Forecasting liver disease burden based on a real life cohort of linked to care patients in Italy. Does the "hidden portion of the iceberg" matter to reach the WHO HCV elimination goals in high HCV prevalent countries?

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INTRODUCTION

Hepatitis C virus (HCV) is a leading cause of liver-related morbidity and mortality worldwide. An estimated 71 million people are affected by chronic hepatitis C (CHC) infection[1] and a significant number of those chronically infected progress to cirrhosis or liver cancer if left untreated.[2] Recent advances in direct acting anti-viral (DAA) treatment of HCV has reinvigorated public health initiatives aimed at identifying affected individuals.

AIM

The goal of this study was to use a new modelling approach, grounded in real-life cohort data of diagnosed and treated patients in Italy, to compare different linkage to care scenarios to the overall HCV infected population in the country. We forecasted the impact of different disease management scenarios on viremic infections, liver related morbidity and mortality through 2030 in order to identify a potential scenario to achieve the World Health Organization (WHO) Targets in Italy.

METHOD

Two Markov-disease burden models were developed to assess the current and future HCV disease burden in Italy. The 'Italy Polaris' model is grounded in the natural history of HCV progression and forecasts the HCV impact in the general population in Italy.[3] A similar HCV disease burden model, grounded in the current distribution of linked-to-care patients of the PITER (Italian Platform for the Study of Viral Hepatitis Therapies) cohort was also developed.[4] We modelled the impact on HCV disease burden according to different linkage to care scenarios.

Two general population scenarios (built in the Italy Polaris model) describe the forecasted disease burden through 2030 and three scenarios based on PITER data evaluate the impact of linkage to care on viremic prevalence.

RESULTS

Table 1. Inputs of the Italy Polaris model

Italy-Specific Model Parameters	Year	Value (Range)	Source
Total Viremic Population	2015	849,000 (371,000-1,240,00)	[5]
Viremic Prevalence	2015	1.39% (0.6%-2.00%)	[5]
Viremic Diagnosed Population	2015	357,000 (255,000-510,000)	Expert Input
Annual Number Treated	2015	31,000	[6]

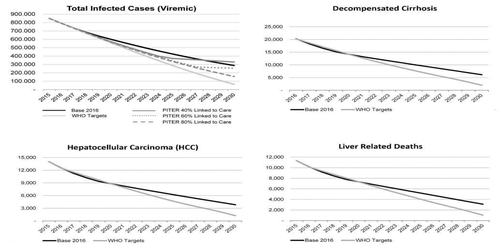
Table 2a. Inputs of the Base 2016 and PITER Scenarios, 2015-2030

	2015	2016	2017	2018	2019	2020+
Annually Treated						
Base 2016	31,000	33,700	29,500	25,300	21,100	16,900
PITER	–	33,700	33,700	33,700	33,700	33,700
Treatment Eligible Stages						
Base 2016	≥F3	≥F3	≥F3	≥F3	≥F3	≥F3
PITER	≥F3	≥F3	≥F0	≥F0	≥F0	≥F0
SVR						
Base 2016	93%	93%	93%	93%	93%	93%
PITER	–	93%	95%	98%	98%	98%

Table 2b. Inputs of the WHO Targets Scenario, 2015-2030

	2015	2016	2017	2020	2022	2025+
Annually Treated						
WHO Targets	31,000	33,700	33,700	35,700	36,700	38,000
Newly Linked to Care						
WHO Targets	30,400	30,400	30,400	33,400	35,400	36,400
Treatment Eligible Stages						
WHO Targets	≥F3	≥F3	≥F0	≥F0	≥F0	≥F0
SVR						
WHO Targets	93%	93%	95%	98%	98%	98%

There were an estimated 849,000 viremic individuals in Italy in 2015 (Table 1), and around 70% of the infected (F0–F3) individuals were within the 1948 to 1978 birth cohorts. Considering the 2016 standard of care, liver related mortality is expected to decline by 65%, achieving the WHO mortality target.



- Under the 40% linked to care scenario, eligible patients to be treated will be depleted by 2025, resulting in a treatment rate decline moving forward. A targeted screening strategy in the 1948-1978 birth cohorts could supplement the pool of diagnosed patients by finding 75% of F0-F3 cases (Table 3).
- Under the PITER 60% linked to care scenario, the patients eligible for treatment are expected to run out in 2028. If treatment is to be maintained at 33,700 through 2030, a screening strategy focusing on individuals born in the years 1958-1978 could be useful to capture 55% of eligible infected patients for treatment (Table 3).
- Under the PITER 80% linked to care scenario, the pool of eligible patients to be treated is expected to be depleted by 2031, and screening limited to those born in the years 1968-1978, which would capture 25% of infected cases, would be sufficient to sustain treatment at levels required to achieve the WHO Targets (Table 3).

Table 3. Distribution of F0-F3 infected cases by birth year in the PITER and Italy Polaris models

Birth Year	Percent F0-F3 infected cases (PITER Model)	Percent of F0-F3 infected cases (Italy Polaris Model)
1938-1948	28	32
1948-1958	35	42
1958-1968	41	26
1968-1978	23	17
1978-1988	10	10
1988+	5	8

CONCLUSIONS

Italy has been considered the country with the highest HCV prevalence rate in Western Europe. However, due to expanded DAA access policies in the past year**,** Italy is on track to achieving the WHO targets, if current treatment levels are sustained.

In the three PITER linkage to care scenarios, the eligible pool of patients to be treated will run out between 2025 and 2031, leaving a significant proportion of infected individuals undiagnosed and without access to care. Targeted screening strategies are required in order to achieve the WHO targets and sustain universal access to DAAs.

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