L'evoluzione nel trattamento dell'epatite C: nuovi modelli di gestione

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Disclosures

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- Gilead Sciences
- Bristol-Myers Squibb
- Janssen-Cilag
- Viiv Healthcare
- Abbott Pharmaceuticals
- Merck Sharp and Dohme
- Abbvie
- Angelini
- GlaxoSmithKline
- Pfizer

HCV matters globally: the WHO has set a goal ...



... elimination of viral hepatitis as a major public health threat by 2030



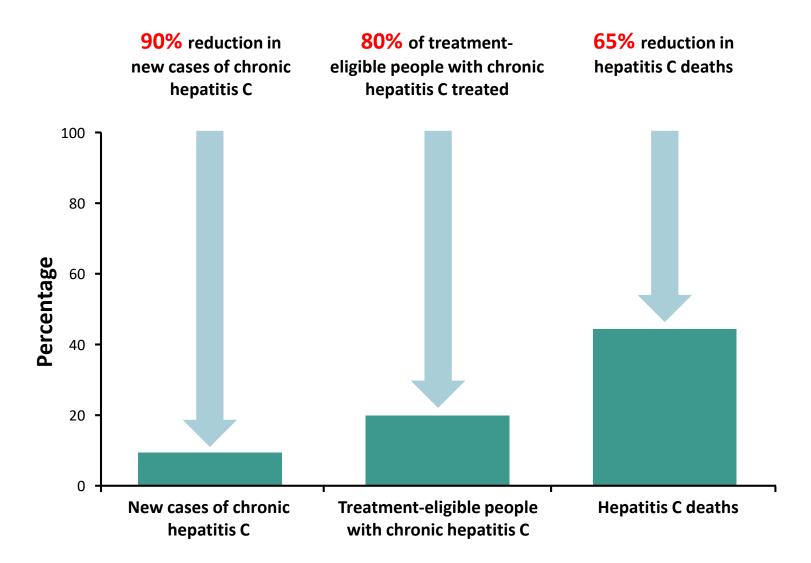
[•] WHO Global Health Sector Strategy on Viral Hepatitis, 2016–2021. Available at:

http://apps.who.int/iris/bitstream/10665/246177/1/WHO-HIV-2016.06-eng.pdf?ua=1; WHO. Combating Hepatitis B and C to Reach Elimination by 2030. Available at:

http://apps.who.int/iris/bitstream/10665/206453/1/WHO HIV 2016.04 eng.pdf?ua=1 (both accessed January 2018)

 Ambitious global targets have been set by the WHO in order to control viral hepatitis by 2030

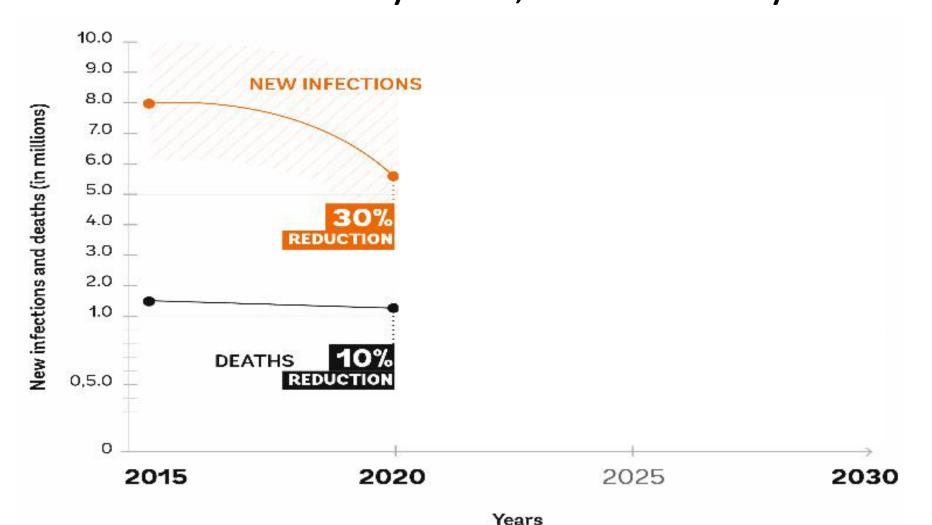




WHO Global Health Sector Strategy on Viral Hepatitis, 2016–2021. Available at:

http://apps.who.int/iris/bitstream/10665/246177/1/WHO-HIV-2016.06-eng.pdf?ua=1; (both accessed January 2018)

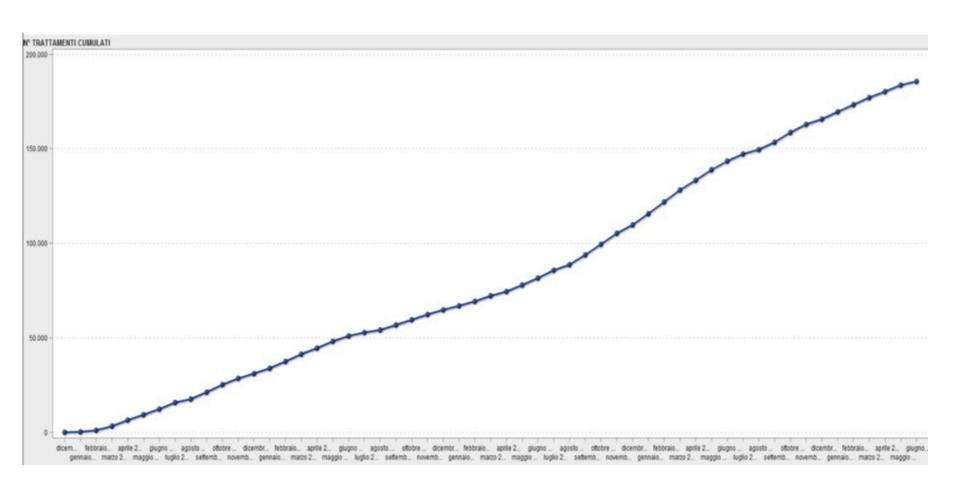
Eliminate viral hepatitis as a major public health threat by 2030, as defined by:



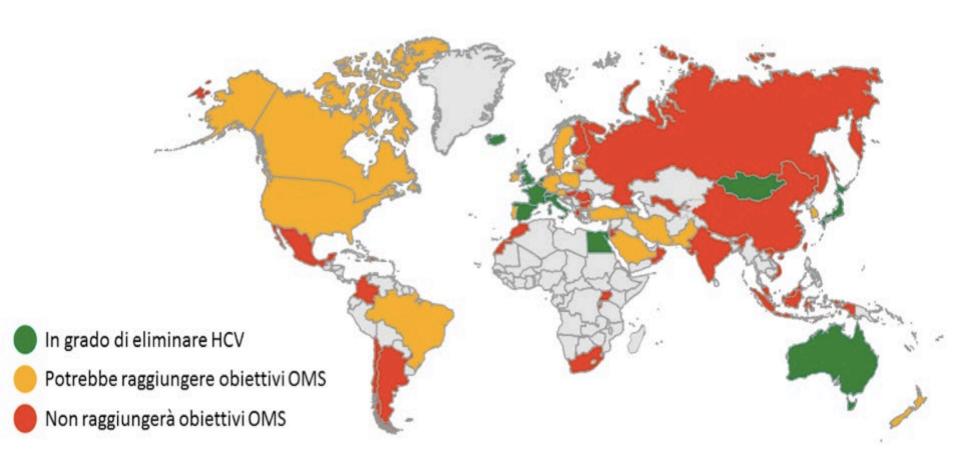
6-10 million infections (in 2015) to 900,000 infections (by 2030)

1.34 million deaths (in 2015) to under 500,000 deaths (by 2030)

24 giugno 2019 185.694 trattamenti «avviati»



Da una analisi dei dati del 2017 al momento solo 9 paesi a livello globale sono in linea con il raggiungimento degli obiettivi OMS



Anno in cui si stima venga raggiunto l'obiettivo 2030 OMS

Paese					Eliminazione
	Incidenza	<u>Mortalità</u>	Diagnosi	Tasso di <u>Trattamento</u>	
Spagna	2024	2020	2021	2020	2024
<u>Francia</u>	2025	2023	2016	2021	2025
Italia	2028	2023	NA	2029	2029
Regno Unito	2029	2028	2025	2023	2029
Germania	2027	2029	2031	2030	2031

Why Talk About Elimination?

We Now Have the Tools: They Fall Under 3 Main Pillars

Effective Care and Treatment

- 1-3 pills/day for 2-3 mos
- Cure rates > 95%
- Few or no adverse events



Prevention Strategies

- Harm reduction
- Needle/syringe programs
- Opioid agonist therapy

Simple Testing and Diagnosis

- Available blood tests
- Point-of-care tests
- Reflex testing





Combined, these tools can be used to eliminate hepatitis C as a public health problem







Why Talk About Elimination?

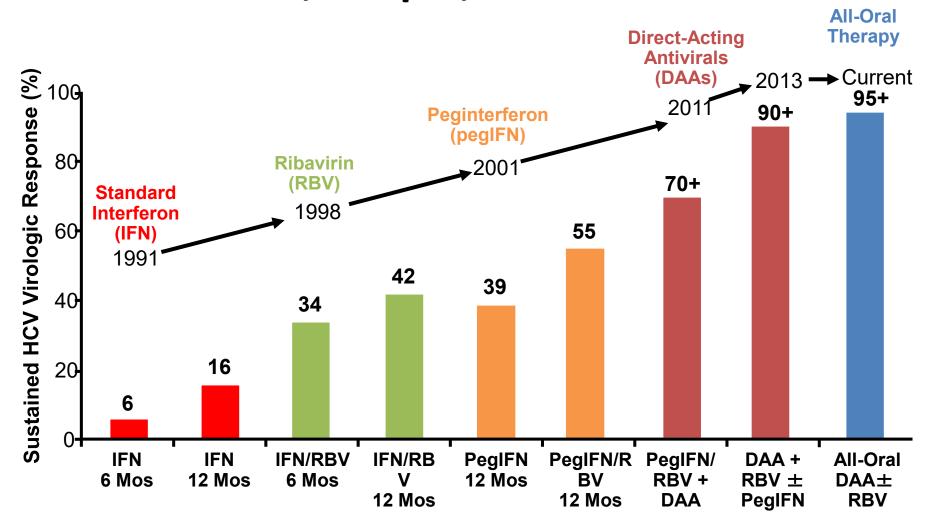
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Effective Care and Treatment

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- Cure rates > 95%
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Current All-Oral Therapies Highly Effective, Simple, Well Tolerated



HCV Direct-Acting Antivirals

Inhibitor Class	Suffix	Examples		
Targeting HC\	/ Protein Pro	ocessing		
NS3/4A protease	-PREVIR	 Glecaprevir, grazoprevir, voxilaprevir 		
Targeting HCV Replication				
NS5 B polymerase	-BUVIR	Nucleos(t)ide: sofosbuvir		
NS5A	-ASVIR	 Elbasvir, ledipasvir, pibrentasvir, velpatasvir 		

Treatment recommendations for HCV-monoinfected or HCV/HIV-coinfected patients with chronic hepatitis C without cirrhosis, including treatment-naïve patients and treatment-experienced patients

Patients	Prior treatment experience	SOF/VEL	GLE/PIB	SOF/VEL/VOX	SOF/LDV	GZR/EBR	OBV/PTV/r + DSV
Genotype 1a	Treatment-naïve	12 wk	8 wk	No	8-12 wk	12 wk (HCV RNA ≤800,000 IU/ml)	No
	Treatment-experienced	12 wk	8 wk	No	No	12 wk (HCV RNA ≤800,000 IU/ml)	No
Genotype 1b	Treatment-naïve	12 wk	8 wk	No	8-12 wk	8 wk (F0-F2) 12 wk (F3)	8 wk (F0-F2) 12 wk (F3)
45.55	Treatment-experienced	12 wk	8 wk	No	12 wk	12 wk	12 wk
Canabina 2	Treatment-naïve	12 wk	8 wk	No	No	No	No
Genotype 2	Treatment-experienced	12 wk	8 wk	No	No	No	No
Constant 2	Treatment-naïve	12 wk	8 wk	No	No	No	No
Genotype 3	Treatment-experienced	12 wk	12 wk	No	No	No	No
Genotype 4	Treatment-naïve	12 wk	8 wk	No	12 wk	12 wk (HCV RNA ≤800,000 IU/ml)	No
	Treatment-experienced	12 wk	8 wk	No	No	No	No
Genotype 5	Treatment-naïve	12 wk	8 wk	No	12 wk	No	No
	Treatment-experienced	12 wk	8 wk	No	No	No	No
Canatina 6	Treatment-naïve	12 wk	8 wk	No	12 wk	No	No
Genotype 6	Treatment-experienced	12 wk	8 wk	No	No	No	No

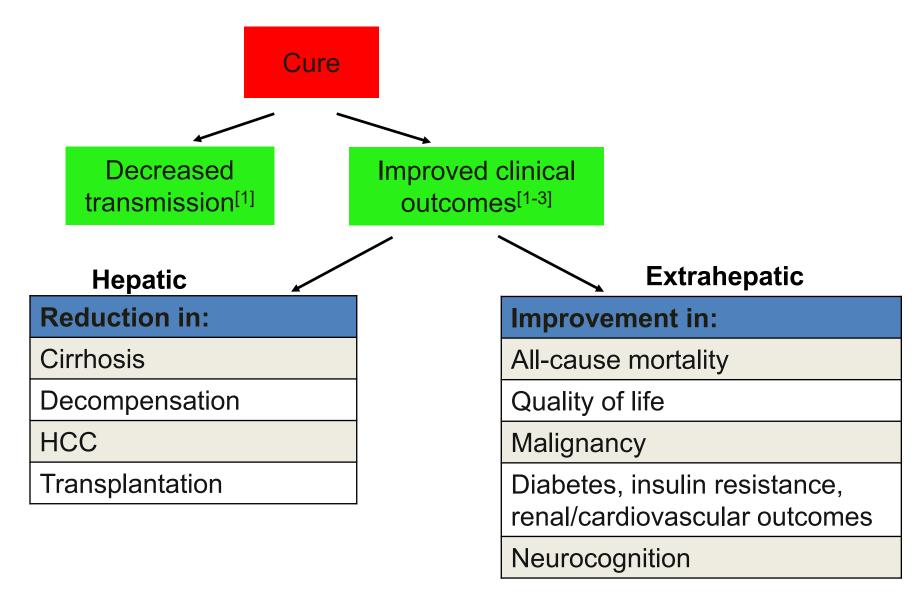
EASL Recommendations on Treatment of Hepatitis C 2018

Treatment recommendations for HCV-monoinfected or HCV/HIV-coinfected patients with chronic hepatitis C with compensated (Child-Pugh A) cirrhosis, including treatment-naïve patients and treatment-experienced

Patients	Prior treatment experience	SOF/VEL	GLE/PIB	SOF/VEL/VOX	SOF/LDV	GZR/EBR	OBV/PTV/r + DSV
Genotype 1a	Treatment-naïve	12 wk	12 wk	No	12 wk	12 wk (HCV RNA ≤800,000 IU/ml)	No
	Treatment-experienced	12 wk	12 wk	No	No	12 wk (HCV RNA ≤800,000 IU/ml)	No
Constant 1h	Treatment-naïve	12 wk	12 wk	No	12 wk	12 wk	12 wk
Genotype 1b	Treatment-experienced	12 wk	12 wk	No	12 wk	12 wk	12 wk
Genotype 2	Treatment-naïve	12 wk	12 wk	No	No	No	No
	Treatment-experienced	12 wk	12 wk	No	No	No	No
Genotype 3	Treatment-naïve	No	12 wk	12 wk	No	No	No
	Treatment-experienced	No	16 wk	12 wk	No	No	No
Genotype 4	Treatment-naïve	12 wk	12 wk	No	12 wk	12 wk (HCV RNA ≤800,000 IU/ml)	No
	Treatment-experienced	12 wk	12 wk	No	No	No	No
Genotype 5	Treatment-naïve	12 wk	12 wk	No	12 wk	No	No
	Treatment-experienced	12 wk	12 wk	No	No	No	No
	Treatment-naïve	12 wk	12 wk	No	12 wk	No	No
Genotype 6	Treatment-experienced	12 wk	12 wk	No	No	No	No

EASL Recommendations on Treatment of Hepatitis C 2018

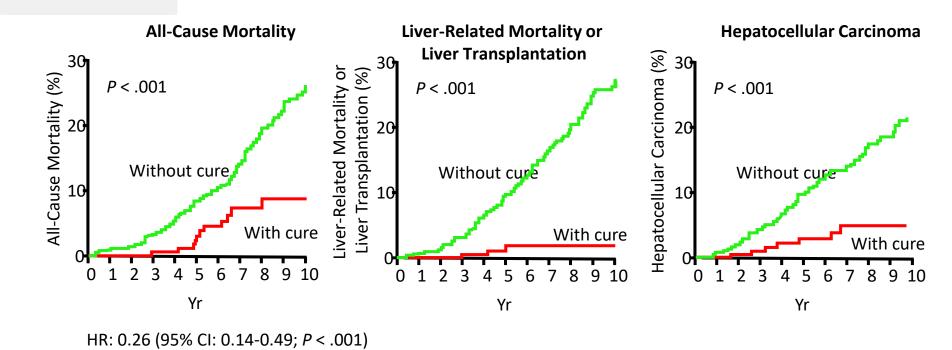
Benefits of Curing HCV Extend Beyond the Liver



^{1.} Smith-Palmer J, et al. BMC Infect Dis. 2015;15:19. 2. Negro F, et al. Gastroenterology. 2015;149:1345-1360. 3. George SL, et al. Hepatology. 2009;49:729-738.

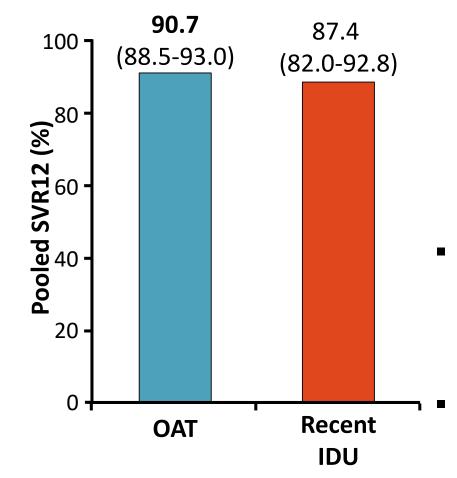


Hepatitis C Virologic Cure Associated With Improved Outcomes

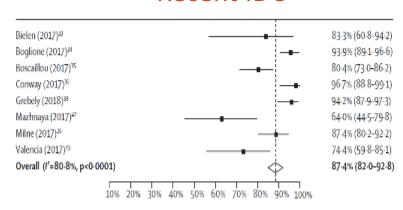


Virologic cure does not protect against reinfection

HCV DAA Therapy Is Effective Among PWID, Even in the "Real-World"

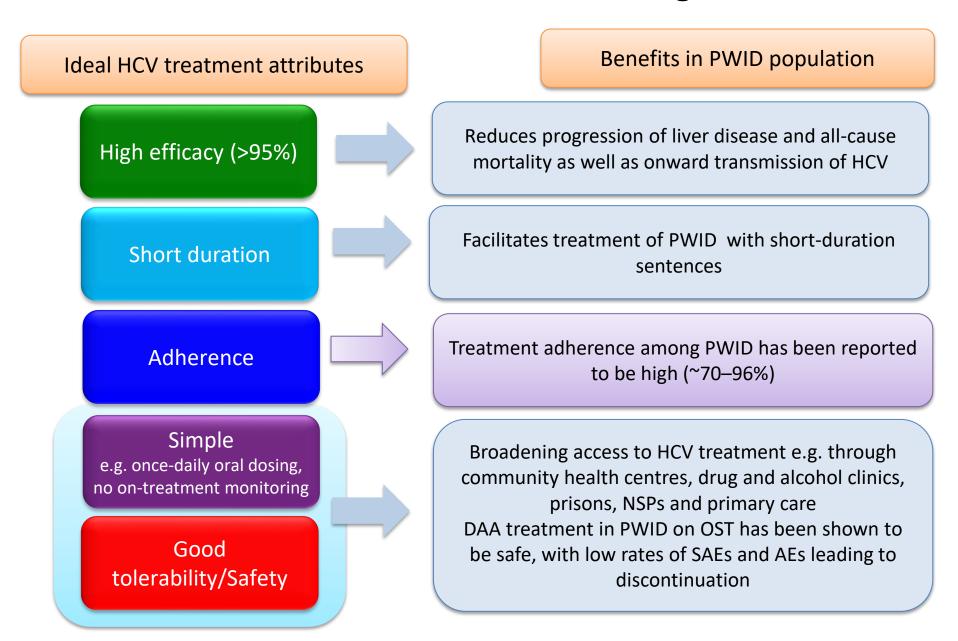


Recent IDU



- In meta-regression analysis, clinical trials significantly associated with higher SVR rates vs observational studies
 - aOR: 2.18 (95% CI: 1.27-3.75; P = .006)
 - Difference due to loss to follow-up, not virologic failure

Attributes of an Ideal HCV Treatment Regimen for PWID

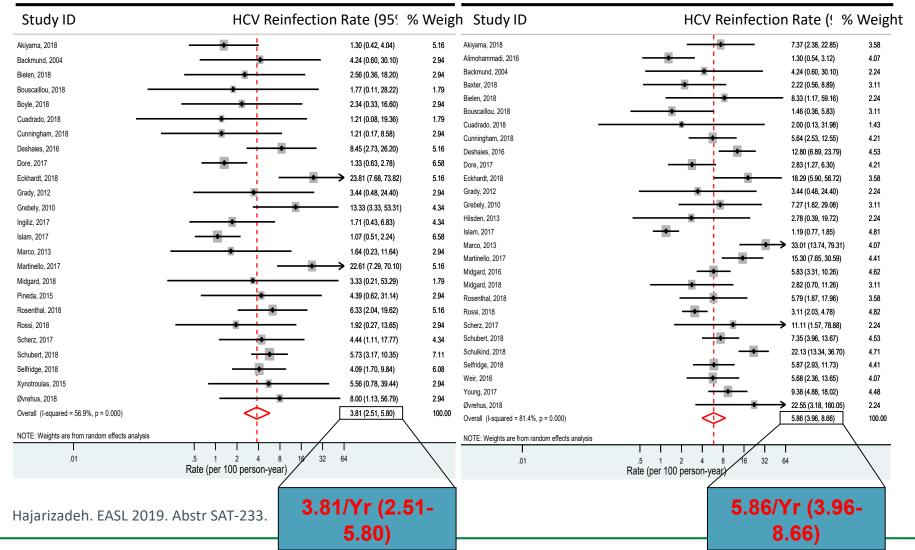


NSP, needle/syringe program; PWID, people who inject drugs.

HCV Reinfection After SVR Among PWIDs



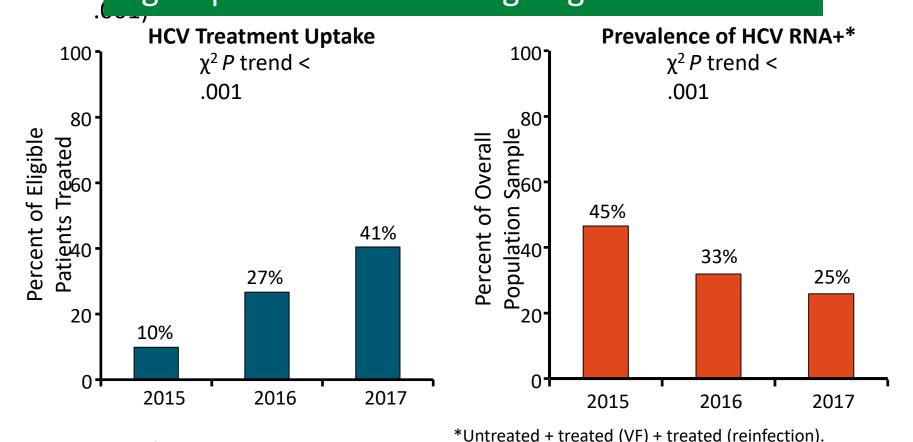
Recent IDU



High HCV Treatment Uptake Among People With Ongoing IDU and Evidence of Treatment as

Prev
Population-level evidence of decrease in
prevalence of HCV viremia among
group most at risk of ongoing transmission

rend <



Iversen. J Hepatol. 2019;70:33.

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Prevention Strategies

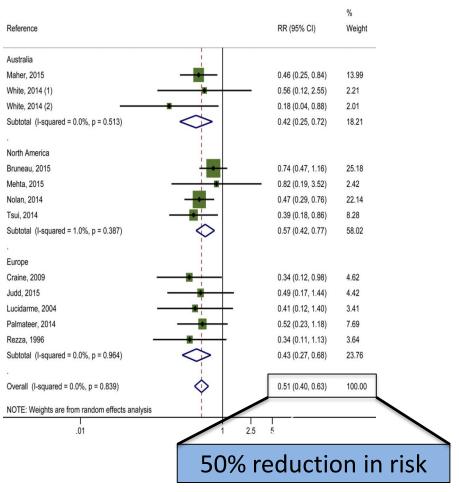
- Harm reduction
- Needle/syringe programs
- Opioid agonist therapy



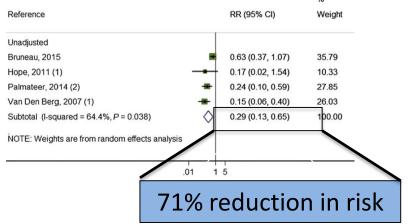


HCV Prevention Among PWID: Harm Reduction and Drug User Health

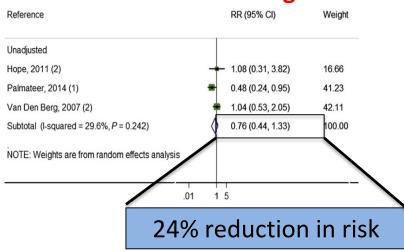
OAT (Methadone/Buprenorphine)



OAT + High Coverage S\(\subseteq P \)



OAT + Low Coverage SSP



Why Talk About Elimination?

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Simple Testing and Diagnosis

- Available blood tests
- Point-of-care tests
- Reflex testing



More than 100k patients are estimated to be drug related, while 230k were infected by glass syringes or transfusions

Patient estimate (considering transmission routes overlap and DAAs treatment)

Transmission route		N. patients¹ (before DAAs)	DAAs cured patients ²	New infections ³	Actual infected ⁴
	Drug related	113.995	12.564	441	101.871
Ø,	MSM with sexual risk practices	39.458	7.990	454	31.922
†	Tattoo & piercing	91.120	15.729	497	75.888
I	Blood transfusion	153.369	34.024	0	119.345
	Vertical transmission	16.738	3.415	42	13.365
	Glass syringe	142.891	32.933	0	109.958
?	Unknown risk factor	136.300	31.661	667	105.306
	Total	693.870	138.316	2.100	557.654

^{1.} Epidemiological model output

185.694 510.276

^{2.} Data from Registri AIFA split by risk factor using model output fibrosis distribution by transmission route

^{3.} Analysis based on bollettino SEIEVA data and expert opinion

^{4.} Column 1 – column 2 + column 3 = current HCV-RNA+ population

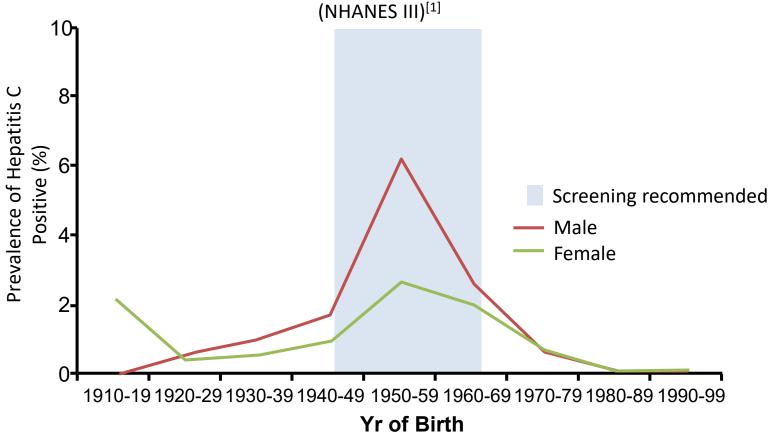
CDC, USPSTF, and AASLD/IDSA HCV Screening Recommendations

Populati on	Recommendation
Age	One-time screening is recommended for persons born between 1945 and 1965, without ascertainment of HCV risk ^[1-3]

- 1. Smith BD, et al. MMWR Recomm Rep. 2012;61(RR-4):1-32.
- 2. US Preventive Services Task Force. HCV Screening Guidelines 2013.
- 3. AASLD/IDSA. HCV Guidelines 2017.

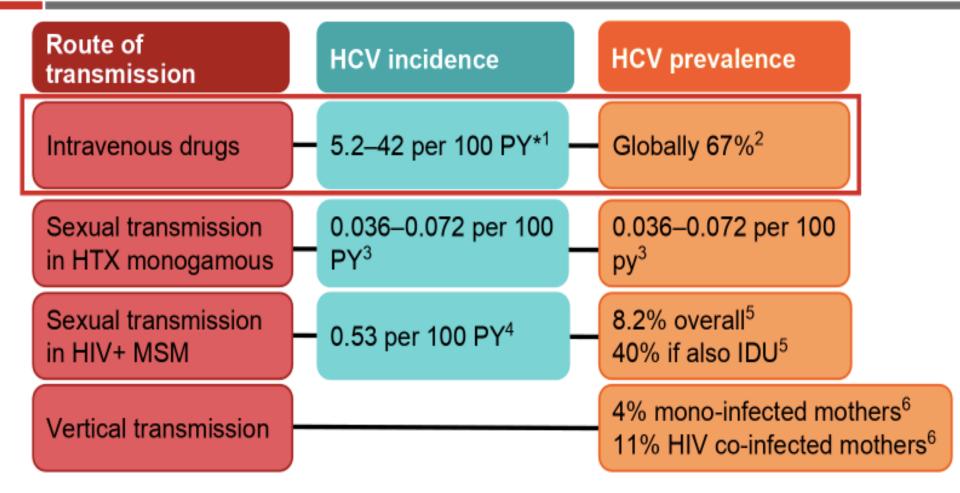
Hepatitis C Prevalence Is Increased in Baby Boomers

Prevalence of Hepatitis C Antibody Positivity in US Population by Sex by Yr of Birth



^{1.} Iwasaki K, et al. ISPOR 2010. Abstract PG17.

Injection drug use is a major route of HCV transmission



 From 1992, very little iatrogenic or nocicomal HCV transmission in developed countries, but high occurence in low income countries prevails⁷

*Current or recent injectors. HTX; heterosexual; IDU; injecting drug user;

MSM: men who have sex with men; PY: person-years

Wiessing L, et al. PLoS One 2014;9:e103345; 2. Grebely J, et al. Antiviral Res 2014;104:62–72; 3. Terrault N, et al. Hepatology 2013;57:881–9; 4. Hagan H, et al. AIDS 2015;29:2335–45; 5. Jordan AE, et al. Int J STD AIDS 2017:28:145–59; 6. Muñoz-Almagro C, et al. Med Clin (Barc) 2002;12:452–4;
 Shepard CW, et al. Lancet Infect Dis 2005;5:558–67

CDC, USPSTF, and AASLD/IDSA HCV Screening Recommendations

Population	Recommendation
Age	One-time screening is recommended for persons born between 1945 and 1965, without ascertainment of HCV risk ^[1-3]
Risk	One-time screening is recommended for persons with these risk factors ^[1,3] : History of illicit injection drug use (IDU) or intranasal illicit drug use History of long-term hemodialysis Receiving a tattoo in an unregulated facility/setting Healthcare workers upon accidental exposure Children born to anti-HCV-positive mothers History of transfusion with blood or organ transplantation before July 1992 Were ever in prison HIV infection Chronic liver disease/hepatitis with unknown cause, including elevated liver enzymes

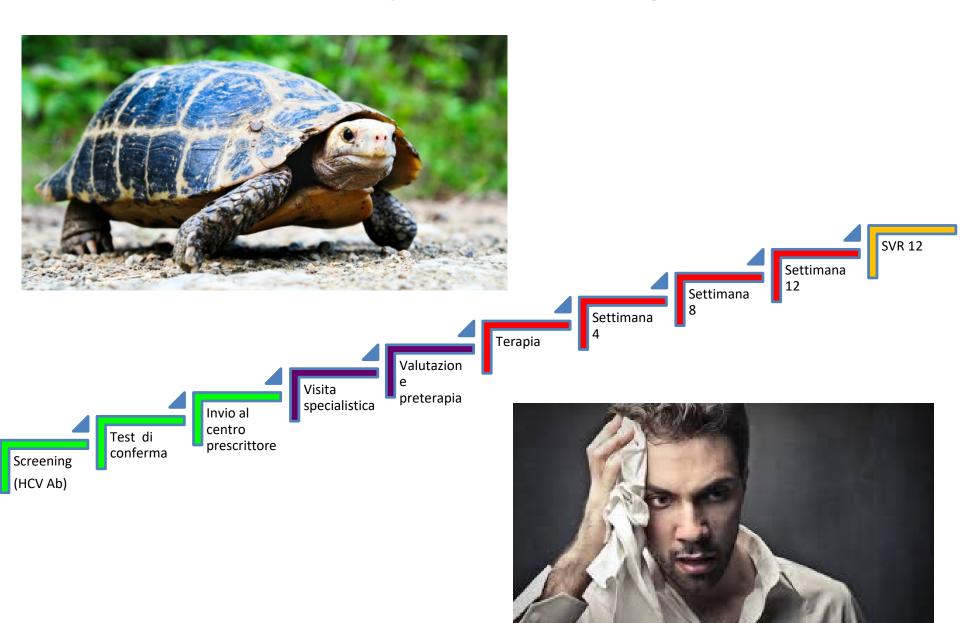
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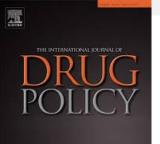
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1. Smith BD, et al. MMWR Recomm Rep. 2012;61(RR-4):1-32. 2. US Preventive Services Task Force. HCV Guidelines 2013. 3. AASLD/IDSA. HCV Guidelines 2017.

Tools for Improved Linkage to Care

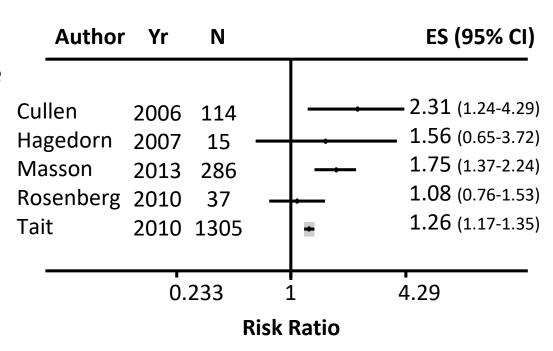




Efficacy of Facilitated Referral for Supporting Linkage to HCV Care

- Systematic literature review and meta-analysis of PWID interventional studies up to July 20, 2016
- 14 studies included; 57% were RCTs
- Interventions to enhance linkage to care included facilitated referral for HCV assessment and scheduling of specialist appointments for clients
- All studies from IFN treatment era and none in low- or middle-income countries

Effect of Facilitated Referral on HCV Linkage to Care





PWID: richiedono approcci specifici di salute pubblica dovute a caratteristiche specifiche di:

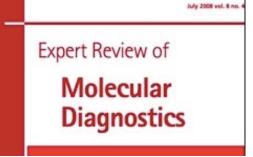
- Alta incidenza
- Alta prevalenza
- Stigma
- Discriminazione
- Difficoltà all'accesso ai servizi

Il modello tradizionale di servizio sanitario nel quale il paziente cerca e trova il servizio, non funziona in questi gruppi

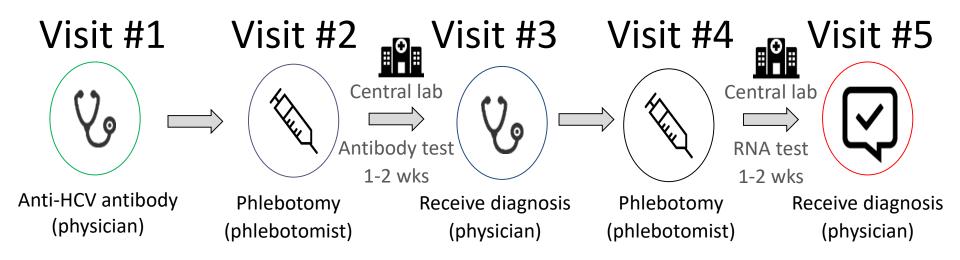


Servono modelli in cui il servizio sanitario cerca pazienti in questi gruppi



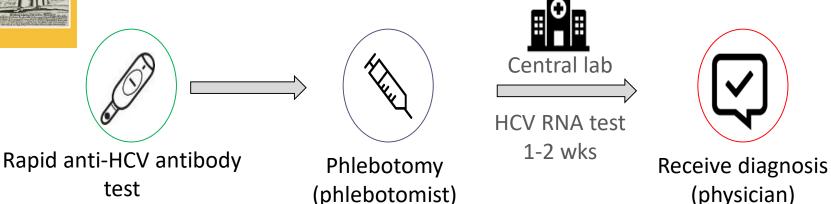


The Long Journey to an HCV Diagnosis . . .





Rapid HCV Antibody Testing



- Single-center free testing clinic
- People randomized to interventions for testing of HIV, HBV, and HCV

Standard serology-based testing (n = 162)

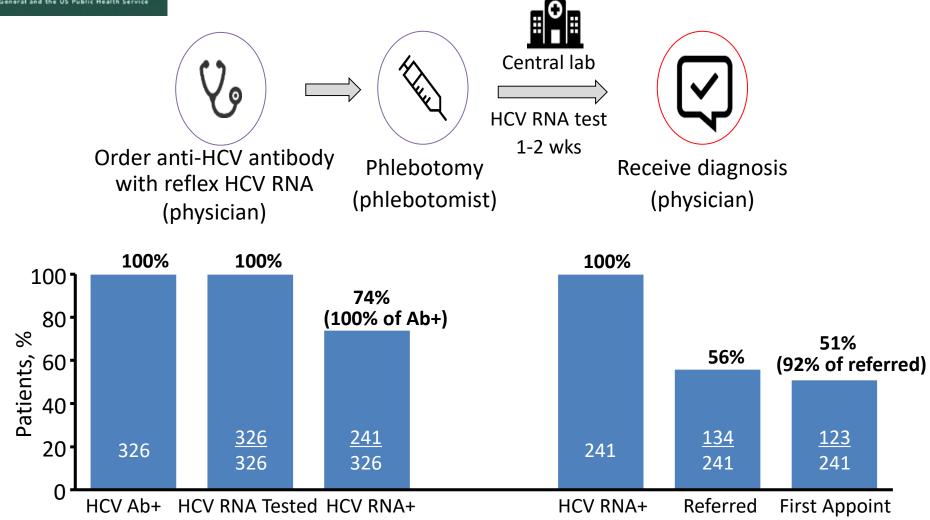
Point-of-care rapid testing (n = 162)

(healthcare worker)

Aware of Status Linked to care



HCV Antibody Testing With Reflex RNA Testing



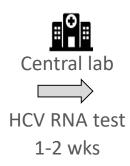
Seña. Public Health Rep. 2016;131(suppl 2):57.



Dried Blood Spot Testing



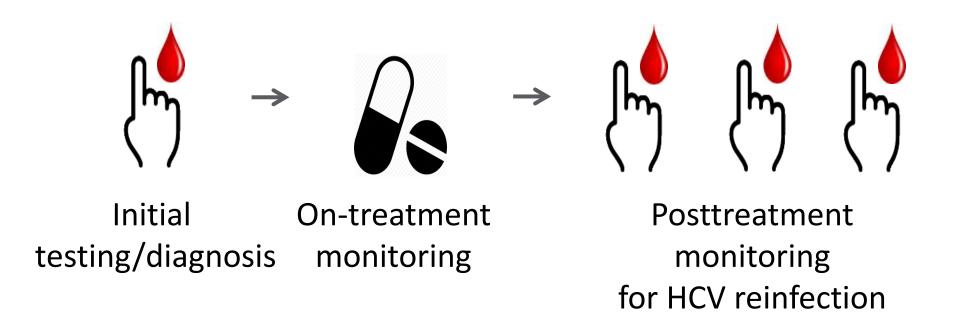
Dried blood spot sample (healthcare worker)



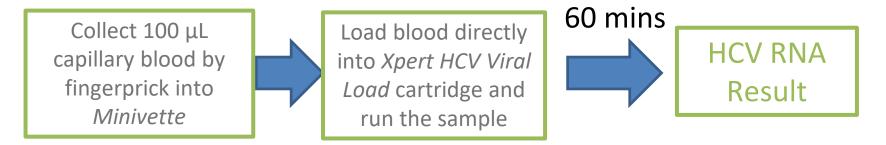


Advantages	Disadvantages
1) Enhances HCV testing and linkage to care	1) Still requires centralized testing
2) Avoids need for phlebotomy	2) Requires second visit to get result
3) Enables reflex virologic testing	3) May yield a lower HCV RNA titer
4) Stable, easy to transport and store	
5) Can be used for other purposes (eg, HIV)	
6) Collection by peers or community workers	

Opportunities for Utilizing POC (Point of Care) HCV RNA Testing

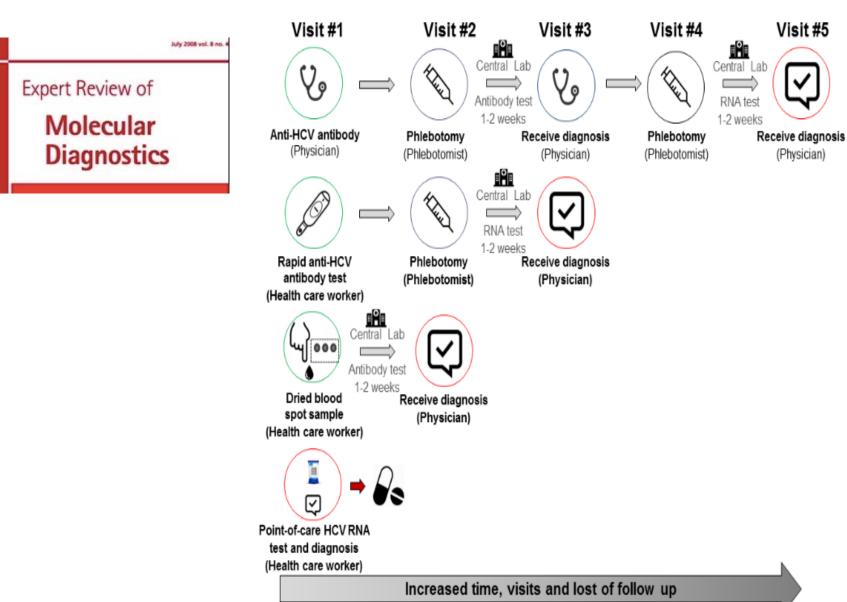


Fingerstick Testing for HCV RNA Detection



- Relatively easy-to-use point-of-care HCV RNA test—GeneXpert
- Real-world performance for HCV RNA quantification very good
 - Venepuncture HCV Viral Load—sensitivity: 99%; specificity: 96%^[1]
 - Modified fingerstick assay—sensitivity: 98%; specificity: 99%^[2]
 - Xpert HCV Viral Load Fingerstick—sensitivity: 100%; specificity: 100%^[3]
- One step closer to a single-visit diagnosis (needs to be more "rapid")

Moving Toward a Single-Visit Hepatitis C Diagnosis





II GIORNATA MONDIALE DEI POVERI

Questo povero grida e il Signore lo ascolta

18 NOVEMBRE 2018

HCV: Where Are the Undiagnosed and Untreated?

















Neurological:

Traumatic brain injury Alcohol withdrawal seizures, epilepsy Korsakoff – Wernicke syndrome Cerebellar degeneration **Syphilis**

Dental

Respiratory:

COPD / asthma Pneumonia Crack lung TB

Mental health:

Substance misuse Depression / anxiety Self harm / suicide Personality disorder **Psychosis**

Skin:

Cellulitis **Abscesses MRSA** Eczema **Psoriasis Fungal** infections

Scabies

Lice

Cardiac:

Endocarditis Cardiomyopathy Hypertension Myocardial infarction

Vascular:

DVT PE Stroke

Leg ulcers

HOMELESS HEALTH **MORBIDITY**

Feet:

Trauma, cellulitis Athletes foot Venous stasis, oedema, infection Peripheral neuropathy **Frostbite**

Gastrointestinal:

Malnutrition Thiamine deficiency Gastritis **Pancreatitis** Peptic and duodenal ulcers Alcoholic liver disease and cirrhosis Oesophageal varices Cancer of the oesophagus and stomach

Genitourinary:

Erectile dysfunction **STIs Recurrent UTIs** Cervical cancer Bladder cancer

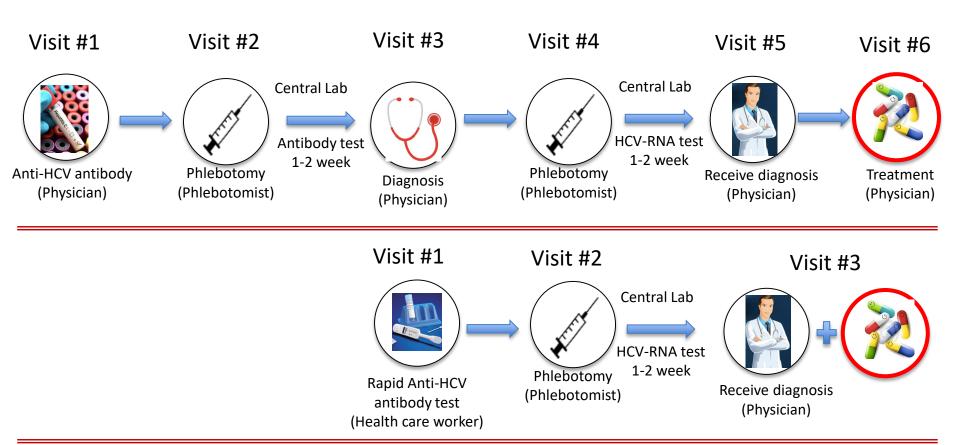
Systemic:

BBVs Septicaemia Anthrax Diabetes Overdose

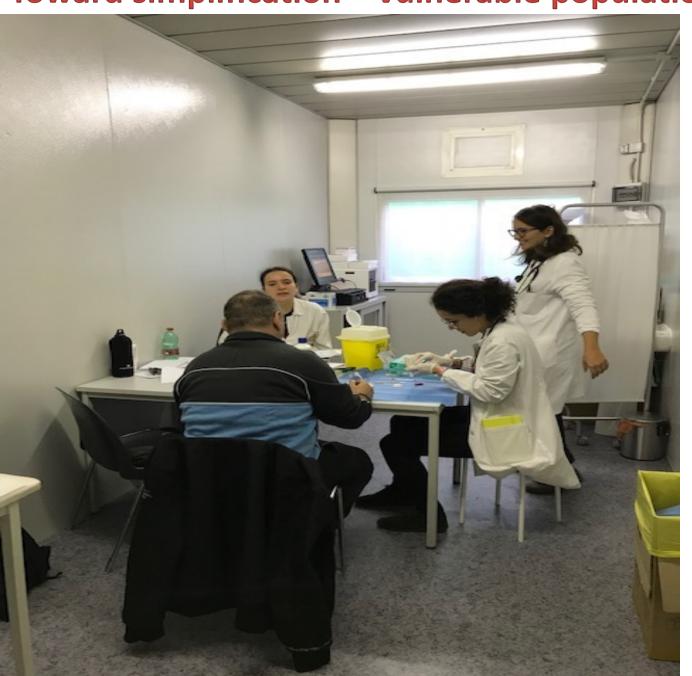
Communicable infections associated with homelessness

Specific infections	Transmission route	Risk factors for infection spreading
HIV, hepatitis	STIs	Sexual risk behavior
B, STIs	5115	traits:
_,		homosexuality/bisexuality,
		multiple sexual partners,
		crack and/or cocaine use,
		street sex work
HIV, hepatitis	Blood-borne	Drug risk behavioral
C, hepatitis B,	infections	traits: sharing syringe,
hepatitis A		needle, and rinse water
Tuberculosis,	Airborne	Overcrowding in shelters,
influenza,	infections	alcohol abuse, drug
diphtheria,		addiction, malnutrition,
pneumococcal		HIV
pneumonia		
Scabies, body	Skin	Overcrowding in shelters,
louse	infections	lack of personal hygiene,
infestation		poor clothing and bedding

Simplification

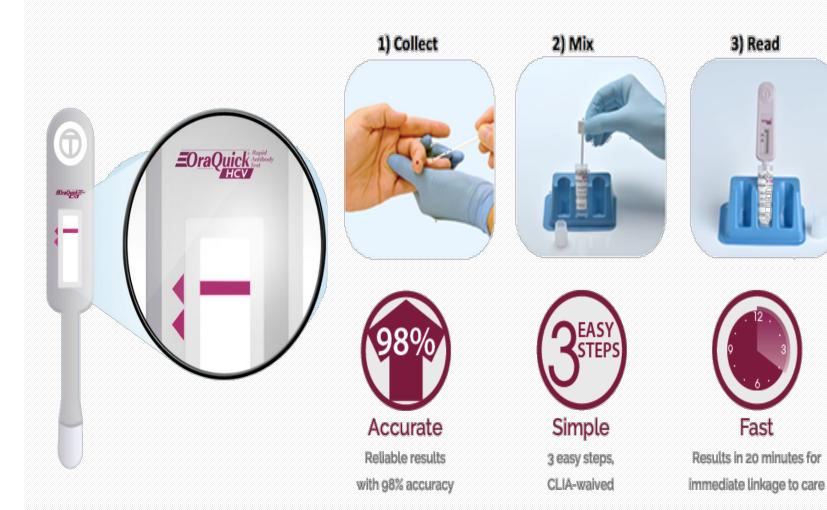


Toward simplification – vulnerable populations

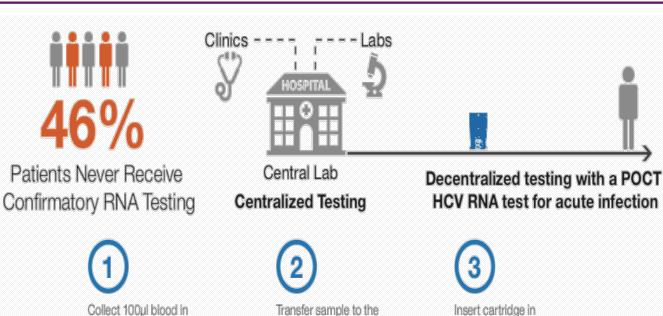




Expanding testing access: HCV-antibodies rapid test



Expanding testing access: HCV-RNA rapid test



cartridge

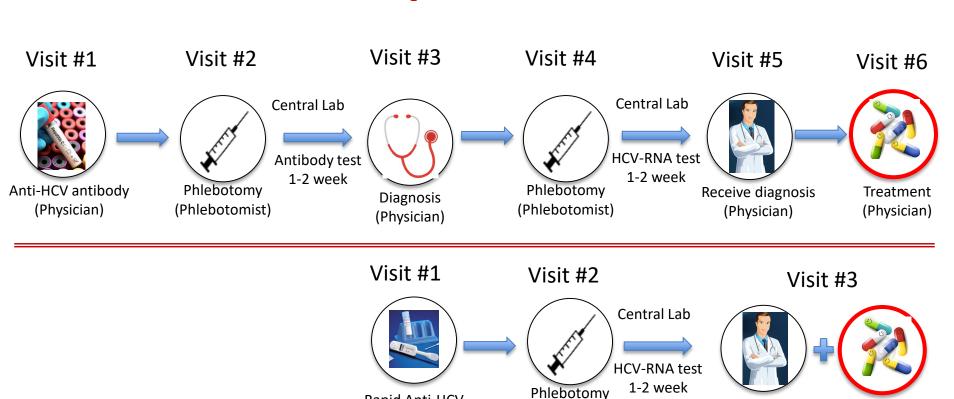


the Minivette provided





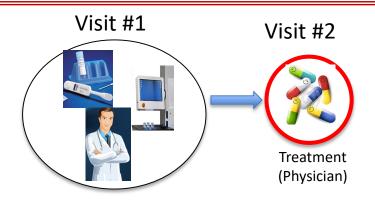
Simplification



Rapid Anti-HCV

antibody test

(Health care worker)



(Phlebotomist)

Receive diagnosis

(Physician)

First Italian experience of the Xpert HCV Viral Load Finger-Stick: a useful street-tool for vulnerable population.

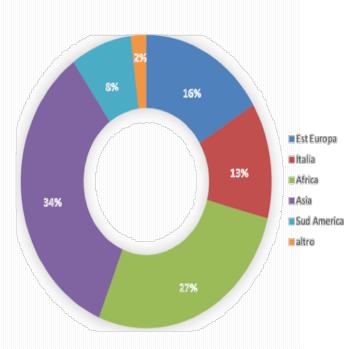


RESULTS

Periodo di riferimento: 12-18 novembre 2018

n. 203	
Sesso (M)	163/203 (80.3%)
Italiani	26/203 (12.8%) *
Età (mediana)	40
Consumatori di sostanze	17/203 (8.4%)
Disoccupati	158/203 (77.8%) – sottoccupati 19.7%
Mai eseguito test HCV	153/203 (75.4%)
Mai eseguito test HIV	142/203 (70%)

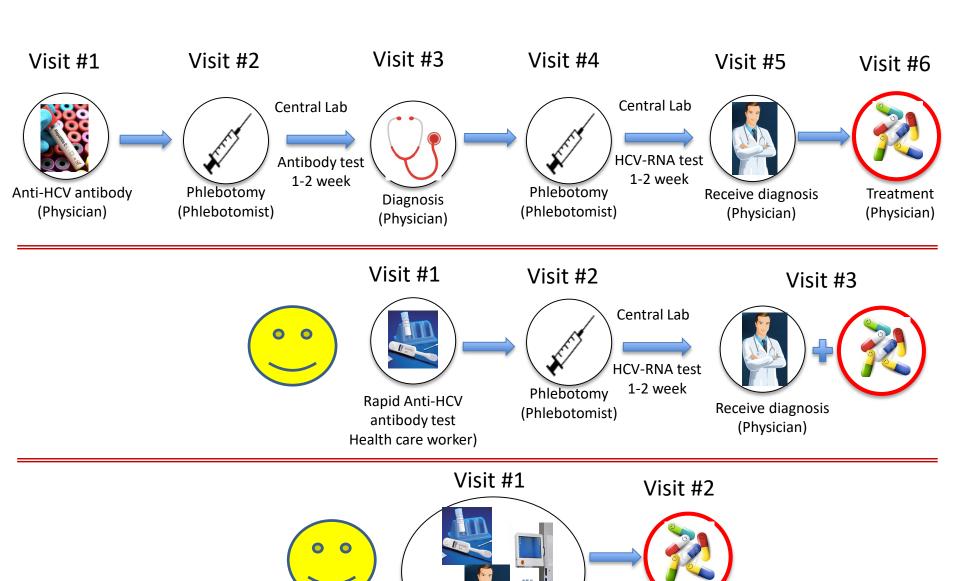
HCV	
Test rapido anticorpale POSITIVO	 10/203 (4.9%) 7/10 già conoscevano il proprio sierostato 4/10 consumatori di sostanze 5/10 italiani, 4/10 Est Europa, 1/10 Africa Mantoux +: 5/10 nessuna coinfezione HIV/HCV
Test rapido molecolare POSITIVO	6/10 (60%) 3/6 (50%) curati



HIV+ → 1/203

Mantoux + → 41/132 (34/132 risultato ignoto)

Our Model



Treatment (Physician)

Tools for Simplifying the HCV Treatment Workup

Fibrosis Assessment Is Essential in ALL Patients, but Simple Tools Are Available

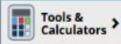
- Presence of cirrhosis may affect regimen, duration, use of ribavirin; also requires careful assessment for signs or history of decompensation and necessitates post-SVR HCC surveillance
- Transient elastography
 - > 12.5 KPa = cirrhosis
- Serum tests
 - FibroTest (0.75 = cirrhosis)
 - APRI or FIB-4; can be done anywhere by any provider
 - Very good negative predictive value—to rule out cirrhosis
- Liver biopsy rarely needed

APRI Online Calculator















Clinical Calculators

CTP Calculator

APRI Calculator

BMI Calculator

CrCl Calculator

FIB-4 Calculator

Glasgow Coma Scale

GFR Calculator

MELD Calculator

SAAG Calculator

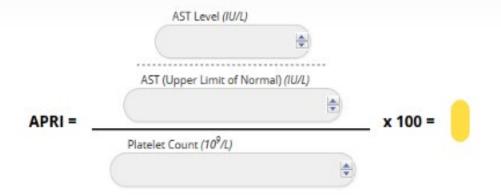
Substance Use Screening Tools

AUDIT-C Questionnaire

AST to Platelet Ratio Index (APRI) Calculator

■ Share

This is an AST to Platelet Ratio Index (APRI) calculator tool. Enter the required values to calculate the APRI value. The APRI Score will appear in the oval on the far right (highlighted in yellow). Most experts recommend using 40 IU/L as the value for the AST upper limit of normal when calculating an APRI value.



Interpretation:

In a meta-analysis of 40 studies, investigators concluded that an APRI score greater than 1.0 had a sensitivity of 76% and specificity of 72% for predicting cirrhosis. In addition, they concluded that APRI score greater than 0.7 had a sensitivity of 77% and specificity of 72% for predicting significant hepatic fibrosis. 1

For detection of cirrhosis, using an APRI cutoff score of 2.0 was more specific (91%) but less sensitive (46%). The lower the APRI score (less than 0.5), the greater the negative predictive value (and ability to rule out cirrhosis) and the higher the value (greater than 1.5) the greater the positive predictive value (and ability to rule in cirrhosis); midrange values are less helpful. The APRI alone is likely not sufficiently sensitive to rule out significant disease. Some evidence suggests that the use of multiple indices in combination (such as APRI plus FibroTest) or an algorithmic approach may result in higher diagnostic accuracy than using APRI alone.²

FIB-4 Online Calculator















Clinical Calculators

CTP Calculator

APRI Calculator

BMI Calculator

CrCl Calculator

FIB-4 Calculator

Glasgow Coma Scale

GFR Calculator

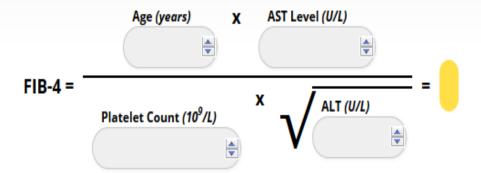
MELD Calculator

SAAG Calculator

Fibrosis-4 (FIB-4) Calculator



The Fibrosis-4 score helps to estimate the amount of scarring in the liver. Enter the required values to calculate the FIB-4 value. It will appear in the oval on the far right (highlighted in yellow).



Interpretation:

Using a lower cutoff value of 1.45, a FIB-4 score <1.45 had a negative predictive value of 90% for advanced fibrosis (Ishak fibrosis score 4-6 which includes early bridging fibrosis to cirrhosis). In contrast, a FIB-4 >3.25 would have a 97% specificity and a positive predictive value of 65% for advanced fibrosis. In the patient cohort in which this formula was first validated, at least 70% patients had values <1.45 or >3.25. Authors argued that these individuals could potentially have avoided liver biopsy with an overall accuracy of 86%.

Who Can Treat HCV Infection?

- Many different types of providers can provide HCV treatment for vast majority of patients in many different settings
- Hepatologists/other specialists only needed for complicated cases: advanced liver disease, serious comorbidities
- Facilitate HCV
 mentorships and
 education/training for
 different types of
 providers

Providers



Task shifting

- Specialists
- Drug and alcohol specialist
- Primary care providers
- Nurses
- Pharmacists
- Peer support workers
- Others

Settings



Sexual health clinics





Drug and alcohol clinics







Pharmacies



Prisons

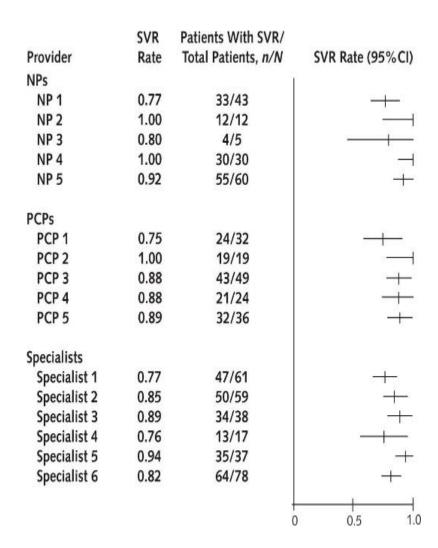
Task Shifting to Community-Based Nonspecialist Providers

- 3-hr education and training
- Overall SVR12 following LDV/SOF: 87%
- No difference in SVR rate by provider type

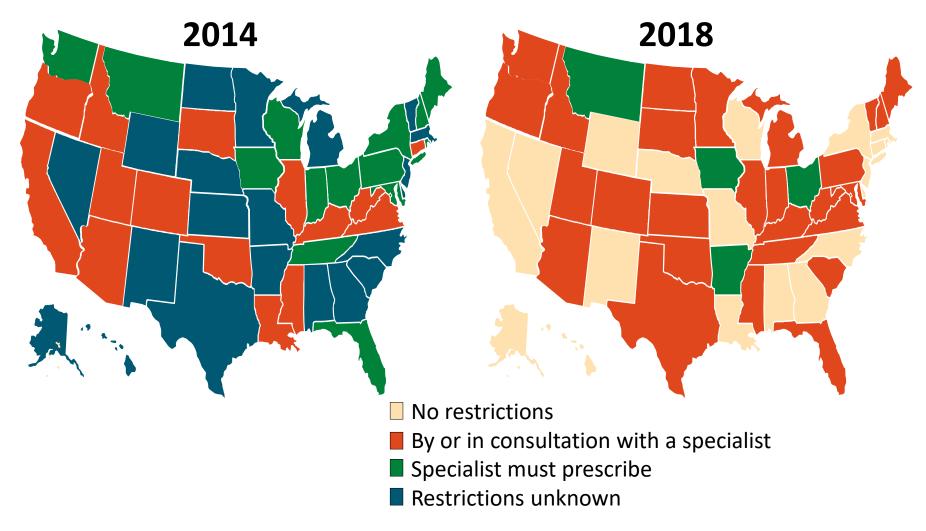
- NPs: 90%

- PCPs: 88%

Specialists: 85%



Prescriber Restrictions



L'eliminazione di HCV è raggiungibile attraverso una strategia nazionale basata su 5 linee strategiche

1) Conoscere l'epidemiologia nazionale dell'epatite cronica C

- ✓ Definire Prevalenze e Incidenza
- ✓ Monitorizzare l'accesso alle cure

2) Identificare gli interventi ad alto-impatto clinico

- ✓ Implementare sistemi di vigilanza per i nuovi casi
- ✓ Implementare misure di riduzione del danno in chi fa uso di sostanze, garantendo un rapido accesso alle cure
- ✓ Disegnare strategie di identificazione delle persone affette da epatite C garantendo loro accesso alle cure
- ✓ Disegnare percorsi di cura standardizzati

3) Identificare le modalità per implementare gli interventi

- ✓ Identificare gruppi di pazienti con bisogni particolari
- ✓ Sviluppare strategie di diagnosi e trattamento decentralizzate per raggiungere tutti i pazienti
- ✓ Analizzare regolarmente i tassi di diagnosi e di trattamento a livello nazionale
- 4) Identificare modelli per facilitare l'accesso alla diagnosi e alla cura dell'epatite C
- 5) Identificare aree in cui l'innovazione tecnologica e culturale sia necessaria per raggiungere gli obiettivi di eliminazione