

HCV: ESTIMATION OF THE NUMBER OF DIAGNOSED PATIENTS IN ITALIAN MEDICAL CENTERS AUTHORISED TO PRESCRIBE NEW ANTI-HCV THERAPIES

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**OBJECTIVE:** The research wants to take a picture of the current scenario regarding HCV infected patients in Italian medical centers and their access to therapy.

In Italy there are restrictions to access to HCV therapies; the study, wants to show the need of changes in access not only for social and medical reasons, but as a need of the System: without changes some centers will stop in prescribing as a consequence of the exhaustion of the advanced patients.

**METHODS:** we made a survey, involving all Doctors in the specialized medical centers. We asked for the total number of patients followed in the center: cured/in treatment patients, waiting to start the therapy (according to access criteria) and patients excluded by the criteria. We also asked when they expect to finish to put in treatment the eligible patients. We finally asked their opinion about the best change in access criteria? We collected the answers in the period May-August 2016 and elaborated the data to produce a report on the real state of access to treatment in Italy and in the various Italian Regions.

**RESULTS:** we collect the answers of 86 Medical Centers on a total of 227 (38%), with a homogeneous geographical distribution. Nationally, the percentage of eligible patients still waiting for a treatment was 26,9%, while on the total amount of patients in care, the cured/on treatment was 44,7%, the eligible still waiting 16,1% and finally the excluded patients 39,2%. The 60,5% of doctors expect to finish the number of eligible patients by the end of 2016, the 32,6% in 2017 (15% by the end of the first quarter), and only the 7% in 2018.

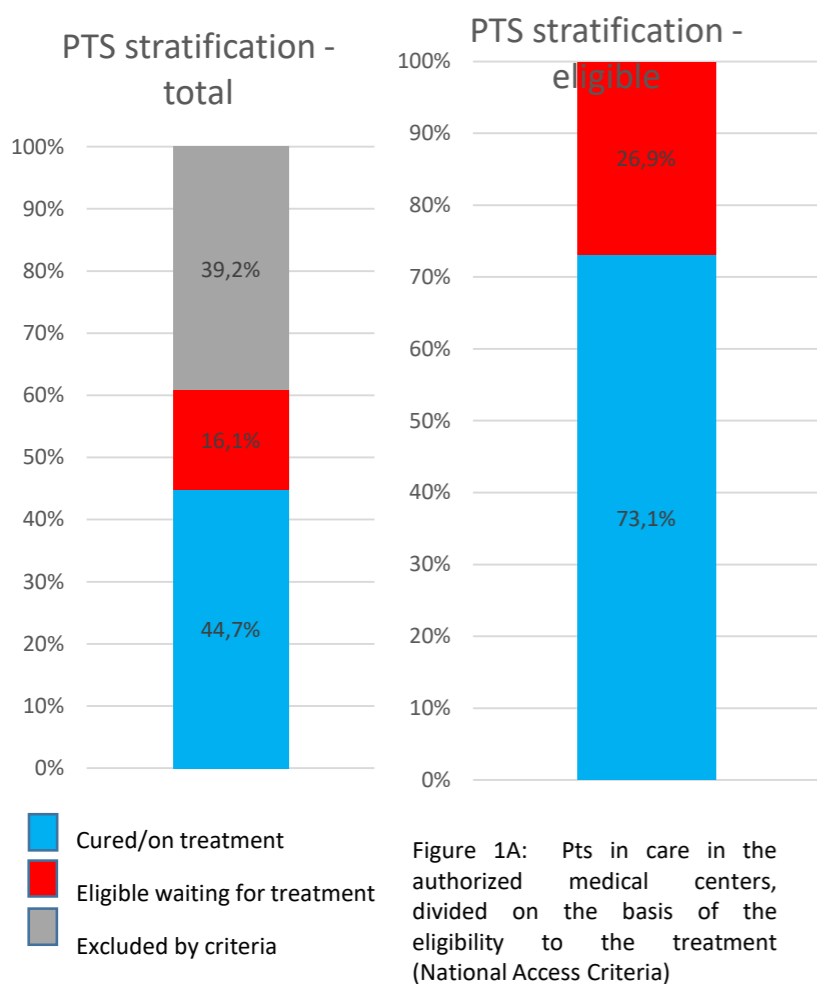


Figure 1A: Pts in care in the authorized medical centers, divided on the basis of the eligibility to the treatment (National Access Criteria)

Eligible Patients waiting for treatment		
PTS (Num)	Answers (NUM)	% on the TOTAL
< 10	11	12,8%
11 - 50	39	45,3%
51 - 100	17	19,8%
101 - 150	7	8,1%
151 - 200	8	9,3%
>200	3	3,5%
TOT	84	100,0%

Figure 1B: number of pts waiting to start treatment; % on the total of waiting pts.

The 76,7% of the Doctors declare that the best change in access is to remove any restriction, establishing prioritization clinical guidelines to drive doctors. We detected a phenomenon that we named "physiologic flow", patients who progressively arrive to the specialized medical centers, quantifiable in the 10% of all the patients in care. Finally we tried to investigate the phenomenon of the acquiring of "generic drugs": 2 doctors on 5 know patients who have bought generic drugs, and 1 on 3 is curing or has cured at least one patient with generics.

End of recruiting	Answers (num)
2° quarter 2016	28
3° quarter 2016	24
1° quarter 2017	13
3° quarter 2017	8
2° quarter 2017	7
2018	6
Total	86

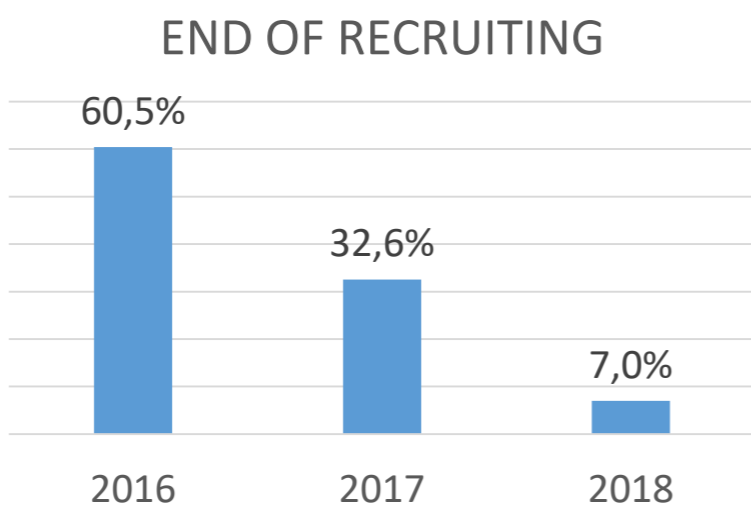


Figure 2: Expected end of eligible patients recruitment in the authorized medical centers

	Answers	%
Universal access, no criteria; clinical guidelines	66	76,7%
Open only for F2 pts	14	16,3%
Open only to F2 pts with an urgency (HIV/HCV, HBV/HCV ecc.)	6	7,0%
TOT	86	100%

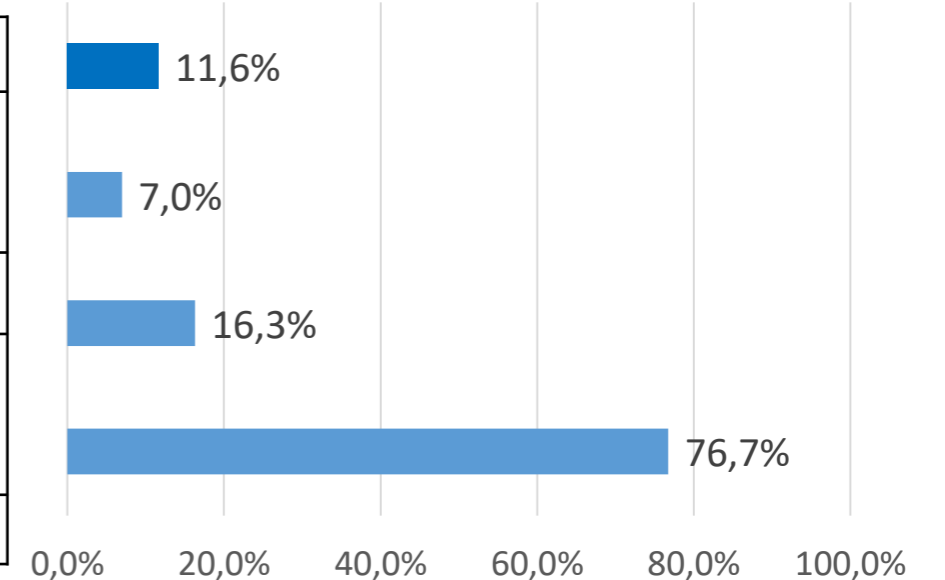


Figure 3: doctors point of view about the change needed in the access to treatment criteria.

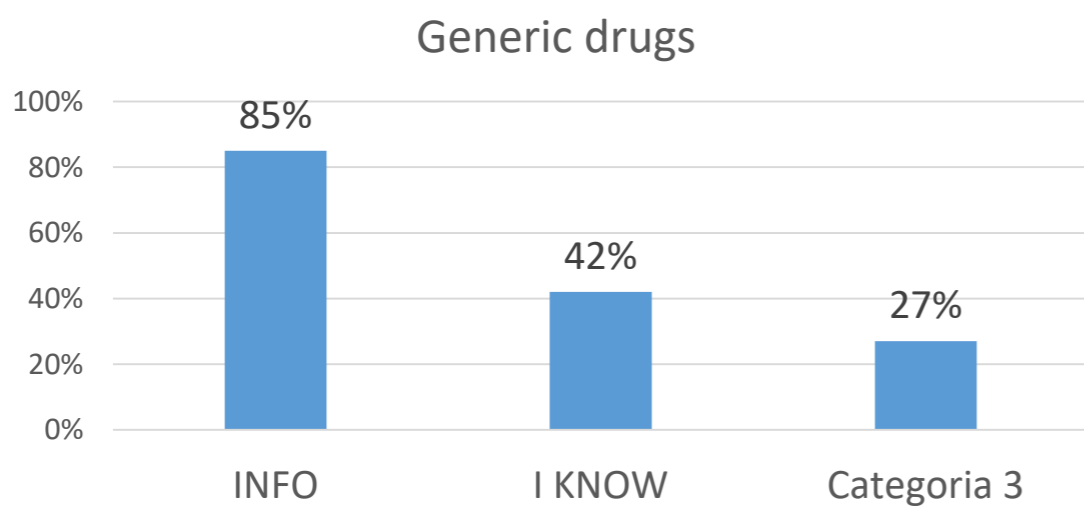


Figure 4: answers of the doctors about the use/acquiring of generic HCV antivirals (not registered in Italy - not legal)

	Data from 86 centers	National data from 227 centers
Centers	86	227 <sup>1</sup>
Pts cured/on treatment	17.767	52.200 <sup>1</sup>
Pts waiting for treatment	7.383	21.691
Pts excluded by criteria	22.962	67.463
Pts in care in the authorised centers	48.112	141.355 <sup>2</sup>

1. Official data from National Medicine Agency - 2. Estimation based on the collected data

Figure 5: Final elaboration of the collected data and estimation of the number of patients in care in Italian specialised and authorized medical centers

**CONCLUSIONS:** This survey is aimed at filling an informative gap able to provide useful actual information in terms of HCV patients real-life management, to highlight the need of changes in access criteria, and finally, to show the need of an action plan to manage the patients out from the specialized and authorized medical centers. These data may be considered as a clear evidence of the real picture of the access to the treatment in Italy, the basis for policy- and decision-makers to plan and manage patients ready to be cured and finally the proof that major changes in access and management of patients out of authorized centers are needed.

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