Biosimilars are revolutionizing oncology treatment by improving access to medications, offering more treatment options, and driving down costs thanks to market competition and expedited approval.

As with any new treatment advance, patients and healthcare providers may have questions about clinical safety and efficacy. Nurses, who are at the forefront of patient education, need to know what to tell patients—and that starts by learning themselves.

In October 2019, the Oncology Nursing Society (ONS) hosted a focus group to assess nurses’ understanding of biosimilars and identify ways ONS can support them as they learn about biosimilars, administer them, and answer patients’ questions. Eleven nurses from various geographical locations, roles, and practice settings shared their personal understanding of and attitudes toward biosimilars. They explored biases that patients and healthcare professionals may have regarding biosimilars, shared barriers they face incorporating the drugs into clinical practice, and brainstormed the essential elements of resources that could be developed to help them learn and teach.

Moderator Kristi Kay Orbaugh, RN, MSN, RNP, AOCN®, said the main concern raised by the focus group is that nurses and patients may not understand what biosimilar medications are, how they are equivalent to their reference products, or whether they are equally effective.

“We came to the conclusion that not everyone understands what a biosimilar is,” Orbaugh said, pointing out that the phrase itself isn’t clear or definitive. To illustrate the point, one focus group participant mused, “Why didn’t we name it bio-the-same?”

“I think it’s really important for the nurse, when chatting with the patient and doing that patient education, to come off very confident. We have the studies. We understand the science. What happens in the reference product should also happen in the biosimilar, from a therapeutic standpoint” Orbaugh stressed. “One of the biggest and most important things that we need to do is make sure

Fast fact:
The first biosimilar came on the market in 2015. As of March 2020, the U.S. Food and Drug Administration had approved 26 biosimilars, largely for oncology, dermatology, and rheumatology. More are coming to market rapidly as patents expire on reference products.

Source: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

Inside:
The focus group brainstormed several analogies to help nurses understand and explain biosimilars to colleagues and patients.

To understand biosimilars and how they differ from generics, think about them mimicking—or mirroring—their reference products.
that nurses are very confident with the fact that this drug is equal to—is just as efficacious as—the reference product. Patients need to know that.” The focus group also covered logistical challenges of biosimilar administration in practice, such as incorporating the drugs into protocols and standards and managing approval and reimbursement.

However, the recurring theme was that nurses lack confidence in their understanding of biosimilars, specifically:

- What biosimilar means
- The differences between generic drugs and biosimilars
- How biosimilars are developed, tested, and approved
- How they can explain it all to patients in a transparent and ethical way

“Nurses are the ones that are right there with the patient at the bedside, at the chairside. They’re the ones that they call and talk to in triage, they’re the ones they tend to be more open with regard to their questions surrounding their treatment,” said Orbaugh, a nurse practitioner for Community Hospital Oncology Physicians in Indianapolis, Ind. “As nurses, we need to make sure that we are as up to date as possible, make sure that the resources we are relying on are foundation-based and evidence-based—and certainly the information needs to be given to patients.”

Participants urged ONS to lead development of those resources. As a step in that direction, the following series of short articles, graphics, and activities explore some of the gaps in understanding revealed by the focus group.

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— Moderator Kristi Kay Orbaugh, RN, MSN, RNP, AOCN®

Biosimilars Focus Group Participants

The Oncology Nursing Society thanks the following participants in the focus group for sharing their expertise and experience.

- Angela Davis, BSN, RN, OCN®
- Kara Flickinger, MSN, FNP-C, AOCNP®
- Stephanie Hammontree, MSN, RN, OCN®
- Megha Shah, BSN, RN, OCN®
- Kimberly Pickel, FNP-BC, AOCNP®
- Melissa Rock, BA, RN, OCN®
- Sonia Sims, MSN, RN, CA-SANE, OCN®
- Elizabeth “Lyn” Wooten, RN, MSN
- Pamela Worthy, RN, BSN, OCN®
- Fatemeh Yousefi, PhD, RN, OCN®
- Moderator Kristi Kay Orbaugh, RN, MSN, RNP, AOCN®
A Fruitful Conversation
Analogies Help Clarify Concepts

When it comes to patient education, the focus group made it clear that one size does not fit all. “Everybody learns differently, so one educational piece is not going to work for everyone,” explained moderator Kristi Orbaugh. For example, people can be visual learners, auditory learners, hands-on learners, didactic learners, or a combination. “Let’s face it. Patients are savvy. If you don’t answer all their questions, they will go home and contact Dr. Google. So you want to make sure that you are giving them good, evidence-based information.”

The nurse participants agreed that there aren’t a lot of resources available yet, and they hoped ONS could spearhead the development of a range of materials. As a first step, they provided several important criteria: short, simple, and reassuring.

“They had a lot of really excellent ideas. What a creative group,” Orbaugh said. Participants suggested flash cards, lists of frequently asked questions, infographics, fact-versus-fiction sheets, short and light-hearted videos, and more.

The group also concluded that analogies can be powerful teaching tools. For example, to help illustrate the difference between a generic and a biosimilar, the focus group came up with a beverage analogy. If you wanted to make Coca-Cola, you could get the exact chemical makeup of Coca-Cola and recreate it. Both beverages would have the same essential chemical makeup. That is generic. On the other hand, biosimilars are more like wine. Even though a vineyard can make many bottles of wine from the same batch of grapes and apply the same label to all of those bottles, no two bottles in the batch would be exactly alike—because wines, like biosimilars, are made in living cells. Like biosimilars, wine undergoes continuous quality control and checks to ensure that each bottle is within a required reference range.

The nurses also likened biosimilars to apples from the same apple tree. The tree consistently produces apples of the same quality. Even though not every apple will be identical, they are considered equivalent and perform equally well.

The participants pointed out that several similar but different sets of resources would be helpful for different audiences—for example, some materials for patients, others for nurses, and still others for additional members of the healthcare team who may inject biosimilars and encounter patient questions, thereby ensuring consistent messaging. In addition, the nurses mentioned they would appreciate different versions of educational resources for patients who start treatment on biosimilars versus those who switch during treatment. Finally, different types of materials might be needed regarding biosimilars that have therapeutic intent versus supportive care.

Will They or Won’t They?
Do all patients need to be educated about biosimilars? One participant wondered, “Do patients need lots of explanation, or are they over-educated and overwhelmed with information?” Another questioned, “Are we making a big deal out of not a big deal?”

Indeed, everyone agreed that not all patients would have questions or concerns. “There is a subset of patients who aren’t really going to care that they’re getting a biosimilar. If their provider feels that it’s appropriate and it’s effective, then I think they are going to be OK with that,” Orbaugh.
said. “But there's a whole other subset that want to make sure, ‘This drug isn't inferior, is it?’”

She continued: “Not everyone is going to have a lot of angst about this. But for those who do, those are the ones we really need to walk that extra mile to help answer those questions and calm those fears and provide them with the information they need to feel at peace.”

The Question of Cost

The focus group talked at length about how to address the potential cost savings associated with biosimilars. Patients sometimes want to know, “Why are you changing? Does it save the doctor money? Does it save the insurance company money? Who is benefiting from the cost effectiveness?”

Orbaugh explained that bringing a brand-name biologic to market takes at least 10 years and an immense amount of money. Bringing a biosimilar to market takes about seven years, she said, and is still very complex, complicated, and expensive. Therefore, biosimilars are not a fraction of the price. Savings from biosimilars are expected to provide financial benefits over time to larger systems that purchase vast amounts, such as Medicare. Biosimilars currently cost about 70% of the cost of their reference products. Savings will add up over time regardless of the size of the institution or buying group. In the meantime, biosimilars are creating market competition, she said, “which always benefits the patient.” We now have several biosimilars to reference products. Various pharmaceutical companies have developed biosimilars to the same reference product. This provides more options to the provider and the patient. The question still remains who will actually benefit the most from this competition and who will see the most potential financial benefit. For example, will insurance companies dictate which biosimilar is prescribed for the patient, or will the individual healthcare system choose the biosimilar based on pricing?

Tips for Talks with Patients

Using case studies and role play, the focus group participants collated the following tips for nurses discussing biosimilars with patients.

- Patients have two main questions: Why are we switching? Is the biosimilar as good/effective?
- Patients are often “Internet educated.” You must help them delineate fact from fiction.
- Do not assume that all patients will have questions or concerns about biosimilars.
- Determine whether a patient wants additional information, rather than overwhelm him or her with too much information. In other words, check for understanding and be open to questions and concerns, but do not create an issue where there is no issue.
- Be alert for non-verbal cues and indirect signals from patients, as well as underlying issues that may cause concern. Address their non-spoken concerns.
- Understand the patient’s insurance coverage and be aware whether the patient has the option to use the reference product or not. Some formularies permit only a biosimilar or only a reference product, in which case a patient will not have a choice.
- Do not make biosimilar discussions all about cost savings.
- Ensure consistent messaging from all staff, not just oncology nurses.
- Be educated and confident. Your attitude and confidence will affect the patient’s attitude and confidence.

As one participant concluded: “We cannot waiver. We must be very confident in what we are saying.”

The oncology nurses also likened biosimilars to apples from the same apple tree. A tree consistently produces apples of the same quality, but not every apple is identical.
One word that kept coming up was that a biosimilar is going to ‘mimic’ what the reference product does,” said focus group moderator Kristi Orbaugh. “These drugs are metabolized and absorbed the same way, and have the same effect on the body. The safety profile and side effects are very similar, and efficacy is the same. They should mimic the reference products.”

According to the U.S. Food and Drug Administration (FDA), a biosimilar is “a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared.” [See: https://www.fda.gov/media/108557/download]

“It always comes up—well, isn’t that just a generic? And it’s not a generic. So we talked a lot about why it was not a generic,” she said.

Although biosimilars and generic drugs are both versions of brand-name drugs, they are different. Generic drugs are made under chemical synthesis; biologics and biosimilars are both biological. They involve complex, large molecules created in a living system (e.g., bacteria, yeast, cell).

Furthermore, generic drugs have the same active ingredients as their brand-name counterparts. A manufacturer of a generic drug must show that the product is bioequivalent to the brand-name drug. On the other hand, biosimilar manufacturers must demonstrate that a biosimilar is “highly similar” to the reference product, except for minor differences in clinically inactive components. “Biosimilar manufacturers must also demonstrate that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness,” according to the FDA.

“We need to think of biosimilars in a very positive light—the fact that they are similar therapeutically, just as potent and as efficacious as that reference product,” Orbaugh said. “The hope is being able to utilize biosimilars and maybe bring down some of the burden on the healthcare system as well as on patients individually. Hopefully the utilization of biosimilars will allow more patients the opportunity to try and potentially benefit from these drugs.”
The first step to patient education is staff education,” a nurse said during the ONS focus group on biosimilars, to the agreement of all participants. However, because biosimilars are relatively new treatments, many nurses have not been educated about them or had substantial experience using them in practice. “I don’t think all nurses know what a biosimilar is,” said focus group moderator Kristi Orbaugh. “We’re seeing more and more come out. And I think as more drugs come off patent, we’re going to see that process speed up. But this is a relatively new ‘drug class’ for nurses.” Therefore, the group agreed that the profession, led by ONS, needs to build a basic foundation of knowledge and understanding. Participants recommended that organizations creating educational materials take the complex topic down to the ground level, where all nurses can learn the fundamental information, then add “bricks” to help nurses grasp the subject on higher and higher levels, as biosimilars develop and expand.

“Nursing education has to start very basic, and then as we begin to feel comfortable with biosimilars, accelerate that education and talk more specifically about the testing, the research, and how we get to that biosimilarity,” Orbaugh explained. Future education also can build upon how biosimilar drugs move through the approval process, as well as insurance coverage and other cost considerations. A strong foundation can start with articles in this publication, as well as resources listed on the last page. The nurses agreed they want materials that are:

- Quick
- Concise
- Evidence-based
- Available at the point of care

In addition to education for nurses and patients, the focus group participants stressed that other personnel need foundational knowledge of biosimilars, such as nonclinical staff who deal with billing and medical assistants who may administer the drugs. This will help ensure that everyone at an institution who encounters patients is prepared to answer questions—and that messaging is consistent across the patient experience.

One participant explained that her employer hosted a nurse-wide, in-service educational session whenever the institution started a new biosimilar. The nursing staff learned together, before the first injection or infusion. Other participants added that talking points and flash cards would be helpful. Orbaugh reminded the nurses that they also can go to the source: information from manufacturers.

“It’s an exciting time. This is such a different world in oncology now than it even was 10 years ago,” she concluded. “Biosimilars are not going away. That’s for sure. We’re going to see more and more of them. So to some extent, I think they’ll become somewhat commonplace.

“Let’s keep raising the bar,” she concluded. “We’ll all rise to it.”
To assess and expand your colleagues’ knowledge of biosimilars, use some or all of the following prompts at a future “journal club” or in-service. Use the articles in this publication and additional resources listed on the next page as potential reading assignments before or after the gathering.

• Show of hands: Who feels confident about the effectiveness of biosimilars? Who does not? Who isn’t sure?
• Show of hands: Who feels confident about their knowledge of biosimilars and ability to communicate information to patients? Who does not? Who isn’t sure?
• What would make you more confident?
• What questions have patients asked you about biosimilars?
• Follow up on each response to the previous bullet: What is the best reply to that question?

Poll Your Practice:
Begin an open dialogue with colleagues regarding nurses’ confidence discussing biosimilars. A few questions to begin:

• Do you feel confident about the effectiveness of biosimilars? Why or why not?
• Do you feel confident about your knowledge of biosimilars? Why or why not?
• Do you know how to talk to patients about biosimilars? Why or why not?
• In your practice, who teaches the healthcare practitioners and other staff about biosimilars?
• What specific education about biosimilars do you need in your practice?

Case Study
Role play based on the following case study. Assign one person the role of the nurse and another person the role of the patient.

Mary is a 76-year-old retired teacher who is being treated for metastatic colorectal cancer. She is currently receiving a chemotherapy regimen in addition to a granulocyte colony-stimulating factor (G-CSF) to reduce the risk of febrile neutropenia.

Mary always actively researches treatment options, is involved in treatment decisions, and is diligent about preventing infection, especially since being hospitalized four years ago due to chemotherapy-induced neutropenia.

Mary’s insurance company recently changed formularies and no longer will cover the brand-name G-CSF. Therefore, Mary’s G-CSF will be switched to a biosimilar.

• What questions and concerns might Mary have, and how would you address each?
• What are the bigger issues underlying Mary’s questions and concerns? (Perhaps she has lingering fear from her previous hospitalization.)
• How can the nurse help Mary understand the biosimilar medication and assuage her fears?

Call for Future Focus Groups
If you are interested in participating in a future ONS focus group, please email focusgroups@ons.org with the subject line “Future ONS focus groups.”

Include the following details about you and your nursing practice.

• Name
• Email address
• Phone number
• Nursing degree(s) and license(s) earned
• Place of employment, including city and state
• Position/title/role at work
• Types of cancer you treat in practice
• Type of work setting (inpatient/ outpatient, etc.)
ONS podcast: “Nurses Need Biosimilars Education and Resources”
https://www.ons.org/podcasts/episode-79-nurses-need-biosimilars-education-and-resources

ONS podcast: “The Need for Biosimilar Patient Education”
https://www.ons.org/podcasts/episode-84-need-biosimilar-patient-education

ONS podcast: “How Biosimilars Could Impact the Future of Cancer Care”
https://www.ons.org/podcasts/episode-10-how-biosimilars-could-impact-future-cancer-care

U.S. Food and Drug Administration: Patient Materials
https://www.fda.gov/drugs/biosimilars/patient-materials

U.S. Food and Drug Administration: Healthcare Provider Materials
https://www.fda.gov/drugs/biosimilars/health-care-provider-materials

Clinical Journal of Oncology Nursing: Biosimilars: Exploring the History, Science, and Progress
https://www.ons.org/articles/biosimilars-exploring-history-science-and-progress

ONS Voice: An Oncology Nursing Overview of Biosimilars
https://www.ons.org/articles/oncology-nursing-overview-biosimilars

ONS Voice: Biosimilars Offer New Options for Treatment and New Concepts for Patient Education

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