DESCRIPTIVE REPORT

Biosimilar strategic implementation at a large health system

Indrani Kar, PharmD, System Pharmacy Services, University Hospitals Health System, Cleveland, OH, USA
Margaret Kronz, PharmD, Cleveland Clinic, Cleveland, OH, USA
Evelina Kolychev, PharmD, University Hospitals Cleveland Medical Center, Cleveland, OH, USA
Paula Silverman, MD, University Hospitals Seidman Cancer Center, Cleveland, OH, USA
Prateek Mendiratta, MD, University Hospitals Seidman Cancer Center, Cleveland, OH, USA
Benjamin K. N. Tomlinson, MD, University Hospitals Seidman Cancer Center, Cleveland, OH, USA
Jeremy Prunty, PharmD, University Hospitals Cleveland Medical Center, Cleveland, OH, USA
Melissa Copley, PharmD, University Hospitals Cleveland Medical Center, Cleveland, OH, USA
Seema Patel, PharmD, Cleveland Clinic, Cleveland, OH, USA
Sara Caudill, PharmD, University Hospitals Cleveland Medical Center, Cleveland, OH, USA
Lisa Farah, RPh, Cleveland Clinic Foundation, Cleveland, OH, USA
Bryan Wesolowski, PharmD, MBA, University Hospitals Cleveland Medical Center, Cleveland, OH, USA
Tyler Crissinger, PharmD, BCOP, University Hospitals Cleveland Medical Center, Cleveland, OH, USA
Colin Kendig, PharmD, University Hospitals Cleveland Medical Center, Cleveland, OH, USA
Eric Szymczak, PharmD, University Hospitals Cleveland Medical Center, Cleveland, OH, USA
Lindsey Duraj, PharmD, University Hospitals Specialty Pharmacy, Warrensville Heights, OH, USA
John Dumot, MD, University Hospitals Cleveland Medical Center, Cleveland, OH, USA
Emily Acheson, PharmD, University Hospitals Specialty Pharmacy, Warrensville Heights, OH, USA
Svetlana Lyamkin, PharmD, University Hospitals Specialty Pharmacy, Warrensville Heights, OH, USA
Michelle King, PharmD, University Hospitals Health System, Cleveland, OH, USA
Allyson Mocilnikar University Hospitals Health System, Cleveland, OH, USA
Kevin Cunningham, PharmD, University Hospitals Health System, Cleveland, OH, USA
Nikola Paulic, PharmD, University Hospitals Geauga Medical Center, Chardon, OH, USA
Uwe Botzki University Hospitals Health System, Cleveland, OH, USA
Rachael Lerman, PharmD, University Hospitals Health System, Cleveland, OH, USA
Robyn Strosaker, MD, University Hospitals Cleveland Medical Center, Cleveland, OH, USA
Shawn Osborne, PharmD, MBA, University Hospitals Health System, Cleveland, OH, USA
Brett Glotzbecker, MD, University Hospitals Seidman Cancer Center, Cleveland, OH, USA

Address correspondence to Dr. Kar (Indrani.Kar@UHhospitals.org).

This article is part of a special *AJHP* theme issue on the impact of pharmacy departments on the medication-use process. Contributions to this issue were coordinated by Stephen F. Eckel, PharmD, MHA, and Rita Jew, PharmD, MBA, BCPPS, FASHP.

https://doi.org/10.1093/ajhp/zxab410

Purpose. This article highlights one health system's response to the market influx of biosimilars with the establishment of a process for formulary review and selection of preferred agents and support for therapeutic interchanges.

Summary. Through assessment of available literature, insurance payor coverage, and manufacturer-anticipated approvals of biosimilars, a strategic stance was developed to guide biosimilar order preparation, review, adoption, and implementation. The electronic medical record (EMR) is prepared for biosimilar implementation at least 6 to 12 months ahead of anticipated formulary review. The review includes assessment of a class (reference product and available biosimilars) after at least 2 biosimilars become available. Key health-system departments and clinicians are enlisted to support review of clinical, safety, and economic implications. Implementation of a preferred product relies on standard education, formulary availability, and staff awareness to address any perceived patient safety concerns and gather provider support. The standard steps developed now apply to all future biosimilar reviews, adoption plans, and ongoing monitoring. Barriers evaluated include changes in payor coverage and challenges in preparation of the EMR for future biosimilars, meeting precertification team education needs, and providing operational support for pharmacy inventory.

Conclusion. To date, use of 5 preferred biosimilar products has led to significant cost savings to the institution, and the process has been endorsed by providers. The institution's successes can be attributed to clear communication with stakeholders and the development of a deliberate process, led by a multidisciplinary leadership team, for managing formulary, safety, and operational barriers in a thoughtful and systematic manner.

Keywords: biosimilar, cost savings, health system, filgrastim, infliximab, pegfilgrastim, trastuzumab

Am J Health-Syst Pharm. 2022;79:268-275

Biosimilars are biologic medications with no clinically meaningful differences from biologic reference medications previously approved by the Food and Drug Administration (FDA). The medications may have different molecular structures or clinically inactive components that FDA classifies as minor differences. A biosimilar undergoes a different FDA review process than the originator novel biologic medication for initial FDA approval. A biologic medication receives a full review of safety and efficacy. The FDA biosimilar review approval process includes analytical, animal, and clinical studies that must demonstrate no clinically meaningful differences, assess toxicity, and evaluate safety, purity, and potency relative to the original biologic.[1-4] The efficacy of a biosimilar is mainly evaluated for one indication and then extrapolated to other indications, and this data is often not published in academic journals or released to the public.[5] There have been no biosimilars for which additional data supporting switching between a reference product and biosimilar has been

published. Consequently, there are currently no biosimilars with interchangeable status per FDA.[1-4] FDA publishes information about approved biologics and biosimilars in the Purple Book, a searchable database.[6] FDA also provides all review documents for biosimilars in the Drugs@FDA portal (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm).

Biosimilars provide a new approach to biologic medication needs and offer compelling cost savings opportunities for hospitals. In this regard Europe has a more established history than the United States, with a defined regulatory process for approving biosimilars. Since 2016 over 70 biosimilars have been approved and come into use in Europe. Approximately 29 biosimilars have been approved in the United States, and many are not yet available on the market.[7] Experts are expecting a significant increase in biosimilar development and use in the United States. For every biologic reference medication, multiple biosimilars can exist, and they often become available at different times. Additionally, insurers have begun to dictate their preference for use of biosimilar versus reference products as well as preference for a specific biosimilar. This presents a challenge and opportunity for hospital system formularies.

To address the challenge of implementing biosimilars, this descriptive report will illustrate how University Hospitals Health System (UHHS), a 15-hospital health system in northeast Ohio, utilizes a standardized formulary process for adult and pediatric patients to overcome this challenge. The system's medication safety & therapeutics (MST) committee and pediatric MST committee manage collaborative interdisciplinary formulary processes that provide governance of medication management, medication guidelines, and medication-use policy for a diverse health system.[8] The health system includes an academic medical center; pediatric, cancer, and women's hospitals; and 11 community hospitals that provide outpatient support through a multitude of outpatient infusion centers. The biosimilar implementation process was developed within the adult formulary with a specific focus on the system's outpatient oncology infusion locations. With direction from the formulary process, UHHS successfully implemented inclusion of several biosimilars across the oncology and nononcology practice settings. UHHS has encountered several challenges, such as the varying numbers of biosimilars for a single reference biologic, third-party insurance preferences, electronic medical record (EMR) documentation (especially as it pertains to billing needs), and cost assessment.

This article highlights one health system's response to the biosimilar market influx through the establishment of a process for formulary review and selection of preferred agents.

KEY POINTS

- This article highlights one health system's response to the market influx of biosimilars through establishing a process for formulary review and selection of preferred agents along with support for therapeutic interchanges.
- Implementation of a preferred product relies on education, formulary availability, and staff awareness to address any perceived patient safety concerns.
- Clear communication with stakeholders and the development of a deliberate process led by a multidisciplinary leadership team can lead to successful implementation of biosimilars.

System strategy development

UHHS developed a strategy leading to a standardized method for review, adoption, and implementation of a biosimilar. The development of the strategy started with the drug policy/formulary pharmacist monitoring manufacturer-anticipated approvals of biosimilars, reviewing available literature on biosimilars, and evaluating local insurance payor mix and biosimilar coverage in 2015. Monitoring included assessment of resources from the organization's group purchasing organization (GPO) and manual assessment of payor coverage. Due to the varying number of agents and timeframes for class approval, a strategic stance was taken so that UHHS could monitor the market and, when possible, assess a class (reference product and available biosimilars) after at least 2 biosimilars become available on the market.

Standard education to increase staff awareness helped to address any perceived patient safety concerns with biosimilars and gain provider support. This strategy was developed and led by the drug policy/formulary pharmacist and the adult oncology formulary subcommittee, including an interdisciplinary team of oncology providers, clinical pharmacists, pharmacy leadership, precertification, supply chain, informatics, and multidisciplinary learners. The goal was to develop a consistent process that would apply to all future biosimilar reviews and adoption plans.

The strategy is further described in Table 1 and in the next section.

Formulary standard process for biosimilars

A formulary analysis includes a robust evaluation of efficacy, safety, and cost; however, with biosimilars additional factors must be considered, including insurance coverage for outpatient biologic products, the EMR build processes, and the potential for diverse locations of administration (hospital, outpatient infusion site, ambulatory care site, specialty pharmacy, physician office, etc). The biosimilar formulary review focuses on cost differences, comparison of indications and available evidence, and insurance payors' choice of agent.

Table 1. University Hospitals Health System's Biosimilar Evaluation and Implementation Strategy

Category	Steps
Formulary and clinical review	• Standard abbreviated monograph review conducted per system policy and standard operating procedure (Figure 1) for a biologic/biosimilar group. • The review includes an assessment of indication, clinical study, insurance coverage, and operational impact. • Biosimilar standard operating procedure (Figure 1) and policy guide the review process. • The intent of the evaluation process is to identify a preferred product (a biosimilar or reference product), when possible, based on full indication coverage, available data, and insurance coverage. • Developed therapeutic interchanges allow for use of nonpreferred products based on data available to support payor denials. • Applicability of adult and pediatric system formulary is assessed.

Proactive informatics involvement	• An order set is an electronic or paper document that organizes relevant orders for a specific treatment for a specific disease indication, including medication orders.
	• Both paper and electronic order sets are prepared such that one nonproprietary product is specified in orders in oncology
	  ◦ In nononcology so far, all approved options are available to order, with notation of a preferred product.
	• In oncology, a nonproprietary product order defaults to a preferred product on dispensation
	  ◦ If the covered product is different from the preferred biosimilar, the covered product is dispensed per therapeutic interchange.

Financial clearance	• The precertification team is aware of preferred products at the institution through education. • When a nonproprietary product order is received, financial clearance personnel submit a clearance request for the preferred agent. • A developed stepwise process is followed if a denial is received.
Contracting	• Contracting and best price negotiations for the preferred product are conducted with the general purchasing organization.
Education/rollout	• Education plan is developed using standard education template and standard memorandum.
Implementation — dispensing product	• When a nonproprietary product order is received, pharmacist verifies product and confirms coverage. • Product label includes full name and suffix.
Implementation — administration	• Dispensed medication is administered. • EMR includes full name in the nursing medication administration record.

Abbreviation: EMR, electronic medical record.

A policy was developed to supplement the health system's formulary process. The policy included the FDA definition of a biosimilar, the process by which a biosimilar is approved, and the formulary review process for a biosimilar. Two essential components to the biosimilar formulary review strategy are the identification of a preferred agent and the creation of therapeutic interchange processes allowing smooth transition to adoption of a preferred agent that address any situations where the preferred product is not covered by insurance. To determine a preferred agent, an abbreviated review monograph is created. The monograph includes indication coverage, clinical study review, insurance coverage review, reimbursement, and operational impact to all hospital, outpatient infusion, home infusion, physician office, and retail spaces. Contracting with the pharmaceutical company to meet the needs of the hospitals, outpatient infusion sites, home infusion operations, and the specialty pharmacy is completed in tandem, along with any additional memoranda or documents. Key health-system departments and clinicians are enlisted to support review of important clinical, safety, and economic implications. This review includes published literature, payor geographic coverage mix, confirmation of appropriate indications, and available switching studies. The policy and monograph review provide an efficient structure for reviewing a group of biosimilars and corresponding reference products to determine a preferred agent. The operational evaluation of a biosimilar is also documented in a standard operating procedure (SOP) for the formulary process and is followed for each biosimilar class review. This includes any system or local site operational suggestions or needs. The steps in the SOP include formulary review, informatics implications, estimation of work effort needed to modify relevant

order sets, the financial clearance process, contracting, education plan, implementation, and any other issues (Figure 1). Formulary subcommittees are also educated on biosimilars and assist in identifying key interdisciplinary stakeholders.

At times, insurance companies choose a preferred agent they will cover before the full health-system formulary biosimilar review is completed. When use of a preferred biosimilar is required by a payor prior to completion of formulary assessment, the process allows a degree of flexibility in utilizing the health system's "emergent nonformulary process." To account for the unpredictability of such instances, an expedited review was created to account for payor coverage denials after completion of the nonformulary process while still planning for a future strategic review for the organization. The existence of this process is crucial for the success of the overall strategy.

Proactive monitoring

As part of its proactive stance, the health system monitors the biosimilar pipeline and market approvals before, during, and after formulary approval of a preferred agent. During the initial monitoring phase, the EMR is prepared for biosimilar implementation by the informatics team at least 6 to 12 months ahead of anticipated standard formulary review completion. When a class of biosimilars and the reference product are expected to be reviewed, the team takes a proactive approach to ensure EMR capability for implementing the biosimilar strategy. The order sets are identified and reviewed with the relevant order set committees. Once a biologic is approved for formulary inclusion, the order set team updates the order to specify a nonproprietary biologic medication name. Pharmacy informatics personnel prepare the nonproprietary medication order set so that when the medication is ordered electronically, the order defaults to the UHHS-preferred product. The electronic medication order prompt specifies the full medication name along with the correct suffix to print on the medication label and nursing medication administration record. Supported secondary alternative products are available for selection by the pharmacist based on therapeutic interchanges approved through the formulary process (Table 2). The EMR process generally takes 3 to 6 months (this is an average turnaround time at UHHS), depending on number of order sets and work effort required.

Implementation

Once a preferred product is selected and approved along with processes

Figure 1. University Hospitals Health System's biosimilar standard operating procedure.

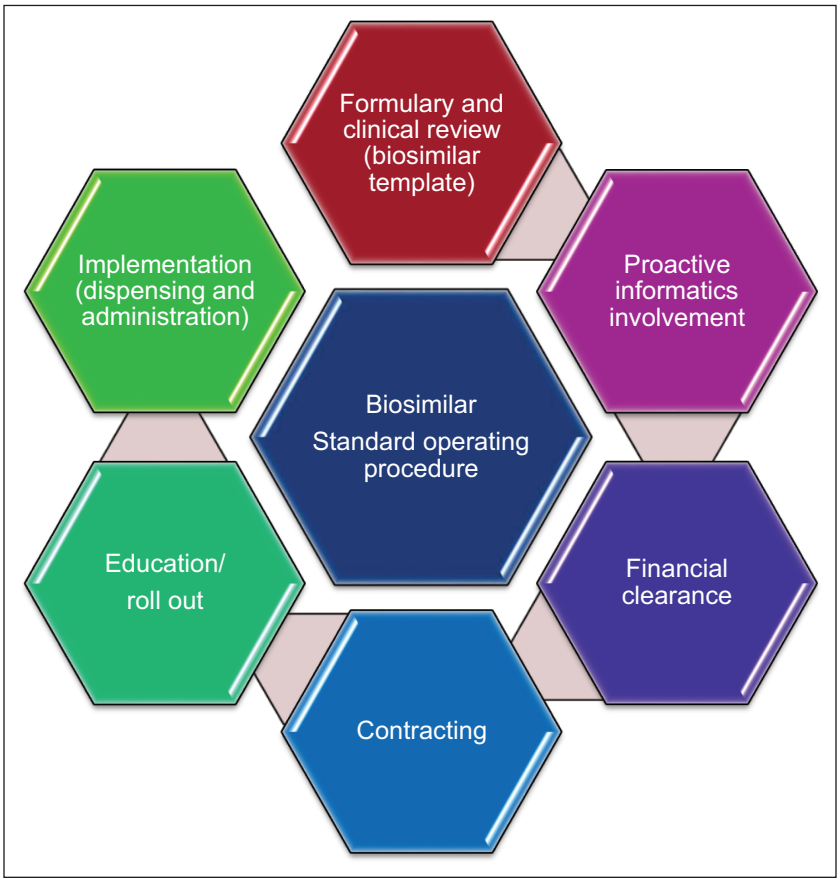

Table 2. Example of Therapeutic Interchange Request for a Biosimilar

Biosimilar therapeutic interchange (starting DATE for new-start patients, biosimilar preferred; biosimilar/reference secondary)		
Medication Ordered	**Precertification Approval**	**Medication Dispensed**
Switching between biosimilars is not recommended due to no evidence available, even if payor requires. An appeal should be attempted. The biosimilar(s) is considered equivalent to the reference product.		
Nonproprietary name	Biosimilar approved	Biosimilar dispensed (formulary preferred agent)
Nonproprietary name	Biosimilar denied; secondary product approved	Secondary preferred product dispensed only for payor denials of primary preferred agent
Nonproprietary name	Above denied; another product approved	Contact pharmacy and refer to nonformulary emergent process for new-start patients

to support therapeutic interchanges, a standard education document for all staff is created.[9] Three key pieces of information are communicated to all staff: preferred product, a standard letter for payors, and a process for denials. Any contracting information specific to a location of administration and additional documents are included as necessary. All documents are approved through the system formulary process. Multiple presentations are given to stakeholders to ensure education about the process reaches relevant areas. The stakeholders span a large interdisciplinary array of individuals, including providers and pharmacy, precertification, and nursing teams.

Biosimilar implementation from the system formulary level focuses on patients newly initiated on an agent ("new start" patients). The conversion of a patient maintained on a reference product to a preferred biosimilar occurs when a new precertification is completed or the provider requests a switch. This is also managed at the local site level by individual hospital pharmacists through physician interactions.[10] Once a biosimilar has been implemented, an executive summary is prepared and presented to maintain accurate documentation of all relevant discussions and process steps for future reference.

The EMR build creates minimal burden on providers and other frontline users. After implementation, the provider orders a medication by nonproprietary name. The order defaults to the institution's preferred formulary product. Then the order is reviewed by a pharmacist who confirms payor coverage in the institution's insurance prior authorization database. The pharmacist can select the secondary preferred product, if dictated by payor coverage, through the supporting therapeutic interchange. The medication is dispensed for administration with a label indicating the full name and corresponding suffix of the medication.

The developed standard steps now apply to all future biosimilar reviews, adoption plans, and ongoing monitoring. This monitoring encompasses feedback from clinicians, evaluation of nononcology impact, and purchasing report assessment. Barriers evaluated include changes in payor coverage, preparation of the EMR for future biosimilars, precertification team education needs, and operational support for pharmacy inventory. To date, use of 5 preferred biosimilar products has led to significant cost savings for the institution, and the process has been adopted by providers. Cost avoidance was calculated by comparing annualized purchases of a given biosimilar with the invoiced cost of the reference product for all cost files in consultation with the institution's general purchasing organization. Cost files include 340B Drug Pricing Program, GPO, and wholesale acquisition costs. For example, implementation of filgrastim, pegfilgrastim, and infliximab biosimilars resulted in an annualized cost avoidance of approximately $500,000, $800,000, and $1.2 million, respectively. The institution's successes can be attributed to clear communication with stakeholders and the development of a deliberative process led by a multidisciplinary leadership team managing navigation of formulary, safety, and operational barriers in a thoughtful and systematic manner.

Case examples

UHHS has implemented 5 biosimilars.

1. **Case 1: filgrastim.** This case was unique as it involved the first biosimilar adopted by UHHS and required extensive preparation and education prior to implementation. The service line stakeholders involved included hematology/oncology, nursing, and pharmacy personnel. Additionally, developing the appropriate informatics requests was integral to success. Due to the amount of EMR order sets impacted (over 300), the time needed to update the EMR was a minimum of 3 months after 6 months of assessment by the EMR team. This work effort helped to develop a standard request process for the order set team and pharmacy informatics team that allows UHHS to prepare the EMR for a biosimilar adoption within 1 to 3 months from assessment to EMR process approval

and implementation. The organization evaluated one biosimilar and an available reference product (filgrastim [Neupogen[a]] and tbo-filgrastim [Granix[b]]). While the institution's strategy is to review a class when 2 biosimilars are available, it was necessary to evaluate this class when 1 biosimilar was on the market due to payor requirements. The region where the institution is located had an acceptable amount of payor coverage for the biosimilar to consider evaluating it. One filgrastim biosimilar was chosen for implementation in adult patients. The biosimilar is available only as a prefilled syringe, which streamlined the implementation. At UHHS, stock is managed locally by each pharmacy manager, so measures to ensure appropriate inventory at all sites were reviewed and considered. Communication with the operations team now occurs at least 1 month prior to a biosimilar implementation to allow for procurement of stock. The filgrastim biosimilar strategy as it pertains to adult patients was implemented in March 2019, and the conversion rate is over 80%.[11,12]

2. **Case 2: pegfilgrastim**. Pegfilgrastim products were the second class of products reviewed. The organization followed the biosimilar strategy in reviewing biosimilars for Neulasta[c] and chose one pegfilgrastim biosimilar for implementation in adult patients. The case was unique as pegfilgrastim has a unique delivery system (Neulasta OnPro[d]) different from that for Neulasta. While the organization uses a large amount of Neulasta OnPro, biosimilars with the same delivery device are not yet available on the market. While the biosimilar was implemented for adult patients (prefilled syringe only) in November 2019, Neulasta OnPro remains on formulary. To address the insurance payor impact on certain patients treated with Neulasta OnPro and guide the providers to the biosimilar when a request for Neulasta OnPro is denied by the payor, a process that gave the precertification team a standard provider letter and standard appeal letter with medical necessity reasons was developed. The form was pilot tested with a few physicians for 1 month to help manage denials. In a small sample of 4 patients, the appeal form helped to overturn the denial of Neulasta OnPro coverage for 2 patients. The forms provide guidance when Neulasta OnPro is denied, so the provider can schedule the patient appropriately and place a new order for nonproprietary pegfilgrastim. The forms were made available to all staff. The pegfilgrastim biosimilar strategy went live in adult patients in November 2019. Denials of the Neulasta OnPro product continued to be an identified challenge in 2020, and additional guidelines are in development to support provider needs when ordering Neulasta OnPro versus the pegfilgrastim biosimilar.
3. **Case 3: infliximab**. Infliximab was the first nononcology biosimilar reviewed through both the adult and pediatric formulary processes. Being the first biosimilar targeting the nononcology population, education and leveraging of pharmacists in physician offices involved in relevant specialty care areas such as digestive health were key to success. The strategy was modified slightly for nononcology, where a preferred agent was chosen for new-start patients and maintenance patients could be either continued on the reference product or be switched to the preferred agent based on payor coverage, pharmacist request, or physician preference. This created flexibility for patients stable on a medication with appropriate payor coverage. This was accomplished by using separate EMR orders for the reference product and biosimilar, with notation of the preferred product in new-start orders. The pediatric MST implemented this strategy in June 2019. Adult use of this biosimilar was implemented in September 2019.
4. **Case 4: trastuzumab**. Trastuzumab was the first therapy-related (as opposed to supportive care) medication for which biosimilars were available. Provider education was critical to receiving support for implementation. Taking the time to provide education prior to implementation was imperative, as was the availability of education on an as-needed basis. A primary preferred product and secondary preferred product were chosen to handle regional payor market coverage and attain eligibility for best pricing. Specific focus was placed on proper contract development with the manufacturers for the medications. The trastuzumab biosimilar was implemented for adult patients in September 2020.
5. **Case 5: epoetin-alfa.** There is one epoetin-alfa biosimilar available. While the institution's strategy is to review a class when 2 biosimilars are available, it was necessary to evaluate this class when 1 biosimilar was on the market due to cost savings opportunities. Due to informatics needs to best support order sets, the biosimilar was made available only in the outpatient setting for adult patients in 2020 based on payor requirement. The inpatient setting availability was completed in June 2021. This stepwise adoption allowed unique informatics barriers to be addressed while taking the time to plan for the inpatient implementation.

Preparation for future biosimilars, such as rituximab and bevacizumab biosimilars for use in adult patients, includes EMR preparation completion and ongoing formulary assessments currently in process. A biosimilar option is available for both reference products as a secondary preferred product due to payor coverage. Once a preferred product is chosen, it will be implemented into the EMR within 1 month.

Each biologic reference product has crucial nuances to be considered upon implementation, and the organization continues to be successful largely due to the standard process. Multiple biosimilar preferred products have been implemented, and monitoring of purchasing and utilization data has shown adoption among providers.

Challenges and lessons learned for future success

Several lessons have been learned during the organization's journey with biosimilar process development and biosimilar implementation. These include the importance of clear communication with all relevant stakeholders, reminders with education for barcoding association, and complete identification of impacted order sets. Additional education was developed for the precertification team and continues to be an ongoing improvement due to staff turnover. Documentation of which product is covered in the hospital's precertification coverage database is crucial for accurate information sharing. The pharmacist then has a clear understanding of which product must be dispensed. The organization continues to make improvements in this space, such as confirmation of precertification coverage ahead of appointments. Pharmacy operations personnel have also brought forward feedback on how to improve the process. This includes timing of when precertification status information is available and the method in which it appears. Several UHHS hospitals do not have precertification coverage information available to pharmacy personnel, which is being addressed with operations staff. Through these discussions, the preferred product now not only defaults for the pharmacist but also requires the pharmacist to select the covered product before being allowed to move forward with verification. This assists the pharmacist in dispensing the correct product.

Biosimilar implementation can also pose a perceived patient safety challenge due to the lack of available literature when reviewing with providers. The level of current biosimilar knowledge among clinicians can lead to incomplete provider support when undergoing this implementation, potentially creating a barrier to safe and effective care to patients. Safety barriers were overcome through the thorough review of the literature as well as early involvement and education of clinicians and other key health-system departments.

Ongoing monitoring is imperative and includes assessment of payor coverage, feedback from providers and pharmacists, and purchasing report assessment. UHHS has found that preparation has been the main driver of a successful strategy, and multidisciplinary inclusion has led to improved process implementation.[9,13] The organization now plans to assess and implement further biosimilars in the pediatric space and continue to apply the biosimilar strategy for additional biologics for use in adult patients.

Future opportunities

The process continues to provide a nimble response to the rapidly changing payor coverage landscape. Constant review of the future pipeline and payor coverage of implemented biosimilars is vital to ensure that formulary preferred agents continue to be appropriate for the organization. Additional advocacy with insurance payors is underway as well. UHHS has found it to be crucial to communicate with payors, making them aware of the need to cover all biosimilars. When a payor prefers one product and requires clinical failure of their preferred biosimilar before using another (eg, one preferred by a specific hospital), this adds to the complexity of biosimilar management by a health system. This is not supported by the evidence for biosimilar approval by FDA and should be a key advocacy concern for pharmacists and stakeholders reviewing biosimilars. UHHS also is advocating with the organization's government relations department and individual payors for best practices related to biosimilars.

Conclusion

The biosimilar strategy at UHHS creates a standardized and connected process with policy, SOP, and standard templates to support many complex aspects of biologic medication selection and leverages the benefits of biosimilar use. Adequate preparation and interdisciplinary stakeholder support will allow the process to be maintained in the future. Our successes can be attributed to clear communication with stakeholders and the development of a deliberate process led by a multidisciplinary team that manages formulary, safety, and operational barriers in a thoughtful and systematic manner.

Acknowledgments

The authors thank the following individuals (listed by title/role or focus area) for their contributions to biosimilars strategic implementation at UHHS: Amy Wakeling, nursing; Richard Creger, pharmacy; Grant Morgan, past pharmacy student; Jason Makii, pharmacy; Melanie Rivera, order set development; Maria Bowen, medication safety/drug information; Henry Champ Burgess, chief pharmacy officer.

Disclosures

The authors have declared no potential conflicts of interest.

Previous affiliations

At the time of writing, Lisa Farah and Dr. Seema were affiliated with UHHS and Dr. Kronz was affiliated with Alleghany Health Network, Pittsburgh, PA.

[a]Neupogen; Amgen, Thousand Oaks, CA.
[b]Granix; Teva, North Wales, PA, and Sicor Biotech, Vilnius, Lithuania.
[c]Neulasta; Amgen, Thousand Oaks, CA.
[d]Neulasta OnPro; Amgen, Thousand Oaks, CA.

References

1. Food and Drug Administration. Biosimilar development process. Accessed March 23, 2021. https://www.fda.gov/files/drugs/published/Biosimilar-Development-Process.pdf
2. Food and Drug Administration. Biosimilar product definitions. Accessed March 23, 2021. https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM581282.pdf
3. Food and Drug Administration. Biosimilar development, review, and approval. Accessed March 23, 2021. https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval
4. Food and Drug Administration. Purple Book: lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations. Accessed March

23, 2021. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or
5. Food and Drug Administration. Industry information and guidance. Accessed March 23, 2021. https://www.fda.gov/drugs/biosimilars/industry-information-and-guidance
6. Food and Drug Administration. Purple Book database of licensed biological products. Accessed March 23, 2021. https://purplebooksearch.fda.gov/
7. Figg R, Harston A. How the U.S. compares to Europe on biosimilar approvals and products in the pipeline. JD Supra. Published March 9, 2021. Accessed July 13, 2021. https://www.jdsupra.com/legalnews/how-the-u-s-compares-to-europe-on-3189962/
8. Kar I, Osborne SM, Glowczewski JE. Implementing a strategy for drug cost management. *Pharmacy Purchasing & Products*. Published September 2017. Accessed March 23, 2021. https://www.pppmag.com/article/2105
9. King M, Osborne S, Strosaker R, et al. Biosimilar implementation and maintenance strategy in a large health system within a changing market. Poster presented at: ASHP Midyear Clinical Meeting; December 2020; virtual meeting.
10. Farah L, Paulic N, Kar I. Implementation of system pharmacy and therapeutics committee approved therapeutic interchanges for biosimilars at a community hospital within a large integrated health system. Poster presented at: ASHP Midyear Clinical Meeting; December 2019; Las Vegas, NV.
11. Kronz M, Gegorski B, Kar I. Maintaining medication safety through biosimilar implementation. ACPE-accredited continuing education session presented at: ASHP Midyear Clinical Meeting; December 2019; Las Vegas, NV.
12. Hakenyos D. Practical considerations for implementation of biosimilars in oncology. *Pharmacy Practice News*. Published December 23, 2020. Accessed March 23, 2021. https://www.pharmacypracticenews.com/Review-Articles/Article/12-20/Practical-Considerations-for-Implementation-of-Biosimilars-in-Oncology/61247?sub=E1B0E355E13B597A788B4A8981BD7AB240F3D9FEB0C3DE9F4B8DC911BE62
13. Tilyou S. Biosimilar switches work at large and small centers. *Pharmacy Practice News*. Published March 4, 2021. Accessed March 23, 2021. https://www.pharmacypracticenews.com/Operations-Management/Article/03-21/Biosimilar-Switches-Work-At-Large-and-Small-Centers/62672