Primary Biliary Cholangitis: New Treatment Goals and Novel Salvage Therapy

1- Introduction

Primary biliary cholangitis (PBC) is a chronic, autoimmune disease characterized by an inflammatory T-cell mediated destruction against biliary epithelial cells. Studies have pointed to a combination of genetic risk factors and environmental triggers, as part of the etiology of PBC.\(^1,2\) It has its highest prevalence in white females, between 40 to 50 years of age, with recent studies showing an unexplained increase in prevalence as of recent years. It is worth noting that prevalence of the disease in other populations besides Caucasians has been hard to estimate given the rarity of the disease. Although it can present asymptomatically, the classical clinical features of PBC include fatigue, pruritus, and, in some cases, xanthelasma. Additionally, patients with PBC are at increased risk for hypercholesterolemia, metabolic bone disease, other autoimmune diseases, cirrhosis, and hepatocellular carcinoma (HCC) in those with cirrhosis. Diagnosis can usually be confirmed by the presence of the anti-mitochondrial antibody, a very specific auto-antibody against multi-enzyme complexes located in the inner mitochondrial membrane, if the usual clinical features of PBC and laboratory abnormalities are present.\(^1,2\)

Currently, ursodeoxycholic acid (UDCA), and obeticholic acid (OCA) are the only...
**Expert Point of View**

Primary Biliary Cholangitis: New Treatment Goals and Novel Salvage Therapy

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FDA approved treatments for PBC. Weight based UDCA is the current first line therapy, followed by the addition of OCA in those with an inadequate response to UDCA, or intolerance to it. Even with the addition of OCA, there are often cases where patients fail to achieve remission of disease. However, many new promising treatment targets have surfaced. Yet, treatment for PBC is currently a very active field of investigation, with various new mechanisms of actions and treatment targets emerging, leading to various clinical trials. In addition, as research points toward better outcomes with more conservative definitions of biochemical remission, treatment guidelines are starting to redefine goals of treatment for PBC patients.

2- Treatment of PBC: The Present
There are currently two FDA approved treatments for PBC: UDCA and OCA.

2.1 UDCA
UDCA is currently the standard first line therapy for PBC patients and has been demonstrated to significantly impact the course of disease. It is a synthetic bile acid with anti-inflammatory, immunomodulatory, and cytoprotective properties. It has additionally been shown to protect cholangiocytes from cholestatic injury by toxic bile acids, like chenodeoxycholic acid (CDCA). It is started at a dose of 13-15 mg/kg/day, initially divided in two doses though if tolerated it can be given once daily. Higher doses confer the same treatment efficacy with increased adverse events rates. Benefits include a reduction in progression to cirrhosis, as well as a decrease in the need for orthotopic liver transplantation (OLT) in PBC patients. It has also been linked to a decrease in LDL levels, development of varices, and slower histologic progression. In fact, patients that are started on UDCA in early stages of the diseases, tend to reach survival rates comparable to the general population. Approximately 40% of patients tend to have suboptimal responses to UDCA therapy which negatively impacts outcomes.2,5

2.2 OCA
OCA was approved by the FDA in May 2016, as a second line drug to be used in combination with UDCA non-responders (UDCA-NR), or as an alternative monotherapy for those who are intolerant to UDCA.2 It is a farnesoid X receptor (FXR) agonist, which leads to suppression of de novo bile acid synthesis and decreased conversion of cholesterol to bile acids. Other mechanisms include anti-inflammatory and anti-fibrotic properties, as well as decreased absorption, secretion, and metabolism of bile acids.2,5

Clinical trials have demonstrated a 25% to 53.9% drop in alkaline phosphatase (ALP) levels in patients started on treatment with OCA in comparison to placebo groups. Reduction in inflammatory markers has also been noted. Additionally, data suggests that the combination of UDCA and OCA could lead to a decrease in the 15-year cumulative incidence of cirrhosis, HCC, OLT need, and death due to liver related complications.2 OCA should be used with caution in patients with cirrhosis. The FDA issued a black box warning in February 2019, given instances of incorrect OCA dosing in cirrhotic patients leading to decompensation, acute liver failure, worsening PBC, and death.2,6

OCA is contraindicated in patients with cirrhosis and evidence of portal hypertension as well as those with decompensated cirrhosis (Child Pugh Turcotte B or C) or a history of prior decompensation.2,6

2.3 Fibrates
Fibrates work by activating the peroxisome proliferator activator receptor (PPAR) alpha. They are traditionally used to treat dyslipidemia. Activation of specifically the α isoform of this receptor, is involved in bile acid synthesis, as well as a decrease of bile acid reuptake by the liver, by inhibitions of transporters. It has also been described to have antithrombotic and anti-inflammatory effects.2,5

Bezafibrate and fenofibrate have been studied as possible treatments in PBC. Fenofibrate is FDA approved for treatment of dyslipidemia, while bezafibrate is not yet approved for use in the US. A meta-analysis by Zhang et al. shows that both drugs, in combination with UDCA, lead to significant improvement in various disease biomarkers (including ALP, liver enzymes, GGT, albumin levels, etc.).

Table 1. Scoring systems for assessment of response to UDCA

<table>
<thead>
<tr>
<th>Name</th>
<th>Response Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLOBE (8)</td>
<td>Bilirubin, ALP, albumin and platelet count 12 months. Age at baseline.</td>
</tr>
<tr>
<td>Paris-I (9)</td>
<td>ALP ≥ 3 X ULN or AST ≥ 2 X ULN or bilirubin = 1.0</td>
</tr>
<tr>
<td>Paris-II (10)</td>
<td>All three of the following: ALP &gt; 1.5 X ULN, AST 1.5 X ULN, bilirubin = 1 mg/dl after 1 year on UDCA</td>
</tr>
<tr>
<td>Rotterdam (11)</td>
<td>Bilirubin ≥ 1 X ULN and/or albumin &lt; 1 x ULN</td>
</tr>
<tr>
<td>Barcelona (12)</td>
<td>Decrease in ALP ≤ 40% and ALP ≥ 1.0 x ULN</td>
</tr>
<tr>
<td>Toronto (13)</td>
<td>ALP &gt; 1.67 x ULN after 2 years of UDCA</td>
</tr>
<tr>
<td>Rochester (14)</td>
<td>ALP ≥ 2 X ULN</td>
</tr>
</tbody>
</table>

Alkaline phosphatase, ALP, upper limit of normal, ULN; aspartate aminotransferase, AST; UDCA, ursodeoxycholic acid
as well as a reduction in the severity of pruritus, without an elevated rate of adverse events. Although fibrates decrease the GLOBE score (Table 1) in PBC patients with suboptimal response to UDCA resistance, survival and rate of OLT seem to be unaffected.2

As previously stated, American Association for the Study of Liver Diseases (AASLD) guidelines recommend fibrates as an alternative to OCA for second line therapy of UDCA-NR. However, they are contraindicated in patients with decompensated liver disease.6

3- Goals of Therapy in PBC

The first line of treatment for PBC is a trial of weight-based (13 mg/kg/day in divided doses) UDCA therapy. Treatment response to UDCA is assessed utilizing serum ALP and total bilirubin (TB) as surrogates for disease activity. Response is usually evaluated after one year of treatment with UDCA, using any of the response criteria described in Table 1. Besides being a UDCA-NR, alternative indications for the addition of a second agent include high risk for progression of disease or evidence of hepatic fibrosis and/or progression to cirrhosis. In those with the above indications, guidelines currently recommend the addition of 5 mg OCA with titration to 10 mg if the patient had adequate toleration but suboptimal response to OCA. Fibrates have recently emerged as an alternative second line of treatment. If failure to reach treatment goals still persists after addition of either of these agents, either OLT or clinical trials are considered. Given that both fibrates and OCA are contraindicated in patients with decompensated cirrhosis, these patients currently lack an established option for second line therapy, besides OTC.1,2,6 Table 2 summarizes the AASLD guideline statements for treatment of PBC.

Table 2. AASLD Guideline Recommendations for Treatment of PBC2,4

1. "UDCA in a dose of 13 to 15 mg/kg/day orally is recommended for patients with PBC who have abnormal liver enzyme values regardless of histologic stage."
2. "Biochemical response to UDCA should be evaluated at 12 months after treatment initiation to determine whether patients should be considered for second-line therapy."
3. "Patients who are inadequate responders to UDCA (Table 1) should be considered for treatment with OCA, starting at 5 mg/day."
4. "Fibrates can be considered as off-label alternatives for patients with PBC and inadequate response to ursodeoxycholic acid, although fibrates are discouraged in patients with decompensated liver disease."
5. "OCA is contraindicated in patients with advanced cirrhosis. This is defined as cirrhosis with current or prior evidence of liver decompensation (e.g., encephalopathy, coagulopathy) or portal hypertension (e.g., ascites, gastroesophageal varices, or persistent thrombocytopenia). Furthermore, we would recommend careful monitoring of any patient with cirrhosis, even if not advanced, receiving OCA."

UDCA, ursodeoxycholic acid; PBC, primary biliary cholangitis; OCA, obeticholic acid

3.1 Predictive Models

Various predictive models exist and are used as tools to assess the prognosis in patients treated with UDCA. The most widely used, and validated predictive model, is the GLOBE score, which is based on data collected from the Global PBC Study group, a multicenter, international study in 15 liver centers, from eight different countries across Europe and North America, comprising 4,500 PBC patients. The GLOBE score predicts the risk of OLT or death a year after initiation of treatment, using factors obtained at the time of initiating UDCA including age, TB levels, serum ALP levels, platelet count, and albumin.6

Multiple other models have been designed to assess the response of patients to UDCA.2 Table 1 summarizes the most widely used models, as well as each of their response criteria. There is currently no agreement on which criteria is the best for defining a UDCA-NR. In general, most include ALP levels, given the existing data supporting its role as a surrogate for response to treatment. It should be noted that normalization of ALP is not a criterion for response, with the Paris-II model having the lowest ALP threshold (1.5 times the upper limit of normal) of all the current models designed.1,2,6,10 Clinical guidelines by the AASLD recommend the use of these criteria, but do not show any preference of one over the other.2

4. Future Goals of Therapy: Are Normalized ALP and Bilirubin Levels the New Goal?

Recent studies point towards normal ALP levels as the desired biochemical goal for effective PBC therapy. Jones et al. demonstrated that PBC patients with any abnormal levels of ALP had significantly higher levels of various inflammatory markers in comparison to those with normalized liver biochemistry, suggesting ongoing disease activity even in what would be considered a “responder” by most criteria.15 Additionally, an analysis made with data extracted from the GLOBAL PBC Study Group, compared ten-year survival rates of a cohort of PBC patients and found an association between normal ALP levels and lower risk for OLT or death in these patients.2

Normal TB levels have also been correlated with better outcomes in PBC patients. The above-mentioned analysis on data from the GLOBAL PBC Study Group demonstrated that TB levels below 0.6 x ULN were correlated with an improvement in 10-year survival, and a decreased risk of OLT or death, in comparison to those with TB levels > 0.6 X ULN (Figure 1). Above these levels, a linear relationship was demonstrated between
TB and the risk for OLT or death (Figure 1). Interestingly enough, patients with TB >0.6 x ULN and normal ALP levels had similar survival rates to those with TB levels <0.6 x ULN. Similarly, Jones et al. found that 88% of those patients with normal ALP levels, which as mentioned above, was correlated with decreased disease activity, presented TB levels <0.6 x ULN.

Given that, as discussed above, none of the existing criteria really prioritize normalization of ALP or TB levels to qualify a successful treatment, it is easy to see how findings like this could have very important implications on the future management of PBC patients, particularly when deciding to start any treatment beyond first line therapy. These results open the door to a revision on what is the current criteria for exploring treatment beyond UDCA, especially now that treatment options for PBC are in rapid development, with multiple promising options of salvage therapy currently under investigation.

Finally, an argument could be made for when exactly we should assess treatment response to UDCA. Most of the predictive models described above set 12 months of treatment as the “checkpoint” for assessing appropriate response in therapy. However, it seems that around 90% of the improvement in those who respond to UDCA is seen within six to nine months of treatment. This leads us to question if an earlier assessment of response to treatment would be more ideal.

5- Treatment of PBC: The Future

5.1 Investigational Fibrates
Seladelpar is a PPAR-δ agonist, a receptor found in hepatocytes, cholangiocytes and various immune cells known to play a role in the pathogenesis of PBC. Its mechanism is thought to consist in a reduction of bile acid synthesis as well as an increase in lipid degradation. It has also been found to show anti-inflammatory and anti-fibrotic activity. ENHANCE 3 studied the efficacy of seladelpar in UDCA-NR. 240 patients were distributed into three treatment arms: seladelpar 5 mg, 10 mg, and placebo. 78.2% of patients in the 10 mg arm, and 57.1% achieved a 15% or greater decrease in ALP, and a TB < ULN. 27.3% of the patients in 10 mg arm achieved normalization of the ALP levels.

5.2. FGF-19 Analogues
Fibroblast growth factor-19 (FGF-19) is another novel treatment target for PBC. FGF-19 is regulated by the FXR, and it acts to decrease the synthesis of bile acids, by downregulation of genetic expression of the rate-limiting enzyme cholesterol-7α–hydroxylase. NGM282 is an analogue of FGF19. In a randomized placebo-controlled trial by Mayo et al., daily administration of either 0.3 mg or 3mg NGM282 demonstrated significant reductions in ALP, AST, ALT and GGT levels in UDCA-NR. At least 50% of the patients taking the experimental drug experienced at the very least a 15% reduction from their baseline ALP level. No difference was observed regarding TB levels between the NGM282 and the placebo group. The drug was also generally well tolerated, with minimal side effects.

5.3. Non-Bile Acid FXR Agonists
New FXR agonists, without a bile acid like structure, are currently under investigation for their utility for treating PBC. These include tropixefor, cilofexor, and EDP-305.

Schramm et al. published results of their randomized clinical trial of tropixefor vs. placebo in patients with PBC with suboptimal response to UDCA. Patients were randomized to receive either 30, 60, 90, or 150 μg of tropixefor once daily for 28 days. Primary endpoints included...
Various immunomodulators have been tested in UDCA-NR patients. However, many of these drugs have not been found to be of any substantial benefit. This includes drugs such as budesonide, rituximab, ustekinumab, azathioprine, mycophenolate, methotrexate, and colchicine. Mesenchymal stem cells (MSC) transplants have been a topic of interest in the treatment of end stage PBC patients as a possible alternative to liver OLT. So far, although clinical trials have been very few, they have shown promising results including improvement in disease biomarkers, relief of extrahepatic symptoms and improvement and/or stabilization of disease by liver histology. As a result, there are ongoing trials with bigger patient samples dedicated to investigating the safety and efficacy of MSC transplants in UDCA-NR patients.

6- Conclusion
The treatment and management of PBC patients is evolving. Although criteria exists to determine the response of treatment and need for second line therapies, data suggests that normalization of ALP and bilirubin may be more important therapeutic targets. Findings demonstrate that even acceptable levels of ALP in PBC patients still may correlate with a certain degree of disease activity. These findings carry even more weight when we look at the high number of promising therapeutic options, with many different mechanisms of action, currently being investigated. Although data is still limited in many of the novel PBC treatments mentioned above, early clinical trials have shown remarkable potential. There is a lot of promise for a future in which we will have multiple safe and efficacious treatment options available, that could help us reach the goal of normalizing serum biochemistries and achieving a complete remission or minimal progression of the disease.

References
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Message from the Editors

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We are happy to present our March issue of e-WGN. With the COVID pandemic almost over, the global gastroenterologists have bounced back with their academic, research and clinical work. COVID has also taught us the possibilities and importance of distant learning as a supplement to personal attendance. This issue announces a novel and important initiative of WGO to educate physicians, nurses and other health care providers about climate change. A series of webinars will deal with various aspects of global climate effect on GI health, green endoscopy, future sustainability and much more. We feel it is a great opportunity for all of us to educate ourselves on this critical global health issue.

As you all know, WGO had its World Congress of Gastroenterology in Dubai, United Arab Emirates in the month of December 2022 in partnership with the Emirates Gastroenterology and Hepatology Society. It was a fantastic Congress covering all aspects of GI sciences and messages in this newsletter from Dr. Eliana Reyes Marte from Dominican Republic and Dr. Adeel Rahat from Pakistan speak volume about success of this meeting.

This issue gives a report of a wonderful course conducted by WGO President Prof. Guilherme Macedo related to endo-hepatology in Porto, Portugal. This was the 10th edition of Clinical Hepatology Preceptorship program.

Prof. Naima Lahbabi-Amrani, our Past President, has given a detailed overview of WGO-RTC (WGO-Rabat Training Center) celebrated in Morocco. This is one of the most cherished activities of our organization and is involved in training doctors from more than 30 countries.

Our Expert Point of View article in this issue deals with an important clinical entity: Primary Biliary Cholangitis. Prof. Nancy Reau and colleagues from Rush University Medical Center in Chicago, Illinois, USA have given an overview of present and futuristic therapy of this disease. Drugs like seladelpar, fibroblast growth factor, non-bile acid FXR agonists, immunomodulators and stem cell therapy will be keenly watched for their potential impact.

It is also wonderful to note that an updated version of WGO’s Global Guidelines on probiotics and prebiotics is around the corner and will be published in multiple languages.

Before we sign off, we request all our WGO member societies to come forward and submit articles related to gastroenterology as well as activities in their respective countries. Let us use this platform to disseminate your ideas as well as activities.
World Congress of Gastroenterology - A View from Pakistan

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The World Congress of Gastroenterology, organized by the World Gastroenterology Organisation (WGO), was held on 10-14 December 2022 at the Dubai Convention and Exhibition Center, hosted by Emirates Gastroenterology and Hepatology Society (EGHS). It was the second time that such a large-scale Gastroenterology Conference took place in the Middle East with the aim of bringing a global perspective to the latest clinical and scientific advances in gastroenterology, hepatology, and related disciplines under one roof.

Eminent gastroenterologists, transplant hepatologists, physicians, and surgeons from around the globe participated in this state-of-the-art scientific program, sharing their valuable knowledge, views, and experience with the audience. A highly engaging scientific program comprised of interactive lectures by global speakers, live transmission sessions, post-graduate courses, and the hands-on gastroscopy and colonoscopy workshops demonstrated live tips and tricks regarding different techniques. There were also case-based video presentations and peer-reviewed oral and poster sessions that were all part of a very well-organized event which deserves all the applause.

In a nutshell, an unprecedented learning opportunity was provided to the attendees by the exceptional international and regional faculty members enabling the doctors to get firsthand knowledge about the research and advancements in the fields of gastroenterology and hepatology.
World Congress of Gastroenterology - A View from the Dominican Republic

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First, I would like to thank the World Gastroenterology Organisation for the wonderful opportunity to participate in the World Congress of Gastroenterology 2022. It was a delight to see such a well-organized program, and even more to hear all the main professors of gastroenterology and hepatology around the world together at this event.

The highlights of the congress were both academic and social. We enjoyed the Symposium on Live Endoscopy and Endoscopy Acute Upper Gastrointestinal Bleeding. It allowed us to see the different and latest approaches for this condition over the world - things we may read about in books and magazines but now appreciate in live sessions.

I am very grateful for the opportunity to take part in the World Congress of Gastroenterology 2022. It was a splendid chance for young specialists to be “on the pulse” in gastroenterology and know modern scientific research directions. Meeting colleagues from many countries with different experiences is the globalization of such contact with those speakers who make a difference in their areas of research. Hopefully, we will meet again at the next WCOG.
Message from the WDHD 2023 Co-Chairs

WDHD 2023 - Your Digestive Health: A Healthy Gut From the Start

Christina Surawicz, MD
Professor Emeritus, Medicine
University of Washington
WDHD 2023 Co-Chair

Carol Semrad, MD
Professor, Medicine
The University of Chicago Medicine
WDHD 2023 Co-Chair

Dear Colleagues,

From birth, the GI tract serves to provide nutrients to our bodies, enhance the immune response, house the intestinal microbiota, and serve as a “second brain” with the brain-gut axis. The dietary needs of the GI tract change from newborn, thru infancy, childhood, and adulthood. The function of the GI tract will be explained and how a healthy diet can promote optimal organ function and a healthy microbiome. Understanding the normal functions of the GI tract and diet will also help identify when to seek GI care for symptoms. There are natural tie ins to prior World Digestive Health Days (WDHD), particularly the 2020 campaign on the gut microbiome and the 2021 campaign on obesity.

World Digestive Health Day is celebrated each year on May 29th with associated events, activities, and initiatives continuing throughout and beyond the campaign year. Through a multi-faceted campaign, WGO will provide simple messages for the general public in order to assist them in understanding the important role of diet in GI health. Multiple informational pieces on the GI tract and a healthy diet are planned and will be distributed worldwide for patients including children, gastroenterologists, primary care providers, and other healthcare professionals.

Through the WDHD 2023 campaign, WGO looks forward to providing a better understanding and recognition of a healthy GI tract, and we invite your participation through educating the public to promote a healthy lifestyle.

Sincerely,

Christina Surawicz, MD
Carol Semrad, MD
AIMS OF THE CAMPAIGN

The aim of the World Digestive Health Day (WDHD) 2023 campaign is to educate the public about the normal functions of the GI tract and ways to keep it healthy, with a focus on healthy eating from infancy thru adulthood. Our goal is to promote a healthy gut for life going forward rather than focusing on diseases and looking for their causes. In diet, we will focus on the need for adequate protein, promoting fiber, and limiting sugary food and drinks.

Through a multi-faceted WDHD 2023 campaign, WGO seeks to raise awareness of the importance of a healthy GI tract with simple information for the general public (adults and children) that includes:

• The normal function of the GI tract
  o Digestion and absorption: Breaks down food so that nutrients and fluids can be taken up in the intestine and provide energy for the body
  o Immune defense: 70-80% of the bodies immune system is in the gut
  o Brain-gut axis: The gut is called the “second brain,” and its interactions with the nervous system are important
  o House of the intestinal microbiome

• How diet affects one’s daily life and its importance to health. Provide parents and caregivers of children evidence-based guidance on the elements of a healthy diet from infancy thru adolescence.

• Develop educational and training materials based on the latest recommendations for healthy eating and distribute to physicians including gastroenterologists and surgeons, dieticians, other health professionals, and the lay public.
International Women’s Day 2023 - #EmbraceEquity
Women in Leadership Roles

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In an enabled world, a woman’s voice matters. However, we have seen that throughout history there has been a significant imbalance between the number of leadership roles that have been awarded to men and women, especially in the medical field. Furthermore, in international medical conferences it is has been observed that the majority of the speakers and faculty present are male. Gender disparity in research and academia also remains. Women are not only more often deprived of major funding, but they are also less likely to attain editorship and authorship of eminent journals. The question arises: how can we overcome these barriers in order to enact change? And how can we achieve leadership and academic advancement for women?

In order to understand the plight of women in the field we must acknowledge what they are facing on a day-to-day basis. The World Gastroenterology Organisation (WGO) has only recently appointed their first female president, Naima Lahbabi-Amrani, in 2019. Moreover, Dr. Sarah Clarke was recently appointed the 122nd president of Royal College of Physicians Council, however she is only the fourth woman to have ever held this position. Higher titles and achievements are more often than not skewed in one direction and this can have a rather dominating effect leading to microaggressions in the workplace, especially towards those that are women of color. Women that occupy prominent positions are also far more likely to battle with imposter syndrome due to feeling out of place with their fellow colleagues.

There are several barriers present that women must face. The aforementioned imposter syndrome leads to many questioning their abilities and their capacity to handle their jobs, which then turns into self-doubt. Women are also more often the primary caregivers for their children and families which leaves them with less time to pursue their career goals. In published literature 47% of women reported that their work life balance was quite challenging for them while 37% were made to feel inferior and

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discouraged from receiving a promotion. The “Great Man” theory is one that has been widely discredited. It states that some individuals (generally men) are natural born leaders, and hence they excel. For women, you have the three C’s that are credibility, capacity, and capability. These three attributes are constantly questioned.

We are caught in an enigma. Is it that men are blocking women, that women are blocking other women, or are women blocking themselves from achieving their fullest potential? With more women entering the field and a work dynamic that is constantly changing, we must ask ourselves why these disparities still exist. One of the biggest factors is the fear of failure and the unknown. Due to an unavailability of female mentors many are faced with a lack of information and often may not know the intricacies of how to conduct themselves, especially in a male-dominated field. If there is no support system available at home, then there will be an increasing reluctance to try something new because the overall benefits are perceived to be low. Furthermore, due to historical factors or institutional memory (bad past experiences), the emergence of young women is often seen as a threat to the status quo as well as to the power of those that are already in a position of authority.

According to the World Economic Forum, Pakistan remained ranked towards the bottom of the most recent global gender index report. In this country, women take up a majority of the seats at medical colleges, however they end up taking a very small part of the actual medical workforce. This is due to the “doctor bride” concept that runs rampant in the country. Akin to a trophy wife, this essentially means that women that strive to become doctors will eventually find a good match, however oftentimes their spouse and in-laws will not allow them to work after they are married.

Now, what are some steps that can be taken to embrace equity? The most important step we must take is to change the mindset of the people. We must establish a concrete policy, throughout all levels of the medical workforce, dedicated to solving the barriers of the women in leadership face. Eliminating bias through institutional policies and providing more sponsors for women will allow them to gain credibility and trust. Furthermore, establishing a mentorship program will allow up-and-coming professionals an opportunity to learn more about their field and to also expand their existing networks. WGO in particular has been a huge supporter and over the years has advocated for an increased representation of women in various committees.

We can see that women are quintessential harbingers of resilience and perseverance and it is time to challenge status quo and to embrace equity in leadership.

DONATE TODAY

Contributions to WGO support and expand the educational, training, research, and awareness programs and initiatives of WGO by strengthening the reach of WGO to areas in the world that benefit directly from the education offered through programs such as Training Centers, Train the Trainers, World Digestive Health Day, Global Guidelines, and international meetings such as the World Congress.

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Introducing WGO Climate Course for Global Gastroenterology “From Basics to Solutions”

Climate change is a rapidly developing public health crisis with significant implications for digestive health and disease. Physicians, nurses, and all healthcare providers involved in digestive care need to understand the challenges we are facing.

To increase awareness and educate health providers, WGO is broadcasting a series of nine interactive webinars, one hour each, occurring every two weeks from March until June 2023.

We have assembled experts from around the world who are the leading authorities on the subjects that will be presented. We hope that you will find this series extremely helpful to your practice and to your understanding of the issues. On completion of this course attendees will have a clear understanding of the issues and will be prepared to take positive actions to help adapt to, and mitigate, climate change.

Subjects will include:
1. Overview of Course and Climate Change Fundamentals
2. Climate Change and GI Health
4. Adaptation, Resilience, and Industry Partnership
5. Understanding the Carbon Footprint of GI Care
6. Greening Endoscopy and Reducing Waste
7. Personal, Systems Advocacy, and Nursing Efforts to Mitigate the Climate Crisis
8. Perspectives
9. Building a Brighter, Sustainable, and Better Future

The series will be broadcast at 07:00 Central US time (corresponding UTC, GMT and local times can be found on the registration page) each second Wednesday from 8 March to 28 June.

Attendance is free of charge, and WGO will provide a certificate of completion for those who attend a majority of the sessions. Registration is encouraged as space may be limited. Details of the course are located here: https://www.worldgastroenterology.org/education-and-training/webinars/wgo-climate-course-for-global-gastroenterology.

Registration can be done using this link: https://us02web.zoom.us/webinar/register/WN_sk1ct05VQ-1Gry5no_Sjhdg
Climate change impacts every aspect of our lives and health, including digestive health.

Droughts, floods and other extreme weather events lead to diminished food production, decreased food quality and safety and higher prices – raising the likelihood for people to turn to processed and less nutritious foods.

Warmer temperatures create ideal conditions for the growth of bacteria and foodborne pathogens that cause food poisoning. And changes in rainfall patterns and water quality can increase the likelihood of waterborne illnesses such as cholera. Climate change and air pollution can also lead to an increase in chronic diseases and infections.

We must strengthen the resilience of food systems, through sustainable agricultural methods and nature-based solutions. We must also work to ensure clean water and air, promote healthy and diverse diets, and improve access to nutritious foods.

By taking decisive action to tackle the climate crisis, we can help to protect the health of people and planet and ensure a more sustainable future for all.

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Upcoming Webinar - *Pregnancy and Liver Disease: Navigating the Complexities on a Global Scale* - Register Today!
Join WGO at Train the Trainers!

Celebrating over 20 years of WGO’s Train the Trainers (TTT) program, TTT continues to expand the educational and training skills of educators in gastroenterology, hepatology, endoscopy, oncology and GI surgery to current educational techniques and philosophies. It brings together faculty and participants from across the globe in intensive and interactive workshops. With many new modules, the workshops are characterized by numerous hands-on sessions with ample opportunity for discussion and interchange. This has proven to be a highly successful method of disseminating teaching skills to GI physicians who hold training positions in their own countries. Delegates are equipped with skills which they can then implement in their countries. 

WGO Member Societies are asked to nominate two physicians who are leaders or up-and-coming leaders in their field (gastroenterology, endoscopy, hepatology or GI surgery).

In partnership with the Asociacion Colombiana De Gastroenterologia (ACG), WGO is pleased to announce the next Spanish language Train the Trainers workshop in Pereira, Colombia. This workshop will be held 16-18 August 2023, prior to the Colombian-Venezuelan Congress. Nominations will close on 1 May 2023.

In partnership with the Saudi Gastroenterology Association (SGA), WGO is pleased to announce the next 4-day Train the Trainers workshop in Jeddah, Saudi Arabia. This workshop will be held 11-14 December 2023. Nominations will close on 1 May 2023.

In partnership with the Indian Society of Gastroenterology (ISG), WGO is pleased to announce the first 4-day Train the Trainers workshop in 2024, to be held in Kolkata, India. This workshop will be held 8-11 February 2024. Nominations will open soon.

The American College of Gastroenterology has contributed to the resounding success of the Train the Trainers program. We celebrate our unique collaboration serving gastroenterology worldwide. For further details on these workshops, please visit our TTT Upcoming Workshop web page (http://www.worldgastroenterology.org/education-and-training/train-the-trainers/upcoming-workshops).

Should you have any additional questions, please contact Milly Gonzalez, WGO Education & Meetings Manager, at mgonzalez@worldgastroenterology.org.
WGO Rabat Training Center Celebrates Its 20th Anniversary

Naima Lahbabi-Amrani, MD
Past President and Chair of Nominations, World Gastroenterology Organisation
Mohammed V University
Rabat, Morocco

The Training Center of the World Gastroenterology Organisation in Rabat (WGO-RTC) has just celebrated its 20th anniversary as well as the 20th International Post-Graduate Course.

For those unfamiliar with the WGO-RTC, I can say that the Moroccan Ministry of Higher Education and WGO have joined forces to launch a truly unique Training Center in the area. This Center is part of the Mohamed V University and is located at the Medicine and Pharmacy Faculty of Rabat. It is open to all gastroenterologists, mainly from Africa, who wish to improve their theoretical and practical knowledge in the field gastroenterology, hepatology and digestive oncology.

The WGO-RTC is the commitment to promoting the highest standards in gastroenterological and hepatological training and education. It is a privileged place for training, exchanging ideas and experiences, where all participants can reconnect with new acquaintances and make new friends.

To celebrate such an event, it is first of all an occasion to take stock of what has been achieved according to the main objectives of the Center, such as:
- to promote the highest quality standards in gastroenterology and hepatology training,
- to promulgate the best rules of practice of the specialty,
- to develop a training program integrating recent advances in gastroenterology and hepatology as well as ethical principles, appropriate to local and regional needs,
- to provide trainees with the most recent learning tools, and
- to promote contact with experts and become a training site for trainers with the ambition of playing the role of leadership for the specialty.

Since its establishment to date, more than 1,500 physicians, representing around 30 countries have been trained: Afghanistan, Algeria, Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Comoros, Congo Brazzaville, Djibouti, Egypt, Gabon, Guinea, Ivory Coast, Lebanon, Madagascar, Mali, Mauritania, Morocco, Niger, Palestine, Rwanda, Senegal, Syria, Tanzania, Togo, Tunisia and the United Arab Emirates. It also gives African trainees the opportunity to stay for longer periods, from a few months to four or five years. The Center claims the privilege of providing some African countries their first gastroenterologists. In fact, many gastroenterologists attended the Center as trainees and are attending today as trainers.

The educational program, which has been validated by different partners, is composed of theoretical courses and hands-on training for each module. The priority is on practical training, with ultrasound and endoscopy technique, for both diagnostic and therapeutic purposes. The various tutorials available provide the opportunity to have a personalized educational program, which can go from training on mechanical or computerized (symbionix) simulators to the acquisition of various endoscopic procedures on pig stomachs (EASIE models).

This “à la carte learning” allows each participant to find their way, depending on their level of training.

Our media center, which is continually evolving, provides trainees with electronic documents selected according to their didactic character. For attendees already familiar with endoscopy, we decided, in light of our first experiences, to replace live-transmission from the hospital by a companionship program so that small groups can work in hand with experts. Interactive teaching plays an important role, including practical workshops and presentations of clinical cases. With the acquisition of videoconference equipment in 2006, telemedicine has been our hobbyhorse with the aim of giving gastroenterologists from other countries the opportunity to benefit from these courses.

Experts recognized worldwide for their competence and teaching skills run all sessions. They come from Algeria, Austria, Belgium, Cameroon, Canada, Egypt, France, Germany, Ireland, Italy, Libya, Morocco, the Netherlands, Portugal, Senegal, Sweden, Tunisia, Turkey, the United Kingdom and the United States.

Celebrating the 20th anniversary also means creating an event, an ap-
propriate time to meet. The 20th International Course (held in 2-11 June 2022) gathered representatives of 20 countries, especially from Africa, to take part in this prestigious International Course and celebrate together the 20 years of their Center. They came from: Benin, Burkina Faso, Cameroon, Congo Brazzaville, Chad, Comoros, Democratic Republic of Congo, Egypt, Gabon, Guinea, Ivory Coast, Mali, Morocco, Mauritania, Niger, Peru, Senegal, Togo and Tunisia. Celebrating the 20th anniversary of the WGO-RTC is furthermore celebrating the success of its trainings. WGO-RTC is delighted by the assistance that we have obtained from the Moroccan hierarchy, University Mohammed V, Faculty of Medicine and Pharmacy of Rabat, the Ibn Sina Hospital as well as all its partners.

This 20th anniversary gives me the opportunity to thank warmly the Munich Gastroenterology Foundation and all scientific societies such as the SNFGE (Société Nationale Française de Gastro-Entérologie), AFEF (Association Française pour l’Étude du Foie), SFED (Société Française d’Endoscopie Digestive), FMCHGE (Formation Médicale Continue en Hépato-Gastro-Entérologie), BSGIE (Sociétés Belge d’endoscopie digestive), GETAID (Therapeutic Study Group of Inflammatory Diseases of the Digestive Tube) and the FFCD (Fédération Francophone de Cancérologie Digestive). We were also glad to have, for several years now, the support of the DGVS (German Society for Digestive Endoscopy), ACHBT (Association Française de Chirurgie Hépato-Biliaire et de Transplantation Hépatique), and the CREGG (Club de Réflexion des Cabinets et Groupes d’Hépato-Gastroentérologie).

A special thank goes to SMMAD (Société Marocaine des Maladies de l’Appareil Digestif), and SMED (Société Marocaine d’Endoscopie Digestive).

Indeed, we are grateful to all our partner societies for their support and confidence which honor the Center and make it a real African hub for training, education, exchange, solidarity and friendship.

This success is also due to some people who spared no effort in the development of WGO-RTC. This is an opportunity to pay a special tribute to Professor Guido Tytgat, WGO Past President and Master of the World Gastroenterology Organisation for his exemplary contribution to the promotion of the specialty in the world, in general and through the Center of Rabat, in particular. We are fascinated by his leadership, his pioneering and innovative contribution to promote gastroenterology, not only within WGO-RTC, but worldwide. He participated, as President of WGO, in the inauguration of the Center 20 years ago. Since then, he has contributed actively and tirelessly to its development. WGO-RTC is proud to dedicate the success of its courses to him. We wish him a speedy recovery and a long life.

To the late Professor Meinhard Classen, Past President of WGO, President of the Munich Gastroenterology Foundation and godfather of the WGO-RTC, for his generosity, both materially and scientifically, Professor Classen is the founder of the WGO-RTC. He participated in its creation and contributed to its development. He has created a special link with the International Digestive Cancer Alliance, which opened new opportunities for training and allows our Center to enhance its ambitions. Thanks to his initiative and his pioneering, WGO has established 23 Training Centers to improve education and training worldwide.

This is also an opportunity for me to pay a great tribute to Professor Najib Zerouali, co-signatory of the agreement with WGO, then Minister of Higher Education and Scientific Research.

As a true visionary, he participated in the sustainability of the Center by creating the appropriate administrative framework.

Many thanks to all the experts and friends of Africa who have individually and tirelessly supported the
activities of the Center. I would like to particularly name the professors and doctors: Alan Barkun (Canada), Mustapha Benazzouz (Morocco), Danny De Looze (Belgium), Lucas Greiner (Germany), Pierre Coulom (France), Fernand Vicari (France) and late Christian Florent (France).

A special recognition goes to the WGO-RTC Committee for its dynamism, volunteer commitment and dedication to WGO-RTC! Finally, I would like to thank all companies who have generously supported the WGO-RTC during these 20 years and asking them to continue to be involved with us in the development of gastroenterology in emerging countries, especially in Africa.

Thanks to these partnerships and friendships, the Center has developed over the past 20 years new education programs in gastroenterology, hepatology, digestive oncology and other related disciplines that are not offered by any national or regional societies across the world. It is an ideal location for all participants to exchange ideas and experiences, renew old acquaintances and make new friends.

For all these reasons, the WGO-RTC is proud to celebrate, thanks to all our partners, but also with them, its 20th anniversary. Last but not least, I wish the new co-directors much success in their wonderful task and the WGO-RTC more fulfillment with a long life.
Clinical Hepatology Preceptorship: A Milestone

Guilherme Macedo, MD, PhD, MACG, FASGE, AGAF, FASLD
Director, WGO Porto Training Center
President, World Gastroenterology Organisation
Porto, Portugal

Recently, in November 2022, the WGO Training Center in Porto celebrated the 10th edition of the Clinical Hepatology Preceptorship. This course consisted of two days dedicated to immersion in clinical features and hands-on techniques taken care by hepatologists, or even more appropriately, endo-hepatologists! It is one of the most acclaimed educational initiatives performed in our center.

In fact, our Faculty of this 10th edition, included members of our local clinical and academic department, performing FibroScan, endoscopic ultrasonography (EUS), ERCP, variceal banding and several sorts of liver biopsy: percutaneous, US guided, EUS guided and transjugular. In ten years, over 170 participants (residents and young specialists) were intensively exposed to the ever-challenging features of chronic and acute liver disease patients.

Another unique characteristic of these courses is the Clinical-Pathology Slide Seminar, where three real-life clinical scenarios, with available liver histology, are vividly and thoroughly discussed with Prof. Fatima Carneiro, a worldwide known pathologist, member of our Training Center Faculty.

These have been ten wonderful years navigating hepatology, teaching, discussing and learning many of the tips and tricks of the fascinating world of liver diseases. Everyone feels grateful for what we have been achieving in these educational events, and the great feedback from the participants is a fulfilling and wonderful measure of success. More to come over the next years in hepatology, right from the heart of WGO Gastroenterology and Hepatology Training Center in Porto, stay tuned!
Now Available! The Updated Probiotics and Prebiotics Guideline

**Francisco Guarner, MD**  
University Hospital Vall D’Hebron  
Barcelona, Spain

**Mary Ellen Sanders, PhD**  
International Scientific Association for Probiotics and Prebiotics  
Centennial, Colorado, USA

**Hania Szajewska, MD**  
Medical University of Warsaw  
Warsaw, Poland

WGO is pleased to announce the publication of the updated Probiotics and Prebiotics Guideline. This guideline is chaired by Dr. Francisco Guarner (Spain) and co-chaired by Dr. Mary Ellen Sanders (USA) and Dr. Hania Szajewska (Poland).

The guideline was created with the global view of many Guideline Review Team experts including Profs. Alejandro Piscoya (Peru), Henry Cohen (Uruguay), Rami Eliakim (Israel), Claudia Herrera (Guatemala), Tarkan Karakan (Turkey), Dan Merenstein (USA), Balakrishnan Ramakrishna (India) and Seppo Salminen (Finland). This updated version revises one that dated to 2017.

Probiotics are live microorganisms that, when administered in adequate amounts, confer a health benefit on the host. Lactobacilli, along with species of *Bifidobacterium*, have historically been common probiotics. In 2020, the genus *Lactobacillus* underwent a major restructuring to address the wide diversity of microbes assigned to this genus. 23 new genera were defined, including some with well-studied probiotic species.

Prebiotics are nondigestible by the host and lead to health benefits for the consumer through positive influence on the resident beneficial microbes.

The administration or use of probiotics or prebiotics is intended to influence the gut environment, which is inhabited by trillions of microbes, for the benefit of human health. Both probiotics and prebiotics have shown to have beneficial effects that extend beyond the gut, but this WGO Guideline will focus on gut effects.

In addition to English, the updated WGO Probiotics and Prebiotics Guideline will soon be available in French, Mandarin, Portuguese, Russian and Spanish. It can be viewed at https://www.worldgastroenterology.org/guidelines/probiotics-and-prebiotics.
Calendar of Events

Due to uncertainties of scheduling from the COVID-19 situation, please check the WGO Meetings and Events Calendar for the latest updates at https://www.worldgastroenterology.org/meetings/meetings-and-events-calendar

**WGO RELATED EVENTS**

**WGO Climate Course for Global Gastroenterology: From Basics to Solutions**
- **When:** March 8, 2023 - June 28, 2023
- **Location:** Online webinar -- every two weeks
- **Country:** Worldwide
- **Organizer(s):** WGO Climate Change Working Group
- **Website:** https://www.worldgastroenterology.org/education-and-training/webinars/wgo-climate-course-for-global-gastroenterology

**Pregnancy and Liver Disease: Navigating the Complexities on a Global Scale**
- **When:** April 17, 2023
- **Location:** Online Webinar
- **Country:** Worldwide
- **Organizer(s):** WGO’s Hepatology Interest Group
- **Website:** https://us02web.zoom.us/webinar/register/WN_iR_cq0HJQNCxv9zqIR0pXg

**CALENDAR OF EVENTS**

**The 53rd Annual Meeting of GEST**
- **When:** March 25, 2023 - March 26, 2023
- **Country:** Tiawan
- **Organizer:** Gastroenterological Society of Taiwan
- **Website:** http://www.gest.org.tw

**26th Annual Meeting of the Asociacion Espanola de Gastroenterologia**
- **When:** March 28, 2023 - March 31, 2023
- **Location:** Madrid
- **Country:** Spain
- **Organizer:** Asociacion Espanola de Gastroenterologia
- **Website:** http://www.aegastro.es

**Midwest Metabolic Clinical Symposium**
- **When:** April 14-16, 2023
- **Location:** St. Louis
- **Country:** USA
- **Organizer:** Saint Louis University School of Medicine
- **Website:** https://slu.cloud-cme.com/course/courseoverview?P=1&EID=13173

**Seoul International Digestive Disease Symposium (SDDS 2023)**
- **When:** April 15, 2023 - April 16, 2023
- **Location:** Seoul
- **Country:** Korea
- **Organizer(s):** The Korean Society of Gastroenterology
- **Email:** gastrokorea@kams.or.kr
- **Website:** https://www.sidds.org/

**Digestive Disease Week® (DDW) 2023**
- **When:** May 6, 2023 - May 9, 2023
- **Location:** McCormick Place
- **Address:** Chicago, Illinois, United States
- **Organizer:** DDW
- **Website:** https://ddw.org/

**Indonesian Digestive Disease Week (IDDW) 2023**
- **When:** May 9, 2023 - May 13, 2023
- **Country:** Indonesia
- **Organizer(s):** Indonesian Society of Gastroenterology
- **Email:** pbpgi.jakarta@gmail.com

**BSG Live 2023**
- **When:** June 19, 2023 - June 22, 2023
- **Location:** ACC
- **Address:** Liverpool, United Kingdom
- **Organizer(s):** British Society of Gastroenterology
- **Website:** https://live.bsg.org.uk/

**2023 International Liver Congress™**
- **When:** June 21, 2023 - June 25, 2023
- **Location:** Vienna
- **Country:** Austria
- **Organizer:** EASL
- **Website:** https://easl.eu/event/easl-congress-2023/

**ALEH XXVII Congreso**
- **When:** August 29, 2023 - September 1, 2023
- **Location:** Bogotá
- **Country:** Colombia
- **Organizer(s):** ALEH
- **Website:** congresoaleh.com

**IFSO Congress 2023**
- **When:** August 30, 2023 - September 1, 2023
- **Location:** Naples
- **Country:** Italy
- **Organizer:** IFSO
- **Website:** https://www.ifso.com/world-congress/
GastroEndo: Congreso Argentino de Gastroenterología y Endoscopia Digestiva 2023  
When: September 7, 2023 - September 9, 2023  
Location: Mar del Plata  
Country: Argentina  
Organizer(s): FAAED, FAGE and SAGE  
Website: https://gastroendo2023.org/ 

EUS ENDO International Live Course 2023  
When: September 28, 2023 - September 30, 2023  
Location: Marseille  
Country: France  
Organizer(s): Dr. Marc Giovannini, Course Director  
Website: https://eus-endo.org/ 

Semana Panamericana de las Enfermedades Digestivas 2023  
When: October 8, 2023 - October 11, 2023  
Location: Santiago  
Country: Chile  
Organizer(s): Organización Panameicana de Gastroenterología y Sociedad Interamericana de Endoscopia Digestiva  
Website: https://www.oppe.org/sitio/ 

UEG Week 2023  
When: October 14, 2023 - October 17, 2023  
Location: Bella Center  
Address: Copenhagen, Denmark  
Organizer: United European Gastroenterology  
Website: https://ueg.eu/week 

ACG 2023 Annual Scientific Meeting & Postgraduate Course  
When: October 20, 2023 - October 25, 2023  
Location: Vancouver Convention Centre  
Address: Vancouver, British Columbia, Canada  
Organizer(s): American College of Gastroenterology  
Website: http://www.gi.org 

JDDW 2023 - Japan Digestive Disease Week 2023  
When: November 2, 2023 - November 5, 2023  
Location: Kobe, Japan  
Organizer: Organization of JDDW  
Website: https://www.jddw.jp/jddw2023/en/index.html 

The Liver Meeting 2023  
When: November 10, 2023 - November 14, 2023  
Location: Hynes Convention Center  
Address: Boston, Massachusetts, USA  
Organizer(s): AASLD  
Website: https://www.aasld.org/the-liver-meeting 

Semana Nacional de Gastroenterología 2023  
When: November 17, 2023 - November 21, 2023  
Location: Cancun  
Country: Mexico  
Organizer(s): Asociación Mexicana de Gastroenterología  
Website: https://www.gastro.org.mx/ 

APDW 2023  
When: December 6, 2023 - December 9, 2023  
Location: Bangkok  
Country: Thailand  
Organizer(s): Asian Pacific Digestive Week  
Website: https://www.apdwcongress.org/ 

APASL 2024  
When: March 27, 2024 - March 31, 2024  
Location: ICC Kyoto  
Address: Kyoto, Japan  
Organizer(s): Asian Pacific Association for the Study of the Liver  
Website: www.apasl2024kyoto.org
www.biocodexmicrobiotainstitute.com/pro: an international hub of knowledge dedicated to microbiota!

Biocodex Microbiota Institute is an international scientific institution that aims to foster health through spreading knowledge about the human microbiota. To do so, the Institute addresses both healthcare professionals and the general public to raise their awareness about the central role of this still little-known organ of the body.

It is designed to provide you with reliable, updated, and adapted content. It is also designed to reflect the dynamism and innovation of the human microbiota.

Available in 7 languages (English, French, Spanish, Russian, Polish, Turkish, and Portuguese), this online international hub provides Healthcare Professional with the latest scientific news and data about microbiota including the Institute's exclusive content such as Microbiota magazine, thematic folders, continuing medical education (CME) courses and interviews with experts. Check them out!

Navigate through this hub of knowledge: www.biocodexmicrobiotainstitute.com/pro