Update on The Global NASH Council

Zobair M Younossi MD, MPH
Chair, the Global NASH Council

The Global NASH/MASH Council

Background

- The Global NASH and Liver Councils (GNC and GLC) were formed in 2014 to bring together experts from around the world to discuss, collaborate and contribute to the field of NASH/MASH and Other Liver Diseases.
- The GNC/GLC has grown organically and has 150 members from 44 countries.
- Alongside a network of leading researchers and clinical practitioners, the council has developed unique resources including the Global NASH Registry and The Global Liver Registry
- The GNC/GLC have published dozens of scientific articles, including many of the seminal publications in the field
- The GNC/GLC regularly convenes members at AASLD and EASL congresses and may expand to other society meetings (APASL, ALEH and others)

1	Argentina
2	Armenia
3	Australia
4	Austria
5	Belgium
6	Brazil
7	Canada
8	Chile
9	China
10	Cuba
11	Denmark
12	Egypt
13	France
14	Germany
15	Greece
16	Hong Kong
17	India
18	Indonesia
19	Ireland
20	Israel
21	Italy
22	Japan
23	Saudi Arabia
24	Malaysia
25	Mexico
26	Moldova
27	Mongolia
28	Pakistan
29	Philippines
30	Portugal
31	Qatar
32	Russia
33	South Korea
34	Singapore
35	South Africa
36	Spain
37	Sweden
38	Switzerland
39	Taiwan
40	Thailand
41	Turkey
42	Vietnam
43	UK
44	USA

The Members of the Council are growing but include the following:

Zobair Younossi, MD, MPH (Chair)

[illegible]

Aijaz Ahmed, MD

[illegible]

Naim Alkhouri, MD

[illegible]

Alina M. Allen, MD

[illegible]

Saleh Ali Alqahtani, M.B.Ch.B., M.S.

[illegible]

Khalid Alswat, MD, FACP, MRCP, MBA-IHM

[illegible]

Quentin M. Anstee BSc(Hons), MB BS, PhD, MRCP(UK), FRCP

[illegible]

Marco Arrese Jimenez MD, FAASLD

[illegible]

Munkhjargal Ayurzana MD

[illegible]

Diana Barb, M.D., F.A.C.E., DABOM

[illegible]

Rita Basu MD

[illegible]

Jérôme Boursier, MD PhD

[illegible]

Paul N Brennan, B.Sc (Hons), MRes, MB ChB, MRCP(UK)

[illegible]

Fernando Bril, MD

[illegible]

Elisabetta Bugianesi MD, PhD

[illegible]

Patrizia Burra, MD, PhD

[illegible]

Maria Buti, MD, PhD

[illegible]

Patrizia Carrieri, PhD

[illegible]

Laurent Castera, MD, PhD

[illegible]

Wah-Kheong Chan MBBS, MRCP, PhD

[illegible]

Yogesh K Chawla MBBS, MD, DM

[illegible]

Abhijit Chowdhury MD

[illegible]

David E. Cohen MD, PhD

[illegible]

Massimo Colombo MD, Prof

[illegible]

Kathleen Corey, MD, MPH

[illegible]

Javier Crespo, MD, PhD

[illegible]

Kenneth Cusi, M.D., F.A.C.P., F.A.C.E.

[illegible]

Victor de Ledinghen, MD, PhD

[illegible]

Nikos Dedes

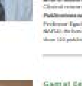
[illegible]

Moisés Diago, MD

[illegible]

Ajay Duseja MBBS, MD, DM

[illegible]



Yuichiro Eguchi MD, PhD

[illegible]

Gamal Esmat MD

[illegible]

Jian-Gao Fan MD, PhD

[illegible]

Marlen I. Castellanos Fernández MD, PhD

[illegible]

Sven Francque MD, PhD

[illegible]

Michael Fuchs, M.D., PH.D.

[illegible]

Adrian Gadano, MD, PhD

[illegible]

Jacob George, MBBS, PhD

[illegible]

Lynn Gerber, MD

[illegible]

Hasmik L. Ghazinyan, MD, PhD

[illegible]

George Goh MD

[illegible]

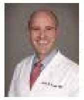
Stuart Gordon MD

Nadege T. Gunn MD, CPI

Hannes Hagström, MD PhD

Saeed Hamid, MBBS, FRCP

Ramazan Idilman MD



Scott Isaacs MD, FACP, FACE

Vasily A. Isakov MD

Ira Jacobson MD

David Jones (OBE), Prof. MD

Satoru Kakizaki MD, PhD, AGAF

Mustafa Kanat MD, Prof

Mohamed El-Kassas MD, PhD

Achim Kautz

Takumi Kawaguchi MD, PhD

Caglayan Kekilkiran, MD

James Kim MBBCh, PgDip, MScCH

Seung Up Kim MD, PhD

Aleksander Krag, MD, PhD, MBA

Andreas E. Kremer, MD, PhD, MHBA

Carina P Kugelmas, MD

Marcelo Kugelmas MD, FAASLD, FACP

Brian Lam, MSHS, PA-C

Jeffrey V Lazarus MD, PhD

Loreta Kondili, MD, PhD

Laurentius A. Lesmana MD.

Chun-Jen Liu, MD, PhD

Rohit Loomba, MD, MHSc

Paula Macedo, MD, Prof

Giulio Marchesini, MD, PhD

Didac Mauricio, MD, PhD

Nahum Mendez-Sanchez MD, MSc, PhD

Suzanne Norris MD

Phil Newsome, MBChB, BSc, PhD, FRCPE

Mazen Noureddin MD, MHSc

Janus Ong MD, MPH

Masafumi Ono MD, PhD

Calvin Q. Pan MD, MACP, FAASLD

George V. Papatheodoridis MD, PhD

Brian Pearlman MD, FACP

Mário Guimarães Pessoa, MD, PhD

Claudia Pinto Marques Souza Oliveira, MD, PhD, FAASLD

Puneet Puri, MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:

Nikolaos Pyrsopoulos, MD PhD, MBA, FACP, AGAF, FACG, FAASLD, FRCP (
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Natarajan Ravendhran,MD,MBA,AGAF,FAASLD.
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Mary E. Rinella MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:

Stuart Roberts, MBBS MD MPH FRACP FAASLD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:

Michael Roden, MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Stefano Romeo, MD, PhD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Manuel Romero-Gomez MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:

Arun J Sanyal, MBBS, MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Jörn M. Schattenberg MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
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Giada Sebastiani, M.D.
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Yosuke Seki MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:

Lawrence Serfaty MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Thrivikrama Shenoy DM
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Yusuke Shimakawa, MD, PhD, DTM, MSc
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Ashwani K. Singal MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Myeong Jun Song MD, PhD
Medical Education:
Current Academic or Administrative Positions:
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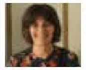

C. Wendy Spearman: MBChB, PhD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Frank Tacke, MD, PhD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Hirokazu Takahashi, MD, Ph.D
Medical Education:
Current Academic or Administrative Positions:
Publications and Presentations:
Comments:

Eugen Tcaciuc MD, PhD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Kessarin Thanapirom, MD, M.Sc.
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Michael Trauner MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:

Sombat Treeprasertsuk MD, PhD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Emmanuel Tsochatzis MD, PhD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Svetlana Turcan MD, PhD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Robert J. Wong, MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Vincent Wong, MBChB
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:

Yusuf Yilmaz MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Seung Kew Yoon MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Dan Yok Young MBBS, PhD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Ming-Lung Yu, M.D, Ph.D
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Shira Zelber-Sagi, Prof., Ph.D
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:

Ming-Hua Zheng, M.D, Ph.D
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Paola Andrenacci, Be.c in Nutrition
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
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Pegah Golabi, MD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Linda Henry, PhD, RN
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Dana Ivancovsky Wajcman, Ph.D
Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:

Kondarapassery Balakumaran Leena, MSc Ed, PhD
Medical Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Henry Mark, BSc, MSc, MBA
Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Maria João Meneses, PhD
Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Fatema H. Nader, MSBM, CCRC, CCRA
Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

James Paik, MS, PhD
Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Maria Stepanova, PhD
Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:
Comments:

Manisha Verma MD, MPH
Education:
Current Academic or Administrative Positions:
Area of Research interests:
Publications and Presentations:

The Global NASH and Liver Councils

Our ambition for the GNC/GLC

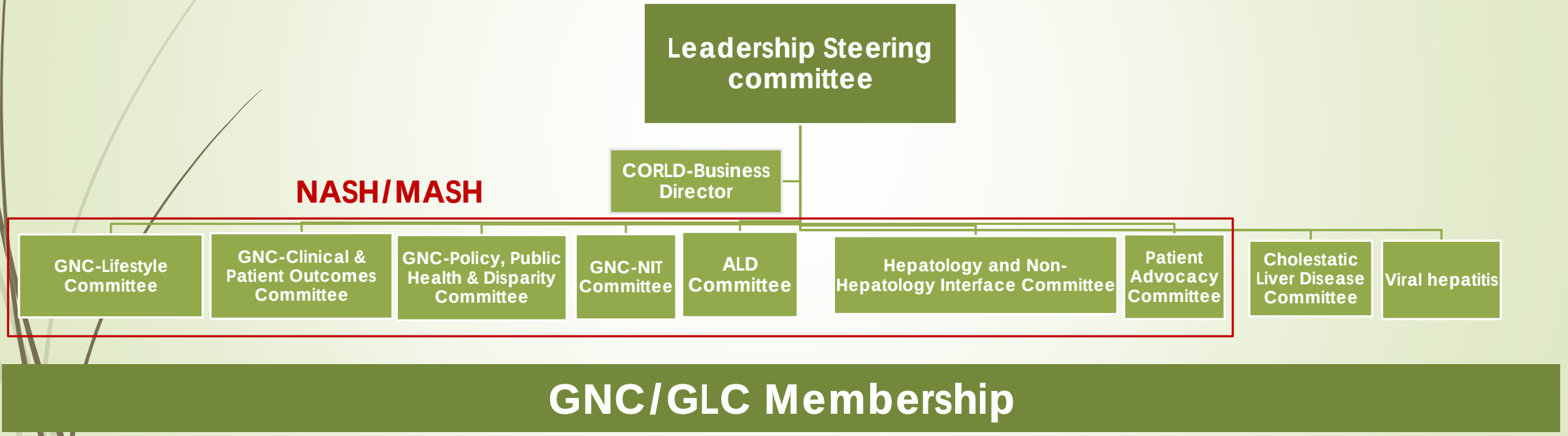
- Recognised leader within the liver health and global health communities as the preeminent global think-tank for steatotic liver disease (SLD) and other important LDs

Vision, Mission and Values

- **Our Vision**: A world where steatotic liver disease (previously known as fatty liver disease) and other common liver diseases are rare and treatment and care for those with the disease is timely
- **Our Mission**: Support experts in different field (hepatology, gastroenterology, diabetology, primary care and nutrition) to advance knowledge and the uptake of solutions to understand, prevent, manage and treat SLD and other common liver diseases
- **Our Values**:
  - **Leadership –** *we're helping to set the global agenda*
  - **Collaboration –** we're *building a global community by collaborating with all stakeholders*
  - **Person-Centred –** *we're addressing questions that matter to patients and affected communities*
  - **Impact focused** – *we're focused on biggest challenges and opportunities*

The Global NASH and Liver Councils

Strengthening leadership and coordination mechanisms



The Global NASH and Liver Councils

Committees leadership and members

Leadership Steering Committee: **Zobair Younossi** (GNC Chair), Jeff Lazarus, Shira Zelber-Sagi , Lynn Gerber, Saleh Alqahtani, Alina Allen, Ken Cusi, Paula Macedo, Laurent Castera, Leyla DeAvila, Henry L, Pegah Golabi, Fatema Nader (PD) and Henry Mark (PD)

Lifestyle Committee Co-Chairs: Shira Zelber-Sagi and Lynn Gerber (PD: Leyla DeAvila)
Members: Dr's Zobair Younossi, Jillian Price, Dana Ivancovsky, Saleh Alqahtani, Ali Weinstein, Paola Andrenacci, Manisha Verma, Carina Kugelmas, Suzi Gerber, Mohamed El-Kassas, CJ Liu, Manirath Srishord, Hirokazu Takahashi, Fatema Nader, Mani Srishord, Andrei Racila

Clinical & Patient Outcomes Committee Co-Chair:s **Zobair Younossi and Saleh Alqahtani** (PD: Henry L)
Members: Patrizia Burra, Robert Wong, Janus Ong, Marlen Fernandez, Ashwani Singal, Jorn Schattenberg, Sven Franque, Stepanova M, Patrizia Carrieri, Jeff Lazarus, Manisha Verma

Policy, Public Health & Health Disparity Committee Co-Chairs: **Zobair Younossi and Jeffrey Lazarus** (PD: Henry Mark)
Members: Nadage Gunn, Claudia Pinto Marques Souza Oliveira, Vincent Wong, Saleh Alqahtani, Alexander Krag, Shira Zelber, Sagi and Henry Mark

Hepatology and Non-Hepatology Interface Committee Co-Chairs: Ken Cusi and Paula Macedo (PD: Pegah Golabi)
Members: Scott Isaacs, Brian Lam, Giulio Marchesini, Amila Gestadelli, James Kim, Jay Shubrook, Gerald Shulman Paul Brennan, Zobair Younossi (Ad-hoc)

NIT Committee Co-Chairs: **Alina Allen and Laurent Castera** (PD: Pegah Golabi)
Members: Mazen Noureddine, Marcelo Kugelmas, Naim Alkhoury, Vincent Wong, Jorn Schattenberg, Yusuf Yilmaz and Zobair Younossi (Ad-Hoc)

Viral Hepatitis Committee Co-Chairs: Maria Buti MD and George Papatheodoridis(PD: Henry L)
Members: Wah Kheong Chan, Mohammad El Kassas, Stuart Gordon, Tatyana Kushner, Vasily Isakov, Ira Jacobson, Ming Lung Yu and Zobair Younossi (Ad-Hoc)

Cholestatic Liver Disease Committee Co-Chairs: Co-Chair: **Andeas Kremer and Z Younossi** (PD: Pegah Golabi)
Mark Swain, Dave Jones, Michael Trauner, Elizabeth Carey, **Nikolaos Pyrsopoulos**

Alcoholic Liver Disease Committee Co-Chairs: Ashwani Singal, Zobair Younossi PD: Fatema Nader)
Members: Juan Pablo Arab, Javier Crespo, Aleksander Krag, Mario Pessoa, Maja Thiele, Robert Wong, Yusuf Yilmaz

Patient Advisory Committee Co-Chaires: Nikos Dedes and Diane Langenbacher
Danjuma Adda, Michael Betel (FLA), Wayne Eskridge (FLF), Achim Kautz, Dee Lee, Vicky Mooney, Peter Schwarz, Lorena Stoopen, Paulette Trevana, ALF representative, Brian Lam, Zobair Younossi (Ad Hoc)

The Global NASH/MASH Council

Formal Endorsements and Collaborations

EASL Endorsed

SASLT
الجمعية السعودية لأمراض وزراعة الكبد
Saudi Society for the Study of Liver Disease and Transplantation

CLDF
Chronic Liver Disease Foundation

AFEF
SOCIÉTÉ FRANÇAISE D'HÉPATOLOGIE
Association reconnue d'utilité publique

AEEH
Asociación Española para el Estudio del Hígado

INASL

Center for Outcomes Research in Liver Disease

The Global Registry

The Global NASH and Liver Registries

Purpose of Global Registries

- Real world data regarding the clinical and PRO outcomes of important liver diseases are not available.
- The Global NASH and Liver Registries were established by COR-LD as a global collaboration effort to obtain clinical and PRO data for important liver diseases
- Historical: HBV, HCV, HDV and NAFLD/MASLD
- Added ALD and PBC as new enrollment criteria
- The Global Registry requires e-data collection after informed consent (IRB approved)
- The Global Liver/NASH Registries currently have 28 active sites
- These sites represent all the continents
- The intention is to compare liver diseases including MASLD, Met-ALD and others from different regions of the world using the Global Registry data

The Global Registries

Types of Liver Disease

Population:

Up to 100,000 subjects will be enrolled into the registries with 10 years of follow up:

1. NAFLD/MASLD: NAFLD/MASLD or NASH/MASH subjects with an established diagnosis by historical liver biopsy or accepted imaging technique (ultrasound, CT, MRI, TE)
2. Chronic HCV with viremia (regardless of treatment)
3. Chronic HBV (who are carriers of HBsAg) (regardless of treatment)
4. Chronic HDV (regardless of treatment)
5. PBC: ***1)*** ALP > 2 x ULN or GGT > 5 x ULN and 2) AMA > 1:40. Other histologic evidence of PBC according to the guidelines are also accepted.
6. ALD: 1) Meet criteria for AUD 2) Evidence of any liver disease (elevated aminotransferases outside the laboratory range, fatty liver SH or cirrhosis) by clinical, laboratory, radiologic or biopsy proven can be considered to have ALD.

Data Collection:

- Clinical and Laboratory data (For GNR: Clinical - 153, Lab – 30)
- Clinical Outcomes and Patient Reported Outcomes
- Liver stiffness, pathology and radiology (if available)
- Baseline and annual follow ups

The Global Registries

Primary Inclusion/Exclusion Criteria

Inclusion:

1) Subjects must be at least 18 years or older to participate 2) Must be able to read in order to complete questionnaires in their local language 3) Must have diagnosis of HCV, HBV, HDV, NAFLD/MASLD/NASH/MASH, PBC or ALD

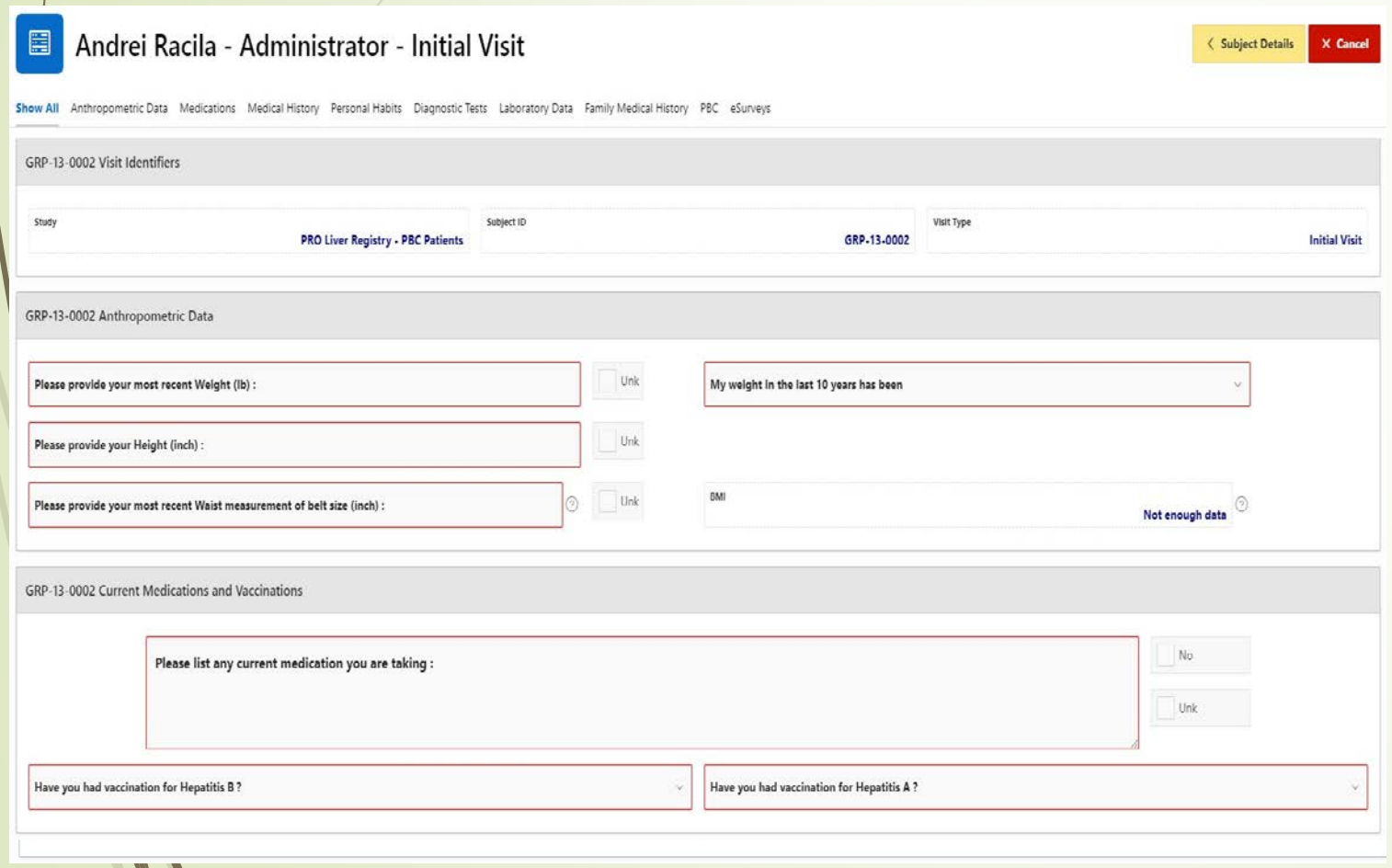
Exclusion:

1) All other causes of liver diseases 2) Pregnancy 3) Inability to provide consent

Study Procedures

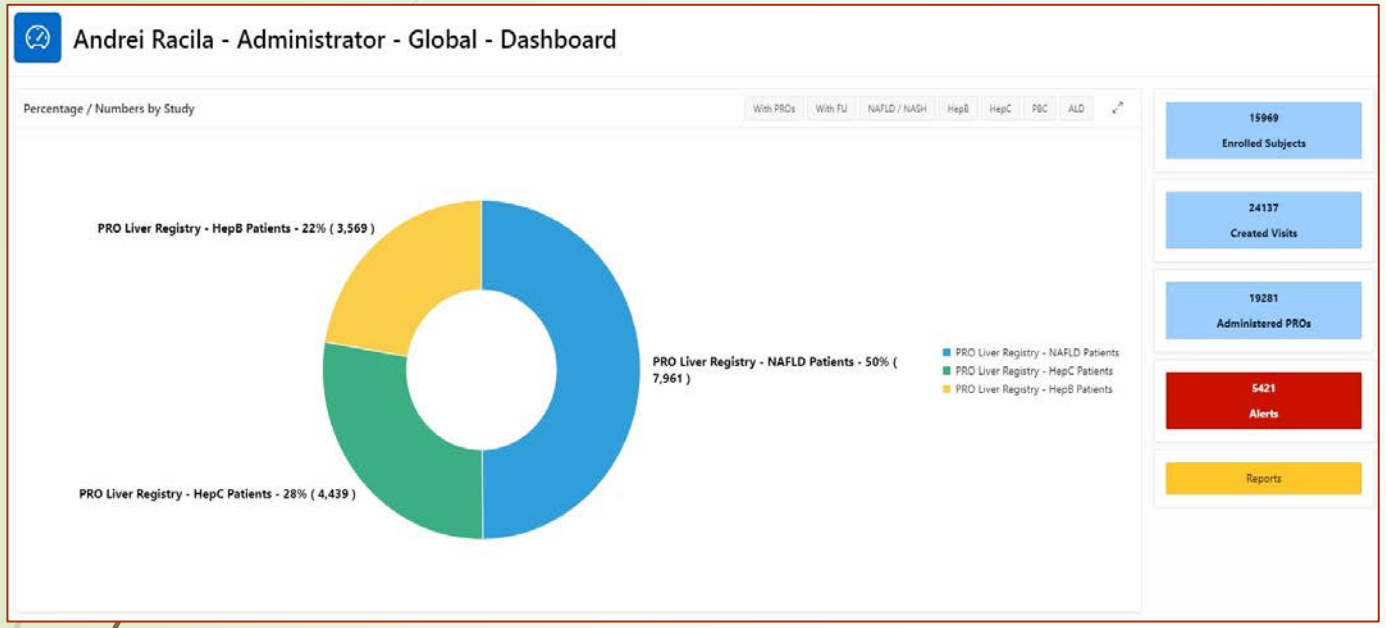
1. IRB approval
2. Review inclusion/exclusion and obtain consent
3. Collect and complete basic clinical information for entry into registry database
4. **PRO's will be administered** at baseline and repeated annually up to 10 years (optional)
   - **HCV**: complete 4 questionnaires: CLDQ-HCV, FACIT-F, WPAI, a Short Form Health Disparity questionnaire
   - **HBV and HDV**: complete 4 questionnaires: CLDQ-HBV, FACIT-F, WPAI, and a Short Form Health Disparity questionnaire
   - **NAFLD/MASLD**: complete 6 questionnaires: CLDQ-NAFLD, FACIT-F, WPAI, Activity Questionnaire, Nutrition Questionnaire and Short Form of Health Insecurity Questionnaire
   - **PBC**: complete 6 questionnaires: CLDQ-PBC, FACIT-F, WPAI, Short Form of Health Disparity questionnaire, PBC-40 and 5D-itch
   - **ALD**: complete 5 questionnaires (CLDQ or CLDQ-ALD (being developed), FACIT-F, WPAI, Short Form of Health Disparity questionnaire and AUDIT-C questionnaire.

The Global Registries
E-Data Collection



- For Sites without Reliable Internet, Spreadsheet Data Entry
- The spreadsheet is designed by GNC and will be uploaded periodically
- Each site will receive a DUA to make sure that sites are compliant with European rules for data

The Global Registries
Enrollement



Total Number of Subjects - 15969

- HepC - 4439
- HepB - 3569
- NAFLD/NASH - 7961
- HepC - Initial - 2976, Initial + FU - 870
- HepB - Initial - 3076, Initial + FU - 782

NAFLD/NASH - Initial - 4875, Initial + FU - 2224

Dr. Ming-Lung Yu (Taiwan) N=4486
Brian Lam (USA) N=3616
Dr. Yusuf Yilmaz (Turkey) N=2503
Dr. Marlen I. Fernandez (Cuba) N=825
Dr. Mohamed El Kassas (Egypt) 798
Dr. Gamal Esmat (Egypt) N=600
Dr. Vasily A. Isakov (Russia) N=500
Dr. Vincent Wong (Hong Kong) N=322
Dr. Khalid Alswat (Saudi Arabia) N=278
Dr. Yuichiro Eguchi (Japan) N=240
Dr. Çağlayan Keklikkıran (Turkey) N=226
Dr. Nahum Méndez-Sánchez (Mexico) N=210
Dr. Ajay Duseja (India) N=203
Dr. Manuel Romero-Gómez (Spain) N=201
Dr. Maria Buti Ferret (Spain) N=178
Dr. George V. Papatheodoridis (Greece) N=159
Dr. Saeed Hamid (Pakistan) N=142
Dr. Wah-Kheong Chan (Malaysia) N=124
Dr. Jacob George (Australia) N=88
Dr. Stuart Gordon (USA) N=80

Global Registry in January 2024

Country	N all	%	N HepB	N HepC	N NAFLD
Australia	106	0.68	11	0	95
China	47	0.30	3	0	44
Cuba	842	5.38	107	339	396
Egypt	1116	7.13	47	1038	31
Greece	159	1.02	66	52	41
Hong Kong	322	2.06	0	0	322
India	176	1.13	18	24	134
Italy	74	0.47	0	0	74
Japan	239	1.53	20	0	219
Malaysia	124	0.79	70	4	50
Mexico	161	1.03	0	29	132
Pakistan	132	0.84	49	26	57
Russia	489	3.13	16	29	444
Saudi Arabia	293	1.87	238	0	55
Spain	378	2.42	125	60	193
Taiwan	4498	28.76	1768	1808	922
Turkey	2760	17.64	856	45	1859
USA	3726	23.82	187	684	2855
Total	15642		3581	4138	7923

Center for Outcomes Research in Liver Disease

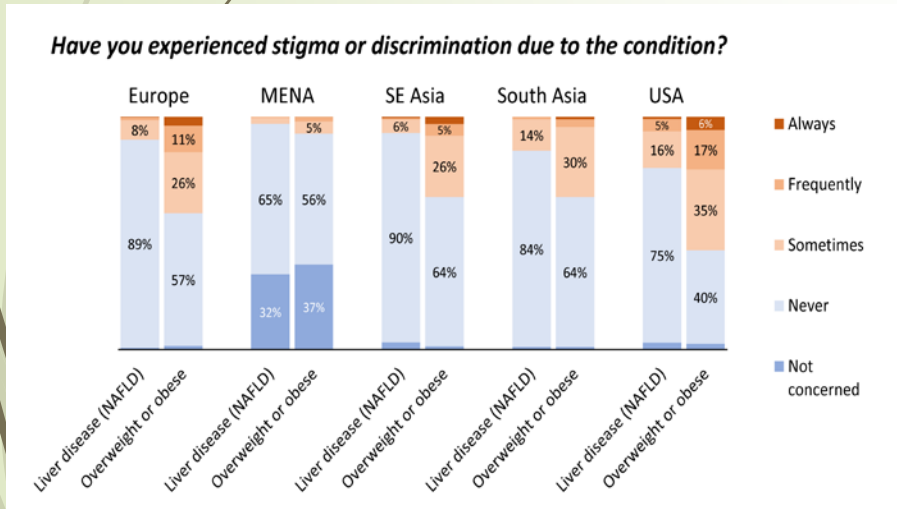
Global Surveys and Global Guideline Unification

The Global NASH/MASH Council

Global Stigma Study

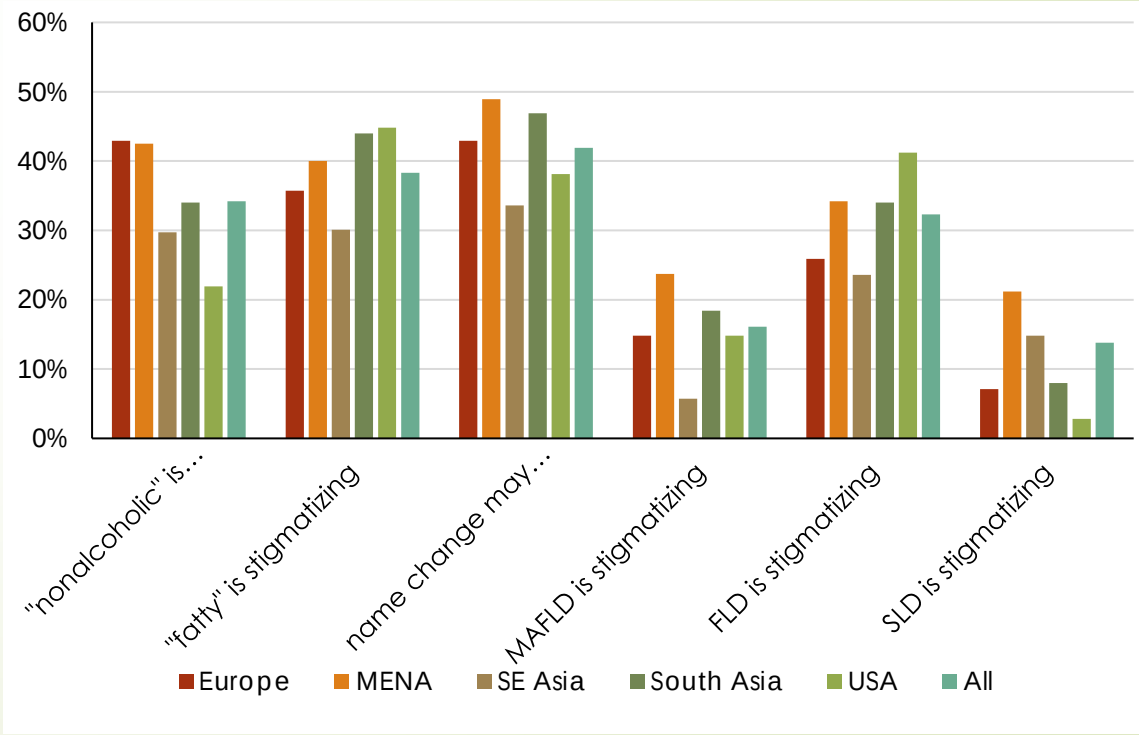
NAFLD <u>patients</u> and history of stigmatization/discrimination

- GNC members created 2 surveys (68-item patient and 41-item provider survey)
- **1976 NAFLD patients [21 countries) and 825 MDs** completed the survey
- The most common terminology used was fatty liver and least common was MAFLD
- **Overall, 25.6% of patients reported stigma related to overweight/obesity and 8.3% reported to NAFLD.**
- **Among providers, 40% believed "fatty" is stigmatizing, while 35% believed that the term "nonalcoholic" is stigmatizing,**



<u>Providers</u> and perception of diagnostic terms

- Overall, FLD was perceived stigmatizing by 32.3% of providers



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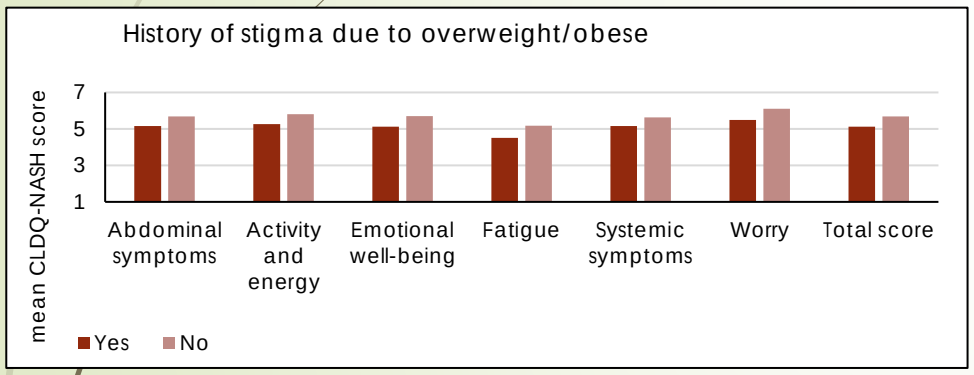
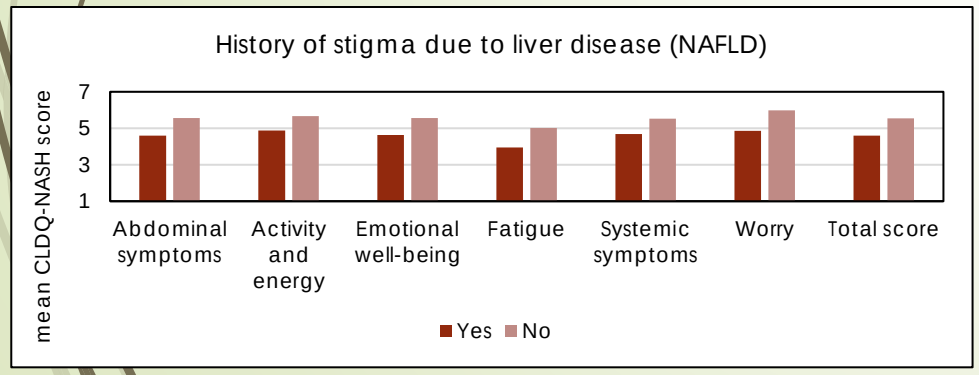
The Global NASH/MASH Council

Global Stigma Study

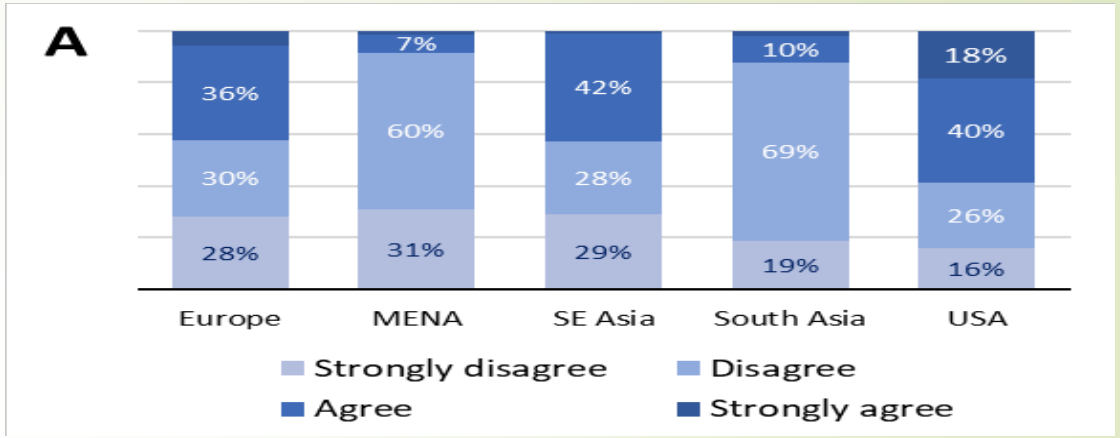
Liver Disease Burden and HRQoL

- GNC Survey included 35-item Liver Disease Burden (LDB; 7 domains) & 36-item CLDQ-NAFLD/NASH/NASH (6 domain)
- Of N=1976 NAFLD patients who completed the Stigma questionnaire, n=637 also completed the CLDQ-NAFLD
- Subjects who reported stigmatization due to NAFLD had substantially lower CLDQ-NAFLD/NASH scores (all p<0.0001).
- In MVA, history of stigmatization due to NAFLD was the strongest independent predictor of lower HRQL (all p<0.01).

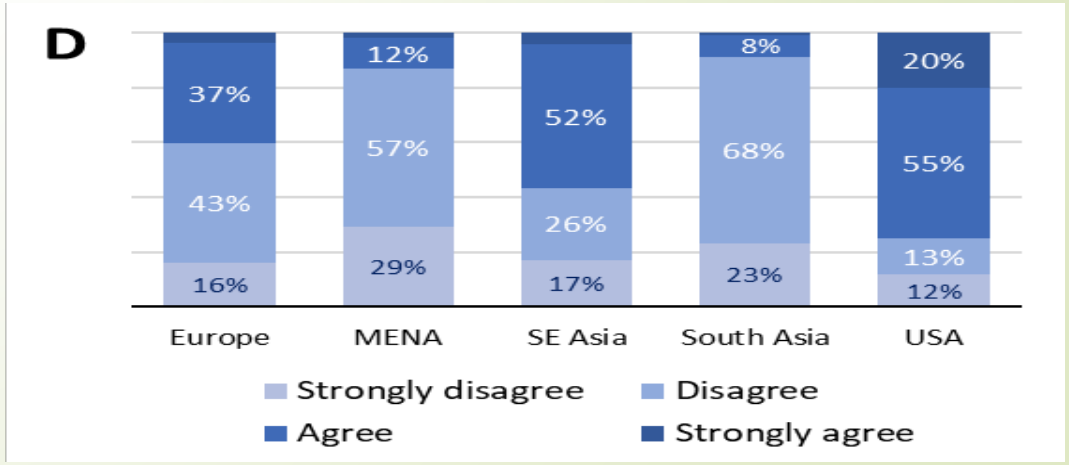




(A) Other people think I am partially to blame for my liver disease;



(D) I feel like I am partially to blame for my liver disease.



Younossi Z et al on behalf of GNC, AASLD 2023

Recent Registry Presentations and Publications

Manuscripts (2018-2022)

- The Impact of COVID-19 Pandemic and Patients with Chronic Liver Disease: Results from the Global Liver Registry. Hepatology Communications 2022
- Global NASH Council. Effects of Alcohol Consumption and Metabolic Syndrome on Mortality in Patients With Nonalcoholic and Alcohol-Related Fatty Liver Disease. Clin Gastroenterol Hepatol. 2019 Jul;17(8):1625-1633.
- Global Nonalcoholic Steatohepatitis Council. Nonalcoholic Steatohepatitis Is the Fastest Growing Cause of Hepatocellular Carcinoma in Liver Transplant Candidates. Clin Gastroenterol Hepatol. 2019 Mar;17(4):748-755.e3.doi: 10.1016/j.cgh.2018.05.057. Epub 2018 Jun 14. PubMed PMID: 29908364.

Presentations 2022

- AASLD 2022 Poster Presentation: Depression and Emotional Distress in Patients with Chronic Liver Disease (CLD): Data from the Global Liver Registry™ (GLR™)
- AASLD 2022: Poster Presentation: Clinical and Patient-Reported Outcome (PRO) Profile of Patients with Hepatitis B Viral (HBV) Infection from the Global Liver Registry™ (GLR™)
- EASL 2022 Poster Presentation: Negative Impact of COVID-19 Infection Related to Life Disruption Events and Health Scores on Patients with Chronic Liver Disease.
- EASL 2022 Poster Presentation: Clinical Presentation of Lean Non-alcoholic Fatty Liver Disease Across the World: Data from the Global NASH Registry. .

Presentations 2023

- EASL 2023: Prevalence and Predictors of Clinically Significant Pruritus in Patients with Non-alcoholic Fatty Liver Disease (NAFLD): Data from the Global NASH Registry™ (GNR™)
- DDW 2023: CLINICALLY SIGNIFICANT PRURITUS IN PATIENTS WITH CHRONIC LIVER DISEASE (CLD): DATAFROM THE GLOBAL LIVER REGISTRY ™ (GLR™)

Presentations 2021

- DDW 2021 Poster Presentation with Post Distinction: Clinical Presentation and Patient-Reported Outcomes in Patients with Chronic Viral Hepatitis: Data from the Global Liver Registry
- DDW 2021 Oral Presentation: Clinical Presentation of Lean NAFLD Across the World: Data from the Global NASH Registry
- EASL 2021: The Impact of COVID 19 Pandemic on Patients with Chronic Liver Disease (CLD): Data from the Global Liver Registry
- AASLD 2021: COVID-19 PANDEMIC AND CHRONIC LIVER DISEASE (CLD), American Association for the Study of Liver Diseases. Virtual, November 2021
- AASLD 2021: FATIGUE AND NON-ALCOHOLIC FATTY LIVER DISEASE: DATA FROM THE GLOBAL NASH REGISTRY, American Association for the Study of Liver Diseases. Virtual, November 2021.

Presentations 2020

- AASLD 2020: Clinical and Patient Reported Outcomes Data of NAFLD: Longitudinal Data from the Global NASH Registry.
- AASLD 2020: The Impact of Chrnoic Hepatitis B on PRO's from the Global Liver Registry
- AASLD 2020: Patient Reported Outcomes in Patients with Chronic Hepatitis C: Data from the Global Liver Registry.

Presentations 2019

- AASLD 2019: Differences in the Clinical Profile of the Most Common Causes of Chronic Liver Disease (CLD) Across the World: Data from the Global Liver Registry.
- AASLD 2019:evere Impairment of PROs in Patients with Chronic Hepatitis C Virus (HCV) Infection Seen in Real-World Practices Across the World: Data from the Global Liver Registry.
- AASLD 2019: Clinical and Patient-Reported Outcomes Data for Patients with NAFLD and NASH Across the World: Data From the Global NASH Registry.
- AASLD 2019:Clinical and PROs in Patients with Chronic Hepatitis B Virus (HBV) Infection Seen in Real-World Practices Across the World: Data From the Global Liver Registry.

Enhancing the Global Implementation of MASLD Guidelines

- Over the past decade **numerous guidelines** have been published related to MASLD/NAFLD and MASH/NASH
- Guidelines have been created by national and regional liver societies (e.g., AASLD, EASL, ALEH, APASL), GI societies (e.g., AGA) and non-GI-Liver Societies (e.g., AACE, ADA, EASD, AHA).
- **There are a few challenges:**
    1. **Implementation of guidelines are always challenging**
    2. **While these guidelines are based on a similar foundation, there are certain differences in their recommendations that can potentially cause confusion in the field which may negatively impact adherence to guidance and possibly worse outcomes**
- These **discrepancies are likely contributing to ineffective imp**lementation of existing guidelines and is counter-productive for raising awareness
- There is a pressing need to help simplify the guidelines both across subspecialities as well as across different regions of the world
- Given the global nature of GNC, we are best positioned to address these issues

Focus and scope

- This project will engage a large group of expert from around the world in a consensus process to consider clinically relevant issues in published MASLD/MASH guidelines
- Areas of focus will include any areas of discrepancy in the following
  - **Practical approaches to risk stratification based on clinical setting (e.g. primary care, GI, endocrinology), region and resource constraints (e.g., availability and validity of different NITs)**
  - **Standard approaches for lifestyle interventions as first line treatment**
  - **Current and future medical treatment options**
    - **i. Drugs that target risks associated with MASLD/MASH or NAFLD/NASH**
    - **ii. Drugs that specifically target the liver**
  - **How to use NITs to monitor patients on treatment**
- Understand regional differences that must be adopted based on the reality of practice
- Develop country/region specific strategies to optimize guideline implementation and increase awareness

Project aims

- The overall aim is to build consensus within the field globally, in part by **addressing areas of divergence** / disagreement in the existing guidelines
- Our goal is to contribute towards streamlining and **simplifying guideline**s and making them practically relevant
- Our goal is to understand different realities based on access to care/NIT and cultural differences in life style
- Overtime, we hope the outcomes of this project will **enhance the effective implementation** of guidelines leading to better outcomes for people living with MASLD / MASH
- Importantly, this work does not aim to replicate or replace existing guidelines, but to support their uptake and use

Steering Committee Members

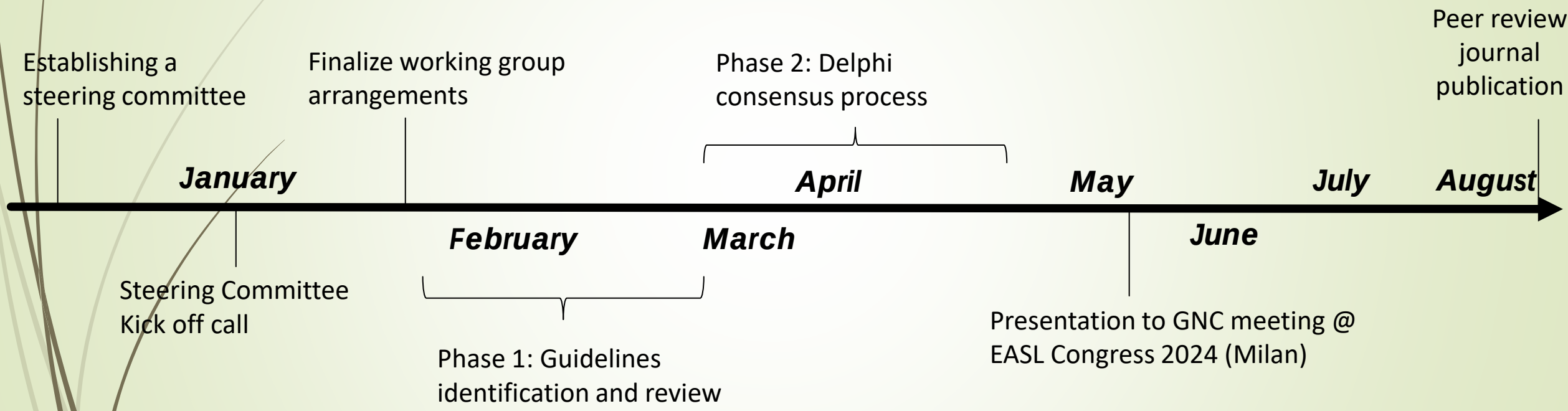
Engagement: The entire membership of the Global NASH Council

1. Zobair Younossi (GNC-US Hepatology and Chair)
2. Alina Allen (GNC-US hepatology)
3. Naim AL Khoury (GNC-US Hepatology)
4. Ken Cusi (GNC-US Endocrinology)
5. Michael Roden (GNC-Europe Endocrinology)
6. Scott Isaacs (GNC-US Endocrinology)
7. Shira Zelber-Sagi (GNC Nutrition Expert)
8. Lynn Gerber (GNC, Exercise and Activity Expert)
9. Laurent Castera (GNC-Europe Hepatology)
10. Jorn Schattenberg (GNC-Europe Hepatology)
11. Vincent Wong (GNC-Hong Kong Hepatology)
12. Saleh AlQahtani (GNC-MENA- Saudi Arabia Hepatology)
13. Yusuf Yilmaz (GNC-MENA-Turkey Hepatology)
14. Mohammed El-Kassas (GNC-MENA-Egypt Hepatology)
15. Ajay Duseja (GNC-India Hepatology)
16. Janus Ong (GNC-Philippines Hepatology)
17. Yuichiro Eguchi (GNC-Japan Hepatology)
18. Mário Guimarães Pessoa (GNC-Latin America Hepatology)
19. Claudia Pinto Oliveira (GNC-Latin America Hepatology)
20. Stuart Robert (GNC-Australia Hepatology)
21. Jian-Gao Fan (GNC- China Hepatology)
22. Jeffrey Lazarus (GNC-Global and Policy)
23. Achim Kautz (GNC- Patient Advocacy)
24. Manuel Romero Gomez (GNC-EU Hepatology)
25. Wendy Spearman (South Africa Hepatology)
26. Amalia Gastaldelli (GNC-EU Endocrinology)
27. Patrizia Burra(GNC-EU Hepatology)
28. Marlen Fernandez (GNC-Cuba Hepatology)
29. Frank Tacke (GNC-EU Hepatology)
30. Jay H Shubrook (GNC-US Primary Care)

Program Directors

A score team of program directors will provide support to the project: Fatema Nader, Linda Henry, Pegah Golabi, Dana Ivancovsky, Layla de Avila, Henry Mark

High-level project timeline



Center for Outcomes Research in Liver Disease

Quality of Life and PROs

Service Capabilities
CORLD, GNC and GLC
PRO and HRQL

- COR-LD has developed and validated 6 reliable health related quality of life (HRQL) surveys:
  1. CLDQ
  2. CLDQ-HBV
  3. CLDQ-HCV
  4. CLDQ-NAFLD-NASH
  5. CLDQ-PSC
  6. CLDQ-PBC

- Industry sponsored clinical trials uses validated instruments to assess PROs in patients with liver disease and CLDQ questionnaires have been extensively used and translated as it is the most reliable tool to detect changes in HRQL

Service Capabilities
CORLD, GNC and GLC
Statistical Analysis

- **Provide statistical expertise and support to clinical, laboratory, and outcomes studies throughout the research lifecycle. Including the preparation of proposals, protocol development, and publications/presentations**.

- Provides statistical data analysis for epidemiology and public health research projects.

- Contribute to and co-author peer-reviewed articles independently and/or in coordination with the lead author/physician.

- Prepare and review reports. Contribute to the statistical methods section and verify for completeness and consistency for reports.

CORLD Manuscripts and Presentations Related to PROs in Clinical Trials (N=151)

1: Younossi ZM, Guyatt G. Quality-of-life assessments and chronic liver disease. Am J Gastroenterol. 1998 Jul;93(7):1037-41. doi: 10.1111/j.1572-0241.1998.00325.x. PMID: 9672326.
2: Younossi ZM, Guyatt G, Kiwi M, Boparai N, King D. Development of a disease specific questionnaire to measure health related quality of life in patients with chronic liver disease. Gut. 1999 Aug;45(2):295-300. doi: 10.1136/gut.45.2.295. PMID: 10403745; PMCID: PMC1727607.
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5: Younossi ZM, McCormick M, Price LL, Boparai N, Farquhar L, Henderson JM, Guyatt G. Impact of liver transplantation on health-related quality of life. Liver Transpl. 2000 Nov;6(6):779-83. doi: 10.1053/jlts.2000.18499. PMID: 11084068.
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13: Ong JP, Younossi ZM. Managing the hematologic side effects of antiviral therapy for chronic hepatitis C: anemia, neutropenia, and thrombocytopenia. Cleve Clin J Med. 2004 May;71 Suppl 3:S17-21. doi: 10.3949/ccjm.71.suppl_3.s17. PMID: 15468613.
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CORLD-PRO Publications

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Center for Outcomes Research in Liver Disease

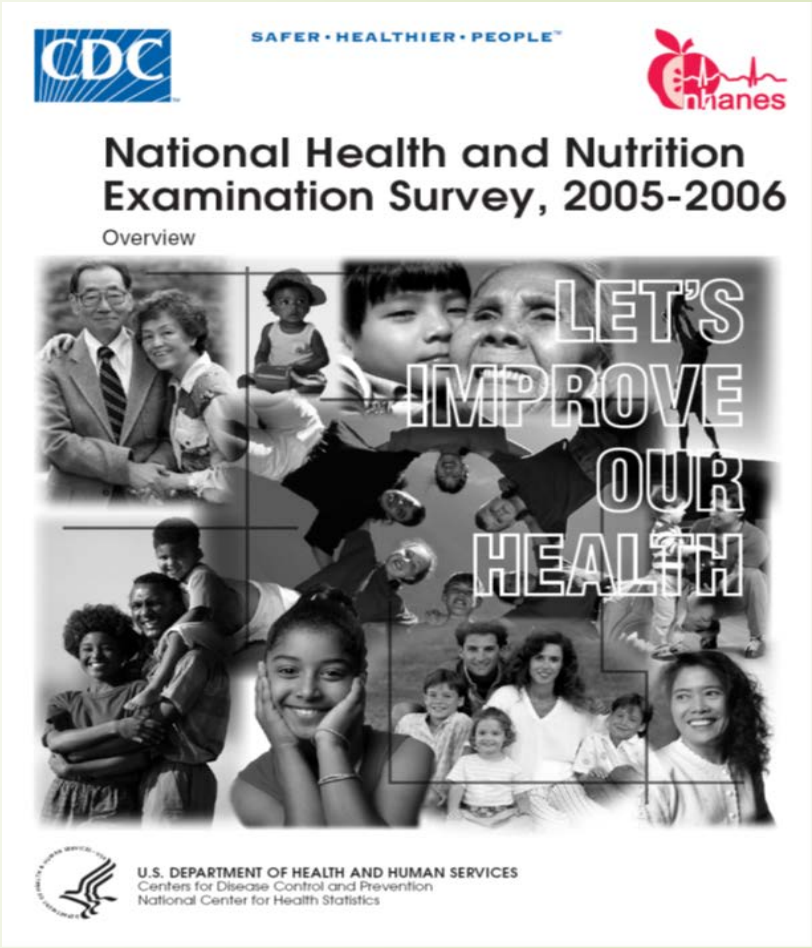
Large Database Analysis

Service Capabilities
CORLD, GNC and GLC
Large Database Analysis

- **Medicare**
  - Demographics, Total Number of Visits, Total Charge, Average Charge, LOS, Mortality, Comorbidity
- **NIS**
  - Inpatient care database; represents 20% stratified sample of US hospitals and 8 million annual admissions
- **SEER**
  - Cancer incidence and survival in US; data collected from 17 population based cancer registries covering 28% of the population
- **NHANES**
  - Health and nutritional status of adults and children in the US; demographic, socioeconomic, dietary, and health related questions
- **MEPS**
  - Households and insurance status; use of medical services, charges and sources of payments, access to care, satisfaction with care
- **Nationwide Readmissions Database (NRD)**
- **National Vital Statistics System (NVSS)**
- **SRTR (Scientific Registry of Transplant Recipients)**

National Health and Nutrition Examination Survey (NHANES)

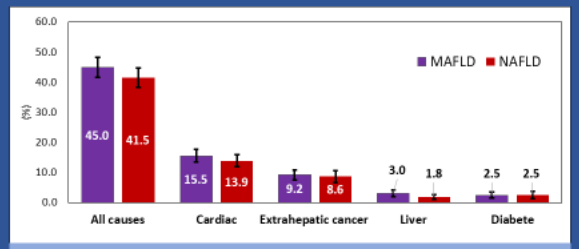
- Conducted by the National Center for Health Statistics, CDC.
- Reported biannually.
- Designed to collect information about the health and diet of people in the United States.
- Includes questionnaires, physical exam, lab work, other tests (hepatic U/S, vision).



National Health and Nutrition Examination Survey (NHANES)

Are There Differences Between Non-alcoholic Fatty Liver Disease (NAFLD) and Metabolic Associated Fatty Liver Disease (MAFLD)?

Cumulative incidence rates (%) of all-cause and cause-specific mortality among Individuals Classified as MAFLD and NAFLD in the U.S.



There were no differences in cumulative all-cause and cause-specific mortality between MAFLD and NAFLD over up to 27 years of follow-up (median, 22.8 years)

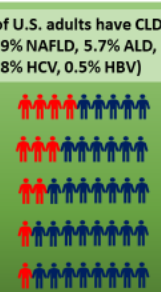
- NHANES III participants (N=12,878) were 43.1 years old; 49.5% male; 20.3% with FLD, 16.5% with NAFLD, and 18.1% with MAFLD.
- NHANES 2017-2018 participants (N=4,328) were 48.0 years old; 49.1% male; 36.8% with FLD; 34.2% with NAFLD and 36.3% with MAFLD.
- Excellent concordance was noted between MAFLD and NAFLD diagnosis in both datasets.
- Except for components of each definition (i.e. alcohol use for MAFLD), no other major differences in clinical characteristics were noted.
- In addition to the stage of fibrosis, insulin resistance was a predictor of liver mortality in NAFLD and alcoholic liver disease was a predictor of mortality in MAFLD.

Conclusion: MAFLD and NAFLD have similar clinical profiles and long-term outcomes. The increased liver-related mortality among MAFLD is primarily driven by alcoholic liver disease.

Younossi, et al. *Hepatology.*

Sarcopenia, Healthy Living and Mortality in Patients with Chronic Liver Diseases

35% of U.S. adults have CLDs (26.9% NAFLD, 5.7% ALD, 1.8% HCV, 0.5% HBV)



40 in 100 adults who have NAFLD had sarcopenia

27 years of follow-up

	Sarcopenia	Mortality	Non-Sarcopenia
NAFLD	42.4%	HR 1.24 (1.01 – 1.54)	20.8%
ALD	53.6%	HR 1.29 (0.76 – 7.93)	27.7%
HCV	57.1%	HR 0.95 (0.43 – 2.09)	28.9%
HBV	32.2%	HR 1.00 (0.05 – 21.0)	20.7%
Control	37.2%	HR 1.04 (0.85 – 1.27)	17.0%

Hazard ratio (HR) adjusted for age, sex, race, income, education, married status, cholesterol, glycemic control (GC), smoking status, blood pressure (BP), BMI, healthy diet, and physical activity (PA)

- Among NAFLD, Sarcopenia was a higher risk of cardiovascular-specific [HR:2.28 (1.71-3.05, p<.01)], cancer-specific [HR:1.90 (1.37-2.65, p<.01)], diabetes-specific [HR:6.42 (2.87-14.36, p<.01)], and liver-specific mortality [HR:2.49 (1.08-5.76, p:0.04).
- Among NAFLD, Sarcopenia was associated with a higher risk of all-cause mortality, especially lean NAFLD and liver mortality in females.
- The Life's Simple 7 (LS7) metrics with the strongest protection against sarcopenia were meeting ideal BMI, followed by ideal BP, ideal PA, and Idea GC among NAFLD.

Attainment of ideal LS7 metrics provides protection against sarcopenia in NAFLD.

Van Dongen, et al. *Hepatol Commun, 2022.*

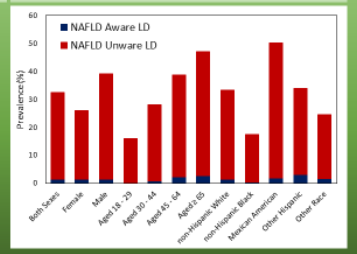
HEPATOLOGY COMMUNICATIONS

Poor Awareness of Liver Disease Among Adults with Nonalcoholic Fatty Liver Disease in the United States

In 2016, 87 million U.S. adults are estimated to have NAFLD

Only 6 in 100 adults who have NAFLD were aware of having liver disease (LD)

Awareness of Liver Disease (LD) Among Adults with NAFLD: 2007-2016



Among Adults with NAFLD:

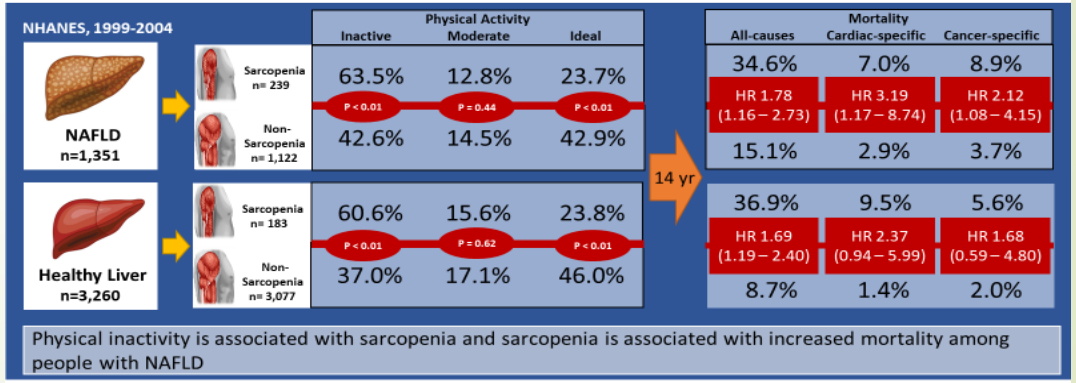
- Awareness of LD was lowest among males, among young adults (18-29 y) and among non-Hispanic Black.
- Worse awareness in young adults were mostly driven by worse measures in Mexican American, low education, active smoker, and hypertension.
- Trends in awareness of LD increased significantly from 4.3% in 2007 to 6.3% in 2016, but trends did not increase significantly within other stratifications of sex, age, or race.

Substantial efforts are need to improve awareness of NAFLD, particularly among the young adults and non-Hispanic Black.

Alqahtani, et al. *Hepatol Commun, 2021.*

HEPATOLOGY COMMUNICATIONS

Contribution of Sarcopenia and Physical Inactivity to Mortality in People with Non-Alcoholic Fatty Liver Disease



Physical inactivity is associated with sarcopenia and sarcopenia is associated with increased mortality among people with NAFLD

Hazard Ratios (HR) with adjustments of age, sex, race, sociodemographic, health behaviors and comorbidities

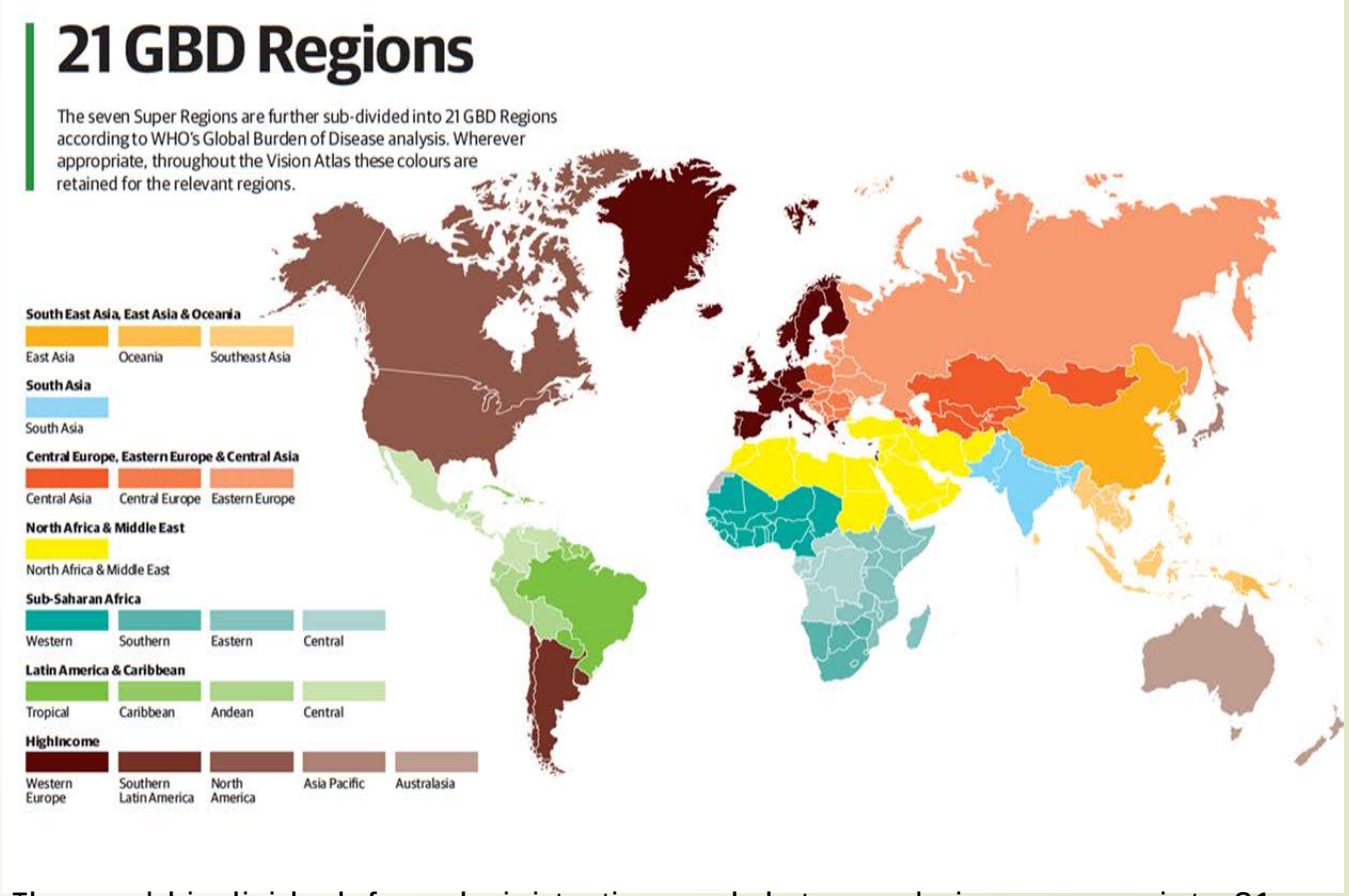
Golabi, et al.

National Health and Nutrition Examination Survey (NHANES)

- Food Insecurity, Household Income, and Education Level Substantially Increase the Risk of Having NAFLD and Advanced Fibrosis Among Adolescent Children in the United States (submitted to Journal of Hepatology)
- Nonalcoholic fatty liver disease (NAFLD) and associated mortality in individuals with type 2 diabetes, pre-diabetes, metabolically unhealthy, and metabolically healthy individuals in the United States. (2023) Metabolism.
- Vigorous physical activity provides protection against all-cause deaths among adults patients with nonalcoholic fatty liver disease (NAFLD). (2023) Alimentary Pharmacology & Therapeutics.
- Sarcopenia Among Patients with Nonalcoholic Fatty Liver Disease (NAFLD) Is Associated With Advanced Fibrosis. (2023) Clinical Gastroenterology and Hepatology.
- The impact of fatigue on mortality of patients with non-alcoholic fatty liver disease: Data from National Health and nutrition examination survey 2005–2010
- Prevalence of high and moderate risk nonalcoholic fatty liver disease among adults in the United States, 1999–2016. (2022) Clinical Gastroenterology and Hepatology
- Are there outcome differences between NAFLD and metabolic-associated fatty liver disease? (2022). Hepatology.
- Contribution of sarcopenia and physical inactivity to mortality in people with non-alcoholic fatty liver disease. (2020) JHEP Reports.
- Mortality risk detected by atherosclerotic cardiovascular disease score in patients with nonalcoholic fatty liver disease. (2019) Hepatology communications.
- The impact of modifiable risk factors on the long-term outcomes of non-alcoholic fatty liver disease. (2020) Alimentary pharmacology & therapeutics.
- Patients with lean nonalcoholic fatty liver disease are metabolically abnormal and have a higher risk for mortality. (2019) Clinical Diabetes.

Global Burden of Diseases, Injuries, and Risk Factors Study (GBD)

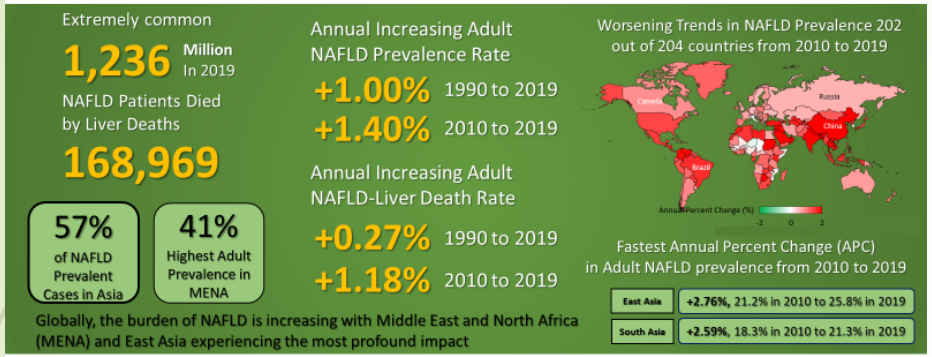
- Institute for Health Metrics and Evaluation (IHME) annually update GBD study to serve as a global public good. https://www.healthdata.org/gbd/2019
- GBD provides an assessment of cause-specific, incidence, morbidity (DALYs) and mortality for 369 causes in 204 countries and territories (21 GBD regions) from 1990 to 2019.



The world is divided, for administrative and data analysis purposes, into 21 GBD Regions according to epidemiological similarities and geographical proximity

Global Burden of Diseases, Injuries, and Risk Factors Study (GBD)

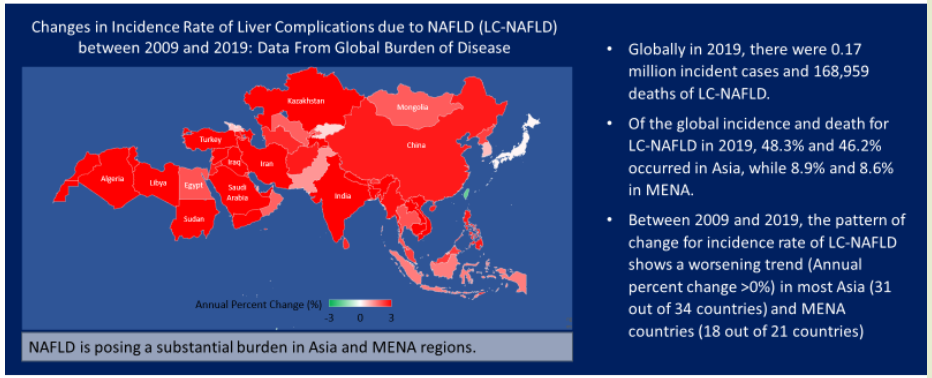
The Burden of Non-alcoholic Fatty Liver Disease (NAFLD) is Rapidly Growing in Every Region of the World from 1990 to 2019



Paik, et al. *Hepatol Commun.*

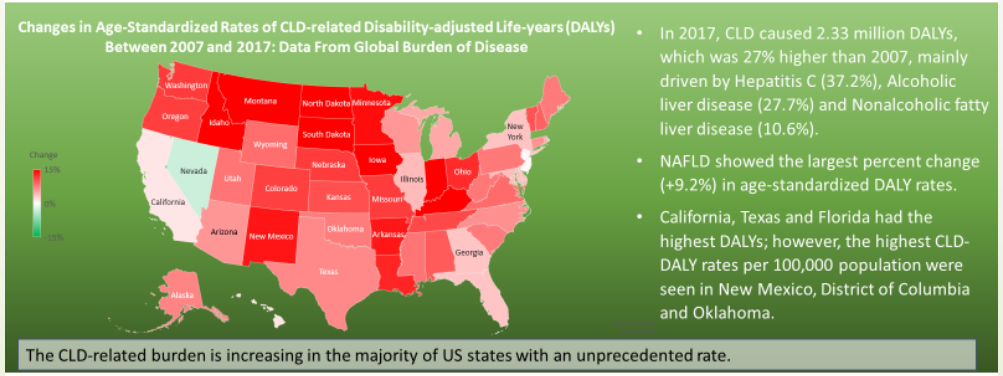
HEPATOLOGY COMMUNICATIONS

The Burden of Nonalcoholic Fatty Liver Disease (NAFLD) in Asia, Middle East and North Africa (MENA): Data from Global Burden of Disease 2009-2019



Pegah Golabi, James M. Paik, Saleh AlQahtani, Youssef Younossi, Gabriela Tuncer, Zobair M. Younossi

Growing Burden of Disability Related to Chronic Liver Diseases (CLD) in the United States: Data from Global Burden of Disease 2007-2017



Paik, et al. *Hepatol Commun.*

HEPATOLOGY COMMUNICATIONS

Global Burden of Diseases, Injuries, and Risk Factors Study (GBD)

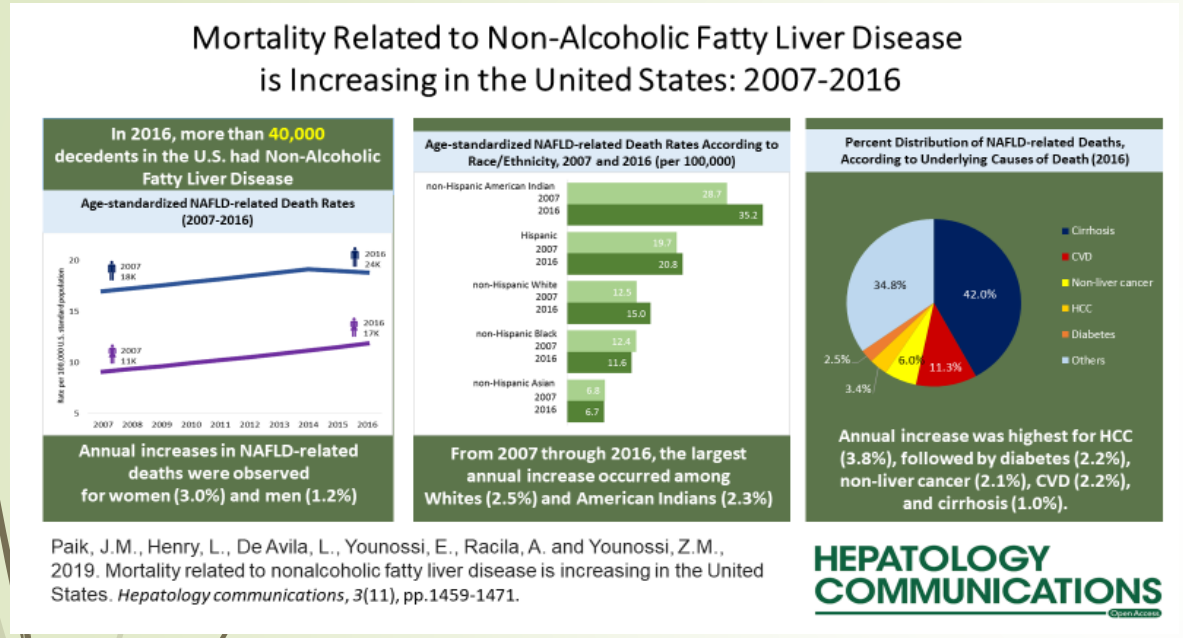
- The burden of nonalcoholic fatty liver disease (NAFLD) is rapidly growing in every region of the world from 1990 to 2019. (2023) Hepatology Communications.
- Nonalcoholic fatty liver disease mortality may not be decreasing: A need for careful interpretation of GBD 2019 estimates of liver deaths. (2023) Cell Metabolism.
- Global burden of NAFLD and chronic liver disease among adolescents and young adults. (2022) Hepatology.
- Dietary risks for liver mortality in NAFLD: global burden of disease data. (2022) Hepatology Communications.
- Burden of non-alcoholic fatty liver disease in Asia, the Middle East and North Africa: Data from Global Burden of Disease 2009-2019. (2021) Journal of Hepatology.
- Recent trends in the global burden of hepatitis B virus: 2007–2017. (2021) Gastroenterology.
- The growing burden of disability related to nonalcoholic fatty liver disease: data from the global burden of disease 2007-2017. (2020) Hepatology communications.
- Changes in the global burden of chronic liver diseases from 2012 to 2017: the growing impact of NAFLD. (2020) Hepatology. (2021 Impact Factor: Top Cited Articles)

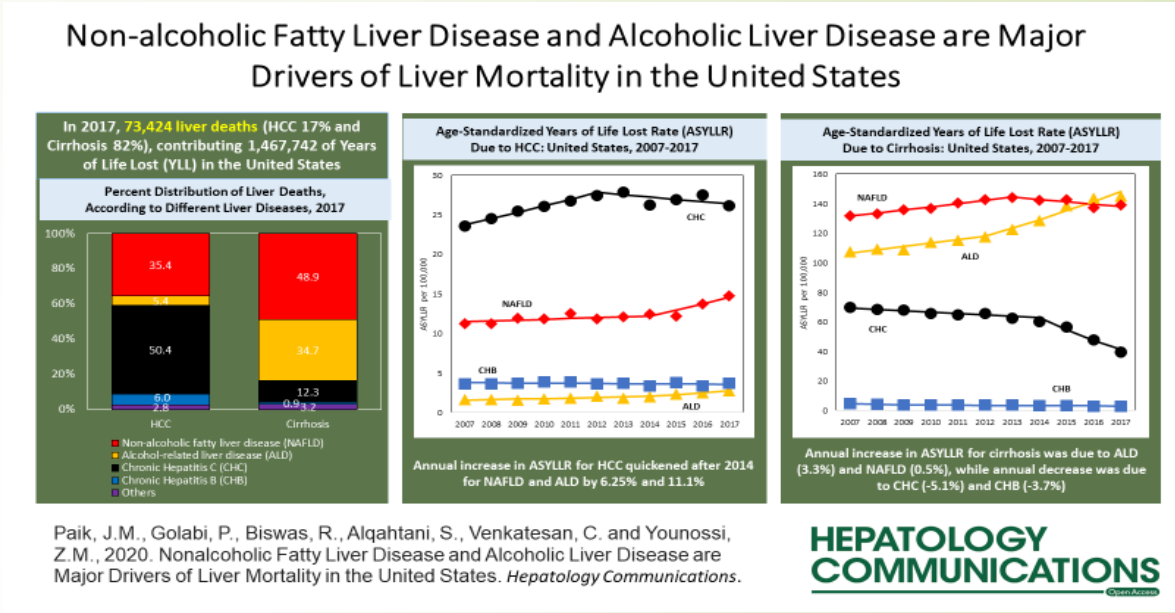
A complete list of publications (+5) is available on request.

National Vital Statistics System (NVSS)

- NVSS by the National Center for Health Statistics (NCHS) of the Centers for Disease Control (CDC) provide multiple cause-of-death data https://www.cdc.gov/nchs/nvss/mortality_methods.htm
- Information from death certificates filed in all 50 states and the District of Columbia.
- More than 99% of deaths in the U.S. are captured.

National Vital Statistics System (NVSS)





- Changes in Mortality Due to Chronic Liver Diseases (CLD) During the COVID-19 Pandemic: Data from the United States' National Vital Statistics System, (2023) PLOS ONE
- Adolescents' Suicide Rates by Ethnicity-Data from the National Vital Statistics System 2015-2020. (2022) Annals of Emergency Medicine.
- Extrahepatic manifestations and healthcare expenditures of non-alcoholic fatty liver disease in the Medicare population. (2022) Hepatology International.
- Nonalcoholic fatty liver disease and alcoholic liver disease are major drivers of liver mortality in the United States. (2020) Hepatology communications.
- Mortality related to nonalcoholic fatty liver disease is increasing in the United States. (2019) Hepatology Communications. (2021 Impact Factor: Top Cited Articles)

National Vital Statistics System (NVSS)

- Changes in Mortality Due to Chronic Liver Diseases (CLD) During the COVID-19 Pandemic: Data from the United States' National Vital Statistics System, (2023) PLOS ONE
- Adolescents' Suicide Rates by Ethnicity-Data from the National Vital Statistics System 2015-2020. (2022) Annals of Emergency Medicine.
- Extrahepatic manifestations and healthcare expenditures of non-alcoholic fatty liver disease in the Medicare population. (2022) Hepatology International.
- Nonalcoholic fatty liver disease and alcoholic liver disease are major drivers of liver mortality in the United States. (2020) Hepatology communications.
- Mortality related to nonalcoholic fatty liver disease is increasing in the United States. (2019) Hepatology Communications. (2021 Impact Factor: Top Cited Articles)

Other Large Data Base

- **Nationwide Readmissions Database (NRD)**
  - Non-alcoholic fatty liver disease is associated with greater risk of 30-day hospital readmission in the United States (U.S.). (2023) *Ann Hepatol*.

- **Surveillance, Epidemiology, and End Results (SEER)**
  - The impact of hepatocellular carcinoma diagnosis on patients' health-related quality of life. (2021) Cancer Med.

- **Medicare**
  - Hospice care utilization among elderly patients who died with hepatocellular carcinoma in the United States. (2021) JHEP Reports.
  - Among Medicare patients with hepatocellular carcinoma, non–alcoholic fatty liver disease is the most common etiology and cause of mortality. (2020) Journal of clinical gastroenterology.
  - Presumed nonalcoholic fatty liver disease among Medicare beneficiaries with HIV, 2006–2016. (2020) Open Forum Infectious Diseases.
  - Extrahepatic manifestations and healthcare expenditures of non-alcoholic fatty liver disease in the Medicare population. (2020) Hepatology International.
  - Resource Utilization and Outcomes of Medicare Recipients with Chronic Hepatitis B in the United States. (2019) Journal of Clinical Gastroenterology.

Service Capabilities
CORLD, GNC and GLC
Meta-Analysis

- Global Epidemiology of NASH. Hepatology 2016
- The global epidemiology of NAFLD and NASH in patients with type 2 diabetes: a systematic review and meta-analysis 2019
- The global epidemiology of nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH): a systematic review. (2023) Hepatology
- The Global Epidemiology of Metabolic Dysfunction Associated Steatotic Liver Disease and Metabolic Dysfunction Associated Steatohepatitis Among Type 2 Diabetes.

SRTR (Scientific Registry of Transplant Recipients)

	Lung	Heart	Liver	Kidney
N in 2006-2021	31,503	38,044	106,639	286,506

Consistently collected parameters:

- Age, gender, race
- State of residence
- Transplant center
- Education
- Insurance
- BMI
- Type 2 diabetes
- Viral hepatitis serology (not viral load)
- History of any cancer
- History of prior transplants
- Functional status (0-100)
- Listing diagnoses (two)
- Select donor's parameters
- Select details of surgery
- Outcomes (long-term mortality and graft loss, annually)

Publications for SRTR (Scientific Registry of Transplant Recipients)

1: Alqahtani SA, Stepanova M, Al Shabeeb R, Eberly KL, Ong J, Younossi ZM. The impact of hepatitis B and C positive serologies on the outcomes of non-hepatic solid organ transplantation in the United States. J Viral Hepat. 2023 Dec 29. doi: 10.1111/jvh.13916. Epub ahead of print. PMID: 38158773.

2: Younossi ZM, Stepanova M, Al Shabeeb R, Eberly KE, Shah D, Nguyen V, Ong J, Henry L, Alqahtani SA. The changing epidemiology of adult liver transplantation in the United States in 2013-2022: The dominance of metabolic dysfunction-associated steatotic liver disease and alcohol-associated liver disease. Hepatol Commun. 2023 Dec 22;8(1):e0352. doi: 10.1097/HC9.0000000000000352. PMID: 38126928; PMCID: PMC10749707.

3: Stepanova M, Kumar A, Brandt P, Gundurao N, Cusi K, Al Qahtani S, Younossi ZM. Impact of Type 2 Diabetes on the Outcomes of Solid Organ Transplantations in the U.S.: Data From a National Registry. Diabetes Care. 2023 Dec 1;46(12):2162-2170. doi: 10.2337/dc23-1085. PMID: 37748128.

4: Stepanova M, Kabbara K, Mohess D, Verma M, Roche-Green A, AlQahtani S, Ong Burra P, Younossi ZM. Nonalcoholic steatohepatitis is the most common indication for liver transplantation among the elderly: Data from the United States Scientific Registry of Transplant Recipients. Hepatol Commun. 2022 Jul;6(7):1506-1515. doi: 10.1002/hep4.1915. Epub 2022 Feb 28. PMID: 35224886; PMCID: PMC9234626.

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7: Younossi ZM, Stepanova M, Ong J, Trimble G, AlQahtani S, Younossi I, Ahmed A, Racila A, Henry L. Nonalcoholic Steatohepatitis Is the Most Rapidly Increasing Indication for Liver Transplantation in the United States. Clin Gastroenterol Hepatol. 2021 Mar;19(3):580-589.e5. doi: 10.1016/j.cgh.2020.05.064. Epub 2020 Jun 9. PMID: 32531342.

8: Stepanova M, Al Qahtani S, Mishra A, Younossi I, Venkatesan C, Younossi ZM. Outcomes of liver transplantation by insurance types in the United States. Am J Manag Care. 2020 Apr 1;26(4):e121-e126. doi: 10.37765/ajmc.2020.42839. PMID: 32270989.

9: Sayiner M, Stepanova M, De Avila L, Golabi P, Racila A, Younossi ZM. Outcomes of Liver Transplant Candidates with Primary Biliary Cholangitis: The Data from the Scientific Registry of Transplant Recipients. Dig Dis Sci. 2020 Feb;65(2):416-422. doi: 10.1007/s10620-019-05786-1. Epub 2019 Aug 27. PMID:

10: Golabi P, Bush H, Stepanova M, Locklear CT, Jacobson IM, Mishra A, Trimble G, Erario M, Venkatesan C, Younossi I, Goodman Z, Younossi ZM. Liver Transplantation (LT) for Cryptogenic Cirrhosis (CC) and Nonalcoholic Steatohepatitis (NASH) Cirrhosis: Data from the Scientific Registry of Transplant Recipients (SRTR): 1994 to 2016. Medicine (Baltimore). 2018 Aug;97(31):e11518. doi: 10.1097/MD.0000000000011518. PMID: 30075518; PMCID: PMC6081090.

11: Younossi Z, Stepanova M, Ong JP, Jacobson IM, Bugianesi E, Duseja A, Eguchi Y, Wong VW, Negro F, Yilmaz Y, Romero-Gomez M, George J, Ahmed A, Wong R, Younossi I, Ziayee M, Afendy A; Global Nonalcoholic Steatohepatitis Council. Nonalcoholic Steatohepatitis Is the Fastest Growing Cause of Hepatocellular Carcinoma in Liver Transplant Candidates. Clin Gastroenterol Hepatol. 2019 Mar;17(4):748-755.e3. doi: 10.1016/j.cgh.2018.05.057. Epub 2018 Jun 14. PMID:

12: Stepanova M, Sayiner M, de Avila L, Younoszai Z, Racila A, Younossi ZM. Long-term outcomes of liver transplantation in patients with hepatitis C infection are not affected by HCV positivity of a donor. BMC Gastroenterol. 2016 Nov 15;16(1):137. doi: 10.1186/s12876-016-0551-z. PMID: 27846801; PMCID: PMC5111255.

13: Stepanova M, Locklear T, Rafiq N, Mishra A, Venkatesan C, Younossi ZM. Long-term outcomes of heart transplant recipients with hepatitis C positivity: the data from the U.S. transplant registry. Clin Transplant. 2016 Dec;30(12):1570-1577. doi: 10.1111/ctr.12859. Epub 2016 Nov 8. PMID: 27739127.

14: Koenig A, Stepanova M, Saab S, Ahmed A, Wong R, Younossi ZM. Long-term outcomes of lung transplant recipients with hepatitis C infection: a retrospective study of the U.S. transplant registry. Aliment Pharmacol Ther. 2016 Aug;44(3):271-8. doi: 10.1111/apt.13693. Epub 2016 Jun 9. PMID: 27279496.

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16: Younossi ZM, Stepanova M, Saab S, Ahmed A, Lam B, Srishord M, Venkatesan C, Wai H, Henry L. The impact of viral hepatitis-related hepatocellular carcinoma to post-transplant outcomes. J Viral Hepat. 2016 Jan;23(1):53-61. doi: 10.1111/jvh.12449. Epub 2015 Aug 20. PMID: 26289820.

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19: Younossi ZM, Stepanova M, Saab S, Kalwaney S, Clement S, Henry L, Frost S,Hunt S. The impact of type 2 diabetes and obesity on the long-term outcomes of more than 85 000 liver transplant recipients in the US. Aliment Pharmacol Ther. 2014 Sep;40(6):686-94. doi: 10.1111/apt.12881. Epub 2014 Jul 16. PMID: 25040315.

20: Stepanova M, Wai H, Saab S, Mishra A, Venkatesan C, Younossi ZM. Theportrait of an adult liver transplant recipient in the United States from 1987 to 2013. JAMA Intern Med. 2014 Aug;174(8):1407-9. doi:10.1001/jamainternmed.2014.2903. PMID: 24978860.

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Projects

Periodic analysis of Global Registry (Ongoing)

- HDV and HRQoL (Complete)
- The Impact of Stigma on HRQoL (Complete)
- Cuban Data Analyses (Complete)
- Turkish Data Analyses (Complete)
- HCV Physicians Survey (Complete)
- NAFLD/MASLD Knowledge Survey of Hepatologists, Gastroenterologists, Endocrinologists and Primary Care Physicians in Saudi Arabia, Turkey, and Egypt (Complete)
- Clinical and PROs in Patients with Chronic Liver Diseases in Saudi Arabia, Turkey, and Egypt (Complete)
- The Burden of NAFLD/MASLD in Saudi Arabia: Data from the Global Burden of Disease 2019 (Complete)
- Prevalence of MASLD in the Middle East and North Africa (MENA): A Systematic Review and Meta-analysis (Complete)

Global Surveys

- NAFLD Global Physicians Survey (Complete)
- The Global Stigma Survey (Main analysis complete, Sub-analysis)
- Stigma in SLD: A Survey of Patients from Saudi Arabia (Complete)
- **Real-world Evidence on Non-Invasive Tests and Associated Cut-offs Used to Assess Fibrosis in Routine Clinical Practice Around the World (Ongoing)**
- **NAFLD/MASLD Investment Farmwork US and Germany (Ongoing)**
- **Global Unification Around SLD- GNC (Ongoing)**

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Abstract Presentations
2014-2023 (n=573)

1. Younossi ZM, et al. Development Of A Primary Biliary Cholangitis (Pbc)-specific Version Of Chronic Liver Disease Questionnaire: Cldq-pbc, Aasld2023
2. Stepanova M, …Younossi ZM. Liver Transplantation For Primary Biliary Cholangitis In The U.S. In 2008-2022, Aasld2023
3. Paik J, Younossi ZM. Assessment Of Hospital Readmission Rates, Risk Factors, Causes And Cost After Discharge With Chronic Liver Disease: Analysis Of The Us Nationwide Readmissions Database, Aasld2023
4. Younossi ZM, et al. Pnpla3-rs738409 CG/GG Genotype is strongly associated with advanced histologic fibrosis and high risk enhanced liver fibrosis score, aasld2023
5. Younossi ZM, et al. Stigma Is A Predictor Of Impairment Of Health Related Quality Of Life Among Patients With Nafld, Aasld2023
6. Paik J, Dipam Shah, Katherine Elizabeth Eberly, Pegah Golabi, Younossi ZM. Alcoholic Liver Disease And Non-alcoholic Fatty Liver Disease Were The Main Drivers Of Cirrhosis Related Deaths Before And During The Covid-19 Pandemic In The United States, Aasld2023
7. Paik J, …., Younossi ZM. Food Insecurity And Household Income Substantially Increase The Risk Of Nafld Among Adolescent Children In The United States, Aasld2023
8. Younossi ZM, et alA Rapid Rise In The Global Prevalence Of Nonalcoholic Fatty Liver Disease (Nafld) And Non-alcoholic Steatohepatitis (Nash) Among Patients With Type 2 Diabetes (T2d), Aasld2023.
9. Pegah Golabi, James M. Estep, Sean C. Felix, Stepanova M, Soroor Owrangi, Brian P. Lam, Maria Joao Meneses, Andrei Racila, Laurent Castera, Maria Paula Macedo, Younossi ZM. Fibrotic Nash Index (Fni) In Diabetics With Non-alcoholic Fatty Liver Disease (Nafld), Aasld2023.
10. Younossi ZM, Paik J, Henry L, Richard F Pollock, Stepanova M, Fatema Nader. Cost-effectiveness Of Identifying High-risk Non-alcoholic Fatty Liver Disease (Nafld) Patients In The United States (U.S), Aasld2023.
11. Younossi ZM, et al. Non-alcoholic Steatohepatitis (Nash) Has Become The Most Common Indication For Liver Transplantation Among Candidates With Hepatocellular Carcinoma In The United States, Aasld2023.
12. Younossi ZM, et al. The Global Survey Of Disease Burden And Stigma Among Patients With Nafld And Their Healthcrae Providers, Aasld2023.
13. Ali Weinstein, Leyla De Avila, Jillian Kallman Price, Carey Escheik, Pegah Golabi, Lynn Gerber, Younossi ZM. Individuals With Advanced Fibrosis Have Worse Fine Motor Performance, Aasld2023.
14. Younossi ZM, et alLiver Transplantation Profile Among Teenagers In The United States, Aasld2023.
15. Mohamed El Kassas, …., Younossi ZM. A Global Survey Of Physician Knowledge About Management Of Chronic Hepatitis C, Aasld2023.
16. Younossi ZM, et al Socio-economic Disparities Drive The Prevalence Of Non-alcoholic Fatty Liver Disease (NAFLD) Among Teenagers In The United States, EASL-ILC. Vienna, Austria. 2023
17. Younossi ZM, et al. Health Economics Of The Enhanced Liver Fibrosis Test In The Detection Of Advanced Liver Fibrosis In Patients With Non-alcoholic Fatty Liver Disease In The UK, EASL-ILC. Vienna, Austria. 2023

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Abstract Presentations
2014-2023 (n=573)

18. Golabi P,….Younossi ZM. Prevalence Of Nonalcoholic Fatty Liver Disease (NAFLD) And Advanced Fibrosis Among Subjects Without Type 2 Diabetes (T2D), ADA. San Diego, CA 2023
19. Younossi ZM, et al. Associations Of Genetic Risk Panel With Enhanced Liver Fibrosis Scores Among Patients With Non-alcoholic Fatty Liver Disease, EASL-ILC. Vienna, Austria. 2023
20. Younossi ZM, et al. Prevalence And Predictors Of Clinically Significant Pruritus In Patients With Non-alcoholic Fatty Liver Disease (NAFLD): Data From The Global NASH Registry™ (GNR™), EASL 2023
21. Stepanova M, …., Younossi ZM. The Impact Of Type 2 Diabetes On The Outcomes Of Solid Organ Transplants In The U.S., ADA 2023
22. Stepanova M, …, Younossi ZM. The Impact Of Hepatitis B And C Serologies On The Outcomes Of Non-liver Solid Organ Transplantation,. 2023
23. Younossi ZM, Paik J. Prevalence And Mortality Of Non-alcoholic Fatty Liver Disease (NAFLD) In Non-diabetics, Pre-diabetics, And Diabetics In The United States, EASL-ILC. Vienna, Austria. 2023
24. Younossi ZM, et al. The Growing Prevalence And Impact Of Type 2 Diabetes Among Liver Transplant Candidates In The United States, EASL-ILC. Vienna, Austria. 2023
25. Younossi ZM,. Stigma In NAFLD And NASH: A Global Survey Of Patients And Providers, EASL-ILC. Vienna, Austria. 2023
26. Younossi ZM, Paik J, Shira Zelber-sagi, Jeffrey V. Lazarus, Pegah Golabi, Janus P. Ong, Saleh Alqahtani, Henry L. The Growing Global Burden Of Non-alcoholic Fatty Liver Disease (NAFLD) Among Teenagers, EASL-ILC. Vienna, Austria. 2023
27. Younossi ZM, et al. Clinically Significant Pruritus In Patients With Chronic Liver Disease (Cld): Data From The Global Liver Registry ™ (Glr™), Ddw. Chicago, IL 2023
28. Golabi P, …Younossi ZM. Prevalance Of Nonalcoholic Fatty Liver Disease (Nafld) And Hepatic Fibrosis Among Patients With Pre-diabetes, Ddw. Chicago, IL 2023
29. Paik J, Ariana Ghafouri, Dipam Shah, Reem Al Shabeeb, Saleh Alqahtani, Younossi ZM. Global Burden Of Nonalcoholic Fatty Liver Disease (Nafld) In The Elderly, Ddw. Chicago, IL 2023.
30. Gerber S, …Younossi ZM. Patient-reported Diet Indicators And Disease Severity For Patients With NAFLD, SBM. Phoneix, AZ. 2023
31. Gerber S, …Younossi ZM.. Diet Satisfaction And Adequate Food Intake In Patients With Chronic Liver Diseases (CLD), SBM.
32. Younossi ZM, et al. Epidemiology And Disease Burden Of Nonalcoholic Fatty Liver Disease (Nafld) In Asia: A Systematic Review, Apasl. Taipei, Tawan. 2023
33. Paik J, ….Younossi ZM. The Burden Of Non-alcoholic Fatty Liver Disease (NAFLD) In Asia, APASL. Taipei, Taiwan. 2023

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Books, Chapters and Supplements
2014-2023 (n=19)

1. Golabi P, Isakov V, Younossi ZM. Nonalcoholic Fatty Liver Disease: Disease Burden and Disease Awareness. Clin Liver Dis. 2023 May;27(2):173-186. doi: 10.1016/j.cld.2023.01.001. Epub 2023 Feb 26. PMID: 37024201.
2. Henry L, Eberly KE, Shah D, Kumar A, Younossi ZM. Noninvasive Tests Used in Risk Stratification of Patients with Nonalcoholic Fatty Liver Disease. Clin Liver Dis. 2023 May;27(2):373-395. doi: 10.1016/j.cld.2023.01.022. Epub 2023 Mar 8. PMID: 37024214
3. Stepanova M, Henry L, Younossi ZM. Economic Burden and Patient-Reported Outcomes of Nonalcoholic Fatty Liver Disease. Clin Liver Dis. 2023 May;27(2):483-513. doi: 10.1016/j.cld.2023.01.007. Epub 2023 Mar 8. PMID:37024220.
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Manuscripts 2014-2023 (N=391)

1. Stepanova M, …Younossi ZM. Impact of Type 2 Diabetes on the Outcomes of Solid Organ Transplantations in the U.S.: Data From a National Registry, Diabetes Care. Diabetes Care . 2023 Sep 25:dc231085. doi: 10.2337/dc23-1085..
2. Younossi ZM, et al.. Identification of High Risk NAFLD Patients in Endocrinology Clinics, Endocrine Practice. Endocr Pract . 2023 Jul 3;S1530-891X(23)00469-X
3. Stepanova M, Younossi ZM. Editorial: optimal combination of non-invasive tests to determine significant fibrosis in non-alcoholic fatty liver disease-authors' reply, APT. 2023 Jun;57(12):1463-1464.
4. Younossi ZM, et al. The Global Burden of Liver Disease, Clinical Gastroenterology And Hepatology. Clin Gastroenterol Hepatol . 2023 Jul;21(8):1978-1991. doi: 10.1016/j.cgh.2023.04.015.
5. Paik J, …., Younossi ZM. Non-alcoholic fatty liver disease is associated with greater risk of 30-day hospital readmission in the United States (U.S.), Annals of Hep.
6. Lazarus JV, Kopka CJ, Younossi ZM, Allen AM. It's time to expand the fatty liver disease community of practice., Hepatology.
7. Henry L, Younossi ZM. Reply: NAFLD/MAFLD: One size does not fit all, certainly not for children!, Hepatology. Hepatology . 2023 Jun 1;77(6):E191.
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9. Younossi ZM, et al. The combination of the enhanced liver fibrosis and FIB-4 scores to determine significant fibrosis in patients with nonalcoholic fatty liver disease, APT. 2023 Jun;57(12):1417-1422. doi: 10.1111/apt.17472. Epub 2023 Mar 26.
10. Henry L, …, Younossi ZM. Noninvasive Tests Used in Risk Stratification of Patients with Nonalcoholic Fatty Liver Disease., Clinics In Liver Disease.
11. Henry A, …, Younossi ZM. Editorial: let's get physical-long-term benefits of vigorous physical activity in patients with nonalcoholic fatty liver disease. APT 2023
12. Harring M, ., Younossi ZM. Sarcopenia Among Patients With Nonalcoholic Fatty Liver Disease (NAFLD) Is Associated With Advanced Fibrosis., Clinical Gastroenterology And Hepatology. 2023 Feb 26;S1542-3565(23)00155-6. doi: 10.1016/j.cgh.2023.02.013. Online ahead of print.
13. Alina M. Allen, Jeffrey V. Lazarus, Younossi ZM. Healthcare and socioeconomic costs of NAFLD: A global framework to navigate the uncertainties., J of Hep
14. Leyla de Avila, …, Younossi ZM. Regular Exercise is Associated with Low Fatigue Levels and Good Functional Outcomes Post- COVID-19: A Prospective Observational Study, American Journal of Physical Medicine and Rehabilitation.
15. Younossi ZM, et alDevelopment and validation of a primary sclerosing cholangitis-specific health-related quality of life instrument: CLDQ-PSC., Hep Comm
16. Younossi ZM. Recent Research and Insights on the Disease Burden of Nonalcoholic Fatty Liver Disease and Nonalcoholic Steatohepatitis., Gastroenterol Hepatol
17. de Avila L, Younossi ZM NAFLD is independently associated with higher all-cause and cause-specific mortality, Clinical Gastroenterology And Hepatology.
18. Younossi ZM, et al. Clinical and patient-reported outcome profile of patients with hepatitis B viral infection from the Global Liver Registry™, J of Viral Hepatitis.
19. Younossi ZM, et al. The global epidemiology of nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH): a systematic review. Hepatology . 2023 Apr 1;77(4):1335-1347.
20. Younossi ZM, et al. The Growing Economic and Clinical Burden of Nonalcoholic Steatohepatitis (NASH) in the United States (U.S.), Journal of Clinical and Experimental Hepatology. J Clin Exp Hepatol . 2023 May-Jun;13(3):454-467. doi: 10.1016/j.jceh.2022.12.005. Epub 2022 Dec 22.
21. Younossi ZM, et al. A Practical Use of Non-invasive Tests in Clinical Practice to Identify High-Risk Patients with Non-alcoholic Steatohepatitis, APT

Center for Outcomes Research in Liver Disease

Economic Analysis

Service Capabilities
CORLD, GNC and GLC
Economic Analysis

- Economic burden, Cost-effectiveness analysis of treatment or screening, budget impact

Completed Projects

- Cost Effectiveness of Screening for HCV
- Economic Burden of NAFLD in the US and 5 EU countries
- Economic Burden of NAFLD in Hong Kong (Complete)
- Economic burden of NASH and NASH Fibrosis in the US
- Economic Burden of NASH in T2D
- Hypothetical Treatment of NASH
- Screening for High-Risk Non-alcoholic Fatty Liver Disease (NAFLD) is Cost Effective in the United States and UK
- The Growing Economic and Clinical Burden of Nonalcoholic Steatohepatitis (NASH) in the United States. (2023)

Ongoing Projects

1. Cost of Inaction in the US, Germany, Spain, Italy, Brazil, Japan, Saudi Arabia
   - Estimate the present and future economic burden of chronic diseases
2. Analyze the clinical data, cost data and quality of life inputs to determine the cost-effectiveness of latest therapies.

Publications Related to Economic Analysis

1. Younossi ZM, Paik JM, Henry L, Yang J, Fernandes G, Stepanova M, Nader F. The Growing Economic and Clinical Burden of Nonalcoholic Steatohepatitis (NASH) in the United States. J Clin Exp Hepatol. 2023 May-Jun;13(3):454-467. doi:10.1016/j.jceh.2022.12.005. Epub 2022 Dec 22. PMID: 37250870; PMCID:PMC10213853.
2. Stepanova M, Henry L, Younossi ZM. Economic Burden and Patient-Reported Outcomes of Nonalcoholic Fatty Liver Disease. Clin Liver Dis. 2023 May;27(2):483-513. doi: 10.1016/j.cld.2023.01.007. Epub 2023 Mar 8. PMID:37024220.
3. Tampi RP, Wong VW, Wong GL, Shu SS, Chan HL, Fung J, Stepanova M, Younossi ZM. Modelling the economic and clinical burden of non-alcoholic steatohepatitis in East Asia: Data from Hong Kong. Hepatol Res. 2020 Sep;50(9):1024-1031. doi:10.1111/hepr.13535. Epub 2020 Jul 20. PMID: 32537840.
4. Younossi ZM, Tampi RP, Racila A, Qiu Y, Burns L, Younossi I, Nader F. Economic and Clinical Burden of Nonalcoholic Steatohepatitis in Patients With Type 2 Diabetes in the U.S. Diabetes Care. 2020 Feb;43(2):283-289. doi:10.2337/dc19-1113. Epub 2019 Oct 28. PMID: 31658974.
5. Younossi ZM, Tampi RP, Nader F, Younossi IM, Cable R, Srishord M, Racila A. Hypothetical treatment of patients with non-alcoholic steatohepatitis: Potential impact on important clinical outcomes. Liver Int. 2020 Feb;40(2):308-318. doi:10.1111/liv.14292. Epub 2019 Nov 25. PMID: 31705834.
6. Bush H, Rafiq N, Younossi ZM. Implementation of Value-based Medicine (VBM) to Patients With Chronic Hepatitis C (HCV) Infection. J Clin Gastroenterol. 2019 Apr;53(4):262-268. doi: 10.1097/MCG.0000000000001174. PMID: 30681638.
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Center for Outcomes Research in Liver Disease

GNC Meetings

The Global NASH Council Regional, National and International Meetings

Year	Title	Location	Sponsor
2023	The Global NASH Council Meeting at AASLD - Hot Topics in MASLD (NIT Risk Stratification, Life Style Intervention and Educational programs to Increase awareness	Cambridge, MA, USA	Siemens Healthineers
2023	The Global NASH Council Meeting at EASL - Role of ELF in Clinical Practice	Vienna, Austria	Siemens Healthineers
2023	The Global NASH Council Meeting at EASL - Identifying Patients at Risk and Raising Awareness in NAFLD	Vienna, Austria	Intercept Pharmaceutical
2023	The Global NASH Council Meeting at EASL - Fatigue and Patient Reported Outcomes in Patients with Primary Biliary Cholangitis	Vienna, Austria	CymaBay
2022	The Global NASH Council Meeting at AASLD - Update on NITs and Treatment for NASH	Washington, DC, USA	Intercept Pharmaceutical
2022	The Global NASH Council Meeting at AASLD - Risk Stratification in Primary Care setting for NASH	Washington, DC, USA	Siemens Healthineers
2019	The Global NASH Council Meeting at AASLD - Global Burden of NASH: 1) Diet and Food Literacy in NAFLD, 2) Economic Burden of NASH in Hong Kong, 3) -NASH and PRO Presentation, 4) Global Burden of Liver Disease	Boston, MA, USA	Intercept Pharmaceutical
2019	Updates on Global NASH Council Collaborations and Clinical Trial Regiments with Treatment Priorities	Vienna, Austria	Intercept Pharmaceutical
2018	Summary of PRO and HEOR Global Advisory Board Meeting	San Francisco, CA, USA	Gilead Sciences
2018	Updates on Global NASH Council Collaborations and Clinical Trial Regiments with Treatment Priorities	San Francisco, CA, USA	Intercept Pharmaceutical
2018	Updates on Global NASH Council Collaborations and Clinical Trial Regiments with Treatment Priorities	Paris, France	Intercept Pharmaceutical
2017	Knowledge Gaps in NAFLD/NASH including Economic Burden & Latest in Diagnostics/Biomarkers	Washington, DC, USA	Intercept Pharmaceutical
2017	PRO Advisory Board at AASLD with Review of PRO and HEOR Collaborations in Liver Disease	Washington, DC, USA	Gilead Sciences
2016	PRO Advisory Board at AASLD with purpose of establishing a global expert council on PRO's and HEOR in Liver Disease	Boston, MA, USA	Gilead Sciences

Search

Year	Title	Location	Sponsor
2022	Expert Panel	Washington, DC, USA	Siemens Healthineers
2020	NIT Meeting	Falls Church, VA, USA	Intercept Pharmaceutical

The Global NASH council Meeting During AASLD 2023 in Boston, MA, USA

Upcoming meetings for 2024:

- GNC Asian Meeting During Asian Pacific Association for the Study of Liver in Kyoto Japan (March 30th, 2024)
- GNC Meeting During National Hepatology Congress and the Turkish Association for the Study of the Liver Meeting in Rize, Turkey (May 7-9th, 2024)
- GNC Meeting for Saudi Arabia and the Gulf Region during SASLT in Riyadh, Saudi Arabia (October 17-19, 2024)

GNC Recognition 2023

Presentations at AASLD 2023 November 2023, Boston MA, USA

1	Abstract #40938 Development Of A Primary Biliary Cholangitis-Specific Version Of Chronic Liver Disease Questionnaire: CLDQ-PBC	Zobair Younossi, Maria Stepanova, Issah Younossi, Andrei Racila
2	Abstract #42850 Non-Alcoholic Steatohepatitis (Nash) Has Become The Most Common Indication For Liver Transplantation Among Candidates With Hepatocellular Carcinoma In The United States	Zobair M. Younossi, Reem Al Shabeeb, Katherine Eberly, Dipam Shah, Veronica Nguyen , Janus Ong, Saleh A Alqahtani, Linda Henry, Maria Stepanova
3	Abstract #43328 A Rapid Rise In The Global Prevalence Of Nonalcoholic Fatty Liver Disease) And Non-Alcoholic Steatohepatitis Among Patients With Type 2 Diabetes	Zobair M. Younossi, Pegah Golabi, Jillian Price, Soroor Owrangi, Nagashree Gundu Rao, Romona Satchi, James M. Paik
5	Abstract #43839 PNPLA3-Rs738409 CG/GG Genotype Is Strongly Associated With Advanced Histologic Fibrosis And High Risk Enhanced Liver Fibrosis Score	Zobair M.Younossi, James M. Estep, Sean Felix, Brian P. Lam., Elena Younossi Nagashree Gundu-Rao, Leyla De Avila, Huong Pham, Becky Cable, Jillian Price, Andrei Racila, Maria Stepanova
7	Abstract #44101 Cost-Effectiveness Of Identifying High-Risk Non-Alcoholic Fatty Liver Disease Patients In The United States	Zobair M. Younossi, James M. Paik, Linda Henry, Richard F. Pollock, Maria Stepanova, Fatema Nader
8	Abstract #45122 Individuals With Advanced Fibrosis Have Worse Fine Motor Performance	Ali A. Weinstein, Leyla De Avila, Jillian K. Price, Carey Escheik, Pegah Golabi, Lynn Gerber, Zobair M. Younossi
10	Abstract #42842 Liver Transplantation Profile Among Teenagers In The United States	Maria Stepanova, Dipam Shah, Reem Al Shabeeb, Katherine Eberly, Veronica Nguyen, Janus Ong, Saleh A Alqahtani, Zobair M. Younossi
11	Abstract #42859 Liver Transplantation For Primary Biliary Cholangitis In The U.S. In 2008-2022	Maria Stepanova, Katherine Eberly , Dipam Shah, Reem Al Shabeeb, Veronica Nguyen, Janus Ong, Saleh A Alqahtani, Linda Henry, Zobair Younossi
12	Abstract #44005 Quantitation Of Plasma Cells, Cytotoxic T Cells, And Kupffer Cells/Macrophages With Hepatic Fibrosis Stage In Non-Alcoholic Steatohepatitis	James M. Estep, Anne Masters, Lakshmi Alaparthi, Gary Bratthauer, Aybike Birerdinc, Fanny Monge, Cassandra Sharp, Daisong Tan, Hala Abdelaal, Zachary Goodman, Zobair M Younossi
13	Abstract #44071 Food Insecurity And Household Income Substantially Increase The Risk Of NAFLD Among Adolescent Children In The U.S.	James M. Paik, Sandy Duong, Shira Zelber-Sagi, Jeffrey V. Lazarus, Linda Henry, Zobair M. Younossi
14	Abstract #44990 Alcoholic Liver Disease And Non-Alcoholic Fatty Liver Disease Were The Main Drivers Of Cirrhosis Related Deaths Before And During The Covid-19 Pandemic In The United States	James M. Paik, Dipam Shah, Katherine Eberly, Peagh Golabi, Linda Henry, Zobair Younossi
16	Abstract #46884 Assessment Of Hospital Readmission Rates, Risk Factors, Causes And Cost After Discharge With Chronic Liver Disease: Analysis Of The Us Nationwide Readmissions Database	James M. Paik, Becky Cable, Linda Henry, Leyla De Avila, Huong Pham, Zobair M. Younossi

Together for Better Liver Health: EASL Event During WHA76 May 22, 2023, Geneva Switzerland

The Global NASH Council participated in a meeting organized by EASL on the sidelines of the 76th World Health Assembly (May 2023) in Geneva, Switzerland. The event, held in a partnership between EASL, AASLD, ALEH, APASL, INASL, EASD, EASO, SOLDA, SAASL, WHF and ESPGHAN as well as a large number of other stakeholders including policymakers, representatives to the UN, WHO staff as well as thought leaders and people affected by NAFLD/MASLD disease.

https://easl.eu/event/easl_76thwha/speakers/

GPS Scholar-2022 The Global NASH Council and the Global Liver Council Members

The Global NASH Council (GNC) and Global Liver Council members have consistently demonstrated exceptional academic productivity, producing a substantial body of high-impact evidence in liver disease and NAFLD/MASLD. Our influential work has not only garnered widespread recognition but has also inspired and influenced the research directions. In the latest data from ScholarGPS (2022), our members have been ranked at the top of the field of liver disease, NAFLD, fatty liver disease and hepatology. Highly Ranked Scholars™-Lifetime are eminent authors whose Top Percentage Ranks places them above 0.05% of all scholars due to highly significant impact and quality of their scholarly contributions based on lifetime contributions.
https://scholargps.com/highly-ranked-scholars?year=2022&ranking_duration=LIFETIME&base_field=&base_specialty=Liver+disease