

DAVID L. WYLES, M.D., FIDSA

Professor of Medicine
University of Colorado School of Medicine

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EDUCATION

1993 Northwestern University; Evanston, Illinois; B.S. Biomedical Engineering
1998 Northwestern University School of Medicine; Chicago, Illinois; M.D.

PRE-GRADUATE EMPLOYMENT

1992-1993 Research Assistant, Division of Biomedical Engineering
Northwestern University McCormick School of Engineering
Mentor: Scott Delp, Ph.D.

- designed and implemented data acquisition protocols
- performed detailed muscle dissection and architecture analysis

1993-1995 Musculographics Inc.
Biomedical analysis, virtual reality medical training and computer-assisted surgical systems.
Northwestern University Research Park; Evanston, Illinois

- developed documentation for biomechanical analysis software
- performed testing of biomechanical analysis software
- generated design parameters in concert with software engineers and orthopedic surgeons for computer-assisted surgical systems

POST-GRADUATE TRAINING

1998-1999 Intern, Categorical Internal Medicine
University of Colorado Health Sciences Center; Denver, CO

1999-2001 Resident, Internal Medicine
University of Colorado Health Sciences Center; Denver, CO

2001-2004 Fellowship, Infectious Diseases
University of Colorado Health Sciences Center; Denver, CO

HONORS

Tau Beta Pi (engineering honor society)
GlaxcoSmithKline HIV fellow, 2002
Kaiser Excellence in Teaching Award nominee, 2009

Kaiser Excellence in Teaching Award nominee, 2013
 Kaiser Excellence in Teaching Award nominee, 2014
 "Best Practices" Lecturer Award UCSD, 2014
 Fellow of the Infectious Diseases Society of America, 2018

ACADEMIC and CLINICAL APPOINTMENTS

2001-2002 Clinician, Infectious Diseases Consult Service, UCHSC; Denver CO
 2001-2005 Clinician, University of Colorado Hospital Infectious Diseases Group Practice; Denver, CO
 2002-2004 Research Fellow, UCHSC Division of Infectious Diseases; Denver CO
 Mentor: Robert T. Schooley, M.D.
 2003-2005 Clinician, University of Colorado Hospital Infectious Diseases Group Practice – HIV/Hepatitis Co-Infection Clinic; Denver, CO
 2004-2005 Instructor, UCHSC Division of Infectious Diseases; Denver, CO
 2005-2011 Assistant Professor of Medicine, UCSD Dept. of Medicine, La Jolla, CA
 2005-present Attending Physician, Infectious Diseases Consult Service, UCSD Medical Center; San Diego and La Jolla, CA
 2005-2016 Attending Physician, UCSD Owen Clinic HIV and Hepatitis Co-infection Clinic; San Diego, CA
 2009-2016 Attending Physician, Internal Medicine Residency Team 5, UCSD Medical Center; San Diego, CA
 2011-2016 Associate Professor of Medicine, UCSD Dept. of Medicine, La Jolla, CA
 2014-2016 Attending Physician, UCSD Infectious Diseases HCV clinic, San Diego, CA
 2014-2016 Director, UCSD Infectious Diseases HCV Clinic, San Diego, CA
 2016-2018 Associate Professor of Medicine, University of Colorado School of Medicine, Aurora, CO
 2016-present Attending Physician, Infectious Diseases Consult Service, Denver Health, Denver, CO
 2016-present Chief, Division of Infectious Disease, Denver Health Medical Center, Denver, CO
 2018-present Professor of Medicine, University of Colorado School of Medicine, Aurora, CO

PROFESSIONAL SOCIETIES and COMMITTEES

Member, American Medical Association, 1997-2001
 Member, American College of Physicians, 1999-2001
 Member and Fellow, Infectious Diseases Society of America, 2001-present
 Contributor, Expert Perspectives III: Strategies for the Management of HIV/HCV Co-Infection, 2002
 Advisor/Instructor, Colorado AIDS Education and Training Center, HCV Center for Excellence, 2002-2005
 Consultant, Colorado AIDS Education and Training Center, HCV Center for Excellence, 2005-2008
 Member, American Society for Microbiology, 2007-2009
 Member, International Society for Antiviral Research, 2008-2009
 Member, European Association for the Study of Liver Disease, 2013-2018
 Member, American Association for the Study of Liver Disease, 2014-2020

ELECTED and APPOINTED POSITIONS

Core faculty member, IAS-USA, 2007-present
Member, AIDS Clinical Trials Group, Hepatitis Transformative Science Group,
2008-2021
Member, IAS-USA Hepatitis Board, 2010-present
Member, International Coalition of Hepatology Education Providers, 2013-2017

Panelist NIH/DHHS: *Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents: Hepatitis C Virus Infection.* 2012-2020. Available at: [Hepatitis C Virus | NIH \(hiv.gov\)](https://www.hiv.gov/hepatitis-c)

- **Lead, Hepatitis C Virus section.** 2021-present

Panelist AASLD/IDSA: Recommendations for Testing, Managing, and Treating Hepatitis C. *Guidelines for treatment of HCV.* 2013-2016.
Available at: <http://hcvguidelines.org>

Co-Chair AASLD/IDSA: Recommendations for Testing, Managing, and Treating Hepatitis C. *When and in Whom to Initiate Therapy and Retreatment of HCV Infection.* 2018- 2022.
Available at: <http://hcvguidelines.org>

CERTIFICATIONS

Diplomate, National Board of Medical Examiners, 1999
Diplomate, American Board of Internal Medicine, 2002
Diplomate in Infectious Diseases, ABIM, 2003, 2013, 2023

Physician, California #A90234, 2005-2016
Physician, Colorado #DR.0038972, 2000-2005; 2016-present
Physician, DEA, #BW7896890, 2002-present

EDITORIAL RESPONSIBILITIES

Reviewer, *Antiviral Therapy*
Reviewer, *Clinical Infectious Diseases*
Reviewer, *Gastroenterology*
Reviewer, *Hepatology*
Reviewer, *Journal of Antimicrobial Chemotherapy*
Reviewer, *Journal of Clinical Microbiology*
Reviewer, *Journal of Clinical Virology*
Reviewer, *Journal of Hepatology*
Reviewer, *Journal of Infectious Diseases*
Reviewer, *Journal of Viral Hepatitis*
Reviewer, *Nature Reviews Gastroenterology and Hepatology*
Reviewer, *Open Forum in Infectious Diseases*
Reviewer, *PlosONE*

Reviewer, *Proceedings of the National Academy of Science*
Reviewer, *Science Translational Medicine*

Editorial Board, IAS-USA *Cases on the Web*; 2011-present
Editorial Board, HCV NEXT; 2014-present
Editorial Board, Open Forum Infectious Diseases; 2014-present

TEACHING RESPONSIBILITIES

Lecturer, Internal Medicine Residents Lecture Series, 2001
Instructor, Pathophysiology of Disease Lecturer, UCHSC HIV Research Seminar, 2002
Invited Speaker, Infectious Diseases Grand Rounds; UCSD
Course director, Infectious Disease Fellow's Principles of Infectious Diseases Lecture Series, 2005-present
Lecturer, Infectious Disease Fellow's Principles of Infectious Diseases Lecture Series, 2003-present
Co-director (2008-2009; 2011-present), Director (2010) UCSD School of Medicine, SOM 208 Microbiology Course. Lectures personally delivered:

- Introduction to Viruses
- Acute Viral Hepatitis

Co-director UCSD School of Medicine, SOMC-242 Microbiology Course, 2012-2015
Director UCSD School of Medicine, SOMC-242-Microbiology, 2016
Lecturer in Careers in Medicine Elective- MED 296E, 2014
Lecturer in Microbiology, University of Colorado School of Medicine, 2016-present

PRESENTATIONS

2003

Invited Speaker, Nevada AIDS Education and Training Center. Hepatitis C and HIV Co-infection. Las Vegas, NV.

2004

Invited Speaker, HIV Community Advisory Board. HIV/HCV Co-infection
Invited Speaker, Hep C Connections
Invited Speaker, Women's Lighthouse Project. Hepatitis C and HIV Co-infection

2005

Invited Speaker, North Dakota Association of Physician Assistants Primary Care Seminar
Natural History and Treatment of HCV in Persons with HIV-1.

2006

Invited Speaker, UCSD Antiviral Research Center. AIDS Clinical Rounds: Hepatitis C from bench to bedside.

Invited Speaker, Brazilian Conference on HIV/AIDS and viral hepatitis. *Combination Therapy for Chronic Viral Hepatitis*. Fortaleza, Brazil.

2007

Invited Speaker, UCSD Medical Grand Rounds. *New Therapies for Hepatitis C*.

2008

Invited Speaker, San Diego Microbiology Group. *Novel Antivirals for Hepatitis C: Progress and Pitfalls*.

Invited Speaker, AIDS Clinical Trials Group Scientific Retreat. *Novel Antivirals for Hepatitis C*. June 25, Washington D.C.

Invited Speaker, American Association for the Study of Liver Disease. Hepatitis Single topic conference- Viral Hepatitis Therapy: Lessons to be learned from HIV. *What is known about Hepatitis C Resistance*. July 24-28, Chicago, IL.

International AIDS Society-USA Cases on the Web. *Issues in the care of HCV/HIV co-infected patients: antiretroviral pharmacokinetics, drug interactions, and liver transplantation*. Available at www.iasusa.org.

2009

Invited Speaker, 47th Annual Meeting of the Infectious Diseases Society of America. State of the Art Symposium: *HIV/HCV co-infection: Where are we in 2009?* October 29 – November 1, Philadelphia, PA.

2009-present

Director, UCSD Infectious Disease Fellowship Core Lecture Series. Lectures personally delivered annually:

- Hepatitis C
- Hepatitis B
- Skin and soft tissue infections
- Bacteremia and line infections
- Approach to the ID Consult
- Emerging Infections

2010

Invited Speaker, Topics and Advances in Internal Medicine. *Hepatitis A, B, and C: When to screen, Whom to treat, and How to treat them*. March 9, San Diego Bay Hilton.

Invited Speaker, International Antiviral Society-USA Spring Update Course. *Investigational Drugs for the Treatment of Hepatitis C Infection*. March 10, Los Angeles, CA. March 22, New York, NY.

Invited Speaker, UCSD Division of Infectious Diseases Research Conference. *Development of novel HCV inhibitors: targeting the IRES and Polymerase*. April 1.

Invited Speaker, International AIDS Society-USA Spring Update Course. *Investigational Drugs for the Treatment of Hepatitis C Infection*. May 17, San Francisco, CA.

Invited Speaker, HIV and Liver Disease Meeting. *Mechanisms of Viral Resistance*. September 25, Jackson Hole, WY.

Invited Speaker, International Antiviral Society-USA Spring Update Course. *What's new in Hepatitis C virus treatment*. March 14, Atlanta, GA.

2010-present

Lecturer, UCSD Internal Medicine Residency Noon Lecture Series. *Topics: Skin and soft tissue infections, Hepatitis C.*

2011

Invited Speaker, International Antiviral Society-USA Spring Update Course. *What's new in Hepatitis C virus treatment.* March 14, Atlanta.

Invited Speaker, International Antiviral Society-USA State-of-the-Art Clinical Conference. Management of Hepatitis C Virus in the New Era. *HCV Resistance to Novel Antivirals: What we know and what we need to know.* April 15, New York.

Invited Plenary Speaker, International Workshop on HIV & Hepatitis Virus Drug Resistance. *How will drug resistance limit new therapies for hepatitis C virus.* June 8, Los Cabos, Mexico

Invited Speaker, UCLA HIV Symposium. *New drugs for the treatment of HCV in HIV co-infected persons.* October 28, Los Angeles, CA.

Invited Speaker, University of Zurich Symposium: HCV – New drugs, new chances and challenges in treatment and diagnostics. *New drugs for HCV and Resistance.* December 8, Zurich, Switzerland.

2012

Invited Speaker, 19th Conference on Retroviruses and Opportunistic Infections. *HCV Resistance: Implications for Drug Development in the Coming Interferon-free World.* March 6, Seattle, WA.

Invited Speaker, Harvard Center for AIDS Research HIV/HCV 2012: Advances in Research and Treatment. *Antiviral Resistance and the Future Landscape of HCV.* April 26, Boston, MA.

Invited Speaker, Annual Meeting of the American Transplant Congress. *New Antivirals for HCV: Current and Future Agents.* June 3, Boston, MA.

Invited Speaker, 2012 Infectious Diseases Society of California Spring Symposium. *New Antivirals for HCV: The Future is Interferon-free.* April 29, Huntington Beach, CA.

Invited Panelist, Annual Meeting of the Infectious Diseases Society of America. Interactive Session: Direct Acting Antivirals for HCV: State-of-the-art. October 19, San Diego, CA.

2013

Invited Speaker, International Antiviral Society-USA Spring Update Course. *What's new in Hepatitis C virus treatment.* March 14, New York, NY.

Invited Speaker, HIV Strategies- 2013 Conference. *Hepatitis C and HIV Co-Infection: The State of Rapidly Evolving Therapy for HCV.* March 16, Eisenhower Medical Center, Rancho Mirage, CA.

Course Chair and Invited Speaker, International Antiviral Society-USA Intensive Viral Hepatitis Workshop. *State of the art HCV therapy and cases.* April 9, Atlanta, GA.

Invited Speaker, International Antiviral Society-USA Spring Update Course: Improving the Management of HIV Disease. *Don't Blink: The Rapid Evolution of Interferon-free Therapy for Hepatitis C Virus Infection*. April 10, Atlanta, GA.

Course Chair and Speaker, IAS-USA Full Day Course: *Management of Hepatitis C Virus in the New Era: Small Molecules Bring Big Changes*. June 4, San Francisco, CA.

Invited Speaker, 2013 Interscience Conference on Antimicrobial Agents and Chemotherapeutics. *HCV Resistance Testing*. September 12, Denver, CO.

Workshop leader and speaker, IAS-USA Intensive Workshop: *Evolving Strategies in Viral Hepatitis Management*. October 23, New Orleans, LA.

Invited Speaker, IAS-USA Full Day Course: Hepatitis C Virus Infection: Looking Beyond the Interferon Alfa Era. *Strategies for Treating HCV in HIV/HCV Coinfected Patients*. October 8, Chicago.

2014

Invited Speaker, VIII Annual Course on Advances in HIV and Hepatitis Virus Infections. *Hepatitis C Virus Therapy: The next 18 months*. February 1, Vigo, Spain.

Course Chair and Speaker, IAS-USA Full Day Course: *Management of Hepatitis C Virus in the New Era: Small Molecules Bring Big Changes*. March 21, San Francisco, CA.

Invited Speaker, International Antiviral Society-USA Spring Update Course: An Advanced CME Live Course in HIV Pathogenesis, Antiretrovirals, and Other Selected Issues in HIV Disease Management. *I Can See Clearly Now IFN Is Gone: New and Soon to be Approved Drugs for HCV*. April 23, Los Angeles, CA.

Course Chair and Invited Speaker, International Antiviral Society-USA Intensive Viral Hepatitis Workshop. *An Intensive Workshop on Evolving Strategies in Viral Hepatitis Management* April 22, Los Angeles, CA.

Invited Lecturer, IDSA Hepatitis C Knowledge Network, Webinar series: Treatment-Experienced Patients and Resistance. April 25. (available on line at: http://www.idsociety.org/HCV_Knowledge_Network_Archive/)

Invited Panelist, American Corrections Association Annual Meeting. *The Changing Landscape: Hepatitis C Treatment in Corrections*. August 17, Salt Lake City, UT.

2015

Invited Speaker, 9th Course on Advances in HIV and HCV Management. *Hepatitis C: The next 18 months*. January 30-31, La Coruña, Spain.

Course Chair and Invited Speaker, International Antiviral Society-USA Intensive Viral Hepatitis Workshop. *An Intensive Workshop on Evolving Strategies in Viral Hepatitis Management* April 28, Los Angeles, CA.

Course Chair and Invited Speaker, International Antiviral Society-USA Intensive Viral Hepatitis Workshop. *An Intensive Workshop on Evolving Strategies in Viral Hepatitis Management* May 19, Chicago, IL.

Invited Speaker, GI and Liver Association of America, Fort Lauderdale Conference. *Management of HCV/HIV Co-Infected Patients*. May 29-30, Ft. Lauderdale, FL.

Invited Speaker, First Annual Conference of the Group for the Study of Viral Hepatitis. *Management of HCV treatment in cirrhosis and retreatment of DAA failures*. September 24, Vigo, Spain.

Course Chair and Invited Speaker, International Antiviral Society-USA Intensive Viral Hepatitis Workshop. *An Intensive Workshop on Evolving Strategies in Viral Hepatitis Management* October 16, San Francisco, CA.

Invited speaker, The Liver Meeting 2015, Annual meeting of the American Association for the Study of Liver Diseases. *Resistance Associated Variants (RAVs): Important in Deciding Best Therapy?* November 16. San Francisco CA.

Invited Speaker, 2015 Ryan White Clinical Care Conference. *State of the Art in Hepatitis C Virus Infection in HIV/HCV Coinfected Patients*. December 16, New Orleans, LA.

2016

Invited Speaker, UCSD Medical Grand Rounds. *HCV: Opportunities and Challenges in a New Therapeutic Era*. January 13, La Jolla, CA

Invited Speaker, UCSD AVRC AIDS Rounds. *On again, off again...on again? Resistance testing for the Management of HCV Infection*. January 29, San Diego, CA.

Invited Speaker, 10th Course on Advances in HIV and HCV Management. *What to do when DAAs fail*. February 6, Vigo, Spain.

Invited Speaker, Infectious Diseases Society of California, 4th IDAC Winter Symposium. *HCV in 2016: More Options and More Questions*. March 5, Berkeley, CA.

Invited Speaker, University of Pennsylvania Hepatology Grand Rounds, *On again, off again...on again? Resistance testing for the Management of HCV Infection*. March 23, 2016 Philadelphia, PA.

2017

Invited Speaker, 6th Nordic Conference of HIV and Hepatitis Drug Resistance and Treatment Strategies. *Post EASL 2017 report on HCV treatment and resistance*. April 24, 2017. Uppsala, Sweden.

Invited Speaker, International Antiviral Society-USA Improving the Management of HIV Disease: An Advanced CME Live Course in HIV Pathogenesis, Antiretrovirals, and Other Selected Issues in HIV Disease Management. *Hepatitis C virus infection management*. May 25, 2017 Berkeley, CA.

Invited Speaker, ID Week 2017 Annual Meeting of the Infectious Diseases Society of America, HCV Symposium: *Retreatment, RASs and Resistance*. October 4, New Orleans, LA.

Invited Speaker, ID Week 2017 Annual Meeting of the Infectious Diseases Society of America, *State of the Art: Clinical Management of Hepatitis C*. October 7, New Orleans, LA

2018

Invited Speaker, ID Week 2018 Annual Meeting of the Infectious Diseases Society of America, HCV Symposium: *Resistance testing primer and Re-Treatment Options for HCV Patients*. October 3, San Francisco, CA.

Invited Speaker, ID Week 2018 Annual Meeting of the Infectious Diseases Society of America, *Staging Liver Disease*. October 3, San Francisco, CA

Invited Speaker, International Antiviral Society-USA Small Group Workshop on Evolving Strategies in Hepatitis C Management. *Viva La Revolucion: Options to Combat HCV Infection*. October 12, 2018 Memphis, TN.

2019

Invited Speaker, AASLD/EASL Special Topic Conference on Hepatitis C. *Is there a risk of Multiresistant HCV?* February 2, Miami FL.

Invited Speaker, University of Colorado Medical Grands Rounds. *Transformative Therapies for HCV: Paving the Way for Elimination?* February 13, Aurora CO.

Invited Speaker, Kentucky AIDS Education and Training Program 10th Annual Intensive Conference on HIV/HCV. *Hepatitis C: Initial Evaluation/Staging of the HCV Patient*. April 26, Lexington, KY.

Invited Speaker, UCSD HIV & Global Health Grand Rounds. *Transformative Therapies for HCV: Paving the Way for Elimination?* May 24, San Diego, CA.

Invited Speaker, ID Week 2019 Annual Meeting of the Infectious Diseases Society of America, HCV Symposium: *HCV Treatment and Re-Treatment*. October 2, Washington DC.

2021

Invited Speaker, Columbian Association of Infectious Diseases Annual Meeting, *Current and Future Treatments for Chronic Hepatitis B Infection: Moving from Control to Cure*. Virtual, September 1, 2021.

2022

Invited Speaker, IAS-USA, *Unique Issues in People with HIV and Hepatitis B/D Co-infections*. Webinar, July 19, 2022.

2023

Invited Speaker, New York State Department of Health AIDS Institute, *Resistance Testing in Hepatitis C Treatment*. Webinar, April 18, 2023.

Invited Speaker, AIDS Healthcare Foundation, *Identification and Management of HCV in Persons with HIV*. Webinar, May 17, 2023.

Invited Speaker, New England AIDS Education and Training Center, *Hepatitis B in people living with HIV. Update and looking to the future*. November 13, 2023.

CLINICAL TRIAL EXPERIENCE

Site Principal Investigator

GS-US-248-0122: A Long Term Follow-up Registry for Subjects Who Achieve a Sustained Virologic Response to Treatment in Gilead-Sponsored Trials in Subjects with Chronic Hepatitis C Infection. Gilead Sciences, NCT01457755

GS-US-248-0123: A Long Term Follow-up Registry Study of Subjects Who Did Not Achieve Sustained Virologic Response in Gilead-Sponsored Trials in Subjects with Chronic Hepatitis C Infection. Gilead Sciences, NCT01457768

M14-004: A Randomized, Open-label Study to Evaluate the Safety and Efficacy of ABT-450/Ritonavir/ABT-267 (ABT-450/r/ABT-267) and ABT-333 Coadministered with Ribavirin (RBV) in Adults with Genotype 1 Chronic Hepatitis C Virus (HCV) Infection and Human Immunodeficiency Virus, Type 1 (HIV-1) Coinfection (TURQUOISE-I). AbbVie, NCT01939197

GS-US-337-1118: An Open-Label, Multicenter Study To Evaluate The Efficacy And Safety Of Sofosbuvir/Ledipasvir Fixed-Dose Combination + Ribavirin For 12 Weeks In Chronic Genotype 1 HCV Infected Subjects Who Participated In A Prior Gilead-Sponsored HCV Treatment Study. Gilead, NCT01987453

GS-US-337-0115: A Phase 3, Multicenter, Open-Label Study to Investigate the Efficacy and Safety of Sofosbuvir/Ledipasvir Fixed-Dose Combination for 12 Weeks in Subjects with Chronic Genotype 1 or 4 Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV)-1 Co-Infection. Gilead, NCT02073656

MK5172-061: A Phase III Open-Label Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of MK 5172/MK-8742 in Treatment-Naïve Subjects with Chronic HCV GT1, GT4, GT5, and GT6 Infection who are Co-Infected with HIV MK-5172-061-796. Merck, NCT02105662

GS-US-342-1139: Comparison of Sofosbuvir/GS-5816 Fixed Dose Combination for 12 Weeks With Sofosbuvir and Ribavirin for 12 Weeks in Adults With Chronic Genotype 2 HCV Infection (ASTRAL-2). Gilead, NCT02220998

M14-226: Ombitasvir/ABT-450/Ritonavir and Dasabuvir With or Without Ribavirin in Treatment-Naïve HCV Genotype 1-Infected Adults With Chronic Kidney Disease (RUBY-1). AbbVie, NCT02207088

GS-US-342-1553: An Open Label Study to Evaluate The Efficacy And Safety Of Sofosbuvir/GS-5816 Fixed Dose Combination With Ribavirin For 24 Weeks In Chronic HCV Infected Subjects Who Participated In A Prior Gilead Sponsored HCV Treatment Study. Gilead, NCT02300103

M14-868: A Randomized, Open-Label, Multicenter Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Co-Administration of ABT-493 and ABT-530 With and Without RBV in Subjects With Chronic Hepatitis C Virus (HCV) Genotype 2 or Genotype 3 Infection (SURVEYOR-II)

IA-001: A Randomized, Double-Blind, Placebo-Controlled Dose Ranging Study Evaluating the Safety, Pharmacokinetics and Clinical Benefit of FLU-IGIV in Hospitalized Patients with Serious Influenza A Infection

National PI/Co-PI or Study Chair/Co-Chair:

PI, AI444-216-0018: An Open-Label Study to Evaluate the Safety of GS-7977+ Ribavirin for 12 Weeks in Subjects with Chronic HCV Infection Who Participated in a Gilead or Pharmasset Sponsored Clinical Study of GS-7977 (PSI-7977) (ALLY-2). Bristol-Myers Squibb, NCT02032888

Chair, ACTG A5320: The Viral Hepatitis C Long-Term Infection Cohort Study (V-HICS).

Co-PI, B2801001: A Phase I/II, Open-Label Dose Escalation Study To Evaluate The Safety And Efficacy Of Single Doses Of TT-034 In Patients with Chronic Hepatitis C (CHC) Infection. NCT01899092

Co-Chair, ACTG A5329: Interferon-Free Therapy for Chronic Hepatitis C Virus Genotype 1 Infection in Subjects with HIV-1 Coinfection Receiving Concurrent Antiretroviral Therapy (ASCENT-C)

PI, GS-US-342-1202: A Phase 3, Open-Label Study to Investigate the Efficacy and Safety of Sofosbuvir/Velpatasvir Fixed Dose Combination for 12 weeks in Subjects with Chronic Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV)-1 Coinfection (ASTRAL-5)

Co-Chair, ACTG A5380: A Phase II Trial of Glecaprevir/Pibrentasvir Fixed-dose Combination Treatment for Acute Hepatitis C Virus Infection (PURGE-C)

GRANTS

Re-Link Denver (PI: Wyles)
Center for Disease Analysis Foundation

01/01/2024-12/31/2024
\$103,000

Principal Investigator (0.12 calendar)

The Re-Link Denver program funded by the CDA foundation seeks to link diagnosed but untreated persons with chronic hepatitis C or B infection back to care. This will be accomplished through active case navigation and deployment of enhanced treatment capacity in primary care.

R01 DA042982-02 (PI: Haukoos, Rowan)

07/01/2017-6/30/2023

(no cost extension)

NIH/HSOD

\$499,734

Co-Investigator (0.3 calendar)

The Determining Effective Testing in Emergency Departments and Care Coordination on Treatment Outcomes (DETECT) for HCV Trial

The major goal of this project is to examine the effectiveness of two HCV screening strategies deployed in urban emergency department settings followed by 2 linkage-to-care strategies aimed at improving engagement in care, and ultimately treatment outcomes.

Completed Grants:

IN-US-342-4467 (PI: Wyles, David)

09/06/2017-10/01/2019

(no cost extension through 3/20)

Gilead Sciences Investigator Sponsored Research

\$404,522

Decreasing recidivism through HCV testing, linkage to care and treatment. The DeCrease-C study.

Major goal: To establish on-site rapid HCV testing in high-risk adult probationers in Denver County and facilitate linkage to HCV evaluation and treatment.

R01 DA040499-01 (PI: Kiser, Jennifer)

07/17/2015-05/31/2020

NIH/NIDA

\$542,045

Co-Investigator (1.2 calendar)

Antiviral Pharmacology and Adherence in Drug Users

Major goal: To develop and evaluate pharmacologic assays to achieve a robust measure of adherence during treatment of chronic hepatitis C with sofosbuvir/ledipasvir in active drug users.

Role: Co-investigator

R21 AI097061-01A1 (PI: Wyles)

04/01/2012-03/31/2014

NIH/NIAID

(no cost extension to 12/31/15)

\$426,063

Analysis of HIV/HCV Sexual Transmission Pairs Using Ultra-Deep Sequencing

Major goal: To analyze the HCV quasispecies diversity in anatomic compartments in HCV transmission pairs to determine the source of sexually transmitted HCV (blood, semen, or PBMCs).

DHHS/CDC
Wyles (PI)

U51 PS003924-01W1
09/30/2012-12/31/2014
\$1,761,040

The Hepatitis Care Connection Program (Hep-Care-Connect)

Major goal: To expand HBV and HCV testing and linkage to care in at risk and under served populations in San Diego County.

NIH
Schooley (PI)

R01 AI076558-01A1
04/01/2009 - 03/31/2014

\$2,777,103

Orally Active Nucleoside Phosphonates for Hepatitis C Virus

Major goals: To identify and optimize acyclic nucleoside phosphonates which demonstrate Hepatitis C virus inhibitory properties in vitro.

NIH/NIAID
Wyles (PI)

K08 AI069989-01A1
06/15/2007-05/31/2012

An in vitro system to study antiviral strategies against Hepatitis C virus

Project will continue to expand the in vitro HCV replication systems to include the full length virus replication system based on the JFH-1 clone. A virus fitness assay using a dual luciferase reporter system (firefly and Renilla) will be developed. Additional antiviral strategies such as lentiviral vectors encoding HCV siRNAs will also be developed.

Role: PI
Mentors: Drs. Robert T. Schooley and Aleem Siddiqui

PUBLICATIONS (in chronological order)

1. Wyles DL and Gerber JG. Antiretroviral Drug Pharmacokinetics in Hepatitis with Hepatic Dysfunction. Clin Infect Dis 2008; 40(1): 174-181.
2. Wyles DL and Gerber JG. Abacavir Pharmacokinetics in Hepatic Dysfunction. Clin Infect Dis 2008; 40(6): 909-10.
3. Wyles DL, Patel A, Madinger N, Bessesen M, Krause PR, and Weinberg A. Development of Herpes Simplex Virus Disease in Patients Receiving Cidofovir. Clin Infect Dis 2008; 41(5): 676-80.
4. Wyles DL, Kaihara KA, Vaida F, Schooley RT. Synergy of small molecular inhibitors of HCV replication directed at multiple viral targets. J Virol 2007; 81:3005-8.
5. Grünberger C, Wyles DL, Kaihara KA, and Schooley RT. Three-Drug synergistic interactions of small molecular inhibitors of HCV replication. J Infect Dis 2008; 197(1):42-5.

6. Wyles DL, Kaihara KA, Schooley RT. Synergy of an HCV NS4A antagonist in combination with HCV protease and polymerase inhibitors. *Antimicrob Agents Chemother* 2008; 52(5):1862-4.
7. Wyles DL. Hepatitis virus co-infection in the SMART study: a marker for non-liver, non-opportunistic disease related mortality. *Clin Infect Dis* 2008; 47(11): 1476-8.
8. Wyles DL, Kaihara KA, Korba BE, Schooley RT, Beadle JR, Hostetler KY. The octadecyloxyethyl ester of (S)-9-[3-hydroxy-2-(phosphonomethoxy) propyl]adenine is a potent and selective inhibitor of hepatitis C virus replication in genotype 1A, 1B, and 2A replicons. *Antimicrob Agents Chemother* 2009; 53(6):2660-2.
9. Morrey JD, Korba BE, Beadle JR, Wyles DL, Hostetler KY. Alkoxyalkyl esters of 9-(s)-(3-hydroxy-2-phosphonomethoxypropyl) adenine are potent and selective inhibitors of hepatitis B virus (HBV) replication in vitro and in HBV transgenic mice in vivo. *Antimicrob Agents Chemother* 2009; 53(7):2865-70.
10. Parsons J, Castaldi MP, Dutta S, Dibrov SM, Wyles DL, Hermann T. Conformational inhibition of the hepatitis C virus internal ribosome entry site RNA. *Nat Chem Biol* 2009; 5(11):823-5.
11. Wyles DL. The Potential for Combination Treatment Using STAT-C Drugs. *Current Hepatitis Reports* 2009 8(4): 167-74.
12. Wyles DL and Schooley RT. Rong's Numbers: Accelerating Progress in HCV Therapeutic Research. *Science Translational Medicine* 2010 2(33): 33ps25 (2010).
13. Carnevali M, Parsons J, Wyles DL, Hermann T. A Modular Approach to Synthetic RNA Binders of the Hepatitis C Virus Internal Ribosome Entry Site. *Chembiochem* 2010; 11(10):1364-7.
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