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HCV – Treatment ratio and governance footprints: analysis of regional differentiation in Italy

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Abstract. – Due to the strongly fragmented reality of HCV treatment in the various Regions of Italy, effectiveness of access to treatment is difficult to gather. The aim of this paper was to analyze regional differences in healthcare governance models regarding HCV, in order to understand the ability of each Region to give access to HCV diagnosed patients.

The analysis was performed by comparing treatment ratios (TR) across all Regions (treated patients/diagnosed patients). Furthermore, the study provides insight to regional regulatory environment and to all HCV treatments entering the market in each Region.

Sicily has the highest TR value (73%), whereas Friuli Venezia Giulia has the lowest (5%). Overall, Regions where a technical document on HCV clinical pathways has been implemented, result in a higher number of treated patients.

Key Words:
Treatment ratio, HCV, Regions.

Abbreviations

HCV = Hepatitis C Virus; KPI = Key performance indicator; TR = Treatment ratio; Rx = prescription.

Introduction

The governance of Hepatitis C Virus (HCV) treatment in Italy is differentiated at regional level under a number of region factors: presence of technical document or guidelines, centralized or de-centralized purchasing, therapy access criteria, registers and number of prescription centres.

Due to such a fragmented model, a clear evidence of number of treated patients and related costs is hard to gather, and more in general it is difficult to compare how effective each regional system is with regard to access to treatment. A single KPI to harmonize the evaluation of cross-regional access to HCV treatment would allow a more objective assessment of the regional governance models.

Objectives

The present analysis aimed to compare the regional healthcare governance models in Italy with regard to HCV in order to assess regional differences in the access pathways to treatment. Specifically, the main goal of the study was to carry out a quantitative evaluation of the ability of a Region to give access to treatment for HCV diagnosed patients (Figure 1).

Materials and Methods

The analysis aimed to introduce a "treatment ratio" (TR) to compare the ratio of patients who received HCV treatment out of the total number of diagnosed patients for HCV across all Regions (Figure 2). The regional prevalence of HCV diagnosed patients was derived from a research study by EPAC. The regional prevalence of patients receiving treatment for HCV was estimated by distributing the overall number of treatments administered in Italy for HCV (derived from official AIFA registers) proportionally to the regional prevalence of Sovaldi payback estimation[2], which was assumed as a proxy for the overall distribution of HCV treatments. Introducing a quantitative KPI such as the treatment ratio allows to critically compare the multifaceted regional governance footprints

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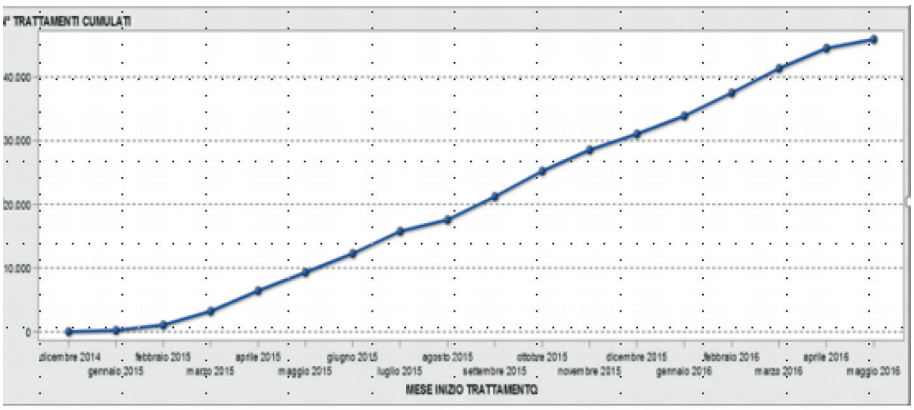

Figure 1. Treated patient trend[1]. Diagnosed Patients – EPAC[3]

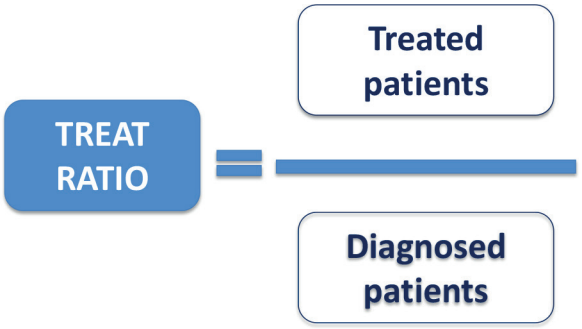

Figure 2. Treatment ratio definition. Source: Treated Patients.

in light of multiple governmental aspects, such as clinical pathways, local regulatory bodies, degree of buying centralization, rx constraints and monitoring, rx centres and coordination.

This quantitative-based/qualitative-adjusted approach allows to understand how each regional regulatory and governance context results in ensuring access to treatment for HCV diagnosed patients, providing an objective assessment of a Region's capacity to treat patients.

The study also provides a comparison of the regional regulatory environment, and a sequencing analysis of all HCV treatments entering the market in each region (first comer, second comer and avg delay).

Results

Sicily is the region with the highest TR value (73%), as a result of a wide treatment access combined with a limited diagnosed prevalence. Conversely, Campania results in a more selective access system, where despite of one of the highest diagnosis prevalence in Italy, only 1 HCV diagnosed patient out of four receives treatment (TR = 25%). Other big-spending regions such as Lombardy and Lazio are tied at a TR value of ~15%, while Veneto is among the most restrictive regions for HCV treatment access (TR = 12%). Friuli Venezia Giulia has the highest diagnosis prevalence (0.683%), but the lowest TR (5%)

Regions	# Treated patients	Treated prevalence (A)	# exemptions for diagnosis	Prevalence of diagnosis (B)	Treatment ratio (A/B)
SICILIA	3.966	0,078%	5.464	0,107%	73%
CALABRIA	1.855	0,094%	4.057	0,205%	46%
PUGLIA	6.392	0,156%	20.714	0,506%	31%
TOSCANA	4.245	0,113%	14.889	0,397%	29%
CAMPANIA	7.657	0,130%	30.448	0,519%	25%
ABRUZZO	480	0,036%	2.076	0,156%	23%
UMBRIA	418	0,047%	2.049	0,228%	20%
SARDEGNA	1.395	0,084%	6.898	0,415%	20%
LIGURIA	1.138	0,071%	6.338	0,398%	18%
MARCHE	625	0,040%	3.684	0,237%	17%
PIEMONTE	2.228	0,050%	14.084	0,317%	16%
LAZIO	2.570	0,044%	16.315	0,278%	16%
MOLISE	147	0,047%	979	0,311%	15%
LOMBARDIA	7.906	0,079%	54.430	0,546%	15%
BASILICATA	445	0,077%	3.401	0,588%	13%
V.D'AOSTA	51	0,039%	400	0,311%	13%
EMILIA	1.959	0,044%	16.292	0,366%	12%
VENETO	1.784	0,036%	15.104	0,307%	12%
BOLZANO	134	0,026%	1.259	0,244%	11%
TRENTO	112	0,021%	1.448	0,270%	8%
FRIULI	407	0,033%	8.394	0,683%	5%

Figure 3. Treatment ratio in the Italian regions.

– this sounds as a further confirmation of how a TR-based comparison offers a more accurate evaluation (Figure 3).

Sovaldi was the first entrant in all Regions, either tied or followed with a median 2 months' delay by Olysio.

Conclusions

TR provides a robust KPI to compare access to treatment across Regions and serves as pivotal reference to investigate how local regulatory decisions and governance models impacts the access to treatment. As a general evidence, Regions where a technical document on HCV clinical pathways has been implemented by local regulatory bodies result in a higher number of treated patients.

Conflict of interest

The authors declare no conflicts of interest.

References

1) http://www.agenziafarmaco.gov.it/sites/default/files/Aggiornamento_dati_Registri_AIFA_DAAs_16.05.2016.pdf
2) http://www.agenziafarmaco.gov.it/sites/default/files/Allegato_1-30.03.2016.pdf
3) EPAC - Epatite c: stima del numero di pazienti diagnosticati ed eleggibili a un trattamento antivirale per l'epatite C residenti in Italia http://www.sosfegato.it/camo/onlus/all/I_Forum_parlamentare_hcv.pdf