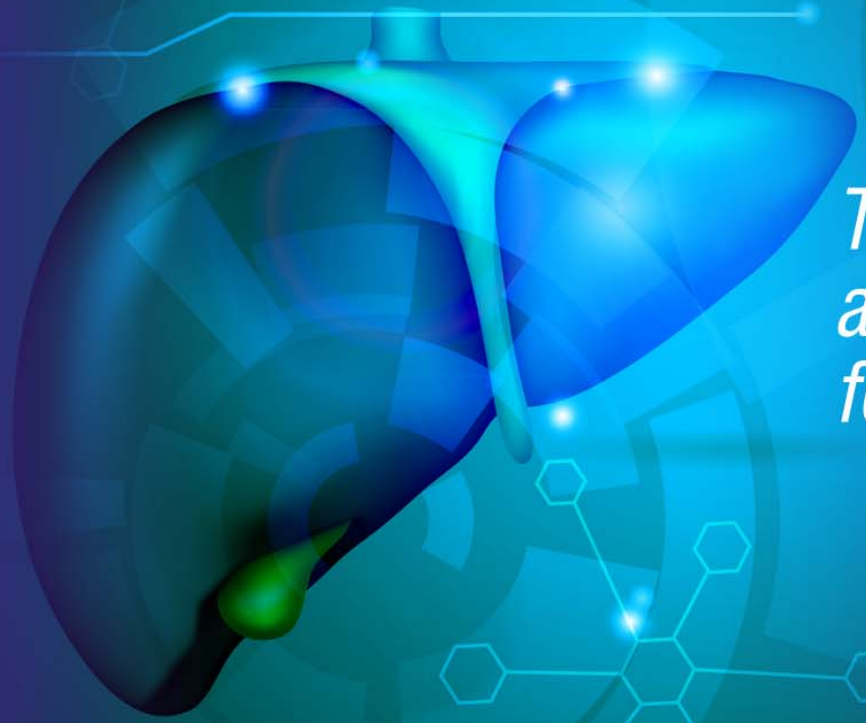
CAPITALIZING ON HCV ADVANCEMENTS:



Treatment Management and Benefit Design Strategies for Managed Care

HCV

Jointly provided by PIM Postgraduate Institute for Medicine and Impact Education, LLC

This activity is supported by an educational grant from Gilead Sciences, Inc.

Held in conjunction with AMCP Academy of Managed Care Pharmacy®

AMCP Nexus 2014: Connecting Health Care and Innovation

Agenda

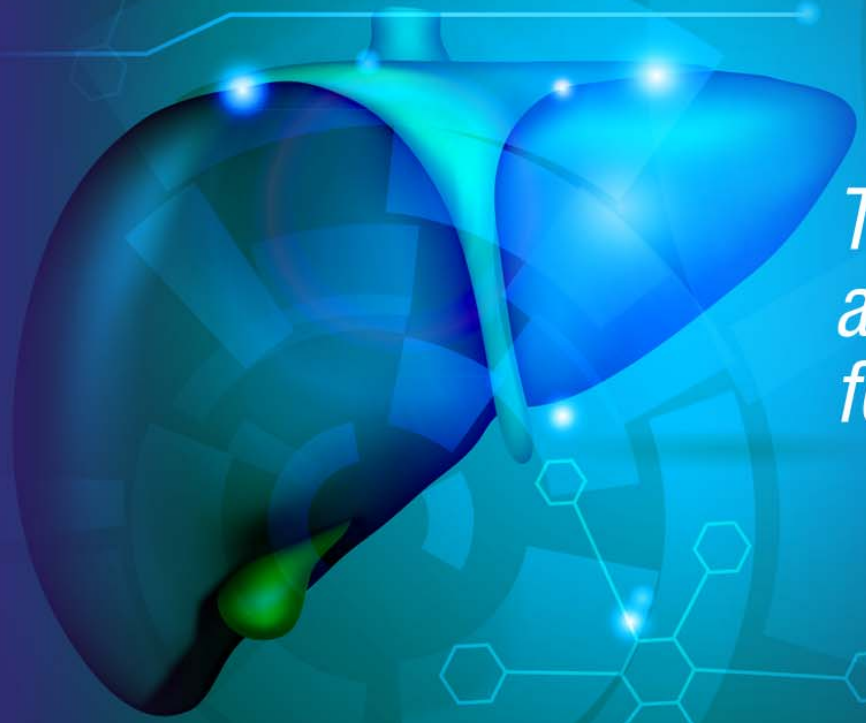
6:20-6:55 AM	• Evolving Guidelines and Evidence-Based HCV Treatments • Therapeutic Recommendations for Various HCV Patient Types *Nancy S. Reau, MD*
6:55–7:30 AM	• Pharmacy Benefit Design Innovations for a New Era of HCV Management • HCV Specialty Pharmacy Services and Disease Management Strategies for Managed Care Pharmacy *Jeffrey D. Dunn, PharmD, MBA*
7:30–7:45 AM	Faculty Discussion Session

Learning Objectives

After completing this activity, the participant should be better able to:

- Apply evidence-based treatment strategies to optimize outcomes for patients with HCV within a managed care setting
- Cite recently updated American Association for the Study of Liver Disease (AASLD), Infectious Diseases Society of America (IDSA), and the American College of Gastroenterology (ACG) treatment guidelines on current and emerging treatment options for HCV, including efficacy, safety, and tolerability
- Recommend benefit design that takes into account patient out-of-pocket expenses (OOP) to remove barriers and improve adherence and overall value for the management of HCV
- Evaluate pharmacy management strategies, including specialty pharmacy services and disease management, that MCOs can implement to improve overall patient outcomes for HCV patients
- Provide accurate and appropriate counsel as part of the managed care treatment team

CAPITALIZING ON HCV ADVANCEMENTS:



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AMCP Nexus 2014: Connecting Health Care and Innovation

Capitalizing on HCV Advancements: Treatment Management and Benefit Design Strategies for Managed Care

Jeffrey D. Dunn, PharmD, MBA

Senior Vice President
VRx Pharmacy Services, LLC

Faculty Disclosure

- The ***faculty*** reported the following financial relationships or relationships to products or devices they or their spouse/life partner have with commercial interests related to the content of this CME activity:

  Jeffrey D. Dunn, PharmD, MBA

  – *Consulting Fees:* Vertex Pharmaceuticals, Janssen Pharmaceuticals, Gilead Sciences, Inc., and AbbVie, Inc.

Clinical Burden of Hepatitis C Continues to Grow

Prevalence in the US ~1.6% of the population (4.1 million)[1]

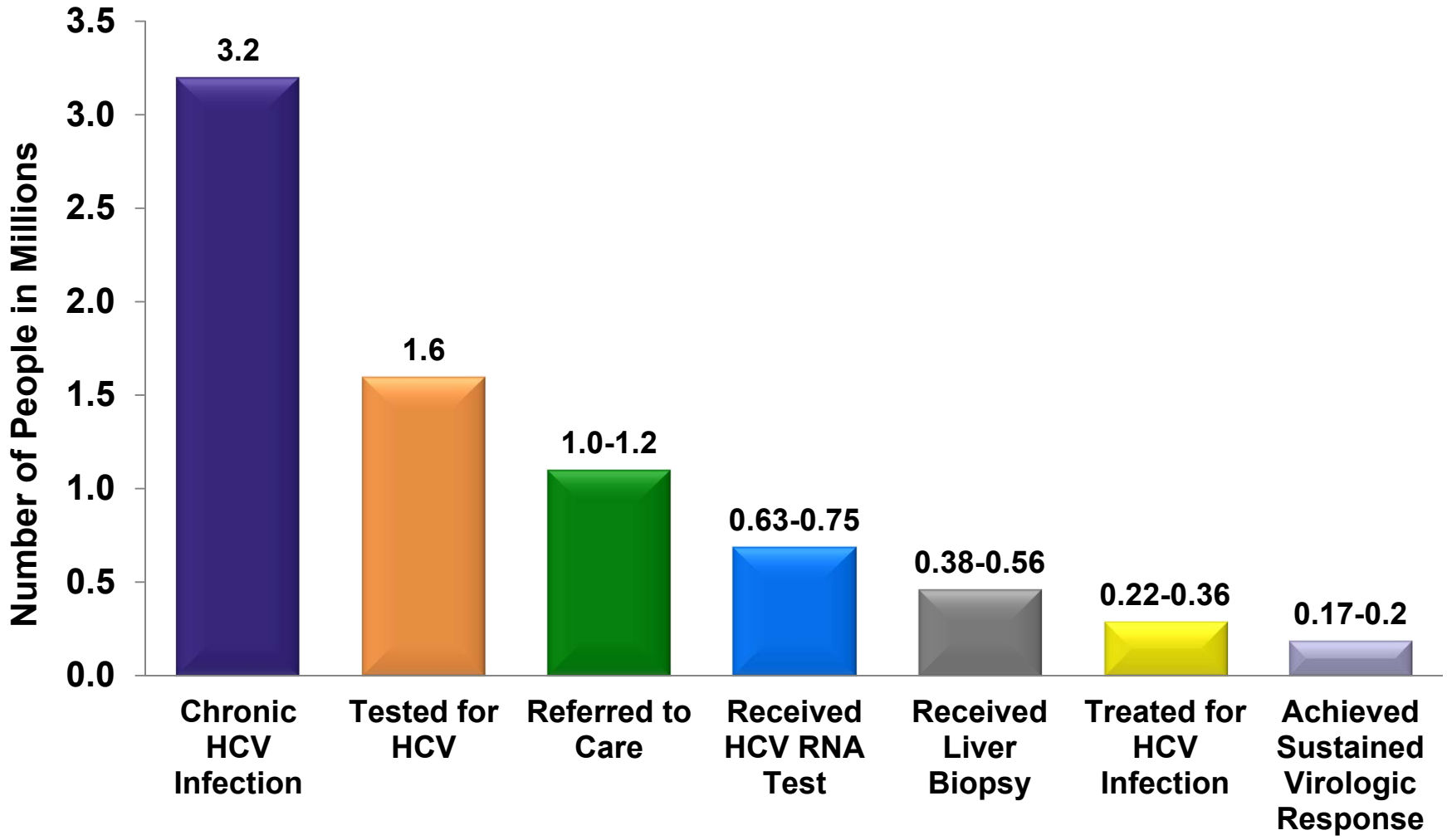
- **Increase in prevalence is projected over the next 3 decades[2]**
- **Majority of currently infected individuals have not yet been diagnosed[2]**

Principal cause of death from liver disease and the leading indication for liver transplantation in the US[1,2]

- **40% of deaths from liver disease can be attributed to HCV[3]**
- **HCV-related cirrhosis accounts for ~40% of liver transplants[4]**

1. Hepatitis C Online. http://www.hepatitisc.uw.edu/go/screening-diagnosis/epidemiology-us/core-concept/all#hcv-incidence-and-prevalence.
2. Centers for Disease Control. http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#.
3. Centers for Disease Control. http://www.cdc.gov/hepatitis/Statistics/2011Surveillance/Commentary.htm#hepC.
4. Pacholczyk M, et al. *Ann Transplant*. 2012;17:5-10.

Prevalence of HCV in the US and Patient Engagement in HCV Care



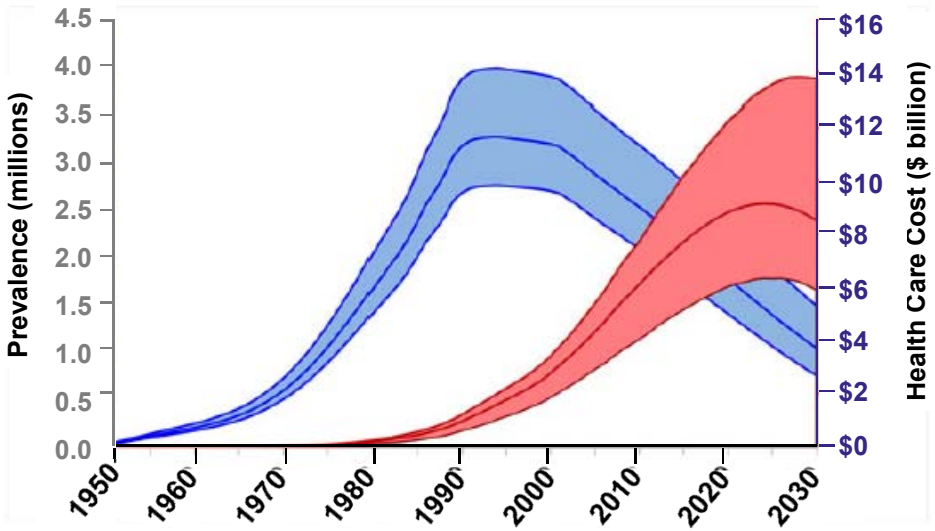
HCV=hepatitis C virus; RNA=ribonucleic acid.

Holmberg SD, et al. *N Engl J Med*. 2013;368:1859-61.

Economic Burden of HCV is Projected to Increase

- **Total health care cost due to HCV infection**
  - **2011: ~$6.5 billion**
  - **2024: ~$9.1 billion**
- **Increasing costs due to more advanced liver diseases including**
  - **Decompensated cirrhosis (46%)**
  - **Compensated cirrhosis (20%)**
  - **Hepatocellular carcinoma (16%)**

Prevalence of HCV and Associated Health Care Costs



Razavi H, et al. *Hepatology*. 2013;57:2164-2170.

Chronic HCV Infection Presents a Significant Challenge to Managed Care

"The Silent Epidemic"

Disease with a long, indolent course

- **Aging of a large pool of enrollees**
- **Many patients are undiagnosed or not on therapy**
- **Many patients are asymptomatic**

Cornerstone therapies have high costs

Davis GL, et al. *Gastroenterology*. 2010;138:513-521, 521 e511-516.
Centers for Disease Control. Hepatitis C Information for healthcare providers. http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#.

Challenges Presented to Managed Care by HCV

Improved methods to enhance identification and treatment of affected patients are needed

- Role of active screening?

Patient adherence to therapy is suboptimal

- Regimens are complex

Long-term monitoring of patients necessary to enhance outcomes

Associated with significant comorbidities, ie, HIV, etc

Current therapies have limitations

- Adverse events
- Convenience

McHutchison JG, et al. *Am J Manag Care*. 2007;13:S327-S336.

Unanswered Questions in the Management of HCV

Will the initial expense of therapy be offset by cost savings from the prevention of future disease burden?

- ***If so, how can MCOs assure patients are receiving the best care with the most efficient use of health care resources?***

What can be done to ensure diagnosis and appropriate treatment of infected patients, which will reduce future health burden?

What methods can be used during treatment to further reduce total HCV costs?

HCV=hepatitis C virus; MCO=managed care organization.

McHutchison JG, et al. *Am J Manag Care*. 2007;13:S327-S336.

Treating HCV

Goal of treatment is to prevent complications and death from HCV infection by achieving virologic cure[1]

Recommended regimens:[2]
sofosbuvir and ribavirin ± pegylated interferon alpha
OR
sofosbuvir and simeprevir ± ribavirin;
simeprevir + RBV + PEGIFN is an alternative for some genotype 1 and 4 infections;
Specific combinations, treatment duration, and alternative regimens depend on HCV genotype, and interferon eligibility

Combination therapy has been shown to be superior to peginterferon monotherapy

1. Ghany MG, et al. *Hepatology*. 2009;49:1335-1374; 2. AASLD/IDSA/IAS–USA. http://www.hcvguidelines.org.

Several Novel HCV Therapies are in the Pipeline

Protease Inhibitors (>5)

- Interferon-free double, triple, and quadruple therapy combinations
- Greater efficacy
- Increased complexity

Others

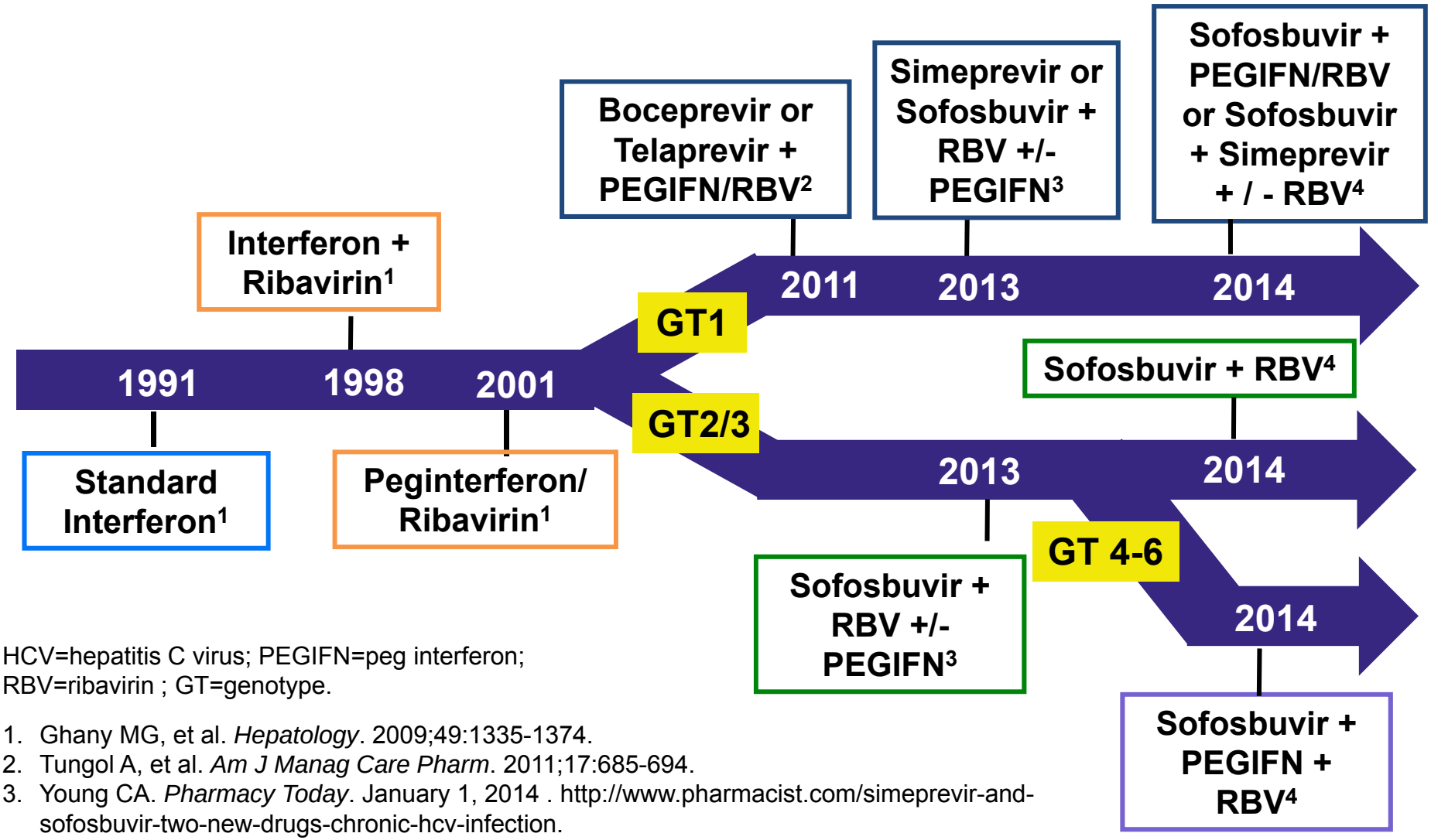
- Polymerase inhibitors
  - Nucleoside and non-nucleoside
- NS5A inhibitors
- Entry inhibitors
- Cyclophilin inhibitors
- MicroRNA inhibitors
- Vaccines

Increased pharmacy cost

- Decreased total cost?
- Improved long-term outcomes?

Poordad F, et al. *Am J Manag Care*. 2011;17:S123-S130.
Franciscus A. http://www.hcvadvocate.org/hepatitis/hepC/Quick_Ref_Guide.pdf Updated September 17, 2014.

HCV Is Evolving Rapidly with a New Standard of Care Emerging



HCV=hepatitis C virus; PEGIFN=peg interferon; RBV=ribavirin ; GT=genotype.

1. Ghany MG, et al. *Hepatology*. 2009;49:1335-1374.
2. Tungol A, et al. *Am J Manag Care Pharm*. 2011;17:685-694.
3. Young CA. *Pharmacy Today*. January 1, 2014 . http://www.pharmacist.com/simeprevir-and-sofosbuvir-two-new-drugs-chronic-hcv-infection.
4. AASLD/IDSA/IAS–USA. http://www.hcvguidelines.org. September 2014.

HCV Therapies in Development: 2014*

On Market

IFN & PEG IFN | Ribavirin | Boceprevir | Telaprevir to be discontinued | Simeprevir | Sofosbuvir

Phase III

ABT-450/r | Ledipasvir | BMS-791325 | Asunaprevir | ABT-267 | Mericitabine | Daclatasvir | ABT-333 | Vaniprevir | Narlaprevir | MK-8742 | BI-207127

Phase II

Sovaprevir | Miravirsen | IDX719 | GS-9451 | MK-5172 | GS-5816 | GS-9669 | VX-222 | Tegobuvir | Silibinin | GS-9620 | ACH-3102 | ABT-072 | Setrobuvir | SCY-635 | ACH-2684 | Danoprevir

Phase I

TT-034 | VGX-6150

Research/Preclinical

Many others, including immune stimulants and gene therapy

- Interferons
- Ribavirins
- Protease inhibitors
- Polymerase inhibitors
- NS5A inhibitors
- Other

*Sample, not an exhaustive list.

HCV Regimens in Development

Regimens with one DAA + PEG-IFN alfa/RBV

- Ritonavir-boosted Danoprevir (PI)
- GS-9451 (Vedroprevir; PI)

Regimens with 2-3 DAAs (± PEG-IFN alfa and/or RBV)

- GS-9526 (PI) + Tegobuvir
- GS-9451 + Tegobuvir (NNI)
- Daclatasvir (NS5A) + Asunaprevir (PI)

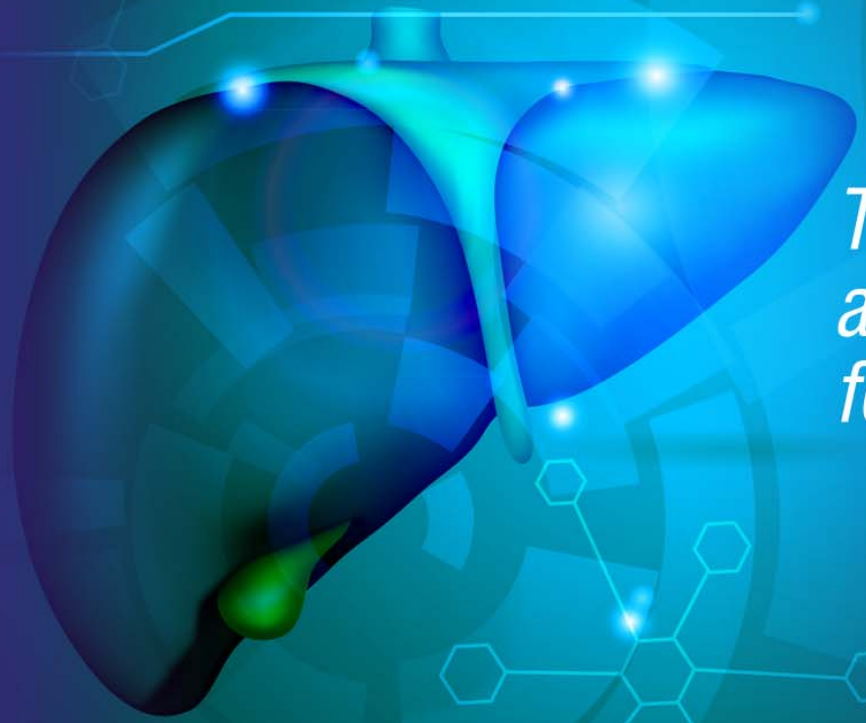
IFN-free regimens

- ABT-450/r + ABT-267 + ABT-333 +/- RBV
- Daclatasvir + Asunaprevir ± RBV
- BI-201335 + BI-207127 ± RBV
- Ledipasvir + Sofosbuvir ± RBV
- Daclatasvir + Simeprevir + RBV
- MK-5172 + MK-8742 ± RBV
- Dataclasvir + Asunaprevir + BMS-79135
- GS-5816 + Sofosbuvir
- Daclatasvir + Sofosbuvir
- ABT-493 + ABT-530 ± RBV
- ABT-450/r/ABT-267 + ABT-333 + RBV

*Sample, not an exhaustive list.

DAA=direct acting antiviral; PEG-IFN=pegylated interferon; RBV=ribavirin; NNI= non-nucleoside NS5B inhibitor; PI=protease inhibitor; NS5A=replication complex inhibitor; NI=nucleoside NS5B inhibitor; Cyp=cyclophilin inhibitor, IFN=interferon; r=ritonavir.

CAPITALIZING ON HCV ADVANCEMENTS:



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Capitalizing on HCV Advancements: Treatment Management and Benefit Design Strategies for Managed Care

Nancy Reau, MD

University of Chicago

Center for Liver Diseases

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  Nancy S. Reau, MD

  – *Consulting Fees:* AbbVie, Gilead, Idenix Pharmaceuticals, Janssen

  – *Contracted Research:* AbbVie, Gilead

Evolving Guidelines and Evidence-Based HCV Treatments

Advice From Our Guidelines?

Recommendations for when and in whom to initiate treatment

Treatment is recommended for patients with chronic HCV infection

Rating: Class I, Level A

Treatment is assigned the highest priority for those patients with advanced fibrosis (Metavir F3), those with compensated cirrhosis (Metavir F4), liver transplant recipients, and patients with severe extrahepatic hepatitis C (Table 1).

Based on available resources, treatment should be prioritized as necessary so that patients at high risk for liver-related complications and severe extrahepatic hepatitis C complications are given high priority (Table 1).

Ratings: See tables

AASLD/IDSA. http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy.September 19, 2014.

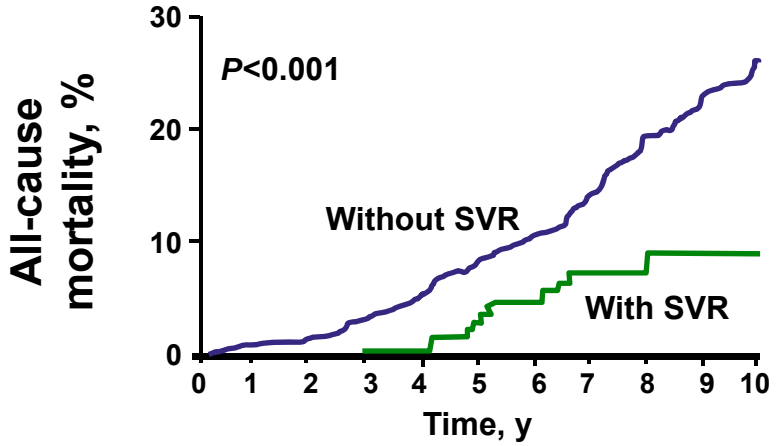
Who Requires HCV therapy?

1. High risk for liver-related complications
2. High risk for progression
3. High risk for transmission
4. Serious extra-hepatic complication
5. Other

SVR is Associated with Reduced Mortality Among HCV-infected Persons

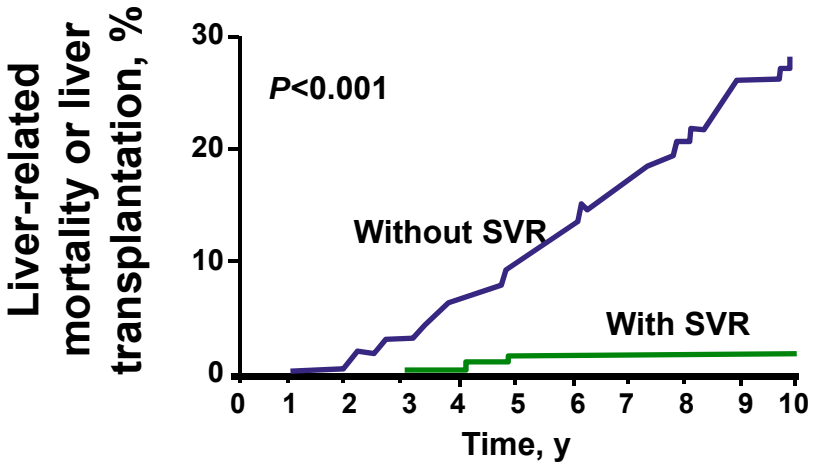
- 530 adults with advanced fibrosis prospectively followed for median 8.4 years after HCV treatment
- 192 (36%) achieved SVR

All-cause mortality



No. at risk											
Without SVR	405	393	382	363	344	317	295	250	207	164	135
With SVR	192	181	168	162	156	144	125	88	56	40	28

Liver-related mortality or liver transplantation



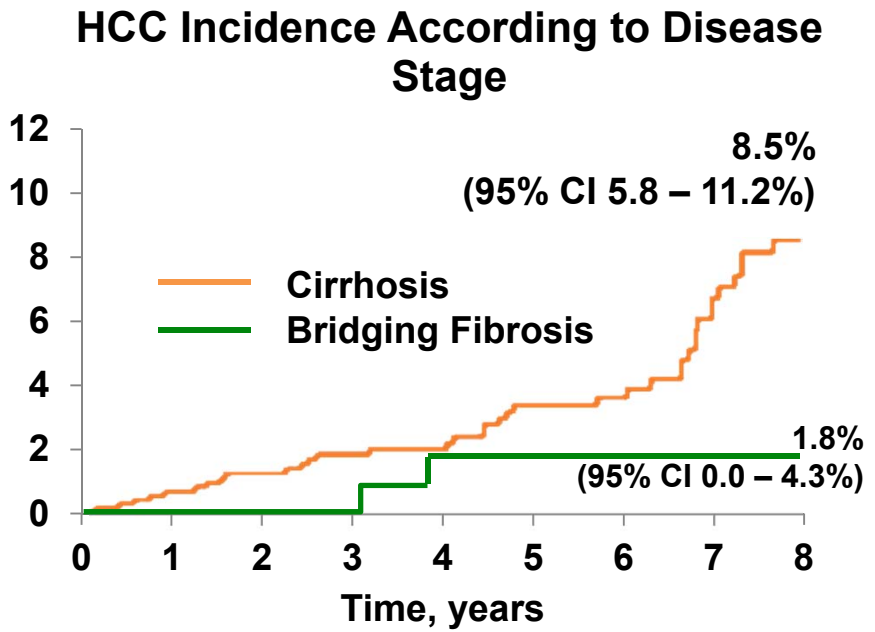
No. at risk											
Without SVR	405	392	380	358	334	305	277	229	187	146	119
With SVR	192	181	168	162	156	144	125	88	56	40	28

Van der Meer, et al. *JAMA* 2012:308:2584-2593.

SVR=sustained virologic response

Hepatocellular Carcinoma in HCV-infected Patients with Advanced Hepatic Fibrosis Following SVR

- 1000 patients followed for median 5.7 years
  - 85% cirrhosis
- Risk of HCC increased with:
  - Age >45 years
  - Platelet count <150 x 108/L
  - AST/ALT ratio > 0.90
  - Diabetes Mellitus



ARE WE ACTING EARLY ENOUGH??

SVR=sustained virologic response;
HCC=hepatocellular carcinoma;
AST/ALT ratio=aspartate transaminase–alanine transaminase ratio

Van der Meer et al. The Liver Meeting 2013;Abstract 143.

Who Requires HCV therapy?

1. High risk for liver related complications
2. High risk for progression
3. High risk for transmission
4. Serious extra-hepatic complication
5. Other

Risk Factors Associated with Faster Fibrosis Progression in Chronic HCV

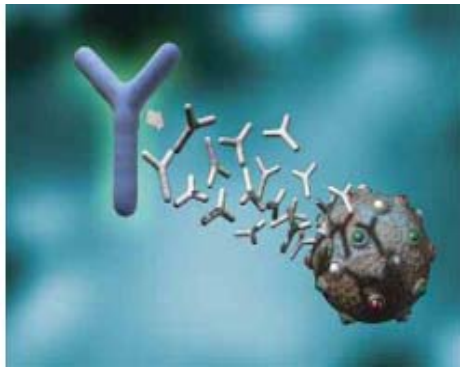
Disease state factors

- Fibrosis stage
- HCV onset after 40 years of age
- Persistently elevated ALT

Host factors

- Male gender
- Age >45 years
- Obesity/steatosis
- Diabetes
- HIV, HBV co-infection
- Immune system compromise
- Iron overload
- Life style (ETOH, smoking)

Viral factors

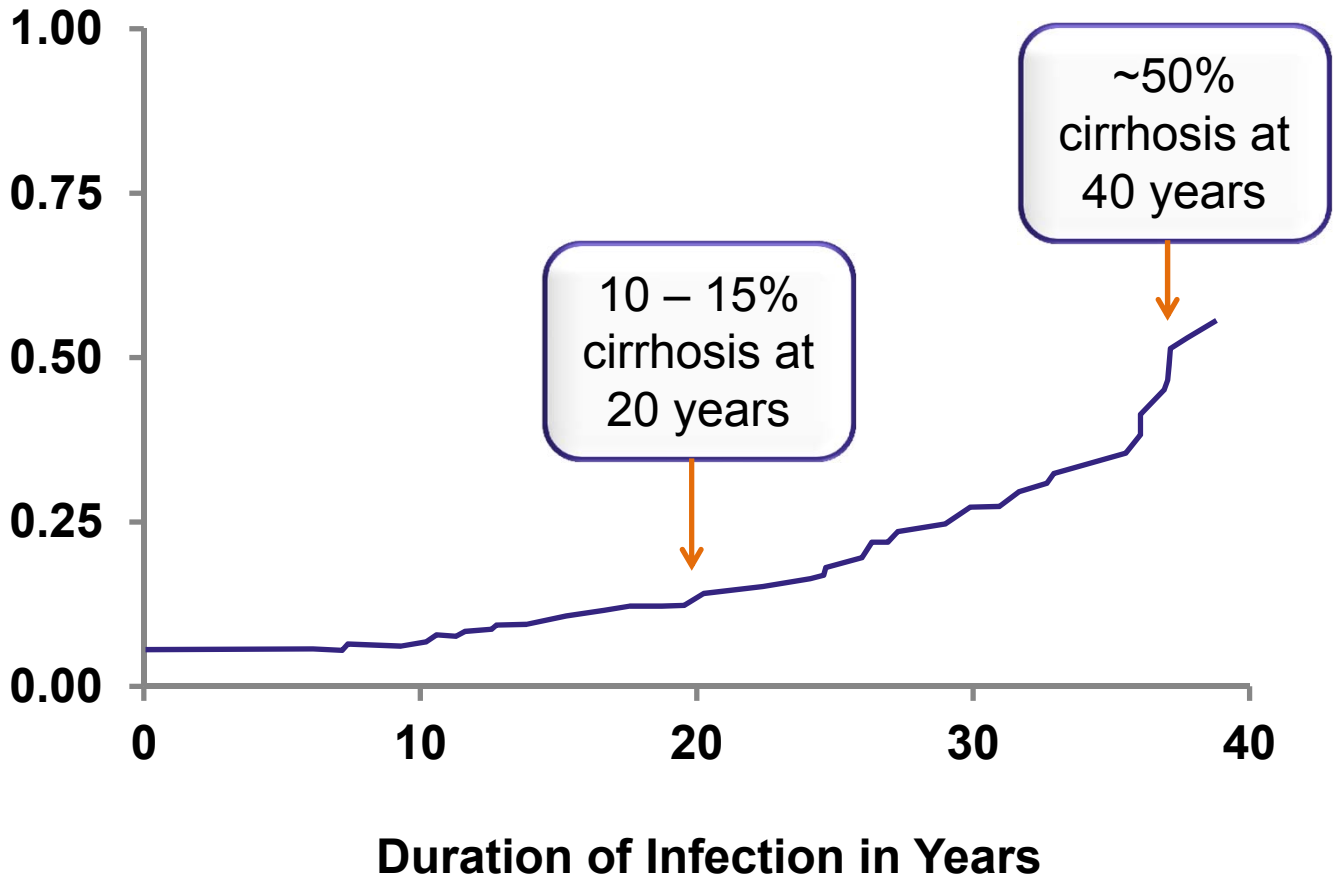


- Genotype 3

ALT=alanine aminotransferase
ETOH=alcohol

Poynard, Afdhal. *Antivir Ther* 2010;15:281-91; Poynard, et al. *Lancet* 1997;349:825-32.

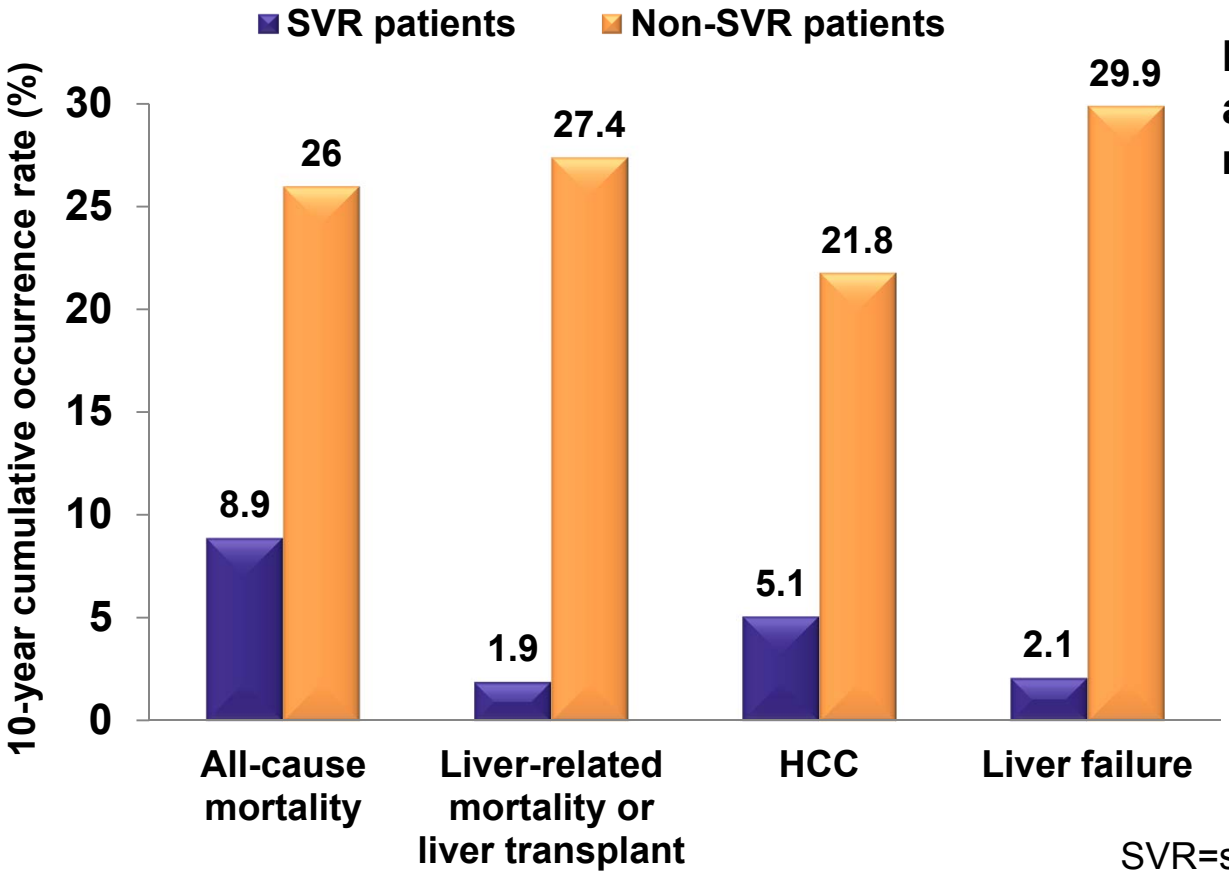
Progression is Not Linear: Importance of Duration and Aging



Adapted from: Poynard T, et al. *J Hepatol.* 2001;34(5):730-739.

SVR and All-cause Mortality in CHC Patients with Advanced Fibrosis

530 patients followed for a median of 8.4 years



Baseline factors significantly associated with all-cause mortality

- Older age
- **Genotype 3 (2-fold increase in mortality and HCC)**
- Higher Ishak fibrosis score
- Diabetes
- Severe alcohol use

SVR=sustained virologic response
CHC=chronic hepatitis C
HCC=hepatocellular carcinoma

Van der Meer A, et al. *JAMA.* 2012; 308:2584–2593.

HCV Genotype 3 in the VA HCV Clinical Case Registry 2000-2009: Cirrhosis and HCC

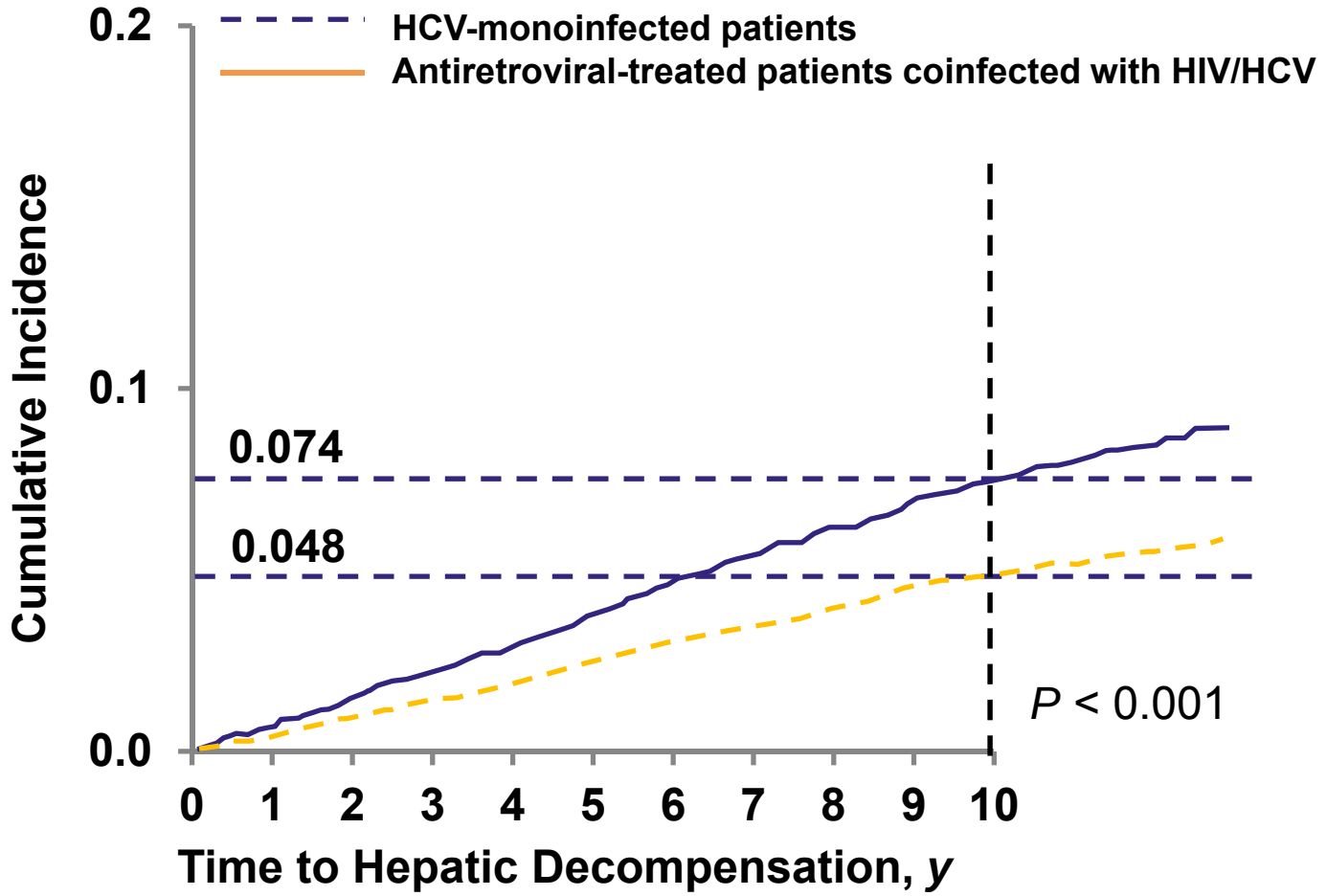
- 88,348 patients with genotype 1 (80%)
- 13,077 genotype 2 (12%)
- 8,337 genotype 3 (7.5%)
- Mean follow-up: 5.4 years
- After adjustment for demographic, clinical and antiviral treatment factors, comparison between genotypes 3 and 1:

	Hazard Ratio	Confidence Interval
Cirrhosis	1.31	1.22.-1.39
HCC	1.80	1.61-2.03

Conclusion: *Genotype 3 associated with significantly higher risk of cirrhosis and HCC vs genotype 1, independent of age, diabetes, BMI, or antiviral treatment*

Kanwal F, et al. *Hepatology.* 2014;60:98-105.

Coinfected Patients Have Higher Rates of Hepatic Decompensation Despite ART



ART=antiretroviral treatment

Lo Re et al. *Ann Intern Med*. 2014:160:369-379

Who Requires HCV therapy?

1. High risk for liver related complications
2. High risk for progression
3. High risk for transmission
   - **MSM with high-risk sexual practices**
   - **Active injection-drug users**
   - **Incarcerated persons**
   - **Persons on long-term hemodialysis**
     - **Rating:** Class IIa, Level C
4. Serious extra-hepatic complication
5. Other

Who Requires HCV therapy?

1. High risk for liver related complications
2. High risk for progression
3. High risk for transmission
4. Serious extra-hepatic complication
5. Other

Extrahepatic Manifestations of HCV

- **Hematologic Disorders**
  - Mixed Cryoglobulinemia
  - Lymphoproliferative Disorders
- **Renal**
  - Membranoproliferative glomerulonephritis (MPGN)
- **Dermatologic Diseases**
  - Porphyria Cutanea Tarda
  - Leukocytoclastic Vasculitis
  - Lichen Planus
  - Necrolytic Acral Erythema
- **Diabetes Mellitus**
- **Autoimmune Disorders**
  - Autoantibodies
  - Thyroid Disease
  - Autoimmune ITP
  - Sjogren's Syndrome
  - Rheumatoid Arthritis
  - Sarcoidosis
  - Myasthenia Gravis
- **Ophthalmologic Features**
- **Neurologic**
  - Mononeuropathy multiplex
  - Acute inflammatory syndromes
  - Cerebral vasculitis

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  - Porphyria Cutanea Tarda
  - Leukocytoclastic Vasculitis
  - Lichen Planus
  - Necrolytic Acral Erythema
- **Diabetes mellitus**

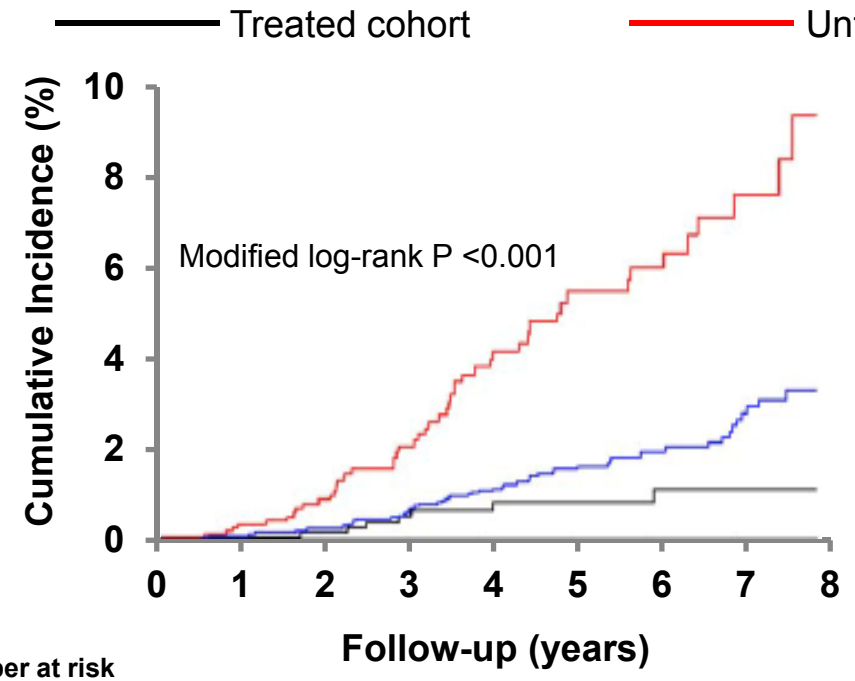
- **Autoimmune Disorders**
  - Autoantibodies
  - Thyroid Disease
  - Autoimmune ITP
  - Sjogren's Syndrome
  - Rheumatoid Arthritis
  - Sarcoidosis
  - Myasthenia Gravis
- **Ophthalmologic Features**
- **Neurologic**
  - Mononeuropathy multiplex
  - Acute inflammatory syndromes
  - Cerebral vasculitis

- **Diabetes mellitus**

- Fatigue
- Poor Quality of Life

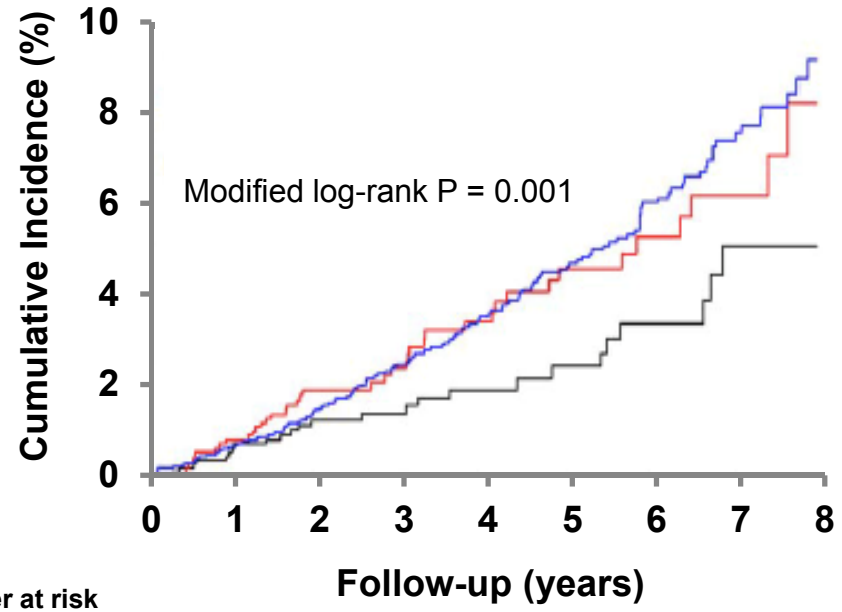
SVR ↓ Complications of DM

Cumulative incidence of ESRD in three study cohorts, analyzed by the modified log rank test with death adjusted as a competing risk event



Number at risk									
Treated	1411	1400	987	755	586	418	303	168	47
Untreated	1411	1388	962	711	530	362	262	152	43
Uninfected	5644	5591	3928	2980	2322	1624	1194	684	201

Cumulative incidence of acute coronary event in three study cohorts, analyzed by the modified log rank test with death adjusted as a competing risk event



Number at risk									
Treated	1411	1394	983	751	580	411	296	161	46
Untreated	1411	1383	955	717	538	367	263	151	42
Uninfected	5644	5566	3889	2935	2276	1590	1157	653	191

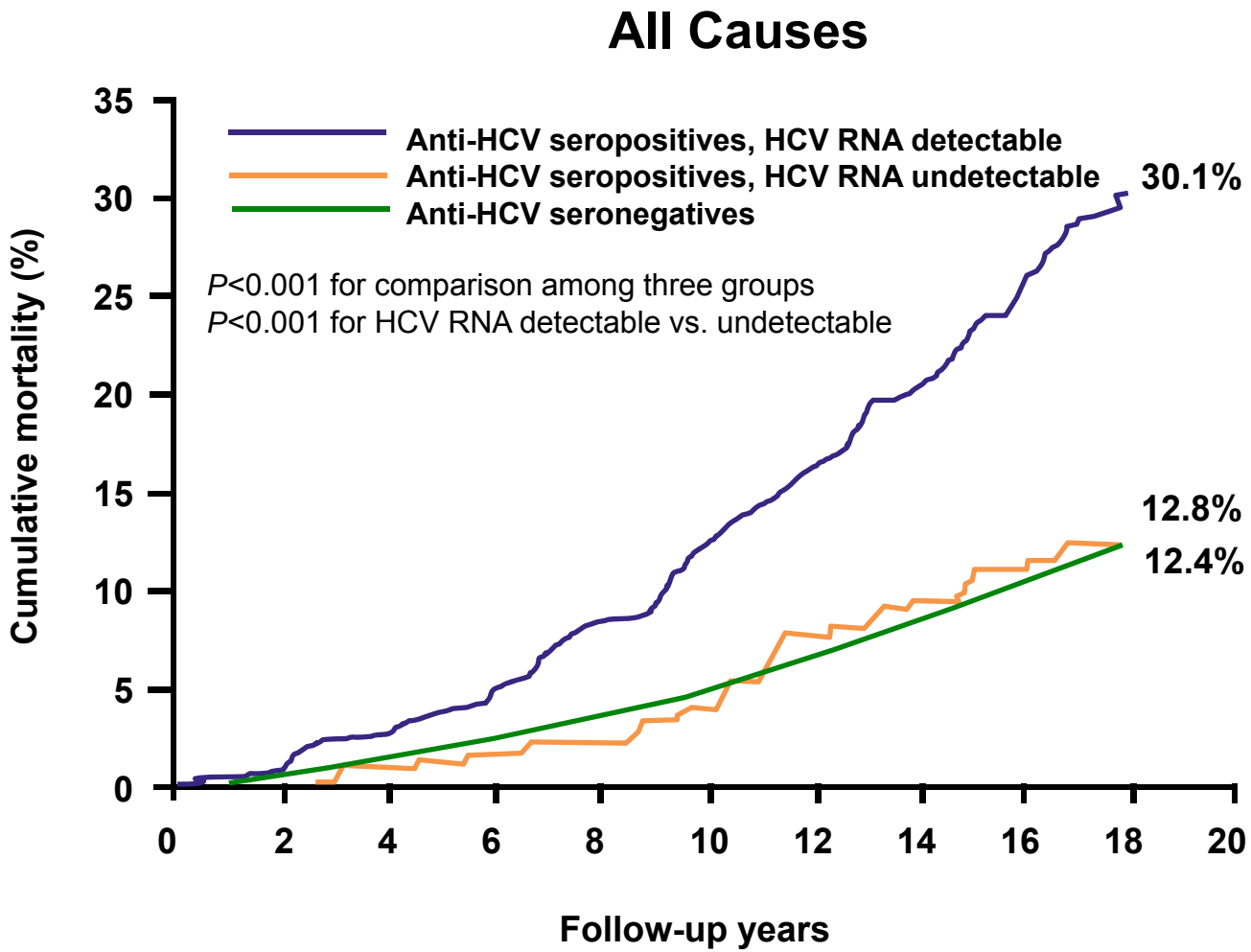
Hsu et al. *Hepatology.* Early Release

SVR=sustained virologic response; DM=disease management; ESRD=end stage renal disease

Who Requires HCV therapy?

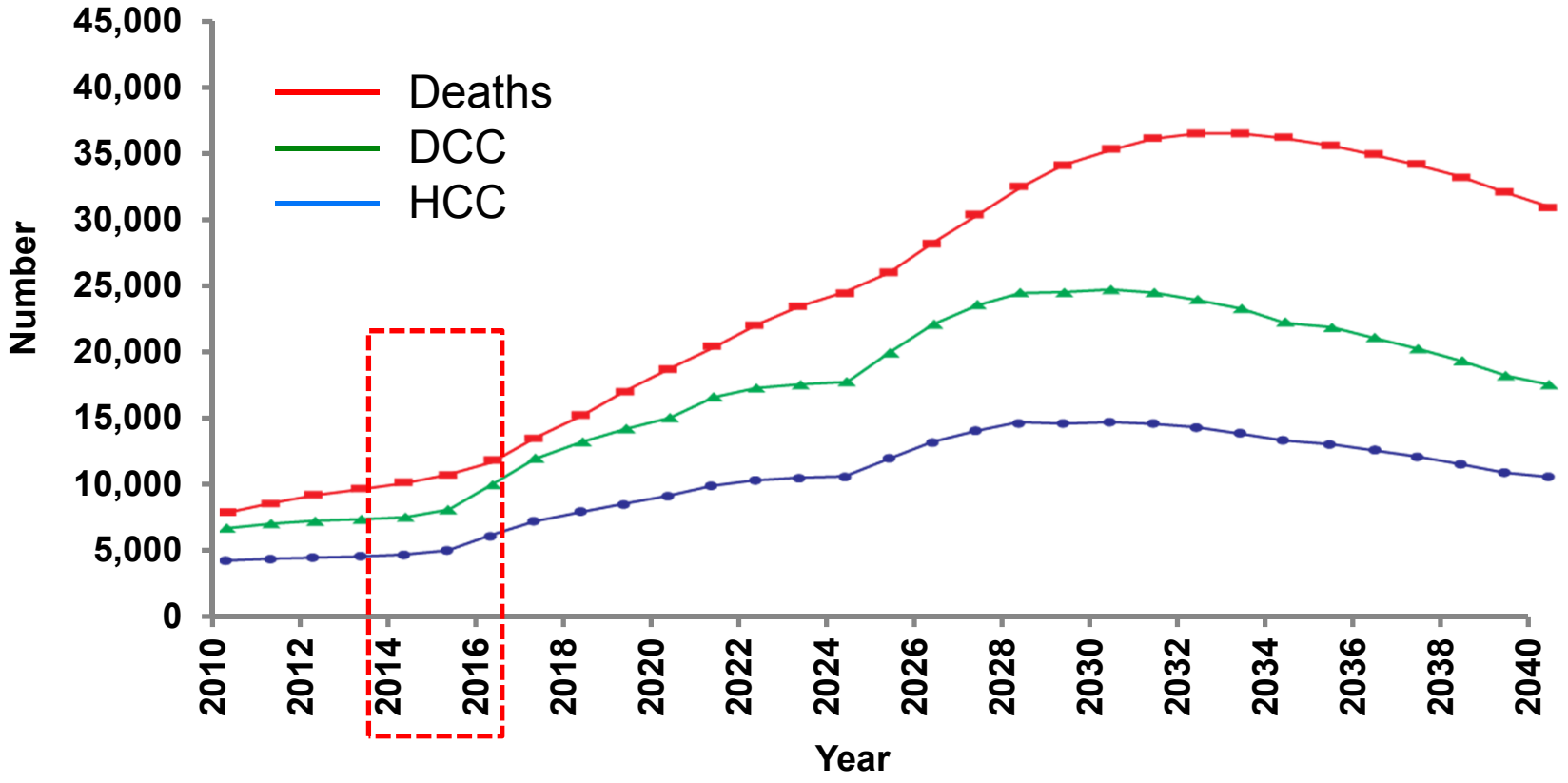
1. High risk for liver related complications
2. High risk for progression
3. High risk for transmission
4. Serious extra-hepatic complication
5. Other

HCV Viral Replication Increases All Cause Mortality



Lee MH, et al. *J Infect Dis.* 2012;206:469-477.

Projected Incidence of HCV Related Liver Cancer and Death Also Expected to Peak in Coming Decades[1]



Between 1995 and 2010, 41% of the 126,862 new primary registrants for liver transplants carried a diagnosis of HCV infection[2]

1. Rein DB, et al. *Dig Liver Dis*. 2011;43:66-72.
2. Biggins SW, et al. *Liver Transpl*. 2012;18:1471-1478.

DCC=decompensated cirrhosis
HCC=hepatocellular carcinoma

Liver Cancer Projected to be the 3rd Leading Cause of Cancer-related Death by 2030

"Projecting Cancer Incidence and Deaths to 2030: The Unexpected Burden of Thyroid, Liver and Pancreas Cancers in the United States."

Cancer Research, published online on May 19, 2014

- Cancer incidence and deaths in the US projected for 2020 and 2030
- Breast, prostate, and lung cancers will remain the top cancer diagnoses
- Lung cancer is projected to remain the top cancer killer
  - Pancreas and liver cancers are projected to surpass breast, prostate, and colorectal cancers to become the second and third leading causes of cancer-related death by 2030

Cancer Res. 1–9. 2014 AACR

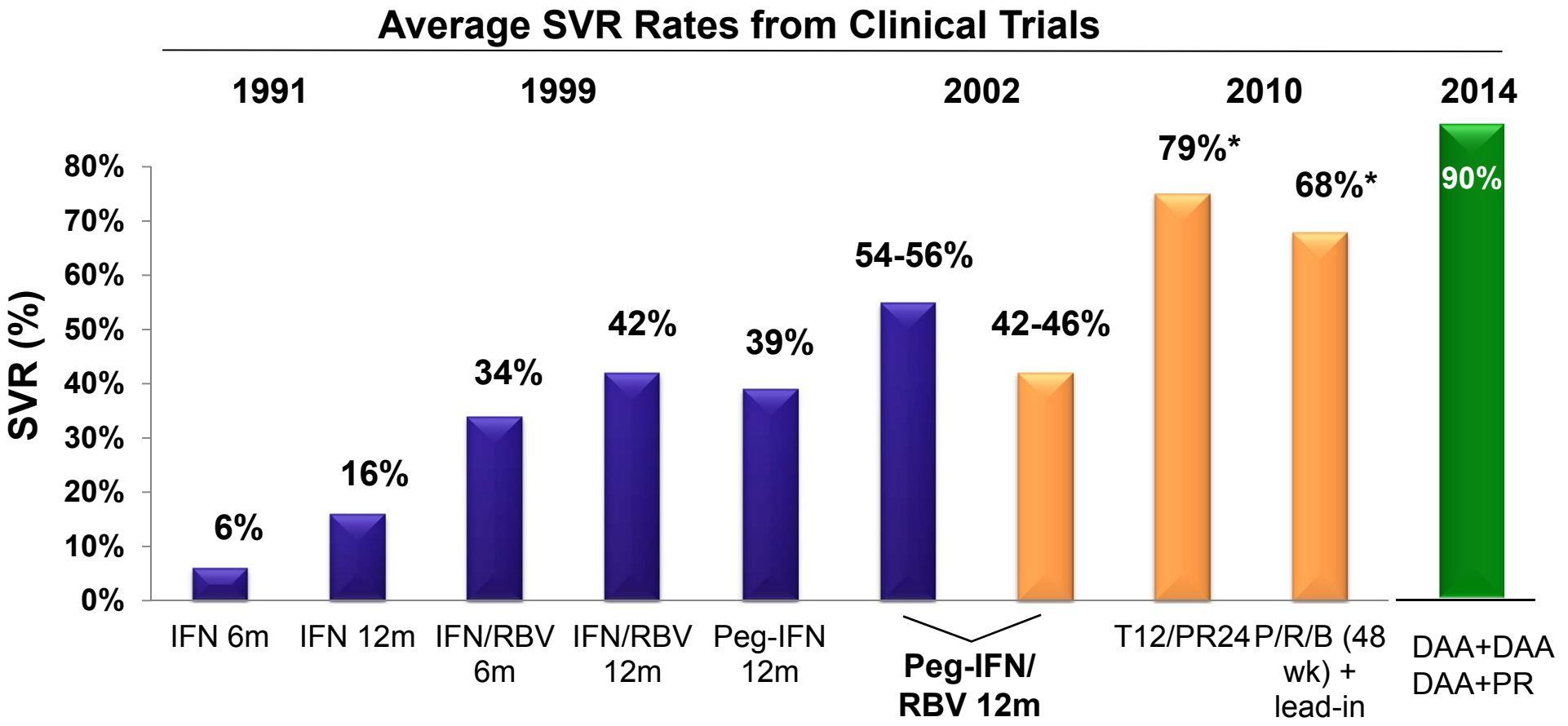
Summary

- Patients with the most immediate need should be prioritized for therapy
- SVR improves Quality of Life and extrahepatic manifestations of HCV
- SVR decreases the risk of HCC and improves liver and all-cause mortality rates

SVR=sustained virologic response
HCC=hepatocellular carcinoma

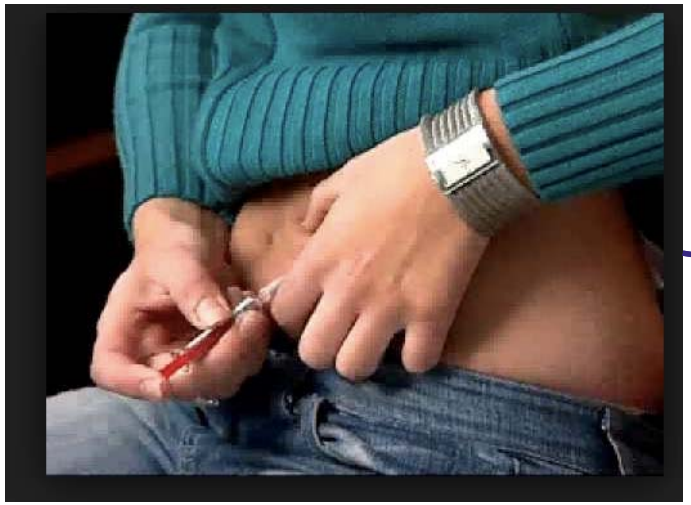
Therapeutic Recommendations for Various HCV Patient Types

Milestones in Therapy of HCV: Overall SVR Rates



Adapted from Strader DB, et al. *Hepatology*. 2004;39:1147-1171. Hezode C, et al. *N Engl J Med*. 2009; 360:1839-1850. Kwo P, et al. Presented at: EASL; April 23, 2009; Copenhagen, Denmark. Abstract 4. Kwo PY, et al. *Lancet.* 2010;376:705-716. Jacobson IM, et al. *N Engl J Med*. 2011;364:2405-2416; Poordad F, et al. *N Engl J Med.* 2011;364:1195-1206. Telaprevir prescribing information. http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/201917lbl.pdf. September 25, 2014.

For Most Patients, Where Are We Now?



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Currently Available Agents

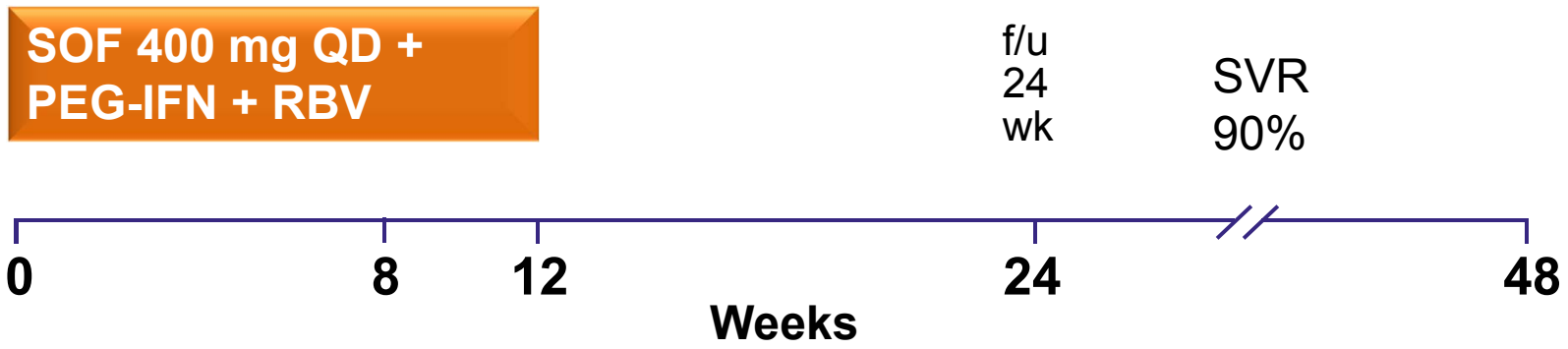
Protease Inhibitor (PI)	Additional Regimen Components	Considerations
Boceprevir (TID) Telaprevir (TID) Simeprevir (QD)	PEGIFN alfa + weight-based RBV	▪ Genotype ▪ Naïve ▪ Previous treatment failure ▪ Compensated cirrhosis ▪ Response guided therapy
Polymerase Inhibitor	**Additional Regimen Components**	**Considerations**
Sofosbuvir (QD)	PEGIFN alfa + weight-based RBV	SOF+RBV for genotype 2/3 SOF+PEG/RBV G1

PEGIFN alfa=peginterferon alfa
RBV=ribavirin

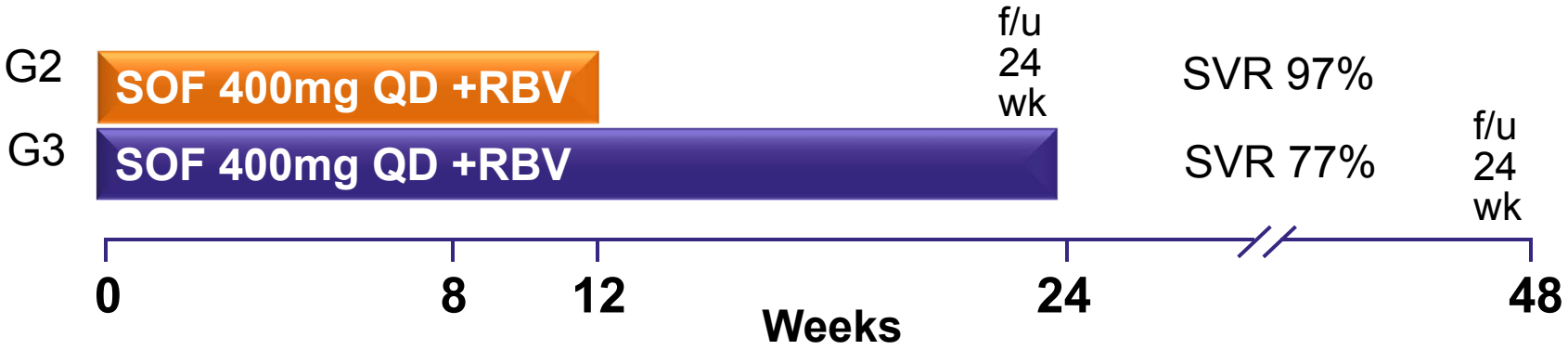
http://www.hcvguidelines.org/full-report-view

First Line Therapy

G1 PATIENTS



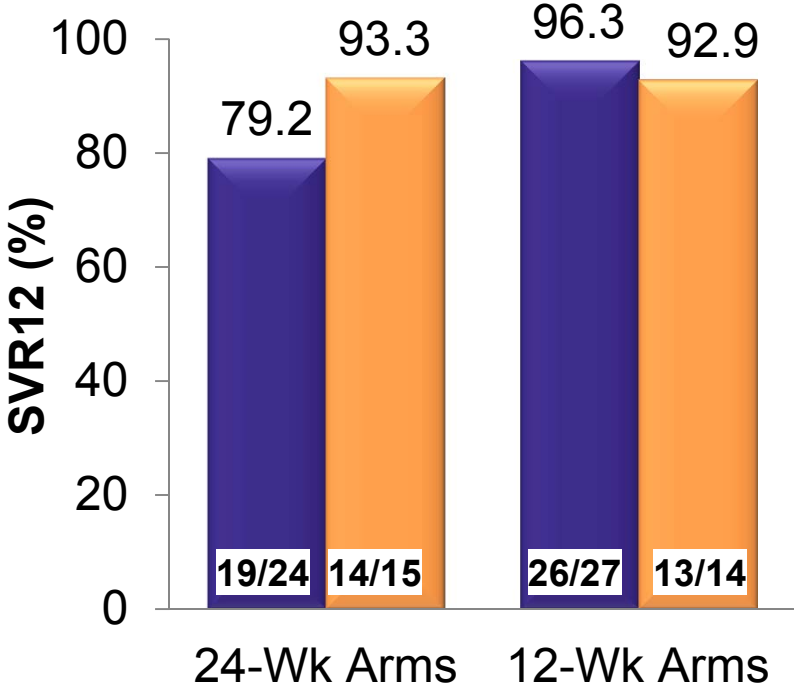
G2/3: ALL ORAL THERAPY



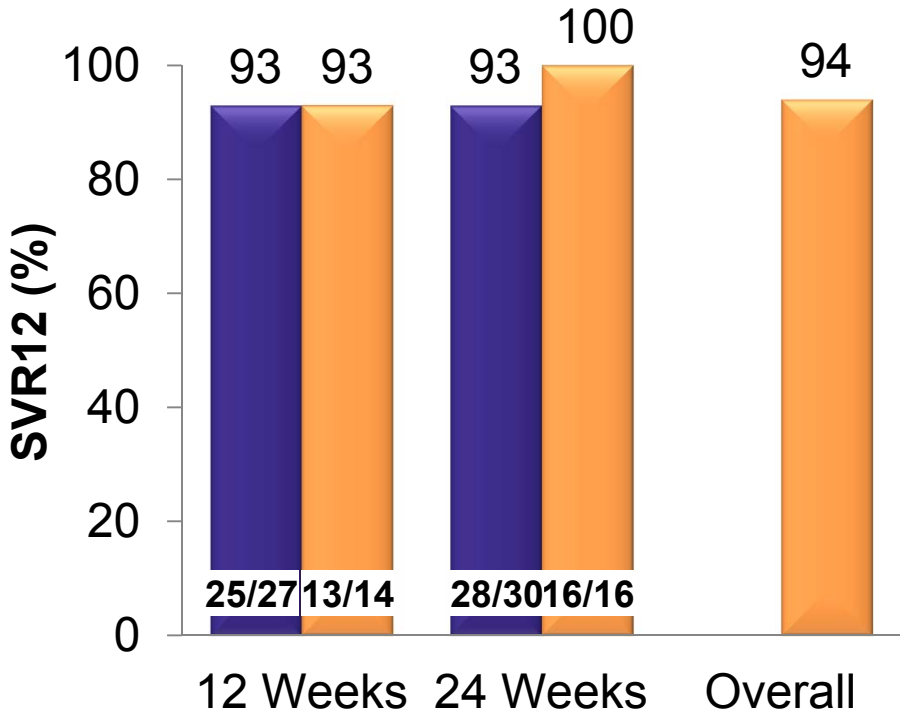
Lawitz EM, et al. *N Engl J Med*. 2013;368:1878-87.
Mishra P. on behalf of the FDA Sofosbuvir Review Team. October 25, 2013

Currently Available BUT Off-Label: COSMOS Sofosbuvir (NUC) and Simeprevir (PI)

Cohort 1 (F0-F2 Nulls): SVR12
(N = 80, all arms)



Cohort 2 (F3-F4 Naives/Nulls): SVR 12



SMV + SOF + RBV SMV + SOF

Sulkowski, et al. *Lancet.* 2014

Initial HCV Treatment Recommendations

Genotype	Recommended	Alternative	NOT Recommended
1	**IFN eligible:** SOF + PEG/RBV x 12 weeks **IFN ineligible**: SOF + SMV ± RBV x 12 weeks	**IFN eligible:** SMV x 12 weeks + PEG/RBV x 24 weeks **IFN ineligible**: SOF + RBV x 24 weeks	TVR + PEG/RBV x 24 or 48 weeks (RGT) BOC + PEG/RBV x 28 or 48 weeks (RGT) PEG/RBV x 48 weeks Monotherapy with PEG, RBV, or a DAA. Do not treat decompensated cirrhosis with PEG or SMV
2	SOF + RBV x 12 weeks	None	PEG/RBV x 24 weeks Monotherapy with PEG, RBV, or a DAA Any regiment with TVR, BOC, or SMV
3	SOF + RBV x 24 weeks	SOF + PEG/RBV x 12 weeks	PEG/RBV x 24-48 weeks Monotherapy with PEG, RBV, or a DAA Any regimen with TVR, BOC, or SMV
4	**IFN eligible:** SOF + PEG/RBV x 12 weeks **IFN ineligible**: SOF + RBV x 24 weeks	SMV x 12 weeks + PEG/RBV x 24-48 weeks	PEG/RBV x 48 weeks Monotherapy with PEG, RBV, or a DAA Any regimen with TVR or BOC
5 or 6	SOF + PEG/RBV x 12 weeks	PEG/RBV x 48 weeks	Monotherapy with PEG, RBV, or a DAA Any regimen with TVR or BOC

AASLD/IDSA. http://hcvguidelines.org/full-report/initial-treatment-box-summary-recommendations-patients-who-are-initiating-therapy-hcv. September 19, 2014.

HCV Treatment Recommendations for Patients in Whom Previous Treatment Has Failed

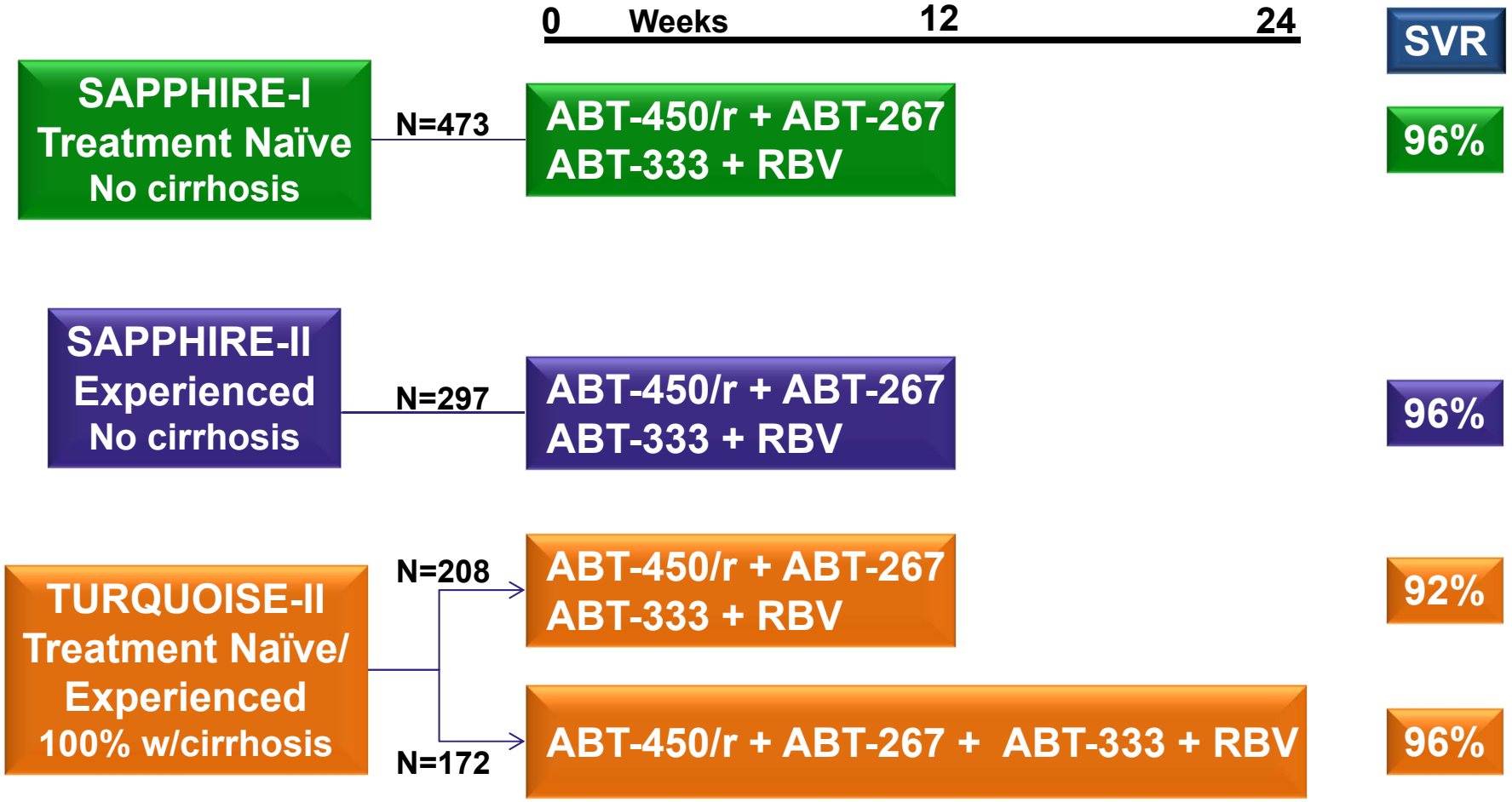
Genotype	Recommended	Alternative	NOT Recommended
Patients in whom previous PEG/RBV has failed			
1	SOF + SMV ± RBV x 12 weeks	SOF x 12 weeks + PEG/RBV x **12-24** weeks **SOF + RBV x 24 weeks** SMV x 12 weeks + PEG/RBV x **48 weeks**	PEG/RBV ± telaprevir or boceprevir Monotherapy with PEG, RBV, or a DAA Do not treat decompensated cirrhosis with PEG or SMV
2	SOF + RBV x 12 weeks	SOF + PEG/RBV x 12 weeks	PEG/RBV ± telaprevir or boceprevir Monotherapy with PEG, RBV, or a direct-acting antiviral agent Do not treat decompensated cirrhosis with PEG
3	SOF + RBV x 24 weeks	SOF + PEG/RBV x 12 weeks	PEG/RBV ± any current protease inhibitor Monotherapy with PEG, RBV, or a DAA Do not treat decompensated cirrhosis with PEG
4	SOF + PEG/RBV x 12 weeks	**SOF + RBV x 24 weeks**	PEG/RBV ± any current HCV protease inhibitor Monotherapy with PEG, RBV, or a DAA Do not treat decompensated cirrhosis with PEG
5 or 6	SOF x 12 weeks + PEG/RBV 12 weeks		PEG/RBV ± any current HCV protease inhibitor Monotherapy with PEG, RBV, or a DAA Do not treat decompensated cirrhosis with PEG
Patients in whom previous treatment with PEG/RBV plus either telaprevir or boceprevir has failed			
1	SOF x 12 weeks + PEG/RBV x 12-24 weeks	**SOF + RBV x 24 weeks** **SOF + PEG/RBV x 24 weeks**	PEG/RBV ± telaprevir or boceprevir or SMV Monotherapy with PEG, RBV, or a DAA Do not treat decompensated cirrhosis with PEG or SMV

AASLD/IDSA. http://hcvguidelines.org/full-report/retreatment-box-summary-recommendations-patients-whom-previous-treatment-has-failed. September 19, 2014.

Expectations: Current Phase 2/3 Clinical Trials

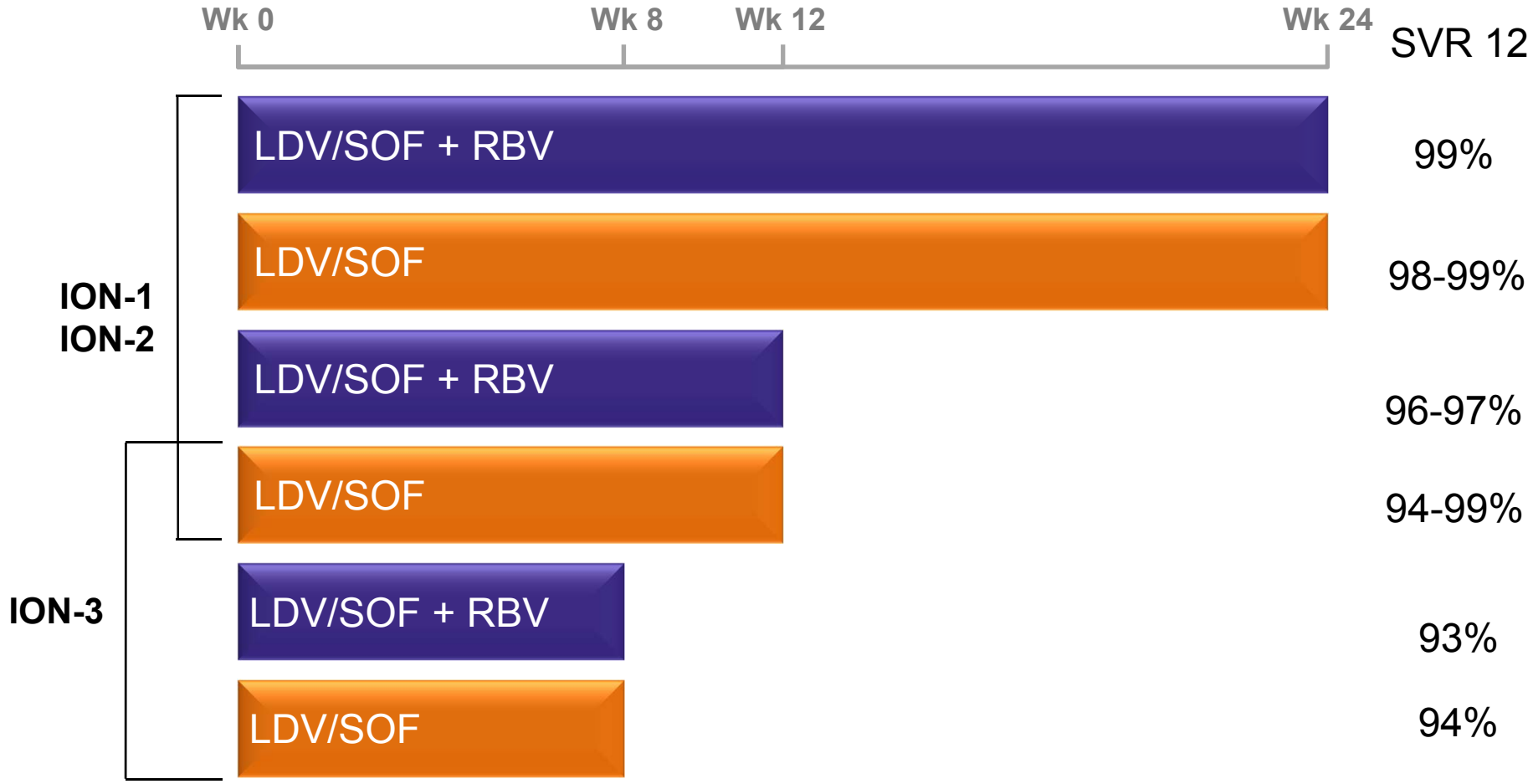
1. All oral therapy is efficacious
2. Baseline characteristics are losing impact
3. Special populations are no longer special

ABT-450/r (PI) + ABT-267 (NS5A) + ABT-333 (NNI) + RBV: SAPPHIRE and TURQUOISE



Feld et al. *NEJM* 2014; Zeuzem et al. *NEJM* 2014; Poordad et al *NEJM* 2014

Sofosbuvir (NUC) + Ledipasvir (NS5A) +/- RBV in G1 97% (1886/1952) Overall SVR



LDV/SOF Phase 3 Program (ION-1, ION-2, ION-3)

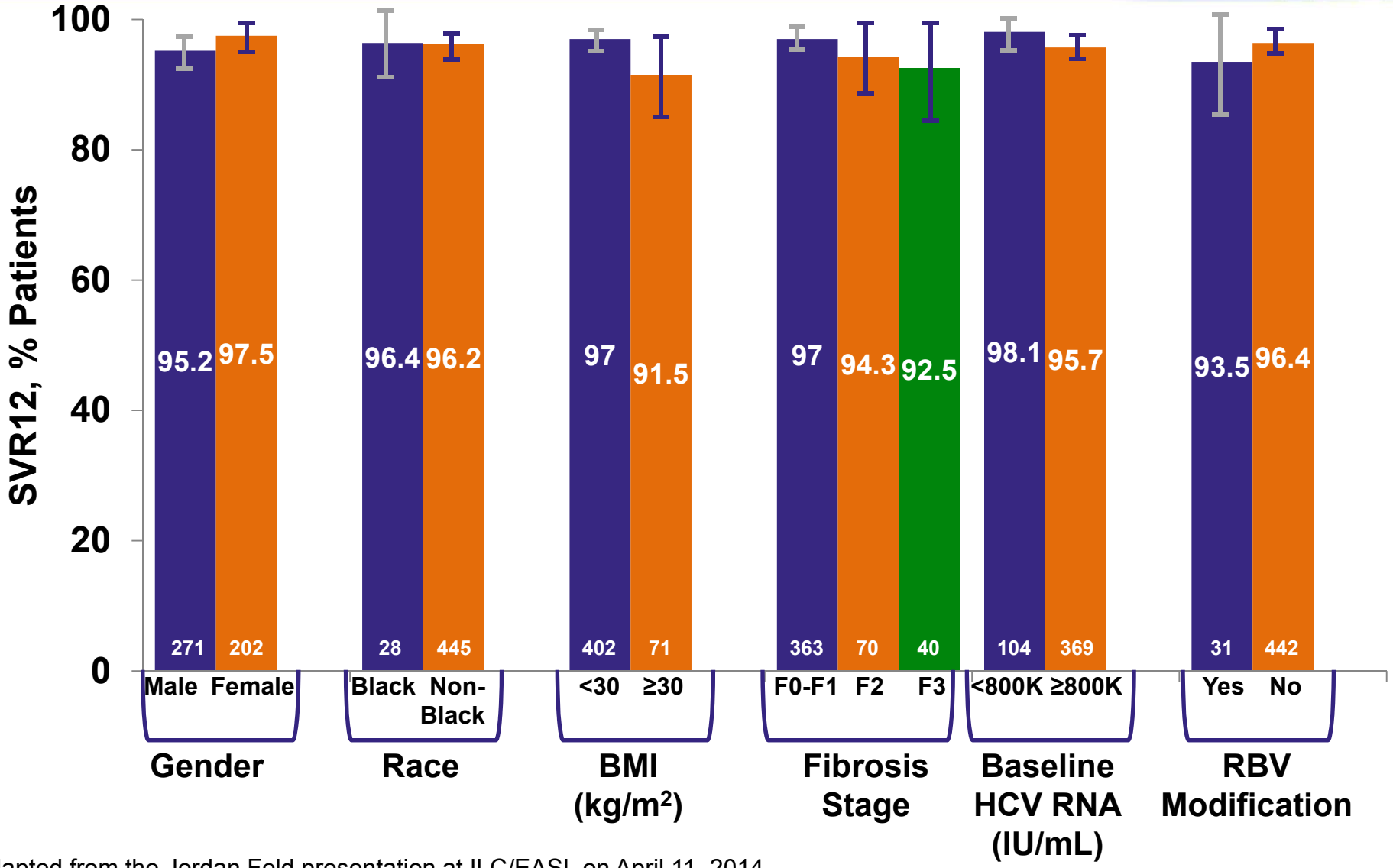
- ION-1 treatment naïve: N = 865
- ION-2 treatment experienced: N = 440
- ION-3 treatment naïve: N = 64

Afdhal et al *NEJM* 2014, Kowdley et al *NEJM* 2014

Expectations: Current Phase 2/3 Clinical Trials

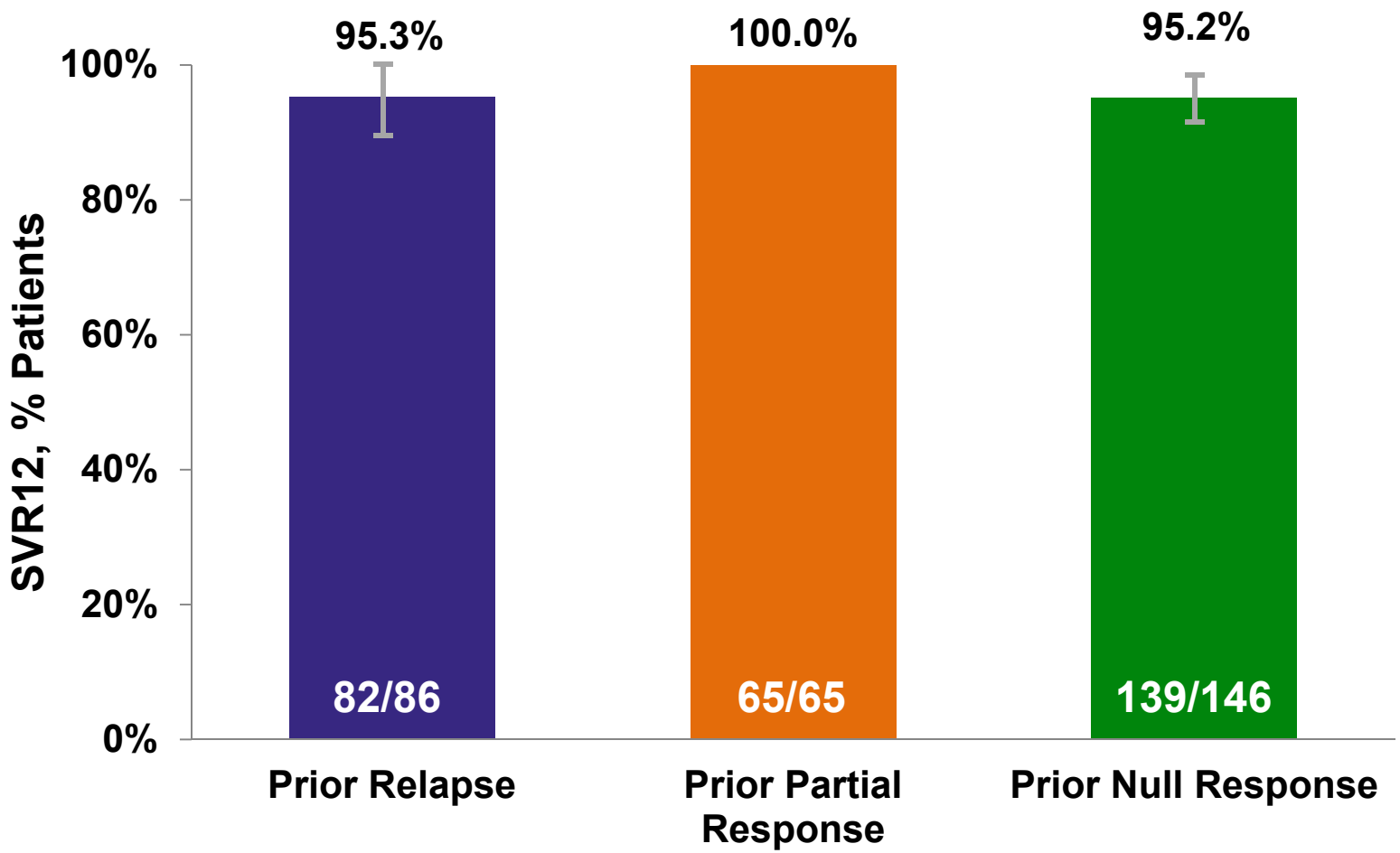
1. All oral therapy is efficacious
2. Baseline characteristics are losing impact
3. Special populations are no longer special

SAPPHIRE-I:
ITT SVR12 Rates in Subpopulations



Adapted from the Jordan Feld presentation at ILC/EASL on April 11, 2014

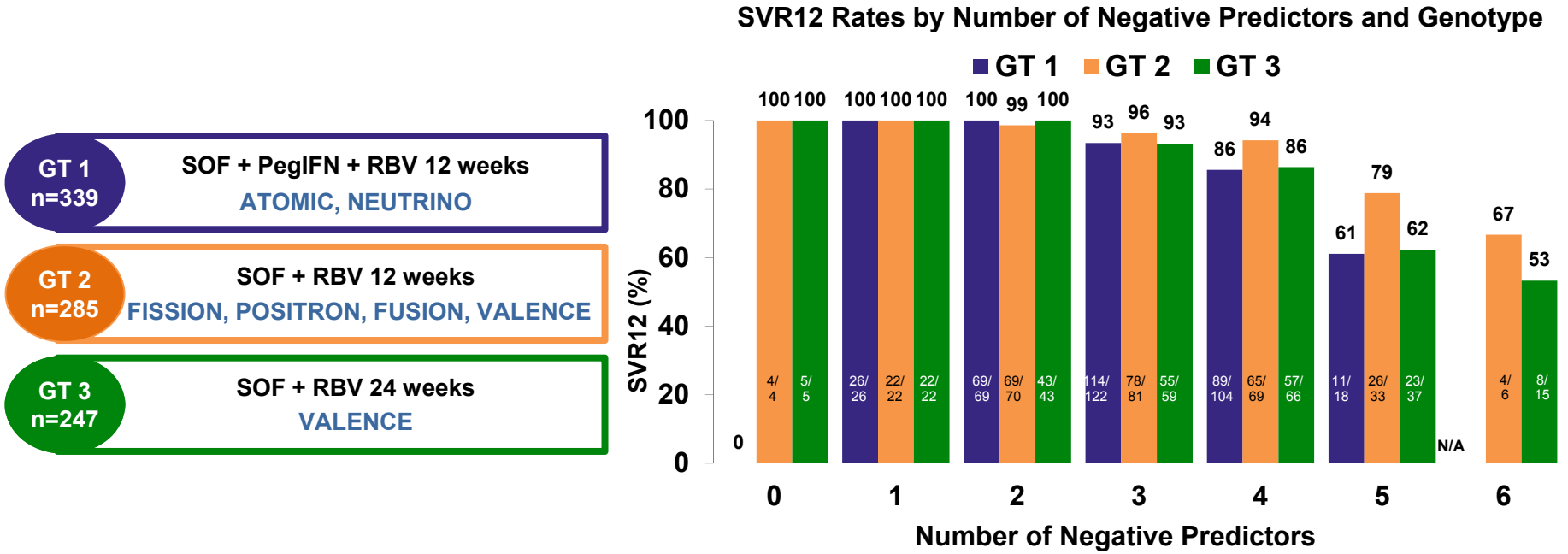
SAPPHIRE-II Results: ITT SVR12 Rates >95% in All Prior Peginterferon/Ribavirin Response Groups



Adapted from the Stefan Zeuzem presentation at ILC/EASL on April 10, 2014

SVR Rates of SOF-Based Regimens Across Genotypes and Among Patients with Multiple Negative Predictive Factors

- Retrospective multivariate analysis of Phase 2 and 3 SOF data identified 6 negative predictors associated with relapse:
  - Prior treatment failure, cirrhosis, IL28B non-CC, HCV RNA ≥ 800,000 IU/mL, body weight ≥ 75kg, male gender
  - 89% of patients in the Phase 3 program had up to 4 negative predictors



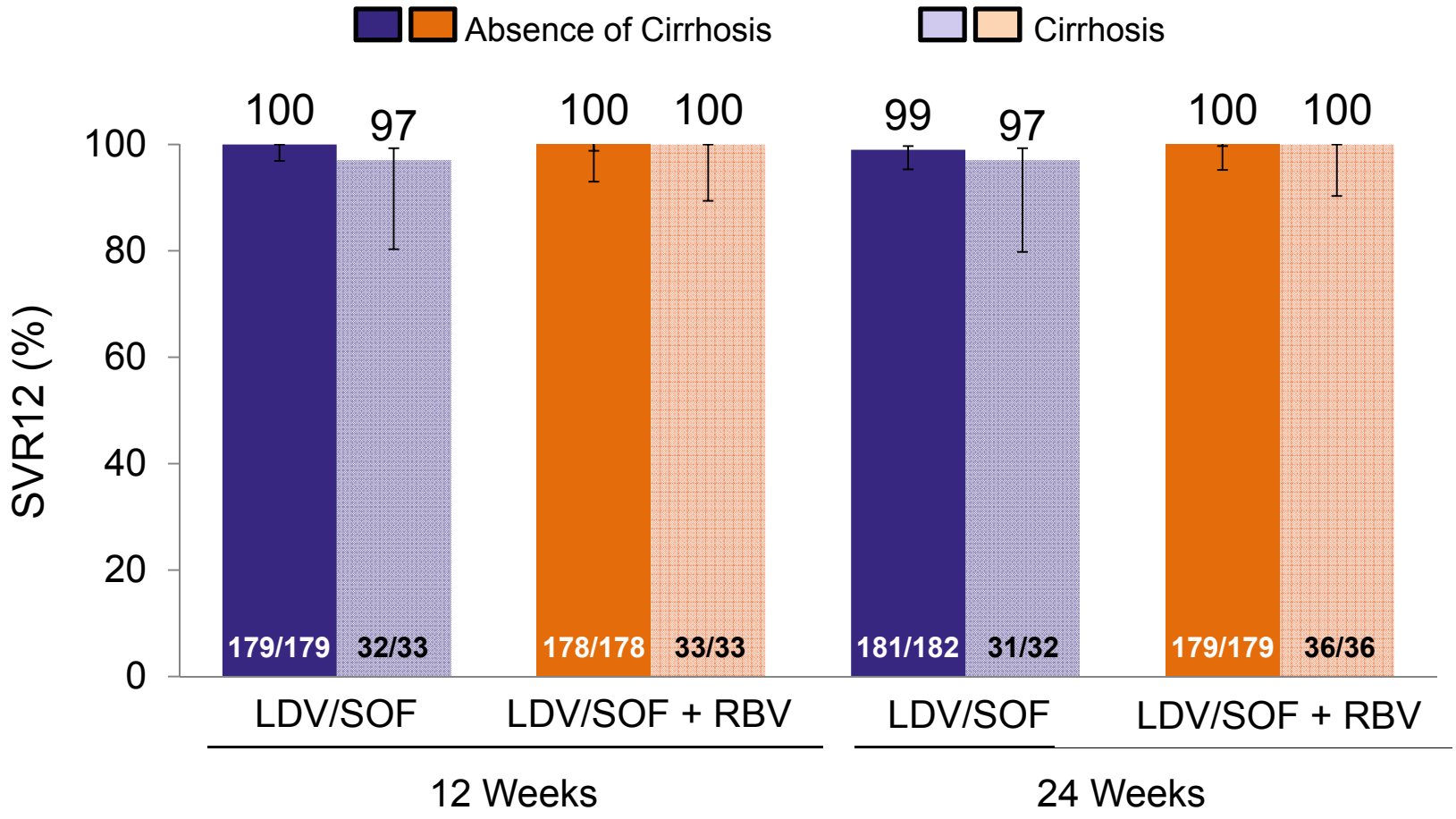
Foster G, EASL, 2014, O66

Expectations: Current Phase 2/3 Clinical Trials

1. All oral therapy is safe and efficacious
2. Baseline characteristics are losing impact
3. Special populations are no longer special

SVR12 by Presence of Cirrhosis

ION-1 (LDV/SOF ± RBV x 12 or 24 weeks)

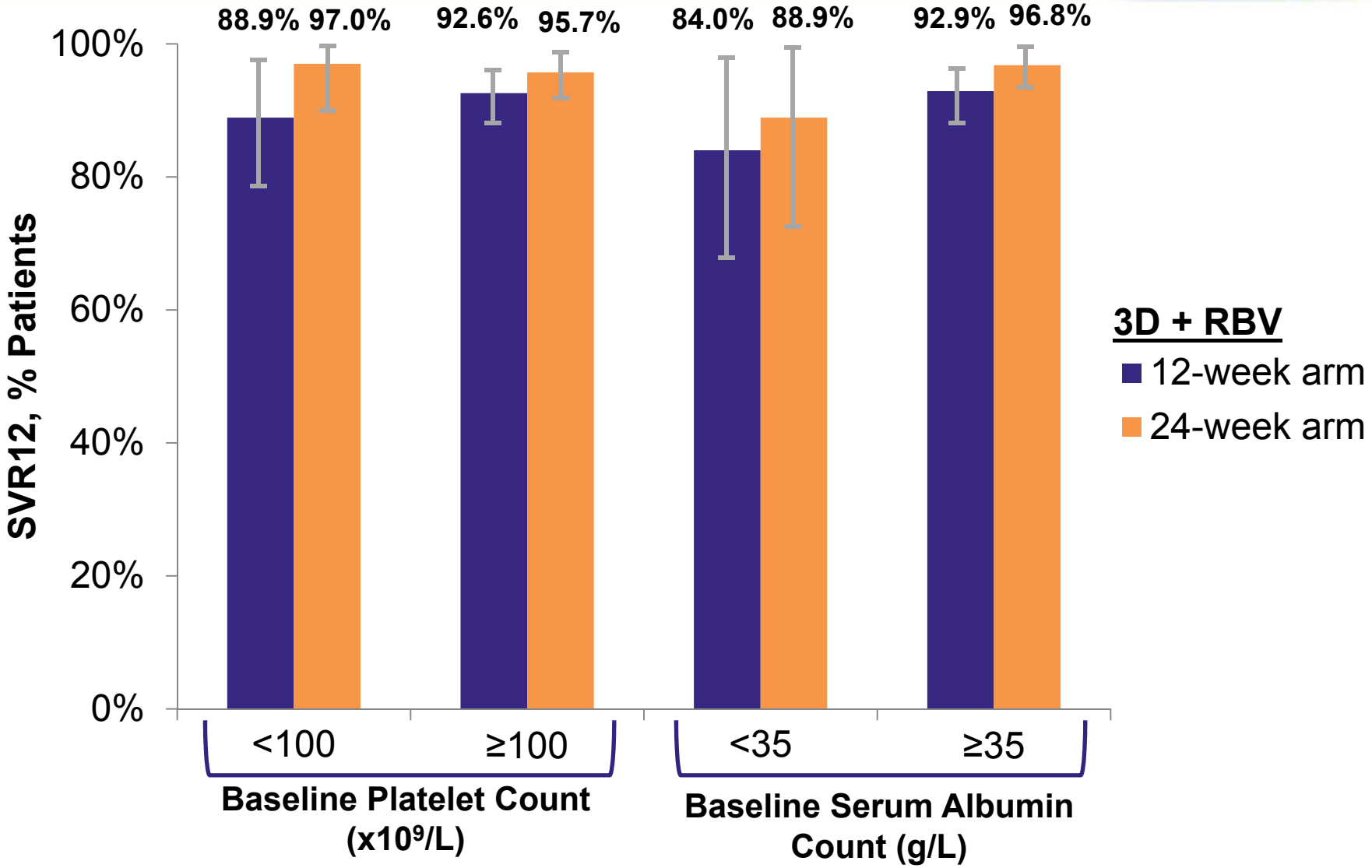


Error bars represent 95% confidence intervals

Mangia A, EASL, 2014, O164

Afdhal N, et al. *N Engl J Med* 2014; 2014 Apr 12 [Epub ahead of print]

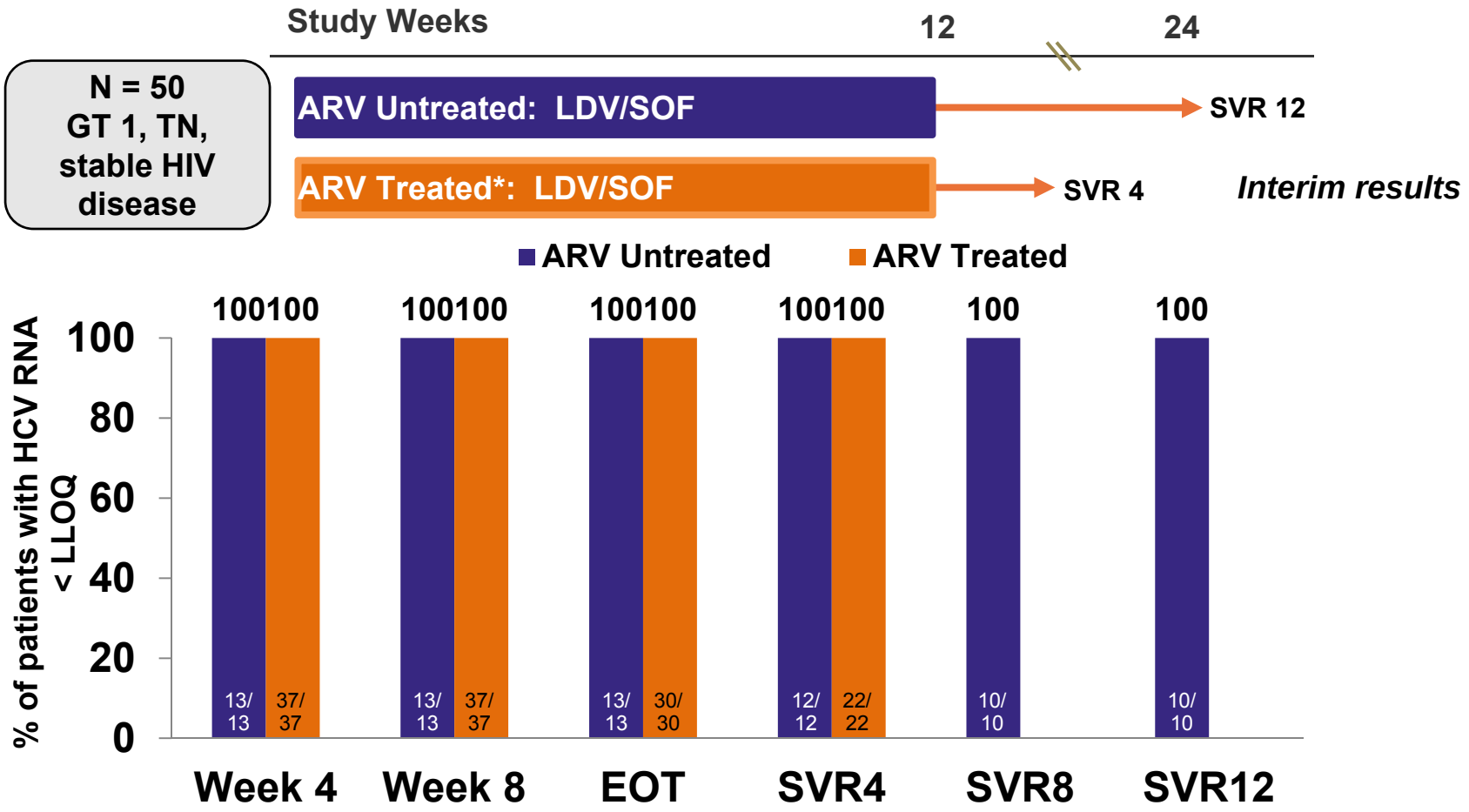
TURQUOISE-II Results: ITT SVR12 Rates by Surrogates of Portal Hypertension and Hepatic Function



Adapted from the Fred Poordad presentation at ILC/EASL on April 12, 2014

LDV/SOF STR for Treatment of HCV GT 1 Co-infected with HIV (Interim Analysis)

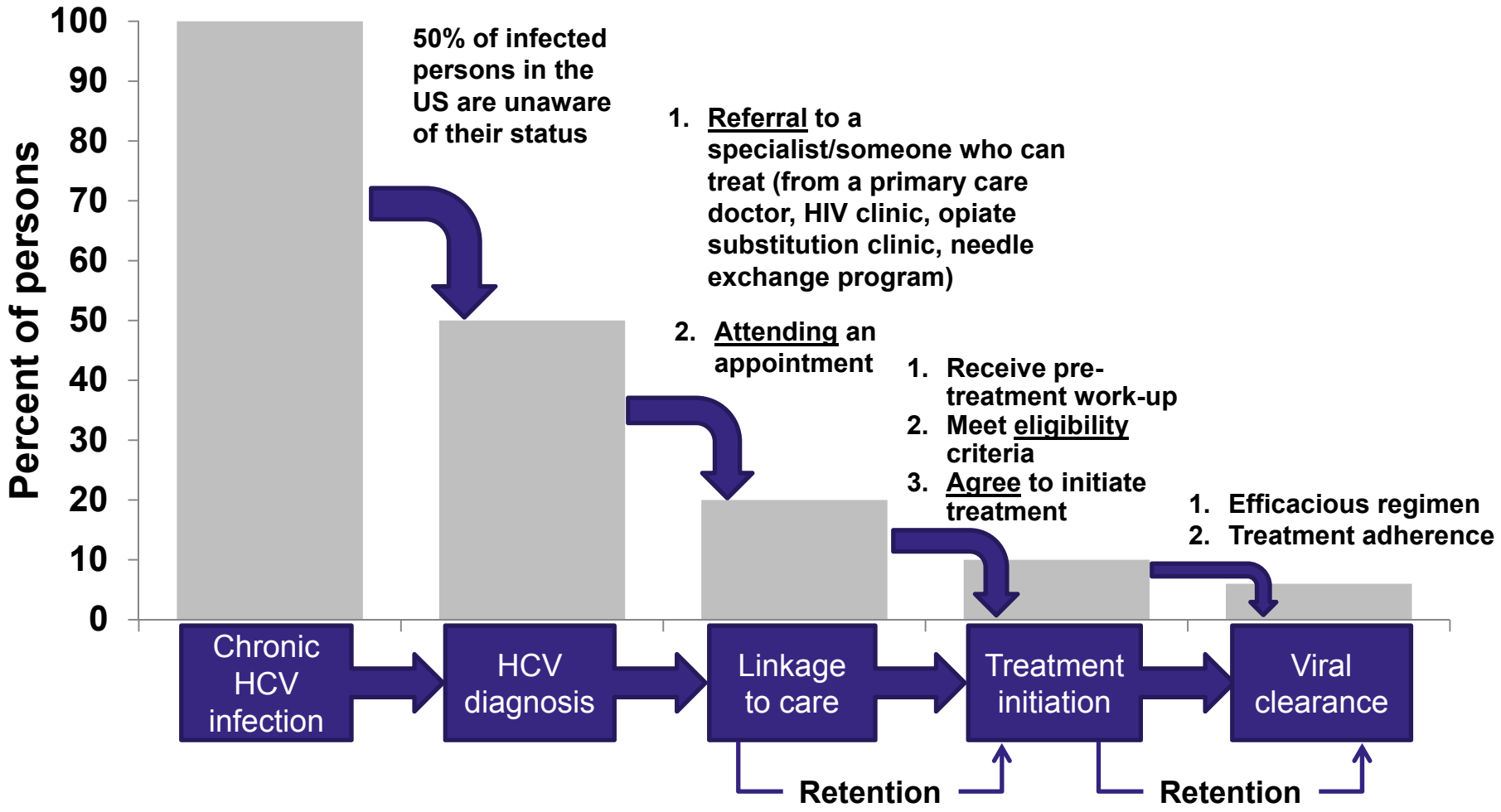
ERADICATE Study (NIAID, LDV/SOF)



- LDV/SOF STR was well tolerated with no discontinuations

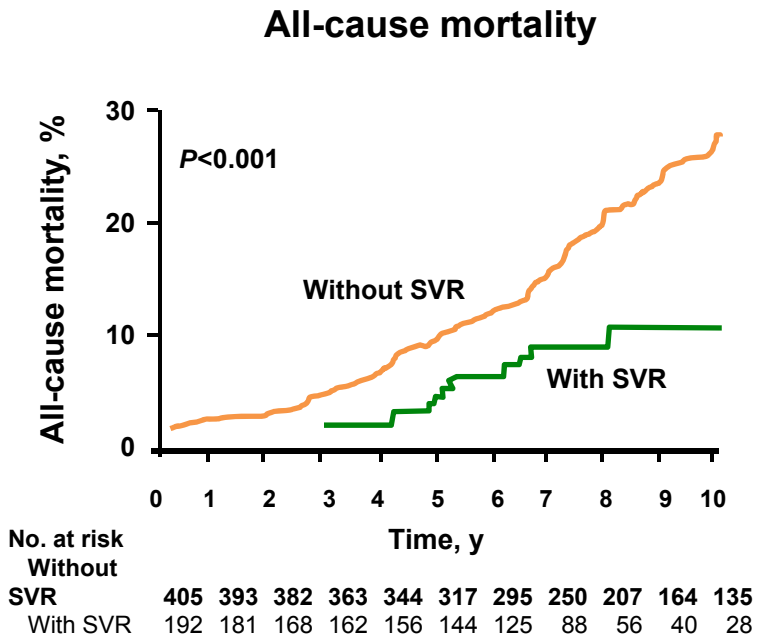
Osinusi A, EASL, 2014, O14

HCV Care Cascade



Afdhal NH, et al. *J Viral Hepat* 2013; 20:745-760.

SVR Improves Short and Long Term Outcomes



- Improves histology
- Decreases risk of cirrhosis, liver cancer, and transplantation
- Improves quality of life
- Improves insulin resistance
- Decreases all cause mortality

Chan CH, et al. *Intern Med J.* 2013;43(6):656-662.;
Daltro-Oliveira R, et al. *Ann Hepatol.* 2013;12(3):399-407.;
van der Meer AJ, et al. *JAMA.* 2012 Dec 26;308(24):2584-2593.Morgan TR, et al. *Hepatology.* 2010;52(3):833-44.

Access?

SundayReview | EDITORIAL

How Much Should Hepatitis C Treatment Cost?

By THE EDITORIAL BOARD MARCH 15, 2014

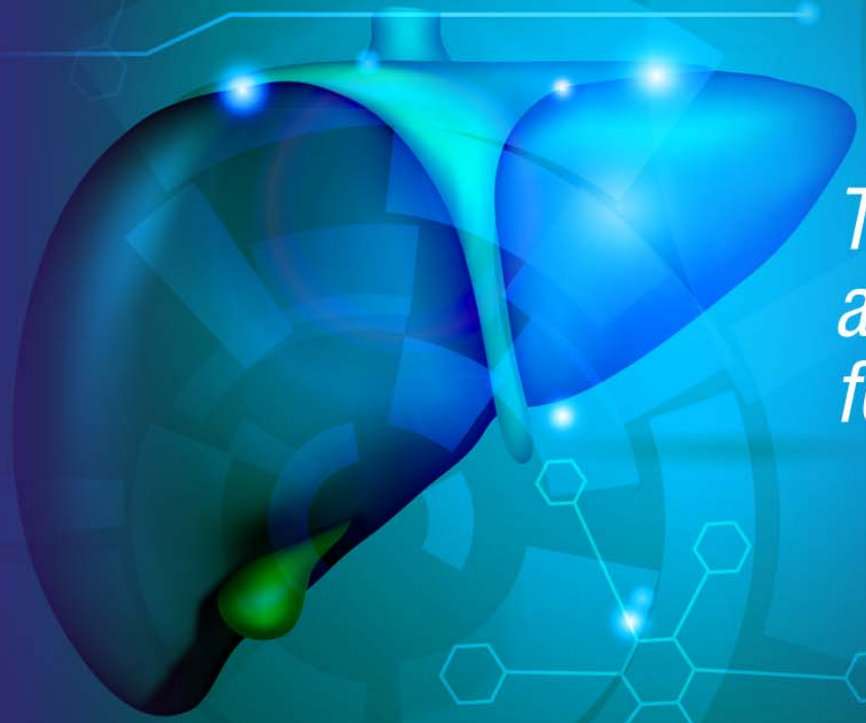
EMAIL

A new pill to treat hepatitis C raises difficult questions about fair

Summary

- HCV is responsible for significant morbidity and mortality in the US
- Effective screening and early eradication are instrumental to decreasing disease burden
- Nearly all patients will achieve a cure with well tolerated all-oral therapy
- Multiple factors continue to make access to providers and therapy an issue

CAPITALIZING ON HCV ADVANCEMENTS:



Treatment Management and Benefit Design Strategies for Managed Care

HCV

Jointly provided by PIM Postgraduate Institute for Medicine and Impact Education, LLC

This activity is supported by an educational grant from Gilead Sciences, Inc.

Held in conjunction with AMCP Academy of Managed Care Pharmacy®

AMCP Nexus 2014: Connecting Health Care and Innovation

Pharmacy Benefit Design Innovations for a New Era of HCV Management

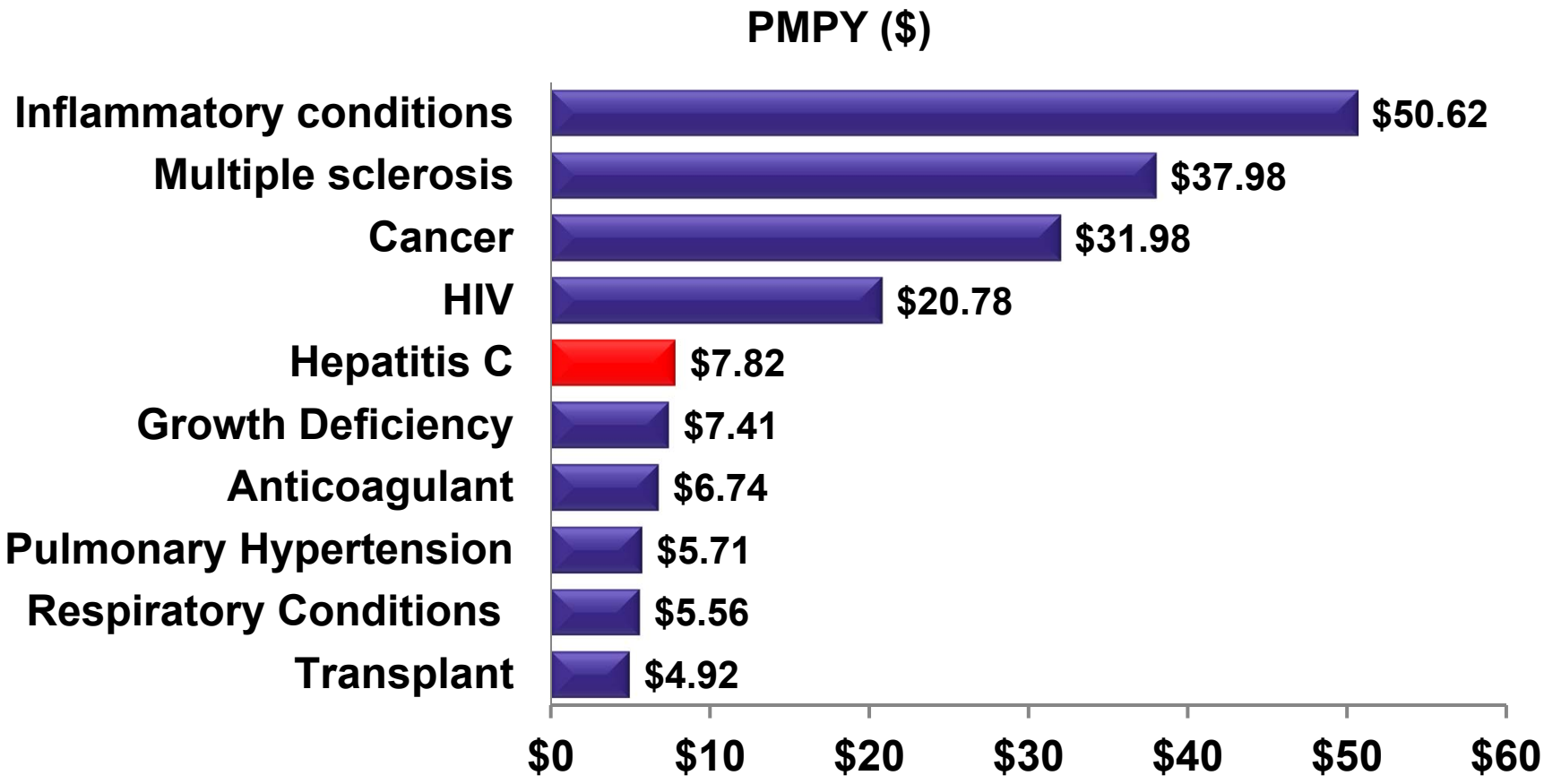
Jeffrey D. Dunn, PharmD, MBA

Senior Vice President

VRx

Salt Lake City, UT

HCV Is a Top 10 Specialty Category Under Pharmacy Benefit



PMPY=per member per year.

Express Scripts. Drug Trend Report. 2013.
http://www.drugtrendreport.com/commercial/specialty-trend-by-therapy-class.

HCV Drug Utilization is the Highest of All Specialty Categories in the Pharmacy Benefit

Rank	Therapy Class	PMPY Spend	Trend		
			Utilization	Unit Cost	Total
1	Inflammatory Conditions	$50.62	9.0%	14.0%	23.0%
2	Multiple Sclerosis	$37.98	0.5%	17.3%	17.8%
3	Cancer	$31.98	3.4%	22.3%	25.8%
4	HIV	$20.78	-2.1%	11.1%	9.0%
5	Hepatitis C	$7.82	28.9%	4.8%	33.7%
6	Growth Deficiency	$7.41	1.7%	7.7%	9.5%
7	Anticoagulant	$6.74	1.7%	0.3%	2.1%
8	Pulmonary Hypertension	$5.71	5.1%	6.2%	11.3%
9	Respiratory Conditions	$5.56	1.5%	25.7%	27.2%
10	Transplant	$4.92	2.2%	-6.9%	-4.7%
	Other	$27.68	-24.9%	43.7%	18.8%
TOTAL SPECIALTY		$207.19	-0.4%	18.7%	18.4%

PMPY=per member per year.

Express Scripts. Drug Trend Report. 2013.
http://www.drugtrendreport.com/commercial/specialty-trend-by-therapy-class.

HCV Drug and Disease Cost Issues

Drug costs	• Drug acquisition
	  • Emerging agents
	  • Emergence of more high cost oral therapies

Clinical burden	• Appropriate diagnosis, adherence, and routine monitoring is difficult • Patient education/health management programs • Management of safety monitoring
Total costs need to be evaluated	• Direct and indirect

Finding a Balance Between Shifting Costs and Patient Nonadherence Can be a Challenge

Member decision factors

- **Cost share**
- **Compliance**
- **Efficacy/tolerability**

Benefit design factors

- **Medical vs pharmacy**
- **Copay vs coinsurance**
- **Specialty tiers**

Pharmacy Benefit Design: Basic Elements

Manage costs by restricting utilization of resources

Medical and pharmacy designs usually independent

Cost sharing used to influence utilization patterns

Patient cost-share related to acquisition cost of service or product

Assumes inelastic demand or willingness to pay

Willey VJ, et al. *Am J Manag Care*. 2008;14:S252-S263.

HCV Benefit Design: Common Components

Cost management				Utilization management			
Drug discounts	Channel management	Rebates	Benefit design options	Medical necessity review	Clinical management via treatment algorithms/ patient eligibility/ duration of therapy	Prior authorization	Formulary management (tiers, utilization caps)

Stern D, et al. *J Manag Care Pharm*. 2008;14(suppl S):S12-S16.

HCV Pharmacy Management Strategies

Incentive programs

Member	Physician: differential reimbursement, P4P

↓

Specialty pharmacy integration

↓

Coordination/collaboration

Data management/widespread use of IT

↓

Case management

Needs to be more active and educated

↓

Patient support programs

Mandatory?	Use of those provided by manufacturers?

P4P=pay for performance; IT=information technology.

Approaches to HCV Pharmacy Benefit Design

Benefit Design

Tiers
- **Evaluating out-of-pocket expenses and distribution**

Biosimilars
- **The first follow-on biologics or biosimilars are in late stage development**

Application of guidelines/algorithms/disease management

Need information concerning retreatment

What to do for patients intolerant to or having contraindications to peginterferon or ribavirin?

Impact of Patient Behavior on Success of the HCV Pharmacy Benefit Design

Disease and Treatment Variables	Healthcare Delivery Variables
• Complex therapy	• Patient awareness/education
• Treatment tolerability and efficacy issues	• Strengthening patient-provider relationships
• Asymptomatic disease	• Patient empowerment
	• Integrated communication channels
	• Medication therapy management
	• Telephonic counseling
	• Medication reminders

Formulary Management

More Formulary Control

Need for data: CER?	**Prior authorizations: levels of evidence**	**Quantity limits**	**Start/stop rules**

Contracts

Work with drug manufacturers; outcomes-based	**Net effective pricing**

CER: comparative effectiveness research

Health Care Reform Is Encouraging a Move Towards Delivering Value, Not Volume

Payment/delivery paradigm emphasis is on rewarding value instead of volume

Value-based purchasing, shared savings, gain-sharing, bundled payments, capitation, etc

Incentives such as the CMS 5-Star Rating System are being implemented to coordinate care among/across providers

Beginning in January 2012, plans with ≥ 4 stars receive bonuses along with higher rebates and plans with ≤ 3 stars will be flagged as "low-quality" on the Medicare website

New structures are promoting actual and virtual integration

Accountable care organizations (ACOs), medical homes, home-based chronic care management, community health teams, health care innovation zones

New Models Based on Consistent Themes Are Being Implemented

Models and Tactics Used by Accountable Care Organizations (ACO)

ACOs provide an organizational structure that supports health promotion, patient-centered care and clinical integration

- **Patient-centered medical homes (Advanced Primary Care)**

Payment mechanisms focused on "fee for value" rather than "fee for volume"

- **Quality incentives for improved processes and outcomes**
- **Likely to take it in steps:**
  - **Fee for service: per case/"at risk" quality payments – bundled – capitation**

Payer Environment Must Continually Adapt as New HCV Therapies Emerge

Present

- **Perverse incentives – volume over value**
- **Unsustainable health care cost trajectory**
- **Medicare and Medicaid will cut payment rates**
- **Will reach a point where we can no longer cost-shift to commercial payers to make up for declining government payment levels**
- **Efficiency gains will not be enough for success**

Future

- **Consequences of care outcomes shared between payers and providers**
- **Primary care is pivotal in managing health and utilization**
- **Proactively managing the health of individuals is rewarded**
- **Proactively managing the health of our communities is rewarded**
- **If we can perform better than others, we have more to gain financially in a capitation environment**

Specialty Care Management

Program

- **Specialty Pharmacy MTM**
  - **Integration with Care Management**
  - **Coordinate site of care**
  - **Ensure appropriate dosing**
  - **Adherence**
  - **Education on use**
  - **Expectation management**

Actions

- **Design program workflow and integration with Care Management**
- **Analyze drug utilization patterns to select targeted drugs/disease states**
- **Train personnel:**
  - **Specialty diseases**
  - **Medications**
  - **Site of care logistics**

MTM=medication therapy management.

Summary

Managed care will be required to develop novel solutions to meet the anticipated growth of the symptomatic HCV population

Providers, patients, and payers are challenged to identify the most effective allocation of agents (especially for specialty)

Limited resources challenge patients, providers, and payers

HCV pharmacy is a current and future concern for plan sponsors and patients

Current plan designs based on older premises often do not apply to the needs of HCV pharmacy

Newer approaches will be considered

Primary stakeholders include patients, physicians, managed care organizations, industry, and payers

HCV Specialty Pharmacy Services and Disease Management Strategies for Managed Care Pharmacy

Emergence of Direct-Acting Antiviral Agents (DAAs) Is Driving Efforts to Carefully Manage HCV Drug Therapy

Price and value of HCV therapies rarely questioned

Vigorous debate about the overall value* of treatments

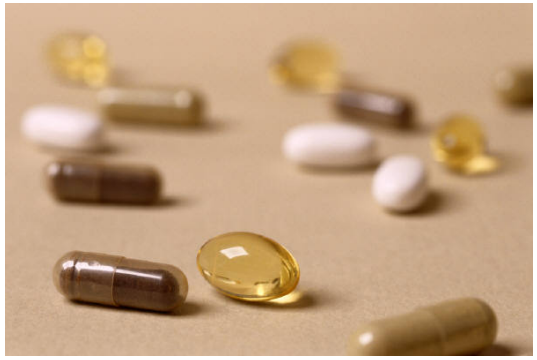
Pre-DAA era → **DAA era**

Payers now actively apply payment reforms and quality measurement to HCV services

*clinical, pharmacoeconomic, humanistic, societal, etc.

Payers Want to Ensure Appropriate Utilization

Right Drug



Is this the correct dose?

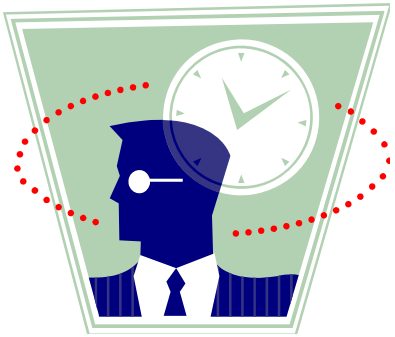
Is this the right time in the regimen?

Does the patient have enough meds? Too many?

Is there another medication that may be more appropriate?

Or may be less expensive yet equally effective?

Right Time



Right Patient

Should therapy be discontinued?

Have labs been performed at the right time to measure results?

Evolving Payer Interventions to Manage HCV Treatment

- HCV has emerged as one of the most important categories to manage
- Payers are using multiple interventions to manage access and use of HCV drugs including
  - Prior authorization with criteria aligned closely with FDA-approved product labels and clinical guidelines
  - Close monitoring of patient response
  - Patient cost-sharing
- Growing cost pressures will influence plans to modify current approaches to managing HCV agents
- Many plans now manage patient access to preferred regimens through the use cost sharing and step edits

Specialty Pharmacy Journal. June 2014. http://www.healthstrategies.com/blog/impact-patients-and-specialty-pharmacies-evolving-payer-interventions-manage-hepatitis-c-agents.

Partnership Between Specialty Pharmacy and Health Plans Can Improve Outcomes

- Health plans partner with specialty pharmacies to help improve patient outcomes while lowering overall costs
- As many as three-quarters of plans now mandate specialty pharmacy use to access HCV products
  - Specialty pharmacists are uniquely positioned close to HCV patients providing plans an ally in their attempts to manage HCV product use and ensure patient adherence to their treatment

Specialty Pharmacy Journal. June 2014. http://www.healthstrategies.com/blog/impact-patients-and-specialty-pharmacies-evolving-payer-interventions-manage-hepatitis-c-agents.

Methods Employed to Manage Utilization of Specialty Rx

Cost

- Network management
- Member cost share
- Quantity restrictions
- Managed formularies
- Rebates

Utilization

- Prior authorization
- Step edits
- Therapy management
- Patient education
- Physician education
- Health care purchaser education

Benefits of Specialty Pharmacy Providers

- Improved outcomes
  - Greater collaboration between providers and adherence programs can improve clinical outcomes
  - Single points of patient contact and connections to related services may help improve the care experience
- Cost savings
  - Synchronized medical and pharmacy services can yield significant total cost savings
- Enhanced delivery of care
    - Utilization of patient registries and clinical pathways allow improved data capture which can be used to optimize the delivery of care

United Health Center for Health Reform and Modernization. April 2014.
http://www.unitedhealthgroup.com/~/media/UHG/PDF/2014/UNH-The-Growth-Of-Specialty-Pharmacy.ashx.

When Does it Make Sense to Use a Specialty Pharmacy Provider?

- Prescription volume is limited
- Relatively small patient population
- Patients are likely to have co-pay issues
- Ongoing patient education necessary
- Prior authorizations are likely
- Side effects need to be managed
- Appeals will be necessary
- Quality data is needed
- Adherence is a challenge

Patient, Provider, and Payer Expectations of Specialty Pharmacy Providers

Access to a Clinical Pharmacist
- Pharmacy and medical benefit
- Engagement with patients
- Engagement with physicians and clinics
- Real time visibility to drug, disease, and patient variables

Patient Access and Empowerment
- Patient assistance programs
- Drug and disease education
- Persistence and compliance

Quality Clinical Programs
- Best practices in formulary and clinical management
- Patient and provider network satisfaction

Predictable Costs
- Value-based health care
- Bending the cost curve
- Documented comparative outcomes

Strategies for HCV Pharmacy Management

- Utilize fibrosis staging to prioritize the need for therapy[1]
  - Accurate assessment of fibrosis is vital in assessing the urgency for treatment
  - Degree of hepatic fibrosis is a robust predictor of disease progression and clinical outcomes
- Identify and encourage use of preferred agents
  - May be different per line of business
- Utilize prior authorization
  - Ensures appropriate genotype, drug selection, and duration
- Encourage collaborative and coordinated care
- Coordinate with specialty pharmacy providers
  - Including disease education and adherence programs
  - Monitoring response to therapy

1. AASLD/IDSA/IAS–USA. http://www.hcvguidelines.org. September 2014.

Use of Technology to Enhance Specialty Pharmacy Data Acquisition, Analysis, and Communication

- Robust and timely data acquisition allows monitoring of utilization and costs
- Application of proven, existing cost management programs
  - Pre-approvals
  - Step therapy
  - Quantity controls
  - Substitutions
- Ability to introduce new programs
  - Limits on point-of-service quantities
  - Tightened access criteria
  - Alternative administration channels
- Coordination with extended care team

Disease Management Strategies and Specialty Pharmacy Drugs

Disease Management Strategies in HCV

- Coordinated disease management is critical to promoting improved health outcomes and cost containment
- Challenges include
  - Managing patients with multiple comorbidities requiring complicated drug regimens
  - Need for ongoing dose adjustment
  - Monitoring for drug-related side effects and drug-drug interactions
  - Poor adherence to the treatment regimen
- “High touch” approach to care management may be required to motivate patients to remain adherent to their treatment plan

HCV Disease Management Plan

Intervention	Timing	Description
HCV Baseline Assessment	Week 0	Collect/verify labs (eg, weight, viral load, biopsy, Hb) and previous HCV therapy, duration, and outcome
Pharmacist Verification	New RXs	Evaluate therapy by genotype, treatment history, effectiveness, and safety; resolve actual or potential drug-related problems
Care Plan	Week 0, PRN	Identify treatment goals and document care plan
Medical Assessment	Week 0, Monthly	Collect/verify allergies, comorbidities, concomitant medications; clinician triage
Patient Education and Training	Week 0, PRN	Clinician initial consult (drug, disease, expectations, AE management; adherence); HCV educational packet; injection training
Support Program Referral	Week 0, PRN	Facilitate enrollment in manufacturer programs and other supportive organizations
Side Effect Management	Week 0, PRN	HCV Care Kits, side effect management guides, and clinician counseling
Adherence and Distribution Calls	At Least Monthly	Outbound call by patient care coordinator to arrange refills, evaluate side effects, education needs, and administration
Futility Rules and Treatment Outcomes	Varies by Regimen	Collect VL and provide recommendations for treatment plan; outreach to obtain SVR results

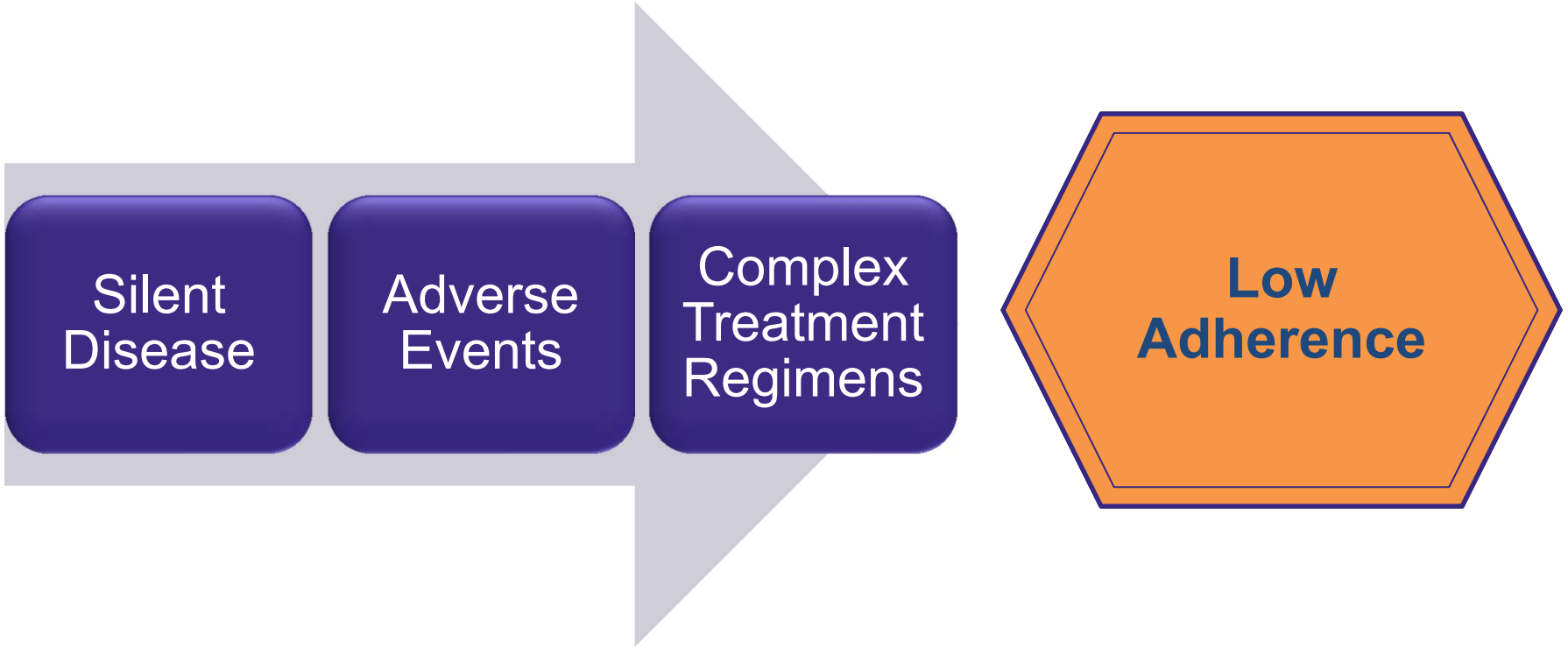
Fairview Hospital Specialty Pharmacy. http://www.fairview.org/Pharmacy/Specialtypharmacy/index.htm.

Use of Evidence-Based Treatment Algorithms to Minimize Variations in Care

- Ensure standards of HCV care are consistently followed
- Monitor therapy to detect and resolve problems
- Identify opportunities for referral to specialists to address specific issues or problems
- Proactively identify opportunities to maintain/improve adherence
- Provide education to empower patients and caregivers to take charge of their therapy

Specialty Pharmacy Initiative: Phase I Environmental Scan. *FMCP*. Nov 2009.

Patient Adherence is Critical to Improved Health Outcomes



Specialty HCV drugs improve outcomes

but …

Patients do not take medications the way they should, or in the way it was studied to produce published results

Adherence Counseling for Patients with HCV

Initial	Ongoing	Follow Up
Therapy and disease state overview including • Disease state education • Drug administration • Treatment-related averse events (AEs) • Importance of adherence • Depression screening	• Discuss diagnosis and treatment • Review dose, administration, duration of therapy • Depression screening • Address barriers to adherence • Provide guidance for missed doses and AE management • Laboratory reminders and importance of follow up testing	• Adherence assessment including medication possession and refills • Address barriers to adherence • Enact dispensing and/or prescriber engagement to support adherence

Dorholt M. *Specialty Pharmacy Times*. August 14, 2014. www.SpecialtyPharmacyTimes.com.

Utilizing Technology to Improve Adherence

Medication Reminders	Reminders pop up when it's time to take a medication; user can mark as taken, snooze, or mark as skipped
Adherence graph	Users can view a graph that charts their adherence through the course of therapy
Viral load graph	Users can enter viral load following lab work and app graphs their data over time
E-mail	Medication regimen, adherence graph, and viral load graph can all be emailed to the doctor/nurse/caregiver
Online tracking	Users document their viral load, doctor visits, symptoms using an app or web-based system

Dorholt M. *Specialty Pharmacy Times*. August 14, 2014. www.SpecialtyPharmacyTimes.com.

Collaborative Care is Critical to Improving Adherence

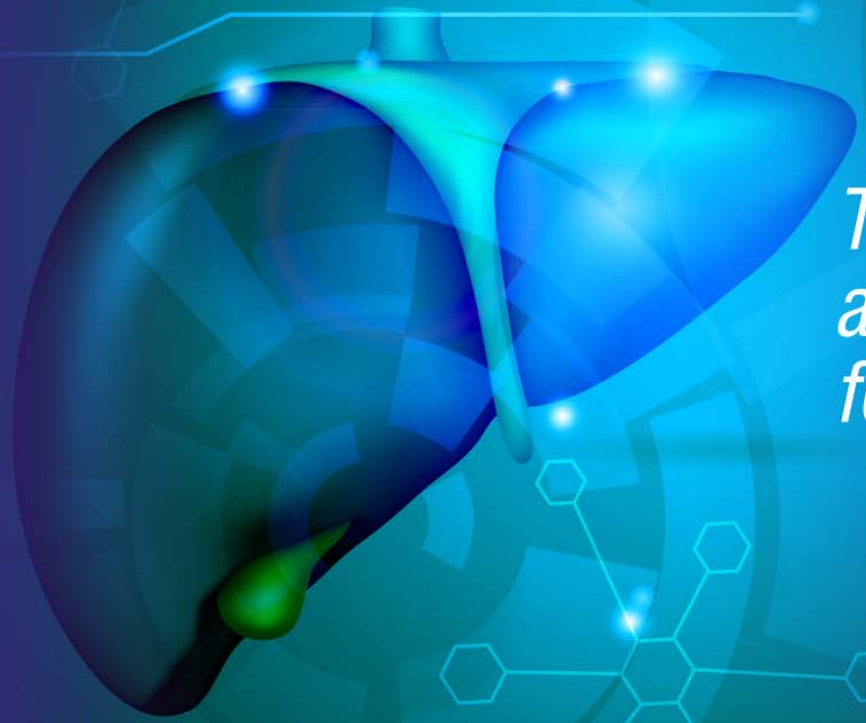
- Collaboration between specialty pharmacists, nurses, and physicians allows the care team to
  - Verify the diagnosis and presence of comorbidities
  - Ensure treatment is aligned with the guidelines
  - Monitor and adjust therapy as required to optimize clinical response
  - Minimize treatment duplication and over/underdosing
  - Manage issues related to complexity of treatment
  - Identify and address barriers to adherence
  - Identify gaps in care
  - Provide patient and caregiver education

Dorholt M. *Specialty Pharmacy Times*. August 14, 2014. www.SpecialtyPharmacyTimes.com.

Summary

- HCV has emerged as one of the most important categories to manage
- Payers are using at multiple interventions to manage access and use of HCV drugs
- Health plan partnerships with specialty pharmacies can improve patient outcomes while lowering overall costs
- Coordinated disease management is vital to promoting improved health outcomes and cost containment
- Use of evidence-based treatment algorithms can minimize variations in HCV care
- Patient adherence is critical to improved outcomes

CAPITALIZING ON HCV ADVANCEMENTS:



Treatment Management and Benefit Design Strategies for Managed Care

HCV

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