

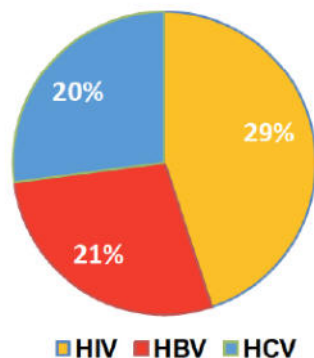
# I Piani di Eliminazione di HCV: Il ruolo dei Ser.D. nel sistema delle reti

Felice Alfonso Nava, MD, PhD

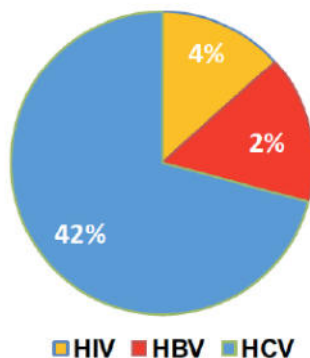
# Epidemiology in key population

Italian PWID <sup>1</sup>				
~450,000	~125,000	~300,000	~27%	>70%
High-risk drug users	Drug users in treatment	Drug users that need treatment	Injecting drug users in treatment	Polydrug users

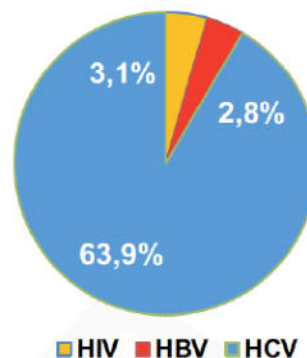
Tested patients in SerD<sup>2</sup>



Positive patients in SerD<sup>2</sup>



Positive patients in DAVIS study (N=543)<sup>3</sup>



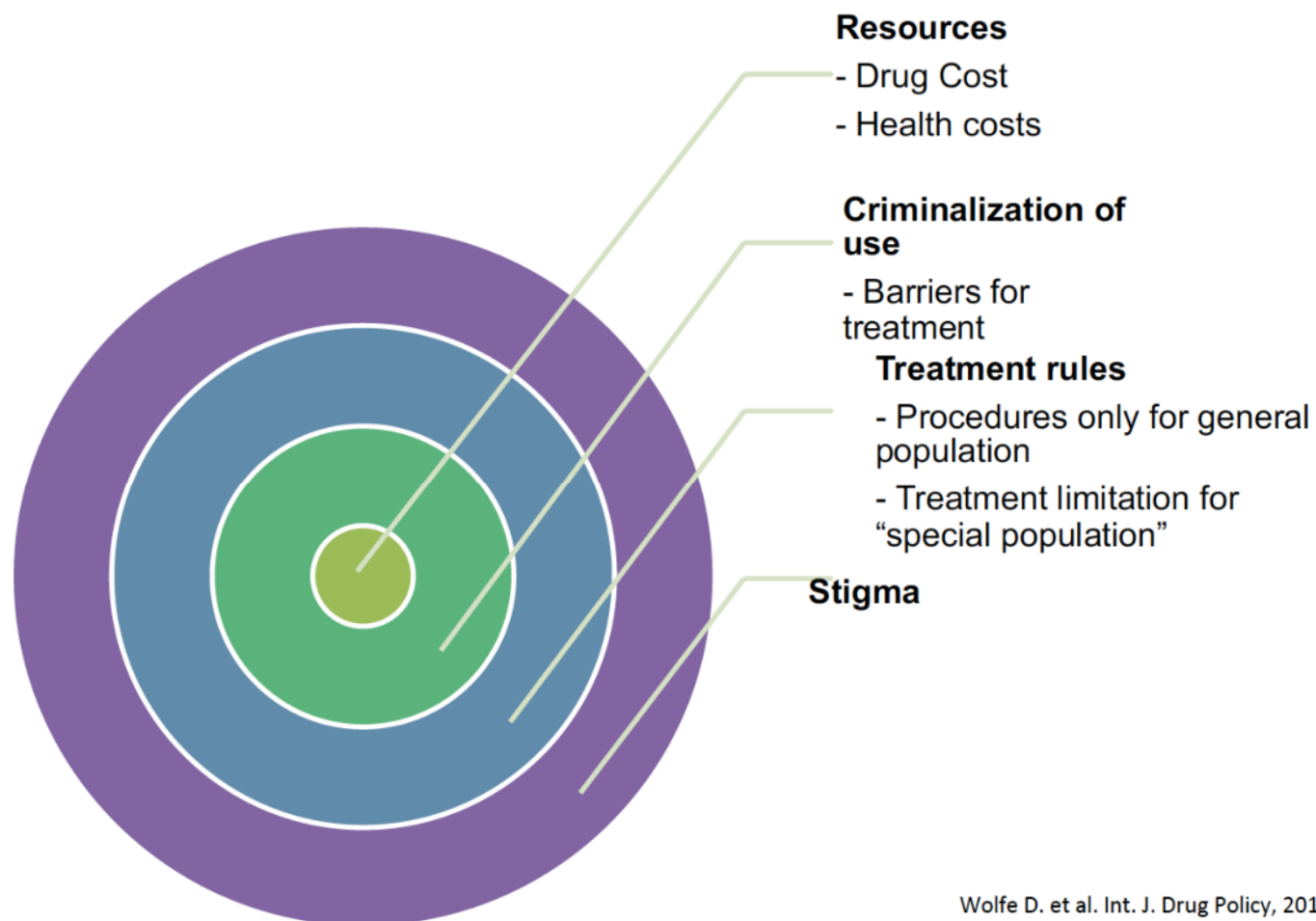
HCV-positive detainees<sup>4</sup>



22–38% HCV positive

1. Nava FA, et al. Italian Quarterly Journal of Addiction 2018;Mission 49:56–61; 2. Annual report to the Parliament 2019 on the status of drugs in Italy. Available at: [http://www.politicheantidroga.gov.it/media/2596/rap\\_2019-dati-2018.pdf](http://www.politicheantidroga.gov.it/media/2596/rap_2019-dati-2018.pdf); 3. Stroffolini T, et al. J Med Virol 2012;84:1608–12; 4. Zampino R, et al. World J Hepatol 2015;7:2323–30

# Structural Barriers



# Operational Barriers



## Patient's correlated

- Anawareness
- Behavioural disorders
- Social and aconomic difficuties
- Weak relationship with doctors
- Stigma
- No motivation to change



## Doctor's Correlated

- Anawareness
- Concern on adherence and reinfection
- Lack of a clinical network
- Lack of communication between spcialists

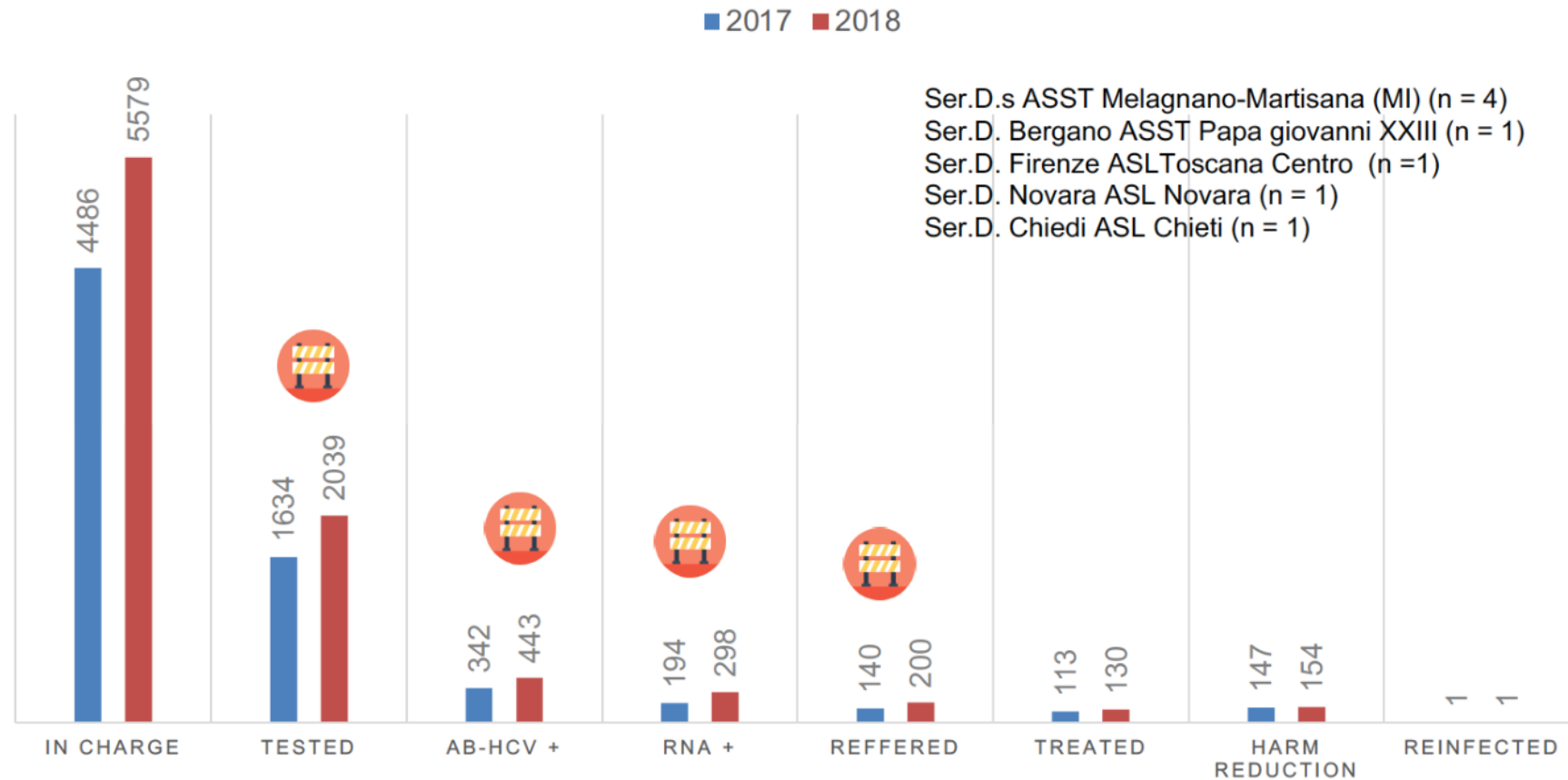


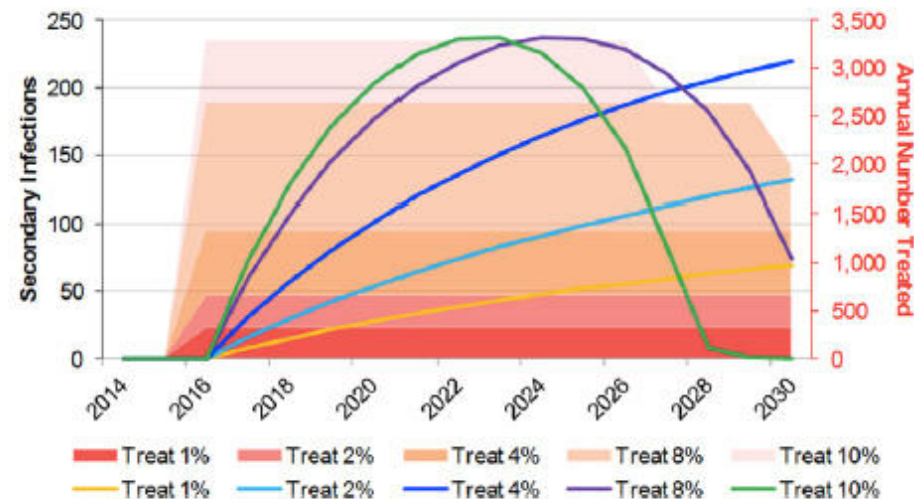
## System's correlated

- Lack of resources
- Lack of specialist collaboration
- Distannce between clinical centers
- No blood collection centers
- No procedures or guidelines

# Italian Barriers

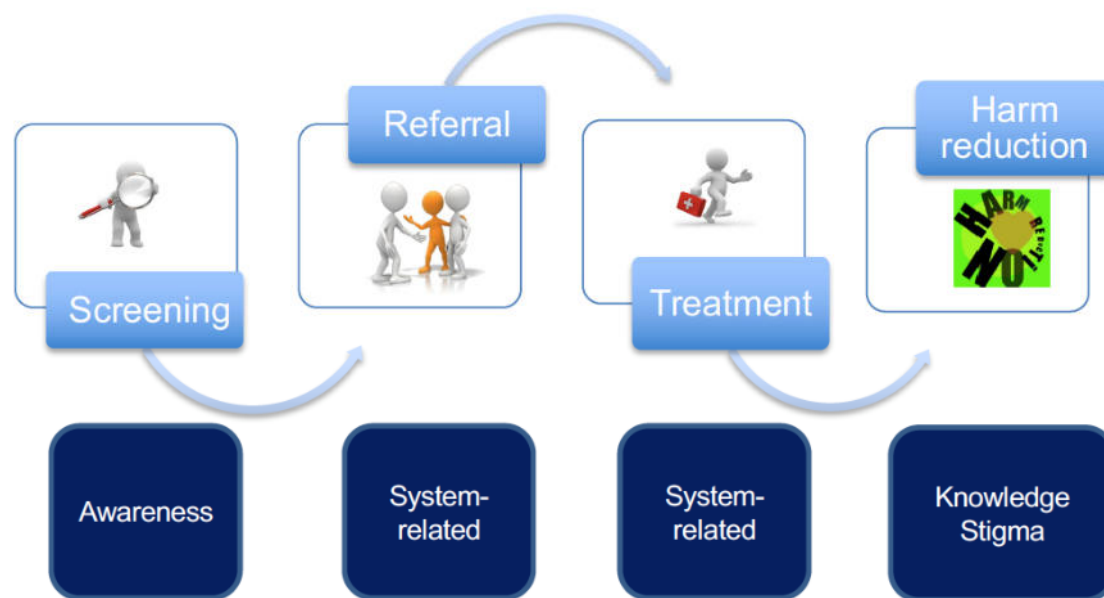
## CASCADE OF HCV CARE IN SER.D.S (SCUDO STUDY)





**Fig. 1.** Modeling the effect of HCV treatment on reinfection in people who inject drugs (PWID). Mathematical modeling was used to evaluate the effect of increased treatment on hepatitis C virus (HCV) reinfection among PWID in Australia. Each line represents the expected number of individuals with HCV reinfection (secondary infections, left axis) in each year, based on a given annual HCV treatment scenario. The colored lines represent the annual proportion of PWID treated per year. Permission to reproduce the image has been obtained from the author.<sup>84</sup> (Courtesy of Homie Razavi, PhD, Denver, CO, with permission; and *Reproduced from* Razavi H. Reducing a country's HCV-disease burden. The 4th International Symposium on Hepatitis in Substance Users (INHSU 2015). Sydney, Australia, October 7–9, 2015, with permission.)

# Treatment of PWID with HCV infection: Essential Step



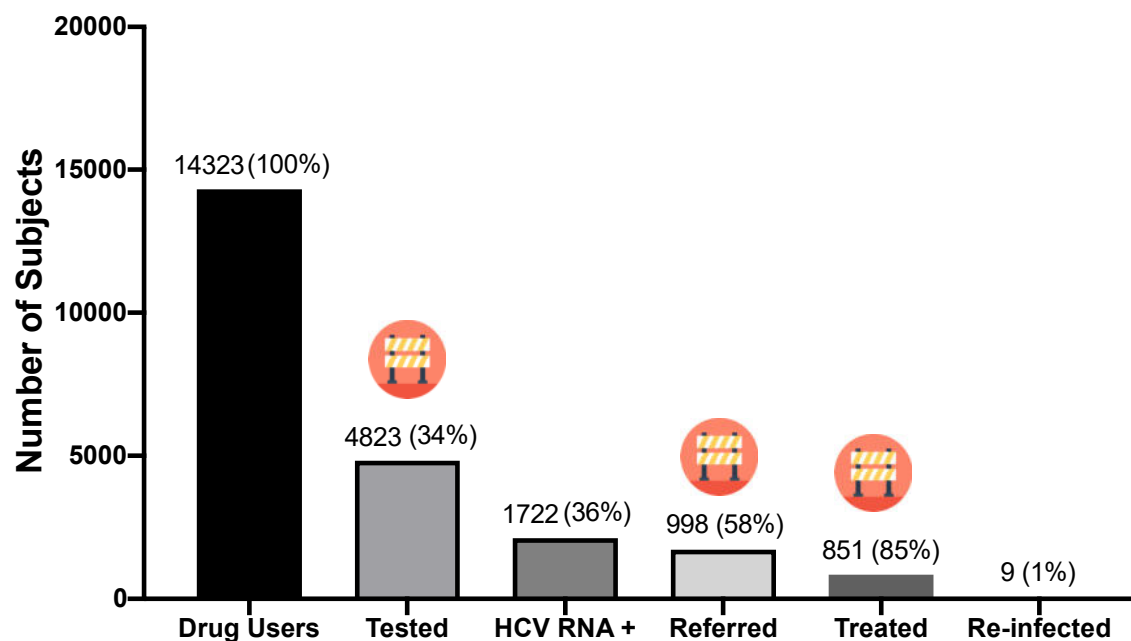


# Epidemiology of Special Population in Veneto Region (31 Dec. 2018)



REGIONE DEL VENETO

Cascade of HCV Treatment in Ser.D.s



Unpublished data

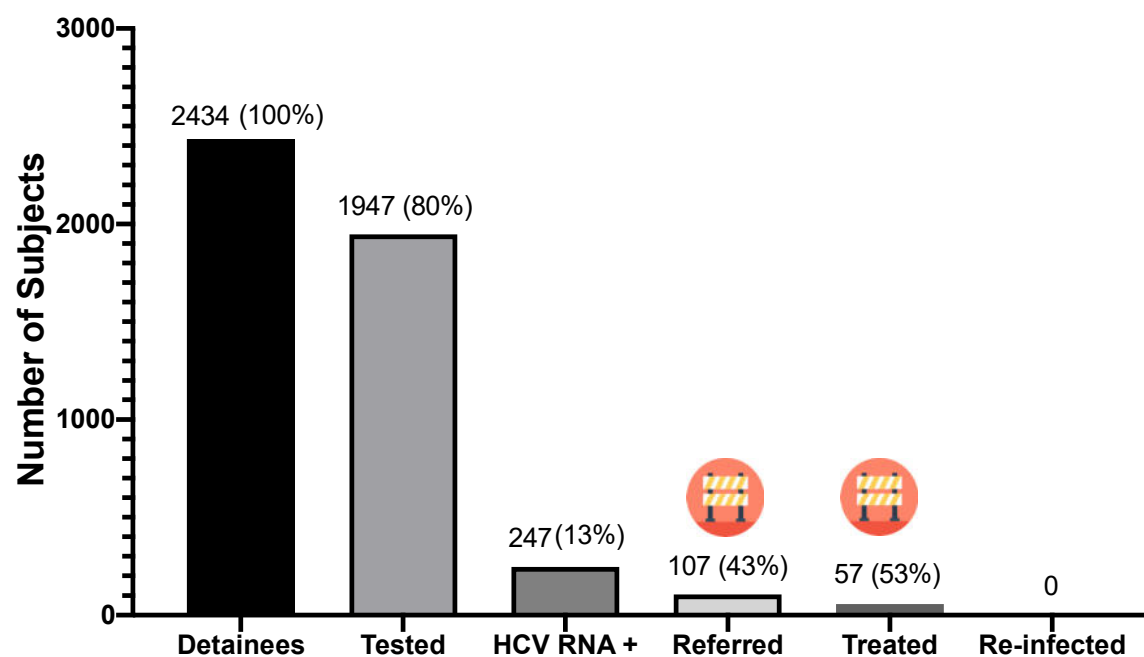


# Epidemiology of Special Population in Veneto Region (31 Dec. 2018)



REGIONE DEL VENETO

Cascade of HCV Treatment in Prisons



Unpublished data

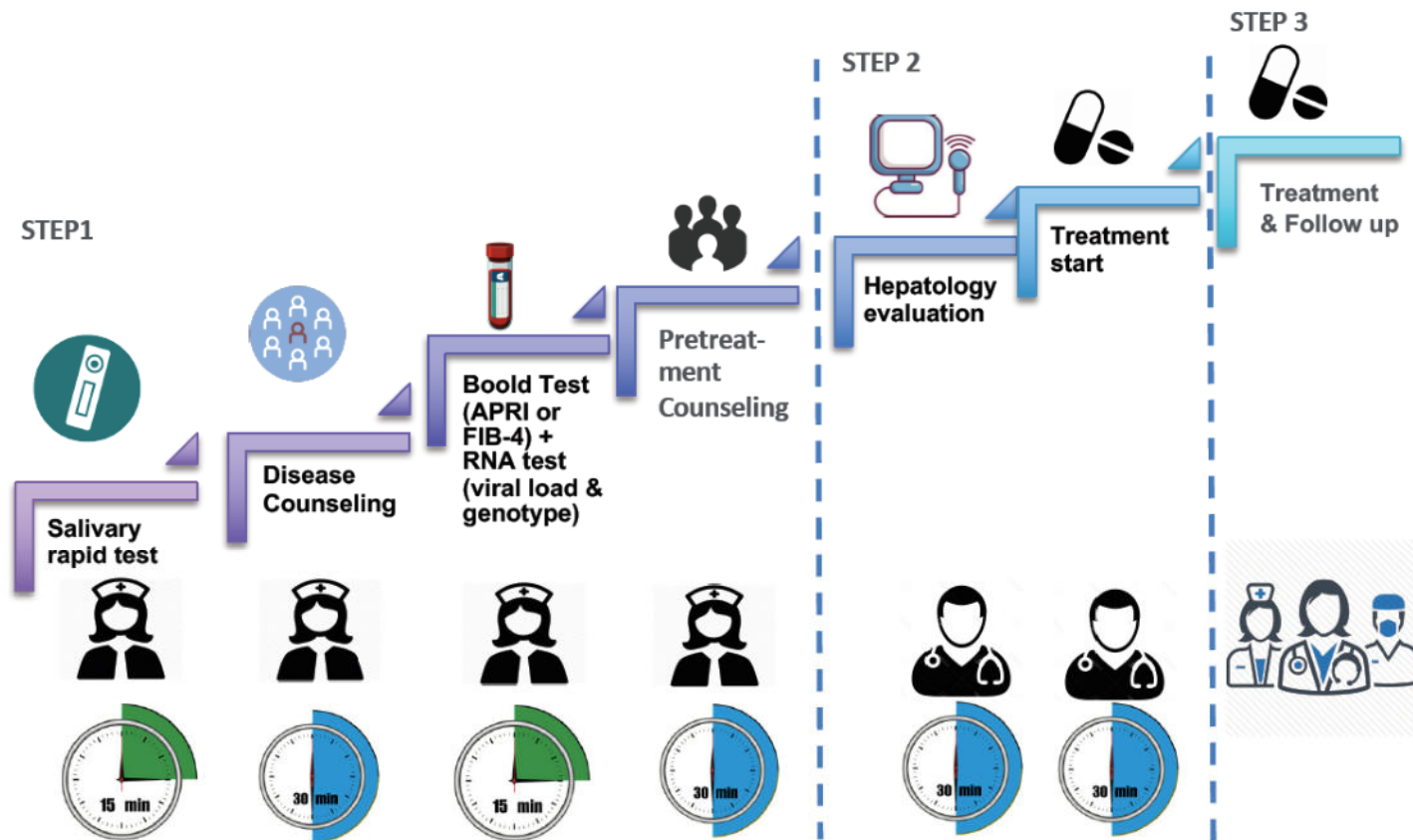
# The Point of Care

The «**Point of Care**» is a *fast track* clinical pathways, a sort of diagnostic therapeutic pathways with the aim to make on site (where is the patient) screening, diagnosis, and treatment

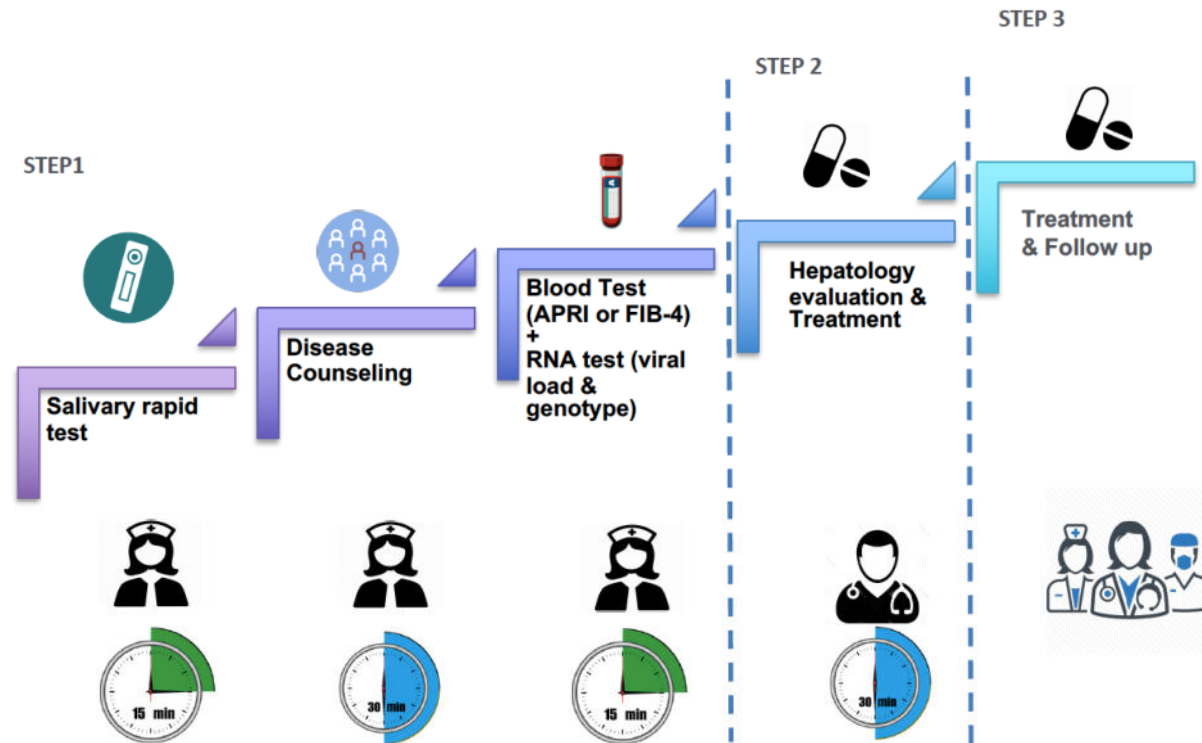
# The Point of Care for PWIDs

The **Point of Care** inside Ser.D.s and Prisons consists of a pre-ordinated sequence of actions able to make diagnosis and to make easy the beginning of treatment (removing referral barrier)

# Test & Treat: Point of Care



# Test & Treat: Point of Care (12 Criteria AIHA Removed)



# EASL HCV treatment recommendations 2020



## Simplified treatment algorithm

- Improving access to HCV therapy has become a worldwide priority
- When genotype/subtype determination is not available, not affordable and/or limits access, simplified treatment should be used to facilitate the cascade of care
- Groups who will benefit from a streamlined care pathway:

PWID	Prisoners	Homeless individuals	Migrants	Rural communities with poor access to care
People with mental health disorders	People with substance use disorders	MSM	Sex workers	Indigenous populations

*"Pangenotypic HCV drug regimens can be used to treat individuals without identifying the HCV genotype and subtype"*

## Genotype/subtype determination-based algorithm

- Where available and affordable, and access to care would not be limited, genotype/subtype determination could optimise results in some groups

GT 1b

GT 3a  
CC

- If sequence analysis of the NS5B coding region is available and affordable it should be performed in:

**Patients born in sub-Saharan Africa, China or South-East Asia**

1l

4r

3b

3g

6u

6v

- EASL CPG HCV. J Hepatol 2020; <https://doi.org/10.1016/j.jhep.2020.08.018>
- CC, compensated cirrhosis; GT, genotype; MSM, men who have sex with men; PWID, people who inject drugs

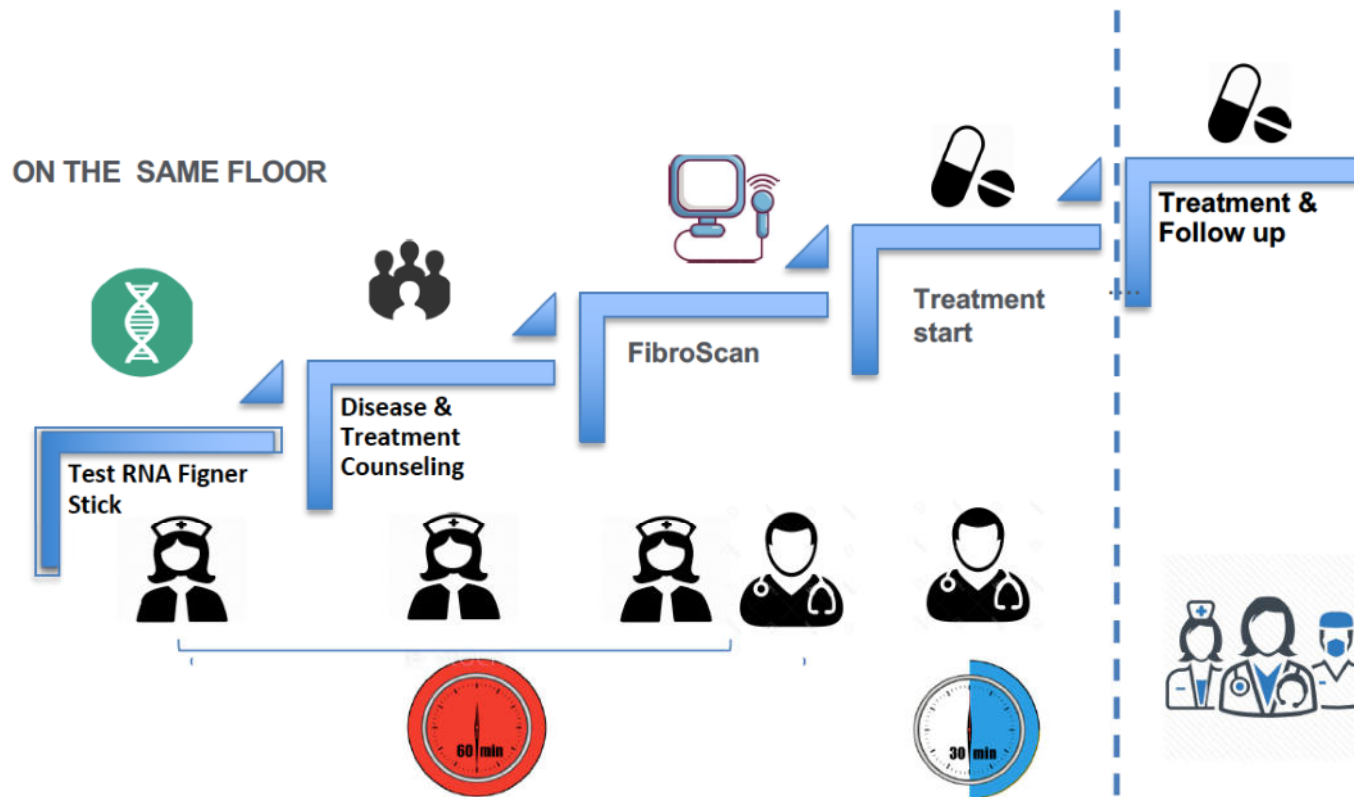
# Simplified, genotyping-/subtyping-free treatment with pangenotypic regimens

- Simplified, genotyping-/subtyping-free pangenotypic treatment must be used **to improve access to HCV treatment** and increase the global infection cure rates **in any setting** where genotype and subtype determination is not available, affordable and/or would limit access to therapy (A1)
- Pre-treatment assessment can be limited to the presence of HCV viraemia and the presence or absence of cirrhosis by a non-invasive method (A1)
- Possible DDIs should be carefully checked and dose modifications implemented when necessary (A1)
- Testing for SVR12 can be omitted in all adherent patients except those with high-risk behaviours and risk of reinfection (B1)

• EASL CPG HCV. J Hepatol 2020; <https://doi.org/10.1016/j.jhep.2020.08.018>  
• DDI, drug–drug interaction; SVR12, sustained virological response 12 weeks after the end of treatment

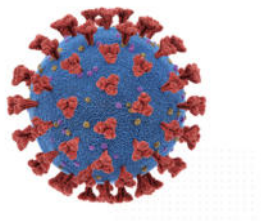


# Test & Treat: Point of Care (Fast-Track) (Genotype Removed)



# Test & Treat Project: SerD e Carceri (DG 791/2018): Progetto Coris

**Proposta di rimodulazione del progetto Coris per  
ravorire l'inizio del trattamento: i presupposti**



Il continuare dell'emergenza COVID-19



*Ministero della Salute*

DIREZIONE GENERALE DELLA PREVENZIONE SANITARIA

UFFICIO 5

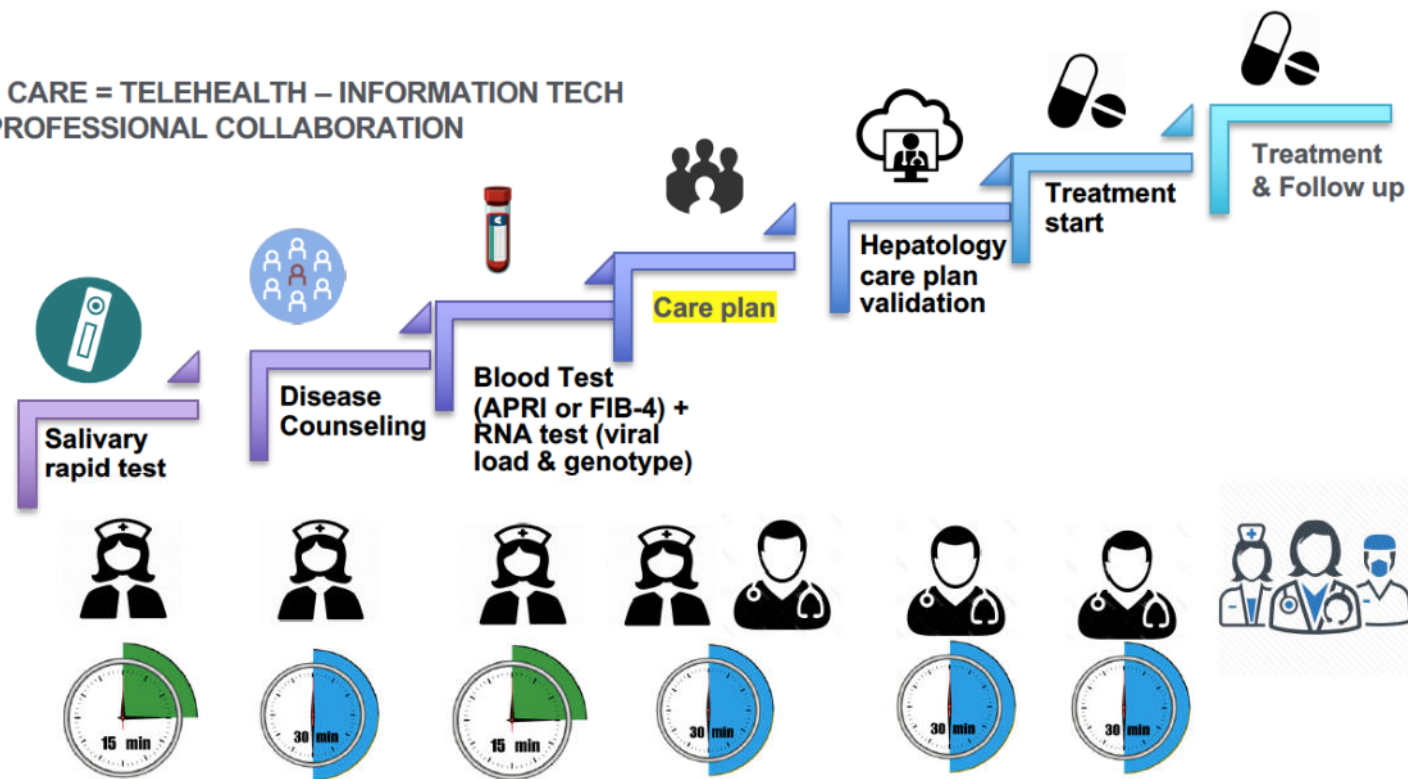
*Prevenzione delle malattie trasmissibili e profilassi internazionale*

Gruppo di Lavoro per la redazione del decreto interministeriale ai sensi dell'art. 25 sexies del  
D.L. 30 dicembre 2019 n. 162

L'offerta di test rapidi (capillari e RNA finger stick) per tutta la popolazione in  
carico ai SerD per il 2020-21

# Test & Treat: Plan of Care

PLAN OF CARE = TELEHEALTH – INFORMATION TECH  
– INTERPROFESSIONAL COLLABORATION



F.A. Nava, Personal Communication

# Test & Treat Project: SerD e Carceri (DG 791/2018): Progetto Coris

## Proposta di rimodulazione del progetto per l'inizio del trattamento: il Piano di cura

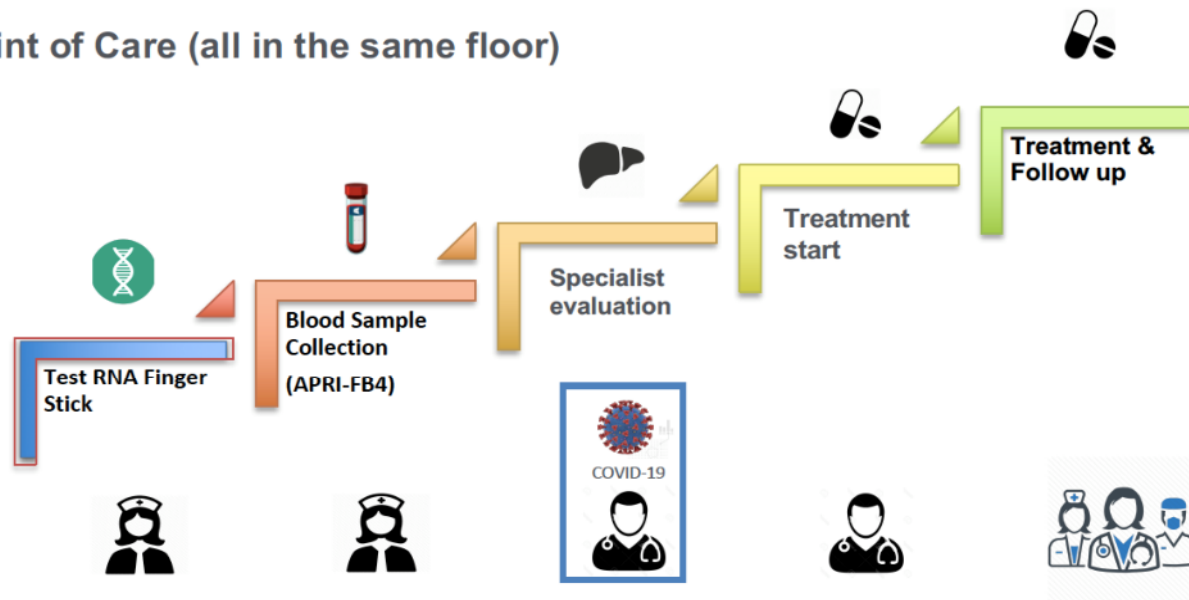
I **medici infettivologi/epatologi** attraverso il **piano di cura** redatto dai **medici dei SerD e delle carceri** all'interno del percorso per i pazienti **HCV +** predispongono l'**inizio del trattamento**:

- scegliendo il farmaco da somministrare;
- stabilendo le modalità di monitoraggio e di follow-up

I **medici dei SerD e presso le carceri**, come predisposto dai **medici infettivologi/epatologi**, eseguiranno il monitoraggio e il follow-up

# Point of Care at COVID-19 Era

Point of Care (all in the same floor)



F.A. Nava, Personal Communication

# EASL HCV treatment recommendations 2020

Treatment-naïve/treatment-experienced patients with or without compensated cirrhosis



## Simplified treatment (no genotype/subtype determination)\*

Genotype	Cirrhosis status	Treatment history	SOF/VEL	GLE/PIB	SOF/VEL/VOX	GZR/EBR
All genotypes	No cirrhosis	Treatment-naïve	12 weeks	8 weeks	No	No
		Treatment-experienced				
	Compensated cirrhosis (CTP A)	Treatment-naïve		12 weeks		
		Treatment-experienced				

- Treatment-experienced defined as previously treated with PEG-IFN + RBV; SOF + PEG-IFN + RBV; or SOF + RBV.
- \*Whenever HCV genotype and subtype determination is not available, not affordable and/or limits access to care.
- CTP, Child–Turcotte–Pugh; EBR, elbasvir; GLE, glecaprevir; GZR, grazoprevir; PEG-IFN, pegylated interferon; PIB, pibrentasvir; RBV, ribavirin; SOF, sofosbuvir; VEL, velpatasvir; VOX, voxilaprevir
- EASL CPG HCV. J Hepatol 2020; <https://doi.org/10.1016/j.jhep.2020.08.018>

# Drug-drug interactions between HCV DAAs and illicit/recreational drugs or drug of abuse

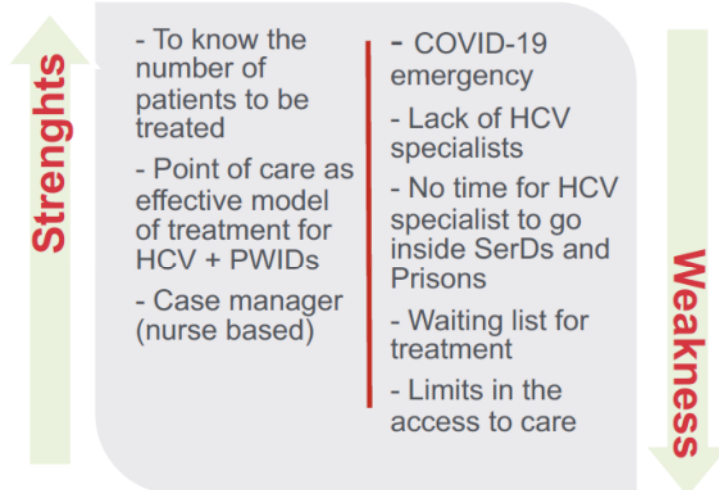
	SOF	SOF/VEL	SOF/VEL/VOX	GLE/PIB	GZR/EBR
Amphetamine	◆	◆	◆	◆	◆
Cannabis	◆	◆	◆	◆	◆
Cocaine	◆	◆	◆	◆	◆
Diamorphine	◆	◆	◆	◆	◆
Diazepam	◆	◆	◆	◆	◆
Fentanyl	◆	◆	◆	■	■
Gamma -hydroxybutyrate	◆	◆	◆	■	■
Ketamine	◆	◆	◆	◆	◆
MDMA (ecstasy)	◆	◆	◆	◆	◆
Mephedrone	◆	◆	◆	◆	◆
Methadone	◆	◆	◆	◆	◆
Methamphetamine	◆	◆	◆	◆	◆
Oxycodone	◆	◆	◆	■	■
Phencyclidine (PCP)	◆	◆	◆	◆	◆
Temazepam	◆	◆	◆	◆	◆

DAAs, direct-acting antivirals; EBR, elbasvir; GLE, glecaprevir; GZR, grazoprevir; PIB, pibrentasvir; SOF, sofosbuvir; VEL, velpatasvir; VOX, voxilaprevir.



# COVID-19 Era: The Active Ingredients

## Points to consider:



## Points to consider:

- Care plan managed by HCV specialist in tele-health
- Clinical evaluation and treatment by addiction specialist
- Operational management made by addiction nurse

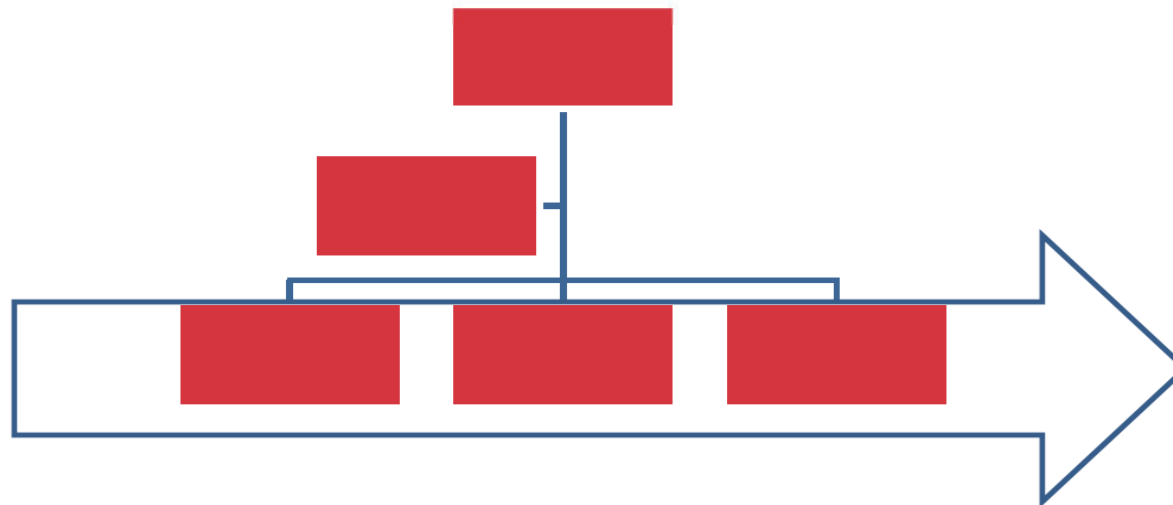


The organization should not preserve the “internal order” that can be a “barrier” for client’s need....

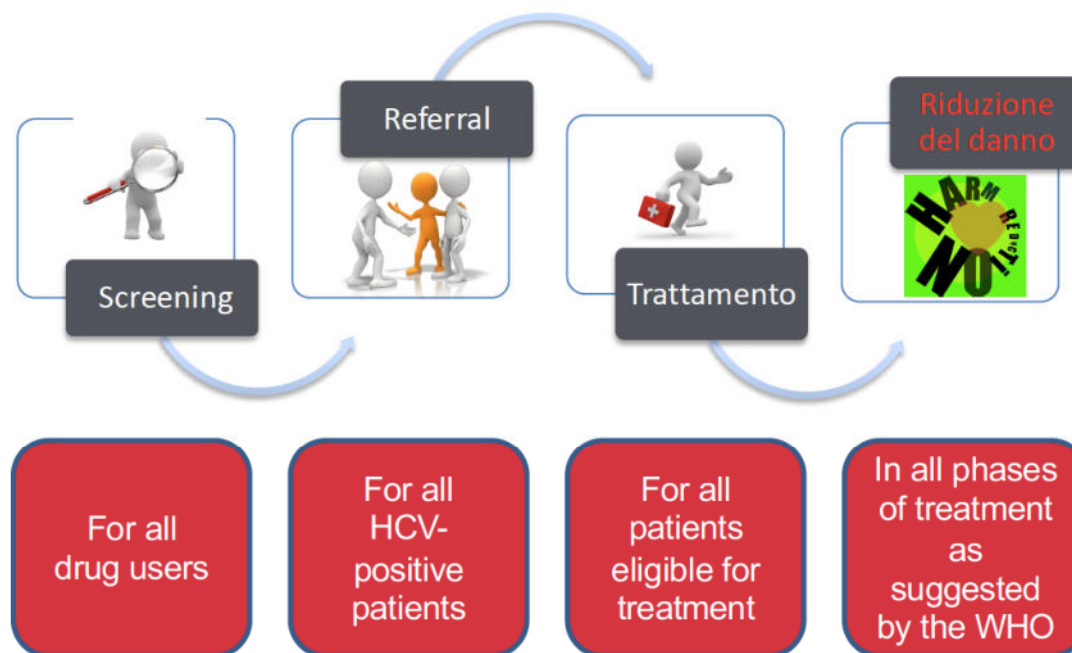


The organization is vertical while the client’s service is horizontal

*George Fisher former Motorola CEO*



# Patient's Journey





**Teoria dei germi**  
**Vaccinare il pesce**

**Teoria del terreno**  
**Pulire la vasca**

# Harm Reduction Kit



Information provided by Dr Felice Alfonso Nava

# Go Beyond: Plan of Care as New Paradigm

- Effective
- Simplify
- Access to care
- Team work & Clinical Network
- Cost-effectiveness (“health return”)

REGIONE DEL VENETO



ULSS6  
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