HCV Treatment Access in the United States: Is There Hope?

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Expert Consultation on the
Evidence for Early Hepatitis C Treatment in the United States
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The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the Centers for Disease Control and Prevention.

Benefits of Treatment

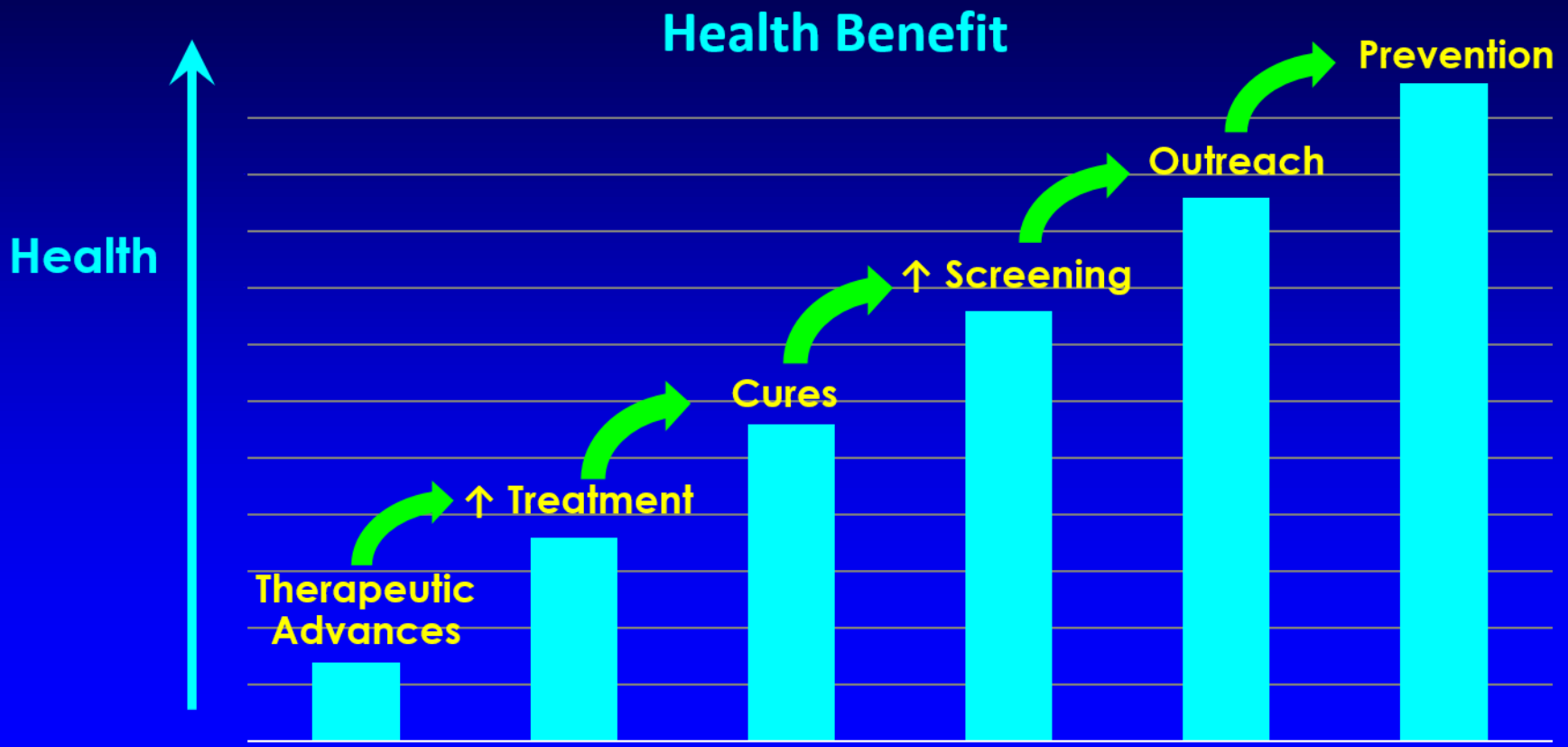
>95% of pts can be cured, safely, easily, and quickly. SVR associated with:

- Reduced all-cause mortality (even in F0-F1)
- Liver mortality and liver transplantation reduced by 90%
- Risk of liver cancer reduced by more than 70%
- Improvement in portal hypertension
- Reduced symptoms and mortality from extrahepatic disease
- Complete or partial remission of non-Hodgkin lymphoma and other lymphoproliferative disorders in up to 75% of cases
- Improvement in quality of life

Delaying treatment decreases the likelihood of SVR and the benefit of SVR.

AASLD/IDSA Hepatitis C Guidance 2015. http://hcvguidelines.org

Dissemination of New Treatments

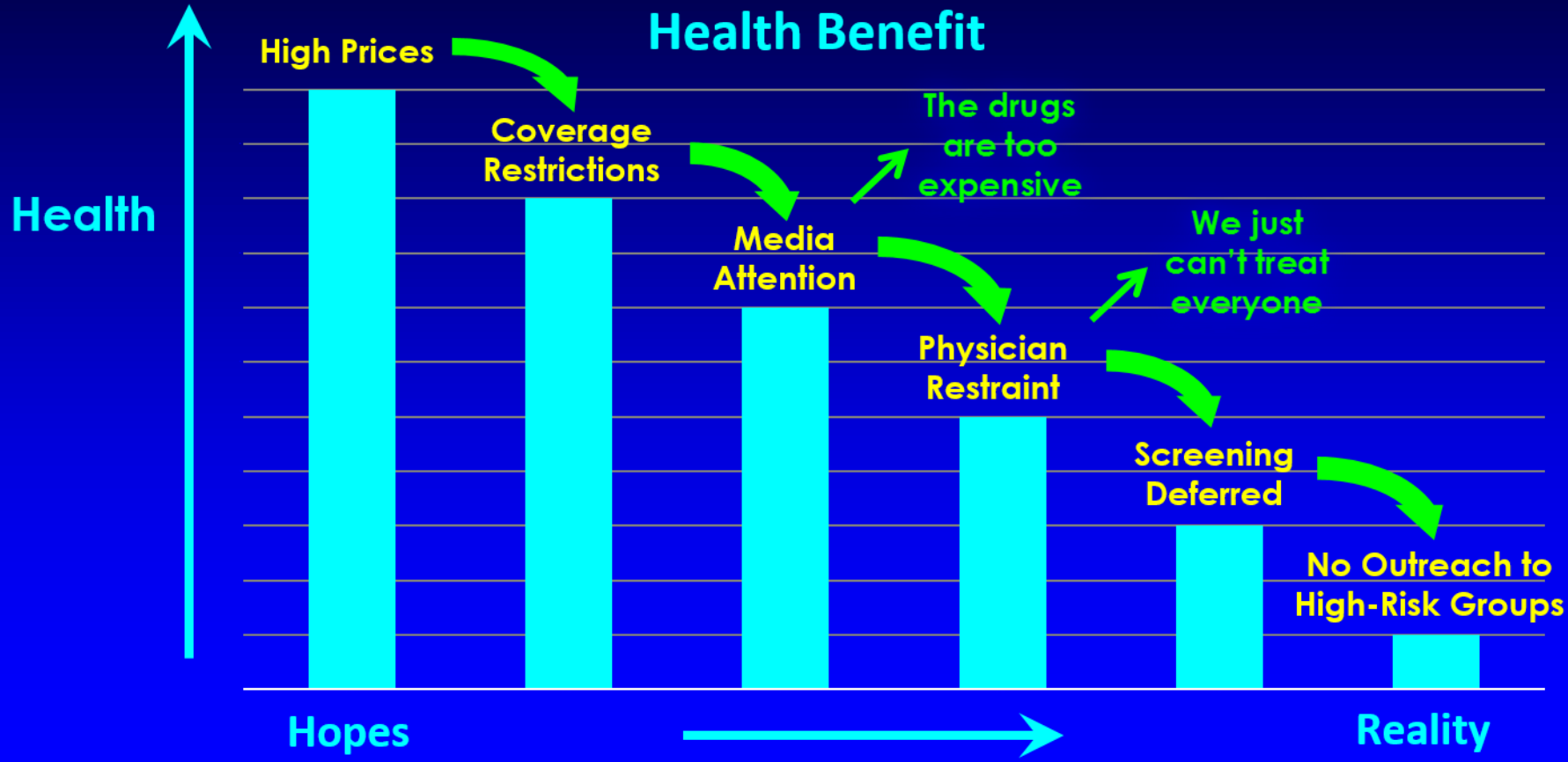


Barriers to HCV Treatment Access

Initial Antiviral Drug Regimens

Regimen	Duration	Wholesale Acquisition Cost
Sofosbuvir	12 weeks	$84,000
Sofosbuvir + simeprevir	12 weeks	$150,000
Sofosbuvir + ledipasvir	8 weeks	$63,000
	12 weeks	$94,500
	24 weeks	$189,000
Paritaprevir/r, ombitasvir, dasabuvir	12 weeks	$83,320
	24 weeks	$166,640
Daclatasvir + sofosbuvir	12 weeks	$147,000
	24 weeks	$294,000

Cascade of Treatment Access Barriers



Coverage Restrictions

Some insurers (public and private) imposed criteria for treatment:

- Advanced fibrosis (F3 or F4)
- Cirrhosis (F4)
- Liver biopsy
- Abstinence from alcohol, marijuana, and illicit drug use
- Mandatory drug and alcohol testing
- Active participation in treatment for substance use
- No substance use treatment in past 12 months
- No substance use diagnosis in past 12 months
- No malignancy of any organ
- Prescriber specialty or "extensive experience" treating hepatitis C

These provisions lack evidence base. Antiviral treatment is effective irrespective of disease stage or substance use.

Rationing = the controlled distribution of scarce resources, goods, or services

Medical Societies Respond to Coverage Restrictions

Unfortunately payers across America are denying treatment. We adamantly disagree with this decision. The decision should be in the hands of the clinician and the patient. Patients should not be denied medications.

— AASLD, October 3, 2014

Deferral based on fibrosis stage is inadequate and shortsighted. There are no data to support the utility of pretreatment screening for illicit drug or alcohol use. These requirements should be abandoned.

— AASLD/IDSA, October 22, 2015

Unfortunately, many insurers – both private and public – are delaying access to new HCV treatments to patients until their disease has progressed and the liver is further damaged. There is no medical evidence to justify that position.

— AASLD, November 16, 2015

http://www.idsociety.org/Hepatitis_C_Antivirals_Statement
http://www.aasld.org/about-aasld/pressroom/aasld-statement-hcv-guidance
http://www.aasld.org/aasld-position-treating-patients-chronic-hcv
http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy
http://www.prnewswire.com/news-releases/leading-liver-doctors-hepatitis-c-patients-must-be-treated-300179479.html

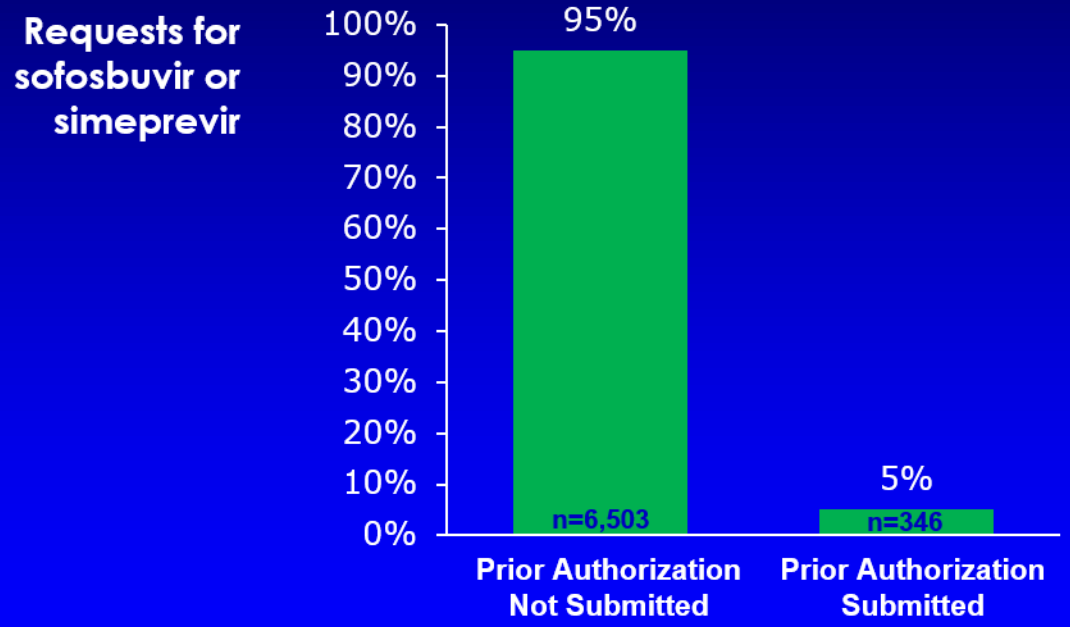
Barriers to HCV Treatment Access

Additional barriers to treatment access

- Onerous prior authorization processes
  - Forms, notes, labs, faxing
  - Missing items, lost pages, more faxing and re-faxing
  - Denials, appeals, second denials, second-tier appeals
- Copays, deductibles, coinsurance
- Media narrative: drugs are impossibly expensive
- Prescriber restraint
- Patient and physician resignation
- Misconceptions about availability and importance of rx
- Missed opportunities
- Staging errors
- Variable progression rates

Prior Authorization Requests for Hepatitis C Therapy, MassHealth, December 2013 – July 2014 (N=6,849)

Massachusetts Medicaid Patients with a Hepatitis C Diagnosis



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Los Angeles County serves ~500,000 people. By August 2016, 81 had started HCV treatment.

Cost-Effectiveness

- Quantitative determination of value achieved by healthcare spending
- Hepatitis C treatment is cost-effective for most patients and cost-saving for many
- Health benefits gained by patients are generally more valuable than any cost savings that accrue to payers.

Chahal JAMA Intern Med 2016;176(1):65-73, Rein Clin Infect Dis 2015;61(2):157-68, Chhatwal Ann Intern Med 2015; 162:397-406, Najafzadeh Ann Intern Med 2015; 162:407-19, Linas Ann Intern Med 2015; 162:619-29, Chidi Value Health 2016;19(4):326-34.

Estimating the Cost Burden

Cost Effective ≠ Affordable

Will cost = $100,000 x 3.5 million people?

- HCV treatment is a one-time expenditure, not an annual one
- It will be spread out over years, perhaps many
  - Many people are unaware they are infected
  - Many people do not see a doctor every year
  - Many providers are unaware of or do not follow screening guidelines
- Most diagnosed patients are not treated ("cascade of care")
- Groups affected by HCV have substantial barriers to care
- Drug prices have been discounted substantially

Need to Control Healthcare Spending

Price ≠ Cost

Cost

(sofosbuvir cost = $1.20*)

- Characteristic of intervention
- Relatively unchangeable without new methods or technologies
- Requires sacrifice by society

Price

- Decision made by corporate executives (sofosbuvir price = $1,000)
- Determines amount of money transferred within society

→ Manufacturing costs are not a barrier to universal access to treatment.

*van de Ven Hepatology 2015; Hill Science 2014; Hill CID 2014.

Consequences of the Hepatitis C Drug Prices and Coverage Limitations

- Confusion and doubt among hepatitis C treaters
- Fear from primary care doctors and patients about testing without available treatment
- Alarm and distress among payers, both public and private
- Declarations by policy groups that hepatitis C treatment is not of value (CTAF, March 2014)
- Difficulty establishing broad baby boomer testing programs, let alone outreach to high-risk groups
- Rationing of treatment

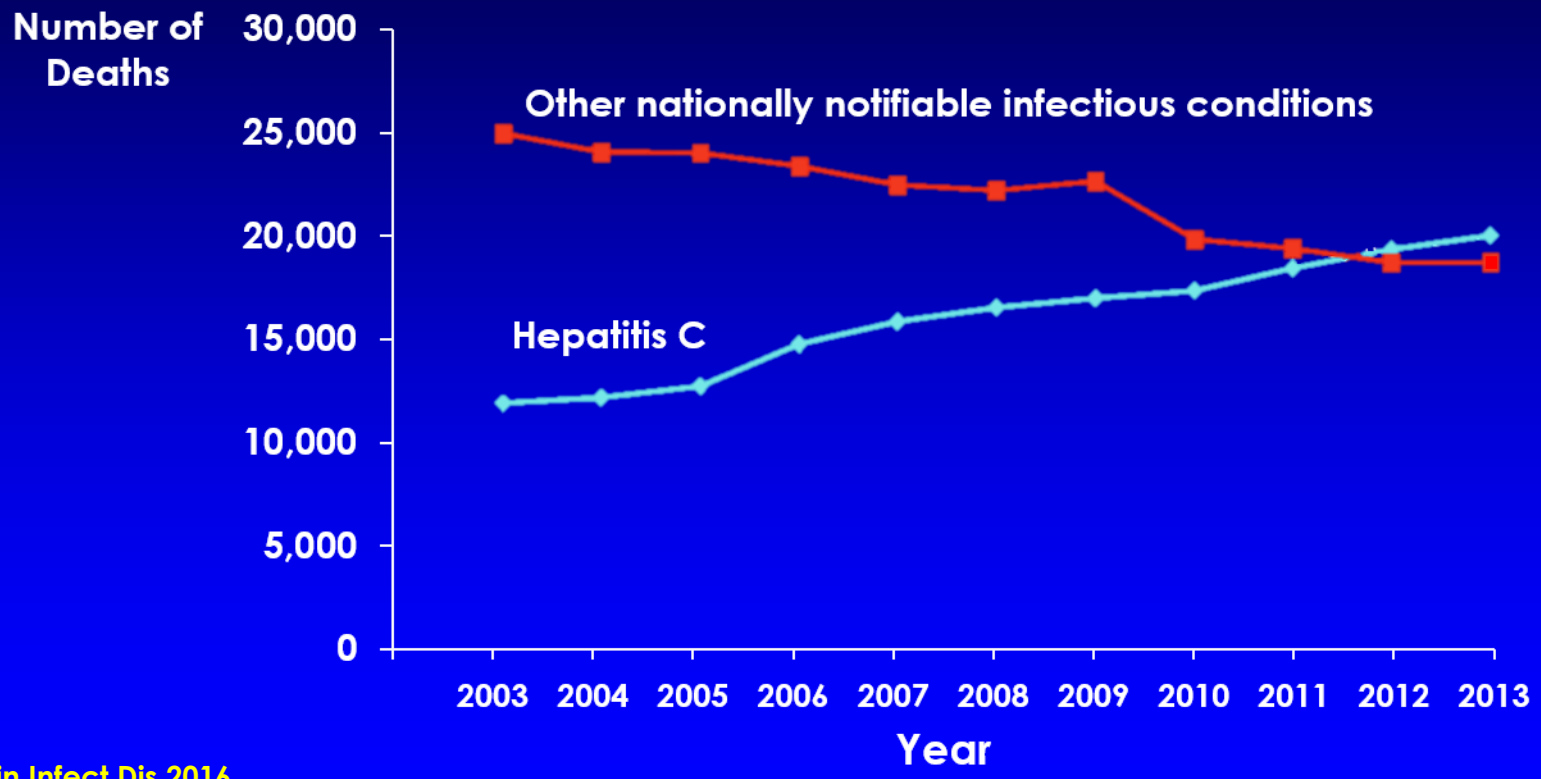
Slide adapted from Camilla S. Graham, MD, MPH

Consequences of the Hepatitis C Drug Prices and Coverage Limitations

- Conflict between patient, provider, and payer over rationing
- Doctors telling patients they must wait till they have severe liver damage to get treated
- Justification for overtly discriminatory practices like mandating "clean" urine toxicology screens as a condition of medical treatment
- Confirmation by patients that they are not "worth" treatment
- Loss of vision about the transformative nature of curative treatments now available

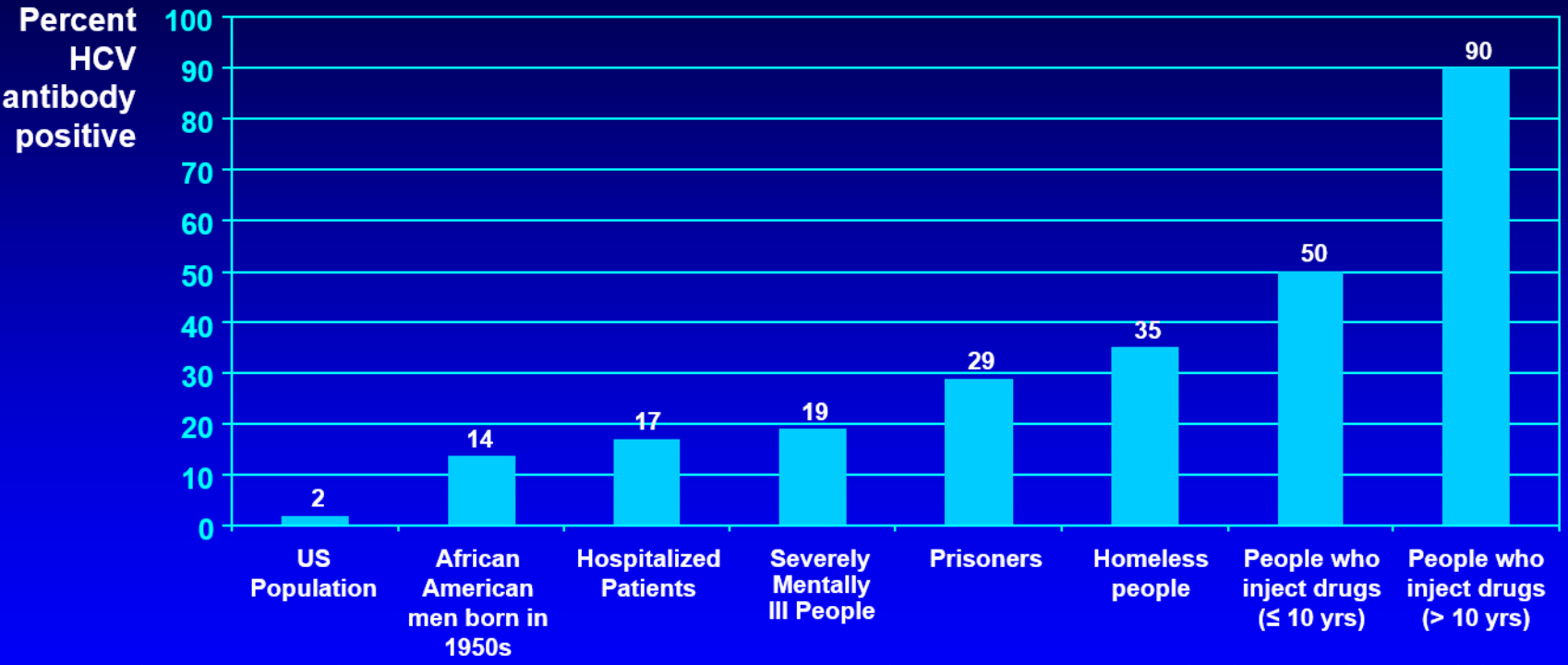
Slide adapted from Camilla S. Graham, MD, MPH

Annual deaths from hepatitis C and all 60 other nationally notifiable infectious diseases, United States, 2003- 2013



Ly Clin Infect Dis 2016

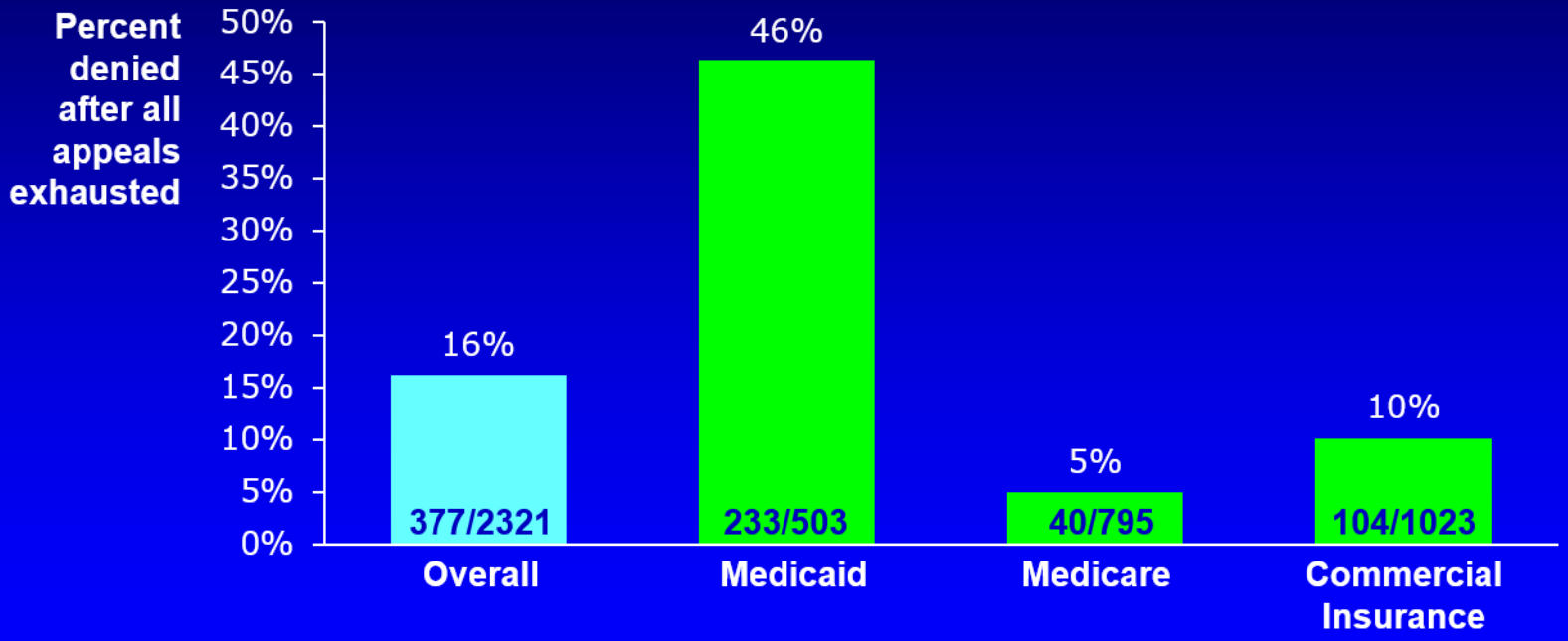
Hepatitis C is a Disease of the Disenfranchised



- Disproportionate treatment rates will sharpen existing disparities

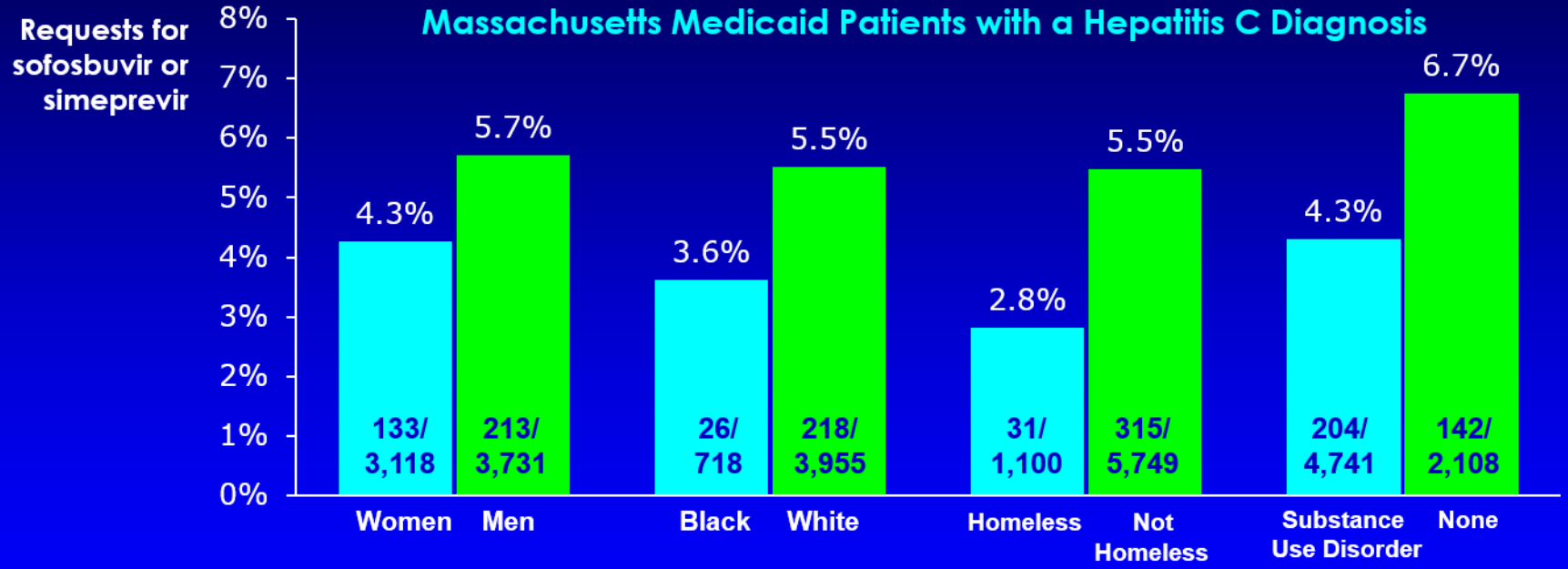
Armstrong Ann Intern Med 2006; Edlin Antiviral Res 2014; Stepanova Hepatology 2011; Edlin Nature 2011; Institute of Medicine 2010; Edlin Hepatology 2005;42:213A

Payer Denial of Hepatitis C Therapy, PA, NJ, DE, MD, Nov 2014 – April 2015 (N=2,321)



Lo Re Clin Gastroenterol Hepatol 2016;14(7):1035-43

Prior Authorization Requests for Hepatitis C Therapy, Massachusetts Medicaid Members, December 2013 – July 2014 (N=6,849)



MassHealth members with a prior authorization request submitted were more likely to be white males and less likely to be homeless or use drugs.

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Can We Find a Solution?

Can we optimize care for patients while at the same time meeting the needs of payers and health systems?

Many solutions have been proposed (some are controversial)

- Ryan-White and ADAP programs for hepatitis C
- Government subsidies
- Federal purchasing and distribution
- Allow Medicare to negotiate prices
- Allow Medicaid programs to negotiate prices as a group
- Allow payers to form purchasing pools to negotiate prices as a group
- Voluntary manufacturer price reductions
- Competition among manufacturers
- Allow drugs to be imported from Canada

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Many solutions have been proposed (some are controversial)

- Government mandated rebates
- Government price regulation
- Mandatory government licensing (under 28 U.S.C. § 1498(a))
- Hepatitis C "mortgage"
- Voluntary removal of coverage restrictions
- Coverage mandates
- Value-based pricing
- Litigation

Litigation

Litigation has challenged the legality of payer coverage restrictions

- **Health plans may not discriminate based on health condition** (Affordable Care Act §1557 (42 U.S.C. 18116), Americans with Disabilities Act)
- **Medicaid may not withhold drugs prescribed for FDA-indicated or medically accepted uses for nonmedical reasons** (Federal Medicaid law 42 U.S.C. § 1396r-8(d))
- November 5, 2015 CMS notice: **States must cover hepatitis C medications**

To date:

- 24 class-action lawsuits, demand letters, or agreements in 12 states
- Commercial payers (13), state Medicaid programs (7), and state prison systems (3)
- Most have resulted in lifting of coverage restrictions

Frameworks for Pharmaceutical Drug Value

Organization	Factors Considered
American College of Cardiology-American Heart Association (ACC-AHA)	• Clinical benefit vs. risks. • Magnitude of net benefit • Precision of estimate based on quality of evidence • Value (cost-effectiveness)
American Society of Clinical Oncology (ASCO)	• Clinical benefit ➢ Overall survival ➢ Progression-free survival ➢ Response rate ➢ Toxicity • Bonus factors ➢ Palliation ➢ Time off all treatment • Cost per month

Neumann N Engl J Med 2015; 373:2595-7

Frameworks for Pharmaceutical Drug Value (cont)

Organization	Factors Considered
Institute for Clinical and Economic Review (ICER)	• Incremental cost-effectiveness plus care value components ➢ Comparative clinical effectiveness ➢ Other benefits and disadvantages ➢ Contextual considerations • Budget impact
Memorial Sloan Kettering Cancer Center	• Efficacy (survival) • Toxicity • Novelty • Research and development cost • Rarity • Population health burden
National Comprehensive Cancer Network (NCCN)	• Efficacy • Safety • Evidence quality • Evidence consistency • Affordability

Neumann N Engl J Med 2015; 373:2595-7

Is There a Way Forward?

Solutions that prioritize the needs of patients can be found if all agree to act in concert rather than as adversaries.

Key stakeholders include:

- Pharmaceutical industry
- Insurance industry
- Federal and state governments
- Public health organizations
- Health systems
- Academic medical centers
- Medical societies
- Prison and jail health
- Clinicians
- Patients
- Advocates
- Community-based organizations

All have a stake in putting the new drugs to the fullest possible use for the benefit of patients.

Is There a Way Forward?

New drugs now provide us with the opportunity to keep people from continuing to get hepatitis C and stop people from dying of hepatitis C.

We can achieve this goal with:

- consensus among stakeholders to use the new hepatitis C therapeutic advances to end the epidemic of hepatitis C morbidity, mortality, and transmission
- unified vision that the new hepatitis C medications will be made available without constraints
- commitment from all stakeholders to work together to achieve this vision.

Is There a Way Forward?

Slide courtesy of CDC Foundation, Mike Luckovich, John Ward