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ORIGINAL RESEARCH ARTICLE

# Biosimilar Knowledge Among Oncology/Hematology Team Members in Colorado, USA: An Educational Initiative and Follow-Up Survey

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## Abstract

**Background** No data exist regarding oncology/hematology team members' knowledge of and views on biosimilars in Colorado, USA. Published research has suggested that health professionals may have a poor understanding of many issues related to biosimilars.

**Objectives** Our goal was to increase oncology/hematology team members' knowledge of biosimilars and then use an anonymous online survey to assess the knowledge gained. We also aimed to examine oncology/hematology team members' overall interest in the subject and their motivation to learn more about biosimilars in the future.

**Methods** In phase I of the project, we developed printed materials covering many topics related to biosimilars, such as definition, regulation, and interchangeability, and the potential of biosimilars in optimal combination therapy for cancer. We distributed our brochures to each participating oncology/hematology office in Colorado. The oncology/hematology team members were then asked to complete the survey.

**Results** A total of 62 team members responded to our survey. Nearly three-quarters of participants were oncology nurses or oncology nurse practitioners. More than 90% of survey respondents identified correct answers about the definition, regulations, interchangeability, safety, cost issues, and use of biosimilars in oncology and in older patients with cancer. Overall, and compared with those who had low levels of interest and motivation, significantly more ($p < 0.05$) study participants were interested in the subject of biosimilars [57 (92%) vs. 5 (8%)], motivated to learn more about them [59 (95%) vs. 3 (5%)], and interested in sharing information about biosimilars with colleagues and patients [51 (82%) vs. 11 (18%)].

**Conclusion** Our results demonstrate that oncology/hematology team members participating in our study became familiar with many important issues related to biosimilars. Many survey respondents were highly motivated to participate in future training focused on biosimilars, which should pave the way for new educational projects in the area.

## Key Points

Our educational initiative helped oncology/hematology team members learn many important concepts about biosimilars.

Most oncology/hematology team members participating in our survey were interested in the subject of biosimilars and expressed a desire to learn more.

Most survey respondents believed they could use information gained from our training to improve patients' understanding of cancer treatment options.

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## 1 Introduction

According to the US FDA, a biosimilar is "highly similar to, and has no clinically meaningful differences in safety, purity, and potency (safety and effectiveness) from, an existing FDA-approved reference product" [1].

As patents for biologics are starting to expire, biosimilars will offer benefits such as better access to healthcare and more affordable treatment options for patients with cancer and autoimmune diseases [2–4]. Biosimilar regulations are still being issued, and the biosimilar marketplace continues to evolve; therefore, education will remain important for not only oncologists and hematologists but also the entire oncology/hematology team (e.g., oncology nurse, oncology nurse practitioner, physician assistant, etc.). As such, these team members need a thorough understanding of the many issues related to biosimilars before offering them to patients. Building an educational campaign to disseminate information focused on biosimilars and engage the entire oncology/hematology team is necessary.

Previous findings indicate that oncology/hematology teams may have a poor understanding of many issues related to biosimilars [5]. A recent survey of US physicians identified several major knowledge gaps regarding biosimilars (e.g., definition, interchangeability, etc.) [5], and one can expect that such knowledge gaps would also be substantial among other health providers, such as nurse practitioners or physician assistants working in oncology/hematology office settings.

We aimed to increase oncology/hematology team members' knowledge of biosimilars and various aspects related to biosimilars, such the approval process, safety, interchangeability, and the potential of biosimilars to enable optimal combination therapy for cancer. In addition, we were interested to learn more about oncology/hematology team members' overall interest in the subject and their motivation to learn more from similar educational initiatives in the future. Finally, we asked some open-ended questions about biosimilars in general and the best format for future training focused on this subject.

## 2 Methods

### 2.1 Study Design

This curriculum-based educational initiative with follow-up assessment had three phases because sequential interventions have been shown to have a greater impact on knowledge and behavior [6]. In phase I, our printed materials ($8.5 \times 11''$ vertical booklet, four pages cover and four inside) were developed. These were designed based on a thorough literature review and tested on volunteers working in various health fields to ensure readability and comprehension. They were then distributed to each participating oncology/hematology office. In phase II, oncology/hematology team members were asked to complete an anonymous online survey to test their knowledge and attitudes towards the subject and explore recommendations and formats for future biosimilars programs. In phase III, we developed a data analysis report.

### 2.2 Inclusion of Oncology/Hematology Team Members

We targeted 82 oncology/hematology teams located within 100 miles of the greater Denver area in Colorado, USA, including offices in Denver, Boulder, Aurora, Lakewood, Colorado Springs, Fort Collins, Parker, Littleton, Greenwood Village, Englewood, Longmont, Wheat Ridge, and Thornton. These offices were identified through the Colorado Department of Health Care, Policy and Financing (https://www.colorado.gov/hcpf). All of the included oncology/hematology teams were identified as physician offices. We obtained exempt determination from the Western Institutional Review Board (WIRB) before implementation of the project.

### 2.3 Survey Design and Data Collection

The survey was conducted using an online survey tool popular among researchers (Surveymonkey®, Palo Alto, CA, USA) [7–9]. The survey contained 22 questions divided into four sections. Our survey was prepared based on a thorough literature review and tested on volunteers working in various health fields [©CMDAT (Complex Mechanisms of Disease, Aging and Trauma) Research Foundation, see the Electronic Supplementary Material]. Survey questions were constructed to assess knowledge of biosimilars overall and of aspects such as safety, the potential of biosimilars to enable optimal combination therapy for cancer, the interest in and motivation to complete future biosimilar-related training, etc. We used a 10-point scale to measure motivation and interest, where 1 indicated no motivation or interest and 10 indicated the strongest motivation or interest. To encourage participation, respondents were given small ($US5) gift certificates, and this incentive was mentioned in the letter accompanying our printed materials.

Informed consent was obtained from all survey respondents before the beginning of the survey. The online survey was completely anonymous. The oncology/hematology team members who participated in the survey were informed that their input would be used in the development of a research

report that may become an educational document for clinical practice. The survey was estimated to take approximately 10–15 min to complete.

### 2.4 Statistical Analyses

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS®) software (version 16, SPSS®, Inc., Chicago, IL, USA). To improve the meaningfulness of participants' responses and because the sample size was relatively small, we combined some of the answers (e.g., "strongly agree" and "agree"). A non-parametric Chi-squared test was used to analyze Linkert scale data [10]. $p$ values $< 0.05$ were considered statistically significant.

## 3 Results

### 3.1 Demographics

A total of 62 team members responded to our survey: most were oncology nurses or oncology nurse practitioners (73%), followed by specialties in the "other" category, such as medical assistants (21%) and patient navigators (6%). The majority of respondents had spent < 5 years in practice (45%), about one-third (29%) "between 5 and 10 years", and 26% had practiced for > 10 years. Nearly 40% of respondents were aged between 21 and 30 years, one-third were aged 31–40 years, and 21% were aged 41–50 years. The smallest group (6%) was aged 51–60 years.

### 3.2 Knowledge of Major Topics Related to Biosimilars

Participants were asked about major topics related to biosimilars. As mentioned, in phase I of the project, we provided printed materials that discussed many topics related to biosimilars, and all oncology/hematology team members were strongly encouraged to read them before beginning the survey.

Most study participants indicated a very good knowledge of all topics related to biosimilars, with > 90% responding correctly to topics such as definition (100%), regulation (98%), interchangeability (92%), safety (95%), cost issues (94%), use in oncology (94%), and, finally, use in older patients with cancer (92%). The correct answer regarding automatic substitution was identified by 86% of survey participants.

### 3.3 Agreement Statements Concerning the Potential of Biosimilars to Enable Optimal Combination Therapy for Cancer

In the next section, we tested various levels of agreement (fully agree, somewhat agree, neither agree nor disagree, somewhat disagree, and fully disagree) concerning the potential of biosimilars to enable optimal combination

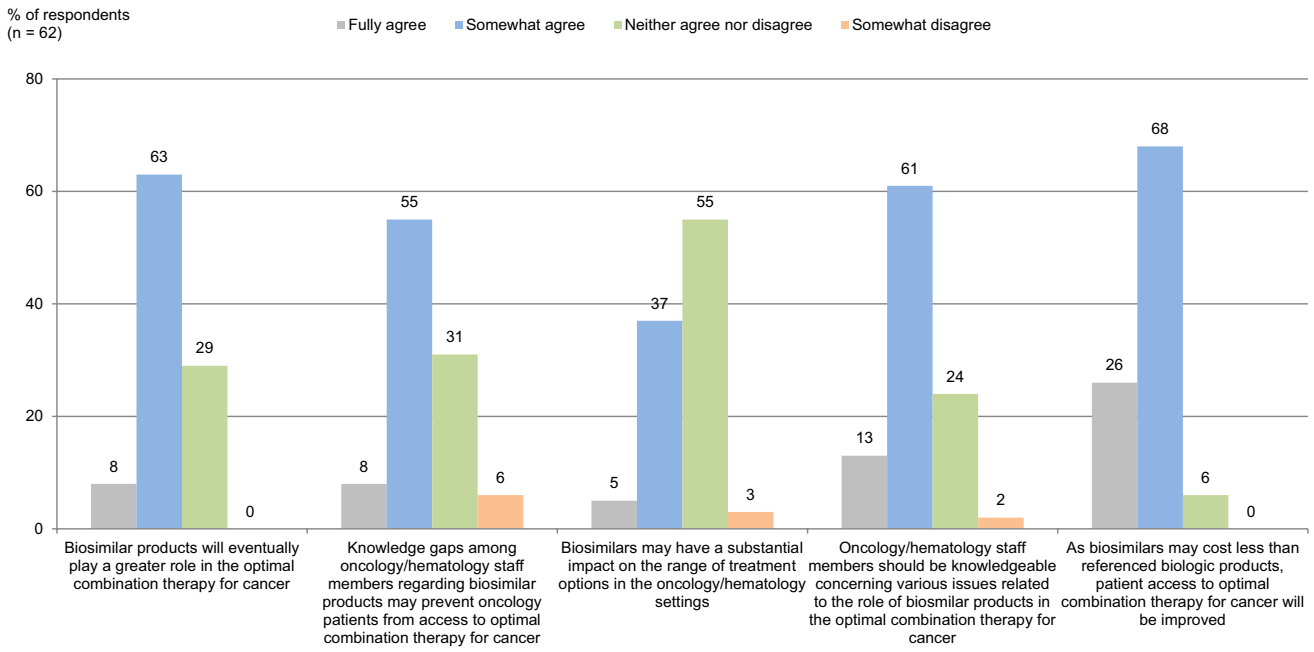


**Fig. 1** Various levels of agreement (fully agree, somewhat agree, neither agree nor disagree, somewhat disagree and fully disagree) with statements concerning the potential of biosimilars to enable optimal combination therapy for cancer

therapy for cancer (Fig. 1). More than 60% of respondents somewhat agreed that (1) biosimilar products will eventually play a greater role in the optimal combination therapy for cancer (63%); (2) oncology/hematology staff members should be knowledgeable concerning various issues related to the role of biosimilar products in the optimal combination therapy for cancer (61%); and (3) as biosimilars may cost less than referenced biologic products, patient access to optimal combination therapy for cancer will be improved (68%). More than half of respondents somewhat agreed that knowledge gaps among oncology/hematology staff members regarding biosimilar products may prevent oncology patient access to optimal combination therapy for cancer (55%). Finally, only about one-third (37%) of respondents somewhat agreed that biosimilars may have a substantial impact on the range of treatment options in oncology/hematology settings.

Compared with respondents who either disagreed or neither agreed nor disagreed, significantly more ($p < 0.05$) respondents either agreed or somewhat agreed that (1) biosimilar products will eventually play a greater role in the optimal combination therapy for cancer [44 (71%) vs. 18 (29%)]; (2) oncology/hematology staff members should be knowledgeable concerning various issues related to the role of biosimilar products in the optimal combination therapy for cancer [46 (74%) vs. 16 (26%)]; (3) as biosimilars may cost less than referenced biologic products, patient access to optimal combination therapy for cancer will be improved [58 (94%) vs. 4 (6%)]; and (4) knowledge gaps among oncology/hematology staff members regarding biosimilar products may prevent oncology patient access to optimal combination therapy for cancer [39 (63%) vs. 23 (37%)] (Fig. 1). The proportion of those who either agreed or somewhat agreed that biosimilars may have a substantial impact on the range of treatment options in the oncology/hematology settings was smaller than that of those who somewhat disagreed or neither agreed nor disagreed with this statement, but the result was not statistically significant (Fig. 1).

### 3.4 Interest and Motivation

In the next section, we tested the level of interest in the subject, the motivation to complete more biosimilar-related training in the future, and interest in sharing information about biosimilars with colleagues and patients. More than one-third (39%) indicated a strong interest (interest rank 8–10) in the subject of biosimilars. More than one-half of respondents (52%) were very motivated (motivation rank 8–10) to complete future training focused on biosimilars. About one-quarter of respondents (26%) were very interested (interest rank 8–10) in sharing the information gained from the training with colleagues and patients. Overall, and compared with those who had low interest and motivation (rank 1–5), significantly more ($p < 0.05$) study participants were interested in the subject of biosimilars [57 (92%) vs. 5 (8%)], motivated to learn more about it [59 (95%) vs. 3 (5%)], and interested in sharing information about biosimilars with colleagues and patients [51 (82%) vs. 11 (18%)] (rank 10–6).

### 3.5 Open Questions Concerning the Subject of Biosimilars in General

We provided open questions/statements concerning the subject of biosimilars in general. Information provided by survey respondents in response to the question "In what ways do you think you may use the information you learned in the program in your practice?" fell into four categories: (1) improve patient education; (2) discuss with colleagues/other team members; (3) provide better information about cancer treatment options (including cost explanation); and (4) less specific response types such as "in many ways" or "in my job" (Fig. 2). Improving patient education and providing better information about cancer treatment options were two leading categories (41 vs. 29%, respectively).

Information provided by survey respondents in response to the question "Are there topics concerning biosimilars which are not well understood and for which a directed education is needed?" fell into six categories: (1) safety and side effects; (2) clinical use/indications; (3) contraindications; (4) unspecified (respondents said "yes" but did not specify the subject of such topic); (5) a single response category including "effectiveness" and "insurance coverage"; and, finally, (6) "no such topics" (Fig. 3). Respondents were most interested to learn more about safety and side effects (42%), followed by clinical use and indications (16%).

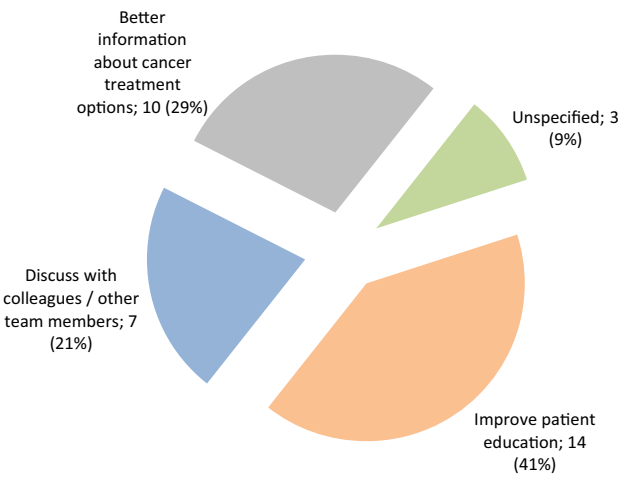


**Fig. 2** Responses to the question "In what ways do you think you may use the information you learned in the program in your practice?"

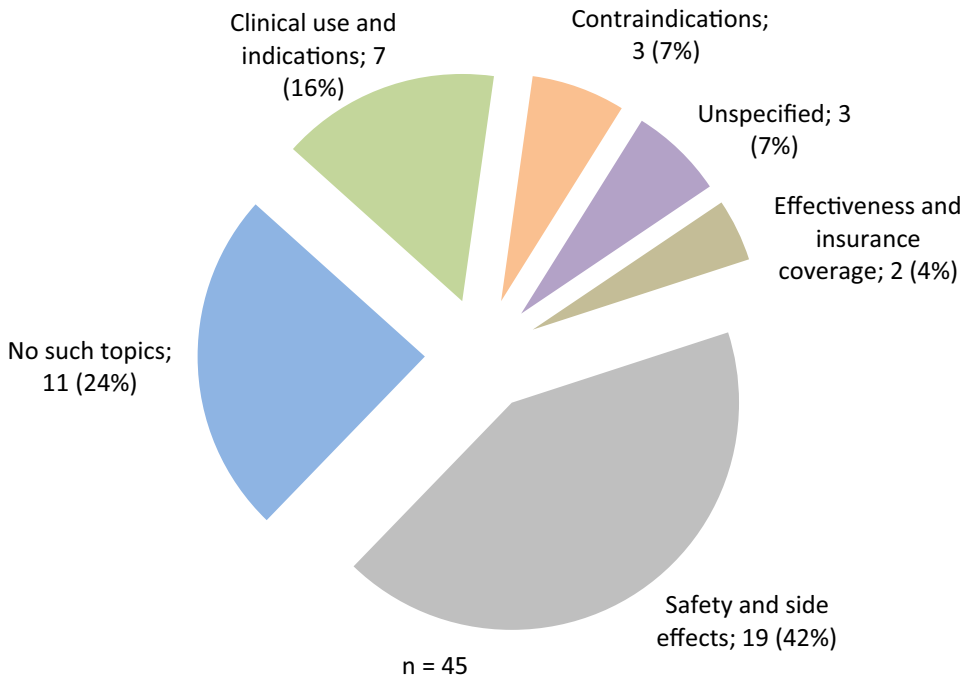


**Fig. 3** Responses to the question "Are there topics concerning biosimilars which are not well understood and for which directed education is needed?"

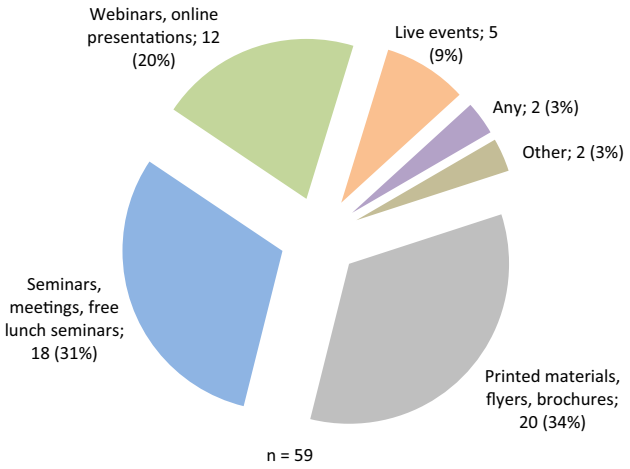


**Fig. 4** Responses ($n=59$) to the question "In your opinion, what is the best way to learn more about biosimilars (e.g. other enduring materials such as flyers, seminars, focused groups, webinars, etc.)"

Information provided by survey respondents in response to the question "In your opinion, what is the best way to learn more about biosimilars (e.g., other printed materials such as flyers, seminars, focused groups, webinars, etc.)" were divided into six categories: (1) seminar, meeting, and free lunch seminar; (2) webinar, online presentation; (3) printed materials, flyers, brochures; (4) live events, any live event (we used this as a separate category because live events can either be seminars/group discussions or online webinars); (5) "any" or "anything involving discussion" (we used this as a separate category because live events can be seminars, webinars, or printed (i.e., brochure); and (6) other unique responses, including professional sites, scientific journals, professional and society meetings and group discussion (Fig. 4). Although printed materials were the most popular way to learn more about biosimilars (34%), nearly 60% of all survey respondents were interested in live events (ranging from seminars and webinars to "any live event," as defined by some participants).

## 4 Discussion

Biosimilars play an increasingly important role in cancer treatment worldwide and will likely also play a role in the USA [11–15]. One oncologic support biosimilar is currently marketed in the USA (filgrastim-sndz), and several therapeutic oncology biosimilars have been approved in the USA but are not yet launched because of ongoing litigation. Many other oncology biosimilars are in development. At the same time, no data exist on oncology/hematology team members' knowledge of and views on biosimilars, and we are unaware of any previous educational projects focused on this subject in Colorado. An assessment of the educational needs of the oncology/hematology team is necessary to identify where and how to direct future educational efforts and optimize utilization of biosimilars aimed to treat cancer to ensure patient access to these medicines.

The goal of the entire oncology/hematology team is to effectively care for patients diagnosed with cancer. As such, these teams generally focus on the care of the patient with cancer throughout the duration of the disease

by administering various interventions such as patient education, general support, chemotherapy, etc. Oncology/hematology teams often become the ultimate source of health information, including the cost of cancer care. Therefore, the entire team (e.g., oncology nurse, oncology nurse practitioner, physician assistant, etc.) should be knowledgeable of important parts of cancer treatment such as biologics and biosimilars.

### 4.1 Knowledge of Major Topics Related to Biosimilars

Most study participants appeared to be knowledgeable regarding many issues concerning biosimilars after receiving our printed materials. Published studies on hematology/oncology team members and their knowledge of biosimilars are lacking, impairing our ability to compare our results. Our results correlate with those from a recent study in Belgian rheumatologists and patients [16]. Although that study did not provide printed materials to its participants, > 90% of rheumatologists in Belgium were aware of the definition of biosimilar products. In contrast, two previous studies indicated that some health professionals were not knowledgeable regarding major issues concerning biosimilars. For example, a study of various US specialty physicians conducted by the Biosimilars Forum [5] found that only about 70% of oncologists could correctly identify a biological drug and select the right answer regarding the FDA approval process. Furthermore, a web-based survey of healthcare providers in the UK found that only 72% of respondents (25% of whom were nurses) could find the correct answer concerning the definition of a biosimilar product [17].

Although the absolute majority (86%) of study respondents identified the correct answer regarding automatic substitution, this seemed to be the most challenging question in this section. As mentioned in our printed materials, Colorado passed biosimilar substitution bills in 2015. One of the bills states that the dispensing pharmacist or the pharmacist's designee must communicate "within a reasonable time to the prescribing practitioner the specific biological product dispensed to the patient including the name and manufacturer of the biological product" [18]. In addition, "The bill allows a pharmacist to substitute a biological product if the federal food and drug administration (FDA) has determined that the biological product is interchangeable with the prescribed biological product and if the practitioner has not indicated that the prescription must be dispensed as written" [19]. Nevertheless, about 14% of participants selected "Although automatic substitution is not allowed for biosimilar products in Colorado, however, if it cannot be avoided, such event must be recorded accurately".

### 4.2 Agreement with Statements Concerning the Potential of Biosimilars to Enable Optimal Combination Therapy for Cancer

Although > 60% of respondents somewhat agreed that biosimilar products will eventually play a greater role in the optimal combination therapy for cancer, only about one-third (37%) of respondents somewhat agreed that biosimilars may have a substantial impact on the range of treatment options in oncology/hematology settings. This may be because biosimilars are relatively new to the US market and to the oncology field overall. There is a potential need for future educational training to discuss the role of biosimilars in cancer care overall and in relation to other treatment options (i.e., chemotherapy). On the other hand, nearly 70% of survey respondents believed that biosimilars may improve patient access to optimal combination therapy for cancer. Similarly, most participants in the Biosimilar Forum also believed that biosimilars may provide benefits such as better treatment options and greater access and utilization in the US healthcare system [5].

### 4.3 Interest and Motivation

Many study participants were highly interested in the topic of biosimilars and motivated to learn more about them in future trainings. Unfortunately, we could not identify any comparison data regarding such interest and motivation among other healthcare providers. However, our findings were not surprising, given that 7000 Colorado residents die from cancer each year [20]. As such, oncology/hematology team members are likely to be very motivated to learn more about other cancer treatment options, including the imminent introduction of biosimilars into oncology practices. At the same time, only about one-quarter of survey respondents were willing to share information from the training with other team members and colleagues. In light of these results, we believe follow-up training will likely increase interest in sharing information about biosimilars with others, including patients.

### 4.4 Open Questions Concerning the Subject of Biosimilars in General

Nearly one-half of all respondents believed they could use the information they learned in the program to improve patient education. This is not surprising, as oncology nurses and other members of the oncology/hematology team are aware of the less than optimal outcomes associated with cancer treatments, as well as the financial burden associated with the use of many cancer treatment medications [21, 22]. One in five respondents believed this training may help improve communication with other team members.

Ultimately, the topic of biosimilars may become more widely accepted among oncology/hematology team members as they share professional information regarding cancer treatment options with each other. After all, every oncology/hematology team member needs to understand this complex and growing component of drug development and how it will affect cancer care.

More than 40% of respondents identified safety and side effects of biosimilars as topics that are not well understood. This is not surprising given that biologics may trigger the production of antibodies, and all biosimilars require complex pharmacovigilance strategies [14, 23]. In the Biosimilar Forum study, more than three-quarters of participants identified "safety, efficacy and potency of biosimilars" as the topic they had the most interest in learning about [5]. In addition, approximately one in six respondents in our study wanted to know more about clinical indications for biosimilars. Only one biosimilar has been approved with a hematology-oncology label in the USA, and as more biosimilars enter the US market, clinical indications for biosimilars are likely to be better understood.

Finally, we asked survey participants about the best way to learn more about biosimilars. Although respondents identified printed materials as the most popular learning method, more than one-half of participants also identified either online (i.e., webinars) or in-person classes (i.e., seminars) as learning alternatives. Clearly, each strategy has its own unique benefits and disadvantages; however, when combined (e.g., printed, online, and in-person), they may target 96% of oncology/hematology team members in Colorado. Future educational interventions should be both multidisciplinary and able to use all the benefits of each educational strategy to its full extent.

### 4.5 Limitations and Future Perspectives

Published evidence regarding printed materials and surveys focusing on biosimilars among oncology/hematology team members is limited. In addition, oncology/hematology team members in Colorado have not previously been exposed to educational initiatives focused on biosimilars. Potentially, this project may serve as a model for organizing similar educational efforts among teams working in the field of gastroenterology, immunology, and others, locally and nationally. In addition, this project has the potential to advance the role of oncology/hematology team members in the area of biosimilar education for patients.

Our intent was to produce printed materials using the best language format for the intended target audience. Nevertheless, our printed materials and survey did not discuss complex topics such as immunogenicity or naming of biological innovator products and biosimilars. In addition, to preserve confidentiality, we did not ask for details of the practices represented by survey respondents. As such, since each oncology/hematology office team consists of several members (e.g., nurse, patient navigator, medical assistant, etc.), all of whom we encouraged to participate, we could have received several responses from one office. We recognize this is a limitation of our study, since we do not know how many offices in the area participated.

## 5 Conclusion

Study results demonstrate that oncology/hematology team members participating in our study became familiar with many important issues related to biosimilars. Many survey respondents were strongly motivated to participate in future biosimilar-focused training, which should pave the way for new educational projects in the area. As more biosimilars enter the US market, a need remains for follow-up training and similar programs in other geographic areas and among other healthcare providers. Furthermore, our educational initiative could serve as a model for educating hematology and oncology teams about biosimilars nationwide. Future education initiatives focused on biosimilars would benefit from including both educational components (e.g., seminars, webinars, and/or brochures) and an educational needs assessment (i.e., survey). Such educational programs should improve access to important cancer treatment options in the USA.

### Compliance with Ethical Standards

This study was determined as exempt by WIRB on 1 September 2017. The study was performed in accordance with the ethical standards of the Declaration of Helsinki. Participants received an information sheet explaining the purpose of our study, how the data would be used, and that the data would be anonymous before they began the online survey.

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**Conflict of interest** Dr. Rovshan Ismailov M.D., M.P.H., Ph.D. received funding from Pfizer Inc. to conduct this study and develop this manuscript. He has also received financial support for educational programs from Pfizer, Amgen, Abbvie, Genentech, Novartis, Santen, and Actelion. Dr. Zaytuna Khasanova M.D. has no conflicts of interest.

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