



Con il Patrocinio del
Ministero della Salute

In collaborazione con
AISF e SIMIT

1 FEBBRAIO 2024 h. 9:00-17:40
RESIDENZIALE + WEBINAR

UN PATTO DI COLLABORAZIONE:
DALL'ELIMINAZIONE REGIONALE
DELL'**EPATITE C** ALLE NUOVE SFIDE
PER LA **SALUTE DEL FEGATO**

10 anni di attività di PITER

PROGRAMMA PRELIMINARE



A che punto è l'Italia verso
l'eliminazione del virus dell'epatite C

Health policies that address HCV
elimination in Italy

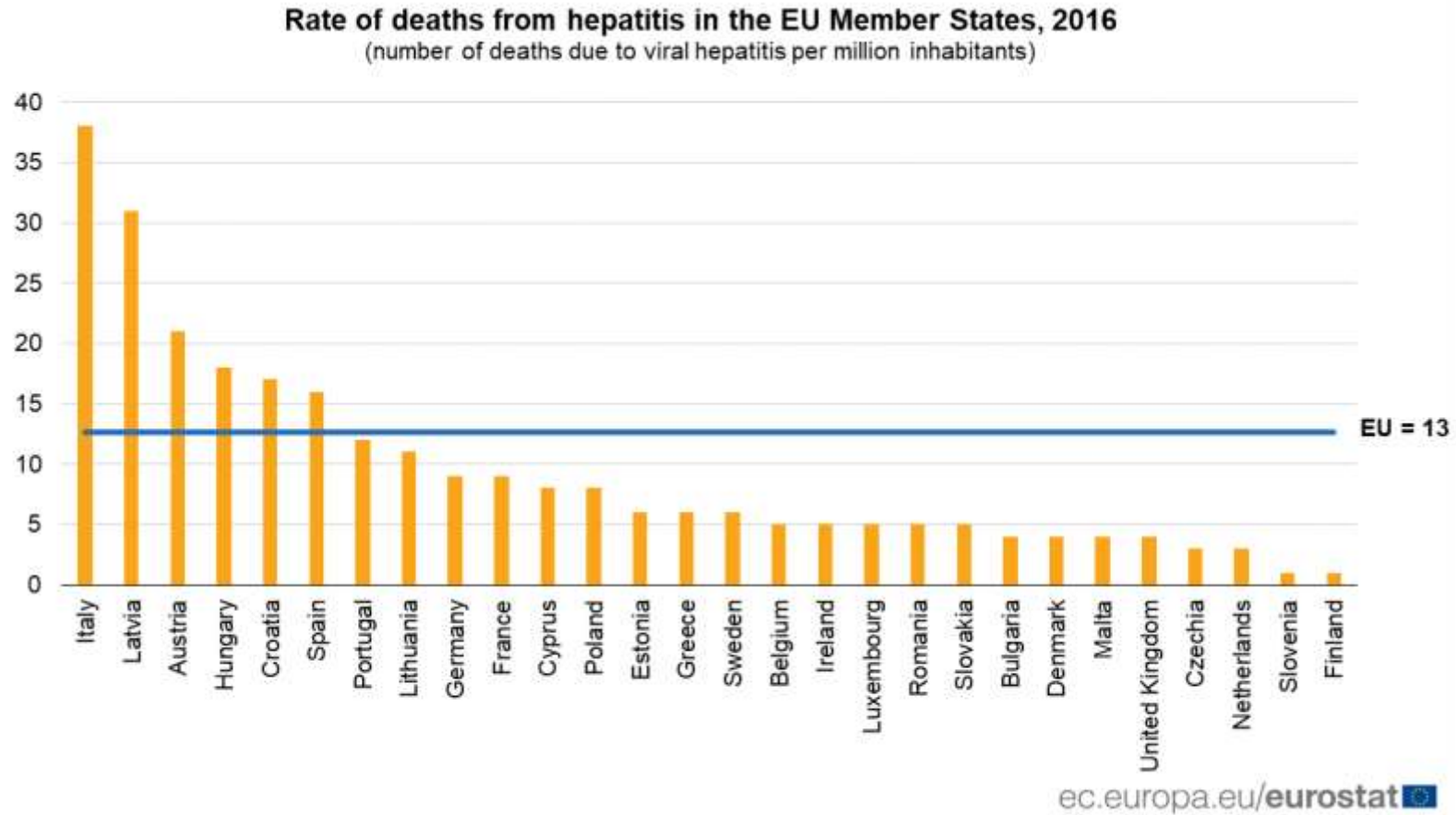
Loreta Kondili

Centro Nazionale per la Salute Globale

ISTITUTO SUPERIORE DI SANITA'

Summary of the HCV Epidemiology in Italy

- A cohort effect has been underlined in Italy with higher prevalences in older age through nosocomial transmission
- New epidemic wave after year 1990 through drug use and esthetic procedures at risk



Italian HCV Elimination Strategies and Health Policy Evolution

2015

Prioritized access to antiviral treatment with new DAA therapy

2016

2017

Universal access is cost-effective vs prioritized access

2018

Dedicated fund for innovative DAAs

2019

Active screening is cost-effective vs treatment of diagnosed patients

2020-2023

Universal access to antiviral treatment with DAAs

Active Screening Approved

Economic evidence can support the allocation of *ad hoc* funds for screening and anti-HCV treatment.

The Journal of
Infectious Diseases

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The Journal of Infectious Diseases



Volume 228, Issue
Supplement_3
15 September 2023

JOURNAL ARTICLE

From Prioritization to Universal Treatment: Successes and Challenges of Hepatitis C Virus Elimination in Italy [Get access](#)

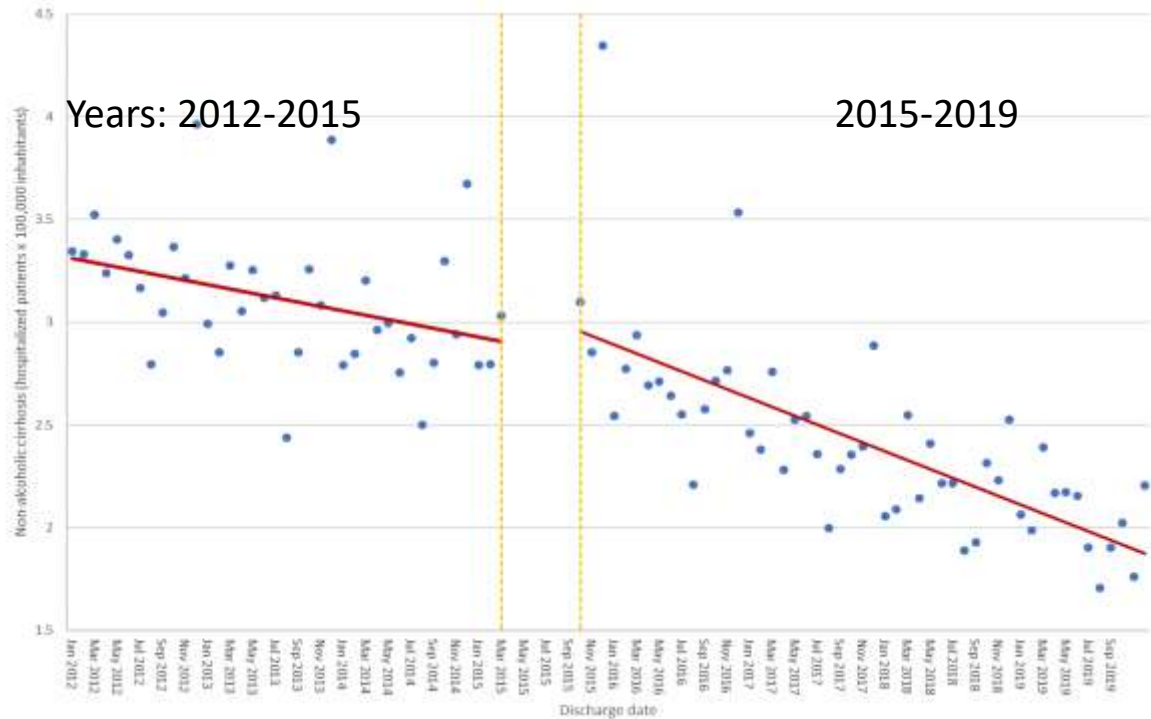
Loreta A Kondili , Lucia Craxi, Felice Nava, Sergio Babudieri, Roberta D'Ambrosio, Andrea Marcellusi, Francesco Saverio Mennini, Sabrina Valle, Pierluigi Russo, Pier Paolo Olimpieri ... [Show more](#)

The Journal of Infectious Diseases, Volume 228, Issue Supplement_3, 15 September 2023, Pages S211-S220, <https://doi.org/10.1093/infdis/jiad038>

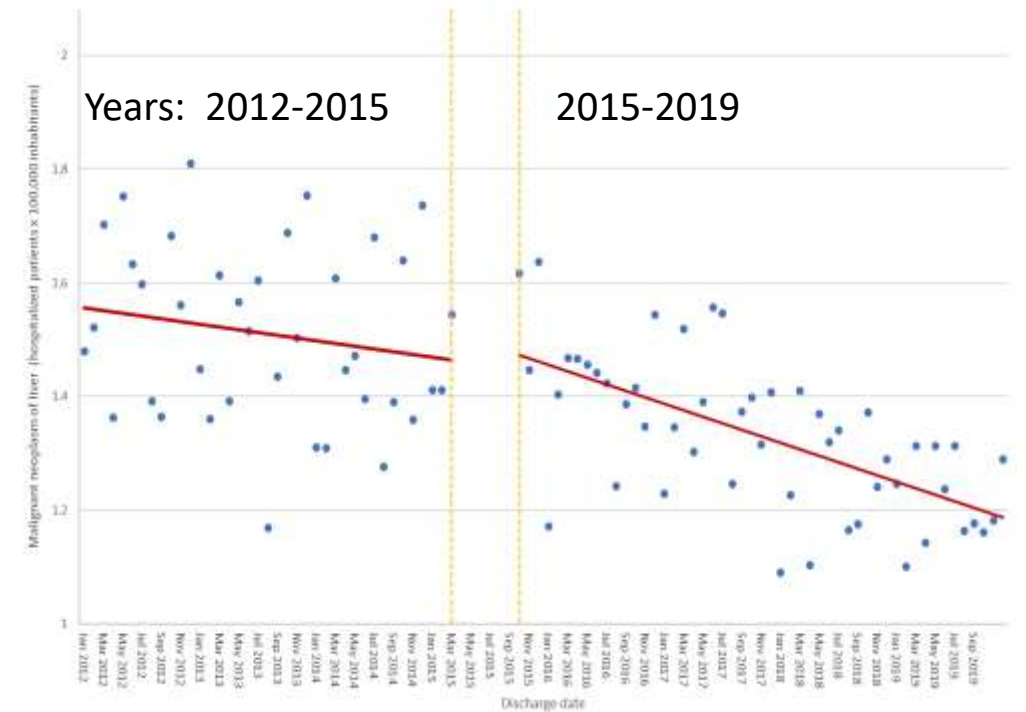
Published: 13 September 2023

Decreasing Hospitalization Rate of patients with HCV-induced liver disease

- Trend of Hospitalizations for HCV Liver Cirrhosis



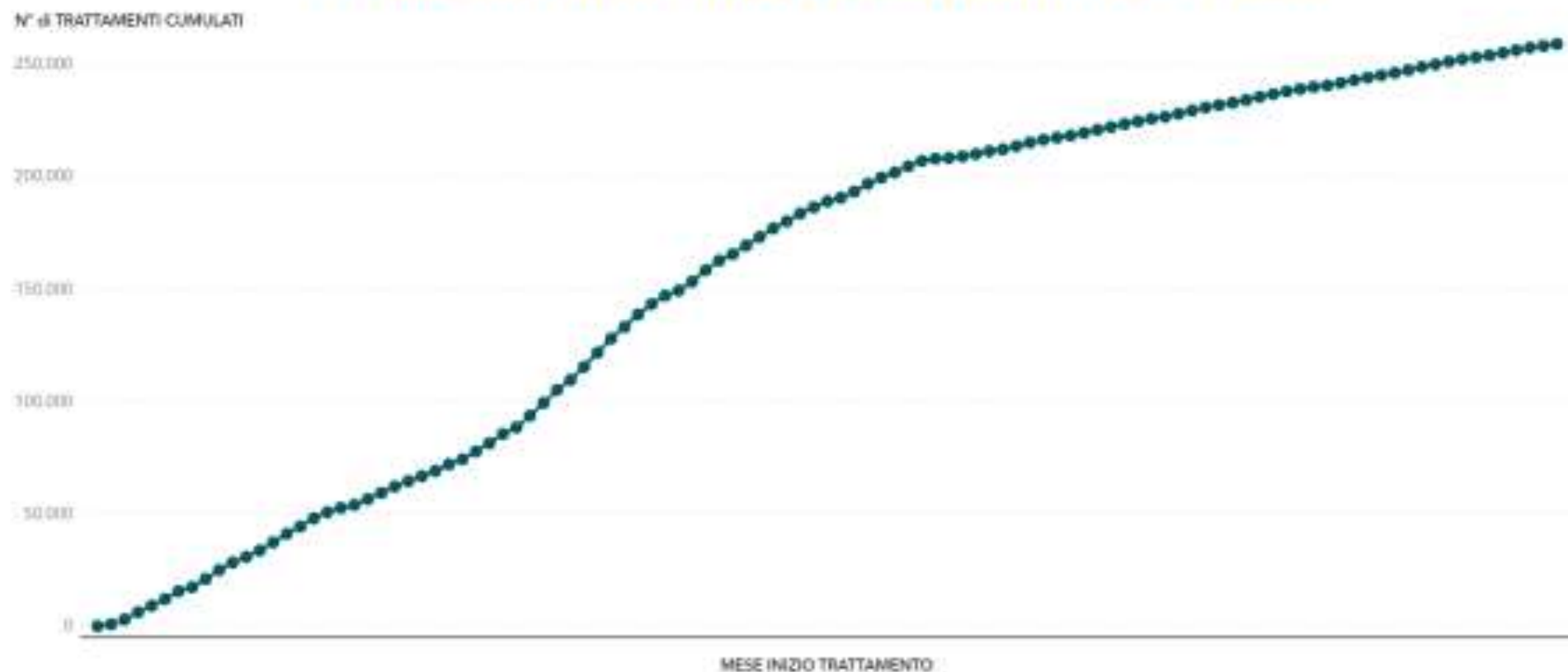
- Trend of Hospitalizations for HCV Liver Cancer



Hospitalizations for HCV and HCV-related diseases in the last decade: data analysis of records of hospital discharge (SDO) at national level

Mennini FS, Sciatella P, Simonelli C, Marcellusi A, Kondili LA. EASL 2022 presentation (submitted manuscript)

Trend cumulativo dei trattamenti avviati



**259.205 «avviati» sono i trattamenti (solo pazienti eleggibili)
con almeno una scheda di dispensazione farmaco**

Scientific evidence that have supported the health policy for HCV elimination in Italy



HEPATOLOGY
 HEPATOLOGY, VOL. 66, NO. 6, 2017

Modeling Cost-Effectiveness and Health Gains of a “Universal” Versus “Prioritized” Hepatitis C Virus Treatment Policy in a Real-Life Cohort

Loreta A. Kondili¹, Federica Romano², Franca Romana Ioffi², Marco Ruggieri², Stefano Rosato¹, Maurizia Rossana Bruno², Anna Linda Zignego², Alessia Ciancio², Alfredo Di Leo², Giovanni Raimondo², Carlo Ferrari², Gloria Talani², Guglielmo Berge², Teresa Antonia Santantonio¹, Pasquale Illari¹, Giovanni Battista Garcia¹, Antonio Galarrini², Luciano Chessa¹, Elie Maria Esm¹, Erica Villa¹, Donatella Ieluzzi¹, Francesco Paolo Russo¹, Pietro Andreone¹, Maria Vici¹, Carmine Coppola¹, Liliusa Chiosella¹, Salvatore Malatola¹, Gabriella Verucchi¹, Marcello Perrino¹, Massimo Zucchi¹, Massimo Puoti¹, Alfredo Alberti¹, Gerardo Nardone¹, Marco Manzi¹, Giuseppe Montalto¹, Giuseppe Foti¹, Maria Grazia Bassi¹, Maria Giovanna Quaranta¹, Amerigo Cicchetti², Antonio Craxi² and Stefano Vella¹ on behalf of the PITER Collaborating Group



ORIGINAL ARTICLE | [Open Access](#) |

Optimization of hepatitis C virus screening strategies by birth cohort in Italy

Loreta A. Kondili ✉, Ivane Gamkrelidze, Sarah Blach, Andrea Marcellusi, Massimo Galli, Salvatore Petta, Massimo Puoti, Stefano Vella, Homie Razavi, Antonio Craxi, Francesco S. Mennini, on behalf of the PITER collaborating group, ... [See fewer authors](#)



ORIGINAL ARTICLE | [Open Access](#) |

The impact of direct acting antivirals on hepatitis C virus disease burden and associated costs in four european countries

Francesco S. Mennini, Andrea Marcellusi, Sarah Robbins Scott, Simona Montilla, Antonio Craxi, Maria Buti, Liana Gheorghie, Stephen Ryder, Loreta A. Kondili ✉

Springer Link

Original Research Article | [Open Access](#) | [Published: 12 October 2021](#)

Economic Consequences of Anti-HCV Treatment of Patients Diagnosed Through Screening in Italy: A Prospective Modelling Analysis

[Andrea Marcellusi](#), [Claudia Simonelli](#), [Francesco S. Mennini](#), [Loreta A. Kondili](#) ✉ on behalf of PITER Collaborating Group available at <http://www.progettopter.it>

[Applied Health Economics and Health Policy](#) (2021) | [Cite this article](#)

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Notiziario

del Istituto Superiore di Sanità

L'Italia con
per l'Europa
nelle p
dell'e

Grup
per
e
e

Eliminazione dell'epatite C cronica
strategie di screening gratuito

L. Kondili, M.G. Quaranta,
M. Andreoni, M. Puoti, S.
S. Vella, A. Marcellusi, G.
I. Gankrelidze, S. Blac
per Gruppo Collabor
della Piattaforma It
della Terapia delle

Implementare le politiche sanitarie
a livello regionale per l'eliminazione
dell'epatite C ai tempi del COVID-19

Il ruolo del Medico di Medicina Generale
nella prevenzione e nella gestione
del paziente con demenza

Raccomandazioni
dal Progetto europeo MEDIRAD:
implicazioni dell'esposizione m
a basse dosi di radiazione

Webinar. Dal Decreto attuativo
sullo screening HCV
all'obiettivo di eliminazione

M.G. Quaranta, S. Valle, L. Craxi,
B. Mattioli, L. Kondili

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Poste Italiane S.p.A. - Spedizione in abbonamento postale - 70% - DCB Roma



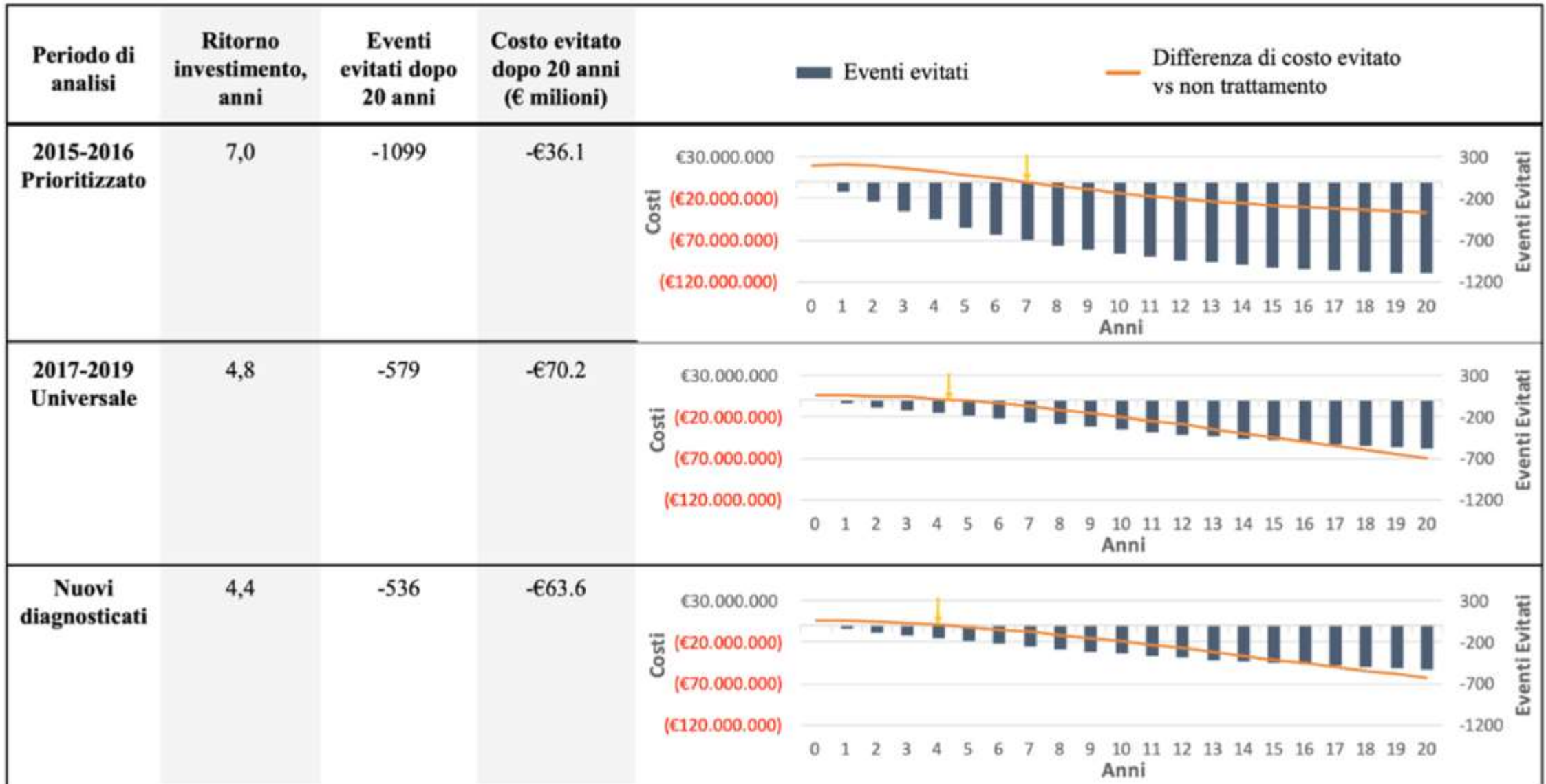
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E LA BIOMEDIC
L'articolo 21/
il divieto di profitto e la cura



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RITORNO D'INVESTIMENTO PER LA TERAPIA ANTI-HCV IN ITALIA

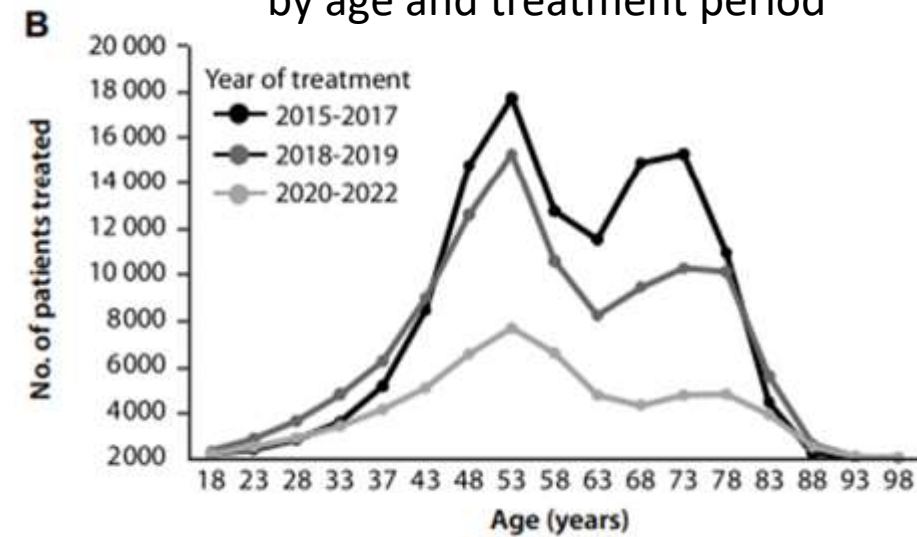


A Law Decree is approved for
FREE OF CHARGE HCV SCREENING

- **71.5 million Euros allocated for first and second level testing (Up to the end of 2023) for:**
 - PWID
 - Inmates
- **General population birth cohort 1969-1889**



Number of Treated patients by AIFA Monitoring Registry by age and treatment period



Direct costs and health effects, by scenario, 2018–2031

Scenario	Cost (€Millions), 2018–2031	QALYs Gained, 2018–2031	ICER Relative to Status Quo (€/QALY)	ICER relative to previous least costly scenario (€/QALY)	
Status quo	5,463	–	–		
GHSS Targets	Graduated screening 1	5,974	144,000	3,552	3,552
	Graduated screening 2	6,028	125,000	4,532	*
	Screening 1948–1977	6,081	142,000	4,349	*
	Screening 1958–1977	6,083	128,000	4,831	*
	Universal screening	6,441	145,000	6,758	562,855

- **Graduated Screening 1: start screening in birth cohorts 1968–87 in year 2020** –identify young population at higher probability of HCV transmission risk
 - expand screening for birth cohorts 1948–67 starting from 2023 – identify older population at risk for disease progression.

Screening pathway as indicated in the law decree (experimental project for 2 years)

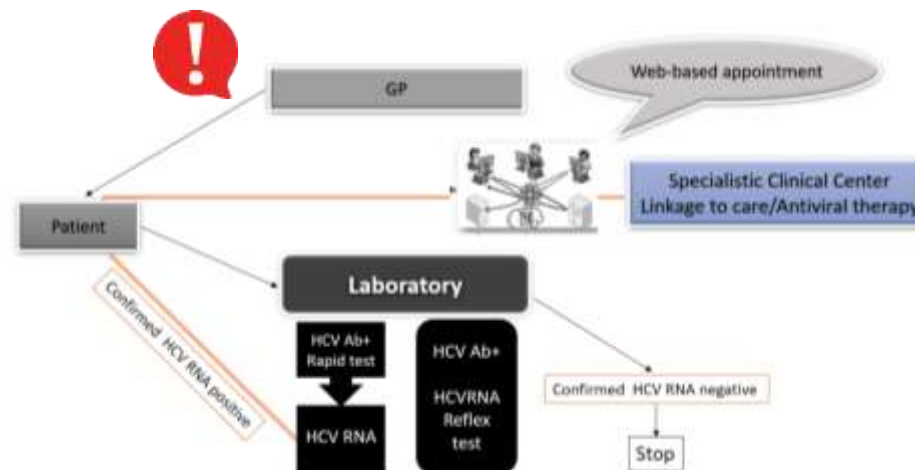
Success in reaching the key populations

General Practitioners Approach

Systematic
opportunistic
hepatitis testing

The point of care should be implemented to simplify the patient pathway to improve information to promote prevention

- Commitment for training, information and collaboration
 - between GPs and Specialists
- **Alerts to remind General Practitioner to test whole**
 - or cohorts of general population





Screening strategy to advance HCV elimination in Italy: a cost-consequence analysis

Andrea Marcellusi¹ · Francesco Saverio Mennini^{1,2} · Massimo Andreoni⁴ · Loretta A. Kondili³ on behalf of PITER collaboration study group

Received: 6 March 2023 / Accepted: 21 November 2023

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Table 4 Epidemiological estimations according to different screening scenarios

	Diagnosed			Death due to HCV			HCC events			DC Events		
	No Screening	Incremental	Fast	No Screening	Incremental	Fast	No Screening	Incremental	Fast	No Screening	Incremental	Fast
Year 1	5310	10,355	55,755	0	0	0	0	0	0	0	0	0
Year 2	10,355	24,252	82,239	377	354	181	936	957	659	576	614	472
Year 3	15,147	51,705	94,818	681	593	286	1324	1454	551	1102	1257	435
Year 4	19,699	80,315	100,794	686	595	344	1589	1,329	367	1470	1235	261
Year 5–10	48,489	88,930	102,593	19,975	9702	4736	6299	2422	1036	4469	1349	282
Total	48,489	88,930	102,593	21,719	11,244	5547	10,148	6162	2613	7618	4455	1450
Vs No Screening		40,441	54,104		- 10,475	- 16,172		- 3986	- 7535		- 3163	- 6168



Screening strategy to advance HCV elimination in Italy: a cost-consequence analysis

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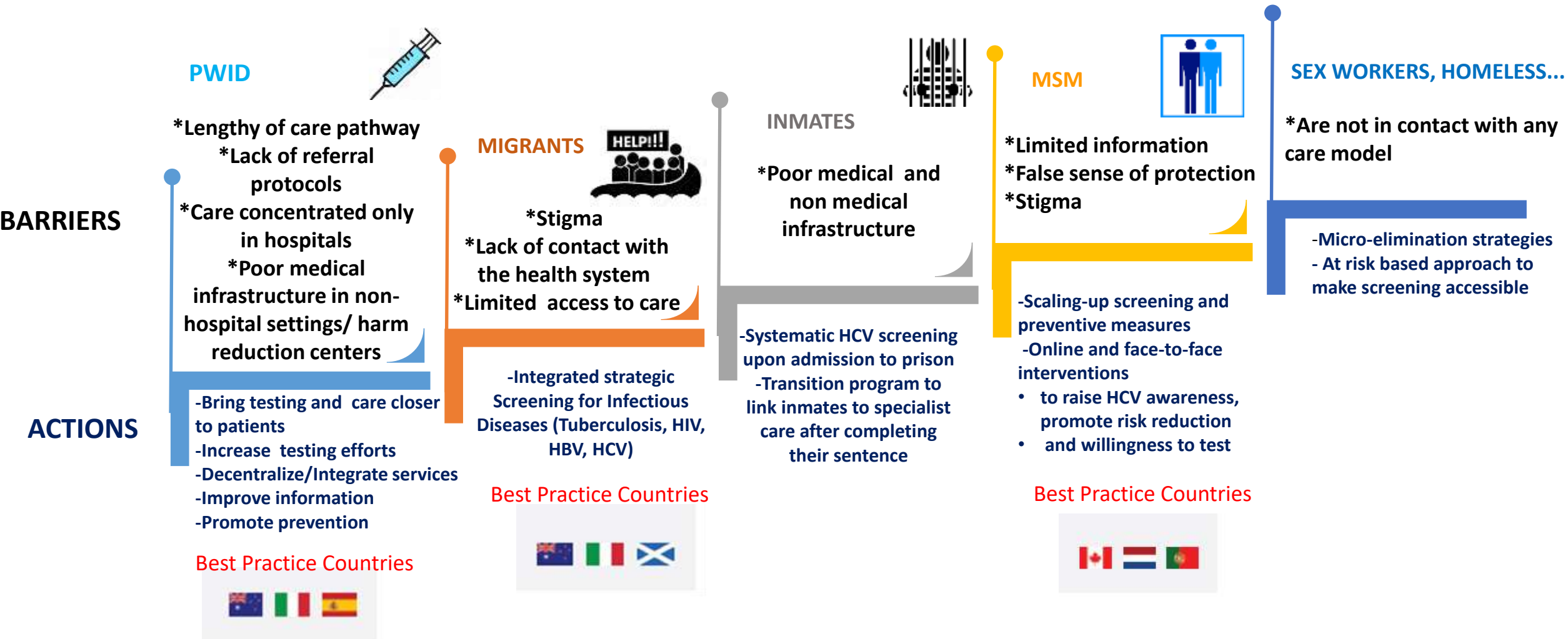
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Conclusions

- For older individuals, HCV screening, despite being cost-efficient, has not yet been implemented for sustainability reasons.
- It is necessary to guarantee dedicated funds and efficiency of the system for the cost-efficient screening of 1948-1968 birth cohort in Italy .
- A delay in HCV diagnosis in the general population from 1968 to 1948, yet not addressed for the HCV free of charge screening, will have important clinical and economic consequences .

Screening and treatment of key populations is an essential public health challenge

Screening programme is not yet reaching all populations at risk---- the road to elimination is still long



Risk of parenterally transmitted hepatitis following exposure to invasive procedures in Italy: SEIEVA surveillance 2000-2021

Susanna Caminada • Annamaria Mele • Luigina Ferrigno • ... Marise Sabato • Maria Elena Tosti • the SEIEVA Collaborating Group • Show all authors

Open Access • Published: March 17, 2023 • DOI: <https://doi.org/10.1016/j.jhep.2023.03.002>

Highlights

- An increased risk of acquiring hepatitis B and C following exposure to invasive procedures was observed
- Compared with hepatitis A (controls), the risk was twice as high for HBV and over five times higher for HCV
- Observance of universal precautions in healthcare settings is crucial

Results

8,176 cases with acute HBV, 2,179 with acute HCV, and the respective age-matched controls with acute HAV infection were selected

Most of the procedures evaluated were associated with the risk of acquiring HBV or HCV.

The strongest associations for HCV infection,

**neurosurgery (OR=11.88; 95%CI=2.40-58.85),
otorhinolaryngological surgery (OR=11.54; 95%CI=2.55-52.24),
vascular surgery (OR=9.52; 95%CI=3.25-27.87).
ophthalmological surgery (OR=8.32; 95%CI=2.24-30.92).
biopsy and/or endoscopic (OR=3.84; 95%CI=2.47-5.95).**

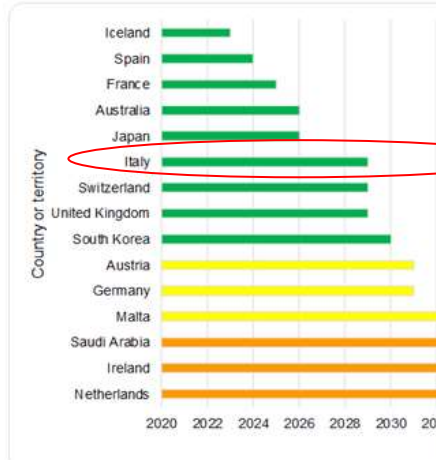
Introducing hospital screening and linkage to care of newly diagnosed patients and those with a known active infection in all hospital wards could constitute a suitable micro elimination strategy, in Italy and in countries with similar HCV epidemiological profile.

What is a Model?

An abstracted description of a process, object, or event
Exaggerates certain aspects at the expense of others



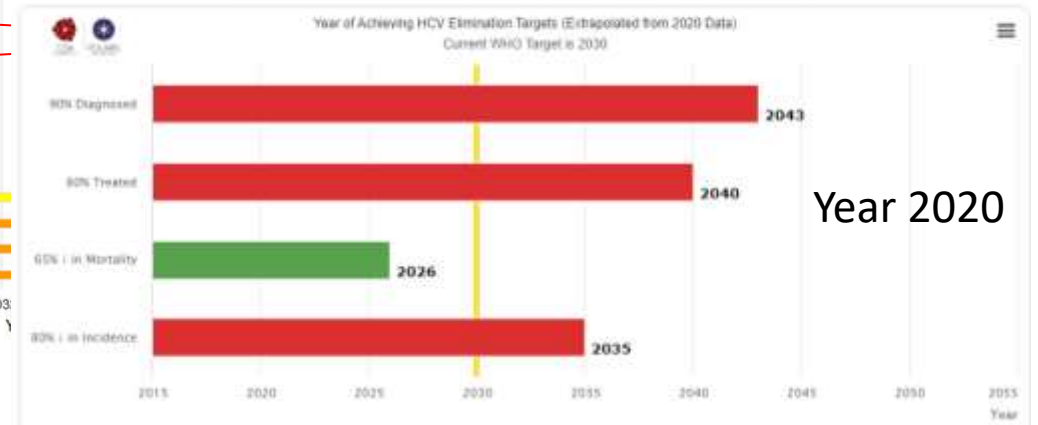
Years 2017-2016



Italy
2019 Population: 60,550,000 | 2019 Adult Population: 50,858,000 | World Bank Classification: High Income

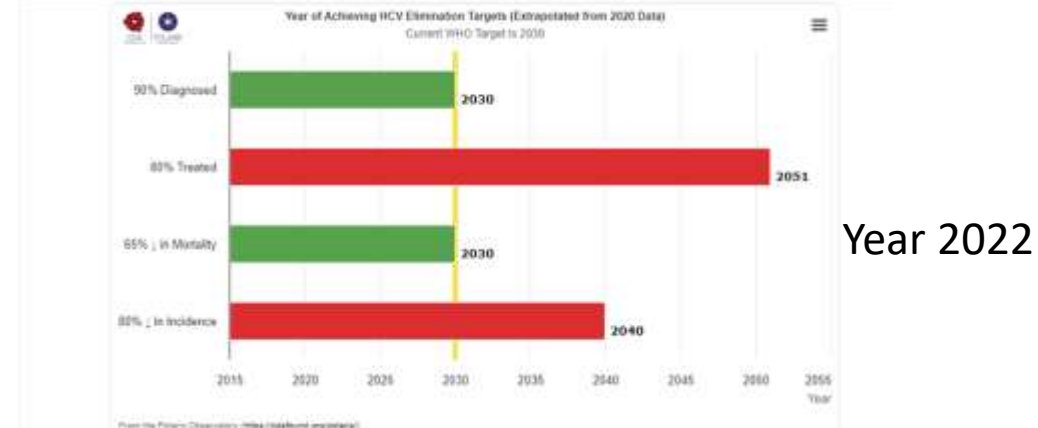
Year of Achieving Elimination Targets (Extrapolated from 2020 Data)
Current WHO Target is 2030

Year of Achieving All Relative Goals for HCV > Year 2043



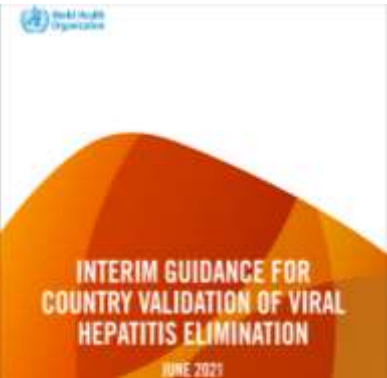
Year 2020

Year of Achieving Elimination Targets



Year 2022

- “Using mathematical modelling alongside empirical data to determine attainment of the elimination targets.
-
- Modelling is not a substitute for the data collection but can be a tool whereby existing data can be used to offer additional insights and help with estimations”



Challenges



- The dedicated fund for screening—end up at Dicember 2023
- No strategies to increase the linkage to care
- General practitioners not fully involved
- Hospital oportunistic screening implemented only in few Regions
- Lack of the perception of risk in the young age of general population = low screening uptake
- Shortage of healthcare personnel (SerD and prisons)
- No *strategic communication aimed* to increasing the awareness and behavioural changes
- No dedicated screening strategies of the most marginalized populations

The active infection rate is lower than the estimated one

bias in testing people that have been treated for HCV infection?

or

higher rate of HCV spontaneous clearance ?

- *Patient Centered* and Integrated approach



Italy could
achieve WHO
elimination
goals
if active action
are taken
NOW!

Grazie!

A BIG
Thank
you!



ITALY
CAN ELIMINATE HEPATITIS
NATIONAL HEPATITIS
ELIMINATION PROFILE

Repubblica & virus (HCV) Repubblica & virus (HBV)

Attivo Plan Attivo Plan

GLOBAL HEALTHY
LIFE