HCV: ESTIMATION OF THE NUMBER OF DIAGNOSED PATIENTS ELIGIBLE TO NEW ANTI-HCV THERAPIES IN ITALY

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Background: HCV affects an estimated number between 130 million and 210 million people worldwide. According to the European Centre for Disease Prevention and Control, Italy has the highest number of HCV-positive patients in Europe and the highest rate of death from cirrhosis and HCC. (1) Nevertheless, studies used to estimate HCV burden of illness in Italy were so far local and old (performed in the 1990s), not mirroring the current state of the art. Two key aspects still recognized as true were 1) the North-to-South gradient of prevalence (3.9%-16.2%) and 2) an age-related increasing prevalence. Epac is the most important Italian NGO for hepatopathic patients, actively involved in the Italian environment, producing data with the direct collaboration of patients, clinicians and Institutions.

Objectives: The present study aims at taking a picture of the up-to-date epidemiological scenario regarding HCV infection in Italy. Epac wanted to provide Institutions with a real number of diagnosed patients, eligible to new anti-HCV therapies, as basis for taking aware decisions concerning future HCV eradication strategies and evidence-based budget allocation.

Methods: A number of source were cross-checked. Starting from all regional data regarding HCV-related exemptions (code O16.070.54), a correction/integration was performed with online questionnaire to associated patients (from which we derived patients cured and also other/no exemptions); survey to all prescribing centers in Italy (from which we derived the percentage of ineligible patients); prevalence of particular subpopulations was also collected (patients HIV/HCV coinfecte); calculation of new diagnosed, dead and cured patients in 2015. Illegal immigrants and active drug addicts (subpopulations currently rarely cured) were excluded from calculations.

Results: A total of 221,549 patients were derived from regional exemptions databases and the average national prevalence was downsized to 0.364% (Figure 1). Adding patients without exemptions/other exemptions derived from the online survey (Figure 2), total was 308,624. We deducted the yearly deaths, cured and not eligible patients and, last, integrated with confirmed and prisoner special groups (data not shown). Prevalence was also estimated at regional level, highlighting a reduction of the typical North-to-South prevalence gradient. Applying the abovementioned corrections/ integrations, total diagnosed and eligible HCV patients in Italy who can be immediately cured are supposed to range 163,148 – 187,756 (Figure 3).

Conclusions: The present study has tried to fill an information gap at national level, which may be of precious help for decision- and policy-makers in defining future therapeutic strategies and budget allocation decisions. In fact, the study provides important information regarding the current HCV epidemiological situation in Italy, which has undergone major changes over the past 10-15 years. According to the results regarding eligible patients, an eradication plan seems to be feasible and applicable in the next few years, also considering the likely price reductions of drugs, already estimated by recent studies (2).

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