WELCOME

Thank you for joining us for the 2016 International Conference on Viral Hepatitis (ICVH).

We welcome you to a state-of-the-science forum at which we will examine sound and practical strategies to understand and enhance the clinical management of hepatitis B virus (HBV) and hepatitis C virus (HCV) infections.

There is clearly a need for this conference. We base this assertion on the rapid changes that are occurring in the science of viral hepatitis, and the multifaceted clinical and behavioral issues that hepatologists, gastroenterologists, and HIV-treating clinicians must understand in order to deliver quality HBV and HCV treatment.

This conference is an important forum to present the best evidence on HBV and HCV treatment, but the primary reason we come together is to rapidly translate these scientific advances into approaches that can make a difference in real-world settings, improving dramatically the quality of life of many persons.

We extend our gratitude to the conference’s Planning Committee, the International Association of Providers of AIDS Care (IAPAC), the University of California, San Francisco (UCSF), and the International Association for the Study of the Liver (IASL). We also express our appreciation to our commercial supporters for their financial contributions.

Finally, a special thank you to our distinguished faculty for what we are sure to be cutting-edge presentations to help advance our learning objectives.

Vicente Soriano, MD, PhD
Co-Chair

Norah Terrault, MD, MPH
Co-Chair

1. Infectious Diseases Physician, Hospital Carlos III, Madrid, Spain
2. Professor of Medicine, University of California, San Francisco, CA, USA
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ACCREDITATION INFORMATION

The 2016 International Conference on Viral Hepatitis (ICVH 2016) is sponsored by the International Association of Providers of AIDS Care (IAPAC), in partnership with the University of California, San Francisco (UCSF) and the International Association for the Study of the Liver (IASL).

LEARNING OBJECTIVES
After completing this activity, participants will be able to:

- Describe strategies for viral hepatitis diagnosis and linkages to evidence-based care and treatment
- Define the characteristics and recommended use of approved agents for the management of viral hepatitis
- Identify treatment options for patients who present with viral hepatitis, including interventions to promote treatment success
- Discuss the management of complications due to viral hepatitis, its treatment, and/or comorbidities
- Explore ways to expand the categories of clinicians engaged in viral hepatitis management, including non-liver-specialists, nurses/nurse-practitioners, and pharmacists in a variety of practice settings, including primary care

TARGET AUDIENCE
The target audience for ICVH 2016 includes liver specialists (gastroenterologists & hepatologists), non-liver specialists (ID-specialized & HIV physicians), nurses, and pharmacists.

ACCREDITATION STATEMENT
The University of California, San Francisco School of Medicine (UCSF) is accredited by the Accreditation Council to provide continuing medical education for physicians.

CREDIT DESIGNATION STATEMENT
The University of California, San Francisco, designates this live activity for a maximum of 10.5 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

COPYRIGHT INFORMATION
All rights reserved. No part of this syllabus may be used or reproduced in any manner whatsoever without written permission except in the case of brief quotations embodied in articles or reviews.

DISCLAIMER STATEMENT
This UCSF CME educational activity was planned and developed to: uphold academic standards to ensure balance, independence, objectivity, and scientific rigor; adhere to requirements to protect health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and, include a mechanism to inform learners when unapproved or unlabeled uses of therapeutic products or agents are discussed or referenced.

This activity has been reviewed and approved by members of the UCSF CME Governing Board in accordance with UCSF CME accreditation policies. Office of CME staff, planners, reviewers, and all others in control of content have disclosed no relevant financial relationships.

NOTICE ABOUT OFF-LABEL USE PRESENTATIONS
ICVH 2016 may include presentations on drugs or devices, or use of drugs or devices that have not been approved by the Food and Drug Administration (FDA) or have been approved by the FDA for specific uses only. The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or device he or she wishes to use in clinical practice.
ACCREDITATION INFORMATION

VERIFICATION OF ATTENDANCE
Please remember to sign-in on the sign-in sheet when you check in at the Registration Desk on your first day. **You only need to sign-in once** for the course, when you first check in.

After the meeting, please visit this website to complete the Electronic CME Certificate Claiming:

http://www.ucsfcmecom/evaluation

Upon completing the Electronic CME Certificate Claiming, your CME certificate will be automatically generated to print.

ACTIVITY EVALUATION
The overall course evaluation is online and part of the Electronic CME Certificate Claiming at: http://www.ucsfcmecom/evaluation

We request you complete the Electronic CME Certificate Claiming within 30 days of the conference in order to receive your CME certificate through this format.

Otherwise you will need to certify your hours with the registration office at registration@ocme.ucsf.edu.

POST-PROGRAM SURVEY
The post-program survey will include a combination of case vignettes and rating questions designed to assess learning retention, as well as changes in clinician knowledge, attitude, confidence, and performance that may have occurred as a result of participation in this activity. This survey will be conducted three months post-conference.

CME CONTACT INFORMATION
For CME questions, please contact the University of California, San Francisco CME office:

UCSF Office of Continuing Medical Education
3333 California Street, Room 450
San Francisco, CA 94118

For attendee information: 415-476-4251
For exhibitor information: 415-476-4253

Visit the CME office’s website at www.cme.ucsf.edu.
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Fairfax, VA, USA

Seng Gee Lim, MD, MBBS
Yong Loo Lin School of Medicine
Singapore

Nancy S. Reau, MD
Rush University Medical Center
Chicago, IL, USA
FULL DISCLOSURE POLICY AFFECTING CME ACTIVITIES

The following faculty speakers, moderators, and planning committee members have disclosed they have no financial interest/arrangement or affiliation with any commercial companies that have provided products or services relating to their presentation(s) or commercial support for this continuing medical education activity:

- Edward Cachay, MD, MAS
- Kelly Eagen, MD
- Diana L. Sylvestre, MD
- John Ward, MD

The following faculty speakers have disclosed a financial interest/arrangement or affiliation with a commercial company that has provided products or services relating to their presentation(s) or commercial support for this continuing medical education activity. All conflicts of interest have been resolved in accordance with the ACCME Standards for Commercial Support:

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## DISCLOSURES

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2016 International Conference on Viral Hepatitis
<p>| DISCLOSURES |
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GENERAL INFORMATION

VENUE
The ICVH 2016 venue is the Mission Bay Conference Center. Plenary sessions and panel discussions will take place in the Robertson and Leach rooms. Poster Abstracts will be displayed in the Robertson Foyer, which is also the site of daily breakfast, coffee breaks, boxed lunches, as well as the Exhibitor Area.

BREAKFAST/COFFEE BREAKS/LUNCH
Continental breakfast will be provided to delegates on a complimentary basis from 7:30-8:30 a.m. on both Monday and Tuesday. Refreshments (during coffee breaks) are provided to delegates on a complimentary basis. Boxed lunch will be provided on both Monday and Tuesday. Please refer to the program for the times of the scheduled lunch breaks.

INTERNET ACCESS
Wireless Internet access is complimentary at the Mission Bay Conference Center by selecting the following network: UCSF Guest.

SOCIAL MEDIA
Join the conference’s Twitter conversation: #ICVH2016

SLIDE PRESENTATIONS/ABSTRACTS
Slide presentations will be available at www.iapac.org post-conference. The Program and Abstracts book distributed at registration will also be available in electronic format post-conference at www.iapac.org.

ARCHIVED WEBCAST SESSIONS
Archived webcasts of sessions in Robertson will be available at www.iapac.org three weeks post-conference.

QUESTIONS
If you have any questions during the conference, please locate an IAPAC staff member by leaving a message at the Registration Desk. If you have any questions post-conference, please contact Jonathon Hess, IAPAC’s Conference Manager, at jhess@iapac.org.

MISSION BAY CONFERENCE CENTER - 2ND FLOOR
## MONDAY, MARCH 14, 2016

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<td>7:30-8:30 a.m.</td>
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<td>8:30-8:45 a.m.</td>
<td>WELCOME BY CONFERENCE CO-CHAIRS Norah Terrault, MD, MPH Vicente Soriano, MD, PhD</td>
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<td>8:45-9:15 a.m.</td>
<td>Viral Hepatitis: A Global Snapshot of Challenges and Opportunities John Ward, MD</td>
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<td>9:15-9:45 a.m.</td>
<td>HBV: When Will It Be a Curable Disease? Marion G. Peters, MD</td>
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<td>9:45-10:15 a.m.</td>
<td>KEYNOTE ADDRESS After the Cure: Looking Ahead in HCV Management Nancy S. Reau, MD</td>
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<td>10:15-10:30 a.m.</td>
<td>QUESTION &amp; ANSWER SESSION</td>
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| 10:30-11:15 a.m. | ORAL ABSTRACT SESSIONS  
Leach  
Session 1: SOF/LDV                                      |
| 10:30-11:15 a.m. | ORAL ABSTRACT SESSIONS  
Robertson Foyer  
Session 2: HCV Treatment Challenges                     |
| 11:15-11:30 a.m. | BREAK                                                                                              |
| 11:30 a.m.-12:15 p.m. | ORAL ABSTRACT SESSIONS  
Robertson Foyer  
Session 3: SOF/VPV (ASTRALs)                           |
| 11:30 a.m.-12:15 p.m. | ORAL ABSTRACT SESSIONS  
Leach  
Session 4: HCV Elimination                            |
| 12:15-1:15 p.m. | LUNCH                                                                                              |
| 1:15-1:45 p.m. | Viral Hepatitis in Children and Adolescents Kathleen B. Schwarz, MD                                |
| 1:45-2:15 p.m. | Viral Hepatitis and Recreational Drug Users Christian Ramers, MD                                    |
| 2:15-2:45 p.m. | Viral Hepatitis and Pregnancy Tram T. Tran, MD                                                      |
| 2:45-3:00 p.m. | BREAK                                                                                              |
| 3:00-3:45 p.m. | Session 1: Acute Viral Hepatitis Daniel Frier, MD Anne F. Luetkemeyer, MD                            |
| 3:00-3:45 p.m. | Session 2: Chronic Viral Hepatitis Edward Cachay, MD, MAS                                            |
| 3:45-4:00 p.m. | BREAK                                                                                              |
| 4:00-5:00 p.m. | Translating Clinical Trial Promise into Real-World HCV Treatment Success  
Moderator: Vicente Soriano, MD, PhD  
Panelist 1: Kosh Agarwal, MD  
Panelist 2: Paul Pockros, MD                           |
| 5:00-5:45 p.m. | POSTER SESSION                                                                                      |
| 5:45 p.m.     | ADJOURN                                                                                             |
**TUESDAY, MARCH 15, 2016**

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<td><strong>Robertson Foyer</strong> NETWORKING/BREAKFAST</td>
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<td>8:30-9:00 A.M.</td>
<td><strong>Robertson</strong> New Tools for Assessing Disease Severity, Progression, and Regression in HBV and HCV Ji-Dong Jia, MD, PhD</td>
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<td>9:00-9:30 A.M.</td>
<td>Non-Alcoholic Steatohepatitis: What Is It and How Do We Treat and Monitor? Zobair M. Younossi, MD, MPH</td>
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<td>9:30-10:00 A.M.</td>
<td>HCV and Organ Transplantation Kosh Agarwal, MD</td>
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<tr>
<td>10:00-10:15 A.M.</td>
<td><strong>Robertson Foyer</strong> BREAK</td>
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<tr>
<td>10:15-11:00 A.M.</td>
<td>QUESTION &amp; ANSWER SESSION</td>
</tr>
<tr>
<td>11:00-11:45 A.M.</td>
<td>Treatment of HCV for Prevention of Transmission Moderator: Vicente Soriano, MD, PhD Panelist 1: Diana L. Sylvestre, MD Panelist 2: Seng Gee Lim, MD, MBBS</td>
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<tr>
<td>11:45 A.M.-1:00 P.M.</td>
<td><strong>Robertson Foyer</strong> LUNCH</td>
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<tr>
<td>1:00-1:30 P.M.</td>
<td><strong>Robertson</strong> Managing HCV Treatment Failure and Drug Resistance in Clinical Practice Vicente Soriano, MD, PhD</td>
</tr>
<tr>
<td>1:30-2:00 P.M.</td>
<td>Recent Advances and Future Prospectives for Therapy of Hepatocellular Carcinoma Morris Sherman, PhD, MB</td>
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<tr>
<td>2:00-2:30 P.M.</td>
<td>Treatment of HCV in Cirrhotic Patients Norah Terrault, MD, MPH</td>
</tr>
<tr>
<td>2:30-2:45 P.M.</td>
<td><strong>Robertson Foyer</strong> BREAK</td>
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<tr>
<td>2:45-3:30 P.M.</td>
<td>Is HIV a Special Population in the Viral Hepatitis Context? Moderator: Jennifer Price, MD Panelist 1: Vicente Soriano, MD, PhD Panelist 2: Maurizio Bonacini, MD</td>
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<tr>
<td>3:30-3:45 P.M.</td>
<td><strong>Robertson Foyer</strong> BREAK</td>
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<tr>
<td>3:45-4:30 P.M.</td>
<td>No One Left Behind: Optimizing the Viral Hepatitis Care Continuum Moderator: Norah Terrault, MD, MPH Panelist 1: Glen Pietrandoni, RPh Panelist 2: Kelly Eagen, MD</td>
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<tr>
<td>4:30-4:45 P.M.</td>
<td>CLOSING REMARKS Bridging Barriers to Improve Viral Hepatitis Outcomes Norah Terrault, MD, MPH Vicente Soriano, MD, PhD</td>
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<td>4:45 P.M.</td>
<td>ADJOURN</td>
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MONDAY, MARCH 14, 2016

Oral Abstract Session 1
SOF/LDV
10:30 A.M. - 11:15 A.M. (Robertson)  
Moderator: Ji-Dong Jia, MD, PhD

15 Ledipasvir/Sofosbuvir Is Safe and Effective for the Treatment of Patients with Genotype 1 Chronic HCV Infection in Both HCV Mono- and HCV/HIV-Coinfected Patients  
Anne F. Luetkemeyer presenting

22 A Single Tablet Regimen of Ledipasvir + Sofosbuvir is Efficacious and Well-Tolerated among People Receiving Opiate Substitution Therapy  
Nancy Reau presenting

25 Ledipasvir/Sofosbuvir (LDV/SOF) for 8 Weeks in Genotype 1 (GT1) Treatment-Naïve (TN) Non-Cirrhotic (NC) Patients with HCV Viral load (VL) <6 million IU/ml (6M): A Comparative Analysis of the Phase-3 ION-3 Efficacy Data to Real World Effectiveness (RWE)  
Norah Terrault presenting

Oral Abstract Session 2
HCV Treatment Challenges
10:30 A.M. - 11:15 A.M. (Leach)  
Moderator: Benjamin Young, MD, PhD

8 Comorbidities and Co-Medications of Patients with Chronic Hepatitis C (CHC) under Specialist Care in the United Kingdom – Challenges for Scaling Up HCV Treatment?  
Benjamin Hudson presenting

42 Bringing Hepatitis C Treatment into the Medical Home  
Joanna Eveland presenting

36 Real-World Effectiveness of Direct-Acting Antivirals for Hepatitis C among HIV-Infected Patients with Genotype 1  
Edward Cachay presenting

Oral Abstract Session 3
SOF/VPV (ASTRALs)
11:30 A.M. - 12:15 P.M. (Robertson)  
Moderator: Seng Gee Lim, MD, MBBS

26 A Phase 3 Double-Blind Placebo-Controlled Evaluation of Sofosbuvir/Velpatasvir Fixed-Dose Combination for 12 Weeks in Treatment-Naïve and -Experienced Genotype 1, 2, 4, 5, 6 HCV-Infected Patients with and without Cirrhosis: Results of the ASTRAL-1 Study  
Anne F. Luetkemeyer presenting

27 Sofosbuvir/Velpatasvir for the Treatment of HCV in Patients with Decompensated Liver Disease: The ASTRAL-4 Study  
Norah Terrault presenting

33 Sofosbuvir/Velpatasvir for 12 Weeks versus Sofosbuvir+Ribavirin for 24 Weeks in GT 3 HCV Patients: The Phase 3 ASTRAL-3 Study  
Nancy Reau presenting

Oral Abstract Session 4
HCV Elimination
11:30 A.M. - 12:15 P.M. (Leach)  
Moderator: Daniel Fierer, MD

19 Chronic Hepatitis C Virus (HCV) Burden in Rhode Island: Modelling Treatment Scale-Up and Elimination  
Ayorinde Soipe presenting

29 Seroreversion of HCV Antibodies in HIV-Positive Patients with Acute Hepatitis C following Sustained Virological Response  
Vicente Soriano presenting
Comorbidities and Co-Medications of Patients with Chronic Hepatitis C (CHC) under Specialist Care in the United Kingdom – Challenges for Scaling Up HCV Treatment?

Benjamin Hudson (presenting), William Irving, Stephen Barclay, Fiona Marra, Alex Walker

HCV Research UK, Glasgow, Scotland

Background: Most patients with CHC can benefit from direct-acting antiviral (DAA). Alongside specific CHC disease indicators, physical/psychiatric comorbidities, lifestyle factors and related co-medications with drug-drug interaction (DDI) potential will inform appropriate CHC treatment selection. We describe demographics, comorbidities and common co-medications of CHC patients currently under specialist care in the UK.

Methods: Retrospective analysis of routinely collected data of CHC patients from 59 UK specialist centres enrolled with the National HCV Research UK Biobank between 03/2012-10/2014.

Results: 6,278 patients were analysed. Median age 52 years (IQR 43-59), 70.4% male, 84.7% white. Genotype 1: 50%, 2: 4.0%, 3: 33.7%, 4: 3.6%, 5/6: 0.3%. Cirrhotic: 23.6% (age >60’s 36.6%). Acquisition mode: injection drug use (IDU) 59.2%, blood products 11.3%, non-UK born 9.4%, other 20.1%. Subgroup analysis for IDU acquisition and age was performed. Social history (Hx): previous/current heavy alcohol use: overall 38.3% (IDU 50.1%), current cannabis use: 24.6% (IDU 35.2%). Comorbidities: Hx of depression: 45.4% (IDU 57.6%), Hx of attempted suicide or inpatient treatment for depression: 19.4% (IDU 27.3%). HIV coinfection 5.0% (IDU: 4.5%). Prevalence of diabetes, cancer and renal dialysis correlated with age (diabetes: overall 11.3%, >60s 22.9%), (cancer: 8.1% vs 18.1%), (dialysis: 1.3% vs 2.2%). Most common co-medications with DDI potential were psychotropics with 38.6% (IDU 53.3%) on either antidepressant (22.9%), opioid replacement (21.2%) or hypnotic (10.4%) (includes polypharmacy). Prescriptions of anti-diabetics, statins, and immunosuppressants rose sharply with age (<60s 11.2%, >60s 31.7%).

Conclusions: We found high levels of co-morbidity, ongoing substance abuse and co-medication with DDI potential in CHC populations under specialist care in the UK. Age-related increasing levels of advanced liver disease, comorbidities, and polypharmacy may further increases the challenges in managing this patient group. CHC treaters need to be aware of DDI potential when choosing appropriate CHC treatments.
Ledipasvir/Sofosbuvir Is Safe and Effective for the Treatment of Patients with Genotype 1 Chronic HCV Infection in Both HCV Mono- and HCV/HIV-Infected Patients

Anne Luetkemeyer (presenting) 1, Mark Sulkowski 2, Curtis Cooper 3, Paul Kwo 4, Kris Kowdley 5, Sarjita Naik 6, Macky Natha 7, Luisa Stamm 6, Phillip Pang 6, Susanna Naggie 8

1. San Francisco General Hospital, San Francisco, CA, USA
2. Johns Hopkins School of Medicine, Baltimore, MD, USA
3. The Ottawa Hospital - Division of Infectious Diseases, Ottawa, ON, Canada
4. Indiana University School of Medicine, Indianapolis, IN, USA
5. Swedish Medical Center, Seattle, WA, USA
6. Gilead Sciences, Inc., Foster City, CA, USA
7. Chelsea and Westminster Hospital, London, England
8. Duke University Medical Center, Durham, NC, USA

Background: The current AASLD/IDSA Hepatitis C Guidance states that HIV/HCV -coinfected persons should be treated the same as persons without HIV infection, after recognizing and managing interactions with antiretroviral medications. We compared the safety and efficacy of the single tablet regimen of ledipasvir/sofosbuvir (LDV/SOF) in HCV genotype (GT) 1 patients co-infected with HIV-1 in the Phase III ION-4 study with HCV mono-infected GT 1 patients in the Phase III ION 1-3 studies.

Methods: In the ION-4 study, 327 GT 1 HCV/HIV-coinfected patients (126 treatment-naïve, non-cirrhotic, 134 treatment-experienced, non-cirrhotic, 20 treatment-naïve, cirrhotic, 47 treatment-experienced cirrhotic) received LDV/SOF 90/400 mg daily for 12 weeks. All patients received an antiviral regimen of tenofovir and emtricitabine with efavirenz, rilpivirine, or raltegravir. In the ION 1-3 studies, 538 GT 1 HCV monoinfected patients (395 treatment-naïve, non-cirrhotic, 87 treatment-experienced, non-cirrhotic, 34 treatment-naïve, cirrhotic, 22 treatment-experienced cirrhotic) received LDV/SOF 90/400 mg daily for 12 weeks. This pooled analysis will assess safety and sustained virologic response at week 12 (SVR12).

Results: Overall, 865 patients were treated with 12 weeks of LDV/SOF in the Phase III ION program. In ION-4, the overall SVR12 was 96% and relapse rate was 3% (10/335). In ION 1-3, the overall SVR12 was 97% and relapse rate was 2% (11/537). The SVR12 by treatment history, cirrhosis status, race and GT 1 subtype are reported in the table. Treatment was well tolerated in both monoinfected and coinfected patients. Most common adverse events (~10% reported in any arm) were fatigue, headache, diarrhea, and nausea. Only two patients discontinued treatment due to an adverse event.

Conclusions: In this pooled analysis, the once-daily, single tablet regimen of LDV/SOF for 12 weeks provided high rates of SVR regardless of presence of HIV infection and is a safe, well-tolerated option for patients with both HCV monooinfection and HIV/HCV coinfection.

Table 1. SVR12 by treatment history, cirrhosis status, race, and GT 1 subtype.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>ION 1</th>
<th>ION 2</th>
<th>ION 3</th>
<th>ION 1-3</th>
<th>ION 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Naive SVR12 (%)</td>
<td>210/213 (99)</td>
<td>208/216 (96)</td>
<td>418/429 (97)</td>
<td>138/146 (95)</td>
<td></td>
</tr>
<tr>
<td>Experienced SVR12 (%)</td>
<td>102/109 (94)</td>
<td>102/109 (94)</td>
<td>175/181 (97)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cirrhosis SVR12 (%)</td>
<td>32/34 (94)</td>
<td>19/22 (86)</td>
<td>51/56 (92)</td>
<td>63/67 (94)</td>
<td></td>
</tr>
<tr>
<td>Noncirrhotic SVR12 (%)</td>
<td>179/179 (100)</td>
<td>83/87 (95)</td>
<td>208/216 (96)</td>
<td>470/482 (98)</td>
<td>250/260 (96)</td>
</tr>
<tr>
<td>Blacks SVR12 (%)</td>
<td>24/24 (100)</td>
<td>24/24 (100)</td>
<td>40/42 (95)</td>
<td>89/90 (99)</td>
<td>103/115 (90)</td>
</tr>
<tr>
<td>Nonblacks SVR12 (%)</td>
<td>188/190 (99)</td>
<td>78/85 (92)</td>
<td>165/173 (95)</td>
<td>431/448 (96)</td>
<td>215/217 (99)</td>
</tr>
<tr>
<td>GT 1a SVR12 (%)</td>
<td>142/145 (98)</td>
<td>82/86 (95)</td>
<td>165/172 (96)</td>
<td>389/403 (97)</td>
<td>239/250 (96)</td>
</tr>
<tr>
<td>GT 1b SVR12 (%)</td>
<td>67/67 (100)</td>
<td>20/23 (87)</td>
<td>43/44 (98)</td>
<td>130/134 (97)</td>
<td>74/77 (96)</td>
</tr>
</tbody>
</table>
Chronic Hepatitis C Virus (HCV) Burden in Rhode Island: Modelling Treatment Scale-Up and Elimination

Ayorinde Soipe (presenting)\textsuperscript{1}, Homie Razavi\textsuperscript{2}, Devin Razavi-Shearer\textsuperscript{2}, Omar Gallaraga\textsuperscript{1}, Lynn Taylor\textsuperscript{1}, Brandon Marshall\textsuperscript{1}

1. Brown University, Providence, RI, USA
2. Center for Disease Analysis, Lafayette, CO, USA

Background: The objective of this study was to identify the most effective HCV treatment and prevention policies that will lead to a substantial decrease, and eventual elimination, of chronic HCV infection in Rhode Island (RI).

Methods: A modelling framework was constructed in Microsoft Excel, and Monte Carlo and sensitivity analyses were done using Crystal Ball add-in by Oracle. RI state-specific data were used to predict the HCV disease burden under four treatment scenarios: (1) continuation of the current HCV treatment paradigm (approximately 120 patients treated annually, Medicaid reimbursement criteria fibrosis stage ≥F3); (2) an immediate scale-up of treatment (to 360 annually), and less restrictive Medicaid reimbursement criteria (fibrosis stage ≥F2); (3) an immediate treatment scale-up and no fibrosis stage-specific Medicaid reimbursement criteria (≥F0) in accordance with American Association for the Study of Liver Diseases/Infectious Diseases Society of America recommendations; and (4), an “elimination” scenario (i.e., a continued treatment scale-up needed to achieve >90% reduction in viremic cases by 2030). We used beta-Project Evaluation and Review Technique (PERT) distributions to model uncertainty intervals.

Results: Immediate treatment scale-up with ≥F2 and ≥F0 fibrosis stage treatment criteria could reduce the number of cirrhotic cases by 25% and 16% respectively, and the number of liver-related deaths by 23% and 14%, respectively in 2030. To achieve a >90% reduction in viremic cases by 2030, almost 2,000 persons need to be treated annually by 2025. This treatment strategy could reduce cirrhosis cases and liver-related deaths by 72.4% and 67.5%, respectively, by 2030.

Conclusion: Substantial increase in HCV treatment availability is required to significantly reduce rates of advanced liver disease and HCV-related death in Rhode Island by the year 2030.
A Single Tablet Regimen of Ledipasvir + Sofosbuvir is Efficacious and Well-Tolerated among People Receiving Opiate Substitution Therapy

Nancy Reau (presenting), Jason Grebely, Stefan Mauss, Ashley Brown, Massimo Puoti, Trevor Hawkins, David Wyles, Macky Natha, Yanni Zhu, Claudio Avila, Gregory Dore, Val Carr

Background: Interferon (IFN)-based therapy has been shown to be safe and effective among people receiving opiate substitution therapy (OST); however, treatment uptake remains low due to poor tolerability to IFN and provider concerns regarding adherence and efficacy. The aim of this study was to compare the safety and efficacy of IFN-free ledipasvir (LDV) and sofosbuvir (SOF) ± ribavirin (RBV) among patients receiving and not receiving OST enrolled in the Phase III ION studies.

Methods: The Phase III ION studies evaluated a fixed-dose combination of LDV/SOF administered for 8, 12, or 24 weeks ± RBV in patients with chronic HCV genotype 1 and included patients who were treatment experienced and with compensated cirrhosis. People with active injecting drug use at baseline were not eligible for inclusion. Safety and efficacy, as measured by SVR12, were compared between those receiving and not receiving OST.

Results: Among 1,952 patients enrolled in the ION studies, 4% (n = 70) were receiving OST. Among people receiving OST (mean age 47 years), 69% were male, 90% white, 89% treatment-naïve, and 10% had cirrhosis. Overall SVR12 rates were comparable between people receiving and not receiving OST (94% vs. 97%, p = 0.244). There was no benefit with the addition of RBV (SVR12 97% in both groups). Treatment was well-tolerated among people receiving OST with no patients discontinuing treatment. Following the end of treatment, there have been no cases of HCV reinfection among people receiving OST.

Conclusion: Patients receiving OST achieve high and comparable response rates compared with those not receiving OST. Adverse events and discontinuations were low. LDV/SOF offers patients an interferon-free single tablet regimen which can be completed in as little as 8-24 weeks.

Disclosure of Interest Statement: This study was funded by Gilead Sciences.
Ledipasvir/Sofosbuvir (LDV/SOF) for 8 Weeks in Genotype 1 (GT1) Treatment-Naïve (TN) Non-Cirrhotic (NC) Patients with HCV Viral load (VL) <6 million IU/ml (6M): A Comparative Analysis of the Phase-3 ION-3 Efficacy Data to Real World Effectiveness (RWE)

Norah Terrault (presenting), Naoky Tsai, Michael Curry, Peter Buggisch, Yoori Lee, Macky Natha, Edward Eggleton, Tom Hahambis, Bruce Kreter, Diana Brainard, Kris Kowdley

Background: The optimal duration of therapy to achieve SVR depends on multiple factors. Patients treated with LDV/SOF with 8, 12 or 24 weeks achieved SVR12 from 94-100% in the ION Phase 3 studies. In a post-hoc analysis of the ION -3 (TN, NC patients) 8 week data, a VL<6M was shown to be the best predictor of SVR.

Methods: Diverse RWE LDV/SOF data is emerging from single-center and multicenter retrospective chart reviews to large multicenter prospective cohorts. In this analysis, the Phase-3 ION-3 data is compared with several real-world cohorts. Patient demographics, characteristics and SVR12 data has been collated and compared.

Results: The ION-3 post-hoc analysis reported 123 patients who were TN, NC and VL <6 M and treated with 8 weeks of LDV/SOF. Mean age was 52, 22% black, 72% GT1a; the SVR12 was 97%. In TARGET; 154 patients received an 8 week regimen with an SVR12 of 97%. In the TRIO cohort, 8-week therapy was initiated in roughly 1/3rd of patients with baseline VL <6 M, SVR12 data in 261 patients is 95%. Buggisch et al shows 100% SVR12 (n = 103). Mean age is 50, 49% GT1a and >90% had comorbid conditions. The GECCO cohort also includes patients with baseline HCV VL >6M, advanced fibrosis and HIV/HCV coinfection; SVR12 is 99% (n = 70). Low rates of adverse events (AEs), relapse rates and discontinuations were seen in all 4 cohorts.

Conclusions: LDV/SOF for 8 weeks in the appropriate patient population yielded high SVR rates in ION-3. Analysis of real world effectiveness data from several diverse and heterogeneous cohorts from the US and EU show SVR outcomes that were consistent with the Phase-3 ION-3 results and supports the use of 8 weeks LDV/SOF in treatment-naïve, non-cirrhotic GT1 patients with a baseline HCV VL <6 million IU/ml.

<table>
<thead>
<tr>
<th>Study</th>
<th>ION-3</th>
<th>TARGET</th>
<th>TRIO</th>
<th>Buggisch</th>
<th>GECCO</th>
<th>VA-Marshall</th>
<th>Total</th>
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<tr>
<td>(NGT 1)</td>
<td>123</td>
<td>154</td>
<td>263</td>
<td>103</td>
<td>70</td>
<td>48</td>
<td>638</td>
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<tr>
<td>Age (mean)</td>
<td>52 (22-73)</td>
<td>58* (19-84)</td>
<td>57 (18-84)</td>
<td>50 * (22-77)</td>
<td>52 * (44-58)</td>
<td>61 (32-75)</td>
<td>N/A</td>
</tr>
<tr>
<td>HIV/HCV</td>
<td>0</td>
<td>1/1</td>
<td>3/3</td>
<td>3/3</td>
<td>7/7</td>
<td>0</td>
<td>14/14</td>
</tr>
<tr>
<td>VL &gt;6 million</td>
<td>0</td>
<td>0</td>
<td>8/8</td>
<td>0</td>
<td>9/9</td>
<td>0</td>
<td>17/17</td>
</tr>
<tr>
<td>Cirrhotics</td>
<td>0</td>
<td>6/6</td>
<td>0</td>
<td>0</td>
<td>3/3</td>
<td>0</td>
<td>9/9</td>
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<tr>
<td>GT 4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2/2</td>
<td>0</td>
<td>0</td>
<td>2/2</td>
</tr>
<tr>
<td>Tx Exp</td>
<td>0</td>
<td>8/8</td>
<td>0</td>
<td>1/1</td>
<td>12/12</td>
<td>5/5</td>
<td>26/26</td>
</tr>
<tr>
<td>SVR12 (%)</td>
<td>97%</td>
<td>97%</td>
<td>95%</td>
<td>100%</td>
<td>99%</td>
<td>98%</td>
<td>97%</td>
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</tbody>
</table>

*Median age used
A Phase 3 Double-Blind Placebo-Controlled Evaluation of Sofosbuvir/Velpatasvir Fixed-Dose Combination for 12 Weeks in Treatment-Naïve and - Experienced Genotype 1, 2, 4, 5, 6 HCV-Infected Patients with and without Cirrhosis: Results of the ASTRAL-1 Study

Anne Luetkemeyer (presenting)1, Jordan Feld2, Kosh Agarwal3, Christophe Hezode4, Tarik Asselah5, Peter Ruane6, Norbert Gruener7, Armand Abergel8, Alessandra Mangia9, Ching-Lung Lai10, Henry Lik Yuen Chan11, Francesco Mazzotta12, Christophe Moreno13, Eric Yoshida14, William Towner15, Tram Tran15, Yanni Zhu17, Evgenia Svarovskaia17, John McNally19, Anu Osinusi17, Tom Hahambis18, Diana Brainard17, John McHutchison17, Ira Jacobson19, Stefan Zeuzem20

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2. University of Toronto, ON, Canada 12. Université Libre de Bruxelles, Belgium
4. Henri Mondor Hospital, University Paris-Est, Créteil, France 14. University of Alberta, Edmonton, AB, Canada
5. Centre de Recherche Bichat-Beaupé, Paris, France 15. Kaiser Permanente, Los Angeles, CA, USA
6. Ruane Medical and Liver Health Institute, Los Angeles, CA, USA 16. Cedars-Sinai Medical Center, Los Angeles, CA, USA
7. Ludwig Maximilian University of Munich, Germany 17. Gilead Sciences, Inc., Foster City, CA, USA
8. University Hospital Estaining of Clermont-Ferrand, France 18. Weill Cornell Medical College, San Francisco, CA, USA
9. IRCCS Hospital ‘Casa Sollievo della Sofferenza’, San Giovanni Rotondo, Italy 19. Mount Sinai Beth Israel, New York, NY, USA
10. University of Hong Kong 20. J.W. Goethe University Hospital, Frankfurt, Germany

Introduction: Velpatasvir (VEL) is a pangenotypic HCV-NS5A inhibitor. This Phase 3 study evaluated treatment with a fixed dose combination of SOF/VEL for 12 weeks in patients with genotype 1, 2, 4, 5, 6 HCV infection.

Methods: Patients with genotype 1, 2, 4, or 6 chronic HCV infection were randomized 5:1 to received SOF/VEL (400 mg /100 mg daily) or placebo for 12 weeks. Patients with genotype 5 infection were enrolled to the SOF/VEL treatment group and patients with genotype 3 were evaluated in a separate study.

Results: 740 patients were enrolled at 81 international sites: 60% male, 79% white, 32% treatment-experienced (TE), and 19% compensated-cirrhosis. Of the 624 patients treated with SOF/VEL, the genotype distribution was 53% GT1, 17% GT2, 19% GT4, 6% GT5 and 7% GT6. Overall SVR12 for SOF/VEL-treated patients was 99.0% and the study met its primary efficacy end-point. SVR12 rates by HCV genotype are presented in the table. Two of 325 patients (0.6%) with genotype 1 infection, including 1 of 73 with cirrhosis, had virologic relapse: 1 genotype 1a treatment-naive non-cirrhotic and 1 genotype 1b treatment-experienced with cirrhosis. No patients with genotype 2, 4, 5, or 6, including 48 with cirrhosis, had virologic failure. Four patients did not achieve SVR12 for non-virologic reasons. Overall, the type, frequency and severity of AEs and laboratory abnormalities were similar in the SOF/VEL-treated patients compared with the 116 placebo-treated patients. Three patients discontinued treatment due to adverse events, 1 treated with SOF/VEL and 2 with placebo. One SOF/VEL-treated patient died 8 days after completion of treatment of unknown causes.

Conclusions: Treatment with the once daily, all-oral, single tablet regimen of SOF/VEL for 12 weeks is well tolerated and results in high SVR12 rates in treatment-naive and treatment-experienced genotype 1,2,4,5,6 HCV-infected patients with and without cirrhosis.

SVR12 Rates by HCV Genotype

<table>
<thead>
<tr>
<th>HCV Genotype</th>
<th>Total (N = 624)</th>
<th>GT-1 (N = 328)</th>
<th>GT-2 (N = 104)</th>
<th>GT-4 (N = 116)</th>
<th>GT-5 (N = 35)</th>
<th>GT-6 (N = 41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cirrhosis</td>
<td>19.4%</td>
<td>22.3%</td>
<td>9.6%</td>
<td>23.3%</td>
<td>14.3%</td>
<td>14.6%</td>
</tr>
<tr>
<td>%, (n/N)</td>
<td>(121/624)</td>
<td>(73/328)</td>
<td>(10/104)</td>
<td>(27/116)</td>
<td>(5/35)</td>
<td>(6/41)</td>
</tr>
<tr>
<td>SVR12</td>
<td>99.0%</td>
<td>98.5%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>97.1%</td>
<td>100.0%</td>
</tr>
<tr>
<td>%, (n/N)</td>
<td>(618/624)</td>
<td>(323/328)</td>
<td>(104/104)</td>
<td>(116/116)</td>
<td>(34/35)</td>
<td>(41/41)</td>
</tr>
</tbody>
</table>
Sofosbuvir/Velpatasvir for the Treatment of HCV in Patients with Decompensated Liver Disease: The ASTRAL-4 Study


1. University of California, San Francisco, CA, USA
2. Intermountain Medical Center, Salt Lake City, UT, USA
3. Baylor Simmons Transplant Institute, Dallas, TX, USA
4. Weill Cornell Medical College, San Francisco, CA, USA
5. Duke University, Durham, NC, USA
6. Washington University School of Medicine, St. Louis, MO, USA
7. Jefferson University Hospitals, Philadelphia, PA, USA
8. University of Pennsylvania, Philadelphia, PA, USA
9. University of Texas Health Science Center, San Antonio, TX, USA
10. The Mount Sinai Hospital, New York, NY, USA
11. New York University Langone Medical Center, New York, NY, USA
12. University of Michigan, Ann Arbor, MI, USA
13. University of Miami, FL, USA
14. University of North Carolina at Chapel Hill, NC, USA
15. Gilead Sciences, Inc., Foster City, CA, USA
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Background: HCV-infected patients with decompensated liver disease have significant morbidity and mortality with limited HCV treatment options. Velpatasvir (VEL) has demonstrated high SVR rates in patients with genotypes 1–6 HCV when used in combination with sofosbuvir (SOF). This Phase-3 study evaluated the safety and efficacy of the fixed-dose-combination (FDC) of SOF/VEL in HCV-infected patients with decompensated liver disease.

Methods: Genotype (GT) 1, 2, 3, 4 or 6 HCV infected patients with CPT-B cirrhosis were randomized 1:1:1 to receive SOF/VEL (400 mg/100 mg) daily for 12-weeks, SOF/VEL+ weight-based RBV for 12-weeks, or SOF/VEL for 24-weeks. Patients with prior liver transplant or hepatocellular carcinoma were excluded.

Results: Of the 267 patients treated, most were male (70%), white (90%) and treatment experienced (55%). Patients had genotype 1 (78%), 2 (4.5%), 3 (15%), 4 (3%) or 6 (<1%) HCV infection. The SVR12 and relapse rates are shown in table 1. SOF/VEL+RBV for 12 weeks resulted in high SVR rates with virologic failure occurring in 1 (1%) of GT-1 and 2 (15.2%) of GT3 subjects respectively. There were no virologic failures among the genotype 2, 4 and 6 infected patients. Among patients who achieved SVR, 47% and 56% had improvements in CPT and MELD scores, respectively. The most common adverse events were fatigue, headache, nausea (anemia in the RBV containing arm). Overall 9 patients discontinued SOF/VEL due to adverse events. 47 (18%) patients experienced serious adverse events and there were 9 deaths (sepsis (3); liver failure (2); cardiopulmonary arrest (2); myocardial infarction (1) and respiratory failure (1); none were related to study drug.

Conclusions: SOF/VEL+RBV for 12-weeks resulted in high SVR rates across all HCV genotypes in decompensated patients with early improvements in liver function. This regimen was well tolerated with AEs consistent with clinical sequelae of advanced liver disease and RBV.
Seroreversion of HCV Antibodies in HIV-Positive Patients with Acute Hepatitis C following Sustained Virological Response

Vicente Soriano (presenting), Carmen de Mendoza, Pablo Labarga, José M. Peña, Pablo Barreiro

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Background: The recognition of epidemics of acute hepatitis C in HIV-positive MSM has prompted to recommend periodic screening of HCV antibodies (HCV-Ab) in this population. Early treatment may provide high rates of viral clearance even using peginterferon-ribavirin therapy. Whereas HCV-Ab generally remain detectable for more than a decade in most chronic hepatitis C patients that achieve SVR (Toyoda et al. CID 2005), little is known on HCV-Ab dynamics and persistence in patients cured following acute hepatitis C, either spontaneously or with antiviral therapy. Moreover, this information is anecdotal in persons with HIV coinfection (García-Costa et al. CID 2009).

Methods: All 2,328 HIV-positive individuals attending a large HIV clinic in Madrid during the last decade were examined. Acute hepatitis C was diagnosed based on HCV seroconversion and/or positive serum HCV-RNA in a previous negative individual with compatible symptoms and/or elevated liver enzymes.

Results: A total of 32 cases of acute hepatitis C were diagnosed during the 10-year study period, all in HIV-positive MSM. Median age 37 (range 27-55) years old. Syphilis was concomitantly diagnosed in 13 (40.6%). Most subjects were on antiretroviral therapy, had undetectable plasma HIV-RNA and CD4 counts >350 cells/mm³. HCV genotypes 1a and 4 were recognized in most subjects (36% and 51%, respectively). All but one depicted HCV-RNA+/HCV-Ab+. One individual with isolated HCV-RNA at presentation became HCV seroreactive one month later. Peginterferon-ribavirin was given for 24 weeks to 17 acute hepatitis C patients, of whom 15 (89%) achieved SVR. Median time for therapy onset was 14 (range 4 -32) weeks. Of the remaining 17 untreated patients, 4 achieved spontaneous HCV clearance at weeks 6, 8, 16 and 144 since diagnosis. At last control, serum HCV-Ab were tested in this population using a commercial EIA HCV-Ab assay (Abbott). HCV-Ab seroreactivity persisted in all but 3 individuals, being achieved the latest SVR with antiviral therapy after a median of 49 (38-95) months.

Conclusion: Seroreversion for HCV-Ab seems to be very rare. It may occur following acute hepatitis C in some HIV-positive subjects that cure the infection with antiviral therapy but not in those that clear the virus spontaneously.

Outcome following Acute Hepatitis C in 32 HIV-Positive Patients

<table>
<thead>
<tr>
<th>Outcome following Acute Hepatitis C</th>
<th>N</th>
<th>Median follow-up (months)</th>
<th>HCV-Ab seroreversion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progression to chronicity</td>
<td>13</td>
<td>57</td>
<td>0</td>
</tr>
<tr>
<td>Spontaneous clearance</td>
<td>4</td>
<td>49</td>
<td>0</td>
</tr>
<tr>
<td>SVR with antiviral therapy</td>
<td>15</td>
<td>34</td>
<td>3</td>
</tr>
</tbody>
</table>
Sofosbuvir/Velpatasvir for 12 Weeks versus Sofosbuvir+Ribavirin for 24 Weeks in GT 3 HCV Patients: The Phase 3 ASTRAL-3 Study

Nancy Reau (presenting), Alessandra Mangia, Stuart K. Roberts, Stephen Pianko, Alexander J. Thompson, Curtis Cooper, Brian Conway, Marc Bourlière, Tarik Asselah, Thomas Berg, Stefan Zeuzem, William K. Rosenberg, Kosh Agarwal, Edward Gane, Catherine Stedman, Francesco Mazzotta, Tram Tran, Stuart C. Gordon, Evguenia Svarovskaia, Lingling Han, Anu Osinusi, Macky Natha, Sean Byrne, Frida Abramov, Diana Brainard, John McNally, Anu Osinusi, Macky Natha, Sean Byrne, Stuart C. Gordon, Evguenia Svarovskaia, Lingling Han, John McNally, Anu Osinusi, Macky Natha, Sean Byrne, Frida Abramov, Diana Brainard, John McHutchison, Nezam H. Afdhal, Graham Foster

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Background: Velpatasvir (VEL) is a pangenotypic HCV NS5A inhibitor and sofosbuvir (SOF) is a pangenotypic NS5B polymerase inhibitor. In Phase 2 studies, the combination of SOF and VEL for 12 weeks demonstrated high efficacy (94%) in patients with genotype-3 HCV. This international, multi-center, Phase 3 study compared treatment with a fixed dose combination (FDC), single tablet of SOF/VEL for 12 weeks to the standard of care, SOF+RBV for 24 weeks, in patients with genotype 3 HCV.

Methods: Patients at 76 sites were randomized 1:1 to receive SOF/VEL (400 mg/100 mg daily) FDC for 12 weeks or SOF (400 mg daily) with RBV (1,000-1,200mg daily) for 24 weeks. HCV RNA was measured with the CAP/CTM HCV 2.0 assay with LLOQ = 15 IU/mL. The primary endpoint was a sustained virologic response (HCV RNA

Results: Of the 552 patients treated, 62% were male, 89% were white, 26% had prior treatment failure, and 30% had cirrhosis. Nine patients, all from the SOF+RBV treatment group, discontinued treatment due to adverse events. Hemoglobin decline and total bilirubin increases were more commonly observed in the group treated with SOF+RBV consistent with RBV-induced hemolysis. No other significant lab abnormalities were observed. The SVR12 rate receiving SOF/VEL for 12 weeks was 95% (221/275) and was statistically superior to the 80% (221/275) SVR12 rate in patients treated with SOF+RBV for 24 weeks (p <0 .001).

Conclusions: The once-daily, all-oral, single tablet regimen of SOF/VEL was well tolerated in treatment-naïve and treatment-experienced genotype-3 HCV-infected patients with and without cirrhosis and showed high SVR12 rates across all patient subgroups. There were no discontinuations due to adverse events and a lower incidence of fatigue, insomnia irritability, pruritus and cough was noted in patients treated with SOF/VEL for 12 weeks compared to patients treated with SOF+RBV for 24 weeks.
Real-World Effectiveness of Direct-Acting Antivirals for Hepatitis C among HIV-Infected Patients with Genotype 1

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Background: There are limited data regarding clinical effectiveness of direct-acting antivirals (DAA) for hepatitis C virus (HCV) in real-world HIV clinical settings. We describe HCV treatment outcomes in a large urban HIV clinic with attention to patients with ongoing barriers to care.

Methods: The study included patients coinfected with HIV and HCV genotype 1 who underwent HCV treatment in a clinic-based setting using sofosbuvir + ribavirin (SOF/RBV), sofosbuvir/simeprevir (SOF/SMV), sofosbuvir/ledipasvir (SOF/LDV), or paritaprevir + ritonavir + ombitasvir + dasabuvir (3D). Primary outcome was sustained viral response (SVR) after 12 weeks of HCV therapy. Ongoing barriers to care are defined as the presence of alcohol/drug use, psychiatric disease, or unstable housing.

Results: Sixty-six coinfected patients with a median CD4 cell count of 395 cells/mm$^3$ (87-1094) were treated for HCV between January 2014 and December 2015. Most patients were male (n = 60, 91%) and their median age was 54 years. Forty-five patients (68%) had either ongoing barriers to care (n = 35, 53%), severe medical comorbidity and/or extensive underlying HIV resistance (n = 10, 15%). Thirty patients (45%) had cirrhosis, 13 (43%) with prior liver decompensation. Forty-five patients (68%) had failed prior HCV treatment, including 6 patients who had failed DAA-containing regimens. Overall, 90% (52/58) achieved SVR. The SVR proportions were 97% (35/36), 76% (13/17) and 66% (2/3) using SOF/LDV, SOF/SMV and 3D regimens, respectively. There was no difference in SVR rates in patients with or without barriers to care. More patients with ongoing barriers to care achieved SVR using SOF/LDV than SMV/SOF (100% vs 70%, p = 0.006). Two patients with cirrhosis failed therapy (one died and another relapsed), both treated with SOF/SMV.

Conclusions: Overall SVR in real-world setting HIV-infected patients with genotype 1 was 97% using SOF/LDV but only 76% using SIM/SOF. Patients with ongoing barriers to care achieved SVR in higher proportions with SOF/LDV rather than SOF/SMV.
42 Bringing Hepatitis C Treatment into the Medical Home

Joanna Eveland
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**Background:** New treatments for hepatitis C virus (HCV) are brief, well tolerated and produce cure rates of over 90%. However only 5% of HCV-positive individuals have been successfully cured. Treatment access is especially limited for those with active substance use.

**Methods:** Our objective was to provide primary care-based multidisciplinary HCV treatment, aiming to increase access while evaluating cost effectiveness, sustainability, patient experience and quality. A particular focus was to develop a model to successfully engage and cure HCV in active drug users. We offered HCV treatment to patients of the Mission Neighborhood Health Center, an FQHC located in San Francisco, utilizing a multidisciplinary care team. Data was collected to track patient demographics, engagement in care, and treatment response. Patient satisfaction was assessed through a phone survey. New HCV-positive patients were linked to HCV care through a “warm hand off” partnership with a local syringe exchange program.

**Results:** Over 50 patients have been referred to the program. Of these, 67% had a substance use disorder, 40% were HIV coinfected, 50% were Latino, 40% were monolingual Spanish speakers, 38% were homeless or marginally housed, and 67% had a mental health diagnosis. As of now, 35 patients have initiated treatment and all have completed treatment with a successful treatment response. There have been no reinfections. Patient satisfaction with the program is high. The program is financially sustainable.

**Conclusions:** Offering HCV treatment in a primary care setting is effective and sustainable. A team-based approach facilitates treatment access and adherence during treatment. HCV education provides patients with motivation towards treatment readiness, while behavioral health evaluation addresses psychosocial barriers to treatment. Access to primary care-based HCV treatment should be expanded. Active drug users can be successfully engaged in treatment and cured using a multidisciplinary model.
High Prevalence of Comorbidities and Complex Polypharmacy with Drug-Drug Interaction (DDI) Potential in Patients with Chronic Hepatitis C (CHC): Consistent Findings from Large Primary Care Databases in the United Kingdom, Germany, and France

Fiona Marra (presenting), Werner Leber, Stephen Barclay, Stefan Christensen, Denis Ouzan, Valérie Oules, Peter McMahon, Karel Kostev, Xavier Ansolabehere

Methods: Patients diagnosed with CHC between 2011 and 04/2015 were identified using Read codes in the Clinical Practice Research Datalink (UK) and ICD10 codes on the IMS® Disease Analyzer (GER/FRA). Inclusion criteria: 18+ years, no evidence of sustained virological response, minimum one-year follow-up. Prescriptions within 12 months of last active date were categorized for DDI potential as either RED (contraindicated) or AMBER (additional monitoring/dose reduction required) with at least one of currently licensed DAA (OBV/PTV/r+DSV, SMV, LDV/SOF, DCV) using www.hep-druginteractions.org. Read/ICD10 coded comorbidities, including those that may make CHC treatment more difficult to manage, were analysed.

Results: 7,949 patients (UK: 4,644/GER: 2,737/FRA: 568) were analysed. Variation in mean age (45.8/51.8/57.1 years) suggests differences in CHC populations; 65%/58%/59% were male. Between 12%-19% of patients were on RED drugs, however only 0.9%-2.9% were on drugs contraindicated for all DAA regimen. 28.9%/35.1%/39.1% were on two or more RED or AMBER drugs; polypharmacy increased with age (18-29 years (15.1%), 30+ years (56.1%)). Most common comorbidities in the UK were: depression (23.3%), cardiovascular disease (21.0%), and COPD/asthma (14.4%); compared to chronic pain syndromes (22.7%/16.6%) and hypertension (22.1%/15.1%) in GER/FRA, depression (14.7%) in GER, and diabetes (8.7%) in FRA.

Conclusion: We observed significant comorbidity and co-prescribing with DDI potential in CHC patients in three countries. The large difference in proportion of co-medications contraindicated to all DAA vs. only to some suggests careful selection of the DAA regimen is required. Treating patients at a younger age likely reduces the risk of DDI.

Awareness of Hepatitis C Screening Recommendations among Primary Care Physicians, North Carolina, 2014-2015

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Background: Approximately 3.2 million Americans have chronic hepatitis C virus (HCV) infection, many of whom are asymptomatic and unaware of their infection. If left untreated, HCV can have serious health consequences. Recent breakthrough treatments allow more patients to be cured. National data suggest higher HCV rates among Blacks and the uninsured. The Centers for Disease Control and Prevention (CDC) (2012) and the United States Preventive Services Task Force (USPSTF) (2013) recommend one-time hepatitis C testing of all adults born between 1945 and 1965 (“baby boomers”), who comprise 75% of HCV cases. The extent of awareness of these recommendations among primary care physicians – the providers who would generally be screening asymptomatic individuals – is unknown. To address this need, we conducted a survey among primary care physicians in North Carolina.

Methods: We mailed questionnaires to a stratified random sample (obtained from the North Carolina Medical Board Roster) of 519 North Carolina family and internal medicine physicians from October 2014 to February 2015. Of these physicians, 347 (67%) responded.

Results: The majority of respondents were white male physicians who worked in single- or multi-specialty group practices. Most (82%) were aware of the hepatitis C screening recommendations. Of the physicians aware of the HCV recommendations, the majority of their patients were white (65%), and most (75%) of their patients were insured or not on Medicaid. Of the physicians aware of the HCV recommendations, 42% practice in rural, 21% in semi-urban, and 36% in urban counties in North Carolina.

Conclusions: Most North Carolina primary care physicians, many of whose patients are white and insured, are aware of hepatitis C screening recommendations. These findings suggest that future research should determine the extent of hepatitis C screening and treatment by primary care physicians in North Carolina.
Prevalence and Molecular Characterization of Hepatitis B in Blood Donors in Botswana

Wonderful Tatenda Choga
Botswana Harvard Partnership, Gaborone, Botswana

Background: Hepatitis B virus (HBV) genome diversity is of concern due to its pathogenic differences. Ten genotypes have been fully defined and they all show unique geographic distribution. The prevalence and molecular characteristics of Hepatitis B virus vary within population groups. In sub-Sahara Africa, genotype A and D are found to be most prevalent. Intracellular and extracellular levels of HBV DNA and Hepatitis B surface antigen (HBsAg) have been revealed as higher in genotypes B and C than in genotypes A and D. The DNA and intracellular accumulation of viral antigens account for the development of hepatocellular carcinoma (HCC). However, there is no data on the prevalence and molecular characterization of HBV in blood donors in Botswana.

Methods: HBV enzyme linked immunosorbent assay (ELISA) was done on blood donor samples by National Blood Transfusion Center, Botswana, in order to obtain and investigating the HBsAg positive samples. 41 plasma samples were obtained. DNA extraction was done using QIAGEN Mini kit as per manufacturer’s instructions. A PCR assay covering positions 2269-2287 and 1175 - 1192 were optimized and used to amplify the region followed by Big Dye sequencing of the PCR product. Genetic analysis of the products was done for molecular characterization.

Results: 36 of the 41 HBV positive samples (87.81%) were successfully amplified. Genotypes A and D were found to be circulating in blood donors.

Conclusions: Genotype A was detected in 21 HBsAg positive blood donors samples were of subtype A1 (58.33%) and 15 samples of genotype D samples of subtype D3 (41.67%) and no escape mutations and drug resistance mutations were found in all the genotyped samples. From the results above, it is clear that A1 is mostly predominant in the circulating genotypes. Need for pre-test prior to transfusion is mostly recommended since most donors are people who assume that they are healthy yet some are being found infected.

The Comparative Efficacy and Safety of Interferon-Free and Interferon-Containing Antiviral Regimens for Hepatitis C Genotypes 1 and 4: Evidence Informing the World Health Organization Guidelines

Eric Druyts (presenting), Sam Keeping, Kristian Thorlund, Chou Roger, Edward Mills

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2. Oregon Health and Science University, Portland, OR, USA

Background: Interferon-containing regimens for hepatitis C are difficult to administer and are no longer of interest given the emergence of highly efficacious interferon-free regimens. As more interferon-free regimens become available it is important that treatment guidelines are updated so that they reflect the current evidence base.

Methods: We performed a systematic literature review to identify trials assessing boceprevir (BOC), telaprevir (TVR), simeprevir (SMV), sofosbuvir (SOF), ombitasvir (OMB), daclatasvir (DCV), and asunaprevir (ASV) containing regimens in genotypes 1 and 4 patients. Outcomes of interest included sustained virological response (SVR) and discontinuations due to adverse events (DAEs). A network meta-analysis (NMA), conducted in a Bayesian framework, was used with single-arm evidence included by simulating a control arm using a collection of trial and patient characteristics. Analyses focused on the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) treatment labels.

Results: A total of 57 studies were identified (38 in treatment-naive; 22 in treatment-experienced). Interferon-free regimens were consistently more efficacious than interferon-containing regimens. Furthermore, interferon-containing regimens, particularly BOC+peginterferon-ribavirin (PR), TVR+PR, and SMV+PR had statistically higher DAEs compared to SOF plus ledipasvir (LDV) and OMB plus paritaprevir (PAR) and dasabuvir (DAS). Interferon-free regimens were statistically comparable, with the exception of SOF+R and DCV+ASV being statistically less efficacious than SOF+LDV, DCV+SOF, and OMB+PAR+DAS. SOF+LDV, SOF+DCV, and OMB+PAR+DAS had the highest SVR rates (>95%). No statistical differences were observed between interferon-free regimens in terms of DAEs. These results were consistent across naive and experienced populations.

Conclusion: This analysis showed that interferon-free regimens are more efficacious and safe than interferon-containing regimens. With few exceptions, efficacy and safety between interferon-free regimens are statistically comparable. NMA is a robust statistical technique that can provide comparative efficacy and safety estimates to inform treatment guidelines for HCV.
Developing a Hepatitis C Treatment Cost Calculator: A Tool to Assist Decision-Makers in the Global Scale-Up of Interferon-Free Antiviral Regimens

Sam Keeping (presenting)\(^1\), Eric Druyts\(^1\), Steve Kanters\(^1\), Kristian Thorlund\(^2\), Chou Roger\(^2\), Edward Mills\(^1\)

1. Global Evaluative Sciences, Seattle, WA, USA
2. Oregon Health and Science University, Portland, OR, USA

**Background:** New treatment regimens entirely comprised of direct acting antivirals (DAA) such as sofosbuvir/ledipasvir have the potential to improve access to treatment for patients chronically infected with hepatitis C virus (HCV) globally. This is due to simplified administration, lower pill burden, and fewer adverse events, compared to traditional regimens containing peg-interferon and ribavirin (PR).

**Methods:** We developed a cost calculator that health service planners can use to forecast the direct treatment costs for different combinations of treatments for HCV. The model allows users to select treatment based on HCV genotype, severity of liver disease and prior treatment experience. We provide case studies (Brazil, Mongolia and the Ukraine) representing a range of HCV epidemic scenarios as well as different levels of available resources to model the difference in average cost per patient and total treatment costs for three different scenarios: A) treatment with PR, B) treatment with SOF+R and C) treatment with SOF+LDV (where indicated) or SOF+RBV. All costs used in the model were converted to 2015 US dollars.

**Results:** The average cost per patient was lowest for scenario A, $5,209 in Brazil, $2,214 in Ukraine, and $1,376 in Mongolia respectively. This pattern was primarily explained by the different pricing arrangement for DAA in each country and durations of treatment. Non-drug related treatment costs were lower in scenarios B and C compared to A in all countries. The total costs of treatment if all patients currently diagnosed with HCV were to be offered treatment ranged from $1.6 to $4.4 billion in Brazil, $80.0 to $362.5 million in Mongolia, and $895.8 million to $2.0 billion in Ukraine.

**Conclusions:** HCV treatment programs require different drug regimens to be used according to disease and patient specific factors. Our tool can help to forecast costs while on treatment for different patient groups and assist with resource planning.

Comparative Efficacy and Safety of Treatments for Patients Infected with Hepatitis C Genotypes 2 and 3: Evidence Informing the World Health Organization Guidelines

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**Background:** Treatment of hepatitis c (HCV) is rapidly evolving thanks to the emergence of highly efficacious, interferon-free antiviral regimens that are simpler to take than interferon-containing regimens. New interferon-free regimens continue to be licensed and therefore treatment must be updated. In clinical trials, the antiviral activity of direct acting antivirals (DAAs) has shown to be genotype specific, with patients infected with genotype 3 who also have cirrhosis achieving some of the lowest sustained viral responses (SVRs).

**Methods:** We carried out a systematic literature review (SLR) to find relevant trials in patients with HCV genotype 2 and 3. Interventions of interest were European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) approved treatment labels for patients chronically infected with genotypes 2 and 3. These were one or a combination of peginterferon-ribavirin (PR), sofosbuvir (SOF), ledipasvir (LDV) and daclatasvir (DCV). Main outcomes of interest were SVRs and discontinuations due to adverse events (DAEs). A Bayesian network meta-analysis was then conducted that used trial and patient characteristics to simulate control arms for single-arm studies.

**Results:** The SLR identified 14 trials in genotypes 2 and 3 populations (11 in treatment-naïve; 6 in treatment-experienced). In treatment-naïve patients, SVRs for regimens including interferon-free antiviral regimens were generally superior to PR alone (69.21%, 95% CI: 50.52-87.90%), with estimates for SOF+LDV (94.91-100.00%) and SOF+PR (99.5% CI: 87.93-100.00%) achieving statistical significance. No significant differences were observed between SVRs for interferon-free antiviral regimens. Rates of DAEs were also comparable across all interferon-free regimens. SVRs and DAEs were all comparable for treatment-experienced patients.

**Conclusion:** Interferon-free regimens have improved efficacy over traditional PR in treatment naïve patients with genotype 2 and 3. However, PR combinations may still be required some patients, such as those with cirrhosis and genotype 3.

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Background: For the HCV-infected African-American population the disparities in access to care and treatment involve a complex set of individual, interpersonal, socioeconomic, and environmental factors that influence the course of HCV infection, resulting in poorer outcomes and survival. The aim of this study was to examine whether the healthcare-seeking behavior and provider responses for HCV-positive African Americans had improved since the introduction of direct acting antivirals (DAAs).

Methods: This study used data from the National Health and Nutrition Examination Survey (NHANES) and Hepatitis C Follow-Up Questionnaire (HCQ) for years 2005-2008 (pre-DAAs) and 2009-2012 (post-DAAs). Participants were 6 years of age or older who tested positive for HCV and who also completed an HCQ; participants were examined within 3 racial/ethnic groups (Caucasian, African American, Hispanic/Other). The healthcare-seeking behavior and provider responses were assessed using 10 HCQ responses.

Results: 132 eligible participants were included in the analysis. The results demonstrated no statistically significant difference of each racial/ethnic group’s HCQ responses pre- and post-DAAs. Findings did show statistically significant associations between participants who had health insurance and reported seeing a doctor about the test result and/or having had a liver biopsy versus those who did not have health insurance.

Conclusions: Healthcare-seeking behavior and provider responses for HCV-positive African Americans had not improved since the introduction of DAAs.

24 High Serum HCV-RNA in Chronic Hepatitis C Virus-Infected Patients Coinfected with HIV despite Successful Antiretroviral Therapy

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Background: Baseline serum HCV-RNA predicts treatment success in chronic hepatitis C virus (HCV)-infected patients. Thresholds at 0.8, 2, 4 and 6 million HCV-RNA IU/mL discriminate treatment outcomes using distinct antiviral regimens. Compared to the general population, immunosuppressed individuals exhibit greater viral load values. This has been confirmed in HIV/HCV-coinfected patients, although little is known about the influence of antiretroviral therapy.

Methods: Serum HCV-RNA results recorded from all chronic hepatitis C patients consecutively attended at our clinic during the last decade were analyzed.

Results: A total of 813 patients with detectable HCV-RNA were identified. HIV coinfection was present in 78.7%, of whom 91% were on antiretroviral therapy. Overall, 467 (57%), 273 (34%), 170 (21%) and 127 (16%) had HCV-RNA >0.8, >2, >4 and >6 million IU/mL, respectively. These high viral load values were found in 60%/36%/23%/18% of HIV positive versus 43%/25%/11%/6% of HIV negatives (p <0.01). In multivariate analysis, higher HCV-RNA values were only significantly associated with HIV coinfection and HCV genotypes 1 or 4. Greater HCV-RNA values were found in HIV patients on than off antiretroviral therapy.

Conclusion: Serum HCV-RNA values above 0.8, 2, 4 and 6 million IU/mL are roughly seen in 43%, 25%, 11% and 6% of chronic HCV monoinfected patients, respectively. The corresponding figures are 1.3 to 3.0-fold greater in HIV/HCV-coinfected patients, who accordingly would benefit less frequently from shorter oral HCV treatment lengths.
HCV Treatment Challenge:
Multiple Rounds of HCV Treatment Failure in an HIV-Coinfected Patient

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Nassau University Medical Center, East Meadow, NY, USA

Background: Hepatitis C virus (HCV) is the most common cause of chronic liver disease in the US. HCV infection progresses more rapidly to liver fibrosis and cirrhosis in HIV-infected persons. Treatment for HCV has evolved significantly since the introduction of highly effective direct-acting antiviral therapies. There have been reported cases who failed multiple rounds of treatment.

Methods: We present a case of an HCV/HIV-coinfected patient who failed multiple regimen HCV treatment. This patient is a 61-year-old Caucasian veteran male with HCV genotype 1a who is on HIV treatment (Truvada/raltegavir). Patient failed treatment initially with Interferon/ribavirin/boceprevir, and later with ledipasvir/sofosbuvir (12 weeks) and subsequently with Viekira pak/ribavirin (12 weeks). With the later 2 regimens, there was an initial treatment response with undetectable viral load between weeks 4-8. Patient did not have cirrhosis or detectable HIV viral load during these treatment courses.

Results: After patient failed with three rounds of HCV treatment, he was tested for resistance. The result showed resistance to most agents with some mutations (Q30R, V36m/V, and D168A) except for simeprevir and sofosbuvir. We also noted there was 5 days gap during ledipasvir/sofosbuvir treatment due to delivery delay. Patient’s medication adherence confirmed repeatedly. Drug-interaction/side effects were not identified. Patient’s fibrosis score later showed severe fibrosis indicating progression of disease but remained well compensated. Currently patient is on simeprevir/sofosbuvir/ribavirin for total of 24 weeks.

Conclusions: As widespread use of HCV treatment increases, the number of patients who are failing multiple rounds of treatment will unavoidably increase. This case provides evidence that 12 weeks of ledipasvir/sofosbuvir or Viekira pak/ribavirin are insufficient in genotype 1a HCV patients with HIV co-infection and prior treatment failure. Such patient might benefit from longer treatment duration or addition of other agents. We also suggest that the role of resistance testing should be considered much earlier to help guide effective treatment in HIV/HCV-coinfected patients.

Treatment of Chronic Hepatitis C Infection with Second Generation Direct-Acting Antivirals by Primary Care Providers in a Community Health Center

Christopher Bositis (presenting), Zachary Bay, Katrina Baumgartner, William Martin, Stephen Ozaroff, John Raser, Isely Naveo, Phuong King, Camilla Graham, Rachel Baden

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2. Beth Israel Deaconess Medical Center, Boston, MA, USA
3. Alameda Health System, Oakland, CA, USA

Background: Direct-acting antiviral (DAA)-containing therapy has made hepatitis C (HCV) treatment shorter, simpler, and more effective, thus making widespread primary care-based treatment possible. However, data on its effectiveness in this setting are lacking. Greater Lawrence Family Health Center (GLFHC), a community health center (CHC) in Lawrence, MA, has provided HCV treatment for its patients since 2008 and was part of the Beth Israel Deaconess Extension for Community Healthcare Outcomes (ECHO) program from July 2012 to July 2015.

Methods: Retrospective chart review of HCV treatment by 3 GLFHC family medicine clinicians using one or more of sofosbuvir (SOF), simeprevir (SMV), ledipasvir (LDV), paritaprevir/ritonavir/ombitasvir/dasabuvir (PrOD), and daclatasvir (DCV). Patients were identified using a combination of the electronic health record, the viral hepatitis team’s patient list, and pharmacy records.

Results: As of December 31, 2015, 99 patients had started treatment containing at least one second-generation DAA, including 54 who were at least 12 weeks post treatment completion. Of these, a sustained virologic response (SVR12) has been documented in 51 (94%); 2 (4%) do have SVR12 results available; and 1 (2%), who self-discontinued treatment prematurely, had virologic rebound after treatment. The majority were male (35, 65%); Hispanic (38, 70%); cirrhotic (30, 56%); infected with genotype 1a HCV (36, 67%); and had a documented history of psychiatric illness (37, 69%) or substance use (38, 70%). 17 (32%) were treatment experienced and 5 (9%) HIV coinfected. SOF/LDV was the most commonly prescribed regimen (24, 44%), followed by SOF/pegylated interferon (PEG)/ribavirin (RBV) (9, 17%). Characteristics of the remaining 45 are similar but more (8, 18%) are HIV coinfected, with more on SOF/LDV (35, 78%) and none on SOF/PEG/RBV.

Conclusions: Primary-care based treatment of chronic HCV with second-generation DAAs has been highly effective in our CHC, despite significant percentages of patients with cirrhosis, previous treatment experience, HIV coinfection, and psychiatric or substance use histories.
A Novel Approach for the Identification of Genomic Signatures of Hepatitis B Virus and its Significance in Clinical Management of Disease

Navkiran Kaur

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Background: Genome-based characterization of microorganism is a sensitive and specific approach to identify specific organism. The present study describes an innovative approach using genomic signatures (GS) to identify mutations in hepatitis B virus (HBV) and its significance in clinical outcome of the disease.

Methods: HBV was used as a prototype model organism for development and validation of GS-based characterization. HBV genotypes (A-H) were analyzed in silico and its GS were identified. These signatures were initially validated on existing database sequences and later on known in house developed HBV controls and clinical isolates obtained from patients infected with HBV. A mass spectrometric (MS) based method for identification of these signatures was developed.

Results: 10 sites, collectively denoting the GS, were identified for HBV genotypes A-H. This signature was validated on 587 database sequences in silico and 212 clinical samples by MS based approach with an accuracy of >95%. Many mixed type infections with a rarer genotype were identified. Additional sites for drug resistance patterns were added.

Conclusion: The GS approach may offer multiple rapid diagnostic opportunities for identifying and characterizing microbes. This method can provide clinicians and researchers with real-time, crucial clinical information that shall enhance the management of microbial infections, reduce healthcare costs and translate into better patient care.

Seroconversion Rates among Healthcare Workers Exposed to Hepatitis C-Contaminated Body Fluids: The University of Pittsburgh Experience

Francesco Egro, Chibueze Nwaiwu (presenting), Saundra Smith, Jay Harper, Alexander Spiess

The University of Pittsburgh, PA, USA

Background: Hepatitis C virus (HCV) transmission to healthcare personnel (HCP) following percutaneous exposure to blood of an HCV-positive source, has been reported to occur at an average rate of 1.8% (range 0-10%). Most studies assessed this risk following needle-stick injury only, and in predominantly non-US centers. We aimed to determine the seroconversion rate after HCV-contaminated body fluid exposure, in a major US academic center.

Methods: A longitudinal analysis of a prospectively maintained database of reported occupational injuries occurring between January 2002 and September 2015 at the University of Pittsburgh Medical Center was performed. Inclusion criteria included HCP who sustained needlestick, laceration, and splash injuries from a known HCV-positive patient. Exclusion criteria included missing data on the type of injury and fluids. Data collected included the type of injury, injured body part, type of fluid, contamination of sharps, involvement of resident physicians, and patients’ HIV and HBV status.

Results: A total of 1,361 cases met the criteria and were included in the study. Most cases were caused by percutaneous injuries (65.0%) compared to 33.7% of mucocutaneous injuries; 7.1% of HCP were resident physicians; 63.3% to the hand, 27.6% of these injuries were to the face and neck, and 3.7% to the arm, foot, leg or trunk. Blood exposure accounted for 72.7% of all cases, saliva for 3.4%, and other fluids for 11%. A total of 6.9% and 3.7% of source patients were co-infected with HIV and HBV, respectively. The calculated seroconversion rate was 0.1% (n = 2) caused by blood exposure secondary to percutaneous injuries.

Conclusions: This study provides the largest and most recent cohort from a major US academic medical center. The seroconversion rate (0.1%) among HCP-exposed to HCV-contaminated body fluids was found to be lower than most of the data found in the literature.
39 Utilizing an Electronic Medical Record (EMR) to Increase HCV Testing within a Large Urban Health System

Oluwatoyin (Toyin) Adeyemi\(^1\), Greg Huhn\(^1\), Marisol Gonzalez-Drigo\(^1\), Daniel Taussig\(^1\), Chissy Braz (presenting)\(^2\), Gregory Norels\(^2\), Crystal Winston\(^1\)

1. The John H. Stroger Jr. Hospital of Cook County, Chicago, IL, USA
2. The Ruth M. Rothstein CORE Center, Chicago, IL, USA

**Background:** This abstract details the provider trainings that were conducted at the Cook County Health and Hospital Systems Ambulatory Clinics to increase hepatitis C screening among the baby boomer population per the CDC recommendations. It describes the tools that were used to notify patients and providers of the need for baby boomer patients to receive a test; as well how previous HIV testing data helped to model the need to implement an HCV pop up into the electronic medical record (EMR) for those patients receiving lab work.

**Methods:** Previous HIV popup implementation data will be used to compare how the implementation of an HCV popup was developed and implemented to successfully increase HCV testing rates within the large urban healthcare setting.

**Results:** Provider trainings are difficult to schedule and although effective not a sustainable practice due to need of dedicated staff to conduct the trainings. An EMR reminder, triggered for the baby boomer population, when a lab is ordered and the patient has no history of an HCV result within the system is the most effective intervention tool used to increase system wide HCV testing. As well proper signage and follow up care procedures. Providers are more willing to test when they are able to have the disease staged by using FibroScan technology and link their patients into follow-up care immediately.

**Conclusions:** It is our recommendation to implement an HCV popup reminder into the EMR in order to increase hepatitis screening among the baby boomer population. Signage with appropriate images in patient areas as well as an educational video for both the providers and patients serves as a valuable tool in increasing tests rates an overall community health.

40 Implementation of a Pilot HCV Consultation Service: Experience from the Clinician Consultation Center

Carolyn Chu (presenting)\(^1\), Joanna Eveland\(^2\), Jason Tokumoto\(^1\), Cristina Gruta\(^1\), Betty Dong\(^1\), Brenda Goldhammer\(^1\), Marliese Warren\(^1\)

1. Clinician Consultation Center, San Francisco, CA, USA
2. Mission Neighborhood Health Center, San Francisco, CA, USA

**Background:** The advent of effective, simple, and well-tolerated hepatitis C (HCV) medications provides primary care providers a new opportunity to incorporate HCV management into their practices. Remote consultation is a viable, cost-effective means of addressing patient-specific issues while providing real-time, case-based provider education and training.

**Methods:** The Clinician Consultation Center (CCC) has provided free telephone consultation on HIV since 1991. In 2014, it introduced a pilot HCV consultation service, delivered by an inter-professional team of expert primary care providers, specialists, and clinical pharmacists. Calls are logged in a secure electronic database and case details are documented using a standardized, HCV-specific consultation data collection form.

**Results:** During the pilot year, CCC provided over 125 consultations regarding HCV-monoinfected and HIV/HCV-coinfected patients. Of those calls, 27% were from infectious disease subspecialists, 26% clinical pharmacists, 11% family physicians, and 10% general internists (26% were other subspecialty providers, nurses, etc.). Treatment selection was the most frequent consultation topic: this included regimen selection/dosing, medication interactions, toxicity/complication monitoring, and medication access. Pre-treatment evaluation was another popular topic, followed by HCV testing, transmission prevention, and cirrhosis management. Discussion of patients that had undergone previous HCV treatment comprised 11% of calls. Survey results indicate the vast majority of users strongly agreed they were pleased with consultation quality and that information received was helpful for their patient management. All callers reported they would use the service again and were also likely to recommend it to colleagues.

**Conclusions:** Over a pilot year, the CCC demonstrated that remote, point-of-care HCV consultation is a feasible and acceptable practice tool/resource that is easily accessible to clinicians of all backgrounds. The CCC intends to broaden its HCV services in order to reach additional communities and practice networks where capacity for HCV care is limited due to a variety of reasons.
41 Chronic HCV Infection Profile in Northwest Spain: Therapeutics Needs based on Current HCV Treatment Guidelines

Berta Pernas (presenting)1, Andrés Tabernilla1, Marta Grandal1, Ana Maríno1, Hortensia Alvarez1, Ángeles Castro-Iglesias1, Álvaro Mena2, Iria Rodríguez-Osorio2, Aitana Morano3, Eva Poveda1

1. Complejo Hospitalario Universitario de A Coruña, Spain
2. Complejo Hospitalario Universitario de Ferrol, Spain

Background: New therapeutic options to treat HCV infection are highly effective, with minimal side effects, presenting a favorable scenario to cure all patients. However, there are limitations, mainly due to economic restrictions. This study evaluates the current profile of HCV infection in our region to know the therapeutic needs based on current treatment guidelines.

Methods: This is a transversal cohort study. Patients with chronic HCV infection in 2 hospitals of Northwest Spain were included in the period June 2014 to December 2015. Epidemiological, clinical and virological characteristics were recorded.

Results: Overall, 413 patients were recorded, 73.1% men, 62.4% HIV-coinfected. Mean time with chronic HCV infection of 16.7 years. The prevalence of HCV genotypes was: 65.2% G1, 2% G2, 18.1% G3 and 14.7% G4. Fibrosis was assessed by transient elastography, with the following distribution: F0-F1 (34.2%), F2 (22.3%), F3 (15.2%) and F4/cirrhosis (28.4%). In addition, 3.9% had previous hepatic decompensations, 0.7% hepatocarcinoma and 3.6% extrahepatic HCV manifestations. According to international guidelines to treat HCV infection, 87.4% of patients should be prioritized for HCV treatment (≥F2, transplant, extrahepatic manifestations, HIV or HBV coinfection). Indeed, during 2015, 48.4% of patients have started treatment with the following direct antiviral agents-based regimens: Pegylated-interferon combinations (3%), sofosbuvir+daclatasvir+ribavirin (19%), sofosbuvir+ledipasvir+ribavirin (50%), sofosbuvir+simeprevir+ribavirin (10.5%), sofosbuvir+ribavirin (3.5%), ombitasvir+paritaprevir+ritonavir+dasabuvir+ribavirin (14%). However, there are still 42.1% of HCV patients who should be prioritized to be treated according to current guidelines.

Conclusions: In Northwest Spain, HCV infected patients are frequently HIV coinfected (62.4%) and have cirrhosis (28.4%). Overall, 87.4% of all HCV infected patients should be prioritized according to International Guidelines for HCV Treatment. There are still 42% of HCV patients to be treated. Therefore, HCV treatment should be promptly initiated to prevent hepatic complications and mortality.

44 Efficacy and Safety of Simeprevir plus Sofosbuvir with or without Ribavirin in Real-World Patients with HCV Infection

Marta Suárez-Santamaría (presenting)1, Álvaro Mena2, Diego Perez-Parente3, Iria Rodriguez-Osorio2, Sandra Suárez-Ordoñez1, Ángeles Castro-Iglesias2, Aitana Morano3, Eva Poveda1, José Domingo Pedreira1, Margarita Suarez3, Luis Morano1

1. Hospital Meixoeiro, Vigo, Spain
2. Complejo Hospitalario Universitario de A Coruña, Spain
3. University Hospital Alvaro Cunqueiro, Vigo, Spain

Background: The simeprevir (SMV) plus sofosbuvir (SOF) regimen is recommended for current HCV treatment guidelines for certain HCV infected patients. The aim of this study was to evaluate the safety and efficacy of this regimen in the clinical practice setting of Northwest of Spain.

Methods: This is an observational and prospective study performed in two reference hospitals in the Northwest of Spain. All HCV infected patients with genotypes 1 and 4 who have initiated SOF+SMV±RBV therapy since the approval of this combination were included. Demographic, clinical and virological data as well as adverse outcomes were recorded.

Results: A total of 87 patients were recorded, 65% men, 30.7% HIV-coinfected. The HCV genotypes/subtypes distribution was: 35% G1a, 46% G1b and G4. Half of them had previously failed to HCV treatment: 26% were relapsers, 44% partial responders, 28% null-responders, and 2% unknown. 83% of patients had cirrhosis assessed by transient elastography. The overall sustained virologic response (SVR) at week 12 was 98.7% without significant differences by gender, HCV genotype/subtype, previous HCV treatment exposure, HIV coinfection or cirrhosis. The addition of RBV had no detectable effects on the SVR. The most common adverse events were fatigue (34.5%), skin disorders (17.1%), anemia (15%), gastrointestinal disorders (15%), and headache (11.5%). Serious adverse events and treatment discontinuation occurred in only (2, 3%) and (3, 5%) of participants, respectively.

Conclusions: This observational retrospective cohort study recognized high rates of SVR (98.7%) at week 12 for the combination of SOF+SMV in HCV infected patients, irrespective of the HIV-coinfection status or previous HCV treatment experience. The combination was also well tolerated even being mostly cirrhotic patients.
HCV Staging: From Research to Clinical Practice

Oluwatoyin (Toyin) Adeyemi¹, Marisol Gonzalez-Drigo¹, Greg Huhn¹, Daniel Taussig¹, Chrissy Braz², Gregory Norels (presenting)², Crystal Winston¹

1. The John H. Stroger Jr. Hospital of Cook County, Chicago, IL, USA
2. The Ruth M. Rothstein CORE Center, Chicago, IL, USA

Background: This abstract details the translational process of taking HCV staging research and incorporating it into the clinical practice. We describe the operational and programmatic features of lessons learned from the EchoSens FibroScan Touch 502 (FibroScan) research experience as part of the clinical decision algorithms related to HCV treatment in the infectious diseases outpatient setting, the Ruth M. Rothstein CORE Center (CORE).

Methods: Prior to FDA licensure of the, there were 14 investigational devices using this technology in the United States. In 2011, a research protocol at CORE was established to assess the accuracy and validity of estimated liver fibrosis using the FibroScan in HIV/HCV and HCV infected patients. Upon FDA approval in April 2014, CORE was the first center in Illinois to adopt the clinical use of Fibroscan and is now a leading referral center.

Results:
1) Study coordinators created databases for the research protocols, however they were not uniformly managed. Thus, database operations for clinic care were streamlined, and a data warehouse backup system was developed.
2) New standard operating procedures beyond the research protocols were developed to capture relevant data for clinical care. Referral forms with release-of-information systems, identifying ICD9/10 codes, and integrated insurance status were developed for billing purposes.
3) The use of FibroScan as a point-of-care tool in assessing liver fibrosis accelerated the risk stratification process for HCV treatment, and provides the central framework which determines the treatment decisions.

Conclusions: Translational research was facilitated by an executive administrative and multi-disciplinary team working together to incorporate this intervention into clinical practice. In this process, marketing strategies and presentations on how to refer for a FibroScan and treatment are key elements. Translational research has been a success story for CORE and for the many patients who benefit from this non-invasive procedure.
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ACKNOWLEDGEMENTS
March 14-15, 2016

Letter of Attendance

To Whom It May Concern:

This letter is a confirmation that ____________________________ attended the 2016 International Conference on Viral Hepatitis, held March 14-15, 2016, at the Mission Bay Conference Center in San Francisco, CA, USA. This two-day conference was sponsored by the International Association of Providers of AIDS Care (IAPAC), in partnership with the University of California, San Francisco (UCSF) and the International Association for the Study of the Liver (IASL).

Sincerely,

José M. Zuniga, PhD, MPH
President/CEO, IAPAC
Proud partners in delivering clinician education about and expanding access to viral hepatitis treatment.

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The 2016 International Conference on Viral Hepatitis is sponsored by the International Association of Providers of AIDS Care (IAPAC), in partnership with the University of California, San Francisco (UCSF) and the International Association for the Study of the Liver (IASL). We wish to express our gratitude to the institutional and commercial supporters whose generosity has made this conference possible.

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