How could Italy reach the HCV elimination by 2030?

Loreta A. Kondili

Center for Global Health. Istituto Superiore di Sanità, Rome, Italy

Dear Editor,

Combatting viral hepatitis is included among the United Nations Sustainable Development Goals, and the World Health Organization (WHO) has set out recommendations to achieve the Hepatitis C Virus (HCV) elimination goal. Boston Consulting Group (BCG) has recently produced a Report entitled *"WINNING THE RACE TO ELIMINATE HEPATITIS C"* with the aim of evaluating the progress made in the last three years, analyzing the main barriers and success factors to achieving HCV elimination. In the BCG Report only 10 of the 29 countries are reported on track to meet the WHO HCV elimination targets, with most countries seeing little real progress since 2017. Italy is the European country with the greatest burden of HCV infection and the highest mortality rate from HCV-related cirrhosis and hepatocellular carcinoma. It was a country on track to achieve the HCV elimination goal until the year 2018 and has been classified as "Follower Country," in the BCG Report. This means Italy can achieve HCV elimination by 2030 but still needs to overcome relevant barriers, as many of HCV infected patients have not been diagnosed yet. As "Follower Country", scaling-up screening campaigns, increasing knowledge among healthcare providers, and developing awareness campaigns that decrease social isolation, mistrust, and stigma are key initiatives to managing the HCV infection and disease burden in Italy [1].

Due to the extensive use of direct acting antivirals (DAA) for the treatment of HCV in 2015-2016, Italy could achieve the WHO's goal of reducing liver-related mortality by 65% earlier than the target year of 2030. It has also been predicted that as long as 40,000 people continue to be treated every year, Italy would achieve the WHO's goal of eliminating HCV infection as a public-health threat by 2030 [2, 3]. However, in Italy, the number of DAA treated patients declined in 2019 and during 2020 almost stopped due to the COVID-19 pandemic [4, 5]. If the active screening is not promoted, the proportion of infected persons who are diagnosed and treated is expected to run out between 2023-2025, leaving a high number of infected individuals undiagnosed and without treatment [2]. In addition, if screening adherence is not appropriately addressed, Italy will not be able to reach the HCV elimination goal. Although a National Hepatitis Plan exists, it has not been funded and implemented. Italy is divided into twenty regions with their own discretion in planning, organizing, and financing health care services within their own territory. Decentralized models for HCV care and lack of uniform strategies across regional networks remain important challenges which emphasize the need for action at the Italy regional level.

Previous studies have reported important medium to long-term health and economic benefits of DAA treatment for the Italian Health System. The initial investment in DAA treatment has been estimated to be recovered in approximately 5.5 years [4]. This evidence, together with a defined, cost-effective, HCV screening strategy in Italy [6], were well received by Italian policymakers and an important political action has recently been approved. An amendment to the Milleproroghe Decree allocated 71.5 million Euros to introduce a free of charge screening, as an experimental project during 2020-2021, for key populations (current intravenous drug users and inmates) and general population cohorts born between the years 1969-1989 [6]. Strategies to increase the screening rate, involving primary health care doctors and optimizing diagnostic procedures by using Reflex Testing, have been recommended for the birth cohort screening of general population. Additionally, inpatients, or outpatients

Corresponding author
Loreta A. Kondili
E-mail: loreta.kondili@iss.it

admitted to the hospital for different reasons, could also be tested for HCV infection. HCV screening tests could be combined with the SARS CoV-2 screening or with COVID-19 vaccination [4, 7].

A forward-looking, people-centered approach is suggested by the BCG report for the HCV management in the key populations. The Caserta Model of Integrated HCV Care, has been shown to reduce treatment drop-outs in high-risk populations by shortening their care pathway [1, 9]. To this regard the HCV screening law decree indicates the point of care as the only path for HCV elimination in key populations. In addition, it is indicated the possibility to carry out rapid HCV RNA testing in People Who Inject Drugs (PWID) as the single step for identifying active HCV infection. This is important to speeding up the treatment process always accompanied by counselling and harm reduction activities [8]. However, there is currently a lack of available specialized care to prisoners and PWIDs which delays their linkage to care. Therefore, it is necessary to simplify linkage to care and treatment of key populations by increasing the role health care workers within the prison and services for drug addiction (SerDs). A specialist could remotely (potentially through the telemedicine) evaluate the patients' clinical data and indication for treatment reported by the Prison's or SerD's doctor. Following this evaluation, the specialist could prescribe the DAA therapy as required by the Italian Medicines Agency (AIFA) indicating also the post-treatment monitoring plan if necessary could be prescribed by a specialist doctor as required by the Italian Medicines Agency. This interdisciplinary integrated organization among SerD specialists, prison doctors and specialists (hepatologists or infectious diseases specialists) could guarantee close monitoring of the compliance with the treatment, based on the therapeutic and the motivational support [8].

Screening is only the first step; sufficient healthcare support has to be provided and tailored efforts must be made to reach otherwise neglected individuals [10]. There is a need to implement micro elimination specific programs in at-risk populations, such as men who have sex with men (MSM) and sex workers. Lack of awareness around the disease, sexual risk norms, HCV stigma, and non-disclosure of HCV status constitute barriers to safer sex and to risk-reduction measures. In addition, migrants, in particular those undocumented, should garner particular screening efforts, as they are the hardest group to track [1]. HCV elimination is an achievable goal in Italy, if real action is taken now. Effective screening should be supplemented with rapid linkage-to-care and treatment of newly diagnosed patients. Establishing an *ad-hoc* fund within the National Plan for the Prevention and Treatment of Hepatitis C for each Italian Region is of paramount importance in order to keep Italy on track to achieve the WHO elimination targets by 2030 [3, 8].

Conflict of interest
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