HCV Elimination:
Lessons Learned from the VA Experience

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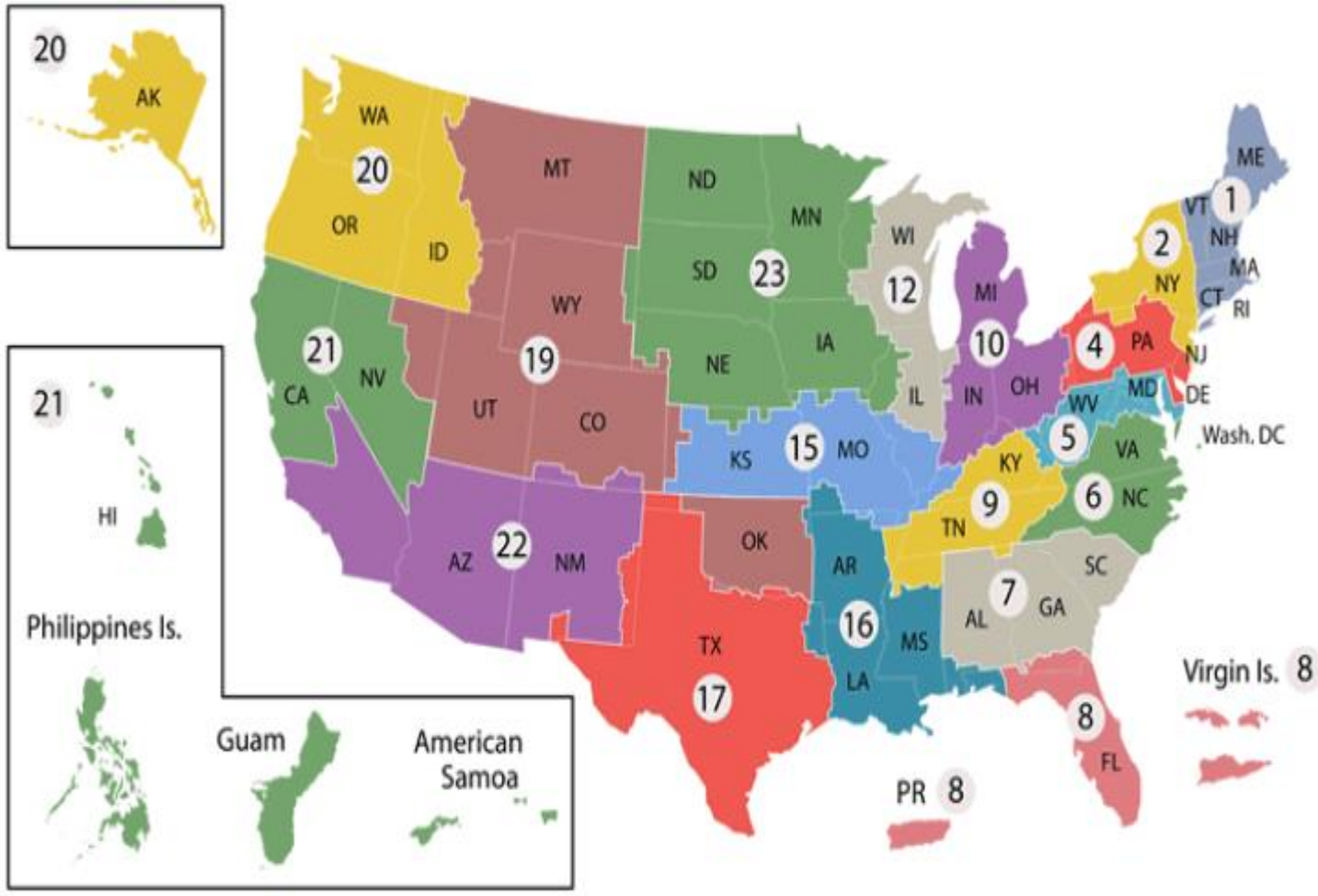
Discussion Points

- Overview of VA structure and Hep C program
- Outreach to difficult to reach populations
- Treatment compliance
- Universal Hep C testing and System Strategies

Veterans Health Administration (VHA) Structure

- 8.9 million Veterans enrolled in VA care
  - 172 VA Medical Centers and >1,000 outpatient clinics
- Organized into 18 Veteran Integrated Service Networks (VISNs)
- Robust EMR >25 years
- One national drug formulary
  - All DAAs covered
    - No prior authorization
    - No restrictions for liver disease, AUD/SUD, re-treatment
    - $11 copay/month for some Veterans



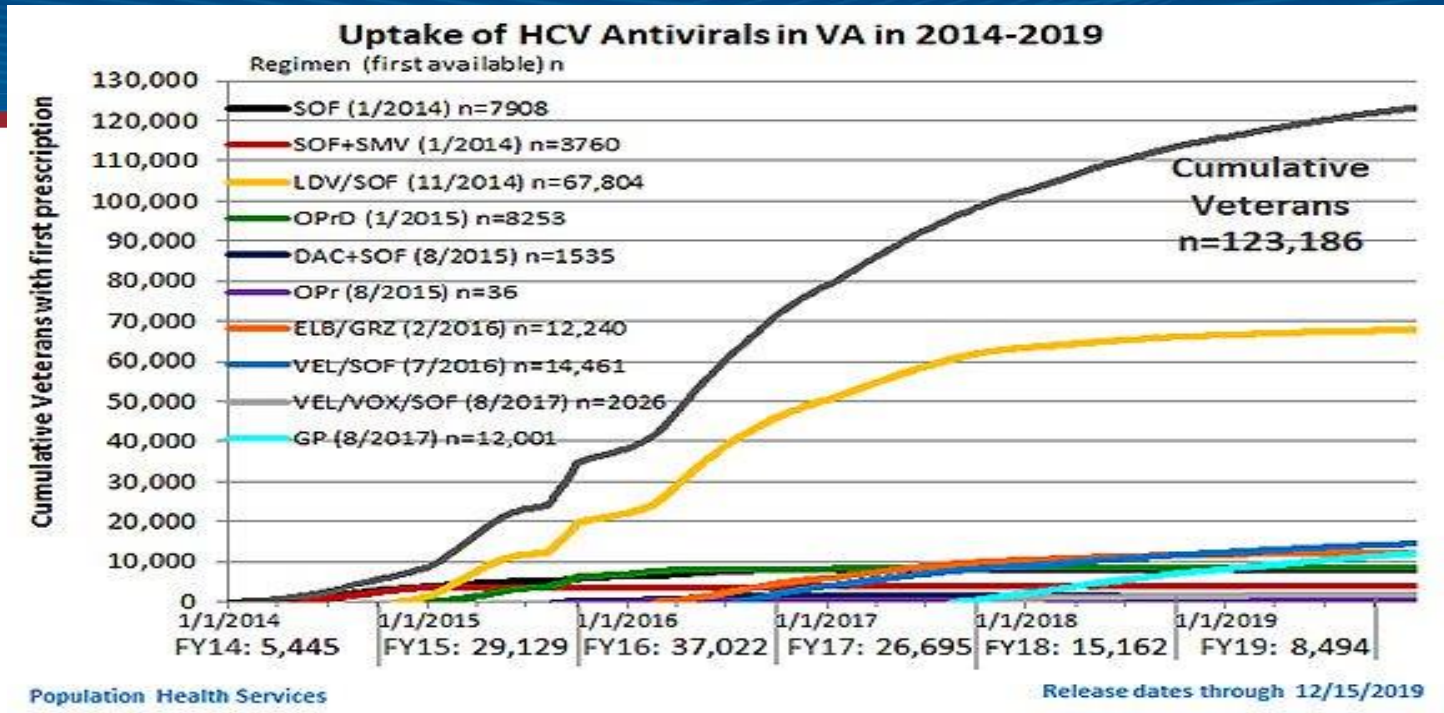
VA National Viral Hepatitis Program

- Established 2001
- Population health framework
  - VA National Hepatitis C Clinical Case Registry
- Policies and Reports
- Education
  - Patient booklets, fact sheets
  - Provider trainings and toolkits
- Comprehensive website

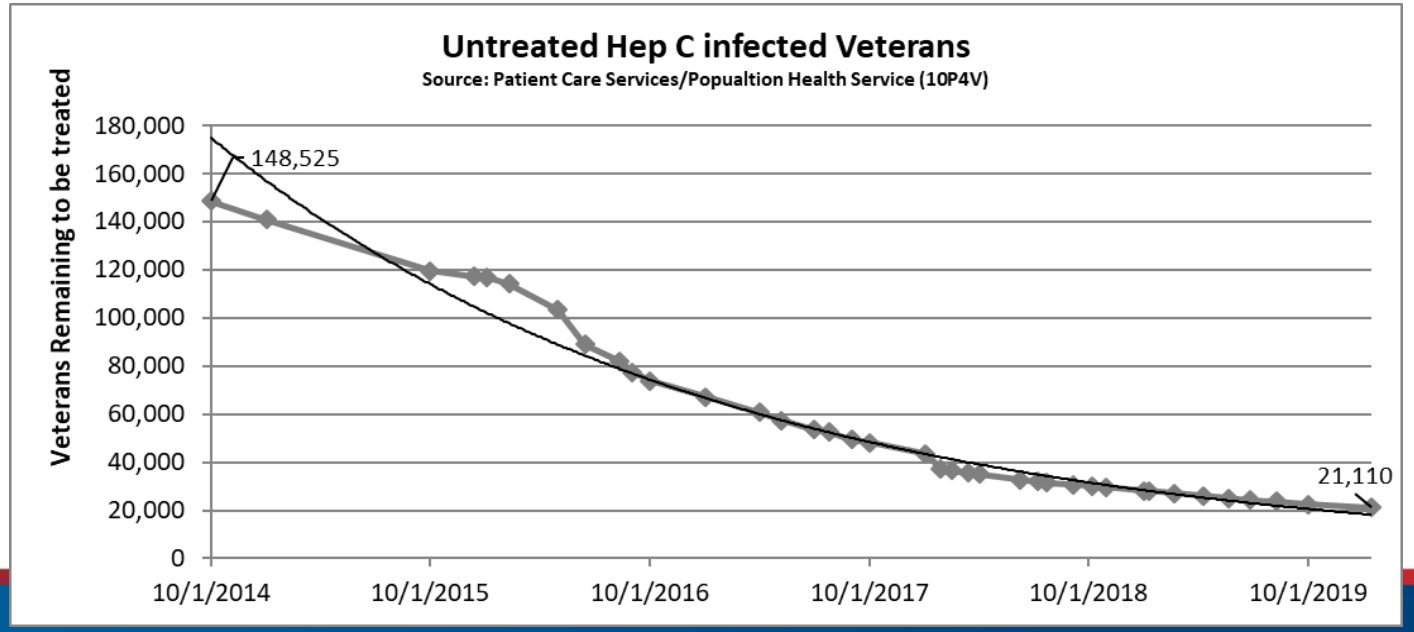
https://www.hepatitis.va.gov/

Progress!

- Over 123,000 Veterans have been treated with oral HCV antivirals since their availability in January 2014

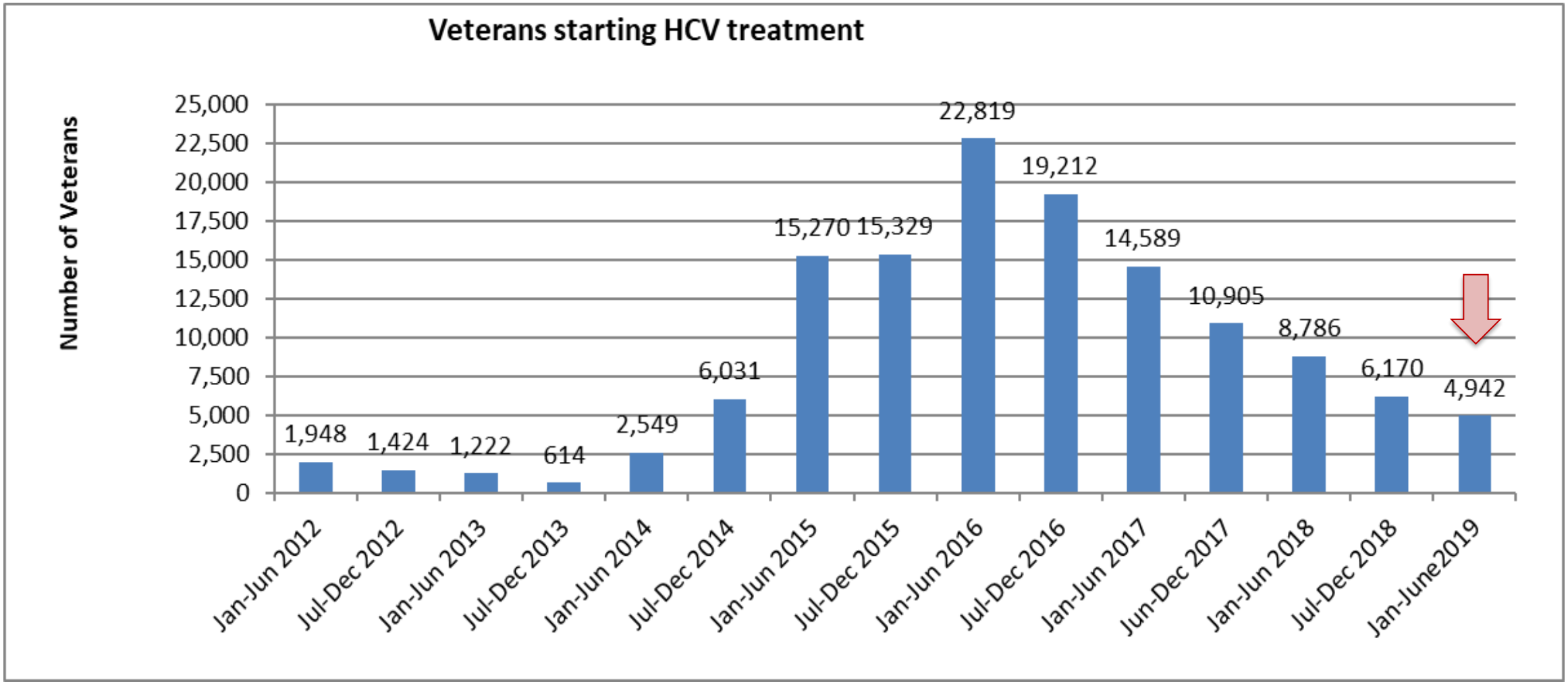


- ~21,000 Hep C patients in VA care remain to be treated
  - ~10,000-12,000 HCV-infected Veterans awaiting treatment are not currently willing or able to initiate/complete HCV treatment



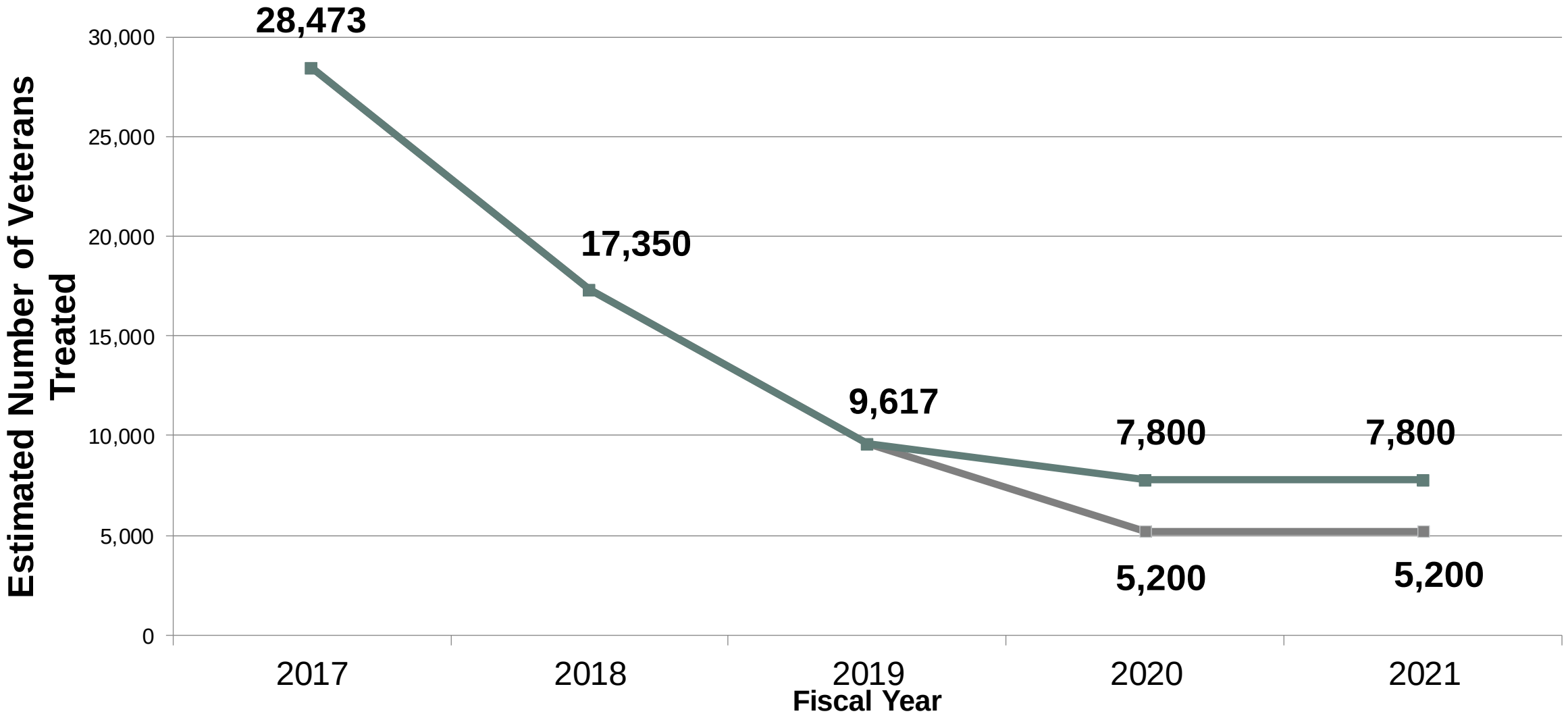
Source: CDW prepared by Population Health Services (10P4V)

VETERANS TREATED OVER TIME

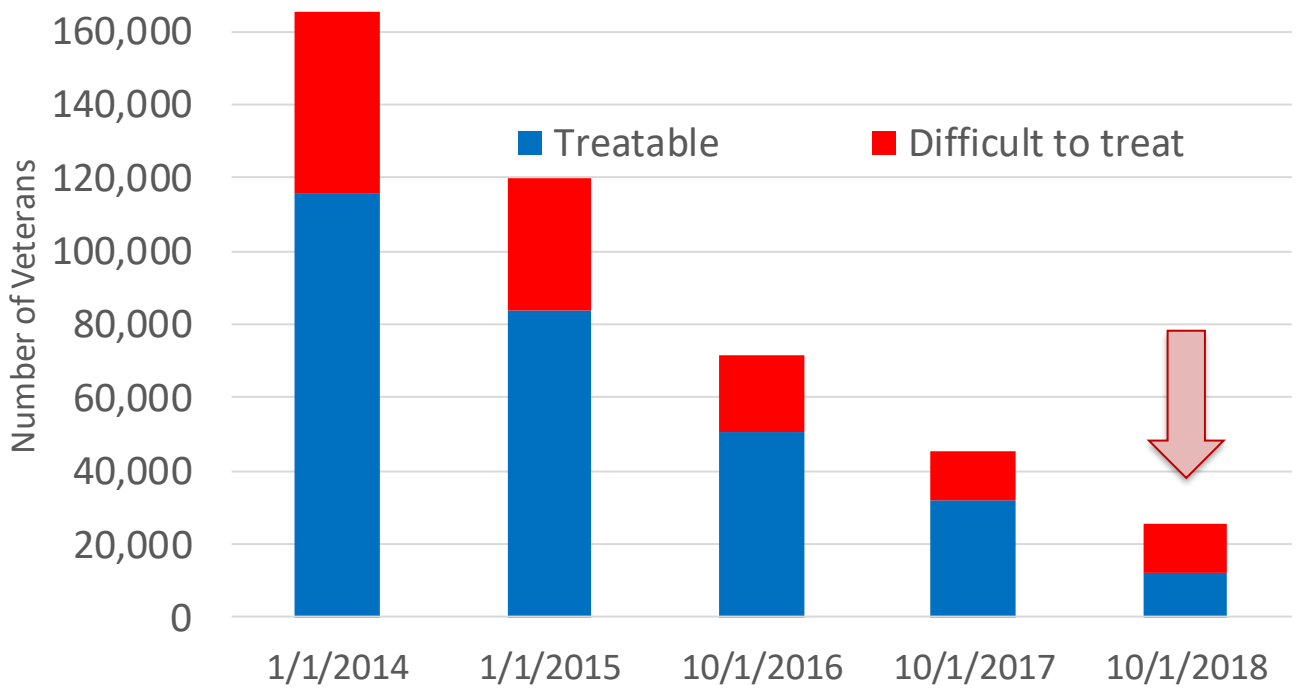


Report date 10/3/2019, source: CDW

Range of Projected HCV Treatment Starts FY20-FY21



Greater Proportion of Remaining HCV Viremic Veterans are Difficult to Engage in Care



Patient Determinants:

- Uninterested/declines treatment
- Inability to make contact by phone or mail
- Inability to adhere to therapy, medical appointments or treatment

Psychosocial Determinants:

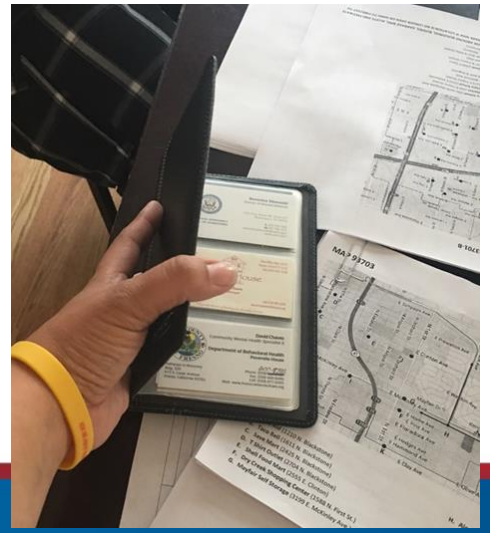
- Homelessness
- Rurality
- Transportation
- Substance or alcohol abuse
- Mental health

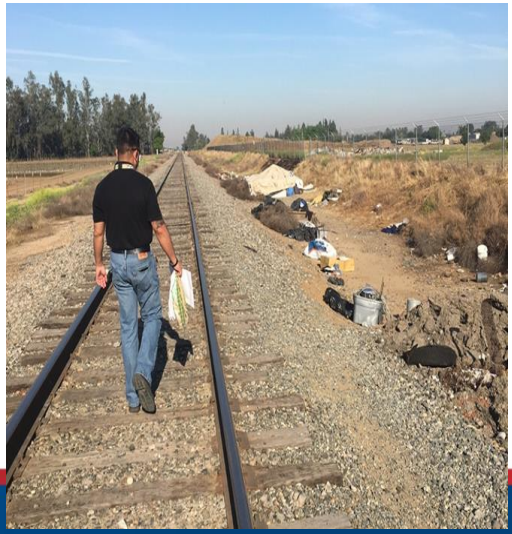
Source: CDW prepared by Population Health Services (10P4V)

Extra Steps: Difficult to Reach Populations

- Care coordination, case management
- Patient navigators
- Peer support specialists
- Transportation
- Contingency management
- Collaborate with Housing and Urban Development programs

Community Outreach Teams





Reducing Stigma

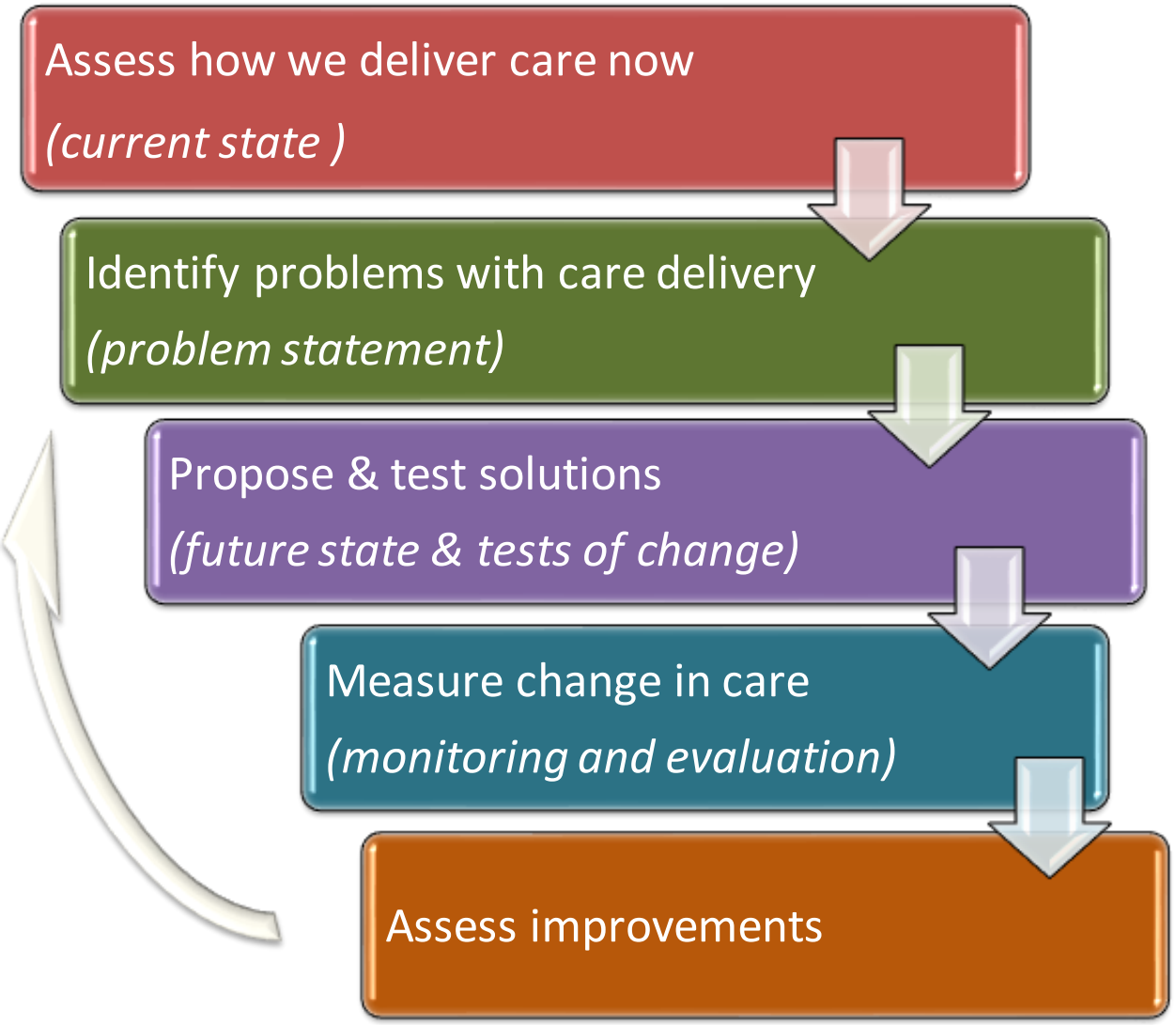
- Incorporate HCV treatment within other clinics
  - Buprenorphine or methadone clinics
  - Mental Health Clinics
  - Primary Care
- ➢ Patients may be more willing to accept treatment in a setting where they are already comfortable
- ➢ HCV treatment with co-occurring substance use treatment can lead to improvements in care
  - greater adherence to medical appointments, medication instructions
  - increased rates of HCV treatment completion
  - improved health status

Action to Improve Access and Service Delivery

- Alternative care/treatment delivery modalities
  - Telehealth
  - Video teleconferencing
  - Electronic consults
  - Group appointments
  - Mobile van outreach
  - SCAN ECHO model
- Integrated, streamlined care
  - Social work, Case management
  - Psychiatry, Psychology, Substance Abuse services

Bring Care to Where the People Are

Hepatitis C Innovation Teams (HITs)



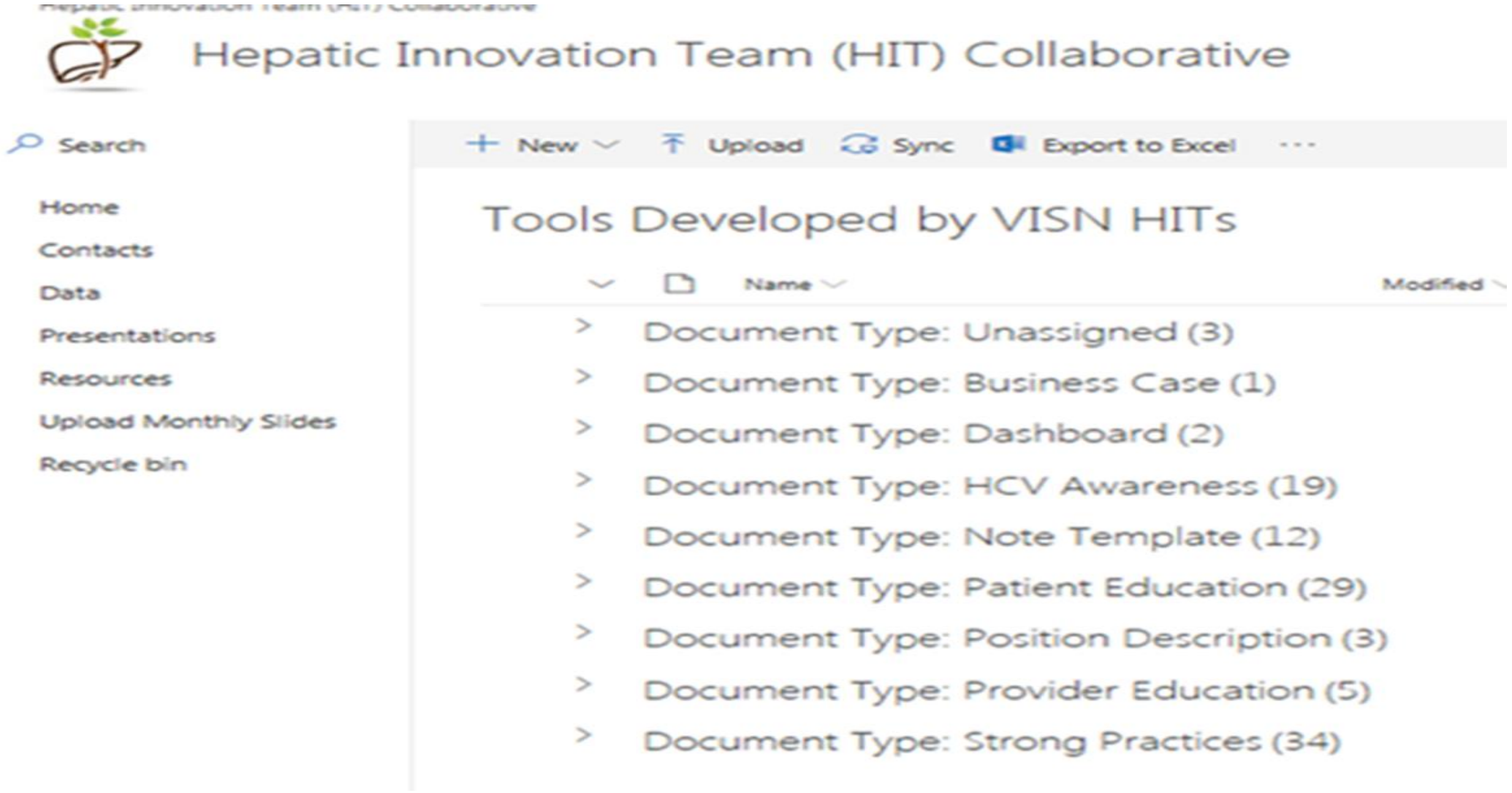
- **Lean** model: **redesign care** based on local processes and desired clinical outcomes
- **Disseminate best practices** that produce measurable improvements in HCV care
- **Multidisciplinary**, regional teams led by a HIT Coordinator(s); leadership support
- **Focused working groups** to address system needs
- Monthly virtual meetings to **share best practices, develop solutions, share strategies**
- Identify **low performers** and pair them with strong practices
- **Building community** among providers

Gap Analysis/Solutions: Example

Hurdle	Task	Hero
Homeless Veterans evaluated with template need to be triaged to HPACT	1. Educate staff on how to refer to HPACT	Jennifer
Confirm Eligibility for VA care during outreach to complete HCV screening and enroll in care	Obtain tablets with SQUARE software downloaded.	Kellie
Increase awareness about HCV testing and treatment for Homeless Veterans	1. Collaborate with community 2. Educate VA staff 3. Outreach materials to community organizations	Jennifer
Obtain Rapid HCV Point of care test kit	1. Identify purchaser: Cost: $17.50 per test, $30 for control solution 2. Policy for use: Lab Service 3. Identify necessary training/and or certification	Chris Sean
Identify need for Provider protocols	1. HPACT template for HCV testing and treatment	Dr. Wong

HPACT – homeless patient aligned care team

Access to Innovation



More than 104,617 Veterans have been CURED!

Sustained Virologic Response in Veterans in VHA Care Starting DAA Therapy in 2014 or Later for the Nation, by VISN and by Station

Nation

Started Rx	Stopped Rx	≥12 Weeks of Available Post-Treatment Follow-Up	≥14 Weeks of Available Post-Treatment Follow-Up	No SVR	SVR12	SVR4-11
122,060	121,035	119,163	118,842	3,152	104,617	4,156

* Included liver transplant patients: 670
* Excluded patients who died on treatment or within 12 weeks of stopping treatment: 1332

97% among those with SVR testing

88% among all patients starting treatment

What is happening to these patients?
Why are patients not completing treatment?

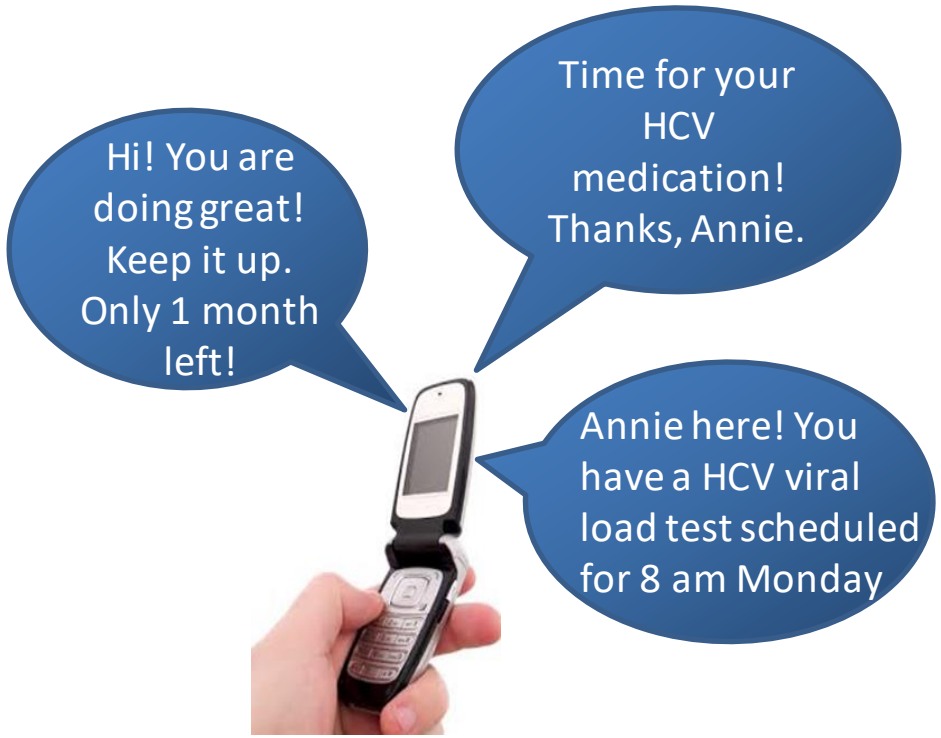
https://vaww.vha.vaco.portal.va.gov/sites/PublicHealth/pophealth/hcvantivirals/HCV%20Antivirals%20Tests/HCV_Direct_Acting_Antivirals.aspx

Numbers into Knowledge… and Action

HIT Collaborative HCV Goals FY19	National Rate	Data Source	Updated
Achieve 90% SVR in Veterans with chronic Hepatitis C (lagging measure)	75.2%	Population Health Services	12/28/2018
Increase (or sustain) Hepatitis C testing rate for birth cohort Veterans to 90% (leading measure)	84.8%	Population Health Services	12/31/2018
Treat 90% of viremic patients (leading measure)		Population Health Services	1/1/2019
Increase (or sustain) SVR12 testing rate for Veterans completing treatment to 90% (leading mea	89.8%	Population Health Services	12/28/2018

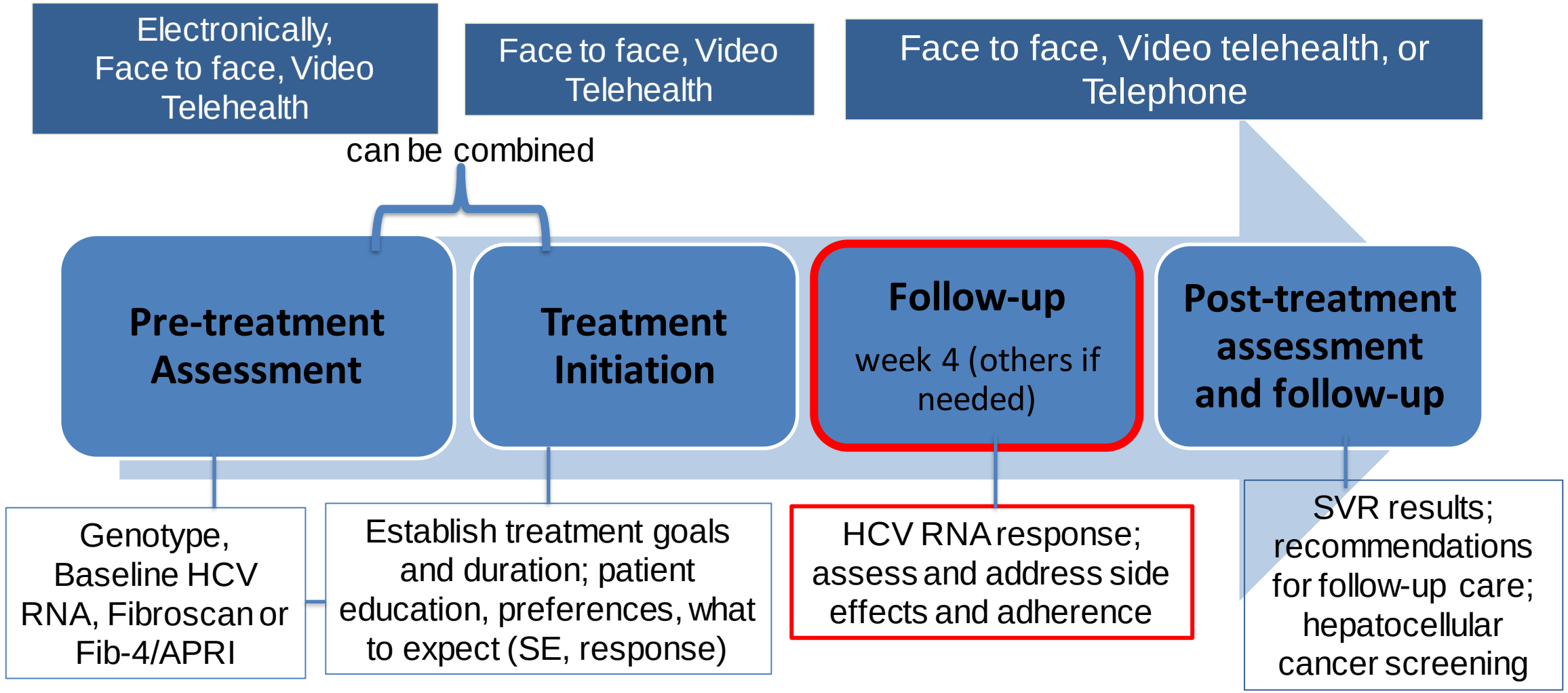
VISN 1 Current Performance		Birth Cohort Screening	Pts Currently Awaiting Tx	SVR12 Testing	SVR - Patients Cured
		81.76%	686 | 173	92.7%	2967
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Birth Cohort Screening	80.40% 6 in VISN 124 in Nation	85.59% 2 in VISN 69 in Nation	80.69% 5 in VISN 119 in Nation	87.64% 1 in VISN 53 in Nation	78.22% 8 in VISN 130 in Nation	79.86% 7 in VISN 126 in Nation	84.77% 4 in VISN 84 in Nation	84.83% 3 in VISN 82 in Nation
Pts Currently Awaiting Tx – FIB-4 <= 3.25	102	196	40	118	46	62	189	49
Pts Currently Awaiting Tx – FIB-4 > 3.25	17	49	10	27	21	11	49	13
SVR12 Testing	89.9% 7 in VISN 63 in Nation	91.0% 6 in VISN 50 in Nation	88.4% 8 in VISN 86 in Nation	93.5% 4 in VISN 21 in Nation	93.6% 3 in VISN 20 in Nation	92.6% 5 in VISN 33 in Nation	95.5% 1 in VISN 4 in Nation	94.1% 2 in VISN 13 in Nation
SVR - Patients Cured	133	754	209	238	417	292	678	246

MOBILE APP



- **Automated texting** to and from Annie allows Veterans to track and monitor their own health
- Clinicians can **create and assign automated protocols** and view graphed or individual Veteran responses
- ANNIE messages are **automated**

Keeping Patients *Engaged*



Where do we go from here?
Universal HCV Testing

CDC HCV TESTING RECOMMENDATIONS

1998

- ✓ Current/past injection drug users, including those who injected only once years earlier
- ✓ Received clotting factor concentrates produced before 1987
- ✓ Ever on long-term hemodialysis
- ✓ Persistently abnormal alanine aminotransferase levels
- ✓ HIV infection
- ✓ Prior recipients of transfusions or organ transplants

2012

- ✓ One-time screening with anti-HCV antibody testing for adults born from 1945 through 1965 regardless of risk

Expected in 2020

- ➢ Calling for universal HCV screening for all adults 18 and older at least once in their lifetime and for all pregnant women during each pregnancy

USPSTF Draft Recommendation Statement

Draft: Recommendation Summary

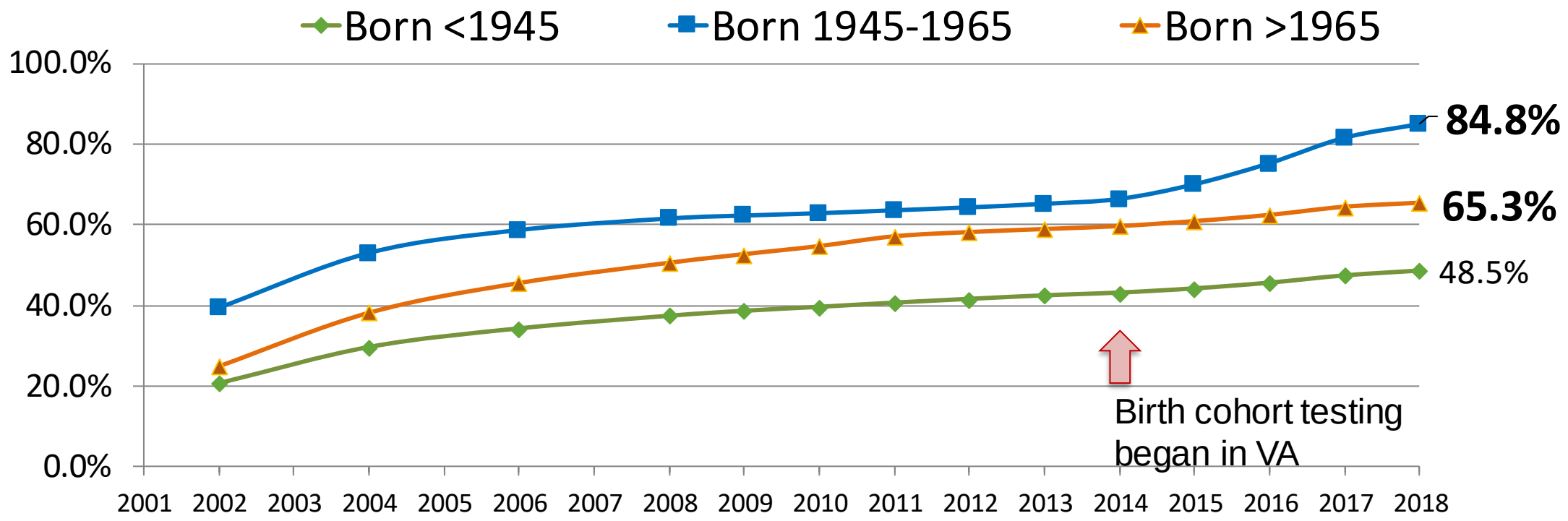
Population	Recommendation	Grade (What's This?)
Adults ages 18 to 79 years	The USPSTF recommends screening for hepatitis C virus (HCV) infection in adults ages 18 to 79 years.	B

AASLD/IDSA HCV Guidance

Recommendations for One-Time Hepatitis C Testing	
RECOMMENDED	RATING
One-time, routine, opt out HCV testing is recommended for all individuals aged 18 years and older.	I, B
One-time HCV testing should be performed for all persons less than 18 years old with behaviors, exposures, or conditions or circumstances associated with an increased risk of HCV infection (see below).	I, B
Periodic repeat HCV testing should be offered to all persons with behaviors, exposures, or conditions or circumstances associated with an increased risk of HCV exposure (see below).	IIa, C
Annual HCV testing is recommended for all persons who inject drugs and for HIV-infected men who have unprotected sex with men.	IIa, C

HCV Testing in Veterans in VA Care

VHA policy recommends one-time HCV testing for those born between 1945-1965, and continue risk-based testing for everyone else –this has always included Vietnam Era Veterans



HCV Testing – Clinical Strategies

1) Automated letters to untested birth cohort patients
   - Letter serves as a lab order
2) Clinical Reminder for Primary Care Providers in EMR
   - 2002–2013: risk-based screening
   - 2014–present: birth cohort AND risk based
3) Auto-reflex HCV RNA testing for HCV Ab+
4) Centralized labs
5) Performance Measure for Network Directors
6) Focus on at-risk groups by partnering with:
   - Mental Health and Substance Use providers
   - HUD-VASH (Veterans Affairs Supportive Housing)
   - Homeless stand-downs / testing events

Dear Veteran,

The [redacted] A Healthcare System wants to inform you about recent healthcare guidelines which recommend that individuals in your age group be screened for hepatitis C infection. Since there is no record of this blood test in your chart, we recommend that you be tested. Individuals who have hepatitis C often do not have any symptoms for many years but can still develop severe liver disease or even cancer. The VA now offers highly effective treatments for hepatitis C, with minimal side effects.

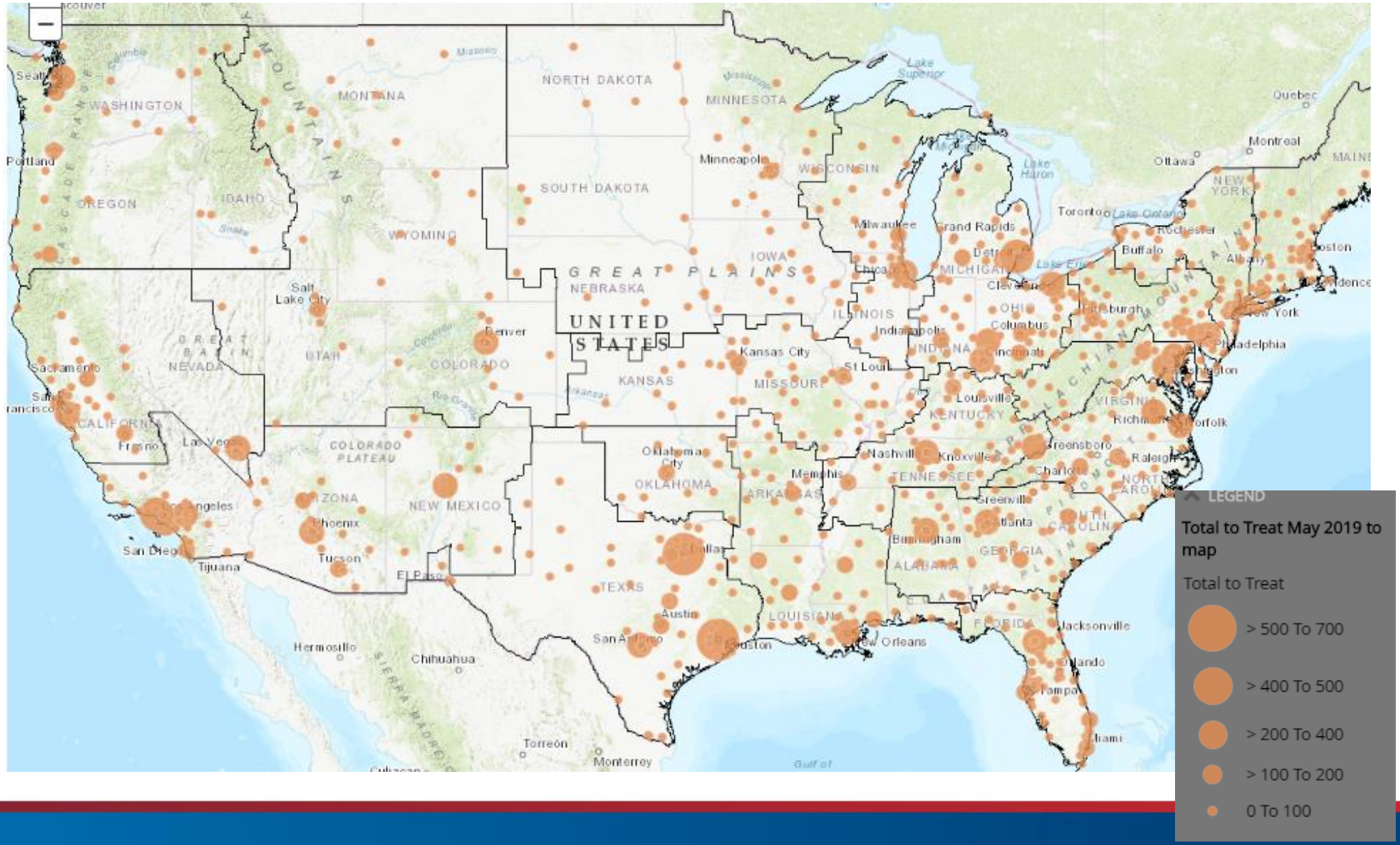
If you wish to be tested, simply bring this letter to the laboratory section during your next visit to the VA or tell the phlebotomist that you received a letter and desire a screening test for hepatitis C. Once testing is complete, you will receive a letter with test results or instructions for further evaluation if necessary.

Please call [redacted] if you have any questions.

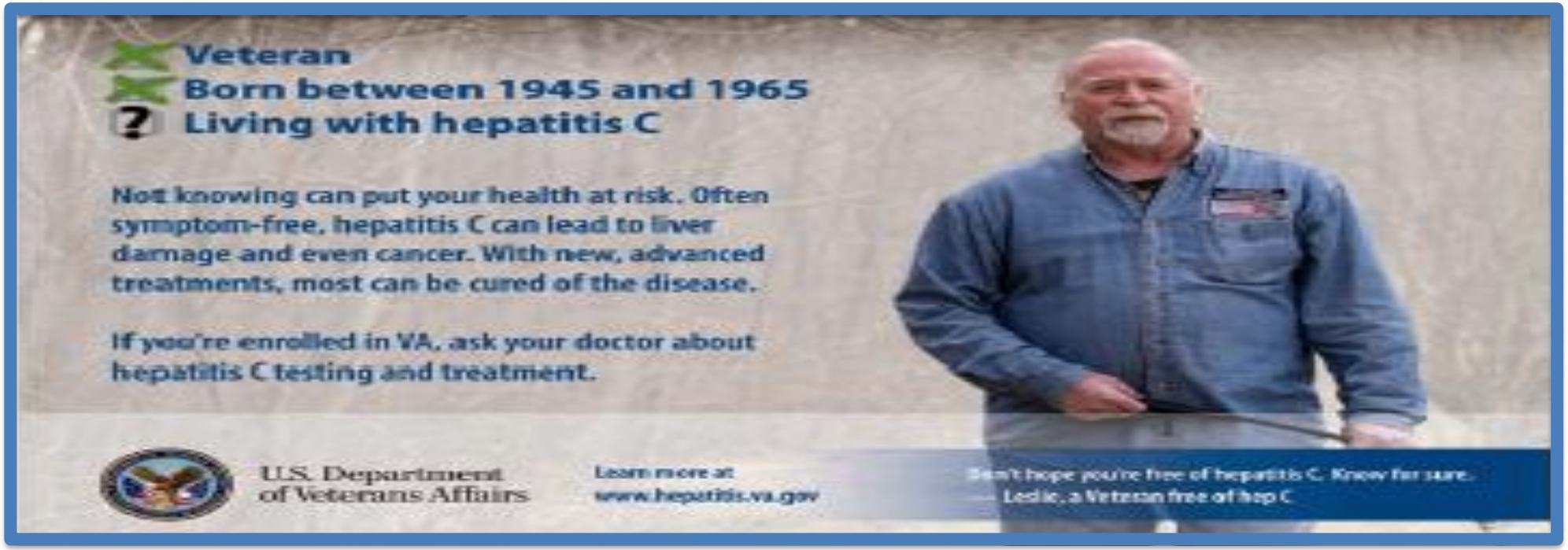
****
Lab Requisition: Hep C AB Total
****

Know your Population

- Map patient locations and resources available in the area
- Direct outreach: phone or letter
- Identify upcoming appointments
- Targeted multimedia campaigns



Multimedia marketing campaigns in high prevalence cities



New York Bronx, Baltimore, Philadelphia

Cleveland, Atlanta, Nashville, Birmingham

Bay Pines, Gainesville

Temple, Dallas, San Antonio, Houston, Denver

Los Angeles, Martinez, Palo Alto, Seattle

Be Ready for Action

- Opt-out HCV testing
- Offer same day HCV treatment starts
- System specific guidance, algorithms, templates
  - Standardized procedures/algorithms for evaluation, risk stratification, referral
- Consult templates with order sets
- Minimize office visits and tests

Summary Table: Treatment Considerations and Choice of Regimen for HCV-Monoinfected and HIV/HCV-Coinfected Patients

Updated August 27, 2018. *Within each genotype/treatment history/cirrhosis status category, regimens are listed in alphabetical order; this ordering does not imply any preference for a particular regimen unless otherwise indicated. Providers should consider the most clinically appropriate option based on patient individual characteristics.* ***Refer to listing in*** **Table 4. HCV Direct-Acting Antiviral Agents by Drug Class.** ***Dosages and administration are noted in footnotes.***

HCV GT	Treatment History	Cirrhosis Status	Treatment Option(s) (in alphabetical order)	Alternative Option(s) (in alphabetical order)
GT1	Naive	Non-cirrhotic	• **EBR/GZR** o If GT1a, test for NS5A RAS prior to treatment[a] o *If GT1a without baseline NS5A RAS:* 12 weeks o *If GT1b:* 12 weeks • **GLE/PIB** x 8 weeks • **LDV/SOF** o If HCV RNA is <6 million IU/mL and HCV-monoinfected: 8 weeks[a,b] o If HCV RNA is ≥6 million IU/mL: 12 weeks • **SOF/VEL** x 12 weeks	*If GT1a with baseline NS5A RAS[c]:* • **EBR/GZR + RBV** x 16 weeks
GT1	Naive	Cirrhotic, CTP A	• **EBR/GZR** o If GT1a, test for NS5A RAS prior to treatment[a] o *If GT1a without baseline NS5A RAS:* 12 weeks o *If GT1b:* 12 weeks • **GLE/PIB** x 12 weeks • **LDV/SOF** x 12 weeks o Consider adding RBV; refer to Table 7 for details • **SOF/VEL** x 12 weeks	*If GT1a with baseline NS5A RAS[c]:* • **EBR/GZR + RBV** x 16 weeks
GT1	Naive	Cirrhotic, CTP B, C	• **LDV/SOF + RBV** (600 mg/day and increase by 200 mg/day every 2 weeks as tolerated) x 12 weeks • **SOF/VEL + RBV** x 12 weeks; start at lower RBV doses as clinically indicated (e.g., baseline Hgb)[d]	• **LDV/SOF** x 24 weeks • **SOF/VEL** x 24 weeks
GT1	Experienced *(NS5A-naive; see Figure 1)*	Non-cirrhotic or Cirrhotic, CTP A	• **GLE/PIB** o *If PEG-IFN/RBV ± SOF-experienced:* 8 weeks if non-cirrhotic or 12 weeks if cirrhotic o *If N53/4A PI + PEG-IFN/RBV-experienced:* 12 weeks o *If SMV + SOF-experienced:* 12 weeks • **SOF/VEL** o *If GT1b and SOF-experienced:* 12 weeks o *If PEG-IFN/RBV ± NS3/4A PI-experienced:* 12 weeks *If only failed PEG-IFN/RBV ± NS3/4A PI:*	*If GT1a and SOF-experienced:* • **SOF/VEL/VOX** x 12 weeks *If GT1a with baseline NS5A RAS[c] and only failed PEG-IFN/RBV ± NS3/4A PI:* • **EBR/GZR + RBV** x 16 weeks

Moving towards Elimination

Issues/Obstacles	Strategies and Solutions
People unaware or uninterested	• Proactive identification and outreach with call or letter • Multimedia campaigns • Messaging in waiting rooms and public areas • Clinical reminders and alerts for providers
Geography or transportation	• Map HCV patient location and resources • Telehealth / virtual care / ECHO model • Mobile outreach
Delivery of treatment	• System specific standardized procedures/algorithms • Templates with order sets • Same day service • Integrate care with Mental health/Substance Use, Primary care
Capacity	• Open up prescribing and follow-up to other providers; NP, PA, PharmD, primary care • Night/weekend clinics • Group appointments

Build health center workforce capacity and expertise

	Detail
Shared Medical Appointments	• Focus on less complicated patients in a group setting • Group visit of 4-8 patients who will be starting treatment • Patients seen 2-4 times on treatment, based on duration of therapy, clinical need
Electronic (e) - consults	• Generate reports to identify patients needing treatment • Chart review to determine candidacy • Provide recommendations for HCV therapy initiation through electronic consult
HCV Telehealth	• Video or telephone follow-up appointments by mid-level providers • Use ECHO model to train providers to provide HCV care at their site (include mid-levels)
Rural Care	• Reach patients located in rural areas that would make travel to medical center clinics a barrier to accessing care • Once a month, provider visits community clinics to initiate treatment; follow-up with CVT or TH
HCV Process Map	• Flow map providing criteria of HCV patients that can be treated by PharmD • Develop site specific inclusion and exclusion criteria
Regional Specialist	• Clinician with HCV expertise in the region provides mentoring/education for other providers (NP,PA, PharmD, MD) • Spoke and hub model of training / resource for HCV related questions

Engaging Pharmacists in the Provision of HCV Care

- **HCV Testing**
  - Active identification and outreach to patients who require testing

→ Increased awareness of HCV in community

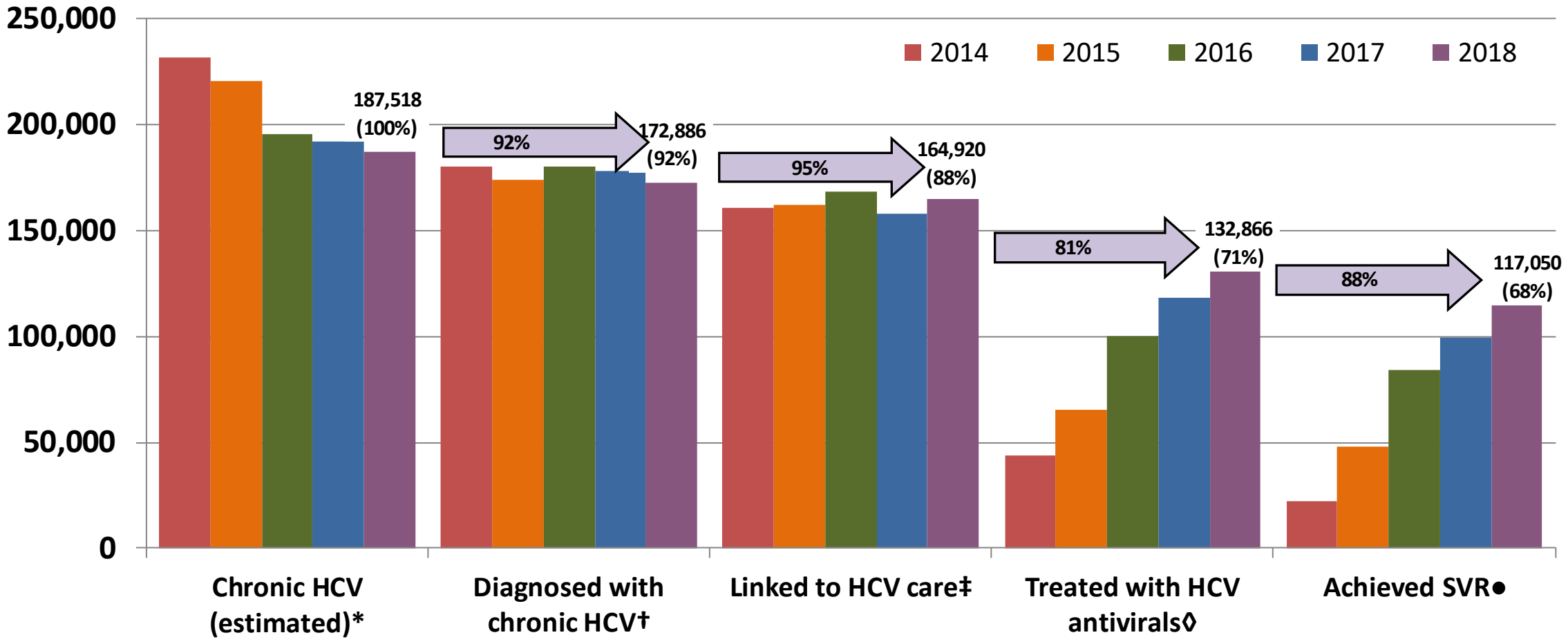
- **Identification of HCV patients as treatment candidates**
  - Report/lists of HCV viremic patients to discuss/evaluate for treatment
  - E-consults to specialists

→ -Improved linkage to care
-Increase treatment rates

- **Co-management / Treatment**
  - Increase capacity

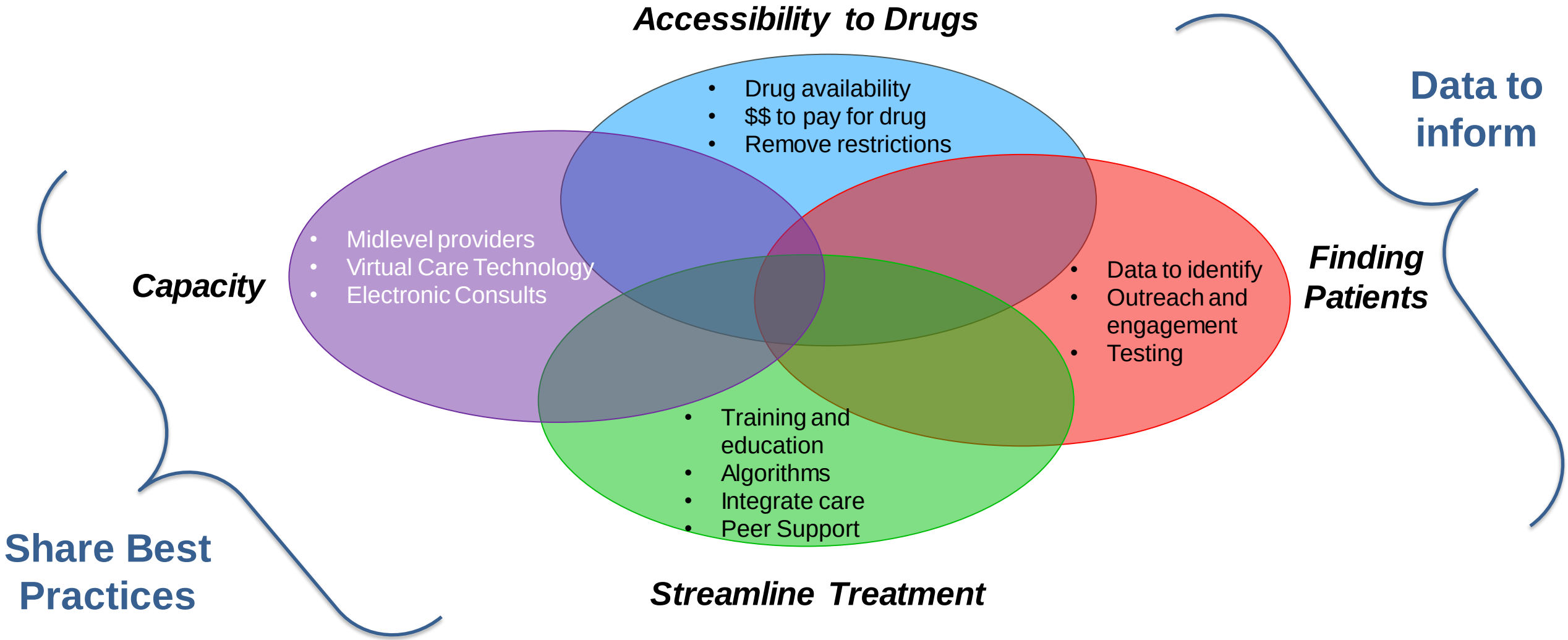
→ -Flexibility for patients
-Greater access
-Cost Avoidance: reduced drug costs from optimization of regimens; reduced drug-drug interactions; facilitation of timely medication refills; closely monitored adherence

VA HCV Cascade of Care Advancements



*Estimated from diagnosed+ratio of prevalence in birth cohort strata in those tested in prior two years applied to those still untested;
†Diagnosed with chronic HCV defined as ever had a detectable HCV RNA or genotype.
‡Linked to HCV care required an outpatient visit in the year, entry in the VHA's HCV registry and HCV entered on the patient's medical record problem list.
◊Treated with HCV antivirals defined as ever received HCV antivirals from VHA as of 31 December of the year.
●Achieved SVR defined as undetectable HCV RNA on all tests after end of treatment including at least one test at least 12 weeks after the end of treatment

Key Drivers of Success



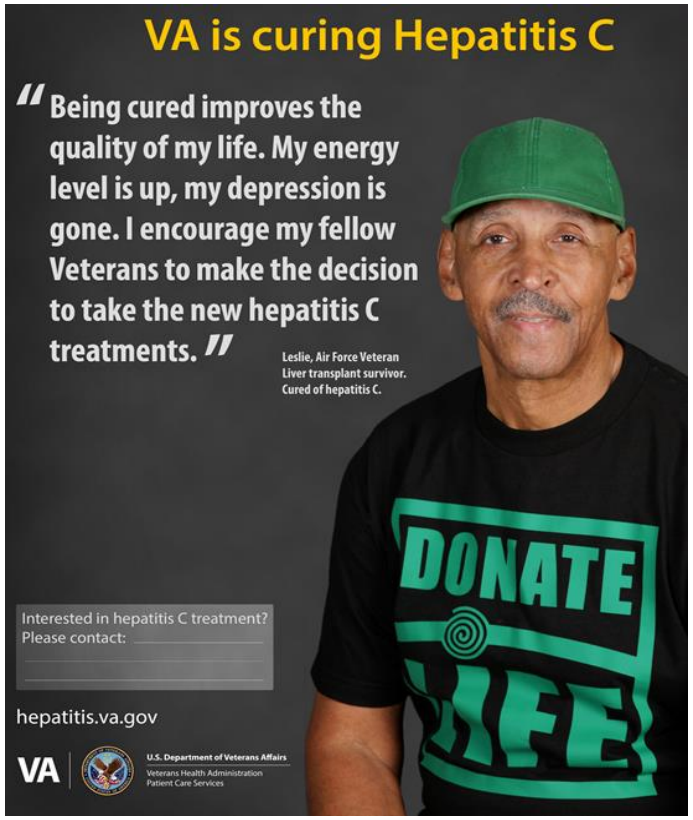
It takes a village…and then some

Whose woods these are I think I know.
His house is in the village though;
He will not see me stopping here
To watch his woods fill up with snow.

My little horse must think it queer
To stop without a farmhouse near
Between the woods and frozen lake
The darkest evening of the year.

He gives his harness bells a shake
To ask if there is some mistake.
The only other sound's the sweep
Of easy wind and downy flake.

The woods are lovely, dark and deep,
But I have promises to keep,
And miles to go before I sleep,
And miles to go before I sleep.

Special Thank You to all of our Veterans and dedicated Staff

- Thank You for choosing VA