



Department of Veterans Affairs

HEPATITIS C TREATMENT :

**REQUEST FOR
CHOICE PROGRAM FLEXIBILITY
TO ADDRESS**

\$500 MILLION SHORTFALL IN FY 2015



Veteran Hepatitis-C Treatment: Summary

- VA is changing the lives of Veterans with Hepatitis-C (HCV)
- The FDA approved two sets of HCV drug treatments in the last 12 months – 4 new drugs. Both sets became available after VA submitted its 2015 Budget requests to Congress
- Of the total 180,000 enrolled Veterans diagnosed with HCV, VA has treated 27,244 (or 15 percent) --
 - 19,600 Veterans treated during FY 2015
 - 7,644 Veterans treated during FY 2014
- VA reallocated nearly \$700 million of base resources to fund HCV treatment in FY 2015
- As of June 2015, VA has exhausted all available FY 2015 resources and is relying on the Choice Program for HCV treatment
- VA is requesting an amendment to the Choice Act, Section 802 to provide \$500 million for critically needed HCV pharmaceutical treatment drugs in FY 2015.



HCV Clinical Considerations and the Veteran Population

- VA estimates that about 180,000 current enrollees diagnosed with HCV
 - VA cares for a population with one of the highest prevalence rates of HCV infection in the country
 - VA estimates there may be an additional 40,000 enrollees with HCV infection not yet diagnosed
- Progression of HCV infection includes serious complications, such as cirrhosis and hepatocellular carcinoma, which typically take decades to occur
 - Most Veterans in VHA care were infected 30-40 years ago
 - Cure of infection significantly decreases mortality and complication rates for some patients
- HCV is a chronic disease and with the newer medications, HCV can be cured in a large proportion of patients treated. Newer medications:
 - Have significantly higher cure rates than older medications
 - Are easier to prescribe (all oral regimens are now available)
 - Have many fewer and milder side effects



Referral of HCV Veterans to Choice Program

Although VA has exhausted its budgeted funds for HCV pharmaceuticals, we are continuing to treat Veterans and are referring HCV positive Veterans to the private sector through the Choice Program.

Care Coordination Challenges

- Continuity of Care – Choice only authorized for 60 day and then need re-authorization but HCV treatment is 12-24 weeks long.
- Risk for interruption of treatment can lead to failure.
- Lack of availability of qualified community providers, particularly given our complex patients with multiple comorbidities.
- High Veteran case load (many patients ready and waiting for treatment -over 130,000 veterans) and limited Choice capacity to handle influx of Veterans ready to use Choice

Duplication of Services

- Privacy issues: will require extra vigilance over release of Info required by Veteran which delays care – (many HCV pts have HIV tests and substance use issues)
- Many Veteran have had workup in VA (imaging, procedures, lab tests) which Choice provider may not have access to and will repeat – driving up Care in Community costs
- No mechanism to measure quality of care being provided (monitoring labs, response, drug interactions) in community as it depends on medical documentation being sent back to VA
- Problem of patient having multiple providers (VA and non-VA)

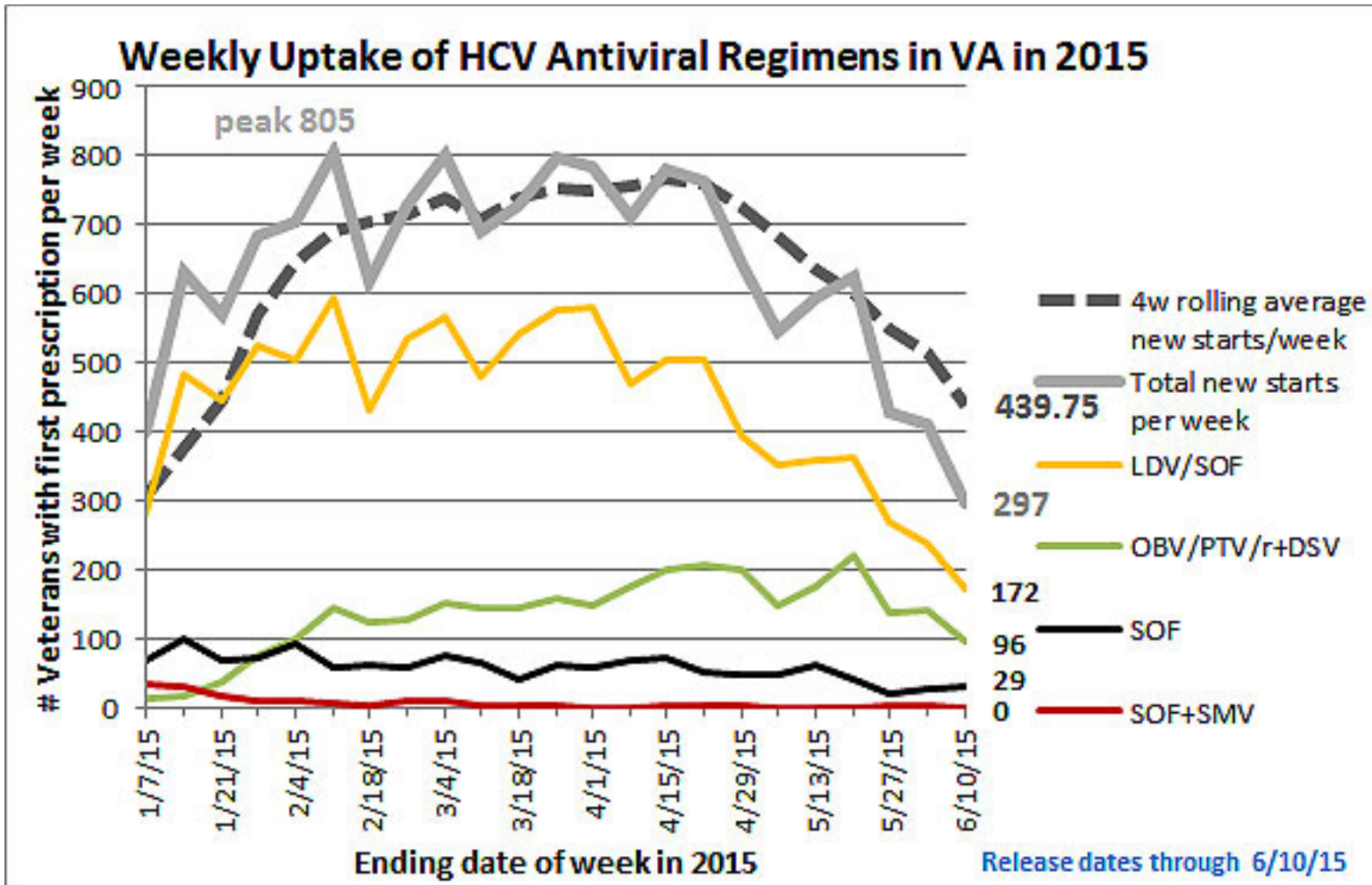


What \$500 Million Buys: Life-Saving HCV Treatment for 13,600 Veterans

<u>Cost</u>	ALD* Patients (75%)	# of Patients	<u>Treatment</u>	<u>Unit Cost</u>
\$64,076,400.00	25%	2,550	Viekira @	\$25,128
\$307,370,880.00	73%	7,446	Harvoni @	\$41,280
\$13,561,920.00	2%	204	Sofo/Riba @	\$66,480
<u>Cost</u>	Non-ALD* Patients (25%)	# of Patients	<u>Treatment</u>	<u>Unit Cost</u>
\$41,863,248.00	49%	1,666	Viekira @	\$25,128
\$68,772,480	49%	1,666	Harvoni @	\$41,280
\$4,520,640	2%	68	Sofo/Riba @	\$66,480
\$500,165,568		13,600	Veterans Treated	



Current uptake rates for HCV treatment



Note: LDV/SOF=Ledipasvir/sofosbuvir; OBV/PTV/r+DSV=Ombitasvir/paritaprevir/ritonavir/dasabuvir; SOF=Sofosbuvir+ Ribavirin; SOF+SIM=Sofosbuvir+simeprevir



Background



Who is being treated and with what regimen

Drug Regimen	Stage of Liver Disease	Usual Duration	Proportion of Population on Regimen	Current cost of Regimen per PBM
Ledipasvir/sofosbuvir	Non-ALD	8-12 wks	49%	\$27,520-\$41,280
	ALD	12-24 wks	24%	\$41,280-\$82,560
Ombitasvir/paritaprevir/ritonavir/dasabuvir	Non-ALD	12 wks	14%	\$25,128
	ALD	12-24 wks	5%	\$25,128-\$50,256
Sofosbuvir+ Ribavirin	Non-ALD	12-24 wks	5%	\$49,860-\$99,720
	ALD	12-24 wks	2%	
Sofosbuvir+simeprevir	Non-ALD	12 wks	<1%	\$61,920-\$123,840
	ALD	12-24 wks	<1%	

Note: ALD = advanced liver disease

Source: Pharmacy Benefits Management

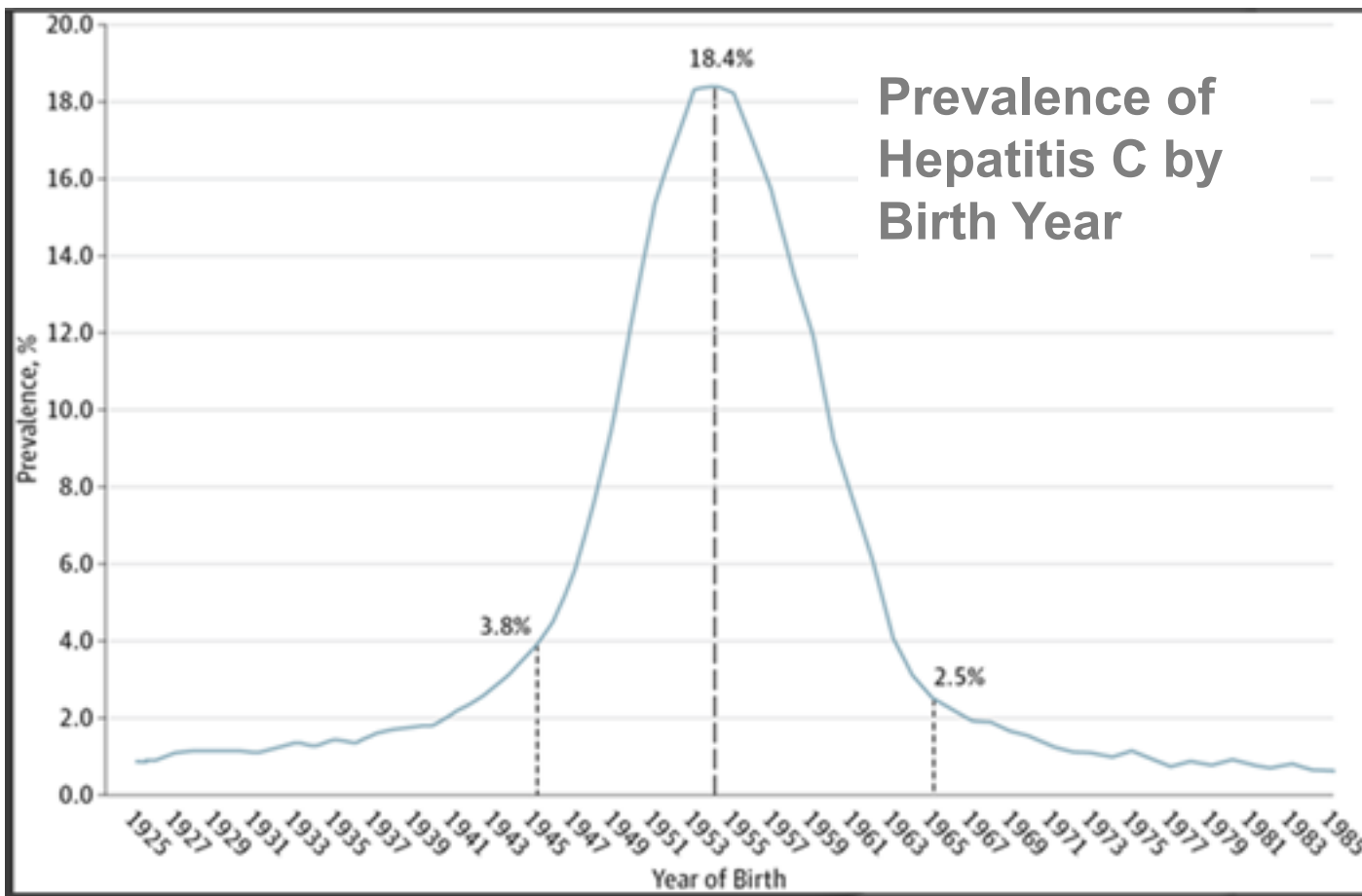


Criteria for patient selection for HCV treatment

- Inclusion criteria
 - Confirmed diagnosis
 - Disease stage (not absolute)
 - Ability to adhere to regimen
- Exclusion criteria
 - Medical comorbidities (e.g., end-stage kidney disease)
 - Inability to adhere because of alcohol/substance use, serious mental illness (not absolute)



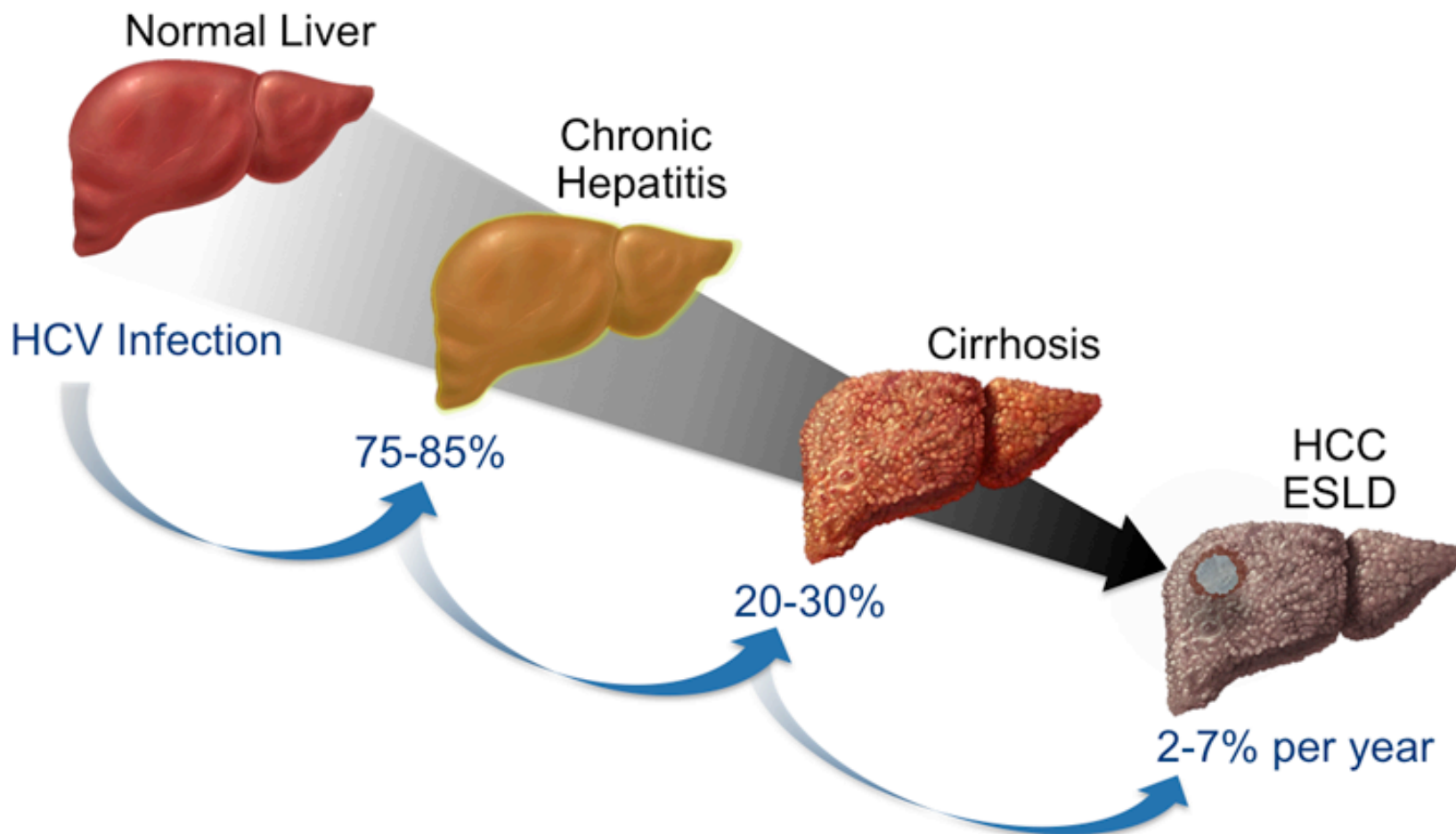
Prevalence of HCV among Veterans by Birth Cohort



Source: Backus L *et al* JAMA 2013; 173(16):1-3



HCV: natural history



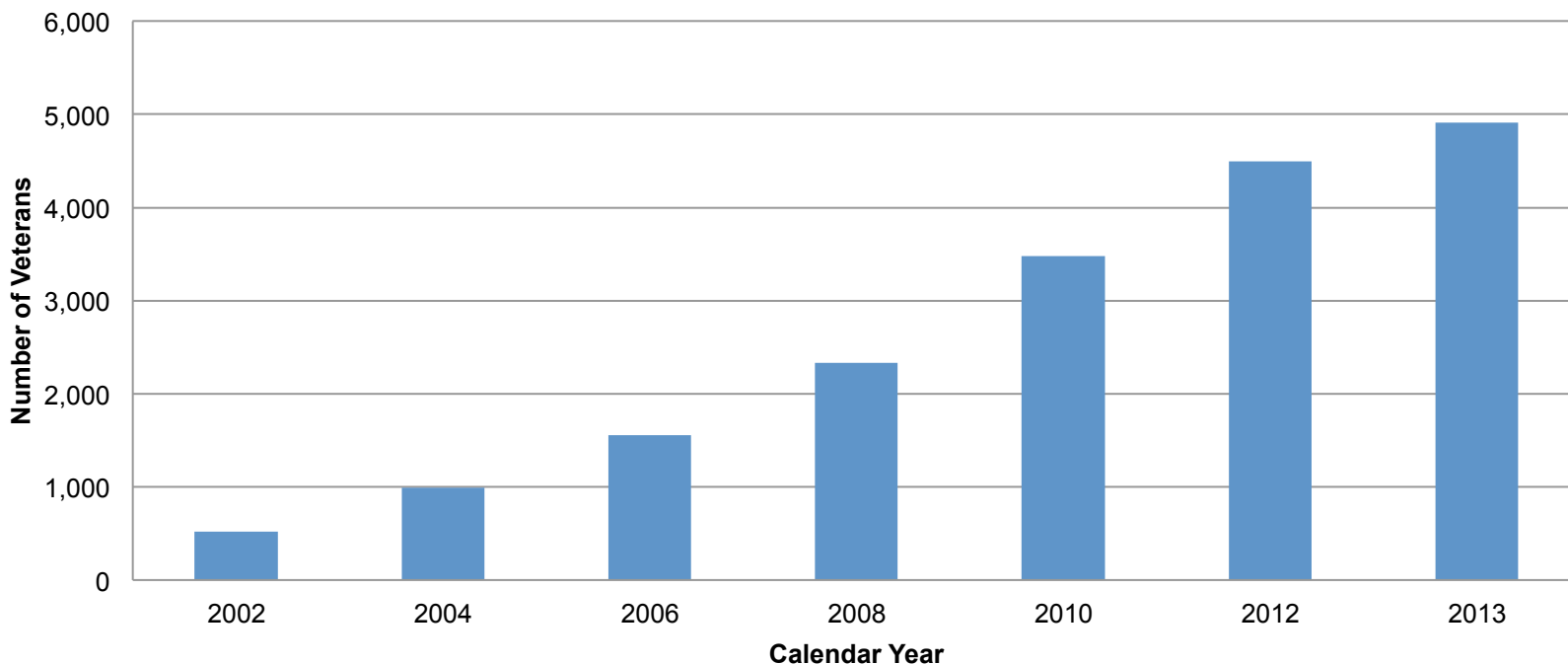
NOTE: HCC=Hepatocellular Carcinoma; ESLD=End Stage Liver Disease

Source: Presentation by Thornton, K., 2013, retrieved on 4/24/15 from: <http://www.hepatitisc.uw.edu/go/evaluation-staging-monitoring/natural-history/core-concept/all>



Prevalence of liver cancer cases in VA HCV patients is increasing rapidly

HCV+ Veterans ever diagnosed with liver cancer*



*median survival for all patients is <24 months

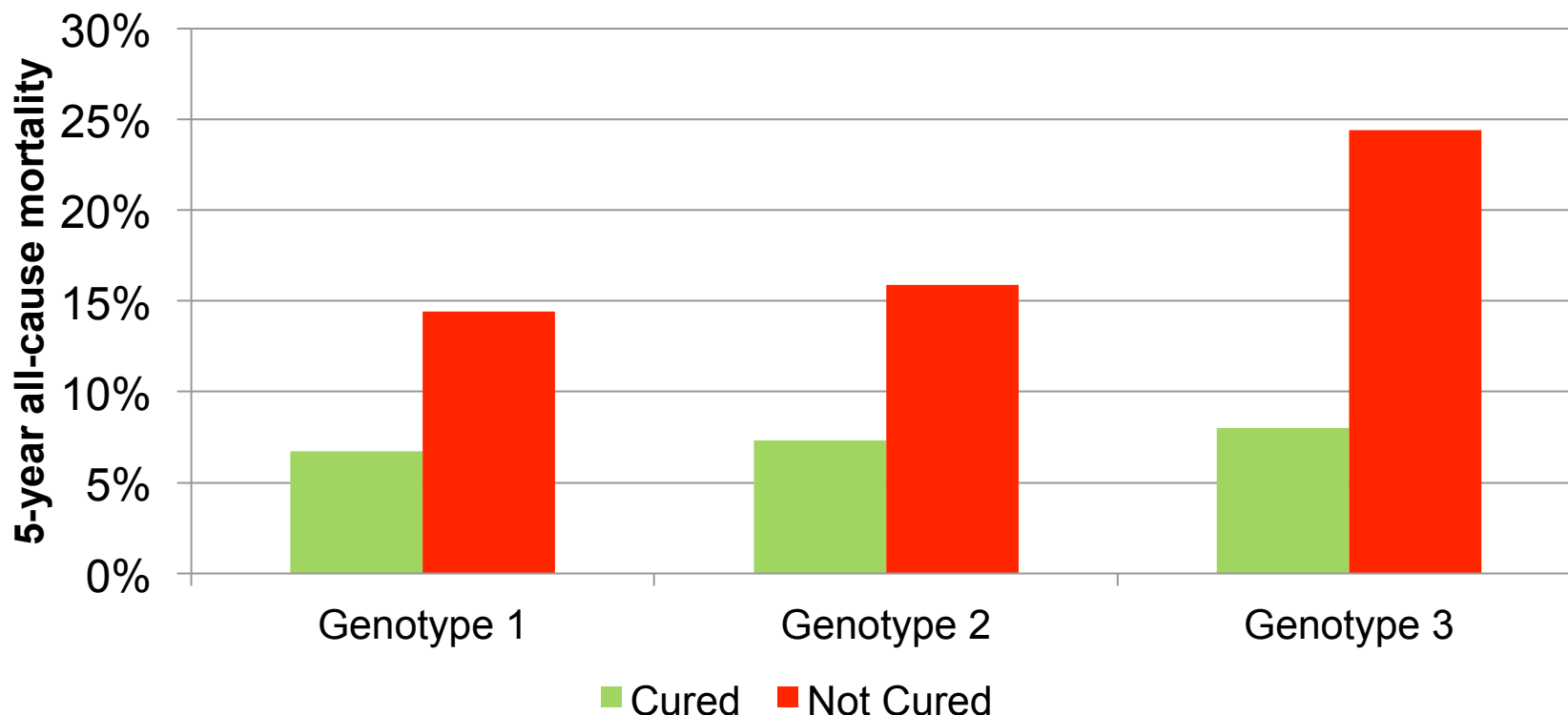
NOTE: Calendar year (CY) 2014 data not yet available; last bar represents CY 2013 data. In CY 2013, VHA had 174,302 Veterans with HCV in care

Source: HCV Clinical Case Registry (CCR)



HCV anti-viral therapy prevents death and complications

HCV Cure and Risk of Death

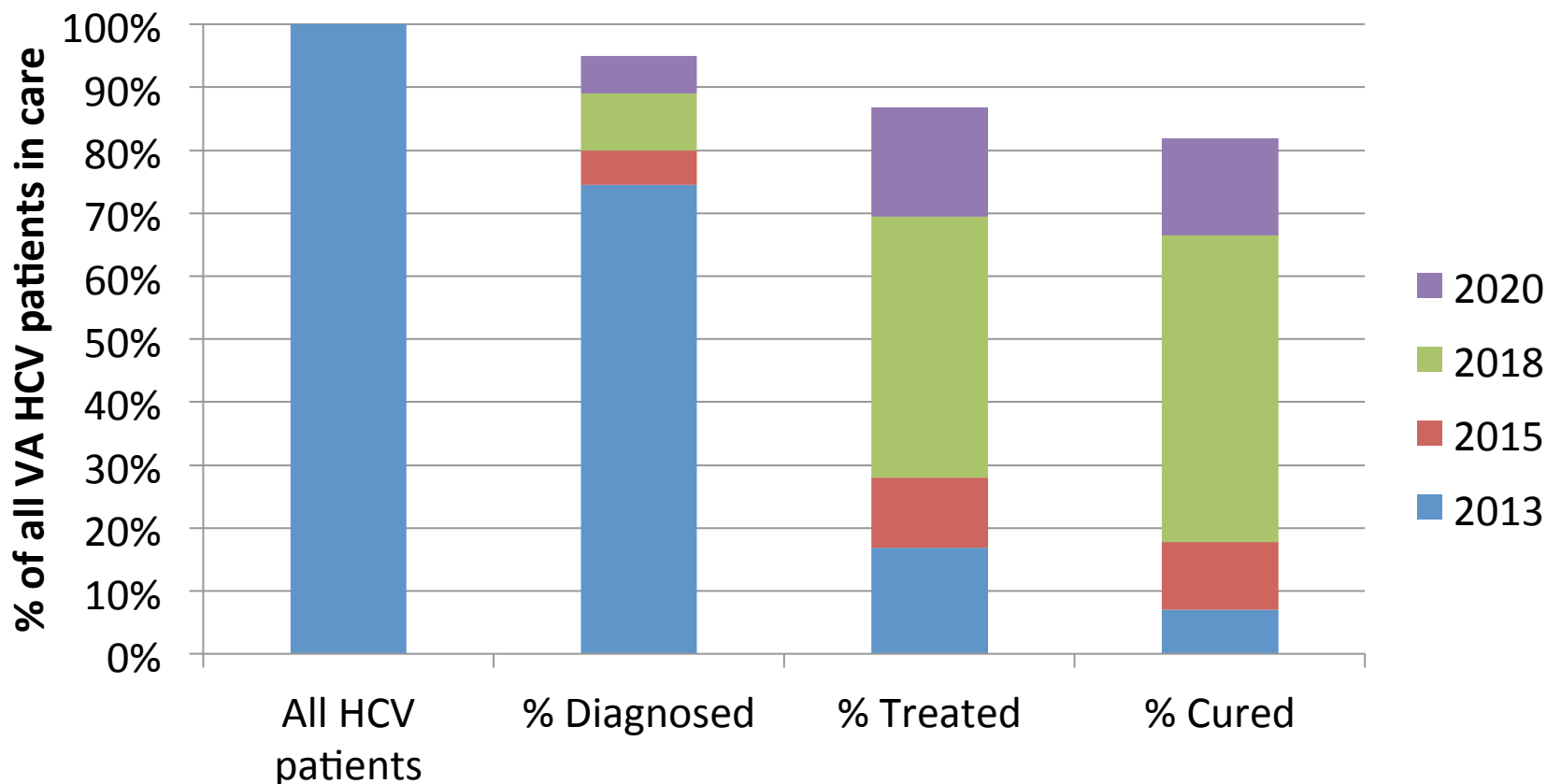


NOTE: Sustained Virologic Response (SVR) = cure

Source: Backus L *et al* Clin Gastroenterol Hepatol 2011 Jun; 9(6):509-516



Milestones for achieving HCV target outcomes by year



NOTE: Sustained Virologic Response (SVR) = cure