* 2017, Beck *et al.* 2017, Chapman *et al.* 2017, O'Callaghan *et al.* 2017, Aladul *et al.* 2018, Pawłowska *et al.* 2019, Barbier *et al.* 2021). It is shown that some pharmacists have, or at least claim to have, a basic knowledge about biosimilars (O'Callaghan *et al.* 2017). On the other hand, it is reported that some pharmacists do not feel sufficiently informed about biologic medicines, and that pharmacists even have some misconceptions about these medicines (Beck *et al.* 2017, Pawłowska *et al.* 2019, Barbier *et al.* 2021). Concerns relate to tolerance, to indication extrapolation, to the differences between the reference product and the biosimilars and to frequent substituting, for example (Beck *et al.* 2017, Aladul *et al.* 2018, Pawłowska *et al.* 2019). However, earlier studies are unable to explain the root cause behind the hesitancy and misconceptions, as various clinical trials have provided evidence-based information on similarity of quality, safety and efficacy of reference and biosimilar medicines. From the per-

spective of pharmacists, cost savings have been considered as an important factor for enhancing the use of biosimilars (Aladul *et al.* 2018, Pawłowska *et al.* 2019).

Perceptions on biologic medicines, their interchangeability and on the pharmacist-led substitution

Studies on different stakeholders' perspectives on biologic medicines, their interchangeability and on the pharmacist-led substitution have also been published, both in Finland (e.g. Sarnola *et al.* 2019, Siirola *et al.* 2019, Tolonen *et al.* 2019) and internationally (e.g. Afzali *et al.* 2021, Arnet *et al.* 2021, Barbier *et al.* 2021, Vogler *et al.* 2021). However, research evidence behind conducted surveys and polls on stakeholder perceptions on the pharmacist-led substitution of biologic medicines has been criticized as scarce and of low to moderate quality, "reflecting low stakeholder knowledge and their cautious attitude towards biosimilars", by a recent systematic review on studies published from 2006 to 2021 (Tolonen *et al.* 2021).

What is known from Finland, Finnish physicians hold a positive view towards the uptake of biosimilars (Sarnola *et al.* 2019). However, they had various views on pharmacist-led substitution (Tolonen *et al.* 2019). In a qualitative study conducted among Finnish community pharmacists, authorities, prescribers and patient organisations', for example, the role of pharmacists, the importance of working competency, and the new responsibilities regarding the patient counselling in the possible automatic substitution were recognised (Tolonen *et al.* 2019). To the best of our knowledge, there are no studies on Finnish pharmacists' perceptions about biologic medicines. Pharmacists have a key role to provide information about these medicines and their proper use. Thus, there is a need for a study on pharmacists' perceptions on biologic medicines. The aim of this study was to explore Finnish community pharmacists' perceptions about biologic medicines, and their knowledge of biologic medicines and their confidence and readiness to dispense these medicines. In addition, this study aimed to explore pharmacists' perceptions about the interchangeability and pharmacist-led substitution of biologic medicines.

Material and methods

Collaboration project

This study is a part of an international research collaboration project started in 2018 and led by the University of Basel in Switzerland. The questionnaire used in this study was compiled together with the members of the international research group representing altogether eight countries: Australia, Belgium, Denmark, Finland, Germany, Switzerland, Thailand, and the United States. This study conducted in Finland acted as the collaboration project's pilot study. Similar questionnaire was distributed in other countries also, with minor differences in the distribution method from country to country. International results have been published separately (Arnet *et al.* 2021).

Study context and data collection

In 2019, there were 815 community pharmacies in Finland (Association of Finnish Pharmacies 2019). There were 4 440 pharmacists, 3 702 dispensers (BSc) and 738 pharmacists with a Master's degree (MSc), working in these pharmacies in Finland (Apteekkien työnantajaliitto 2019). In this study, pharmacists refer to both dispensers and pharmacists with a Master's degree.

This study was conducted in the autumn of 2019. Pharmacists working in community pharmacies were chosen as the target population. An electronic survey was available for the members of The Finnish Pharmacists' Association and The Finnish Pharmacists' Society. Since no registers of pharmacists working in a particular sector are publicly available, reaching pharmacists via these two professional organizations was considered to be the most effective way to collect the data. This was also supported by that fact that many pharmacists in Finland work in community pharmacies, and the rate of organising into professional organisations or trade and labour unions is high in Finland (Association of Finnish Pharmacies 2019, Lyly-Yrjänäinen 2019). Via these two professional organizations, 4 030 pharmacists working in community pharmacies full-time or part-time were invited to participate (Kataja A, The Finnish Pharmacists' Association 2021,

personal communication, Ali-Kovero T, The Finnish Pharmacists' Society 2021, personal communication).

These two professional organisations first informed their members about the upcoming survey. After that, they shared a cover letter, information letter of the study and a link to the questionnaire via their newsletter. The questionnaire was available in both official languages of Finland: Finnish and Swedish. After two weeks of the link sharing, one reminder via the newsletter was sent. Data collection was finished after three weeks (September 23 to October 13, 2019). Respondents did not receive any financial or other compensation for their participation.

The study setting and research process were in accordance with the local and national ethical instructions for research (Finnish National Board on Research Integrity 2021). According to the instructions, this study did not require ethical approval.

Questionnaire and data analysis

The questionnaire contained 17 questions consisting of background questions, questions related to 1) knowledge of and perceptions about biosimilars, 2) interchangeability and pharmacist-led substitution of biologic medicines and 3) information sources on biologic medicines (Appendix 1). The themes were based on earlier literature (Beck *et al.* 2017, Chapman *et al.* 2017, O'Callaghan *et al.* 2017, Pawłowska *et al.* 2019) and the expertise of the international research group. The questions reported in this article relate to the knowledge of and perceptions about biosimilars and interchangeability and substitution of biologic medicines. The questions related to the information sources on biologic medicines and open-ended question at the end of the questionnaire are reported separately.

Knowledge of and perceptions about biosimilars were examined with 5-point Likert scale questions (1 = Strongly agree, 2 = Agree, 3 = Neither agree nor disagree, 4 = Disagree, and 5 = Strongly disagree) and 3-point Likert-scale questions (1 = Agree, 2 = Disagree, and 3 = Uncertain) (Appendix 1). Knowledge of biosimilars was also examined with a structured multiple-choice question that had one correct

answer. Perceptions about the interchangeability and substitution of biologic medicines were examined with structured multiple-choice questions and a 5-point Likert-scale question. The respondents were asked to state their working sector and education in the beginning of the survey. The answers of pharmacy students and pharmacists working in a sector other than community pharmacies were excluded from this study.

Seventeen pharmacists in two local pharmacies piloted the questionnaire electronically in the autumn of 2019. Some minor modifications were made to the questionnaire, such as simplifying the answer options. The responses from this pilot study were not included in the results.

In the analyses, the respondents' number of working years and the experience of dispensing biologic medicines were used as background variables. The working years were categorized into three groups (Table 1). The dispensing experience items were also combined to form three classes: Daily (every day or multiple times a day), Weekly (2–6 times a week) and Rarely (grouping once a week, less than once a week and never). The 5-point Likert scale items concerning perceptions about and knowledge of biosimilars were combined to form three classes: Agree (including original classes: Strongly Agree and Agree), Neither agree nor disagree, and Disagree (including original classes: Disagree and Strongly Disagree).

The data were analyzed with SPSS Statistics for Mac, Version 25.0 (SPSS Inc., Chicago, IL, USA) using frequencies, percentages and cross-tabulation for descriptive analysis. Associations between categorical variables were assessed by Pearson's χ^2 . P-value of <0.05 was considered statistically significant.

Results

Study population

In total, 190 responses were obtained. Twenty-two responses were excluded from the study because the respondents reported being pharmacy students or working in a sector other than community pharmacy. Thus, the final study population consisted of 168 community pharmacists, resulting to the response rate of 4%.

Table 1. Characteristics of the study population, n = 168.

	% (n)
Sex	n = 168
Male	8 (14)
Female	92 (154)
Age, years	n = 164*
22–32	26 (43)
33–42	29 (47)
43–52	27 (45)
53–62	18 (29)
Working experience in a pharmacy as a pharmacist or a dispenser, years	n = 160*
< 5	25 (38)
5–19	42 (65)
> 19	33 (51)
Dispensing experience of biologic medicines	n = 168
Daily	20 (34)
Weekly	53 (89)
Rarely	27 (45)
Education	n = 168
Dispenser (BSc Pharm)	84 (141)
Pharmacist (MSc Pharm)	16 (27)

*In the survey, not all respondents answered all the questions.

The characteristics of the participants are presented in Table 1. Respondents were 22 to 62 years old, and they had worked as pharmacists in a community pharmacy up to 37 years and for 14 years on average.

Twenty-six percent (n = 43) of the respondents reported feeling sufficiently informed about biosimilars in general (Table 2). Thirty-five percent (n = 58) of all respondents reported feeling sufficiently informed to dispense biosimilars to patients. In addition, 19% (n = 31) of the respondents reported being confident in handling patient queries regarding their biologic therapy. A fifth (20%, n = 33) of the respondents reported being comfortable explaining the benefit and risk of biosimilars to patients. Some statistically significant differences were found between respondent groups (See Appendix 2). For example, respondents who had worked in a community pharmacy for less than five years, reported more often being sufficiently informed about biosimilars in general (45% versus 17% and 20%, p = 0.021), being confident in handling patient

queries regarding their biologic therapy (40% versus 9% and 10%, p = 0.000), and being comfortable explaining the benefit and risk of biosimilars to patients than those who had worked longer (27% versus 17% and 18%, p = 0.005).

Of the respondents 87% (n = 139) disagreed with the statement that biosimilars should never be used (Table 3). 74% (n = 122) agreed with the statement that biosimilars should be used when the biosimilar has the lowest price. In addition, 53% (n = 85) disagreed with the statement that biosimilars should be used when the originator medicine is ineffective. Correspondingly, 47% (n=77) of the respondents disagreed with the statement that biosimilars should be used when the originator medicine causes adverse reaction.

Interchangeability and substitution of biologic medicines

Seventy-three percent (n = 122) of the respondents knew that substitution of biologic medicines by a pharmacist is not currently permitted in Finland (Table 4). Of the respondents

Table 2. Pharmacists' knowledge of and perceptions about biologic medicines, n = 168.

	% (n)
Which statement best describes what you understand a biosimilar to be?	n = 166*
A similar copy of a biologic medicine	61 (101)
A generic biologic medicine	34 (57)
I have heard about biosimilars, but I am not sure what they are	4 (7)
A new biologic medicine	1 (1)
I have never heard about biosimilars	0 (0)
I am familiar with the term biosimilar	n = 168
Agree	78 (131)
Neither agree nor disagree	14 (23)
Disagree	8 (14)
I feel sufficiently informed about biosimilars	n = 167*
Agree	26 (43)
Neither agree nor disagree	23 (38)
Disagree	51 (86)
I feel sufficiently informed to dispense biosimilars to patients	n = 167*
Agree	35 (58)
Neither agree nor disagree	24 (40)
Disagree	41 (69)
I am confident in handling patient queries regarding their biologic therapy	n = 168
Agree	19 (31)
Neither agree nor disagree	23 (39)
Disagree	58 (98)
I am comfortable explaining the benefit and risk of biosimilars to patients	n = 166*
Agree	20 (33)
Neither agree nor disagree	23 (39)
Disagree	57 (94)

*In the survey, not all respondents answered all the questions.

31% (n = 51) felt comfortable with substituting a biological medicine with a biosimilar, in a situation where substitution at the pharmacy is permitted, while 35% (n=59) disagreed with the statement about being comfortable with substituting.

Forty-two percent (n = 71) of the respondents shared the opinion that substitution of a biologic medicine by a pharmacist should not be permitted on treatment initiation and it should be a prescriber decision (Table 4). Similarly, 38% (n = 64) of the respondents thought that substitution of a biologic medicine by a pharmacist should not be permitted during a patient's treatment course. However, 17% (n = 28) of the respondents reported that it should be permitted on treatment initiation,

and respectively 28% (n = 46) of the respondents reported that it should be permitted during a patient's treatment course, but only when the prescribed drug is not available.

Discussion

Our pilot study provides a picture of the Finnish pharmacists' current perceptions and knowledge about biologic medicines. To the best of our knowledge, this is the first study considering solely the views of Finnish pharmacists about the subject. According to our findings, most of the respondents were familiar with biosimilars. However, a third struggled with defining biosimilars and mistakenly mixed them with generic medicines. Only a minority of respond-

Table 3. Pharmacists' opinions on the use of biosimilars, % (n), n= 168.

In your opinion, when should biosimilars be used?	Agree	Disagree	Uncertain
They should never be used (n = 160*)	1 (1)	87 (139)	12 (20)
When the biosimilar has the lowest price (n = 165*)	74 (122)	11 (18)	15 (25)
When the originator medicine is ineffective (n = 161*)	21 (34)	53 (85)	26 (42)
When the originator medicine causes adverse reaction (n = 163*)	23 (38)	47 (77)	30 (48)

*In the survey, not all respondents answered all the questions.

Table 4. Pharmacists' perceptions about substitution of biologic medicines, n= 168.

	% (n)
To your current knowledge, is substitution of biologicals by a pharmacist currently permitted in Finland?	n = 167*
Yes	5 (9)
Yes, but only with insulin products	12 (20)
No	73 (122)
I don't know	10 (16)
In your opinion, should substitution of a biological by a pharmacist be permitted on treatment initiation?	n = 167*
Yes, similarly to current generic substitution	28 (46)
Yes, but only when the prescribed drug is not available	17 (28)
No, this should be a prescriber decision	42 (71)
I don't know	13 (22)
In your opinion, should substitution of a biological by a pharmacist be permitted during a patient's treatment course?	n = 167*
Yes, similarly to current generic substitution	21 (35)
Yes, but only when the prescribed drug is not available	28 (46)
No, this should be a prescriber decision	38 (64)
I don't know	13 (22)
I am comfortable with substituting an originator biological medicine with a biosimilar, in a situation where substitution at the pharmacy is permitted	n = 167*
Agree	31 (51)
Neither agree nor disagree	34 (57)
Disagree	35 (59)

*In the survey, not all respondents answered all the questions.

ents felt sufficiently informed about biosimilars. Pharmacists hoped to enhance the uptake of biosimilars and recognize situations where the use of biosimilars is relevant. Nonetheless, they felt uncomfortable with substituting biologic medicines without consulting a physician.

This study shows that most pharmacists are familiar with the term biosimilar. Despite this familiarity, biosimilars were quite often mistakenly understood as generic medicines. Our study is in line with earlier studies (Chapman *et al.* 2017, O'Callaghan *et al.* 2017). Unfamiliarity with biologic medicines and with the terminology may lead to uncertainty in reflecting the topic of biosimilars. This may be because biosimilars are not as commonly used as originator biologic medicines, since physicians rarely prescribe them (Sarnola *et al.* 2019), and thus, pharmacists are not used to handle these medicines and discussing about them on a daily basis. Yet, knowing the terminology is important as it enables appropriate patient counseling and information retrieval, for example. However, not only Finnish pharmacists experience uncertainty. According to a recent review, the knowledge and confidence of healthcare professionals (including other professionals than pharmacists also) vary from country to another and between clinical profiles and studies (Halimi *et al.* 2020). Another systematic review even suggests an overall lack of biosimilar knowledge based on 17 European and three North American studies analysed (Leonard *et al.* 2019), indicating a clear need to create evidence-based continuing educational programs and harmonizing the terminology related to biologic medicines (Halimi *et al.* 2020).

In addition to uncertainty in the terminology, we found that pharmacists felt insufficiently informed about biosimilars, or how to dispense them to patients. Similar results have been observed also in France (Beck *et al.* 2017). The information flow from policy to practice appears to be insufficient. This may be because of the poor usability of the existing information, such that it is not streamlined with the information sources that pharmacists use in their practical work. Consequently, the further exploration of information sources used by Finnish pharmacists is clearly warranted, so that their information retrieval could be

supported and improved. However, after the conduction of this study, measures to improve information sources of healthcare professionals have been and are yet to be conducted. The price comparison of biologic medicines with the same active ingredient can now be done in Terveystietä-portal, for example (Duo-decim 2021). Furthermore, patient data systems will include the information on interchangeable biologic medicines for prescribers in 2022, given that the organization, in which the prescriber works in, includes the changes on national medication list and pharmaceutical database definitions into its patient data system (Finnish Institute for Health and Welfare 2021, Social Insurance Institution of Finland 2021).

According to our findings, the pharmacists' working years appeared to influence their knowledge of biosimilars. Pharmacists who had worked in a community pharmacy for less than five years, felt more sufficiently informed about biosimilars than pharmacists who had worked in a pharmacy for longer. Current Finnish pharmacy education curriculum contains courses on biologic medicines (University of Eastern Finland 2021, University of Helsinki 2021, Åbo Akademi 2021). Therefore, pharmacists who have graduated in recent years probably have more knowledge on biologic medicines. They also seem to have more confidence in handling patient queries regarding biologic medicines and in explaining benefit and risk of biosimilars. However, our study shows that the overall level of knowledge about this issue is quite poor. Both pharmacy students and community pharmacists should be provided additional training about biologic medicines. It should also be studied more closely, what kind of education pharmacists hope to gain on biologic medicines, and whether the insecurity on giving advice is linked to the lack of knowledge on the medicines themselves, or to their complex structure, the device or some other point related to these medicines.

Our study shows that pharmacists hope to enhance the uptake of biosimilars and most pharmacists know when it would be reasonable to use biosimilars. It seems that pharmacists have a fairly good understanding of biosimilars, especially when compared to the result that they themselves felt not having been suf-

ficiently informed about biosimilars. However, we found that there is still some uncertainty on this, and some of the pharmacists think biosimilars should be used, for example, when the originator medicine is ineffective, which is clearly incorrect (Cohen *et al.* 2018). This further highlights the importance of education and additional training following graduation. In addition, professionals' misconceptions on biologic medicines should be studied more closely in the future. Based on this study and multiple earlier studies (e.g. Beck *et al.* 2017, Leonard *et al.* 2019, Sarnola *et al.* 2020), some pharmacists, physicians and other healthcare professionals have critical perceptions and even misconceptions on biologic medicines that may contribute to poorer uptake of more affordable treatment options.

According to our study, even though pharmacists are willing to use biosimilars, they think that substituting biologic medicines should be a prescriber decision and not permitted automatically, as with the generic substitution in pharmacies. This is in line to pharmacists feeling they have been insufficiently informed about biosimilars. Pharmacists' hesitant views on automatic substitution are understandable since even though biologic medicines have been used for a long time, substituting a biologic medicine is still totally uncommon to many. If pharmacist-led substitution takes place in Finland, pharmacists would have more responsibility in connection with substitution and patient counseling (Tolonen *et al.* 2019). Pharmacists may also be concerned for new work tasks that might come along with the initiation of automatic substitution of biologic medicines. For example, it might increase the need to communicate with the prescriber and the caregiver. Similar hesitation is seen with physicians (Sarnola *et al.* 2020). Stakeholders, such as patient organisations, have also voiced concerns over patient counseling if the automatic substituting procedure is implemented (Tolonen *et al.* 2019). Therefore, firstly, it should be confirmed that pharmacists are properly informed and confident when it comes to biologic medicines before the possible implementation of automatic substitution. Secondly, patients should be given uniform information by all healthcare professionals, which requires collaboration between

physicians, nurses and pharmacists, for example. Regardless, the substitution of biologic medicines in pharmacies could be a more efficient way to enhance the uptake of biosimilars in comparison to voluntary prescribing guidelines.

Lastly, when discussing the results of our study, it should be noted that the topic of biologic medicines has been very timely during the recent years, and after our data collection in 2019, the uptake of biosimilars has increased, further research has been published and discussion on the topic has become more widespread, delightedly. Recent report shows that in 2020; although the share of biosimilars among all new treatment initiations and among all prescriptions is less than 50 per cent with many biologic medicines, respectively; the share of biosimilars in treatment initiations was 78% for adalimumab and 62% for etanercept (Saastamoinen 2021). This indicates that the uptake of biosimilars has increased in the out-patient care, especially for those biologic medicines for which biosimilars are now available (e.g. adalimumab and etanercept). Yet, means to achieve savings in medicinal costs are still needed, and further thoughts on the optimization of prescribing and the pharmacist-led substitution of biologic medicines are welcomed.

Strengths and limitations

Our results are in line with studies conducted in other countries and in Finland (e.g. Beck *et al.* 2017, Chapman *et al.* 2017, O'Callaghan *et al.* 2017, Sarnola *et al.* 2019, Tolonen *et al.* 2019). In addition, as the pilot study for an international research project (Arnet *et al.* 2021), our study has provided valuable methodological information for the studies conducted in the other countries and for the international collaboration study. What should be noted is that the international study (Arnet *et al.* 2021) has provided novel information, although the results from different countries are not directly comparable due to the differences between countries, for example regarding the varying uptake of biosimilars across countries, and thus, possible differences in knowledge and attitudes of respondents.

The study has also some limitations. We got rather small number of respondents and a low response rate. Therefore, results should be treated with caution and should not be general-

ized as such. What should also be noted is that the calculation of response rate is based on the number of responses and the number of pharmacists that were reached, and not all Finnish community pharmacists, as we were unable to reach all community pharmacists with our survey. It should also be noted that those that shared a special interest towards the area of this study or had more experience with biologic medicines might have been more eager to respond to the survey. The low response rate may also be resulted by the fact that many respondents may discard their newsletters and did not actually read an invitation to participate.

The low yield of respondents might be related to the subject being uncommon. The topic may have felt inconvenient for pharmacists who might not have handled biologic medicines on a daily basis, and therefore they may have felt uncomfortable answering the survey. In addition, relatively low response rates have been reported in earlier studies (Beck *et al.* 2017, Chapman *et al.* 2017), which may reflect the difficulty of studying one's knowledge of a topic that is not commonly addressed.

Pharmacists' training regarding biologic medicines and the information sources on biologic medicines used by pharmacists should be explored in the future. In addition to current quantitative data, obtaining qualitative data on pharmacists' perceptions on this topic would provide new insights.

Conclusions

According to this study, Finnish community pharmacists have a reasonable level of knowledge about biologic medicines. Pharmacists hope to enhance the uptake of biosimilars. However, they feel they do not have enough information on biosimilars. Furthermore, pharmacists are not very confident either to dispense biologic medicines or to substitute them should substitution in pharmacies become possible. There is a need to provide additional training on biologic medicines in general and specifically regarding biosimilars. Additional training is needed, especially for pharmacists who have been longer in work-

ing life and therefore have not received relevant training during their education. Should the substitution of biologic medicines in pharmacies become permitted, it must be confirmed that pharmacists have the required information and confidence to conduct the substitution.

Tiivistelmä

Farmaseuttien ja proviisorien näkemyksiä biologisista lääkkeistä sekä niiden vaihtokelpoisuudesta ja lääkevaihdosta apteekeissa – Pilottitutkimus suomalaisissa apteekeissa

Senni Kaunisto

Yliproviisori, proviisori
Lääkkeiden hintalautakunta,
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Affiliaatio tutkimuksen teon aikaan:
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Johdanto: Biologisten lääkkeiden käyttö lisääntyy nopeasti, ja niitä käytetään yhä enenevässä määrin useiden yleisten sairauksien hoitoon. Biologiset lääkkeet ovat usein perinteisiä lääkkeitä selvästi kalliimpia, ja ne aiheuttavat merkittäviä kustannuseriä yhteiskunnalle. Niiden hintakilpailu on kuitenkin edelleen hyvin vähäistä. Biosimilaarit on kehitetty vastaamaan viitevalmistetta teholtaan, turvallisuudeltaan ja laadultaan. Biosimilaarien käytön otolla ja niiden aikaansaamalla hintakilpailulla on mahdollista saada aikaan kustannussäästöjä – edellyttäen, että näitä lääkkeitä on saatavilla ja että niitä otetaan käyttöön. Tämän tutkimuksen tavoitteena oli selvittää suomalaisten apteekeissa työskentelevien farmaseuttien ja proviisorien näkemyksiä biologisista lääkkeistä sekä näiden lääkkeiden vaihtokelpoisuudesta ja lääkevaihdosta apteekeissa. Lisäksi tutkittiin farmaseuttien ja proviisorien varmuutta ja valmiuksia toimittaa näitä lääkkeitä.

Aineisto ja menetelmä: Tutkimus oli kansainvälisen tutkimusprojektin pilottitutkimus, ja se toteutettiin sähköisellä kyselyllä apteekien farmaseuttiselle henkilöstölle syksyllä 2019. Analysoinnissa käytettiin frekvenssija-kaumia, ristiintaulukointi ja χ^2 -testiä.

Tulokset: Yhteensä 168 kyselylomaketta analysoitiin. Vastaajista 61 % tiesi, että biosimilaari on samankaltainen kopio verrattuna alkuperäisvalmisteseen. Neljäsosa (25 %) vastaajista koki omaavansa riittävästi tietoa biosimilaareista yleisesti. Vastaajista 74 % halusi biosimilaareja käytettävän, kun ne ovat hinnaltaan edullisimpia. 35 % vastaajista ei kuitenkaan kokenut olevansa valmis vaihtamaan alkuperäisvalmistetta biosimilaariin, jos lääkevaihto apteekeissa olisi sallittua. Useat vastaajista kokivat, että biologisten lääkkeiden lääkevaihdon tulisi olla lääkärin päätös lääkehoidon aloituksessa (42 %) ja lääkehoidon aikana (38 %).

Johtopäätökset: Suurimmalla osalla farmaseuteista ja proviisoreista on kohtuulliset tiedot biologisista lääkkeitä, ja suurin osa heistä tiesi, mitä biosimilaari tarkoittaa. He eivät kuitenkaan koe, että heillä on riittävästi tietoa biosi-

milaareista. Farmaseutit ja proviisorit eivät koe olevansa valmiita vaihtamaan biologisia lääkkeitä automaattisesti apteekissa nykyisillä tiedoillaan. Farmaseutit ja proviisorit tarvitsevat lisäkoulutusta biologisista lääkkeistä yleisesti ja biosimilaareista. Ennen mahdollisen biologisten lääkkeiden lääkevaihdon mahdollistamista apteekissa on varmistuttava, että farmaseuteilla ja proviisoreilla on riittävä osaaminen.

Avainsanat: biologinen lääke, biosimilaarit, näkemykset, tietämys, kyselytutkimus, farmaseutit, proviisorit, vaihtokelpoisuus, lääkevaihto

Conflicts of interest

No conflicts of interest declared.

Funding statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Appendix 1. Questionnaire in English: background information.

Gender:

- Male
- Female

Age: _____ years

For how many years have you been working in a community pharmacy (as a pharmacist or a dispenser)? _____

In which working sector are you currently employed?

- Community pharmacy
- Hospital pharmacy
- Government/regulatory agencies
- University
- Pharmaceutical companies or wholesale company
- I am not in working life
- Other, what? _____

Education:

- Pharmacist with a 3–4 year degree (BSc or equivalent)
- Pharmacist with a 5– year degree (MSc or equivalent)
- Pharmacy student
- Other, what? _____

The first part is about dispensing biologicals. Biologicals refer to both originator biologic products and to biosimilars.

1. On average, how often do you dispense biologicals?

- Every day or multiple times a day
- 2 to 6 times a week
- Once a week
- Less than once a week
- Never

2. On average, how often do you dispense biosimilars?

- Every day or multiple times a day
- 2 to 6 times a week
- Once a week
- Less than once a week
- Never

This next part is about your attitude towards biosimilars.

3. Which statement best describes what you understand a biosimilar to be? Please select one answer

- A new biological
- A generic biological
- A counterfeit copy of a biological
- A similar copy of a biological
- I have heard about biosimilars, but I am not sure what they are
- I have never heard about biosimilars

4. For each of the following statement, please select one option which best describes your opinion.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	I am familiar with the term biosimilar
I feel sufficiently informed about biosimilars						
I feel sufficiently informed to dispense biosimilars to patients						
I am confident in handling patient queries regarding their biologic therapy						
I am comfortable explaining the benefit and risk of biosimilars to patients						
I am comfortable with substituting an originator biological medicine with a biosimilar, in a situation where substitution at the pharmacy is permitted						

The next questions are about substitution and interchangeability of biologicals. Substitution of a medicine occurs when a pharmacist substitutes one drug for another without contacting the prescribing physician.

5. To your current knowledge, is substitution of biologicals by a pharmacist currently permitted in Finland?

- Yes
- Yes, but only insulin products
- No
- I don't know

6. In your opinion, should substitution of a biological by a pharmacist be permitted on treatment initiation?

- Yes, similarly to current generic substitution
- Yes, but only when the prescribed drug is not available
- No, this should be a prescriber decision
- I don't know

7. In your opinion, should substitution of a biological by a pharmacist be permitted during a patient's treatment course?

- Yes, similarly to current generic substitution
- Yes, but only when the prescribed drug is not available
- No, this should be a prescriber decision
- I don't know

8. In your opinion, when should biosimilars be used? For each of the following scenarios, select the option that best describes your opinion.

- Agree
- Disagree
- Uncertain
- They should never be used
- When the biosimilar has the lowest price
- When the originator medicine is ineffective
- When the originator medicine causes an adverse reaction

This final part of the questionnaire is about your information sources on biologicals.

9. In your working career, have you received any training on the topic of biologicals (e.g. continuous educational courses, lectures, discussions, symposiums etc.)?

- Yes
- No
- Don't know

10. Would you be interested in receiving additional training on the topic of biologicals?

- Yes
- No
- Don't know

11. On average, how often do you refer to each of the following information sources about biologicals? For each of the following, select the option that best describes your opinion.

	Every day or multiple times a day	2 to 6 times a week	Once a week	Less than once a week	Never
1. Databases: e.g. Duodecim drug information database, "Tietotippa", "drugs and prices" database					
2. SmPC/package leaflet					
3. Healthcare professionals and colleagues					
4. Professional non-scientific publications					
5. Health institution guidelines (e.g. from a hospital)					
6. Pharmaceutical companies (marketing/ educational materials and educational events)					
7. Patient organisations					
8. Health authorities and regulatory agencies (e.g. educational materials, European Public Assessment Reports EPAR etc.)					
9. Scientific publications					

Would you like to convey further opinions and experiences about biologicals and biosimilars and their substitution? You can also comment this survey in general.

Questionnaire in Finnish: taustatiedot.

Sukupuolesi

- mies
 nainen

Ikäsi (vuosina): _____

Kuinka monta vuotta olet työskennellyt apteekissa (farmaseuttina/proviisorina)? _____

Millä sektorilla työskentelet tällä hetkellä?

- apteekissa
 sairaala-apteekissa
 kunta- ja valtiosektorilla
 yliopistolla
 lääketieteellisyydessä tai lääketukku-kaupassa
 en ole työelämässä
 muualla, missä? _____

Koulutuksesi?

- Farmaseutti
 Proviisori
 Farmaseutti- tai proviisoriopiskelija
 Jokin muu, mikä? _____

Ensimmäisen osion kysymykset liittyvät biologisten lääkkeiden toimittamiseen apteekissa. Biologisilla lääkkeillä tarkoitetaan sekä alkuperäisiä biologisia lääkkeitä että biosimilaareja.

1. Kuinka usein toimitat biologisia lääkkeitä keskimäärin?

- joka päivä tai useita kertoja päivässä
 2–6 kertaa viikossa
 kerran viikossa
 Harvemmin kuin kerran viikossa
 en koskaan

2. Kuinka usein toimitat biosimilaareja keskimäärin?

- joka päivä tai useita kertoja päivässä
 2–6 kertaa viikossa
 kerran viikossa
 Harvemmin kuin kerran viikossa
 en koskaan

Seuraavan osion kysymykset liittyvät näkemyksiisi biosimilaareista.

3. Mikä seuraavista vaihtoehdoista kuvaa mielestäsi parhaiten biosimilaaria?

Valitse vaihtoehdoista yksi.

- uusi biologinen lääke
- geneerinen biologinen lääke
- väärennetty kopio biologisesta lääkkeestä
- samankaltainen kopio biologisesta lääkkeestä
- olen kuullut biosimilaareista, mutta en ole varma, mitä ne ovat
- en ole koskaan kuullut biosimilaareista

4. Valitse jokaiselle listan vaihtoehdoista mielipidettäsi parhaiten kuvaava vaihtoehto.

	Täysin samaa mieltä	Samaa mieltä	Ei samaa eikä eri mieltä	Eri mieltä	Täysin eri mieltä	Tiedän, mitä biosimilaari tarkoittaa
Minulla on riittävästi tietoa biosimilaareista						
Minulla on riittävästi tietoa biosimilaarien toimittamisesta potilaille						
Tunnen oloni varmaksi vastatessani asiakkaiden esittämiin kysymyksiin heidän biologisista lääkkehoidoistaan						
On helppoa selittää asiakkaalle biosimilaarien hyötyjä ja haittoja						
Minulle olisi helppoa vaihtaa alkuperäinen biologinen lääke biosimilaariin, jos lääkevaihto apteekissa sallittaisiin						

Seuraavan osion kysymykset liittyvät biologisten lääkkeiden lääkevaihtoon apteekissa ja niiden vaihtokelpoisuuteen. Lääkevaihdoilla apteekissa tarkoitetaan farmaseutin tai proviisorin tekemää lääkevaihtoa ilman yhteydenottoa lääkkeenmäärääjään.

5. Onko biologisten lääkkeiden lääkevaihto apteekissa Suomessa mielestäsi sallittua?

- Kyllä
- Kyllä, mutta vain insuliinivalmisteiden kohdalla
- Ei
- En osaa sanoa

6. Pitäisikö mielestäsi biologisten lääkkeiden lääkevaihto apteekissa olla sallittua lääkkehoidon aloituksessa?

- Kyllä, samalla tavalla kuin nykyisessä lääkkehoidossa
- Kyllä, mutta vain silloin, kun lääkärin määräämää lääkettä ei ole saatavilla
- Ei, lääkkehoidon pitäisi olla lääkärin päätös
- En osaa sanoa

7. Pitäisikö mielestäsi biologisten lääkkeiden lääkevaihto apteekissa olla sallittua potilaan lääkkehoidon aikana?

- Kyllä, samalla tavalla kuin nykyisessä lääkkehoidossa
- Kyllä, mutta vain silloin, kun lääkärin määräämää lääkettä ei ole saatavilla
- Ei, lääkkehoidon pitäisi olla lääkärin päätös
- En osaa sanoa

8. Missä tilanteissa biosimilaareja pitäisi mielestäsi käyttää? Valitse jokaiselle listan vaihtoehdoista mielipidettäsi parhaiten kuvaava vaihtoehto.

- Samaa mieltä
- Eri mieltä
- En osaa sanoa
- Niitä ei pitäisi käyttää lainkaan
- Kun biosimilaari on hinnaltaan edullisin
- Kun alkuperäinen biologinen lääke on tehoton
- Kun alkuperäisen biologisen lääkkeen käytössä on ilmennyt haittavaikutuksia

Tässä kyselyn viimeisessä osiossa selvitetään biologisiin lääkkeisiin liittyvää tietolähteiden käyttöä.

9. Oletko saanut koulutusta biologisista lääkkeistä työurasi aikana (esimerkiksi osallistuminen täydennyskoulutukseen, luennoille, keskustelutilaisuuksiin, kongresseihin tms.)?

- Kyllä
- En
- En osaa sanoa

10. Olisitko kiinnostunut saamaan lisäkoulutusta biologisista lääkkeistä?

- Kyllä
- En
- En osaa sanoa

11. Kuinka usein käytät keskimäärin seuraavia tietolähteitä hakiessasi tietoa biologisista lääkkeistä? Valitse jokaiselle listan vaihtoehdoista sen käyttöä parhaiten kuvaava vaihtoehto.

	Joka päivä tai useita kertoja päivässä	2–6 kertaa viikossa	Kerran viikossa	Harvemmin kuin kerran viikossa	En koskaan
1. Tietokannat: Duodecim lääketietokanta, Tietotippa, Lääkkeet ja hinnat -tietokanta ym.					
2. Pakkausseloste					
3. Terveydenhuollon ammattilaiset ja kollegat					
4. Ammatilliset lehdet					
5. Hoitoyksikön ohjeistukset (esim. sairaalasta saadut ohjeistukset)					
6. Lääkeyhtiöiden materiaali (esim. markkinointi-materiaali, koulutusmateriaali, koulutustilaisuudet)					
7. Potilasjärjestöt					
8. Viranomaiset (esim. koulutus- ja tiedotusmateriaalit, EPAR-yhteenvedot)					
9. Tieteelliset julkaisut					

Haluaisitko vielä tuoda esiin näkemyksiäsi ja kokemuksiasi biologisista lääkkeistä ja biosimilaareista? Vastaa alla olevaan kenttään.

Appendix 2. Pharmacists' perceptions about biologic medicines and dispensing them % (n), N = 168.

	Working experience in a pharmacy < 5 years	Volume of dispensing biologic medicines 5–19 years	>19 years	Daily	Weekly	Rarely	All respondents
I am familiar with the term biosimilar							
	p = 0.090*	p = 0.104*					
Agree	92,1 (35)	76,9 (50)	66,7 (34)	94,1 (32)	75,3 (67)	71,1 (32)	78,0 (131)
Neither agree nor disagree	5,3 (2)	15,4 (10)	21,6 (11)	2,9 (1)	16,9 (15)	15,6 (7)	13,7 (23)
Disagree	2,6 (1)	7,7 (5)	11,8 (6)	2,9 (1)	7,9 (7)	13,3 (6)	8,3 (14)
I feel sufficiently informed about biosimilars							
	p = 0.021	p = 0.021	p = 0.021	p = 0.038			
Agree	44,7 (17)	17,2 (11)	19,6 (10)	42,4 (14)	27,0 (24)	11,1 (5)	25,7 (43)
Neither agree nor disagree	21,1 (8)	25,0 (16)	21,6 (11)	15,2 (5)	22,5 (20)	28,9 (13)	22,8 (38)
Disagree	34,2 (13)	57,8 (37)	58,8 (30)	42,4 (14)	50,6 (45)	16,2 (27)	51,5 (86)
I feel sufficiently informed to dispense biosimilars to patients							
	p = 0.056	p = 0.056	p = 0.056	p = 0.063			
Agree	47,4 (18)	32,3 (21)	24,0 (12)	54,5 (18)	33,7 (30)	22,2 (10)	34,7 (58)
Neither agree nor disagree	21,1 (8)	18,5 (12)	36,0 (18)	15,2 (5)	24,7 (22)	28,9 (13)	24,0 (40)
Disagree	31,6 (12)	49,2 (32)	40,0 (20)	30,3 (10)	41,6 (37)	48,9 (22)	41,3 (69)
I am confident in handling patient queries regarding their biologic therapy							
	p = 0.000	p = 0.304					
Agree	39,5 (15)	9,2 (6)	9,8 (5)	29,4 (10)	18,0 (16)	11,1 (5)	18,5 (31)
Neither agree nor disagree	28,9 (11)	18,5 (12)	29,4 (15)	23,5 (8)	23,6 (21)	22,2 (10)	23,2 (39)
Disagree	31,6 (12)	72,3 (47)	60,8 (31)	47,1 (16)	58,4 (52)	66,7 (30)	58,3 (98)
I am comfortable explaining the benefit and risk of biosimilars to patients							
	p = 0.005	p = 0.397					
Agree	27,0 (10)	16,9 (11)	17,6 (9)	27,3 (9)	17,0 (15)	20,0 (9)	19,9 (33)
Neither agree nor disagree	43,2 (16)	20,0 (13)	15,7 (8)	30,3 (10)	23,9 (21)	17,8 (8)	23,5 (39)
Disagree	29,7 (11)	63,1 (41)	66,7 (34)	42,4 (14)	59,1 (52)	62,2 (28)	56,6 (94)
I am comfortable with substituting an originator biological medicine with a biosimilar, in a situation where substitution at the pharmacy is permitted							
	p = 0.697	p = 0.001					
Agree	36,8 (14)	29,2 (19)	26,0 (13)	35,3 (12)	40,9 (36)	6,7 (3)	30,5 (51)
Neither agree nor disagree	36,8 (14)	32,3 (21)	36,0 (18)	32,4 (11)	31,8 (28)	40,0 (18)	34,1 (57)
Disagree	26,3 (10)	38,5 (25)	38,0 (19)	32,4 (11)	27,3 (24)	53,3 (24)	35,3 (59)