Monitoring and Management of NASH is an Unmet Need Among Hepatologists and Endocrinologists: An International Mixed-Method Study in Europe and the USA

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Introduction

- Patients with Non-Alcoholic Steatohepatitis (NASH) are often asymptomatic, yet are at increased risk of cardiovascular disease (CVD)
- They can also progress to advanced fibrosis/cirrhosis with the risk of developing hepatocellular carcinoma (HCC)

Objective

As part of a broader study aimed at identifying and understanding various types of clinical practice gaps & challenges experienced by specialists involved in NASH care, the findings on monitoring and management challenges are presented here

Method & Sample

- Mixed-methods study with hepatologists and endocrinologists practicing in Germany, Italy, the UK and the US.
 - Qualitative semi-structured interviews informing a quantitative online survey

Phase 1: **Identify Context & Priorities**

- Literature review
- Multidisciplinary discussions
- Areas of exploration
- Study design
- Ethics approval (IRB)

Phase 2: **Qualitative Exploration** 45 minute semi-structured interviews

Qualitative analysis (NVivo)

Phase 4: Triangulation & Interpretation

Phase 3:

Quantitative Validation

Quantitative analysis (SPSS)

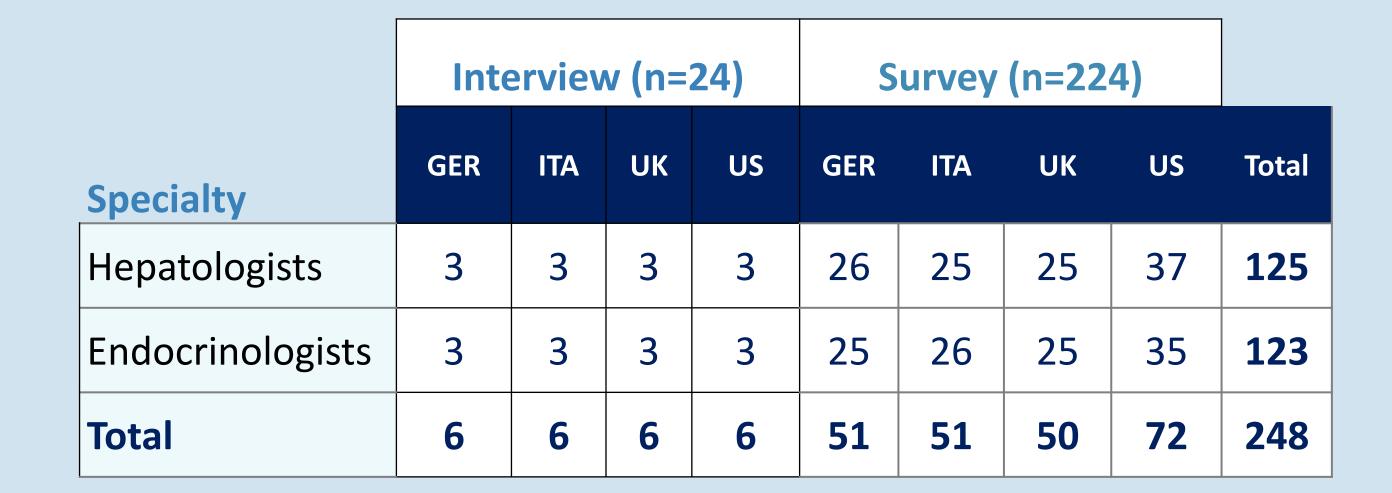
• 15-minute online survey

1. Liver Institute Northwest and Elson S. Floyd College of Medicine,

Washington State University, Seattle, WA, USA

2. AXDEV Group Inc., Brossard, QC, Canada

- Triangulation of findings
- Multidisciplinary interpretation
- Evidence-based identification of gaps, needs, barriers, and challenges



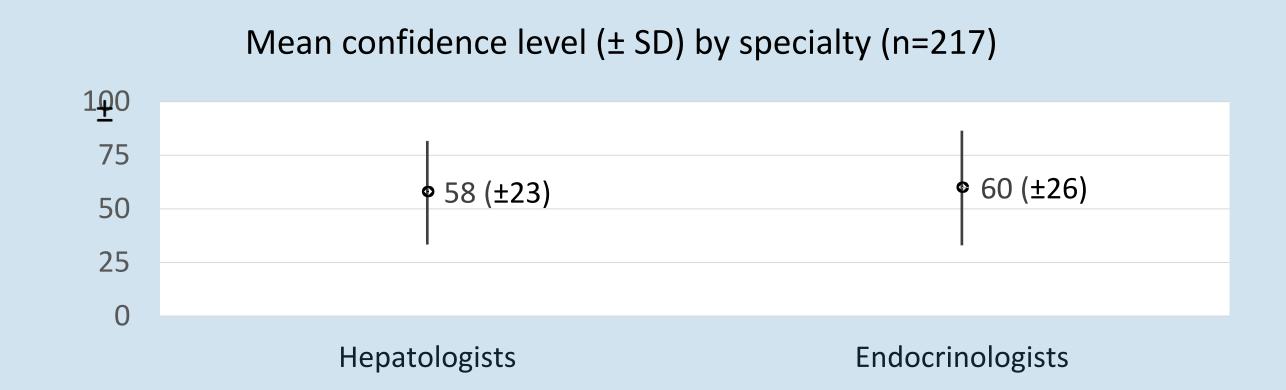
Results

- Interviewed physicians reported no specific CVD evaluation process for patients with NASH
 - Raised concerns that patients did not take CVD risks seriously enough to make lifestyle changes.

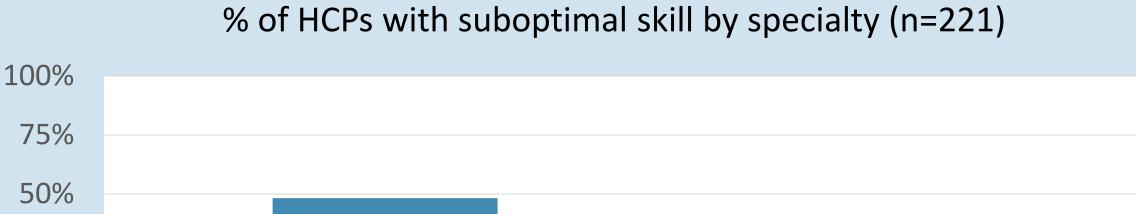
"I don't have a specific protocol for NASH patients with cardiovascular disease, as opposed to just following patients with cardiovascular disease in a general sense." -Endocrinologist, US

"...they have hypertension, and then you discover that they were diagnosed by their GPs, and they were initiated to treatment years ago, the patients do not check their blood pressure at home..." -Hepatologist, Italy

Mean confidence level in predicting patient CVD risk was suboptimal



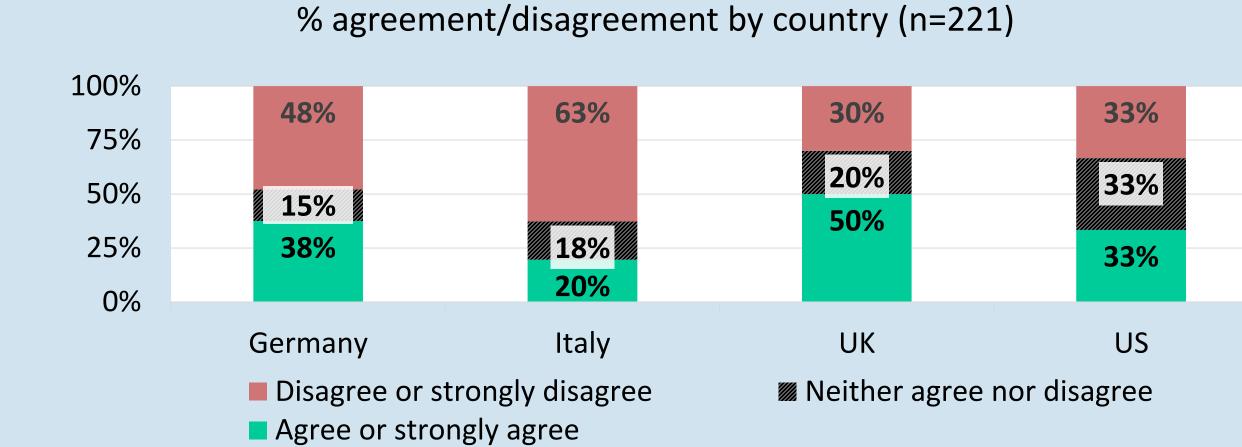
- Difference by specialty not significant (p=.459)
- More hepatologists than endocrinologists reported suboptimal skills in minimizing risks of CVD events
 - Higher % of suboptimal skill also in US (44%) & UK (43%), compared to Italy (35%) and Germany (18%)





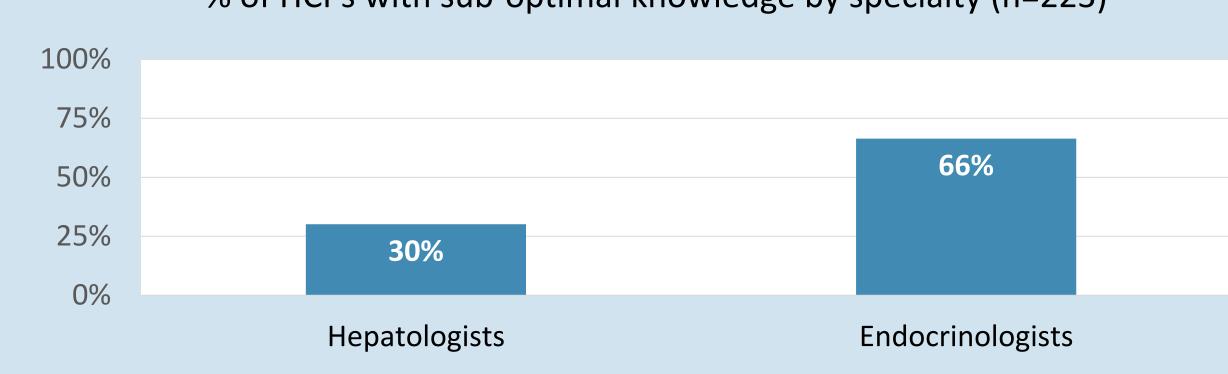
Significant difference by specialty (p<.001)

 Of surveyed respondents, 35% agreed/strongly agreed with "I find it impossible to monitor the effectiveness of exercise and diet"



Significant difference by country (p<.05)

- More endocrinologists than hepatologists reported suboptimal knowledge when determining follow-up frequency
 - % of HCPs with sub-optimal knowledge by specialty (n=223)



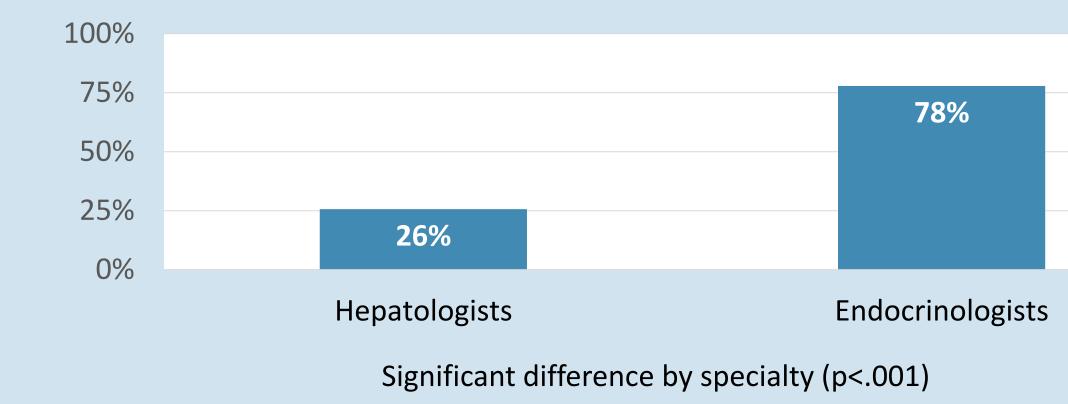
Significant difference by specialty (p<.001)

- Interviewed hepatologists reported that many patients and general practitioners were unaware of the importance of follow-up to monitor NASH progression.
- "...there sometimes can be issues with losing people to follow-up. It's an asymptomatic condition. [...] All we do is do some tests on them and say 'come back'. They sometimes can't see the point of that." -Hepatologist, UK

"If I see a patient with F2 or F3 fibrosis then I'm going to ask them to come see me at least once or twice a year to monitor that. But that doesn't always work, sometimes patients don't want to do that, sometimes the GP doesn't think it's necessary." -Hepatologist, Germany

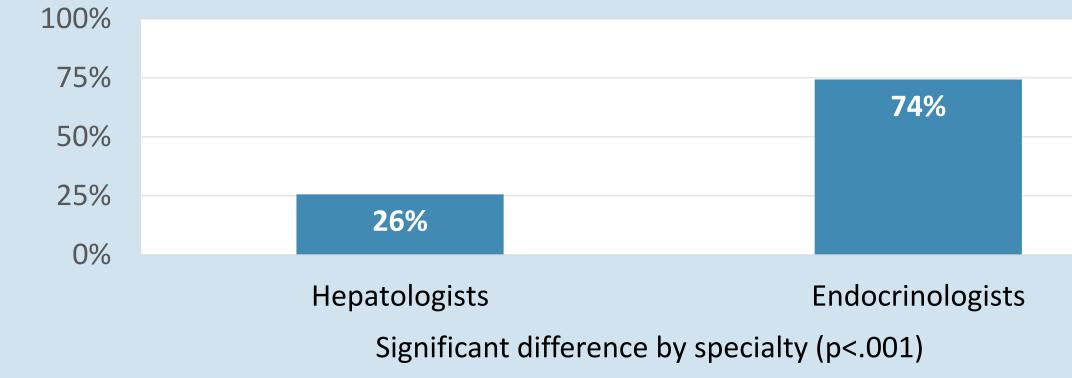
Endocrinologists reported suboptimal skill quantifying fibrosis





 Endocrinologists also reported suboptimal skill estimating HCC risk

% of HCPs with sub-optimal skill by specialty (n=218)



- Interviewed hepatologists and endocrinologists expressed a need for more reliable tests to predict HCC
- "...we do not have a specific factor that we can evaluate in order to understand how things will go. There is the alpha-fetoprotein, but that can only be measured in the presence of HCC. If there is no HCC, the alpha-fetoprotein will be normal. [...] if it is at an early stage, it is not necessarily detected." -Endocrinologist, Italy

"I'm not sure how sensible that is or the evidence base behind doing six-month ultrasounds [...] ultrasound is a really poor modality in overweight patients with NASH. [...] AFP, we monitor it, but it's not great, and not all liver cancers have raised AFP." -Hepatologist, UK

Conclusion

- Challenges faced by specialists in management of NASH have been identified regarding:
- o follow-ups
- There is a demonstrated need for tailored educational interventions addressing gaps in knowledge, skill, and confidence.
- Complex case scenarios could be used to address:

- Such interventions would contribute to: more consistent follow-up and monitoring of disease progression
- reduction of risks and complications
- enhancements in care of patients with NASH or at risk of developing NASH

Disclosure

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- monitoring of risk of CVD and HCC
- fibrosis stage
- CVD and HCC risks
- the need to promote lifestyle changes
- 3. International Atherosclerosis Society, Milan, Italy
- 4. Universita' degli Studi di Milano and IRCCS MultiMedica, Milan, Italy
- 6. Oxford Centre for Diabetes, Endocrinology and Metabolism, NIHR Oxford Biomedical Research Centre, University of Oxford, Oxford, England, UK
- 7. AXDEV Global Inc., Virginia Beach, VA, USA 5. Heart Institute (InCor) University of São Paulo Medical School Hospital, São Paulo, Brazil