

Giornate Infettivologiche “Luigi Sacco” 2022

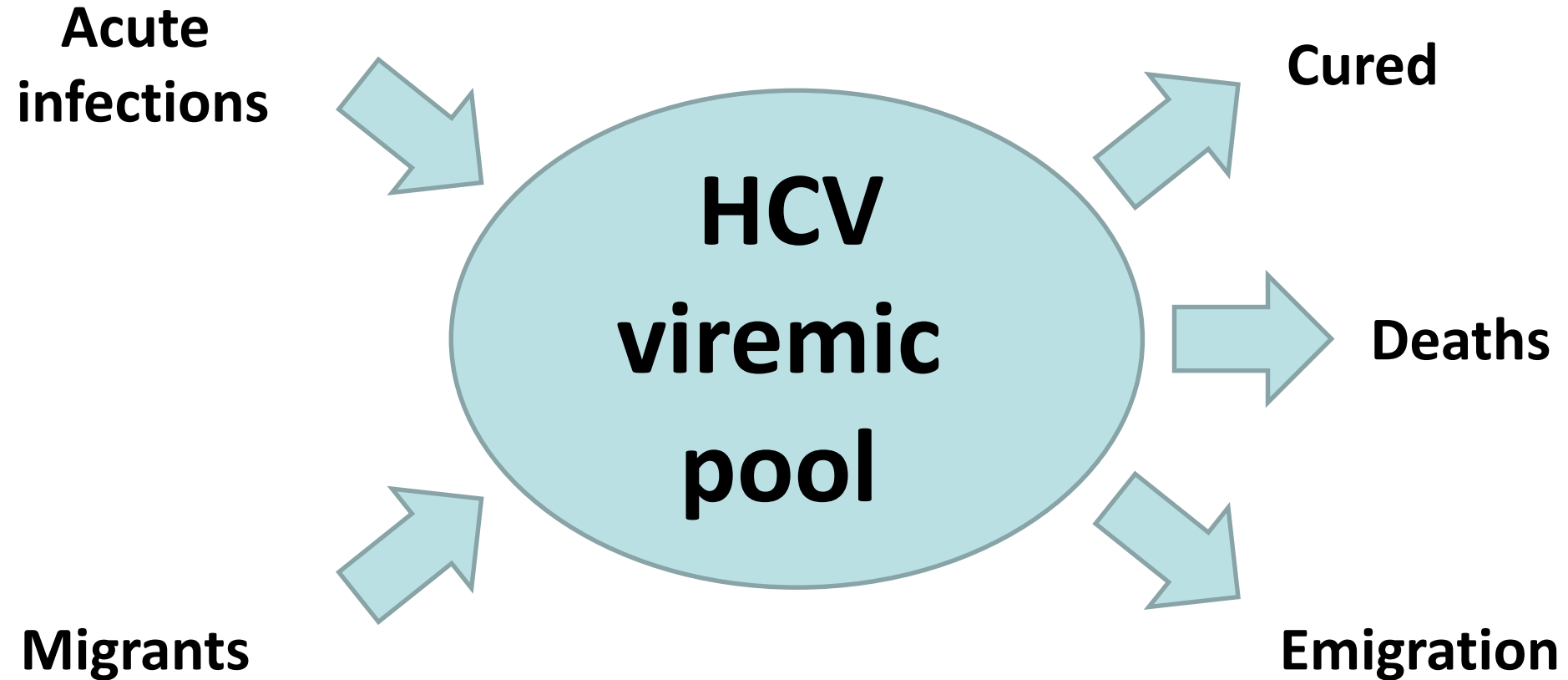
**HCV: epidemiologia italiana e strategie di
eliminazione nel contesto nazionale**

Milano, 14 Ottobre 2022

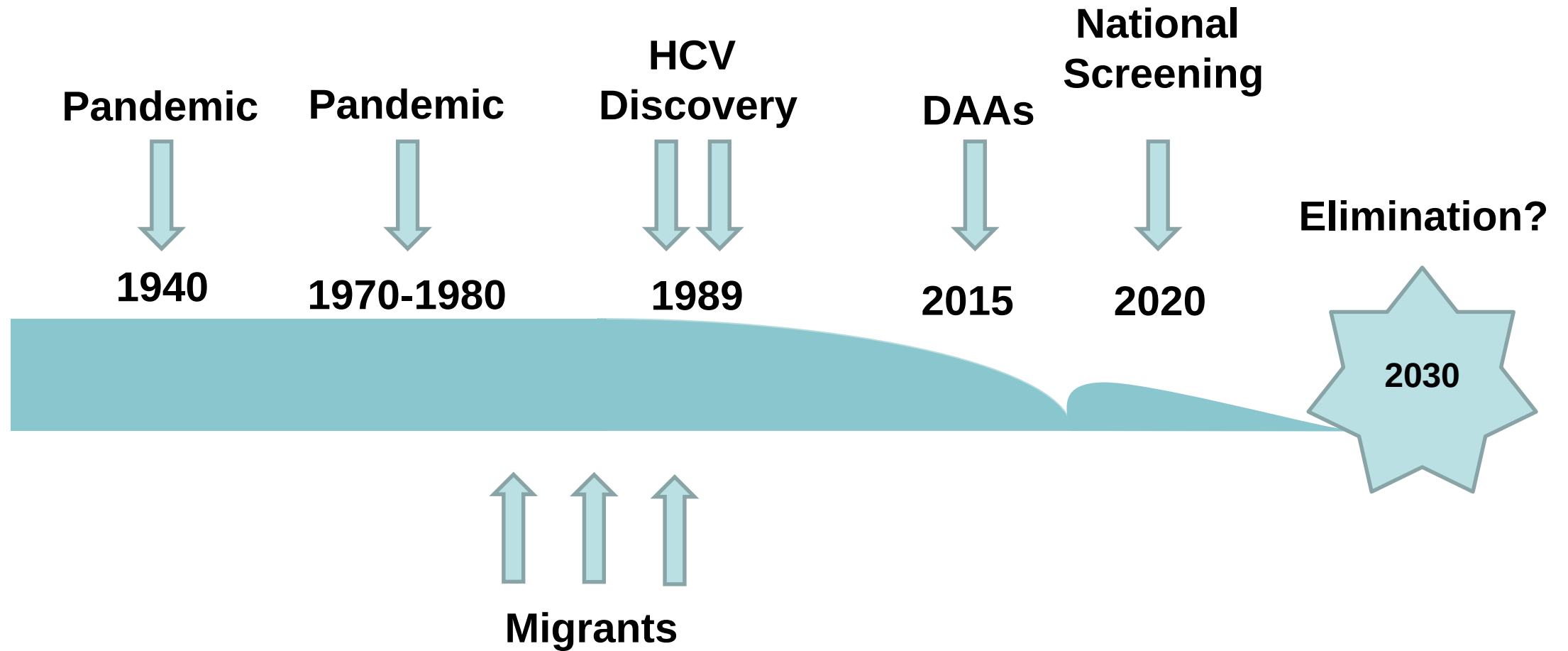
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Humanitas Research Hospital, Rozzano, Italy

Hepatitis Epidemiology: a Dynamic Process



Key Steps in Italian HCV Epidemiology



Acute HCV In Italy: Data from SEIEVA

Acute hepatitis C: the yearly incidence of reported acute hepatitis C decreased from 2 (1991) to 0,2 cases/100.000 (2010)

TABLE I. Incidence (per 100,000 Inhabitants) of Symptomatic Acute Hepatitis C Notified in Italy by Age Groups

Year	Age groups (years)			Total	
	0–14 Incidence	15–24 Incidence	≥25 Incidence	Incidence	Population surveyed
1991	1	5	2	2	16,401,503
1992	0	4	2	2	22,622,762
1993	0	3	1	2	22,622,762
1994	0	3	2	2	22,804,610
1995	0	2	2	2	23,060,981
1996	0	2	1	1	25,900,850
1997	0	1	1	1	31,882,134
1998	0	1	1	1	31,882,134
1999	0.2	1	1	1	32,331,986
2000	0.1	0.7	0.7	0.7	33,429,357
2001	0.4	1	1	0.7	33,429,357
2002	0.1	1	1	0.7	33,429,357
2003	0.1	0.6	0.9	0.7	33,429,357
2004	0.1	0.4	0.7	0.6	33,701,132
2005	0	0.6	0.6	0.5	35,194,296
2006	0.06	0.5	0.6	0.5	35,194,296
2007	0.03	0.4	0.6	0.5	35,194,296
2008	0.02	0.4	0.5	0.4	32,710,179
2009	0	0.2	0.2	0.2	41,332,167
2010	0	0.2	0.4	0.2	41,612,521

SEIEVA 1991–2010.

In 2010, 72,6% of the population was covered by SEIEVA

The decrease was greater among persons aged 15–24 years (25-fold) than among persons >25 years (10-fold).

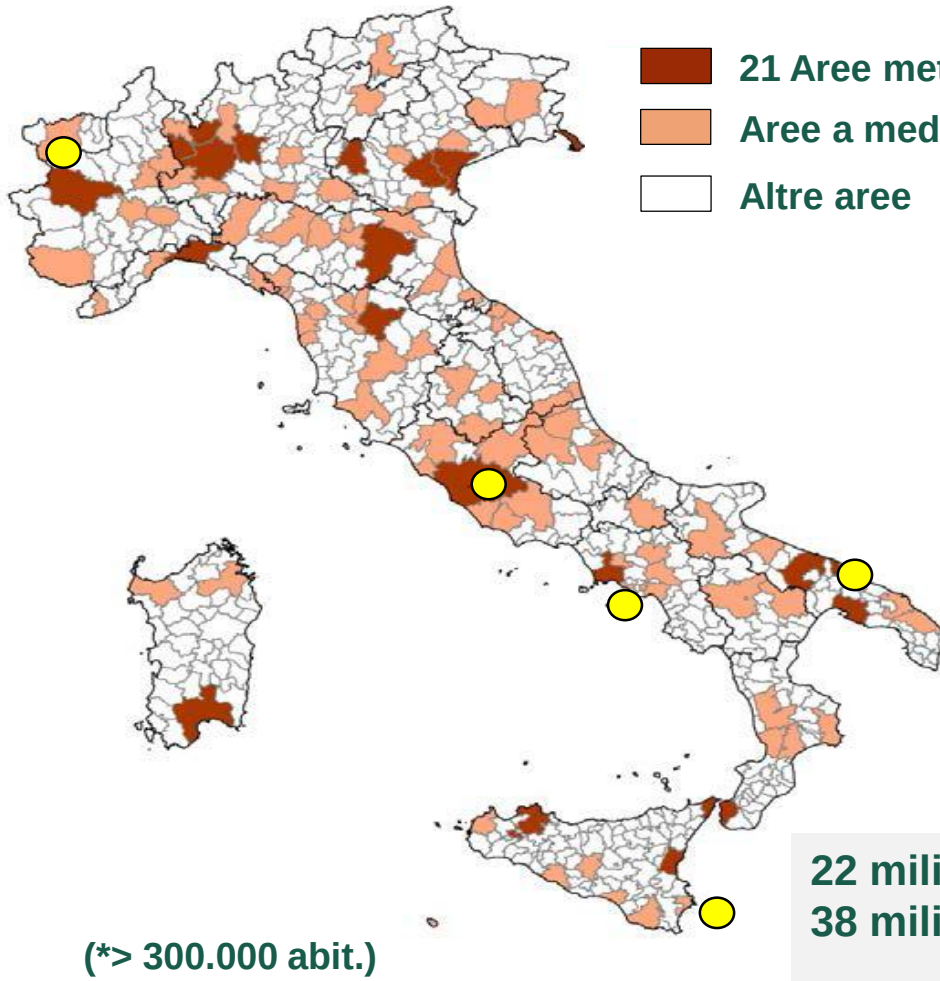
HCV prevalence trend

Town (Italian Region)	Sample	anti-HCV prevalence (%)	Year of sampling
Valentano (Lazio) ¹	681	8,4	1994
Sersale (Calabria) ²	1352	12,6	1996
Buonalbergo (Campania) ³	488	16,2	1997
Camporeale (Sicilia) ⁴	721	10,4	1999
Cittanova (Calabria) ⁵	1645	6,5	2001
Vicenza (Veneto) ⁶	965	2,6	2002
Putignano (Puglia) ⁷	2195	2,6	2005-2007

1. **Stroffolini** *et al*, Ital J Gastroenterol. 1995 Jun;27(5):235-8.
2. **Stroffolini** *et al*, Ital J Gastroenterol Hepatol. 1997 Oct;29(5):415-8.
3. **Maio** *et al*, J Hepatol. 2000 Jul;33(1):116-20.
4. **Di Stefano** *et al*, J Med Virol. 2002 Jul;67(3):339-44.
5. **Pendino** *et al*, Hepatology. 2005 May;41(5):1151-9.
6. **Fabris** *et al*, J Clin Gastroenterol. 2008 May-Jun;42(5):527-32.
7. **Cozzolongo** *et al*, Am J Gastroenterol. 2009 Nov;104(11):2740-6.

7 studies carried out in Italy from 1994 to 2007
5 Italian Regions; small towns

HCV Prevalence In Italy



Andriulli et al. - 2018:

Prevalenza d'infezione HCV nel 2015 in 5 aree metropolitane*:

Torino (Nord)

Roma (Centro)

Napoli, Bari e Catania (Sud)

Campionamento (4907 persone) random dalle liste di assistiti di Medici di Medicina Generale (MMG)

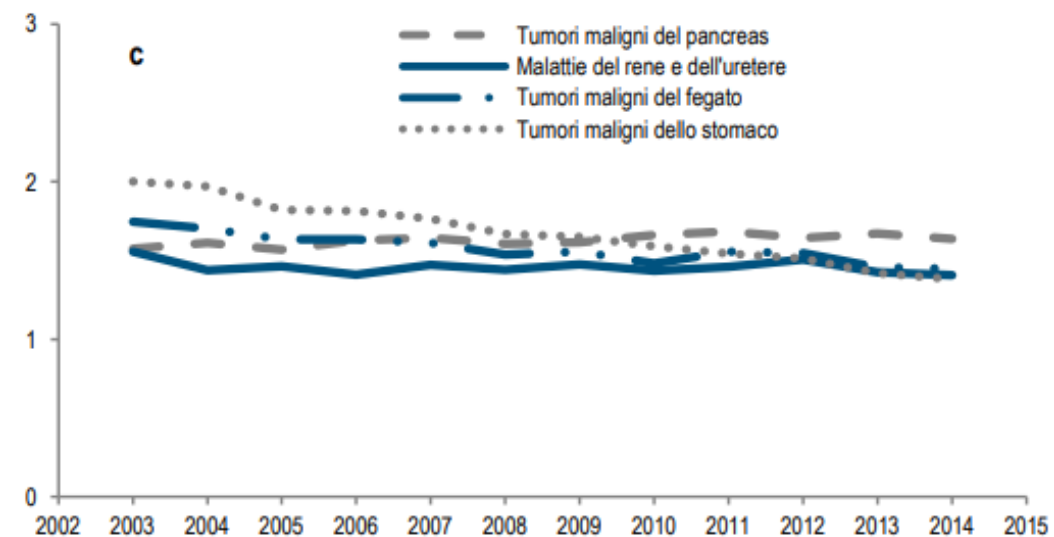
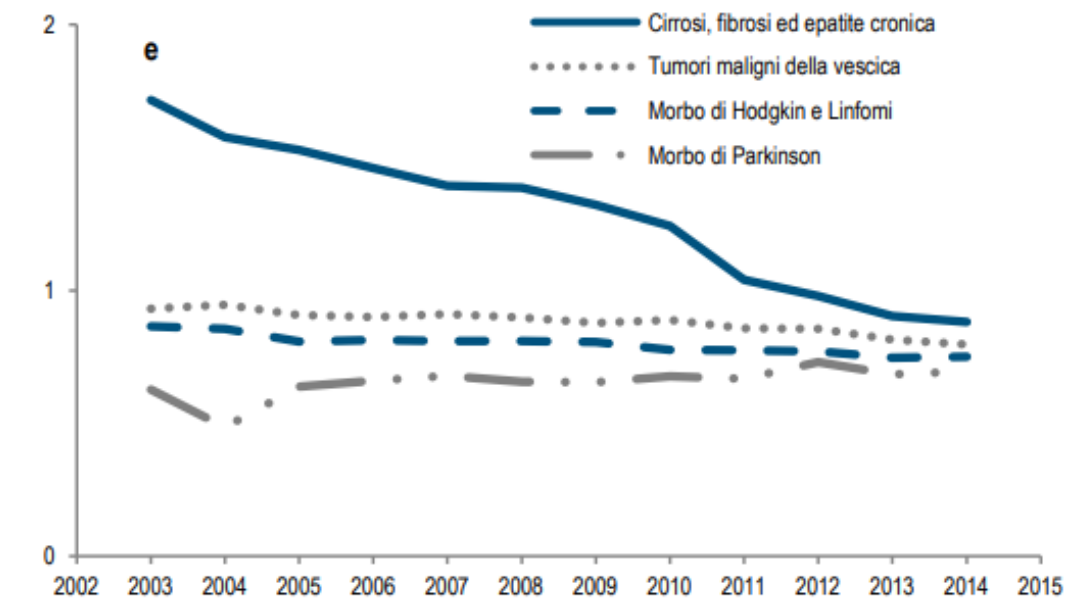
22 milioni di persone risiedono in 21 Aree metropolitane
38 milioni (63%) in centri medio-piccoli

ISTAT, 2017. Codice ISBN 978-88-458-1916-2

Prevalenze dell'infezione da HCV nel 2015 in 5 aree metropolitane

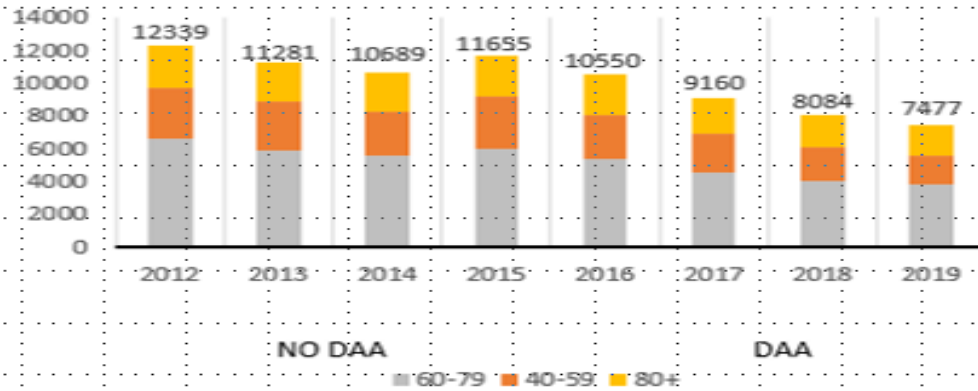
	prevalenza infezione da HCV (%)		
	Nord	Centro	Sud/isole
classi di età	Torino	Roma	Napoli-Bari-Catania
<31	0.0	1.0	0.0
31-40	0.6	2.6	0.9
41-50	1.1	1.8	1.7
51-60	2.9	1.2	0.7
61-70	2.6	1.1	2.3
71-80	3.2	6.4	8.6
> 80	0	4.8	5.8

Mortality for Liver Diseases in Italy

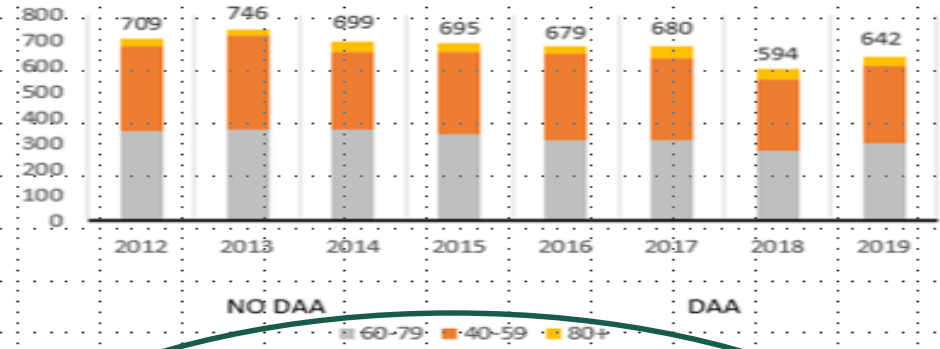


Impact of DAAs on Hard Endpoints in Italy

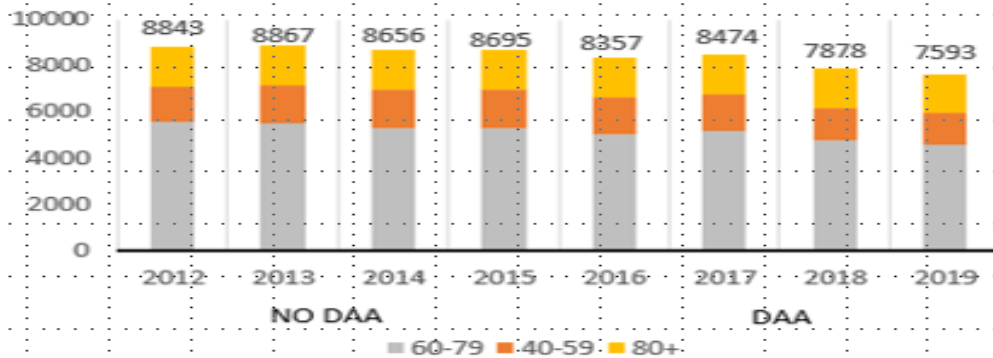
Annual incident hospitalizations for cirrhosis without mention of alcohol, by age cohort.



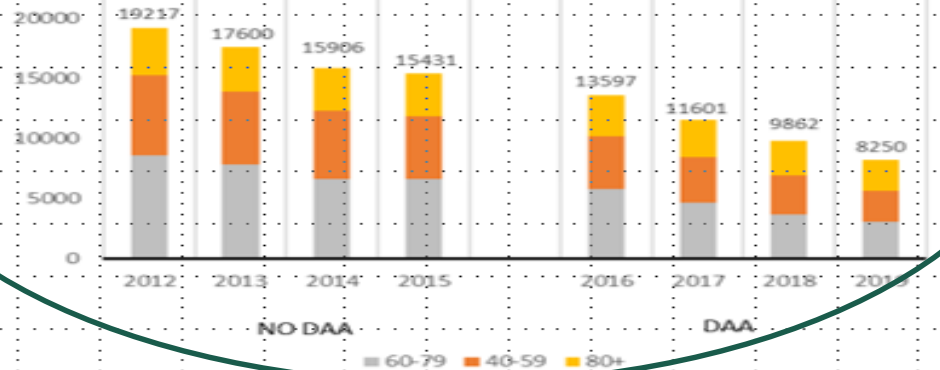
Annual incident hospitalizations for cirrhosis with mention of alcohol, by age cohort.



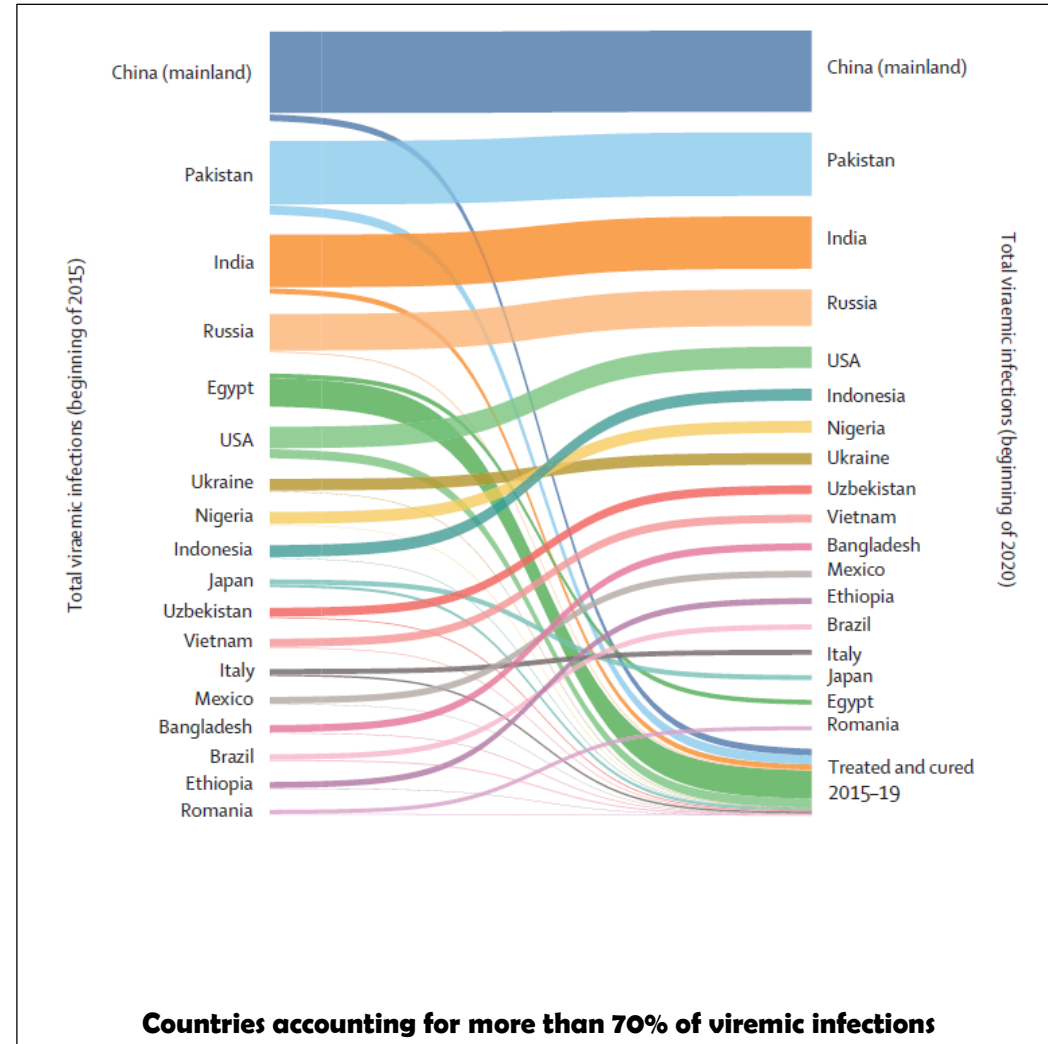
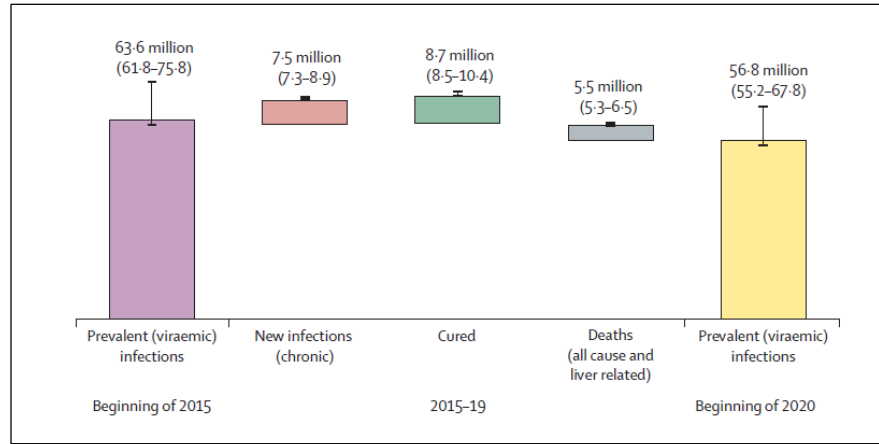
Annual incident hospitalizations for HCC, by age cohort



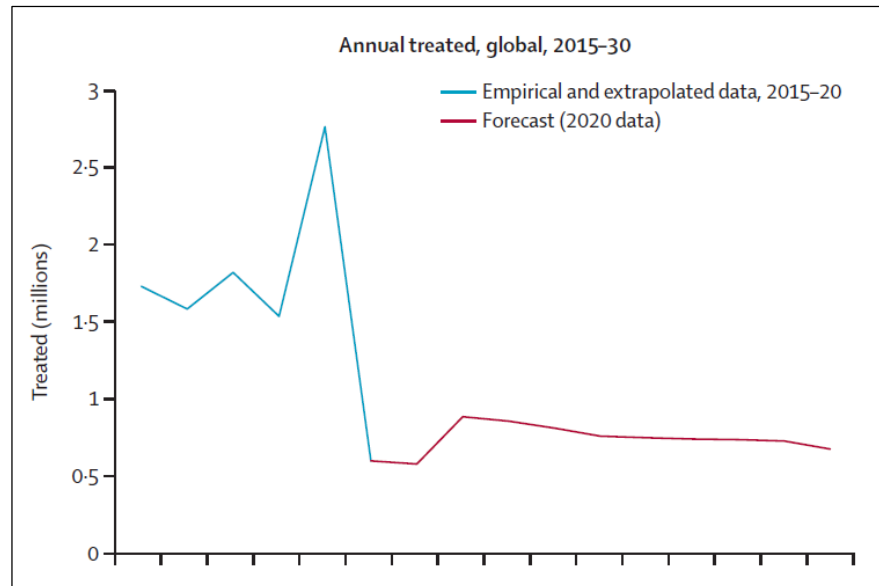
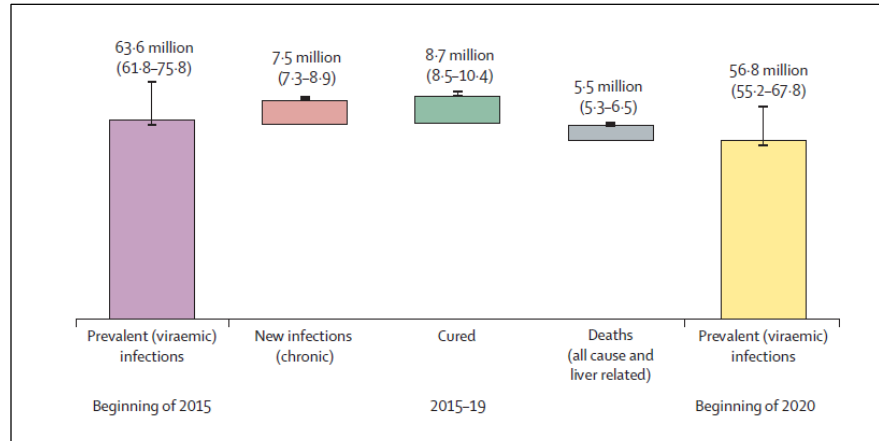
Annual incident hospitalizations for HCV by age cohort



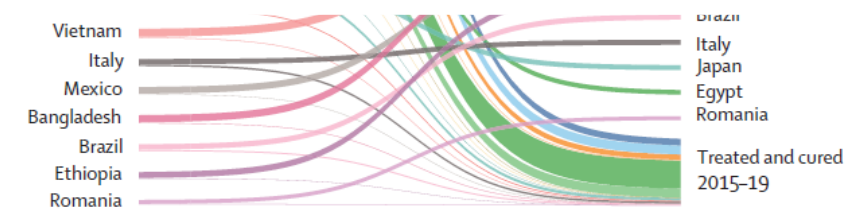
Global Change in Viremic HCV Infections (2015-2020)



Global Change in Viremic HCV Infections (2015-2020)

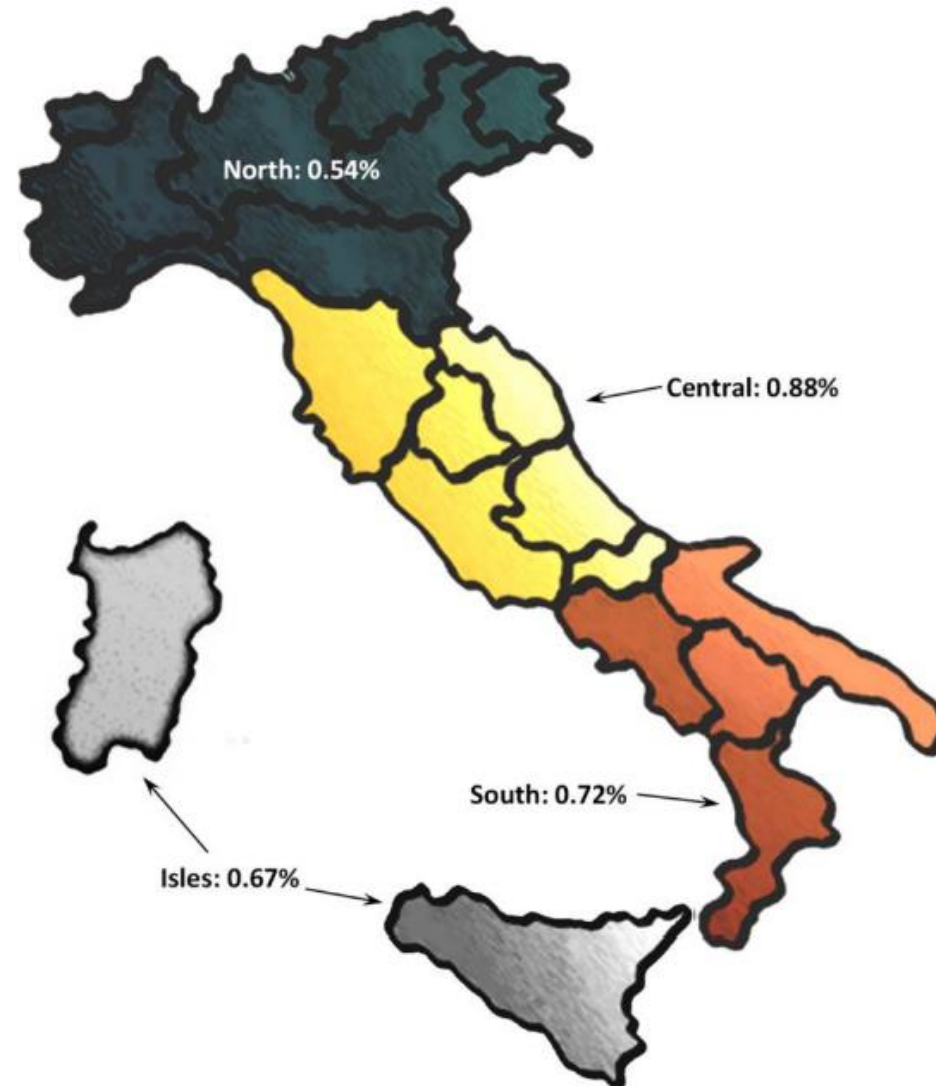


	Viraemic prevalence in 2015*†	Viraemic population (1000s) in 2015*†	Viraemic prevalence in 2020*†	Viraemic population (1000s) in 2020*†
(Continued from previous page)				
Europe, western				
Austria	0.3% (0.1-0.4)	25 (5-39)	0.2% (0.0-0.3)	15 (3-23)
Belgium	0.3% (0.2-0.6)	31 (22-77)	0.2% (0.1-0.5)	24 (17-59)
Denmark	0.2% (0.2-0.3)	11 (10-16)	0.1% (0.1-0.2)	7 (6-10)
Finland	0.4% (0.3-0.5)	22 (17-28)	0.3% (0.3-0.4)	19 (15-25)
France	0.3% (0.2-0.3)	183 (143-234)	0.2% (0.1-0.2)	112 (88-143)
Germany	0.3% (0.2-0.5)	254 (152-457)	0.2% (0.1-0.4)	189 (113-340)
Greece	1.0% (0.7-1.3)	106 (75-136)	0.9% (0.7-1.2)	96 (68-123)
Iceland	0.2% (0.2-0.3)	0.7 (0.6-0.9)	0.1% (0.1-0.1)	0.3 (0.2-0.3)
Ireland	0.6% (0.4-1.1)	30 (20-51)	0.6% (0.4-0.9)	27 (18-46)
Israel	0.9% (0.6-1.3)	73 (47-111)	0.7% (0.5-1.1)	61 (39-91)
Italy	1.4% (0.6-2.0)	888 (388-1298)	1.0% (0.4-1.4)	577 (252-843)



Countries accounting for more than 70% of viremic infections

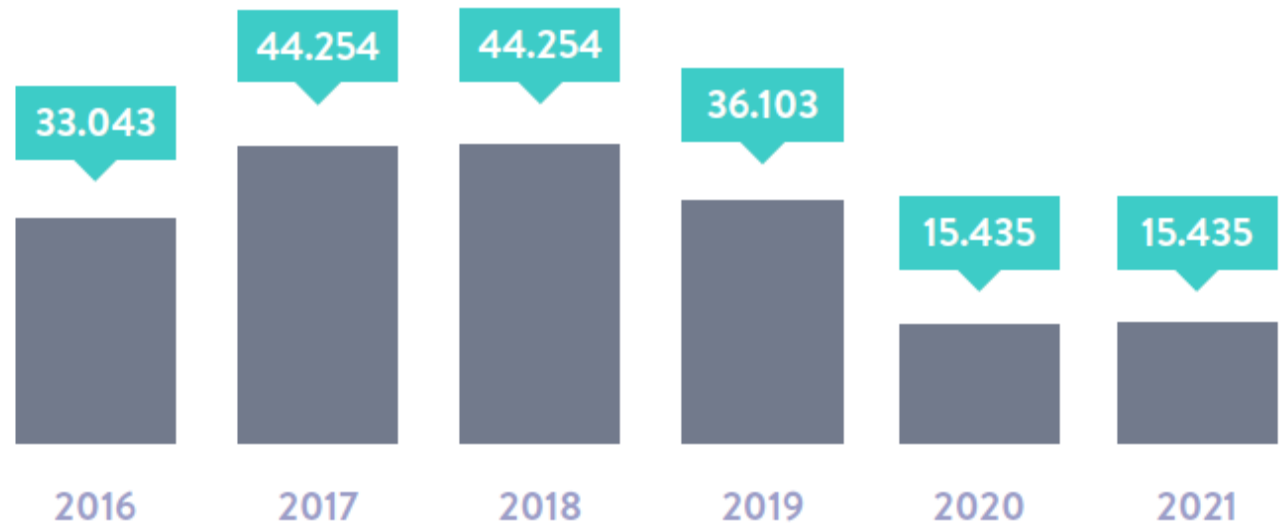
HCV Epidemiology in Italy in 2021



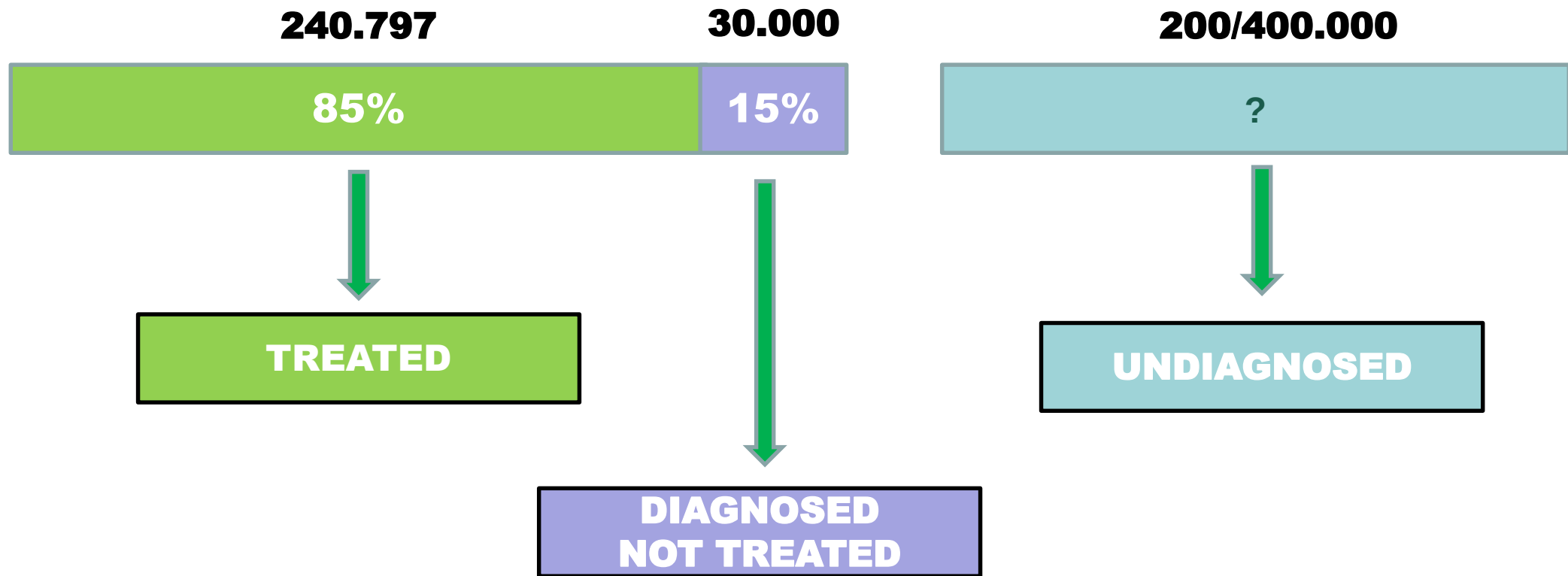
Numero di Trattamenti HCV in Italia

233.229

Numero di persone trattate
per HCV, cumulativo, fino
al 7 febbraio 2022 ¹¹

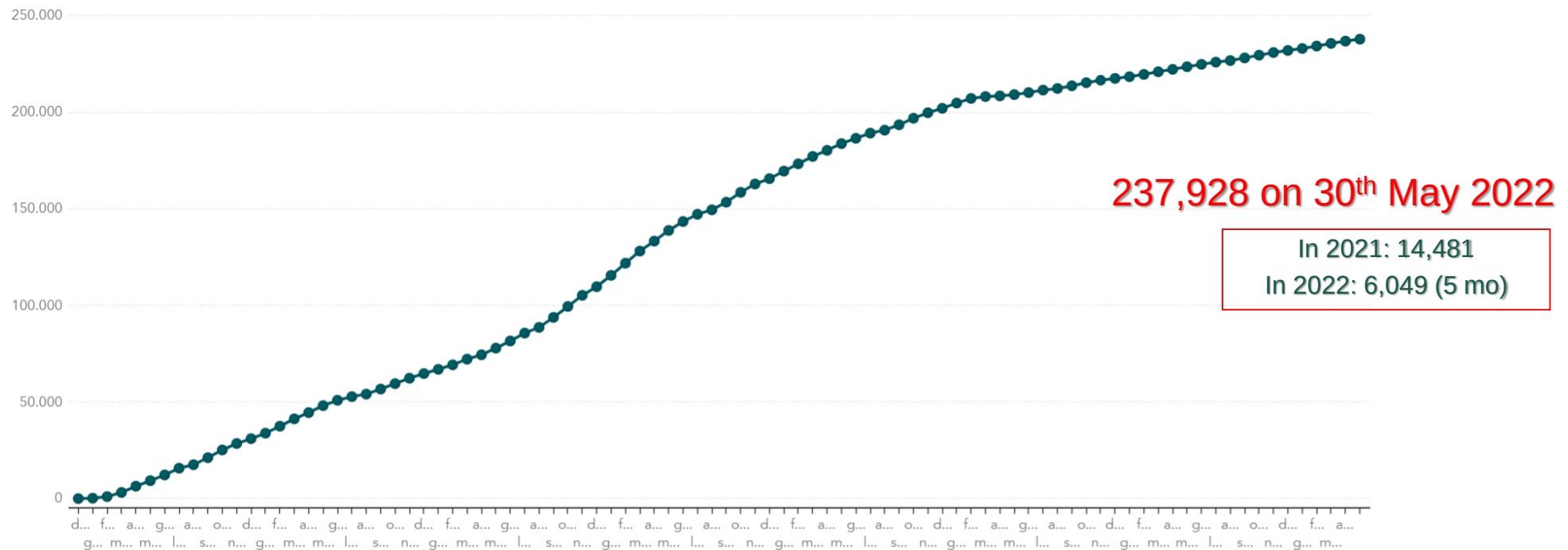


Screening and linkage to Care to Achieve HCV Elimination in Italy



Is Italy on Track with the WHO Goal?

- 2018: Italy on track to eliminate hepatitis C infection by 2030
- 2019: Italy no more on track
- At least 30,000 diagnosis and ~55,000 treatments *per year* needed (modeling analysis*)



*HCV elimination reachable by 2037 w/out screening policies

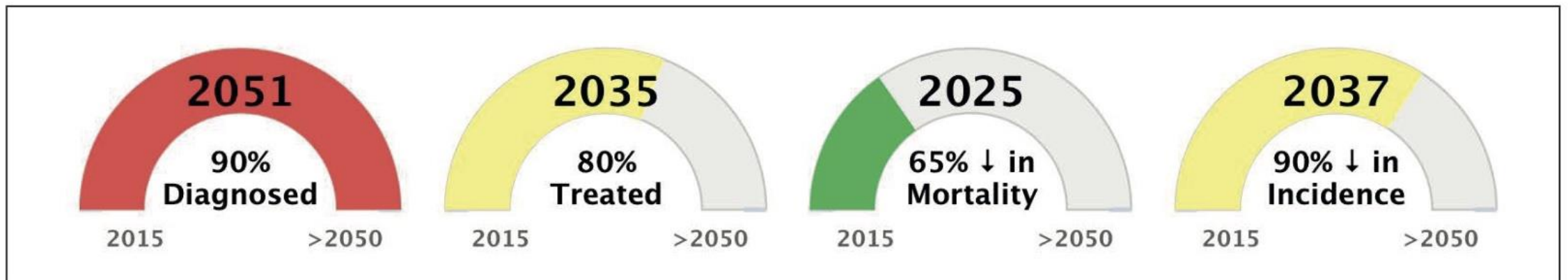
<https://www.AIFA.gov.it>; Kondili LA, et al. Ann Ist Super Sanità 2020

Is Italy on Track with the WHO Goal?

Ann Ist Super Sanità 2020 | Vol. 56, No. 3: 325-329
DOI: 10.4415/ANN_20_03_10

Tailored screening and dedicated funding for direct acting antiviral drugs: how to keep Italy on the road to hepatitis C virus elimination?

Loreta A. Kondili¹, Sarah Blach², Homie Razavi² and Antonio Craxi³



HCV Screening: Different Approaches Lead to Different Results

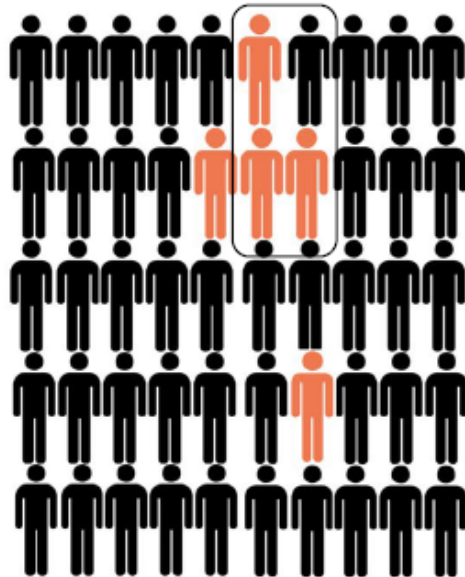
EDITORIAL

Liver
INTERNATIONAL

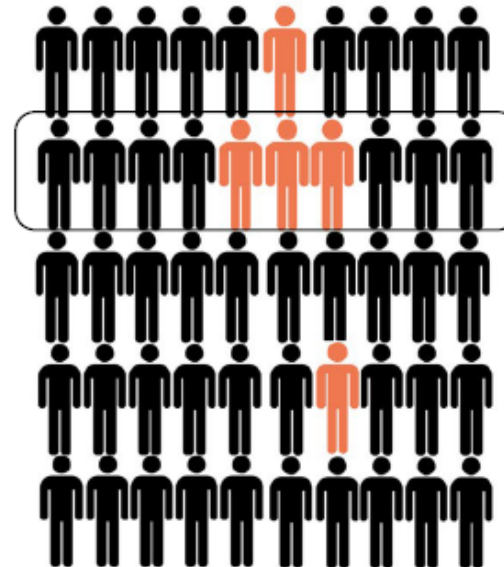
WILEY

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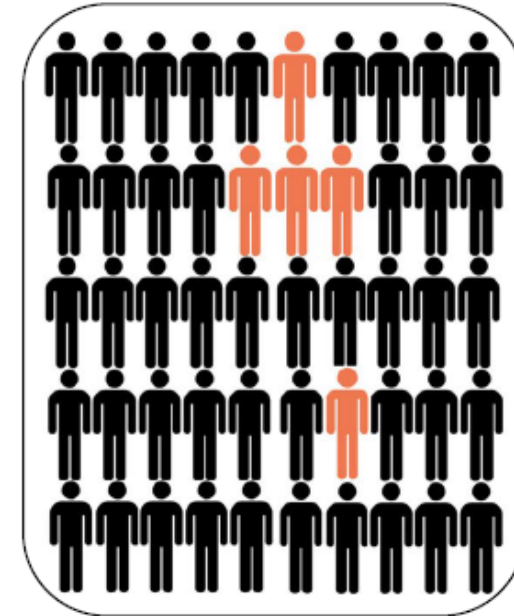
Risk factors-based screening



Age cohort-based screening



Universal screening



The 1969-1989 Birth Cohort

- «Graduated screening strategy»
 - ✓ Individuals at high risk of HCV infection and asymptomatic
 - ✓ High(er) HCV spread risk
 - ✓ Self-exhaustion of elderly HCV cohorts
- The most cost-effective screening strategy when compared to others
 - ✓ At-risk populations, only
 - ✓ 1948-1977 birth-cohort
 - ✓ 1958-1977 birth-cohort
 - ✓ 1968-1987 birth-cohort, and then 1948-1967 (starting from 2023)
 - ✓ 1948-1967 birth-cohort, and then 1968-1987 (starting from 2023)
 - ✓ Universal screening

Decreto attuativo, ex-post DL Milleproroghe

- Con il DL «**Milleproroghe**» **2020** è stato approvato l'emendamento che stanziava **71,5 milioni di euro per il biennio 2020-2021**, per attuare l'avvio di una **campagna di screening gratuito per l'HCV**, per le seguenti fasce di popolazione:
 - tutta la popolazione iscritta all'anagrafe sanitaria e nata dal 1969 al 1989;
 - i soggetti seguiti dai servizi pubblici per le Dipendenze (SerD), indipendentemente dalla coorte di nascita e dalla nazionalità;
 - i **soggetti detenuti in carcere**, indipendentemente dalla coorte di nascita e dalla nazionalità
 - Il **17 dicembre 2020** la Conferenza Stato-Regioni ha deliberato la ripartizione delle somme destinate al finanziamento dello screening nazionale gratuito per l'epatite C, sancendo l'Intesa sul decreto attuativo del Ministro della Salute ex-post DL "Milleproroghe" e chiedendo che l'utilizzo dei fondi venisse prorogato al 31 dicembre **2022**.
-

Regional Plans for HCV Elimination following the Milleproroghe Decree

Region	Screening Modalities
Piedmont	SERD, prisons, 1969-1989
Liguria	SERD, prisons, 1969-1989
Lombardy	SERD, prisons, 1969-1989 Prolonged DAA prescription by SERD
Veneto	Update former screening and treatment activities
Emilia Romagna	SERD, prisons, 1969-1989 HCV screening offered concomitantly to routine blood-tests
Marche	SERD HCV screening in leader territory Companies GPs educational and Pharmacies involvement
Umbria	SERD, prisons, 1969-1989
Campania	Awareness campaign
Basilicata	SERD, prisons, 1940-1989 GPs involvement (fee; POC)
Calabria	Prisons
Sicily	Screening HCV plan implementation

- ☐ Active Call
- ☐ GPs Involvement
- ☐ Pharmacies Involvement
- ☐ Age bracket extension
- ☐ Implementation of pre-existing plans

- ✓ Early development of SERD and prisons screening plans
- ✓ Trentino, Tuscany, Abruzzo, Latium, Sardinia, Puglia: screening modalities and /or resources to be defined

Hepatitis C virus screening in the 1969–1989 birth cohort: Is not enough!

Mauro Viganò 
Federica Cerini
Sofia Ridolfo
Maria Grazia Rumi



Azienda Ospedaliera
Ospedale Niguarda Ca' Granda

Since February 2021 – Jan 2022
San Giuseppe Multimedica, Milan, Italy
4914 patients were tested.

1498 subjects born between 1969 and 1989: 0,07% HCV-RNA positive
1948 - 1968: 0.23% (3/1327) HCV RNA positive

Ospedale Niguarda – Milano (Jun 2019 – Nov 2019)
9,740 tests (anti-HCV) at Surgical Pre-Admission and Internal Medicine Dpt;
any birth-cohort

Anti-HCV positive in 295 (3.3%) and HCV-RNA positive in 140 (1.4%).

Puoti M, Personal Communication 2021

Article

High Rates of Hidden HCV Infections among Hospitalized Patients Aged 55–85

Annarita Valeria Piazzolla ¹, Giulia Paroni ², Francesca Bazzocchi ³, Mauro Cassese ⁴, Antonio Cisternino ⁵, Luigi Ciuffreda ⁶, Franco Gorgoglione ⁷, Leonardo Gorgoglione ⁸, Vincenzo Palazzo ⁹, Natale Sciannamè ¹⁰, Marco Turchini ¹¹, Pasquale Vaira ¹², Giovanna Cocomazzi ¹, Maria Maddalena Squillante ¹, Filippo Aucella ¹³, Nicola Cascavilla ¹⁴, Salvatore De Cosmo ¹⁵, Michelantonio Fania ¹⁶, Antonio Greco ¹⁷, Antonio Laborante ¹⁸, Maurizio Leone ¹⁹ , Evaristo Maiello ²⁰, Mauro Salvatori ²¹, Lazzaro Di Mauro ² and Alessandra Mangia ^{1,*} 

Inpatient aged 35 to 85 (Feb 2020 – Feb 2021)

11,748 screened patients

Anti-HCV positive in 3.03% and HCV-RNA positive in 0.97%

BRIEF REPORT



Implementation of HCV screening in the 1969–1989 birth-cohort undergoing COVID-19 vaccination

D'Ambrosio R, et al. Liver Int 2022

Four tertiary Hepatology Centers:
IRCCS Ca' Granda Ospedale Maggiore Policlinico
ASST GOM Niguarda
ASST FBF – Milan
AO Papa Giovanni XXIII Bergamo

POC assay – 1969-1989 cohort

7219 screened patients 5 (0.07%) anti-HCV positive at confirmation test and **4 (0.05%) HCV-RNA positive**

RESEARCH LETTER



Hepatitis C screening during SARS-CoV-2 testing or vaccination. Experience in an area of southern Italy in the province of Salerno

Torre P, et al. Liver Int 2022

USCA and COVID-19 Vaccination Hub – Salerno Province
(May 2020 – Jul 2021)

3,000 tests (anti-HCV); any birth-cohort

Anti-HCV positive in 7 (0.23%) and HCV-RNA positive in 3 (0.1%). Two (0.07%) unaware of HCV



C devi pensare.

Se il tuo anno di nascita è tra il 1969 e il 1989
fai il test per l'**EPATITE C**

Screening Epatite C



Scheda informativa

Screening gratuito per l'Epatite C

Rivolto a: **Cittadini**



Regione
Lombardia



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Scheda informativa

Screening epatite C



Menu strumenti

Schede informative

Servizi online

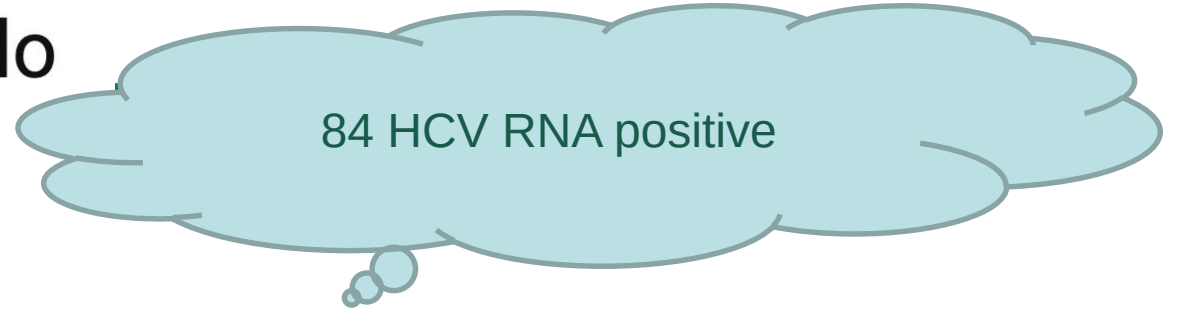
In absence of a pre-existing HCV elimination plan, the 2019 Milleproroghe Decree provided financial tools and general lines to promote HCV screening programs

HCV screening strategies are managed at Regional level; their applicability is influenced by economic, bureaucratic and organizational issues

Epatite C, in Lombardia 478 persone positive su 52.224 testate. Moratti: lo screening può prevenire le malattie del fegato e scongiurare il tumore.

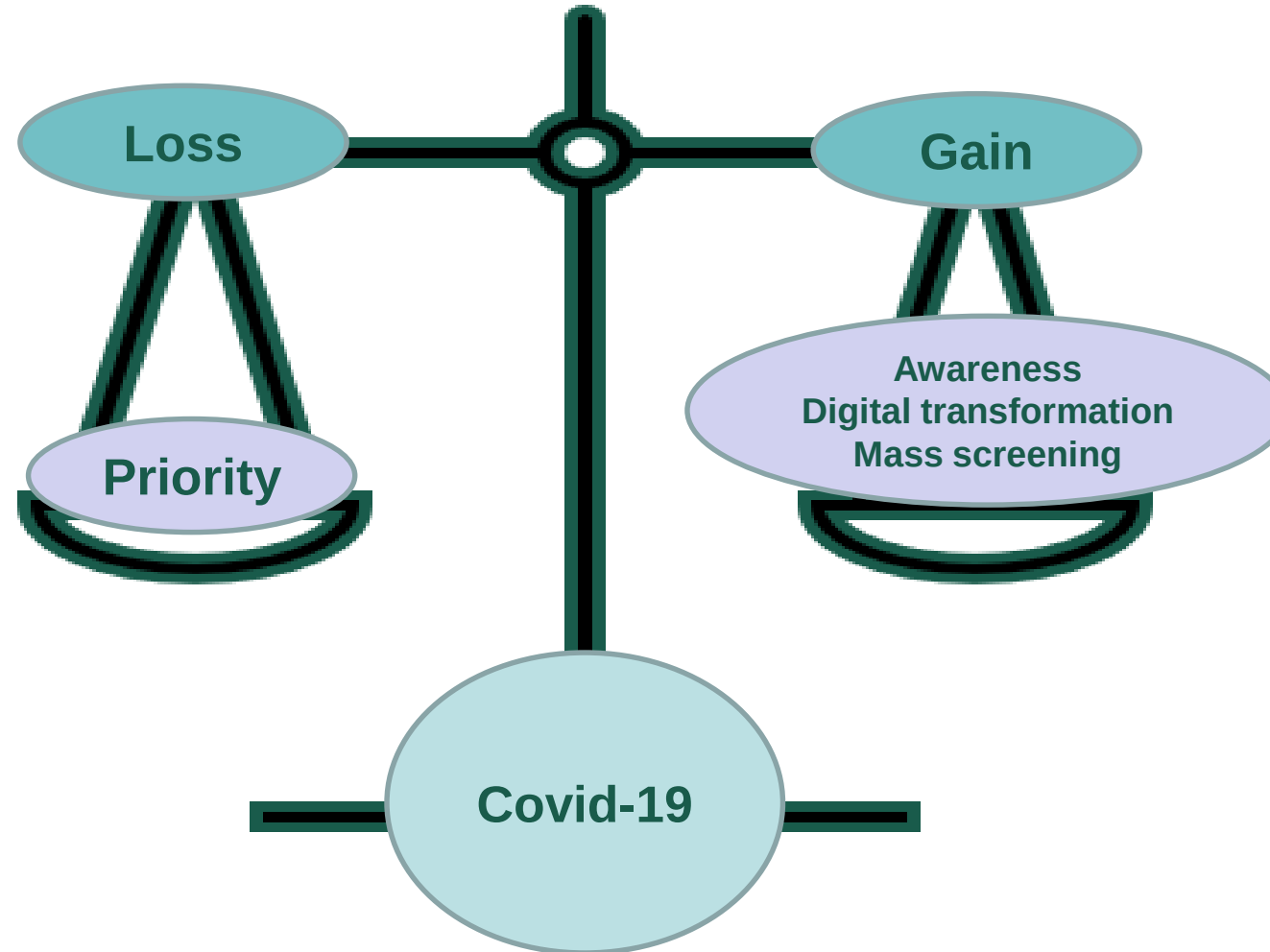
By redazione - 23 Settembre 2022

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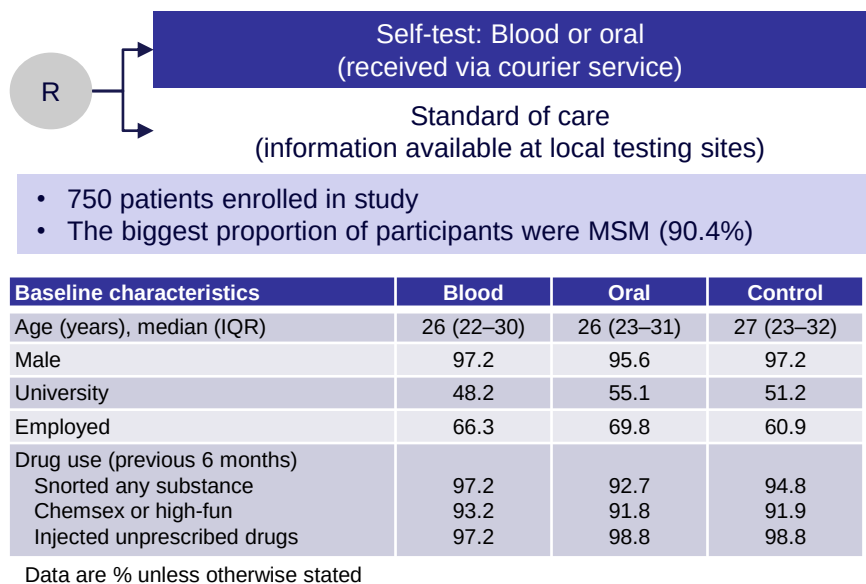
Spontaneous, limited real-world screening programs revealed low-than-expected rates of active HCV infection, also in unaware subjects, thus opening the way to rethink the «1969-1989 birth-cohort approach»

Covid-19 and impact on HCV elimination programm



Randomized Controlled Trial Of Home-based Hepatitis C Self-testing For Key Populations In Malaysia

Evaluation of the impact of HCV self-testing on the uptake of HCV Ab testing compared with standard of care: A nationwide study in Malaysia using an online platform



Self-testing using an online model can increase uptake of HCV Ab testing in key populations, including those who have been hesitant or unable to access existing services but it is important to evaluate resource use with governments; the WHO strongly recommend offering self-testing as an additional approach to HCV testing services

Screening and linkage to Care to Achieve HCV Elimination in Italy

L'investimento di 71,5 milioni riguarda solo la prima parte dello screening raccomandato ai fini dell'eliminazione dell'infezione da HCV

- Bisogna garantire fondi dedicati e l'efficienza del sistema per lo **screening di tutta la coorte di nascita 1948-1988**, come indicato in Italia ai fini dell'eliminazione di HCV .
- Lo screening è solo il punto di partenza; all'efficienza degli screening deve corrispondere un rapido *linkage to care* e avviamento dei pazienti ai trattamenti.

Screening e prospettive future: il ruolo di ACE



ALLI
CONTRO L'EPATITE

Grazie!

Obiettivi di advocacy:

- Derogare la conclusioni dello screening a dicembre 2023

o anti-HCV e
er tutta la
iorenne

gli obiettivi di
piano dei Dg ASL/AUSLL