

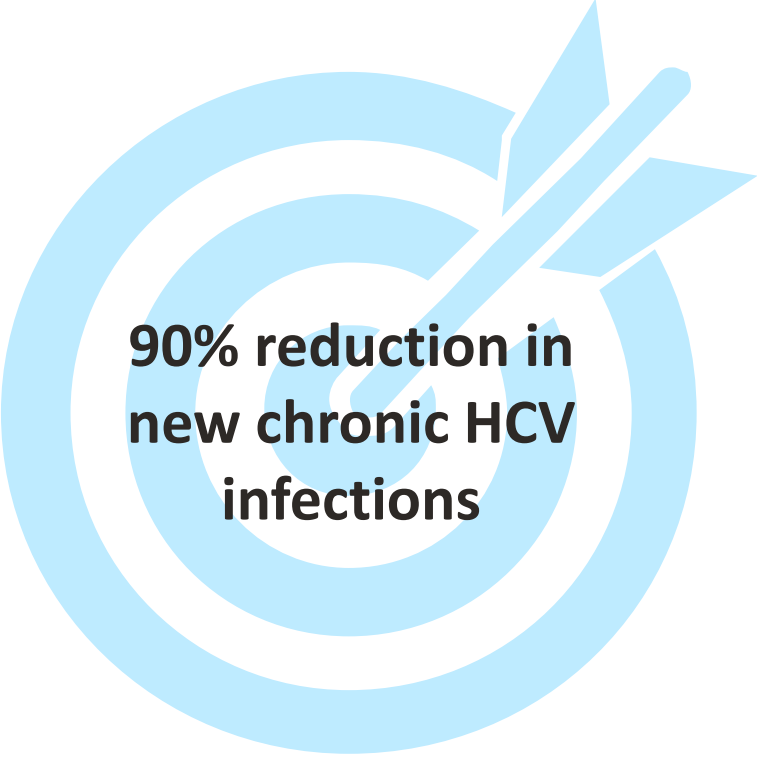
HCV-free Prisons: sfide e soluzioni per una realtà possibile **(R. Ranieri)**

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Regione Lombardia - Ospedale Santi Paolo e Carlo Milano
Roma Agorà Penitenziaria
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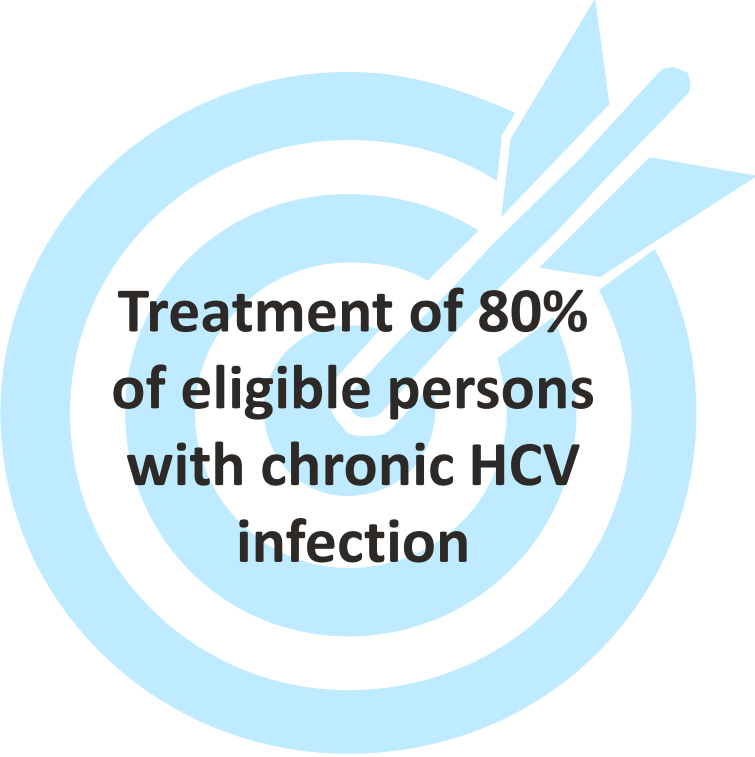
WHO Vision: Eliminate Viral Hepatitis as a Major Health Threat by 2030



“A world where viral hepatitis transmission is halted and everyone living with hepatitis has access to safe, affordable and effective care and treatment services”



**90% reduction in
new chronic HCV
infections**



**Treatment of 80%
of eligible persons
with chronic HCV
infection**



**65% reduction in
mortality rates**

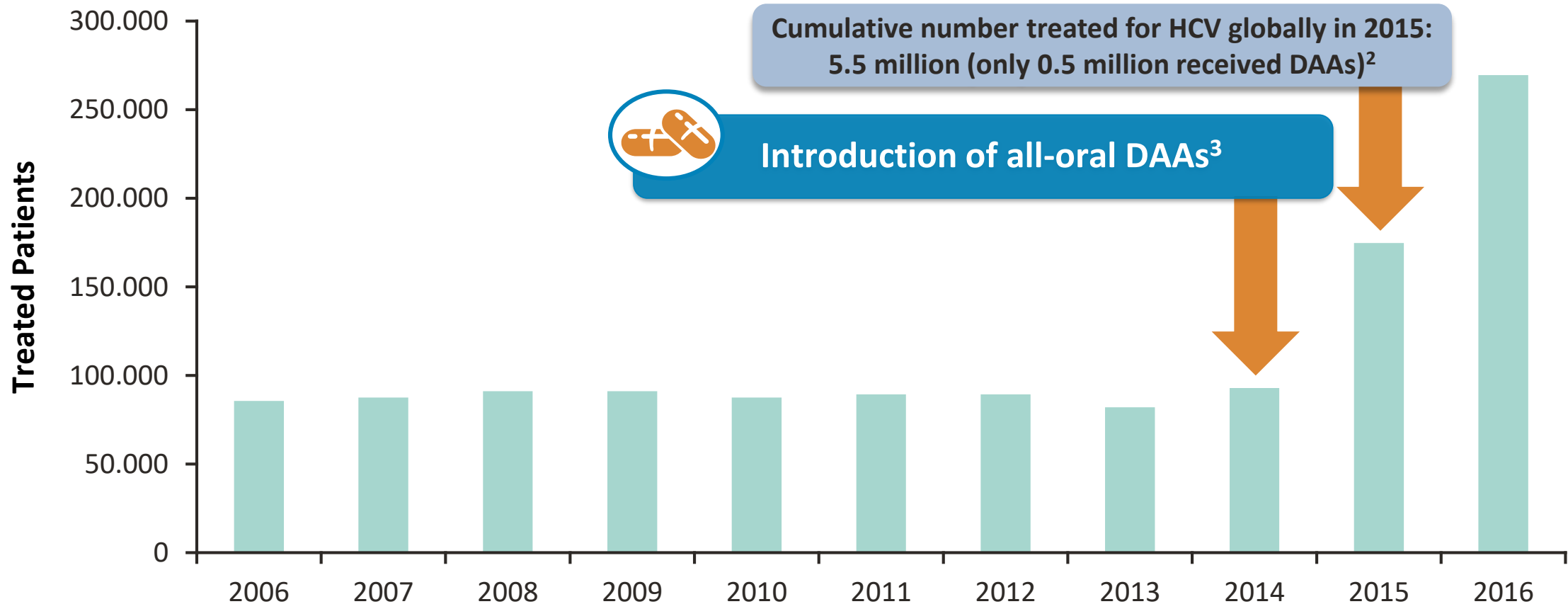


Micro-elimination – A path to global elimination of hepatitis C

Jeffrey V. Lazarus^{1,2,*}, Stefan Wiktor³, Massimo G. C. ⁴,
on behalf of the EASL ⁵, ⁶, ⁷, ⁸, ⁹, ¹⁰, ¹¹, ¹², ¹³, ¹⁴, ¹⁵, ¹⁶, ¹⁷, ¹⁸, ¹⁹, ²⁰, ²¹, ²², ²³, ²⁴, ²⁵, ²⁶, ²⁷, ²⁸, ²⁹, ³⁰, ³¹, ³², ³³, ³⁴, ³⁵, ³⁶, ³⁷, ³⁸, ³⁹, ⁴⁰, ⁴¹, ⁴², ⁴³, ⁴⁴, ⁴⁵, ⁴⁶, ⁴⁷, ⁴⁸, ⁴⁹, ⁵⁰, ⁵¹, ⁵², ⁵³, ⁵⁴, ⁵⁵, ⁵⁶, ⁵⁷, ⁵⁸, ⁵⁹, ⁶⁰, ⁶¹, ⁶², ⁶³, ⁶⁴, ⁶⁵, ⁶⁶, ⁶⁷, ⁶⁸, ⁶⁹, ⁷⁰, ⁷¹, ⁷², ⁷³, ⁷⁴, ⁷⁵, ⁷⁶, ⁷⁷, ⁷⁸, ⁷⁹, ⁸⁰, ⁸¹, ⁸², ⁸³, ⁸⁴, ⁸⁵, ⁸⁶, ⁸⁷, ⁸⁸, ⁸⁹, ⁹⁰, ⁹¹, ⁹², ⁹³, ⁹⁴, ⁹⁵, ⁹⁶, ⁹⁷, ⁹⁸, ⁹⁹, ¹⁰⁰, ¹⁰¹, ¹⁰², ¹⁰³, ¹⁰⁴, ¹⁰⁵, ¹⁰⁶, ¹⁰⁷, ¹⁰⁸, ¹⁰⁹, ¹¹⁰, ¹¹¹, ¹¹², ¹¹³, ¹¹⁴, ¹¹⁵, ¹¹⁶, ¹¹⁷, ¹¹⁸, ¹¹⁹, ¹²⁰, ¹²¹, ¹²², ¹²³, ¹²⁴, ¹²⁵, ¹²⁶, ¹²⁷, ¹²⁸, ¹²⁹, ¹³⁰, ¹³¹, ¹³², ¹³³, ¹³⁴, ¹³⁵, ¹³⁶, ¹³⁷, ¹³⁸, ¹³⁹, ¹⁴⁰, ¹⁴¹, ¹⁴², ¹⁴³, ¹⁴⁴, ¹⁴⁵, ¹⁴⁶, ¹⁴⁷, ¹⁴⁸, ¹⁴⁹, ¹⁵⁰, ¹⁵¹, ¹⁵², ¹⁵³, ¹⁵⁴, ¹⁵⁵, ¹⁵⁶, ¹⁵⁷, ¹⁵⁸, ¹⁵⁹, ¹⁶⁰, ¹⁶¹, ¹⁶², ¹⁶³, ¹⁶⁴, ¹⁶⁵, ¹⁶⁶, ¹⁶⁷, ¹⁶⁸, ¹⁶⁹, ¹⁷⁰, ¹⁷¹, ¹⁷², ¹⁷³, ¹⁷⁴, ¹⁷⁵, ¹⁷⁶, ¹⁷⁷, ¹⁷⁸, ¹⁷⁹, ¹⁸⁰, ¹⁸¹, ¹⁸², ¹⁸³, ¹⁸⁴, ¹⁸⁵, ¹⁸⁶, ¹⁸⁷, ¹⁸⁸, ¹⁸⁹, ¹⁹⁰, ¹⁹¹, ¹⁹², ¹⁹³, ¹⁹⁴, ¹⁹⁵, ¹⁹⁶, ¹⁹⁷, ¹⁹⁸, ¹⁹⁹, ²⁰⁰, ²⁰¹, ²⁰², ²⁰³, ²⁰⁴, ²⁰⁵, ²⁰⁶, ²⁰⁷, ²⁰⁸, ²⁰⁹, ²¹⁰, ²¹¹, ²¹², ²¹³, ²¹⁴, ²¹⁵, ²¹⁶, ²¹⁷, ²¹⁸, ²¹⁹, 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The Changing Paradigm of HCV Treatment Has Led to a Significant Increase in the Number of Patients Being Treated

Total Number of Patients Treated in EU¹



1. Adapted from the Polaris Observatory. Available at: <http://cdafound.org/polaris-hepC-graphs/>;

2. WHO Global Hepatitis Report, 2017. Available at: <http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/>;

3. CDC Hepatitis C: 25 years since discovery. Available at: <https://www.cdc.gov/knowmorehepatitis/media/pdfs/hepc-timeline.pdf>.

All Patients Are Now Prioritized for Treatment

WHO¹

Last updated April 2016

AASLD²

Last updated September 2017

EASL³

Last updated April 2018

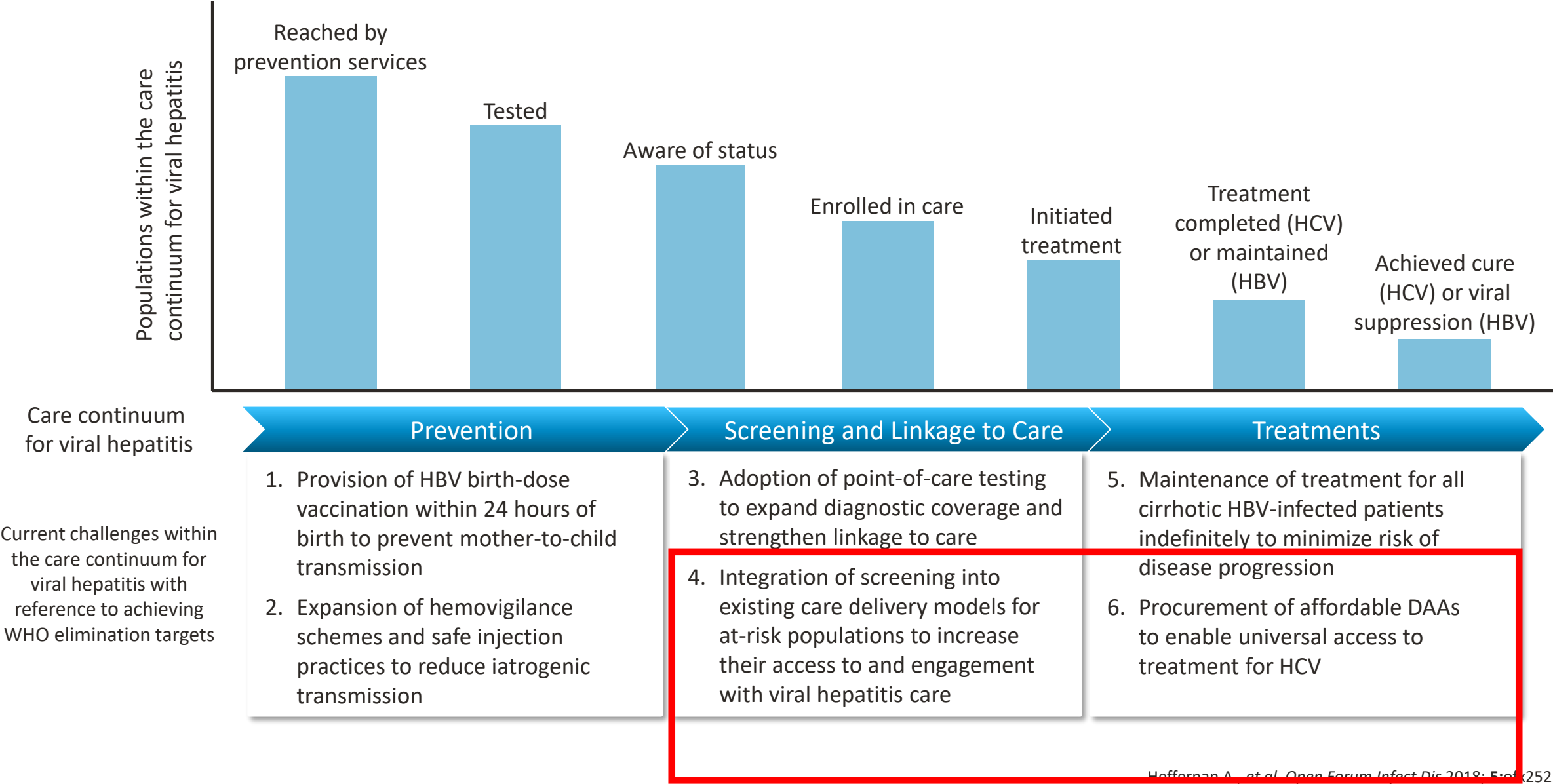
Treatment is indicated for:

All adults and children with chronic HCV infection, including PWID

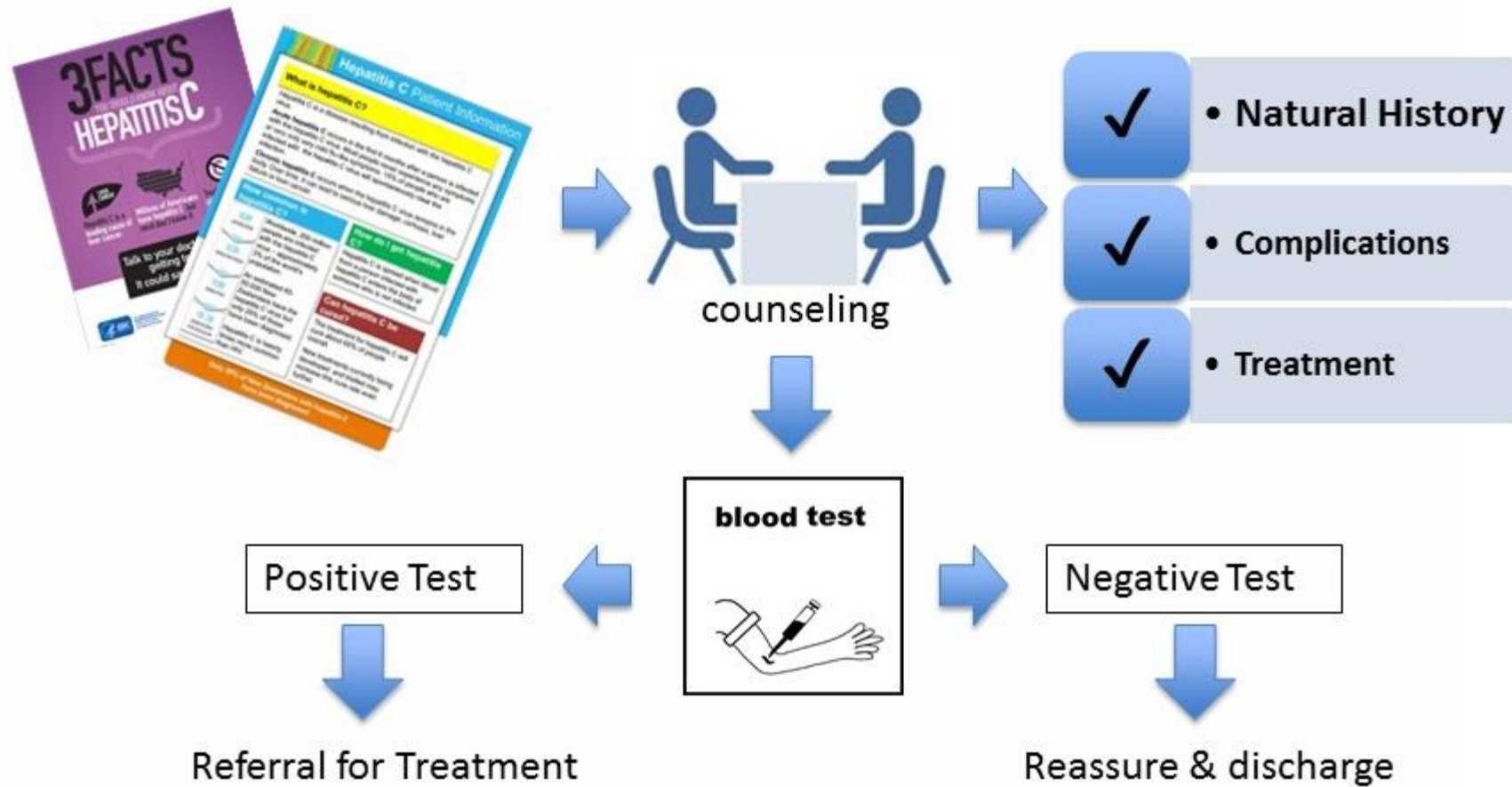
All patients with chronic HCV infection, except those with short life expectancies that cannot be remediated

All patients with HCV infection must be considered for therapy, including TN patients and individuals that failed to achieve SVR after prior treatment

Overview of the WHO Care Continuum for Viral Hepatitis and the Associated Challenges Encountered When Aiming toward WHO Elimination Targets



Screening Must Be Linked to Care



High-Risk Populations Face Unique Challenges

Prisoners

PWID

MSM

Stigma and discrimination¹⁻³

Substance abuse^{1,2}

Lack of specialists/
coverage of services^{1,2}

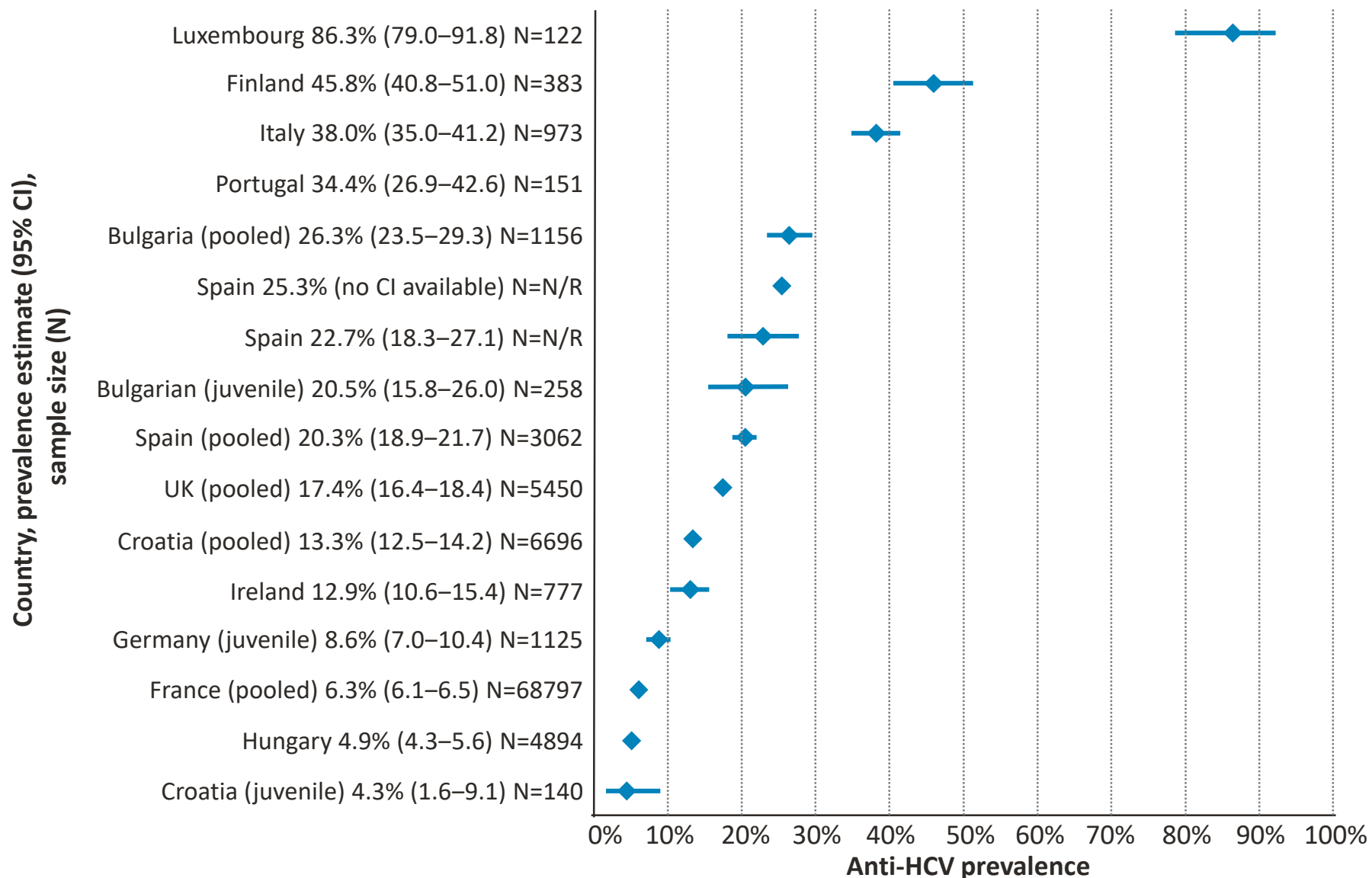
Lack of HCV
awareness in
patients and HCPs¹⁻³

Lack of additional
support, i.e. harm-
reduction services²

Socioeconomic
factors^{1,2}

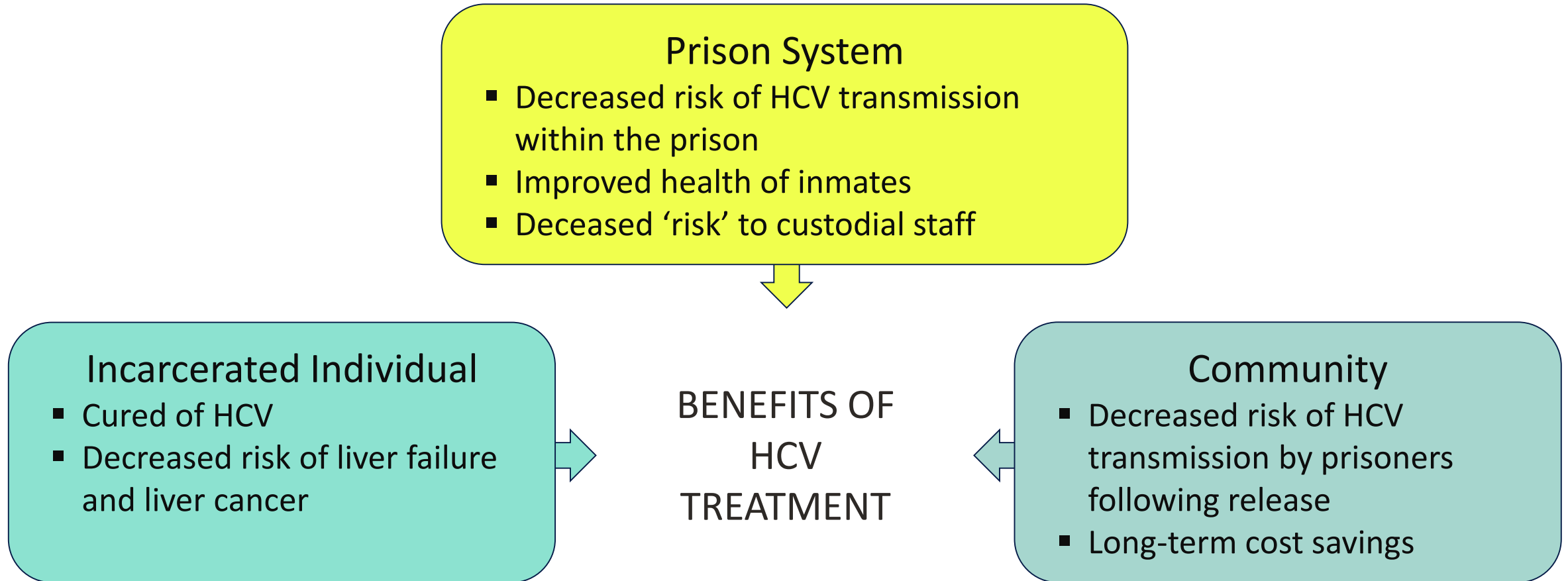


Anti-HCV Prevalence among People in Prison across the EU/EEA

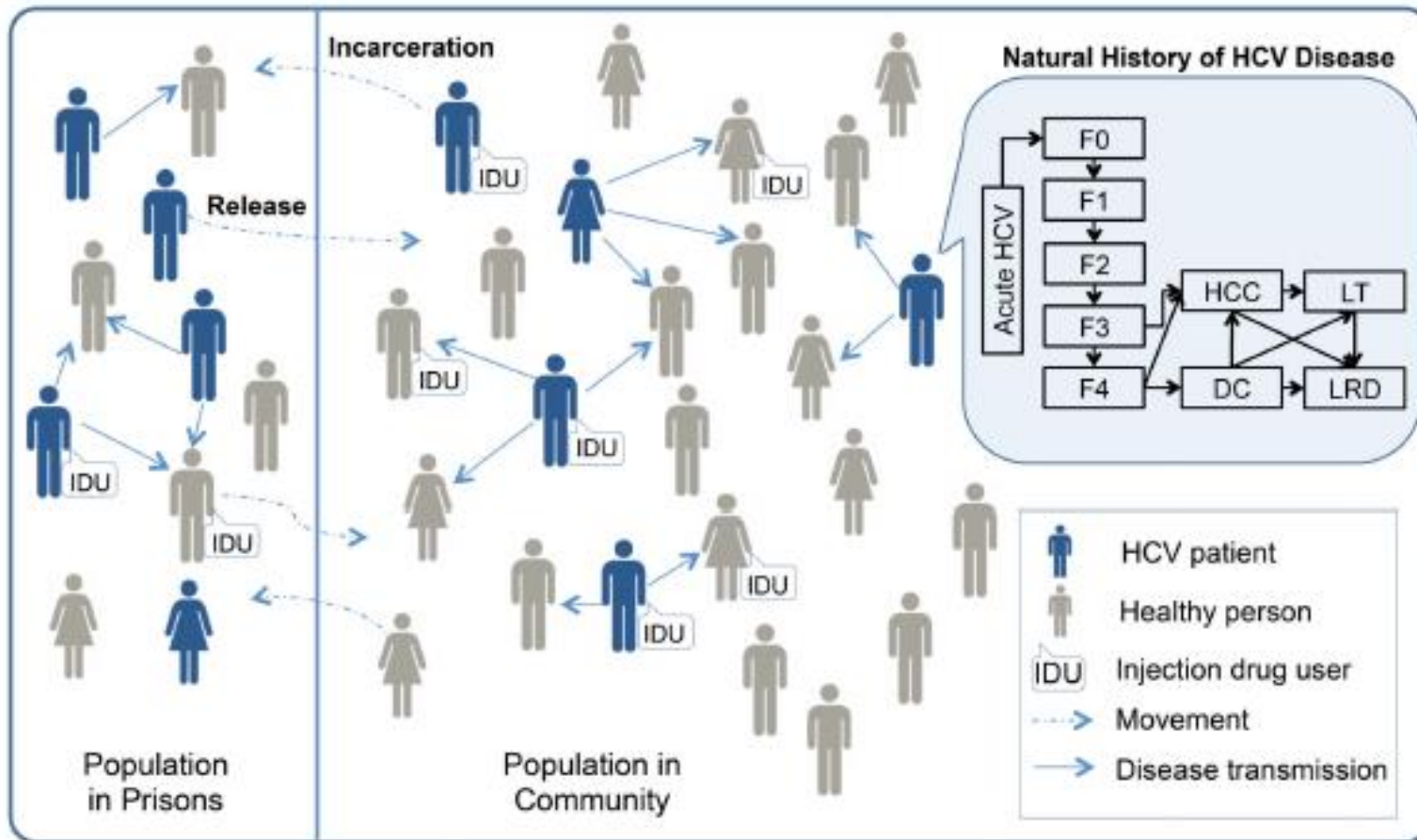


All but 4 estimates (Germany, France, Hungary, Croatia) were above 10% prevalence

Benefits of Targeting HCV in Prisons



Benefits of Treatment in Prison



- Risk-based and opt-out screening and treatment
- Prevent new infections – 90% in the community!
- Highly cost-effective
- But would require increase in healthcare budget

- Potential to decrease HCV in prison
- And in the community!!

RESEARCH

Open Access



Harm reduction and viral hepatitis C in European prisons: a cross-sectional survey of 25 countries

Rob Bielen^{1,2}, Samya R. Stumo³, Rachel Halford⁴, Klára Werling⁵, Tatjana Reic⁶, Heino Stöver⁷, Geert Robaey^{1,2,8†} and Jeffrey V. Lazarus^{3,9*†}

Background: Current estimates suggest that 15% of all prisoners worldwide are chronically infected with the hepatitis C virus (HCV), and this number is even higher in regions with high rates of injecting drug use. Although harm reduction services such as opioid substitution therapy (OST) and needle and syringe programs (NSPs) are effective in preventing the further spread of HCV and HIV, the extent to which these are available in prisons varies significantly across countries.

Conclusion: Despite the existence of evidence-based recommendations, infectious disease prevention measures such as harm reduction programs are inadequate in European prison settings. Harm reduction, HCV testing/screening, and treatment should be scaled up in prison settings in order to progress towards eliminating HCV as a public health threat.

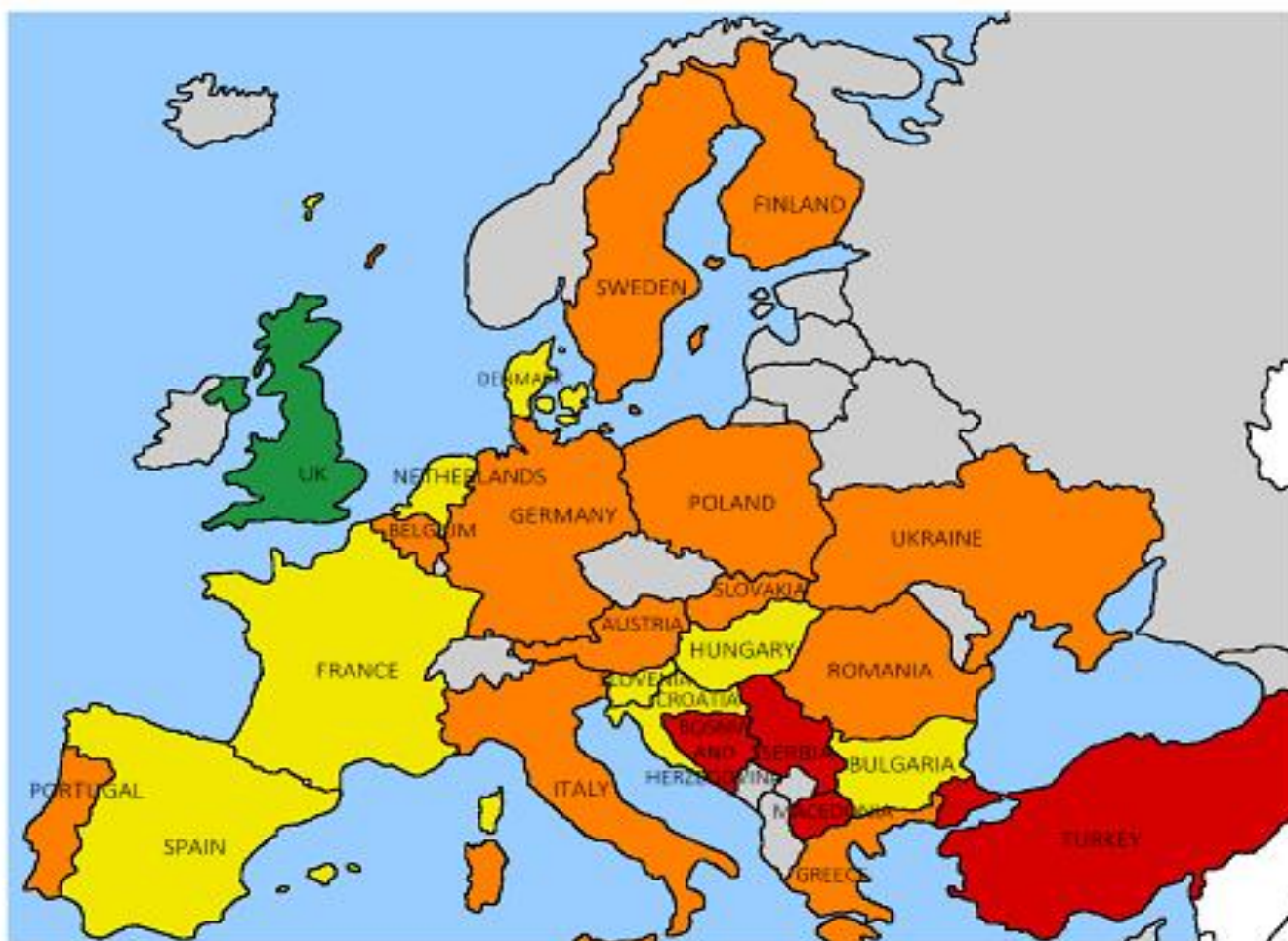


Fig. 1 Availability and coverage of HCV testing/screening in European prisons. *Green:* universal screening in prison upon entry, opt-out procedure; *yellow:* testing/screening for HCV available in prison, extent unknown, but highlighted as an at-risk population for HCV; *orange:* testing/screening available in prison, extent unknown, not highlighted as an at-risk population for HCV; *red:* no data available from the literature, prisoners not highlighted as an at-risk population for HCV; *gray:* not part of the Hep-CORE dataset

Dove eravamo?

Success of HCV Treatment in Prisons

Study site	N	Male, %	Mean age	Treatment	Completed Rx, %	Overall SVR, %
Rhode Island	90	96	38	IFN/RBV	46	29
Virginia	59	83	41	IFN/RBV	NR	36
Canada	114	100	38	IFN/RBV	NR	52
Italy	39	98	36	PegIFN/RBV	26	13
Connecticut	68	85	41	PegIFN/RBV	69	47
Rhode Island	71	100	41	PegIFN/RBV	46	28

RESEARCH ARTICLE

Open Access

Prevalence and epidemiological correlates and treatment outcome of HCV infection in an Italian prison setting

Micaela Brandolini¹, Stefano Novati¹, Annalisa De Silvestri², Carmine Tinelli², Savino Francesco Antonio Patruno³, Roberto Ranieri⁴ and Elena Seminari^{1*}

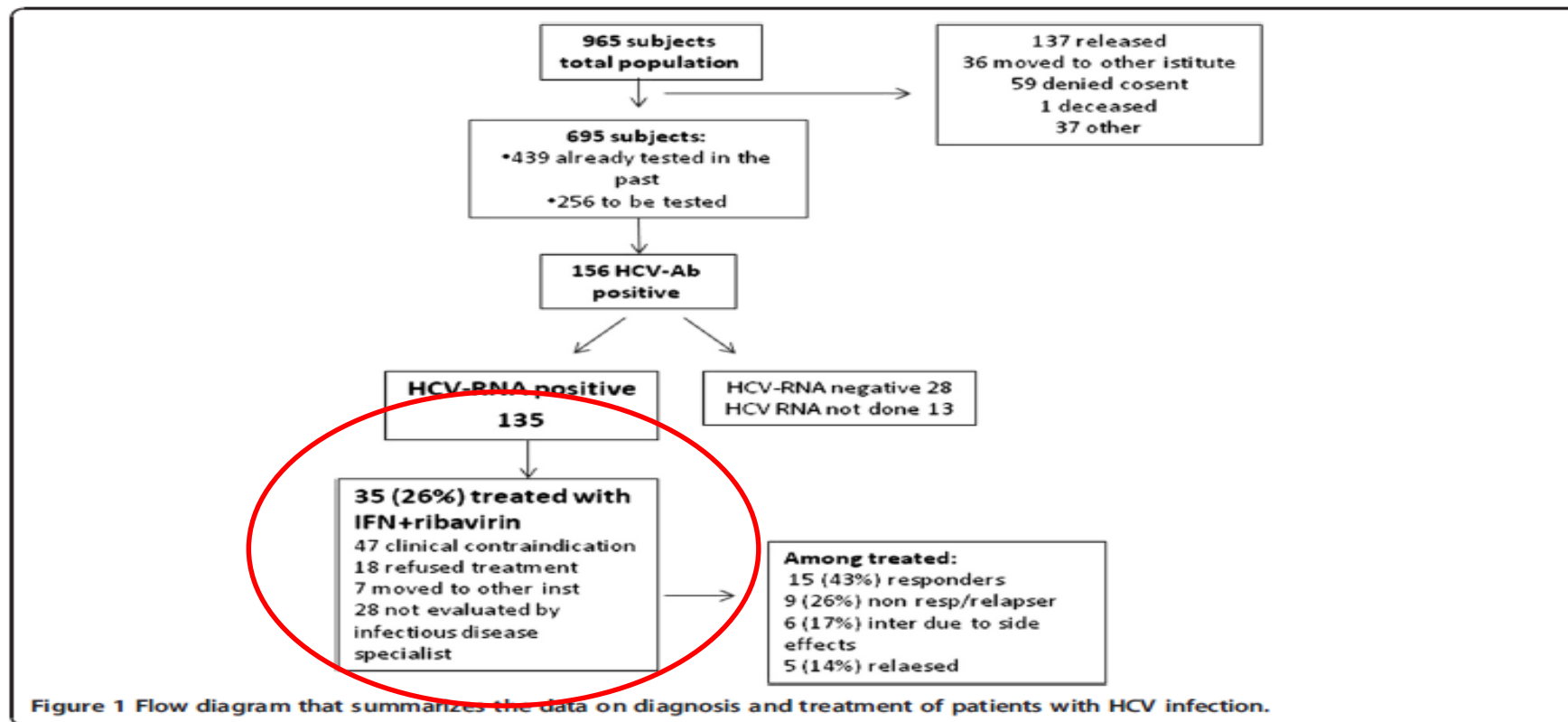
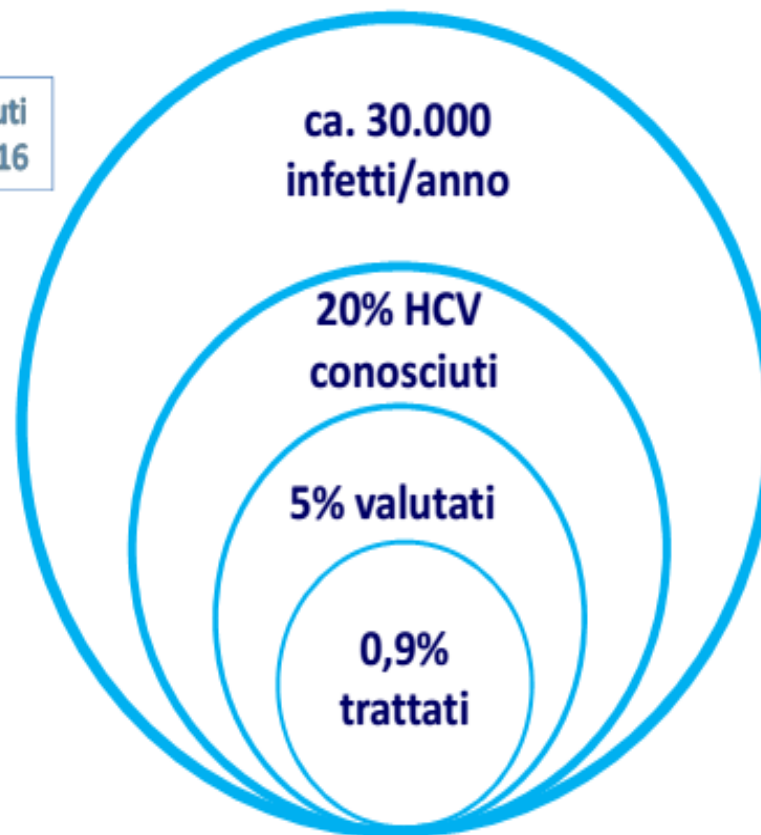


Figure 1 Flow diagram that summarizes the data on diagnosis and treatment of patients with HCV infection.

Stime pazienti HCV detenuti trattati

(Penitenziari italiani 2016)

101.995 detenuti
presenti nel 2016



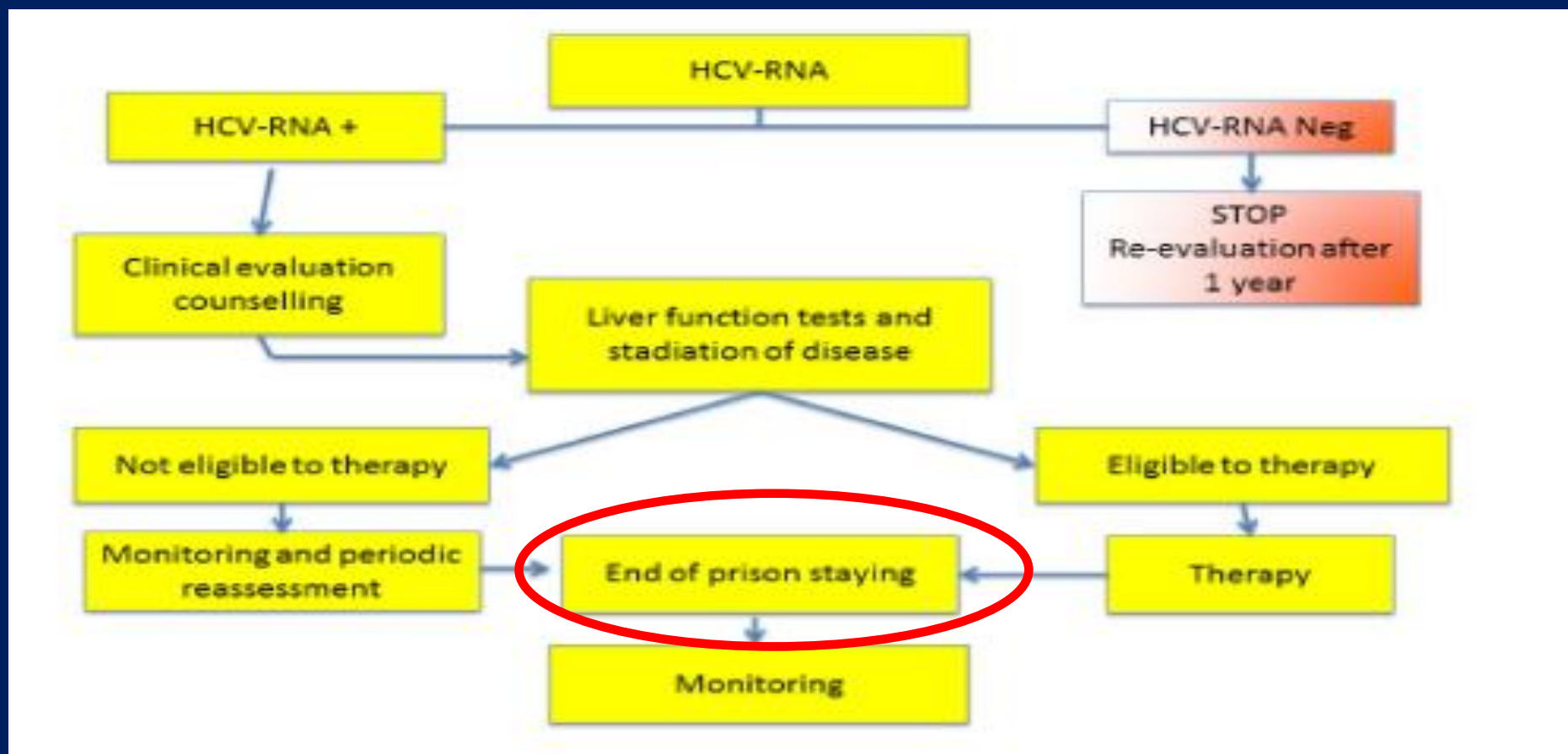
Stime SIMSPe

Dove siamo?

REVIEW

Management of HCV infection in the penitentiary setting in the direct-acting antivirals era: practical recommendations from an expert panel

Ranieri Roberto^{1,2} · Starnini Giulio^{2,3} · Carbonara Sergio^{2,4} · Pontali Emanuele^{2,5} · Leo Guido^{2,6} · Romano Antonio⁷ · Panese Sandro⁸ · Monarca Roberto^{2,9} · Prestileo Tullio¹⁰ · Barbarini Giorgio^{11,12} · Babudieri Sergio^{2,13} · on behalf of the SIMSPe Group



Hepatitis C Management in Prisons: An Insight Into Daily Clinical Practice in Three Major Italian Correctional Houses

Antonella Foschi, M.D.¹

Maddalena Casana, M.D.¹

Anna Radice, M.D.¹

Roberto Ranieri, M.D.¹

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Short Report

Treatment with direct-acting antivirals in a multicenter cohort of HCV-infected inmates in Italy



Emanuele Pontali^a, Vito Fiore^b, Anna Maria Ialungo^c, Roberto Ranieri^d, Oscar Mollaretti^e, Giorgio Barbarini^f, Daniele Marri^g, Tullio Prestileo^h, Serena Dell'Isola^c, Elena Rastrelli^c, Guido Leo^e, Giulio Starnini^c, Sergio Babudieri^{b,*}, Giordano Madeddu^b, Gruppo Infettivologi Penitenziari

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^h ARNAS, Ospedale Civico-Benfratelli Palermo, Palermo, Italy

Dove arriveremo?

Demonstration of Near-Elimination of Hepatitis C Virus Among a Prison Population: The Lotus Glen Correctional Centre Hepatitis C Treatment Project

Sofia R. Bartlett,¹ Penny Fox,² Harris Cabatingan,³ Anissa Jaros,³ Carla Gorton,⁴ Rhondda Lewis,⁴ Eugene Priscott,⁴ Gregory J. Dore,^{1,a} and Darren B. Russell^{4,5,6,a}

¹Kirby Institute, UNSW Sydney, ²Department of Medicine, Cairns Hospital, ³Lotus Glen Correctional Centre, Mareeba, ⁴Cairns Sexual Health Service and ⁵James Cook University, Cairns, and ⁶Melbourne University, Australia.

Micro-elimination of hepatitis C virus (HCV) infection through rapid uptake of government-funded direct-acting antiviral therapy within an Australian prison setting is demonstrated. During a 22-month period, 119 patients initiated treatment for chronic HCV infection, with HCV in-prison viremic prevalence declining from 12% to 1%.

Prison Programs Ongoing

- Prison elimination programs ongoing
- Australia – SToP-C¹
 - Treatment as prevention trial in 4 Australian prisons
- Lotus Glen Correctional Facility, Queensland, Australia²
 - First data points...
 - Test and treat – decreased prevalence from 12% to 1%
- Spain³
 - Screened all on entry
 - Offered treatment to all infected – > 90% accepted (SVR rate similar to general population)
 - Reduced prevalence to < 1%
- Many others... Italy?

1. Kirby Institute, SToP-C project. Available at: <https://kirby.unsw.edu.au/project/stop-c>;

2. Bartlett S, et al. *Clin Infect Dis* 2018; ePub ahead of print (doi: 10.1093);

3. Crespo J, et al. *Rev Esp Sanid Penit* 2017; **19**:70–73.

EASL Recommendations on Treatment of Hepatitis C 2018[☆]

European Association for the Study of the Liver*

- Treatment with new pangenotypic regimens can be initiated without knowledge of the genotype and subtype in areas where genotype determination is not available and/or not affordable, or to simplify treatment access (**B1**).

- Treatment should be considered without delay in incarcerated individuals) (**A1**).

- In patients with socioeconomic disadvantages and in migrants, social support services should be a component of HCV clinical management (**B1**).
- Peer-based support and patient activation assessment are recommended to improve HCV clinical management (**B2**).
- Patients with harmful alcohol consumption during treatment should receive additional support during antiviral therapy (**B1**).

Recommendations

- HCV treatment should be delivered within a multidisciplinary team setting, with experience in HCV assessment and therapy (**A1**).
- HCV-infected patients should be counselled on the importance of adherence for attaining an SVR (**A1**).

- Patients with no to moderate fibrosis (METAVIR score F0-F2), with SVR and no ongoing risk behaviour should be discharged, provided that they have no other comorbidities (**A1**).
- Patients with advanced fibrosis (F3) or cirrhosis (F4) with SVR should undergo surveillance for HCC every 6 months by means of ultrasound (**A1**).

- The risk of reinfection should be explained, to positively modify risk behaviour (**B1**).
- Following SVR, monitoring for HCV reinfection ideally through bi-annual, at least annual HCV RNA assessment should be undertaken in PWIDs or men who have sex with men with ongoing risk behaviour (**A1**).
- Retreatment should be made available, if reinfection is identified during post-SVR follow-up (**A1**).

- Drug-drug interactions are a key consideration in treating HIV-HCV coinfecting patients, and close attention must be paid to anti-HIV drugs that are contraindicated, not recommended or require dose adjustment with particular DAA regimens (A1).

Table 4D. Drug-drug interactions between HCV DAAs and central nervous system drugs

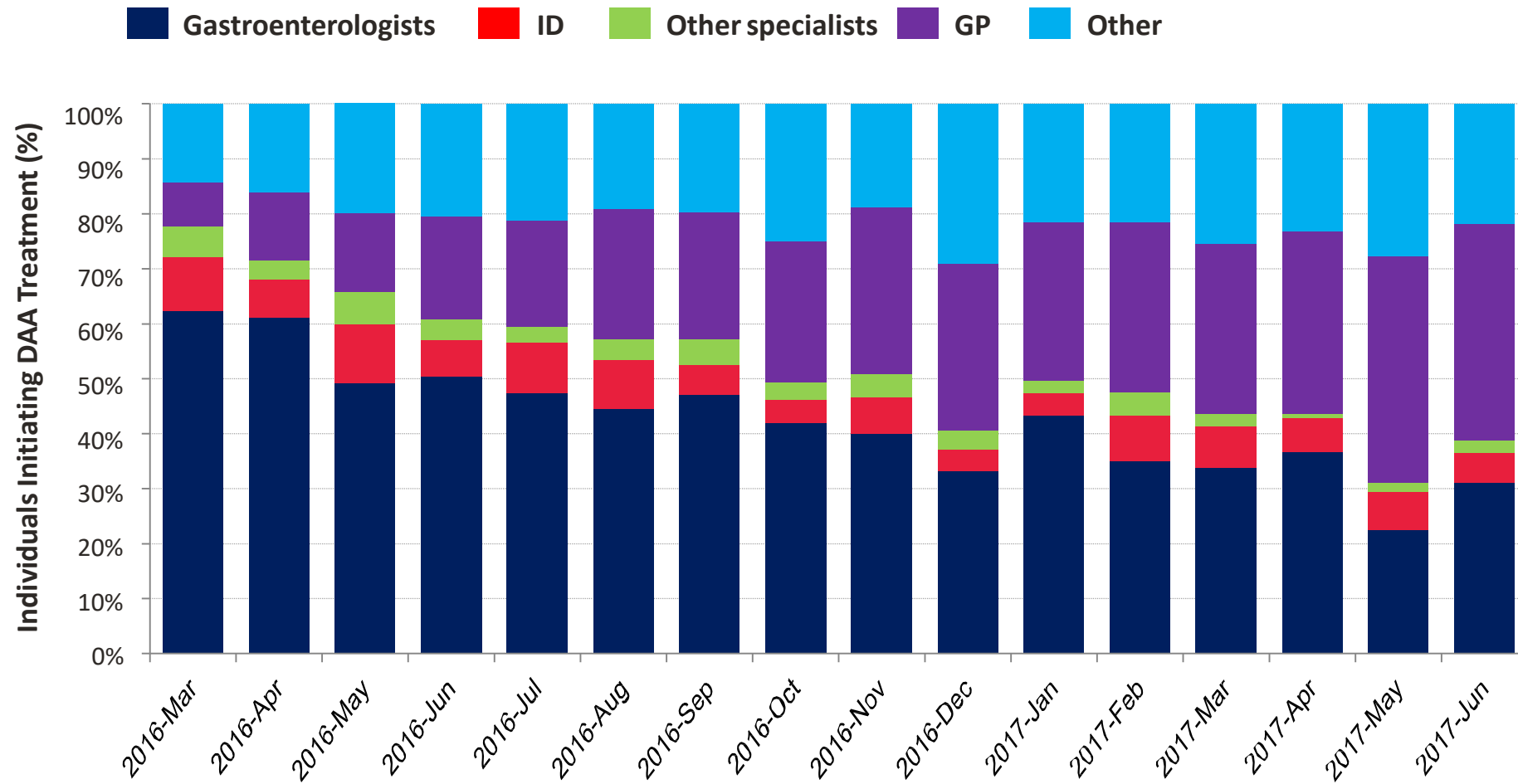
		SOF	SOF/ LDV	SOF/ VEL	OBV/ PTV/r + DSV	GZR/ EBR	SOF/ VEL/ VOX	GLE/ PIB
Anti-depressants	Amitriptyline	◆	◆	◆	■	◆	◆	◆
	Citalopram	◆	◆	◆	◆	◆	◆	◆
	Duloxetine	◆	◆	◆	◆	◆	◆	◆
	Escitalopram	◆	◆	◆	◆	◆	◆	◆
	Fluoxetine	◆	◆	◆	◆	◆	◆	◆
	Paroxetine	◆	◆	◆	◆	◆	◆	◆
	Sertraline	◆	◆	◆	■	◆	◆	◆
	Trazodone	◆	◆	◆	■	◆	◆	◆
	Venlafaxine	◆	◆	◆	■	◆	◆	◆
Anti-psychotics	Amisulpiride	◆	◆	◆	◆	◆	◆	◆
	Aripiprazole	◆	◆	◆	■	■	◆	■
	Chlorpromazine	◆	◆	◆	■	◆	◆	◆
	Clozapine	◆	◆	◆	■	◆	◆	■
	Flupentixol	◆	◆	◆	■	◆	◆	◆
	Haloperidol	◆	◆	◆	■	◆	◆	◆
	Olanzapine	◆	◆	◆	■	◆	◆	◆
	Paliperidone	◆	■	◆	◆	◆	■	■
	Quetiapine	◆	◆	◆	●	■	◆	■
	Risperidone	◆	◆	◆	■	◆	◆	◆
	Zuclopentixol	◆	◆	◆	■	◆	◆	◆

Table 4E. Drug-drug interactions between HCV DAAs and cardiovascular drugs.

		SOF	SOF/ LDV	SOF/ VEL	OBV/ PTV/r + DSV	GZR/ EBR	SOF/ VEL/ VOX	GLE/ PIB
Anti-arrhythmics	Amiodarone	●	●	●	●	■	●	■
	Digoxin	◆	■	■	■	◆	■	■
	Vernakalant	◆	◆	◆	■	◆	◆	◆
	Flecainide	◆	◆	◆	■	◆	◆	◆
Beta-blockers	Atenolol	◆	◆	◆	◆	◆	◆	◆
	Bisoprolol	◆	◆	◆	■	◆	◆	◆
	Carvedilol	◆	■	■	■	◆	■	■
	Propranolol	◆	◆	◆	◆	◆	◆	◆
Calcium channel blockers	Amlodipine	◆	■	■	■	◆	◆	◆
	Diltiazem	◆	■	■	■	◆	■	■
	Nifedipine	◆	◆	◆	■	◆	◆	◆
Hypertension and heart failure agents	Aliskiren	◆	■	■	●	◆	●	●
	Losartan	◆	◆	◆	◆	◆	◆	◆
	Doxazosin	◆	◆	◆	■	◆	◆	◆
	Enalapril	◆	◆	◆	■	◆	■	■

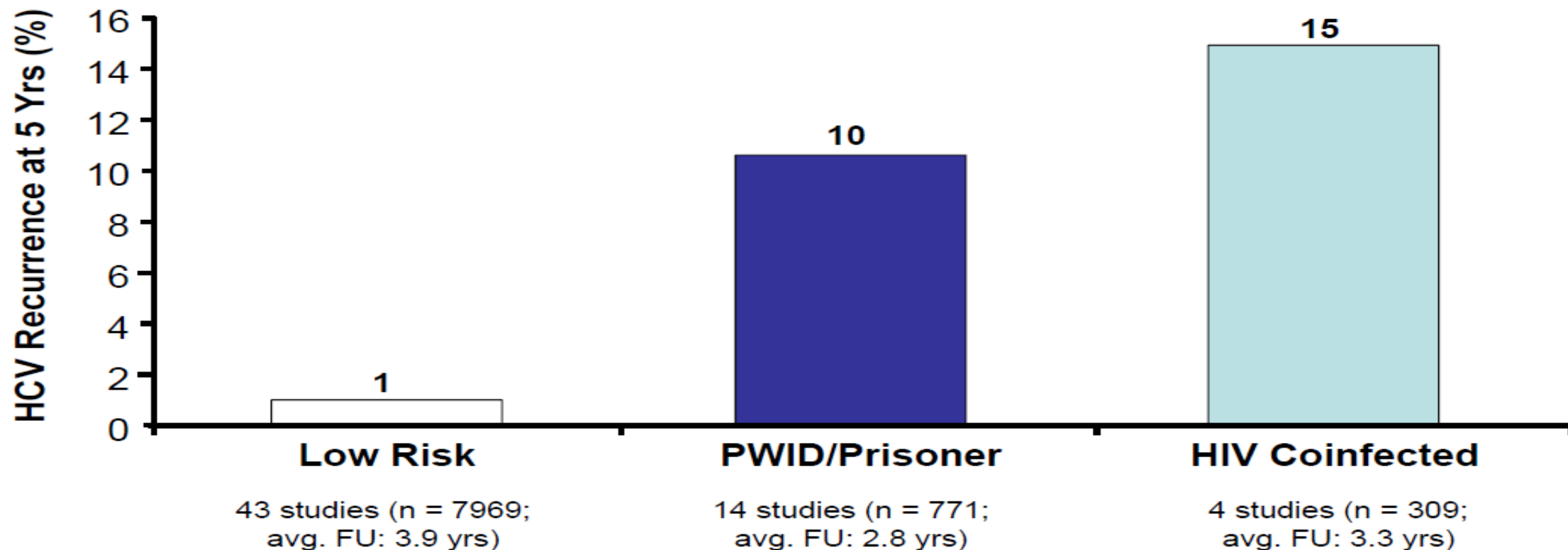
Increasing Involvement of Non-specialists

MERCK & CO., INC.
Kenilworth, N.J., U.S.A.





HCV Reinfection Over 5 Yrs by Study Population



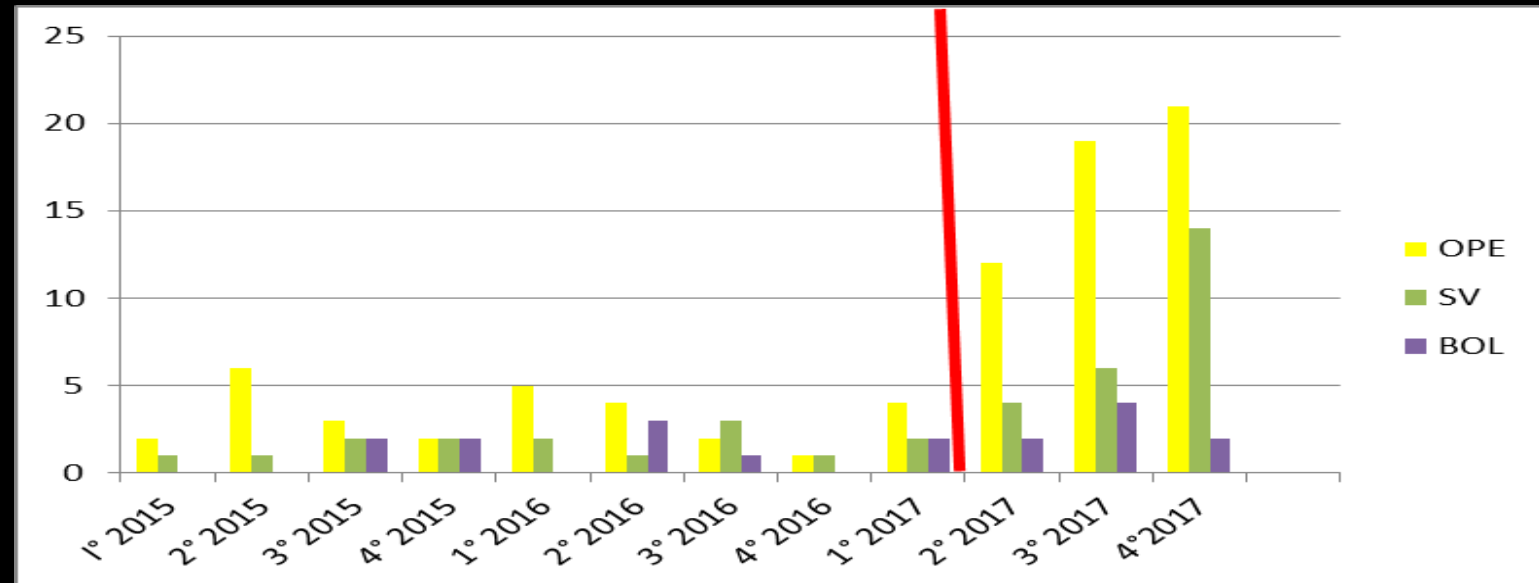
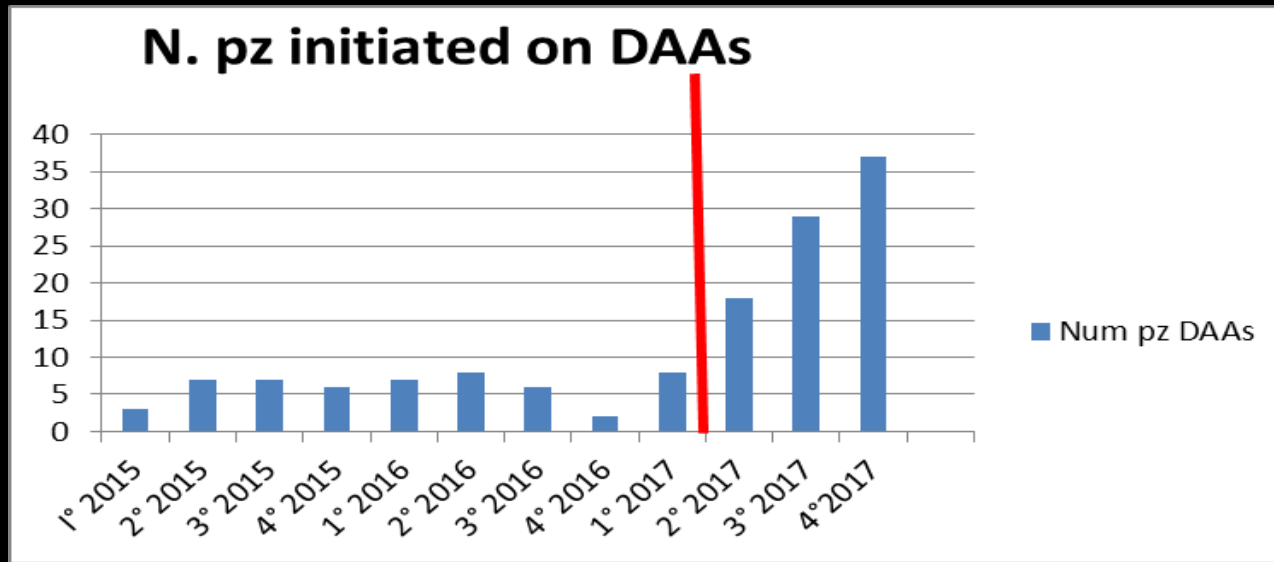
Milano protocol for eligibility and treatment

1. Inmates found to be HCV-Ab positive are promptly evaluated for liver functionality through blood tests and ultrasound contemporary with HCV RNA testing and genotyping.
2. In HCV RNA positive liver fibrosis assessment through elastometry is performed and counseling on treatment options are offered.
3. All eligible cases are discussed in a team including evaluation of co-morbidities, potential drug to drug interaction and judiciary concerns (duration of sentence , awaiting trials, possibility of transfer).
4. Hard copy of documentation is given to the patients at each step of the process, to ensure linkage to care in case of sudden release or unplanned transfer.
5. Patients eligible for treatment are informed about therapeutic options and schedules.
6. Drugs are sent to the prison from the central hospital pharmacy and taken in charge by Nurses. A specific nursing protocol for dispensing of DAAs has been implemented in order to reduce missing doses, improve adverse effects managements and ensure documentation and traceability.
7. An agreement with judiciary system has been reached to keep the patients in the same institution for the whole duration of treatment.
8. Patients started on treatment are evaluated monthly by ID specialist and followed on a daily basis by ward nurse and Detox team (nurse and psicologist) who reinforce adherence and address concomitant problems. Blood tests are performed monthly including HCV RNA determination. Clinical and virological follow up is carried out based on grade of fibrosis before treatment.
9. Once the treatment is completed a document including diagnosis, drug regimen, outcome and indication for medical facility is given to the patient aiming to ensure linkage to care when released.

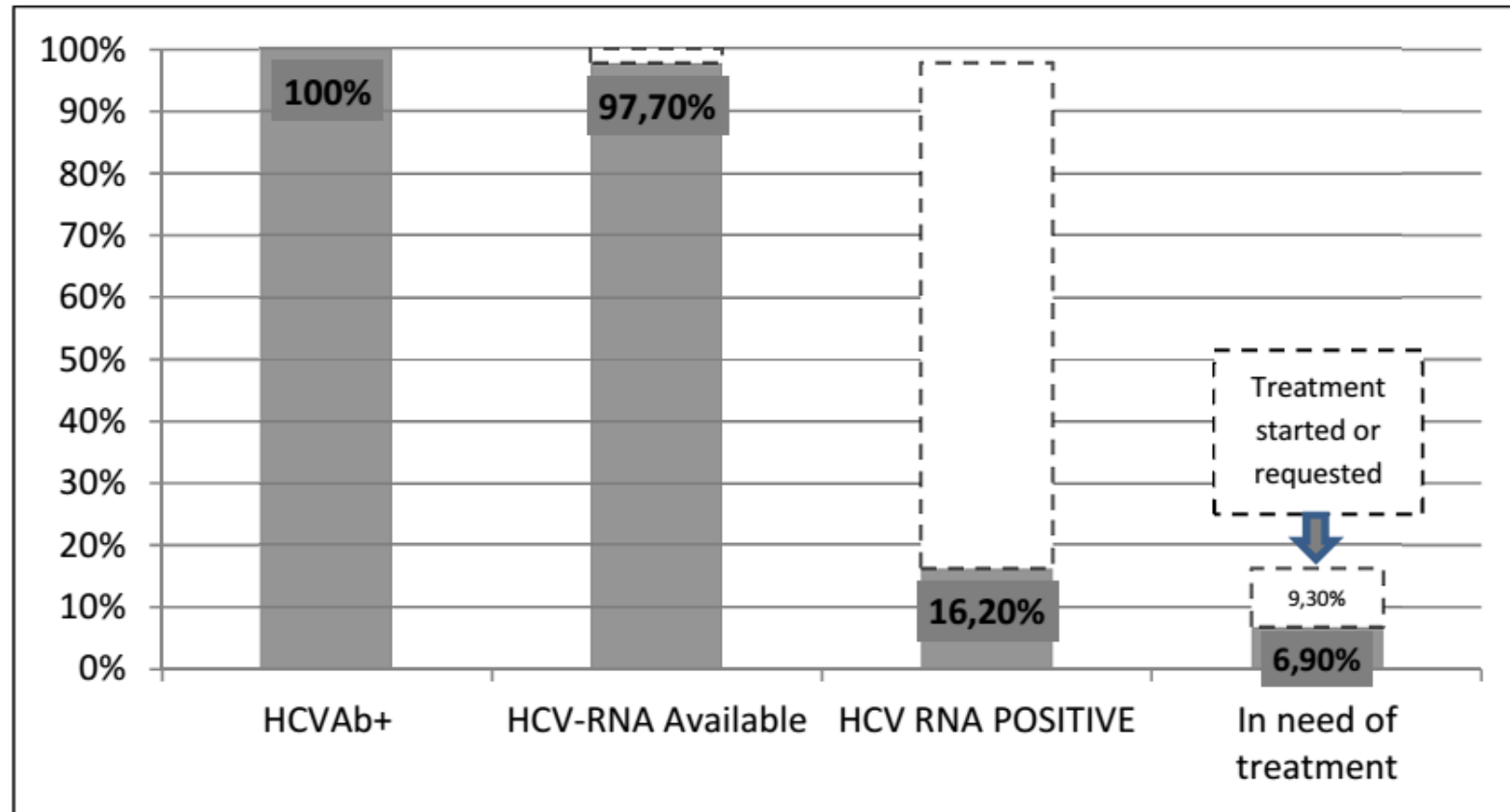
Trattamento con DAAs a Milano

- Numero pazienti trattati al 30 settembre 2018 : 240
- Maschi: 224 (94%)
- Femmine: 14
- Transgender: 2
- F3–4: 96 (40%)
- HIV/HCV trattati: 78 (33%)
- PWID trattati : 144 (60%)
- SVR 12: 97%
- Percentuale di pazienti riferiti alle Unità Ospedaliere di Epatologia/Gastroenterologia/Malattie Infettive: 40%

Trend dei trattamenti con DAAs per anno e per istituto



Cascade of care Milano



Situazioni su cui implementare intervento: pazienti difficili

- 1. Paziente Opera anni 45 cirrosi HCV positiva GT 3
 - Portatore di epilessia in terapia con Fenobarbital , TD ev
 - Non desiderio di cambiare terapia antiepilettica
 - Intervento motivazionale psichiatra psicologo SERD infettivologo
 - Visita neurologica(cambio terapia)
 - Terapia con DAAs (ottima compliance e negativizzazione già al 1^ mese)
 - EOTR, in attesa di SVR
-
- 2. Paziente di San Vittore 36 anni, cirrosi HCV GT 3
 - alcoolista trattato con DAAs a Bollate nel 2016
 - SVR mantenuta fibroscan stiffness da 53 Kpa a 11Kpa post trattamento. Rilasciato in libertà nel 2017, affidato a Comunità terapeutica e riferito a Malattie Infettive San Paolo
 - 2018 ricaduta nell'alcoolismo e nuova carcerazione. SVR mantenuta, ma rischio di reinfezione a aggravamento cirrosi COUNSELLING!!!!

PROPOSTE FINALI

- TEST RAPIDO ES SALIVARE E dove possibile HCV-RNA rapido (gene expert)
- Tempestivo counselling ed intervento multispecialistico
- Ecografia epatica (eventuali lesioni o cirrosi)
- No fibroscan uso scores: APRI, FIB 4
- Trattamento in sede anche prima di conoscere genotipo
- Quando possibile trattamenti brevi
- Utilizzo infermiere per controllo effetti collaterali e compliance
- Prelievo durante trattamento solo a cirrotici o se altri problemi
- SVR 12(24) discharge pz F1-F2 con recounselling su rischi reinfezione
- Follow up F3-F4 sec. Linee guida
- Documentazione e linkage to care
- Accordo con la Magistratura