



Bridge the GHAPP

Gastroenterology & Hepatology
Advanced Practice Providers

NEWSLETTER

VOLUME 4

LETTER FROM THE CHAIR

Dear GHAPP Family,

We are ramping up for our GHAPP Fifth Annual Conference happening next month from September 29th through October 1st in Nashville, Tennessee. Our objective for the annual national GHAPP conference is to bring together Advanced Practice Providers from across the nation for an in-depth review and discussion on the latest developments and current concepts for patients with GI disorders and chronic liver disease.

Be sure to read the article by Nicole describing additional conference highlights.

In this issue, we are fortunate to present 2 featured articles. Sharon delivers an outstanding synopsis on Biosimilars, and Allysa provides an excellent overview on Covid-19 and the Liver. Thank you both for your contributions to this issue.

If you are not a member of GHAPP, we would love for you to join. Exclusive Membership includes daily news on GI and liver disease topics, access to an abstract library updated weekly, educational programs and on-demand materials, and information from our faculty and expert team. Within our website, we have a learning center with a fantastic number of resources at your fingertips to learn more about GI and liver disease best practices. Best of all, it is FREE!

There are so many ways to become involved with GHAPP. We need YOU and your expertise. We are looking for members to serve on the following committees: Member Engagement Committee, Evidence-Based Practice and Research Committee, Education Committee, and Publication Committee. In addition to committee work, please let us know of your interest in becoming a faculty member with us. We have opportunities for abstract reviewers, education event planning, and speakers.

Remember, we are on this journey together!

All my best,

Amanda

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COMMITTEE NEWS

Member Engagement Committee (MEC)

The GHAPP MEC is excited to announce that we will expand to include more committee members. Applicants will be reviewed, and those chosen will move forward to be approved by the Board of Directors. Their new term will begin during the Annual Conference.

For the 5th Annual GHAPP Conference, the MEC committee plans to continue holding prior events that proved to be successful in the past, including the New Attendee/Member Social Hour and yoga. The Social Hour event will allow new GHAPP participants to mingle with peers. Yoga was so popular last year that registration for the event has already maxed out this year!

If you are a new GHAPP member and/or a first-time attendee at the conference, please make sure to reach out to one of the MEC committee members and visit the MEC table so that we can welcome you to the GHAPP family! We strive to make everyone feel welcome and supported to foster an engaging experience for our members.

Our Member Spotlight is shared across GHAPP professional social media platforms including Twitter, Instagram, and Facebook. **If you would like to nominate a colleague, please contact Katherine Meneses @ KMeneses@mednet.ucla.edu. Thank you!**

Congratulations to our 2022 Member Spotlights

January - Jordan Mayberry, PA, UT Southwestern, Dallas, TX

February - Allison Hobbs, MSN, APRN, FNP-C, University of Louisville, KY

March - Nana Bernasko CRNP, DNP, WHNP-BC, Penn State Hershey Medical Center, PA

April - Geo Mathew, PA-C, Digestive Disease Center, Bakersfield, CA

May - Christen Craig, NP-C, Kansas City Gastroenterology and Hepatology Physician Group, Kansas City, MO

June - Tracy Gowan, MSN, APRN, FNP-C, University of Louisville Health Hepatitis C Center, Louisville, KY

July - Maribel Torres, FNP, Adventist Health Specialty Clinic, Hanford, CA

August - Shannon J. Todd PA-C, MHS, MPAS, Henry Ford Health, Grand Rapids, MI

September - Michelle Jenkins, PA-C, MedStar Georgetown Transplant Institute, Fairfax, VA

Evidence-Based Practice & Research (EBP/R) Committee

During the annual GHAPP Conference, be on the lookout for information on the upcoming **GHAPP Mentorship Program**. You may sign up to participate as a mentor or mentee online or at the GHAPP booth in the exhibit hall. The program is one year. Mentors and mentees will be matched based on mutual interests. The sign-up period runs through the fall of 2022, and the formal program begins in January 2023. Details can be found at GHAPP.org.

Please watch your inbox for the **GHAPP Needs Assessment survey**. The 19-item questionnaire will help GHAPP leadership better understand who our members are, what needs should be addressed, what GHAPP is doing well, and what else might interest you as a GHAPP participant. Please take 5-10 minutes to respond to the questionnaire.

Have you signed up for the workshop, "**How to Rock a Literature Review: Strategies to Conduct a Search and Critique the Evidence**," taking place at the annual conference on Thursday, September 29, from 5-7 pm? The EBP/R Committee is excited to host and facilitate this workshop. If you are interested in learning new skills or brushing up on best practices related to literature searches and critique, this workshop is for you! More information is available at ghapp.org.

Our APPs have been quite busy disseminating research, quality improvement, and other work products through publications! Several GHAPP members presented posters in May at the Digestive Disease Week Conference. **Barbra Cave, PhD, APRN, Tracy Gowan, APRN, and Allison Hobbs, APRN** from the University of Louisville and UofL Health, presented "Implementation of CDC Guidelines for Universal Screening for Hepatitis C and HIV, and Pre-Exposure Prophylaxis Implementation in a Single-Center Kentucky Hospital" and **Glenda Quinones, DNP, APRN**, University of Miami, presented "Knowledge Awareness of Depression Screening in Individuals with Chronic Liver Disease among Healthcare Providers in Miami, Florida: A Quality Improvement Project." **The entire EBP&R Committee** had an abstract accepted at the American College of Gastroenterology (ACG) conference to be presented in October entitled "Getting to Know Our Membership: The Gastroenterology and Hepatology Advanced Practice Providers." **Mackenzie McArthur, MPAM, DMSc, PA-C**, Atrium Health, had three additional abstracts accepted to ACG: "Neurogenic Bowel Dysfunction: A Healthcare Disparity," "Health Care Professional's Bowel Management Practices for Neurogenic Bowel Dysfunction: Development of a Web-Based Survey," and "Abnormal Glucose Breath Test Does Not Correlate With Patient's Self-Reported Symptoms and Their Severity." **Renee Pozza, PhD, CNS, FNP-BC**, Azusa Pacific University, delivered a podium presentation at the AANP National Conference in June entitled "Fatty Liver Disease: Best Practices for the Nurse Practitioner" and was a co-author of the manuscript "Efficacy and Safety of a Botanical Formula Fuzheng Huayu for Hepatic Fibrosis in Patients with CHC: Results of a Phase 2 Clinical Trial" in *Evidence-Based Complementary and Alternative Medicine*.

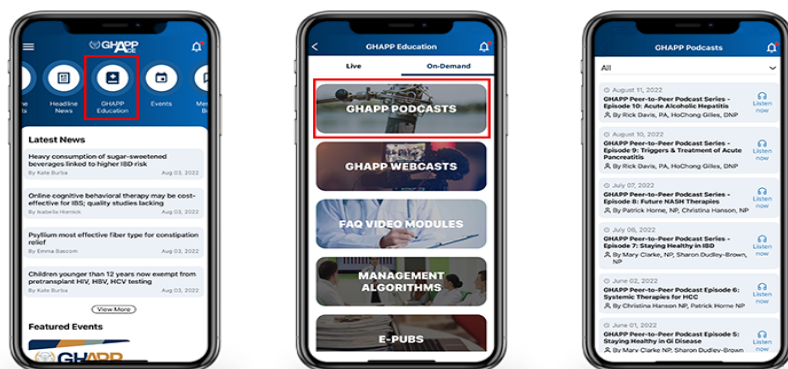
Glenda Quinones, DNP, APRN, was honored with the APRN/CRNA of the Year by the University of Miami for consistently demonstrating excellence in practice. Congratulations, Glenda!

**If you have an abstract or manuscript accepted for publication,
please share your good news with GHAPP by
emailing info@ghapp.org**

Education Committee

2022 has been a great year for live programming! We are pleased to have hosted approximately **475** existing or new GHAPP members at the **10** regional meetings! The education presented by our expert faculty was rated outstanding, and the peer-to-peer interaction was immensely appreciated.

To date, our esteemed faculty has hosted 8 Peer-to-Peer Podcasts on various GI and Liver related topics. They are fantastic! You can catch these informative podcasts on the GHAPP ACE App >Education >On Demand tab.



We look forward to seeing everyone at the GHAPP National meeting this Fall. If you cannot attend this year, there are always opportunities for peer-to-peer education throughout the year. Please continue to visit The GHAPP website @ www.ghapp.org.

If you are interested in joining the Education Committee, the application can be found at: <https://podio.com/webforms/27387820/2115590>

Publication Committee

The Publication Committee is looking for new members for the upcoming term. The term for new members will begin during the annual conference. The application to apply can be found via the Publication Committee link: <https://podio.com/webforms/27387416/2115571>

5th ANNUAL NATIONAL CONFERENCE HIGHLIGHTS

Nicole Martinez de Andino, RD, APRN

Just around the corner is the 5th Annual National Conference, running **Thursday, September 29th through Saturday, October 1st**. What's new with this year's conference? Lots of things, including a new location! Take advantage of this year's southeastern location, Nashville, TN. Nashville is not only America's Music City but also bursting with breweries, creative culinary options, shopping, and sporting events. In fact, it was named one of the top US cities for a weekend trip by *Thrillist*.

Inside the conference are several new offerings, including boot camps and specialty development workshops. The ABCs of IBD will cover the basics to prepare us for caring for our patients with inflammatory bowel disease. Topics include pathophysiology, diagnosis and management, and tips for working with special populations. This boot camp will be offered at the start of the conference on Thursday afternoon—an excellent foundation for the main conference’s IBD sessions. If you are ready to rock in Music City, sign up for the Evidence-Based Practice and Research committee’s How to Rock a Literature Review workshop for tips to critique existing data sources and literature and strategies for writing a review. Learn from your colleagues about self-care, billing and coding, salary negotiating, and presentation skills, all covered in the Professional Development workshop. The conference will wrap up Saturday with Hepatology 101 boot camp. Designed to introduce and/or reinforce hepatology topics many of us encounter in our practice. Viral hepatitis, fatty liver disease management, liver function tests, cirrhosis management, and bile duct disease will be covered in the 2-hour course.

FEATURED ARTICLE: A Brief Update on Biosimilars for GHAPP

Sharon Dudley-Brown, PhD, FNP-BC, FAAN

In the field of gastroenterology and hepatology it is well known that biologics have changed the treatment landscape for patients with inflammatory bowel disease (IBD), enabling more patients to achieve and maintain remission, and obtain improved quality of life (Buchner, Schneider & Lichtenstein, 2021). This article will briefly describe biosimilars and their use in patients with IBD.

As part of the affordable care act (ACA), passed in 2010, the notion of biosimilars began in the US, creating an abbreviated pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product (US Food and Drug Administration, 2018). While there are multiple FDA-approved biosimilars in the US, few are currently commercially available.

A biosimilar is a non-patented biologic that is highly similar to, and with no clinically meaningful differences from an already FDA-approved, patented biologic agent, also referred to as the reference product (a.k.a. originator or innovator) (Buchner et al, 2021; Vakil & Fanikos, 2019). Biosimilars are not generic drugs, but they serve in a similar capacity in that they may provide a cost-effective alternative to biologic therapy, thereby improving access to treatment for patients across a

multitude of diseases, including IBD (Sheldon, 2021).

Some key points about biosimilars are as follows: 1) they have been shown to be highly similar to the reference product in extensive comparative analytical studies, and 2) they must demonstrate similar efficacy and safety compared to the reference product in that no differences in safety or efficacy are expected. Interestingly, there are extrapolations of indications for biosimilars such that clinical efficacy and safety have already been demonstrated by reference product, eliminating the need to demonstrate the efficacy of a biosimilar in all indications (US Food and Drug Administration, 2015, 2018).

While recommendations for starting biologics in patients with IBD include the choice of starting on a biosimilar, the notion of switching off the reference product to a biosimilar has been more controversial in the rheumatology and gastroenterology fields than in others. For example, in IBD, many insurance companies and pharmacy benefit managers (PBMs) (companies that manage prescription drug benefits on behalf of health insurers) have required nonmedical switching from a reference product to a biosimilar (to date, solely in reference to infliximab). This non-medical

switching is mandatory, and few exceptions are allowed, such as instability of the patient's clinical condition and pregnancy (Sheldon, 2021).

Efficacy and safety data from switching studies in both rheumatology and gastroenterology have generally shown no differences between biosimilars and their originator biologics, but additional data are needed to explore potential switching risks in various populations and scenarios. Specific to IBD, accumulating evidence supports the safety and efficacy of biosimilars to treat IBD, and single-switch studies in IBD support the switch between reference infliximab and biosimilar infliximab. However, other than case reports, there is little evidence of multiple switches in patients with IBD to date.

Because more studies are needed on switching from reference to multiple biosimilars or vice versa, the FDA has designed the notion of interchangeability. Interchangeability means that the interchangeable product is expected to produce the same clinical result as the reference product in any given patient and that switching between the interchangeable biosimilar reference product does not increase safety risks or decrease effectiveness compared to using the reference product without such switching between products. This notion of interchangeability allows a product to be substituted for the originator biologic without the prescriber's approval at the pharmacist level, and it has been legislated in the US on a state-by-state basis. There is currently one interchangeable biosimilar for adalimumab, and it will be commercially available in 2023 in the US (US Food and Drug Administration, 2018).

Benefits of Biosimilars

In Europe (the EU is currently the most advanced biosimilar market worldwide) and other countries outside the US, biosimilars offer cost savings. It is thought that the savings realized by using biosimilars may be redirected to pay for novel therapies that address unmet needs. However, it is not clear whether the cost benefits will benefit patients in the US. On a theoretical basis, overall

cost savings may help improve the acceptance of biosimilars and benefit the rising costs of medical care in the US (Sheldon, 2021).

Patient Education

Patient education on the use of biosimilars is important because more biosimilars will be available in the US in 2023, including those for the reference product adalimumab. There is evidence from the field of rheumatology that proactive discussions with patients regarding the use of and switch to biosimilars improve their acceptance and tolerability. The use of shared decision-making and conversations that incorporate positive framing may help increase patient satisfaction and enhance adherence to biosimilars in IBD. Patient perception and acceptance are critical to the uptake and adherence to these biosimilars (Sheldon, 2021). Both the AGA and the CCF have patient education materials relevant for IBD patients (see box).

Summary

There are no clinically meaningful differences between biosimilars and their reference products in terms of safety, efficacy, purity, and potency; thus, biosimilars are safe and effective in the treatment of IBD. Because clinical efficacy and safety have already been demonstrated by the reference product, indications of a biosimilar are extrapolated to all indications of the reference product. The landscape of biosimilars for the management of IBD is growing in the US. It is therefore imperative that advanced practice providers be vigilant in their use of biosimilars in their IBD patients and remain abreast of the development and ongoing utilization of biosimilars, including the terms of interchangeability and switching.

Information for Patients & Providers:

American Gastroenterological Association:

<https://gastro.org/news/what-your-patients-need-to-know-about-biologics-and-biosimilars/>

Crohn's & Colitis Foundation: <https://www.crohnscolitisfoundation.org/what-is-ibd/medication/biosimilars>

American Association of Nurse Practitioners (AANP):

<https://storage.aanp.org/www/documents/education/gastroenterology/AANP-Biosimilars-Patient-Tool.pdf>

Podcast: <https://aanp.podbean.com/e/46-biosimilars-changing-the-treatment-landscape-for-inflammatory-conditions/>

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Sheldon, L. K. (2021). Biosimilars for inflammatory conditions (Monograph for American Association of Nurse Practitioners (AANP)). <https://aanp.inreachce.com/SearchResults?searchType=1&category=7de589e2-ae34-4d2e-b7b6-1626bdb9193d>

US Food and Drug Administration. (2018). Guidance for industry. Biosimilars: Questions and answers regarding implementation of the Biologics Price Competition and Innovation Act of 2009. Department of Health & Human Services.

FEATURED ARTICLE: Updates on COVID-19 and the Liver

Allysa D. Saggese, MSN, AGPCNP-BC

With regards to Coronavirus Disease 2019 (COVID-19) and the liver, the concerns are multifaceted – direct viral effects on the liver, mental health effects, and isolation affecting timely medical care – to name a few. This article will briefly cover the research on both the direct and indirect effects of Coronavirus on liver disease.

There was an initial concern that COVID-19 would affect organs other than the lungs where ACE-2 is expressed, such as intestines, vascular endothelium, and cholangiocytes in the liver (Yadav, et al, 2020). However, despite initial findings that liver enzymes rose during active COVID-19 infection, it was determined to not be related to activation of the ACE-2 pathway (Bloom, et al, 2021; Jothimani, et al, 2020). Instead, potential drug-induced liver injury during treatment, ischemia, supportive care, or a general viral/illness reaction such as from cytokine storm is the more likely culprit and most often resolved with resolution of the illness or supportive care

(Jothimani et al, 2020; Rabiee et al, 2020). Another factor to take into consideration is a prior underlying liver disease, such as Non-Alcoholic Fatty Liver Disease (NAFLD), creating baseline elevations that may or may not have been known prior to illness (Rabiee et al, 2020).

For those with cirrhosis, they were found to have an increased risk of mortality due to the immunocompromised state caused by cirrhosis. The risk of poor outcomes from COVID-19 infection increases in those with decompensated cirrhosis (Martinez and Franco, 2021). Interestingly, it was found that “liver transplantation restores hepatic function in patients with decompensated cirrhosis, thus reducing the risk of COVID-19 mortality to that of the general population” (Martinez and Franco, 2021, p 1139). Additionally, those with cirrhosis had lower mortality risk from COVID-19 if they contracted the virus after vaccination (either partial or full) and were more likely to have better

outcomes if their cirrhosis was compensated versus decompensated (John, et al, 2022).

In those patients with NAFLD or Non-Alcoholic Steatohepatitis (NASH), studies found that they were at higher risk of COVID-19 morbidity and mortality, likely due to the coupled comorbidities of diabetes and obesity, known factors in COVID-19 risk and prognosis (Martinez and Franco, 2021). With this in mind, the importance of vaccination against COVID-19 becomes even more apparent in this population (Martinez and Franco, 2021).

When quarantines were first implemented, it was found that for every week of time spent at home, there was a 19% increase in binge drinking (Bloom and Fontana, 2021). Overall, after the first year of COVID-19, the increase in alcohol consumption led to about 8,000 new cases of alcoholic liver disease (ALD), and 18,000 cases of decompensated cirrhosis, according to one limited study (Julien, et al, 2021). This caused the rate of ALD for liver transplantation (LT) listing to increase beyond projections, though the overall rate of listing and transplantation did not change (2021). This was likely because those with other liver diseases were not seeking medical care for a period of time.

ALD now accounts for 40% of all newly listed patients, making it the leading indication for LT (Bloom and Fontana, 2021).

For patients with liver transplantation, studies have shown that both LT patients and non-LT patients tend to have similar risk of mortality from COVID-19 (Kulkarni, 2021). Among transplant patients, mortality was lower for those with LT than those with other organ transplantations (2021). Starting in late 2020 - early 2021, there was consideration for, and successful transplantation of, livers from donors who had active COVID-19, to recipients who were convalesced, and later on those who were vaccinated, as it did not appear that COVID-19 was transmitted in liver tissue, and patients could be protected from potential infection by having immunity (Romagnoli, 2021)

The impact of COVID-19 virus on those with liver disease is both direct, such as in treatment of COVID-19 and elevated liver enzymes, and indirect, as in the impact of increased substance use and avoidance of care. COVID-19 has also affected the delivery and pursuit of healthcare for patients, and the after-effects from these lost months will be felt for years to come.

Sources:

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EDUCATIONAL RESOURCE



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GHAPP ACE (Application for Clinical Exchange) is a medical-based platform that facilitates education, resources, and information for NPs and PAs who treat patients with GI and liver disorders – bringing advanced practice providers to one place, one app, to enhance knowledge in gastroenterology and hepatology.

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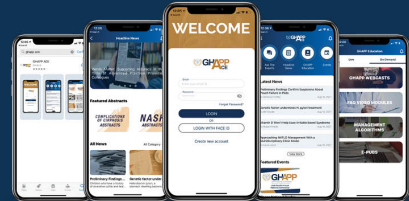


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