BIOSIMILAR IMPLEMENTATION STRATEGIES:

Survey Results and Practice Insights

ashp Foundation™

www.ASHPFoundation.org

INTRODUCTION

The ASHP Foundation ("the Foundation") presents this report in support of ASHP's vision that medication use will be optimal, safe, and effective for all people, all the time. An advisory committee of experts led the execution of a survey and the creation of this report to raise awareness of effective biosimilar implementation strategies in health systems and diverse care settings.

The projected growth in drug costs continues to be a major concern for health systems already struggling to address increased labor expenses and decreased revenue that has yet to fully recover since COVID-19.[1] Although the reason for this increase in costs is multifactorial, a leading factor is the growth in high-cost biologics and their expanded use. It's not unusual for the cost of these agents to exceed hundreds of thousands of dollars each year for an individual patient. One bright light is the potential to significantly offset these cost increases by implementing biosimilars.

As shown below, a biosimilar is a biological product that is highly similar with no meaningful differences to its reference product (the originator product approved by the FDA).

Biosimilars have been used for years in Europe and have high market penetration compared to the United States, although the United States has seen more use in recent years.[2] The uptake in the United States has been slower, partly due to delays in product launches held up by manufacturer patent challenges. Currently, there are 40 approved biosimilars reaching across multiple service lines, including oncology, immunology (gastroenterology and rheumatology), ophthalmology, and endocrinology.[3] As real-world experience increases, so does confidence in their use.

FDA'S DEFINITIONS

BIOSIMILAR

A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.

BIOLOGIC

Biological products are a diverse category of products and are generally large, complex molecules.

REFERENCE PRODUCT (ORIGINATOR)

A single biological product already approved by the FDA against which a proposed biosimilar product is compared.

INTERCHANGEABLE BIOSIMILAR

An interchangeable product is a biosimilar product that is expected to produce the same clinical result as the reference product in any given patient.

Implementation does vary by prescriber specialty, with uptake the greatest among oncology.[4] Some prescribers and patients also remain skeptical because, although biosimilars must demonstrate that there are no clinically meaningful safety or efficacy differences from the reference product for FDA approval, head-to-head trials with the reference product are not required. Some of the barriers to adoption noted in prior research included the complexity of the prior authorization process, increased out-of-pocket costs for patients, pharmacy benefit manager (PBM) formularies that favor the reference products, prescriber concerns about switching stable patients, confusion about the interchangeability designation, and lack of real-world data or application of worldwide data in practice.[5] Participation in the 340B program has also been suggested to slow the uptake of biosimilars.[6,7] Nevertheless, the implementation of biosimilars remains a significant opportunity to reduce costs and leverage the expertise of the pharmacy enterprise within the organization. This ASHP Foundation survey project was supported by Viatris with the following primary objectives:

- Explore trends in the strategies health systems use to evaluate, implement, and monitor the use of biosimilars.
- Understand therapeutic area priorities for implementing biosimilars.
- Examine relationships between strategies implemented and therapeutic area priorities.

The survey was developed with input from an advisory committee (AC) of experts who had been actively prescribing or managing the implementation of biosimilars. Many survey items, such as implementation strategies, pharmacist roles and performance measures, were adapted from previous research results published in the ASHP Foundation report *Accelerating the Adoption of Biosimilars.*[5] Strategies covered a range of domains, including organization alignment (e.g., operational and formulary management strategies), payer alignment, and physician and patient engagement. The AC reviewed, refined, and prioritized the items. The resulting set of items underwent pilot testing, minor revision, then were included in the final survey.

WHO COMPLETED THE SURVEY

The biosimilar implementation survey was administered via an email invitation with a link to the online Qualtrics survey (Qualtrics, Provo, UT). A stratified random sample of active ASHP members was sent an initial invitation email with a short screening survey to ensure the inclusion of members who have biosimilars on their formulary or are evaluating biosimilars for their organization's formulary. A total of 331 eligible ASHP members accepted the invitation. The survey was launched on June 8, 2023, and closed on July 10, 2023.

One hundred ninety-eight (198) pharmacists completed the survey, resulting in a response rate of 60% (198 out of 331). The vast majority (185 out of 198) work in hospitals and health systems, and 93% responded their organization has a formulary. In addition, half of the panelists indicated their organization was part of an integrated delivery network, and 80% reported that their hospital or health system is a 340B-covered entity.

Forty-two percent of participants were in leadership roles at the business unit or higher level, such as Assistant Director, Director of Pharmacy, or Chief Pharmacy Officer. Other participant roles were manager/supervisor (17%), acute-care pharmacist (10%), clinical generalist/specialist/coordinator (8%), ambulatory care pharmacist (6%), and drug information/medication safety pharmacists (6%), with the remaining (e.g., specialty pharmacists, informatics, community) accounting together for 19 other responders.

CURRENT STATE OF BIOSIMILAR USE

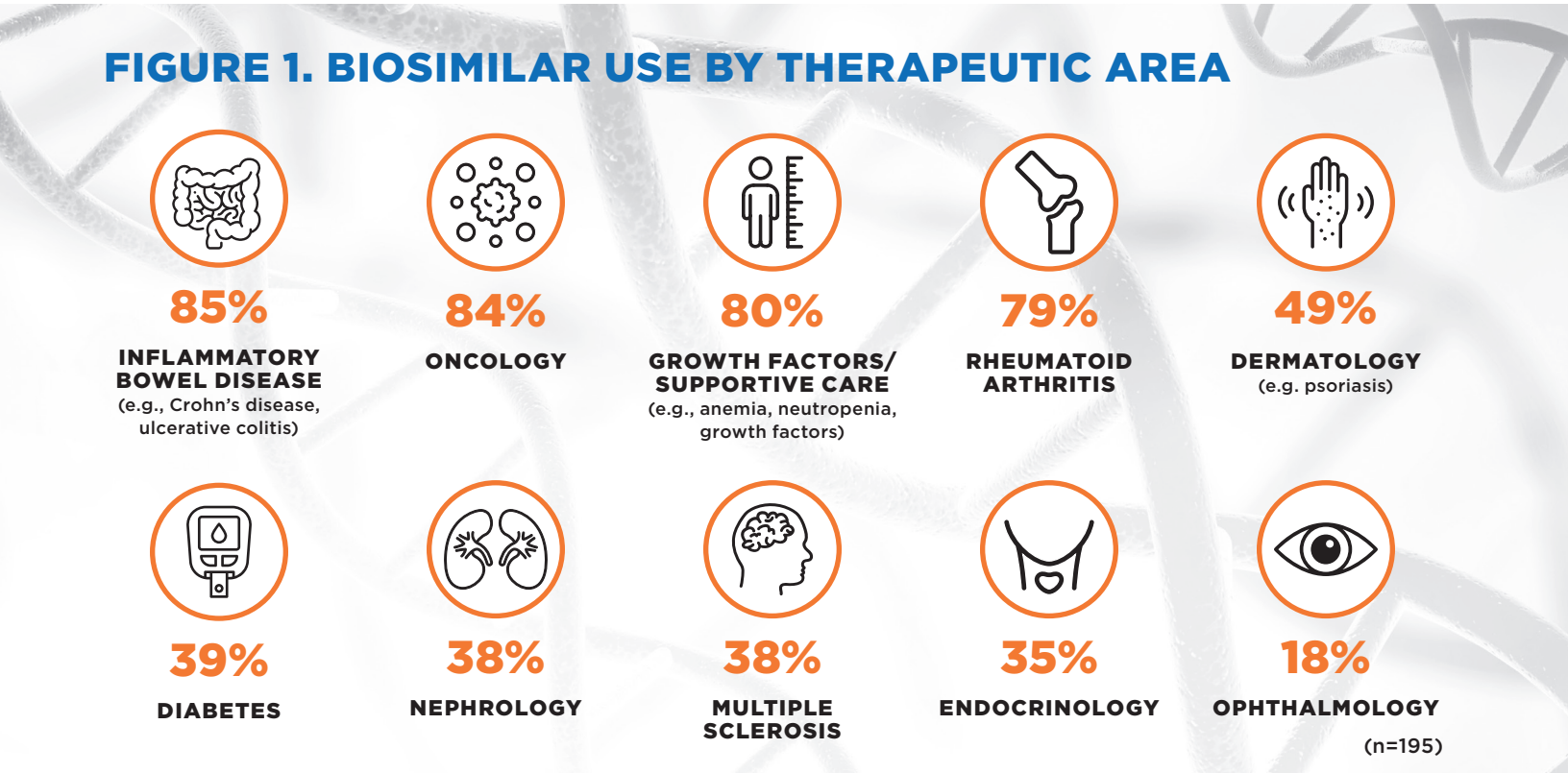
KEY POINTS

- All participants reported some use of biosimilars in their practice setting.
- Most panelists indicated they have multiple biosimilars on the formulary.
- The highest use of biosimilars is in inflammatory bowel disease, oncology, growth factors and supportive care, and for rheumatoid arthritis.

Panelists who indicated they had "any use" of a biosimilar, defined as "dispensed or administered to a patient, whether or not it is on the formulary," were able to move on to complete the remainder of the survey. Therapeutic areas with the most use were inflammatory bowel disease, oncology, growth factors and supportive care, and rheumatoid arthritis (Figure 1). Most of the panelists (88%, n=195) have multiple biosimilars on the formulary.

The panelists indicated that biosimilars used most often were for the following reference products: rituximab, Infliximab, filgrastim, pegfligrastim, epoetin alfa, trastuzumab, and bevacizumab, which aligned with the therapeutic areas (Figure 2). The survey results for "any use" reflect only those products available on the U.S. market during data collection. Although approved several years ago, adalimumab was marketed in the U.S. in the summer of 2023, corresponding to the close of this survey. Further growth in adalimumab and other biosimilars is anticipated after payers announce their 2024 formulary decisions, as payer status is a key factor influencing prescribing. Other areas where use was less prevalent included ophthalmology drugs, which continues to see hesitancy among prescribers.

FIGURE 1. BIOSIMILAR USE BY THERAPEUTIC AREA



We asked the panelists who said they have a formulary (93%, n=188), about the likelihood of them evaluating a biosimilar for addition to the formulary or if they had already added one. Hematopoietic agents, the first biosimilars to become available, including filgrastim (Neupogen), pegfilgrastim (Neulasta), and epoetin alfa (Epogen, Procrit), were most commonly "already added" to the formulary (Figure 3). Oncology biosimilars also have been added to the formulary most frequently including the biosimilar monoclonal antibodies—bevacizumab (Avastin), trastuzumab (Herceptin), and rituximab (Rituxan)—which became available in 2019. These trends reflect similar findings in other market reports.[3,4]

The survey results showed low use and formulary addition of insulin biosimilars. Insulin glargine-yfgn (Semglee) was the first interchangeable biosimilar product approved in the U.S. in July 2021 for the treatment of diabetes, but the market uptake remains low.[3] Within the current results, the advisory committee suggests that responders may interpret the insulin biosimilars as a therapeutic interchange in the inpatient setting and not as a biosimilars conversion *per se*.

As noted above, lower adalimumab (Humira) uptake is not surprising since the first adalimumab biosimilar was launched when the survey was in the field, along with several others after the survey closed. Ranibizumab (reference product Lucentis) uptake is low due to ophthalmologists' concerns about the safety and efficacy of biosimilars. Also expected to impact the implementation of biosimilars is the interchangeability designation made by the FDA pursuant to the Biologics Price Competition and Innovation Act (BPCIA); however, this has caused confusion and may not be as relevant in the health-system setting because the interchangeability impacts dispensing rather than prescribing and is most relevant to self-injectables dispensed by retail pharmacies. Physicians may prescribe any biosimilars or reference products regardless of the interchangeable designation.[8] Interchangeability is a significant opportunity for community and specialty pharmacies because the biosimilar can often offer a cost advantage to the patient and can easily be switched by the pharmacist, state law permitting. Other considerations impacting implementation include payer coverage and cost-sharing, which may still favor the reference product.

FIGURE 2. BIOSIMILAR USE

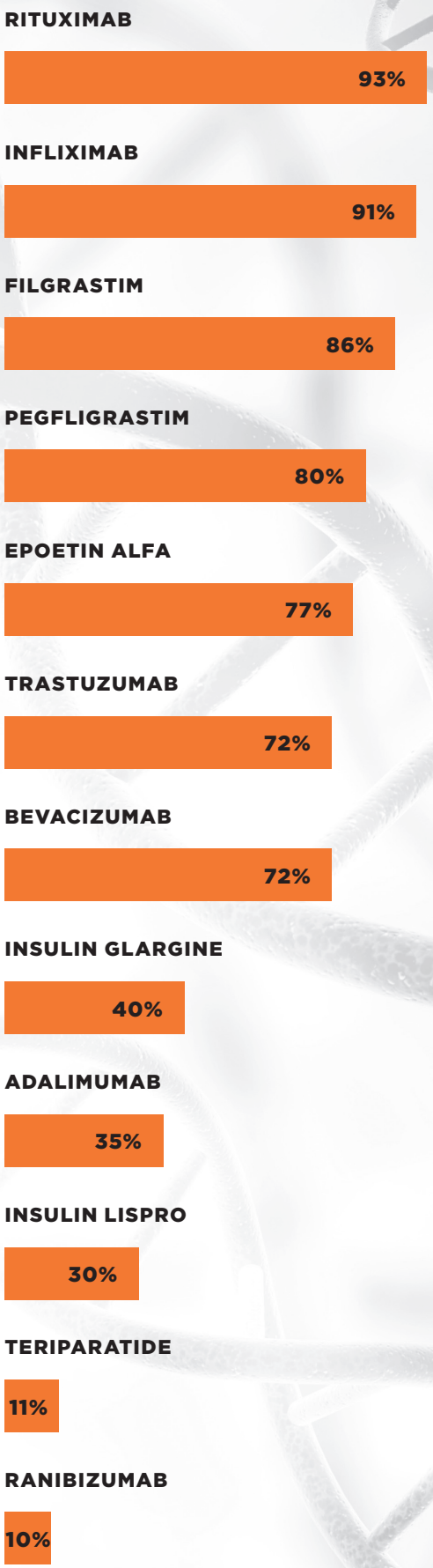
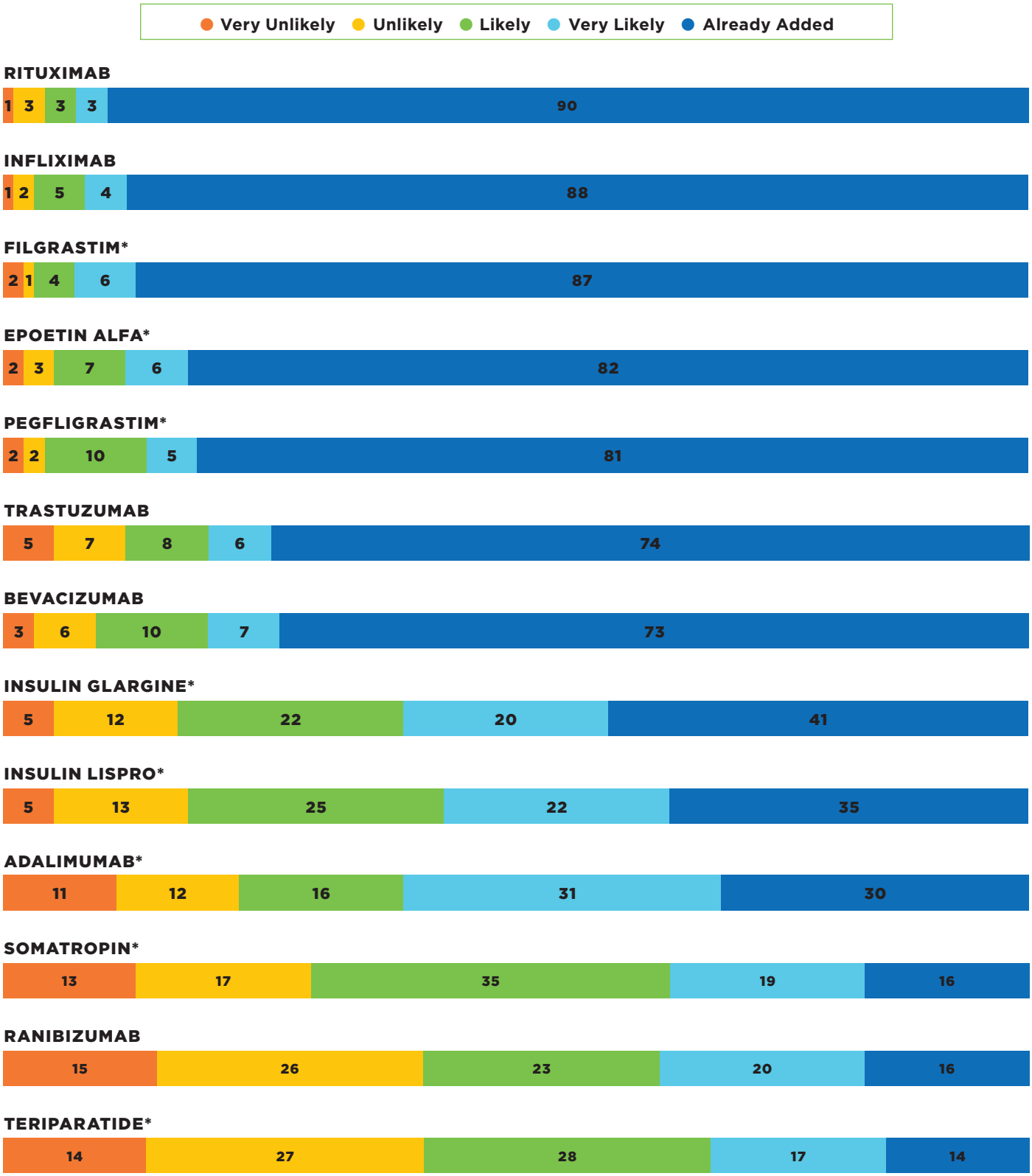


FIGURE 3. LIKELIHOOD TO EVALUATE FOR FORMULARY (%)



* Self-injectables, delivery devices may vary. For a list of approved biosimilars and their dosage forms see: US Food and Drug Administration Purple Book Database of Licensed Biological Products https://purplebooksearch.fda.gov/advanced-search

PERFORMANCE MEASURES

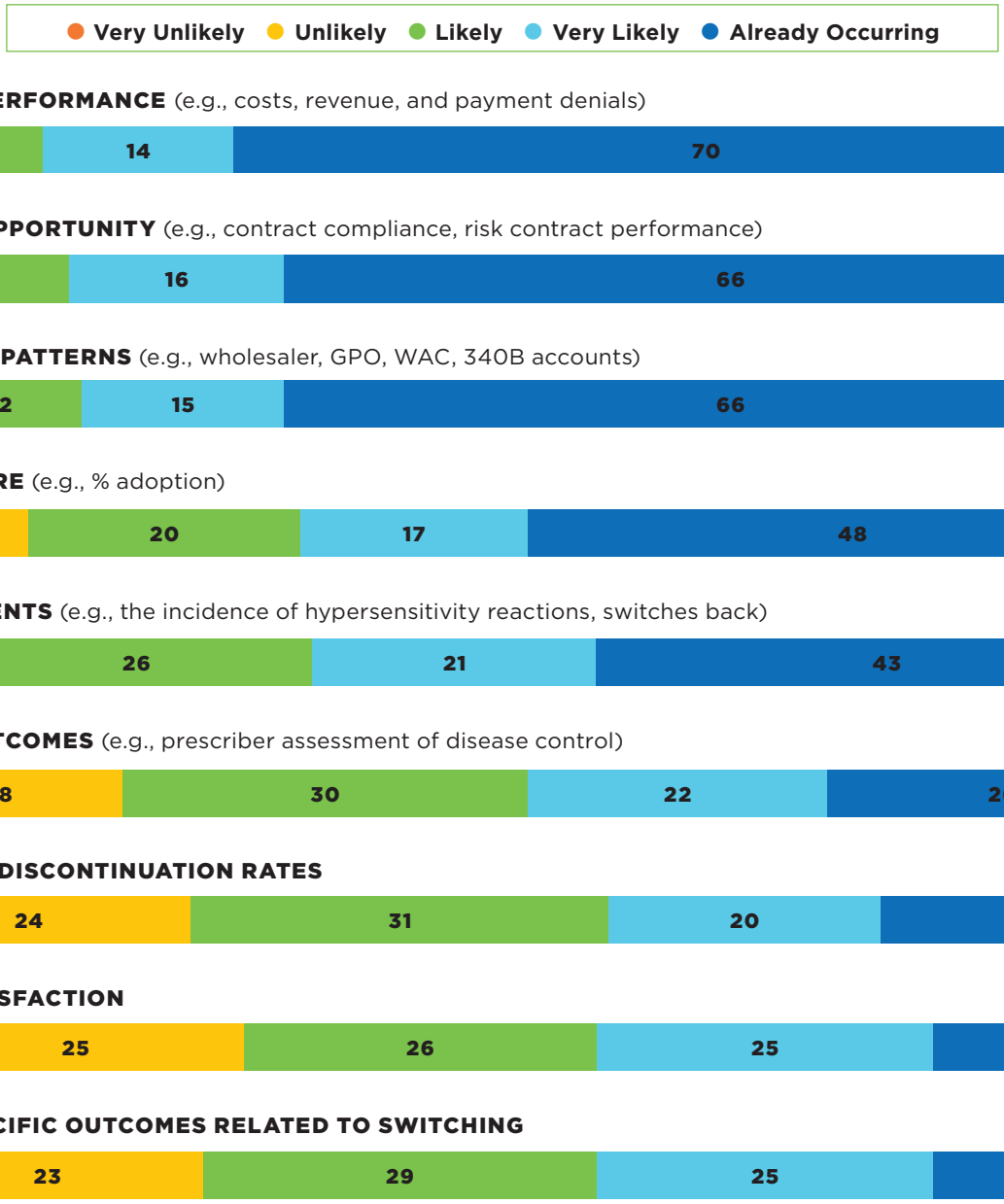
KEY POINTS

- Top measures reported include financial opportunity (e.g., contract compliance, market share) and financial performance (e.g., costs, revenue, and payment denials).
- Adverse events and clinical outcomes were less frequently implemented as measures of biosimilar implementation.
- There is an opportunity to increase monitoring and reporting of patient-specific outcome measures related to switching (e.g., adherence or discontinuation rates and adverse events or "switchbacks") and patient satisfaction.

Monitoring performance outcomes when implementing biosimilars is critical to support implementation, particularly with new biosimilars early in their adoption phase. Authors of a recent report that examined real-world switching and outcomes with infliximab biosimilars used in rheumatoid arthritis concluded that there is a need for more real-world evidence to support implementation.[9] Survey panelists were asked what biosimilar performance metrics were being collected and reported and, if they were currently collecting those metrics, the likelihood of them recommending the metric to their peers, which would be a high-level indicator of effective practice (Figure 4). The top metrics collected were financial performance measures (e.g., costs, revenue, and payment denials), financial opportunity (e.g., contract compliance, risk contract performance), and purchasing patterns (e.g., wholesaler, GPO, WAC, 340B accounts). One limitation to consider when evaluating the responses is that others within the organization or other entities might be monitoring that data. For example, a specialty pharmacist may have reported a higher review of patient outcome metrics because that is built into their workflow.

"We monitor closely the financial impact, but I believe there is definitely an opportunity to expand monitoring to include patient-centric performance measures. I believe this—following up with patients and understanding the patient experience—is the biggest opportunity, in my opinion, and this survey confirmed that."

FIGURE 4. LIKELIHOOD TO COLLECT OUTCOME (%)



OPERATIONAL IMPLEMENTATION STRATEGIES

KEY POINTS

- Several strategies that have been implemented rely on technology support (Table 1). The top operational strategy organizations have implemented is the development of therapy-specific plans and order sets in the electronic health record (EHR) for each biosimilar based on preferred therapies.
- Organizations have implemented strategies to increase access to biosimilars, including creating a centralized team to facilitate prior authorization. In addition, they have utilized technicians for prior authorization coordinating access to medication assistance programs.
- There is an opportunity to expand operational strategies, including using pharmacy technicians and optimizing the use of technology.

While operational strategies may vary by type of organization or organization-specific processes, it is important to support prescribing biosimilars as part of a coordinated effort that aligns with organization goals and integrates with existing processes. The most cited strategy already implemented is the development of therapy-specific plans and order sets in the electronic health record (EHR) for each biosimilar based on preferred therapy (Figure 5), which was also recommended by those who already had implemented the strategy, with 84% reporting that they were likely or very likely to recommend it to their peers (Appendix A). The second most implemented strategy was having a centralized authorization team that obtains and facilitates prior authorizations for biosimilars. While this may not be possible in all organizations, a single contact with experts would create efficiencies. Although there is an opportunity to implement this advanced pharmacy technician role to help accelerate biosimilar implementation, only 33% responded that they utilize pharmacy technicians to complete prior authorizations and coordinate copay assistance programs. According to the ASHP National Survey of Pharmacy Practice in Hospital Settings: Workforce—2022, 20% of all hospitals reported pharmacy technicians involved in patient assistance program management.[10] Those who had implemented these strategies also said they were very likely to recommend them to their peers (Appendix A), which points to opportunities for consideration, including the opportunity to implement this advanced pharmacy technician role to help accelerate biosimilar implementation.

FIGURE 5. OPERATIONAL STRATEGIES (%)

TABLE 1. TOP THREE TECHNOLOGY STRATEGIES

1. Create a biosimilars adoption dashboard
2. Develop therapy-specific plans and order sets in the electronic health record (EHR) for each biosimilar based on preferred therapies
3. Integrate prior authorization information in the EHR that follows the tiered structure at the point of prescribing and includes requirements (e.g., failure or intolerance of other therapy, laboratory parameters)

PATIENT CARE AND FORMULARY MANAGEMENT STRATEGIES

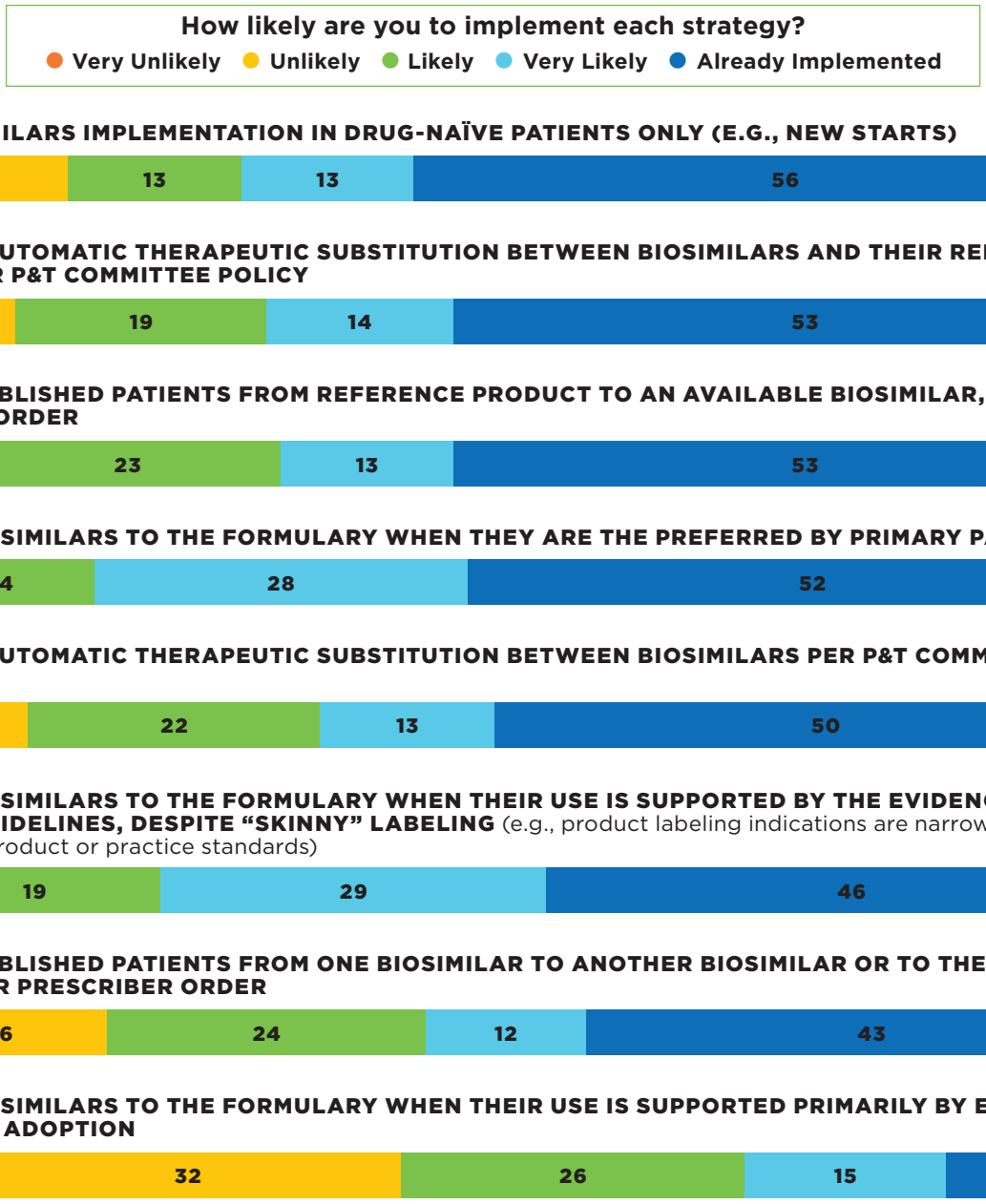
KEY POINTS

- The top patient care and formulary management strategy implemented is starting biosimilars on drug-naïve patients (e.g., new starts).
- Health-system formulary decisions are complex and include considerations around contracting, payer formulary decisions, and medication- and patient-specific factors.
- Indicated as already implemented by just over half of the panelists, there is an opportunity for health systems to evaluate the implementation of therapeutic substitution between biosimilars and their reference product.

There are several formulary management considerations when implementing biosimilars within a health system. These include the need to stock payer-preferred products, consideration of revenue impact, and reconciling product labeling with the evidence. Furthermore, prescribers need to be confident that their patients will not see an increase in their out-of-pocket costs and that the biosimilar will be both safe and effective. Generally, prescribers are more comfortable with implementing biosimilars in drug-naïve patients rather than established patients, with over 50% of our panelists indicating that they had implemented biosimilars in this patient population (Figure 6).[4] Therapeutic substitution between biosimilars and the reference product, as well as between biosimilars, was also a strategy implemented by half of the panelists, and over 90% of those who had already implemented it indicated they would recommend it to their peers (Appendix A). Overall, there seems to be an opportunity to expand existing formulary management tools to support the implementation of biosimilars.

"There doesn't seem to be a one-size-fits-all formulary management strategy and decisions may need to consider payer and revenue implications, patient access, and physician confidence."

FIGURE 6. PATIENT CARE AND FORMULARY STRATEGIES (%)



PATIENT ENGAGEMENT STRATEGIES

KEY POINTS

- The top implemented strategies to engage patients included equipping clinical pharmacists and physicians with talking points for patients, creating standardized, foundational information when there is a planned biosimilar change, and allowing adequate time for the patient conversation.
- There is a significant opportunity to expand patient engagement strategies for implementing biosimilars.

The strategies included in this section were implemented by less than half of the panelists. This may be because patient engagement activities occur in other areas of the health care delivery system or prescriber confidence, payer formulary decisions, and cost-sharing are considered more important. Only 17% of panelists indicated that there was follow-up communication with patients to ask them about their experiences and address any concerns (Figure 7). However, this may occur outside of the pharmacy or by the specialty pharmacy. The advisory committee strongly agreed that there is a significant opportunity to increase activities related to patient engagement and interest in strategies (i.e., responding likely or very likely), such as creating customizable medication information, equipping clinicians with talking points for patients, and following up with patients regarding their experience and outcomes.

Although the numbers already implemented were small across all strategies, a large percentage (>90%) of those panelists were likely or very likely to recommend these strategies to their peers. Health-system pharmacists would have a prominent role in implementing most of these strategies (Appendix A).

"Patients need to be assured and supported across care settings when biosimilars are initially prescribed or switched, and this will be even more relevant when changes are made with self-injectables, which may be more apparent to the patient."

FIGURE 7. PATIENT ENGAGEMENT STRATEGIES (%)

EQUIP CLINICAL PHARMACISTS AND PHYSICIANS WITH TALKING POINTS FOR PATIENTS (e.g., similar to generic switches, reassure them there was a rigorous FDA review process)

CREATE STANDARDIZED, FOUNDATIONAL INFORMATION WHEN THERE IS A PLANNED BIOSIMILAR CHANGE, AND CUSTOMIZE IT TO THE INDICATION OR SITUATION (e.g., established therapy vs. new starts)

ALLOW FOR ADEQUATE TIME DURING THE PATIENT ENCOUNTER FOR THE PRESCRIBER AND PATIENT CONVERSATION WHEN CONVERSION TO A BIOSIMILAR IS PLANNED

PROVIDE TIMELY WRITTEN COMMUNICATION TO PATIENTS PRIOR TO A PLANNED CHANGE CURRENT TREATMENT TO A PREFERRED BIOSIMILAR

PROACTIVELY DETERMINE WHICH PRODUCT THE PATIENT SHOULD RECEIVE ON THEIR NEXT VISIT AND DISCUSS OPTIONS WITH THE PATIENT IN ADVANCE

FOLLOW-UP WITH PATIENTS AFTER TREATMENT TO ASK ABOUT THEIR EXPERIENCE AND ADDRESS ANY CONCERNS

CONNECT PATIENTS WITH OUTSIDE INFORMATIONAL RESOURCES (e.g., patient-facing organizations and patient champions already on a biosimilar)

PAYER ENGAGEMENT AND POLICY STRATEGIES

KEY POINTS

- Two of the top strategies describe opportunities to directly engage with payers, including working with your own organization's internal managed care/payer contracting team and having an ongoing dialog with primary payers on their pending policy changes.
- There is an opportunity to provide feedback to the organization on payer performance by reviewing prior authorization requests and denials for specific issues or trends (e.g., certain prescribers/facilities requesting the reference product, adverse events).
- Incentives for implementation need to align with savings achieved with all stakeholders, including patients.

Only 20% of panelists indicated they had come together with the payer to remove barriers (e.g., eliminating prior authorization, reducing patient cost-sharing) when biosimilars are ordered rather than reference products. However, the responses indicated an interest in implementing these strategies (Figure 8), revealing an opportunity for health-system pharmacists to become more proactive in their organizations' contracting process and building a dialogue with payers, a strategy that has also been recommended by a convening of pharmacy executive leaders.[11] Bringing pharmacy's expertise to the table will help to align drug contracting and formulary management with organization goals and will engage caregivers and bring the patient experience into the conversation. Given the high cost and stakes with biosimilars, this seems to be a natural fit for pharmacy to develop an active role. Advisory committee members indicated that the ability to work proactively with payers is highly dependent on the regional insurance providers, and the role may be outside of the pharmacy. It was suggested that pharmacists could contact their internal plan liaisons to help build those relationships.

"Health systems need to see what payers are going to do in the upcoming months, and hopefully weigh-in. They're in discussions now (in September) about the formulary updates coming in January."

FIGURE 8. PAYER ENGAGEMENT STRATEGIES (%)

WORK WITH YOUR ORGANIZATION'S INTERNAL MANAGED CARE/PAYER CONTRACTING TEAM WHEN NEGOTIATING CONTRACTS

REVIEW PRIOR AUTHORIZATION REQUESTS AND DENIALS FOR SPECIFIC ISSUES OR TRENDS (e.g., certain prescribers/facilities requesting the reference product, adverse events)

DEVELOP AND MAINTAIN AN ONGOING DIALOG WITH PRIMARY PAYERS ON THEIR PENDING POLICY CHANGES

COMMUNICATE WITH PAYERS TO PROVIDE ADVANCE NOTICE TO YOUR ORGANIZATION TO ALLOW TIME TO COORDINATE IMPLEMENTATION WITH THE PRESCRIBERS (e.g., change education materials, order sets, provide staff education, etc.)

WORK TOGETHER WITH THE PAYER TO REMOVE BARRIERS (e.g., eliminating prior authorization, reducing patient cost-sharing) when biosimilars are ordered rather than reference products

ENTER A VALUE-BASED OR OUTCOMES-BASED CONTRACT WITH A PAYER

WORK WITH PAYERS TO ALIGN PERFORMANCE METRICS

PHARMACISTS' ROLES IN BIOSIMILARS IMPLEMENTATION

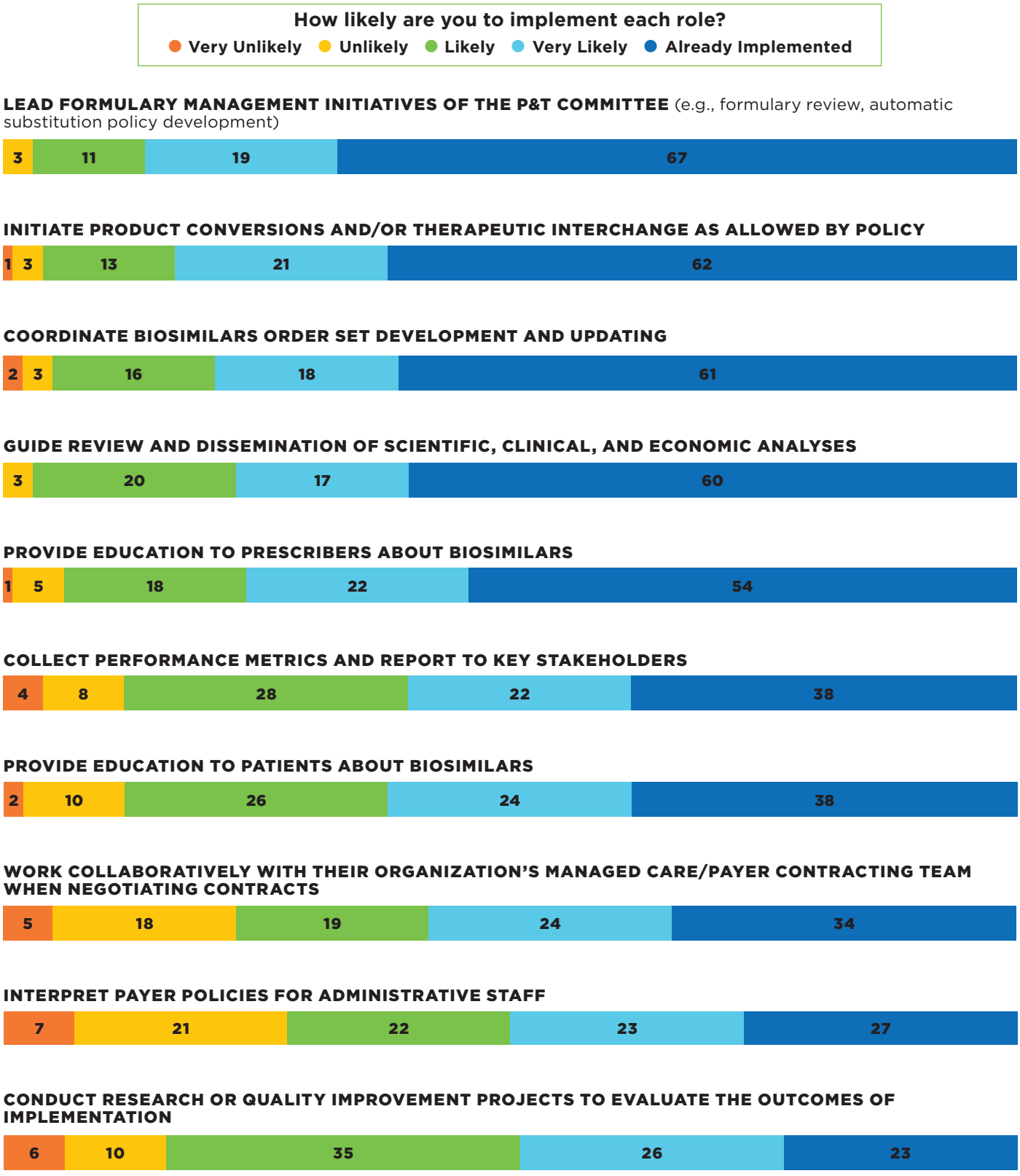
KEY POINTS

- Top roles for pharmacists included traditional functions, such as leading formulary management initiatives of the P&T committee (e.g., formulary review, automatic substitution policy development) and initiating product conversions and/or therapeutic interchange.
- The pharmacy has a role in coordinating biosimilar order set development and updating the technology supports.
- Areas of future opportunity include more involvement in patient education, developing performance dashboards, and working with payers and the contracting team.

The top roles for pharmacists cited as implemented include operational support and formulary review (leading formulary management initiatives for the P&T Committee) and guiding review and dissemination of the evidence and analysis (67% and 60% implemented, respectively) (Figure 9). Operational support roles, including initiating product conversions and therapeutic interchange, as well as coordinating biosimilar order set development and updating, have been implemented by 62% and 61% of panelists, respectively. Additional roles likely to be implemented include conducting research or quality improvement projects, collecting performance metrics, and reporting outcomes to key stakeholders.

The survey results indicate pharmacists may be able to develop a more substantial role in payer and policy strategies within organizations, with less than half of organizations indicating a role in these areas. However, those who had implemented those roles were likely or very likely to recommend those roles to their peers, including interpreting payer policies for administrative staff and working collaboratively with their organization's managed care/payer contracting team when negotiating contracts. There is a strategic opportunity to broaden pharmacy leadership to achieve payer alignment with organization goals. Finally, survey results indicate an opportunity for pharmacists to advance their role in patient and physician education about biosimilars. In the future, there will continue to be the launch of several biosimilar products that may vary regarding formulation, concentration, and interchangeability status and require pharmacists to lead education efforts and develop workflows to ensure the best outcomes for patients.[12]

FIGURE 9. PHARMCISTS' ROLES (%)



OPPORTUNITIES FOR PRACTICE AND RESEARCH

The data suggests several areas that are opportunities for practice and research related to biosimilar implementation, including expansion of pharmacist roles, enhanced implementation support, and alignment of incentives that include the patient (Table 2). In a recent ASHP survey of health-system specialty pharmacists, expanded use of biosimilars was the highest-rated opportunity for practice in the next one to five years.[13] Roles for pharmacists and pharmacy technicians are evolving in this space. There are opportunities to provide strategic leadership when implementing biosimilars and strengthen the collection and monitoring of performance metrics and application of technology. While pharmacy technicians have been incorporated into some activities, such as obtaining medication assistance or prior authorization, organizations can explore additional roles to enhance operational efficiencies. As new biosimilars are marketed, providers and patients will need additional education and resources to support implementation, access, and adherence. Another opportunity for pharmacists is to conduct and disseminate real-world evidence on using biosimilars. Finally, pharmacists must continue to monitor this evolving marketplace and new partnerships shaping the industry, such as where payers are purchasing manufacturing capabilities.[3,14] There are also policy changes on the horizon that may remove some barriers to biosimilar implementation, including changes in Medicare reimbursement for 340B drugs that currently can favor the reference product and opportunities to streamline the prior authorization process.[16] Policy changes do need to provide incentives for implementation that align for all stakeholders, including passing savings on to patients, whether in the form of reduced co-pays or premiums. Finally, it is important that rules and regulations at the state level such as those that apply to interchangeability, remain relevant and support efficiency while optimizing the benefit to patients.[12] Pharmacists are uniquely positioned to take a leadership role as experts in their organizations on the evolving biosimilar marketplace and, most importantly, to ensure maximum benefit to patients.

TABLE 2. OPPORTUNITIES FOR PRACTICE AND RESEARCH

EXPAND PHARMACY WORKFORCE ROLES

- Conduct practice-based research
- Explore opportunities for pharmacy technician support in medication assistance and prior authorization processes
- Collect and monitor performance measures, including patient outcomes

DEMONSTRATE STRATEGIC LEADERSHIP

- Optimize the application of technology that supports implementation
- Develop relationships with payers and health-system contracting team
- Understand the implications of new supplier-manufacturer partnerships

ADVOCATE FOR PATIENT ACCESS

- Document the importance of access to 340B pricing
- Ensure incentive models and resulting savings reach the patients/consumer
- Advocate for greater process efficiencies, such as streamlined prior authorization processes and state-level support for interchangeability

SUMMARY

Many strategies can support the implementation of biosimilars with the opportunity to expand access and reduce healthcare costs. The survey results show that many strategies have been applied in practice and those who have implemented would recommend many to their peers. Pharmacists have an opportunity to lead as experts within their organization by implementing strategies to advance operations, formulary management, patient and provider engagement, and payer alignment to support the safe and effective implementation of biosimilars.

Acknowledgements and Disclosures

This report is part of an ASHP Foundation project sponsored by Viatris Inc.

REFERENCES

1. American Hospital Association. Massive Growth in Expenses and Rising Inflation Fuel Continued Financial Challenges for America's Hospitals and Health Systems. April 2022. Accessed October 2, 2023. https://www.aha.org/guidesreports/2023-04-20-2022-costs-caring
2. NORC at the University of Chicago. Understanding Stakeholder Perception of Biosimilars. (2021 April 4). Accessed on April 10, 2022 at https://www.norc.org/PDFs/Biosimilars/20210405_AV%20-%20NORC%20Biosimilars%20Final%20Report.pdf
3. Vizient Pharmacy Outlook. Summer 2023. Accessed September 24, 2023. https://campaigns.vizientinc.com/flipbook/202307-PMO/
4. Cardinal Health. Cardinal Health 2023 Biosimilars Report. Tracking Market Expansion and Sustainability Amidst a Shifting Industry. Accessed on September 23, 2023. https://www.cardinalhealth.com/en/product-solutions/pharmaceutical-products/biosimilars/biosimilars-report.html
5. ASHP Foundation. Accelerating the Adoption of Biosimilars. Accessed on September 23, 2023. https://ashpadvantagemedia.com/adoptbiosimilars/files/ASHP_Biosimilars_Report_FINAL.pdf
6. Bond AM, Dean EB, Desai SM. The Role of Financial Incentives in Biosimilar Uptake in Medicare: Evidence from the 340B Program. Health Aff (Millwood). 2023;42(5):632-641. doi:10.1377/hlthaff.2022.00812
7. Biosimilars in the United States 2023-2027: Competition, savings, and sustainability. IQVIA Institute for Human Data Science. January 2023. Accessed on September 24, 2023. https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2023-2027
8. Park J, Woolett G. Designation of Interchangeability (IC) for Biosimilars in the US: To Be IC or Not IC? That Is the Question. Pharmacy Times. September 14, 2023. (Accessed on September 24, 2023.) https://www.pharmacytimes.com/view/designation-of-interchangeability-ic-for-biosimilars-in-the-us-to-be-ic-or-not-ic-that-is-the-question
9. Yin Y, McDermott C, Lockhart C. Real-world switching and discontinuation outcomes of infliximab biosimilars in patients with rheumatoid arthritis: A scoping review. J Manag Care Spec Pharm. 2023;29(9):985-998. doi:10.18553/jmcp.2023.29.9.985
10. Pedersen CA, Schneider PJ, Ganio MC, Scheckelhoff DJ. ASHP National Survey of Pharmacy Practice in Hospital Settings: Workforce - 2022. Am J Health Syst Pharm. 2023;80(12):719-741. doi:10.1093/ajhp/zxad05
11. ASHP Pharmacy Executive Leadership Alliance (PELA®) Symposium: Service Line Business Development and Payer Engagement. Am J Health Syst Pharm. 2023;80(16):1106-1110. doi:10.1093/ajhp/zxad110
12. Cisek S, Choi D, Stubbings J, Bhat S. Preparing for the market entry of adalimumab biosimilars in the US in 2023: A primer for specialty pharmacists. Am J Health Syst Pharm. 2023;80(18):1223-1233. doi:10.1093/ajhp/zxad120
13. Kelley TN, Canfield S, Diamantides E, Ryther AMK, Pedersen CA, Pierce G. ASHP Survey of Health-System Specialty Pharmacy Practice: Practice Models, Operations, and Workforce-2022 [published online ahead of print, 2023 Sep 24]. Am J Health Syst Pharm. 2023;zxad235. doi:10.1093/ajhp/zxad235
14. Barrie R. Pharmaceutical Technology. CVS Health enters biosimilar fray with launch of new subsidiary. August 24, 2023. (Accessed online 10/2/23) https://www.pharmaceutical-technology.com/news/cvs-health-enters-biosimilar-fray-with-launch-of-new-subsidiary/
15. Luo J, Gellad WF. Electronic Prior Authorization for Prescription Drugs - Challenges and Opportunities for Reform. N Engl J Med. 2023;388(10):867-870. doi:10.1056/NEJMp2214620

APPENDIX A. BIOSIMILAR IMPLEMENTATION STRATEGIES

Biosimilar Implementation Strategies	Already Implemented*	Very Likely to Recommend
Operational Strategies		
Develop therapy-specific plans and order sets in the electronic health record (EHR) for each biosimilar based on preferred therapies.	112	84%
Have a centralized authorization team that obtains and facilitates prior authorizations for biosimilars.	96	80%
Report performance to the Pharmacy and Therapeutics (P&T) Committee (or designated committee).	84	83%
Identify physician champion(s) to support the work and deliver the message to key stakeholders, including other physicians in the organization.	73	85%
Utilize pharmacy technicians to complete prior authorizations and coordinate copay assistance programs.	62	85%
Create a biosimilar adoption dashboard to track and report progress.	62	82%
Integrate prior authorization information into the EHR that follows the tiered structure at the point of prescribing and includes requirements (e.g., failure or intolerance of other therapy, laboratory parameters, etc.).	60	87%
Establish a subcommittee for each therapeutic area to review biosimilars for formulary addition and monitor their use.	59	75%
Present successes and lessons learned to departments impacted by conversions (e.g., gastroenterology, rheumatology, and ophthalmology).	45	78%
Formulary Strategies		
Begin biosimilar implementation in drug-naïve patients only (e.g., new starts).	107	82%
Switch established patients from reference product to an available biosimilar, per prescriber order.	102	74%
Implement automatic therapeutic substitution between biosimilars and their reference product per P&T Committee policy.	101	88%
Add new biosimilars to the formulary when they are preferred by primary payers.	99	84%
Implement automatic therapeutic substitution between biosimilars per P&T Committee policy.	96	88%
Add new biosimilars to the formulary when their use is supported by the evidence and/or national guidelines, despite “skinny” labeling (e.g., product labeling indications are narrow compared to the reference product or practice standards).	89	79%
Switch established patients from one biosimilar to another biosimilar or to the reference product, per prescriber order.	82	77%
Add new biosimilars to the formulary when their use is supported primarily by European studies and adoption.	31	90%

Biosimilar Implementation Strategies	Already Implemented*	Very Likely to Recommend
Patient Engagement Strategies		
Equip clinical pharmacists and physicians with talking points for patients (e.g., similar to generic switches, reassure them there was a rigorous FDA review process).	75	91%
Create standardized, foundational information when there is a planned biosimilar change, and customize it to the indication or situation (e.g., established therapy versus new starts).	70	89%
Allow for adequate time during the patient encounter for the prescriber and patient conversation when conversion to a biosimilar is planned.	51	78%
Provide timely written communication to patients prior to a planned change of current treatment to a preferred biosimilar.	47	77%
Proactively determine which product the patient should receive on their next visit and discuss options with the patient in advance.	41	83%
Follow up with patients after treatment to ask about their experience and address any concerns.	33	94%
Connect patients with outside informational resources (e.g., patient-facing organizations and patient champions already on a biosimilar).	32	81%
Payer Engagement Strategies		
Work with your organization's internal managed care/payer contracting team when negotiating contracts.	64	83%
Review prior authorization requests and denials for specific issues or trends (e.g., certain prescribers/facilities requesting the reference product, adverse events).	61	89%
Develop and maintain an ongoing dialog with primary payers on their pending policy changes.	56	77%
Communicate with payers to provide advance notice to your organization to allow time to coordinate implementation with the prescribers (e.g., change education materials, order sets, provide staff education, etc.).	43	88%
Work together with the payer to remove barriers (e.g., eliminating prior authorization, reducing patient cost-sharing) when biosimilars are ordered rather than reference products.	37	86%
Enter a value-based or outcomes-based contract with a payer.	28	82%
Work with payers to align performance metrics.	24	92%

* *This column displays the number of those who responded "Already Implemented." The number of panelists who scored "likelihood to implement" for each item ranged from 184–195.*

About the ASHP Foundation

The ASHP Foundation was established in 1968 by ASHP as a nonprofit, tax-exempt organization. As the philanthropic arm of ASHP, the Foundation shares ASHP's vision that medication use will be optimal, safe, and effective for all people, all of the time. Our mission is to support ASHP by advancing the professional practice of pharmacists and the pharmacy workforce by funding research and education that improves health outcomes through optimal, safe, and effective medication use. To learn more about the Foundation's programs, visit **ashpfoundation.org**.

4500 East-West Highway, Suite 900
Bethesda, Maryland 20814

ashpfoundation.org

@ASHPFoundation @ASHPFoundation

The ASHP Foundation is a 501(c)3 nonprofit organization, and all contributions are tax deductible to the extent allowed by law.