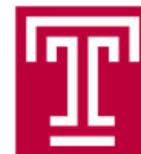


Direct Acting Antivirals: Access and Education

HCV: The Silent Epidemic

David Koren, PharmD

October 18, 2017



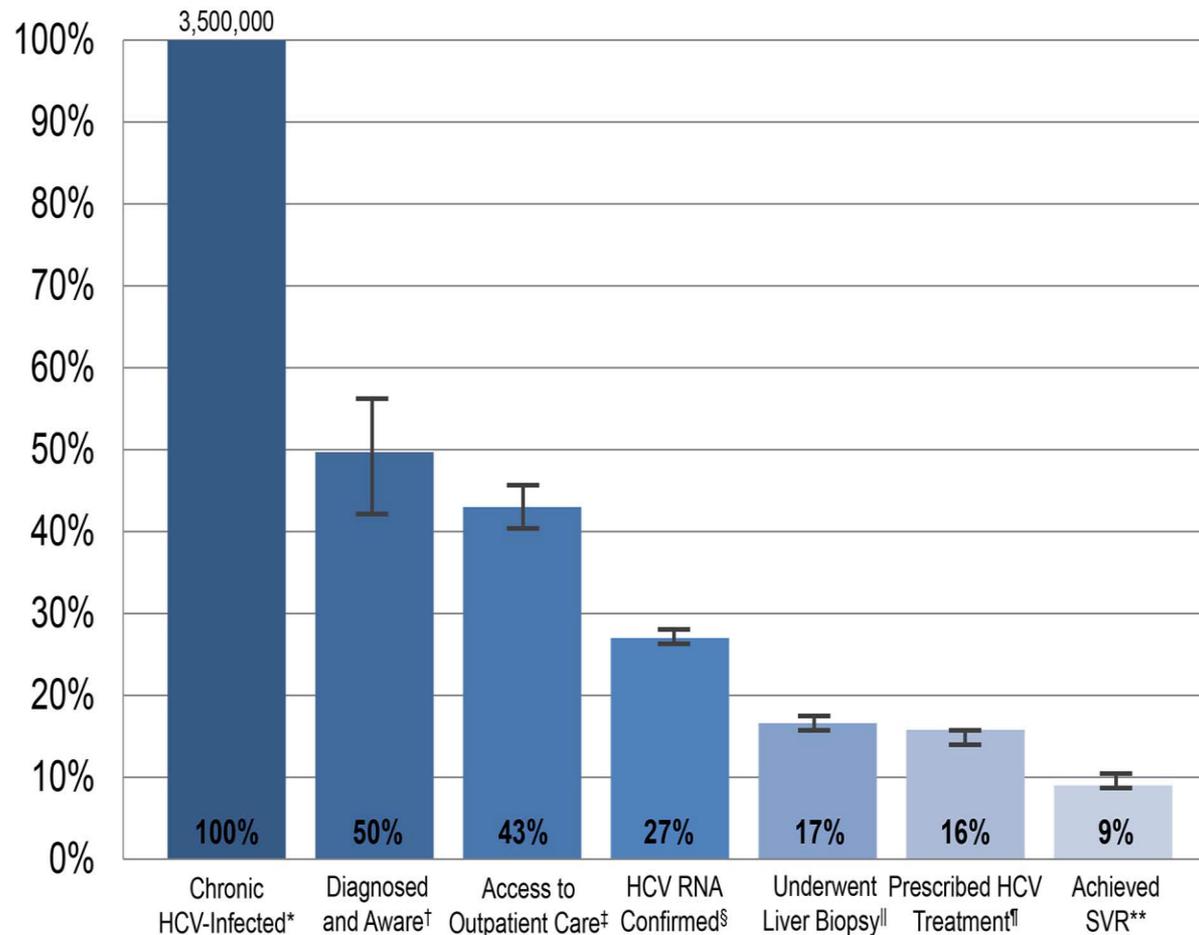
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Disclosure

- Dr. Koren has served on a Hepatitis C Medical Advisory Panel for Gilead Sciences.

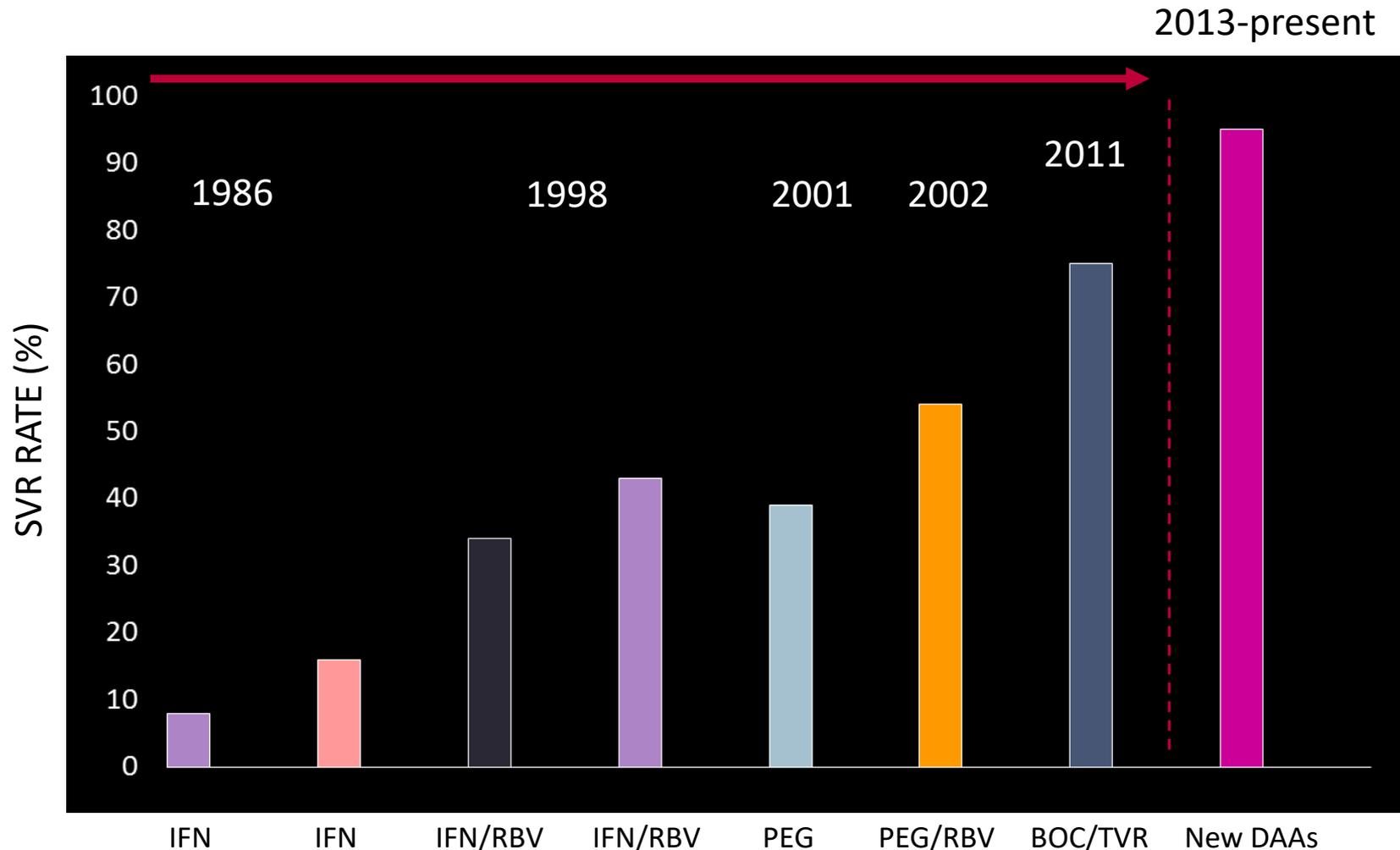
The national chronic HCV cascade



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Hepatitis C Treatment options



Why isn't everyone on treatment?

- Insurance restrictions are moving targets
 - Provider type
 - Fibrosis score
 - Sobriety restrictions
 - Deadlines to meet
- Administrative burden
- Cost of Cure



RI Medicaid Denied 65% Of Requests For Hepatitis C Drugs

By KRISTIN GOURLAY · AUG 27, 2015

Hepatitis C may not take as big of a chunk out of the state's Medicaid budget as previously projected. One reason?

A majority of patients who requested treatment have been denied.

New drugs for hepatitis C can cure the disease in most patients. But they're so expensive, health insurers have placed limits on who qualifies for them. Rhode Island's Medicaid program restricts the drugs to people with advanced liver damage and those who have abstained from drugs and alcohol for at least six months.

If you think **\$1,000 a pill** is OK, stop reading this.



More than 3 million Americans have Hepatitis C. Gilead Sciences' Hepatitis C drug Sovaldi is the latest attempt to gouge every last cent out of our health care system no matter the consequences on public health. Our State and Federal leaders are breaking the bank by paying whatever Gilead and its pharma allies demand without question.

HEPCAP

HEPATITIS C ALLIES OF PHILADELPHIA

[Health](#) — Health Cents

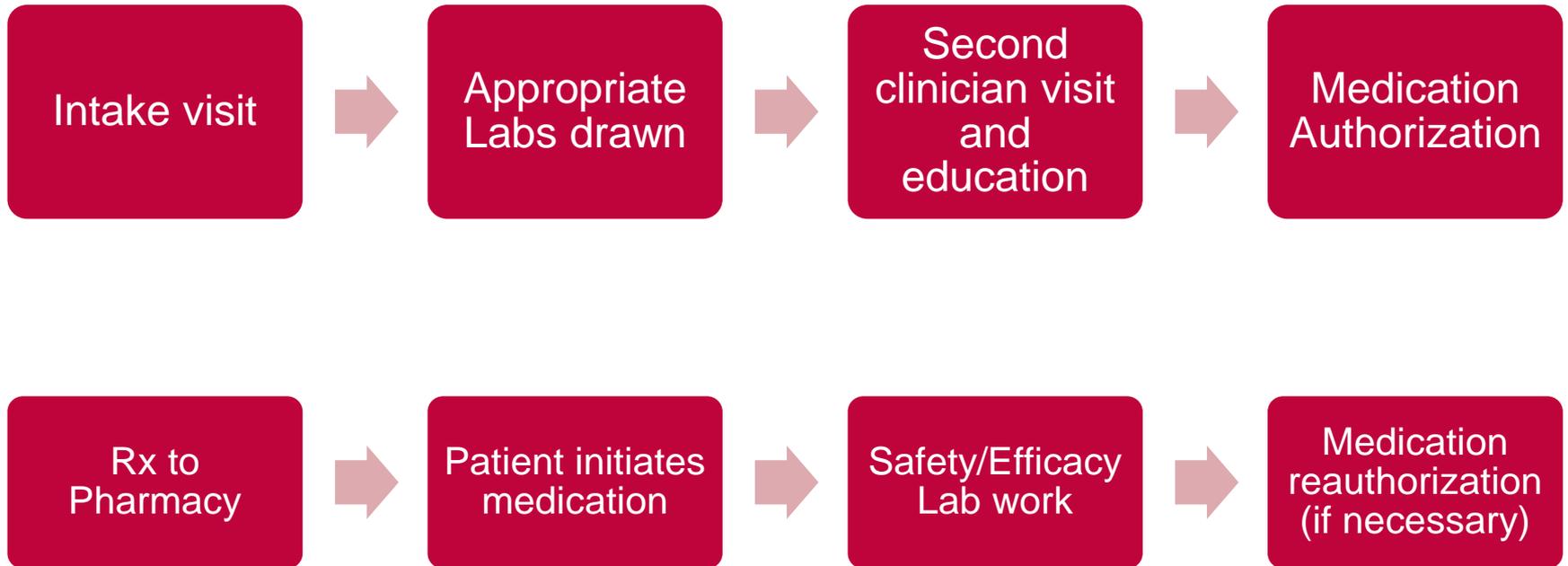
In major shift, Pa. to expand hepatitis C treatment for Medicaid patients

Updated: MAY 16, 2017 — 9:18 PM EDT



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General Process for medication access



Required labs



The virus

- HCV Antibody (Ab)
- HCV Viral Load
- Genotype/Subtype
- Resistance panels?
 - NS5a
 - NS3/4

Coinfections

- HIV
 - CD4/VL
- Hepatitis B
 - Surface Ab / Ag
 - Core Ab

The patient

- Metavir scoring
 - Biopsy
 - Fibroscan
 - Blood markers (eg: Fibrotest/APRI)
- Imaging
 - Ultrasound / MRI / CT
 - Screening for HCC
- Comprehensive Metabolic Panel
- Complete Blood Count
- INR

Note: This is not a comprehensive list!



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Required documentation

- Sobriety
 - Alcohol and Illicit substances (not always a barrier to treatment)
- Mental Health
 - Linkage to care? Treatment? (not always a barrier to treatment)
- Adherence
- Drug interactions

Assess your resources

Create a systematic approach to medication access



- What insurances do my patients use regularly?
 - Do they prefer any specific agent
- What labs are required for approval
 - Can an order panel be created?
 - Is there an expiration date
- Is specific documentation required by the provider (eg: sobriety/mental health)
- Who will be completing paperwork?

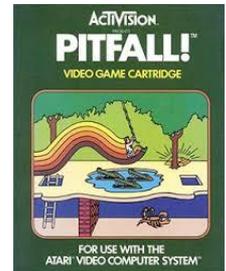


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Potential pitfalls

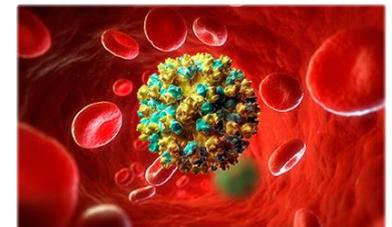
- What if your patient doesn't meet insurance restriction?
 - Will they at some point?
 - What is the follow-up process for this patient
- What if your provider prefers an agent over the preferred agent?
 - Medical documentation is necessary
 - Prepare for the need for a peer-to-peer appeal



The counseling process (1)

HCV pathophysiology

- What is the liver?
 - Why do we need it?
- What is HCV?
- What does the virus do in the body
 - What other things can cause liver damage?
- What are the stages of liver disease/fibrosis?
- Why do people need treatment?
 - What are complications of cirrhosis?
- What is a genotype?
- What is HCV cure



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The counseling process (2)

- Lab review
 - What kind of HCV do you have?
 - Genotype / Viral Load / Resistance (if applicable)
 - How “bad” is your liver?
 - Metavir and Presence/Absence of cirrhosis
 - Do you have comorbidities?
 - What can you do to keep your liver healthy?
 - Diet/Exercise

The counseling process (3)

- Your treatment journey
 - Strict adherence for 2-3 months (or longer)
 - Need for lab draws
 - Need for follow up post DAA completion
 - Cure
 - Follow up monitoring



The medication

- Name of medication
- Administration requirements
 - Time of day
 - Food requirements
 - Storage
- Drug-Drug interactions
 - Existing and expected
- Adverse Drug Reactions
 - Contingency plan



Medication acquisition

- Where is the medication coming from
 - Specialty pharmacy (contracted?)
- How much will it cost
 - Copay assistance cards
 - PAN foundation (www.panfoundation.org)
- How are refills handled?
 - Patient responsibility



Setting expectations

I HAVE NO IDEA
WHAT'S GOING
TO HAPPEN.

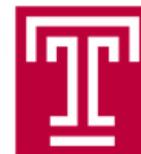


AND I LOVE IT.

- “So you’ll write me a prescription today?”
 - Treatment is a process

- “I lost my bottle, can you give me more?”
 - Treat your medications like gold

- “I’m planning a major surgery in a month”
 - Set contingency plans



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Follow up counseling

- Initial check-in

- “How are you taking the medication daily?”

- Time
 - With/without food

- Initial adherence

- Coaching/congratulating

- Adverse drug reactions

- Assessment of severity

- Coaching through minor adverse effects
 - Immediate appointment with clinician for major adverse effects

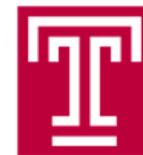


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Questions?

Thank you for your time!



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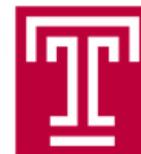
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