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WORKSHOP IN PHARMACOECONOMICS: AN ITALIAN EXPERIENCE OF MULTI-STAKEHOLDER HTA CONSENSUS Americo Cicchetti¹, Antonio Gasbarrini², Matteo Ruggeri¹, Dario Sacchini², Elena Paola Lanati³, on behalf of WEF study group

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BACKGROUND

HTA is a very challenging issue in many countries, including Italy, where it has been officially mentioned for the first time in the National Healthcare Plan 2006-2008. In Italy only few groups are recognized at international level, some pertaining to central and regional Institutions, some being small independent working groups. The Technology Assessment Unit (UVT), situated at the Policlinico Gemelli – Cattolica University in Rome, was the first HTA group and can be considered a pioneer in Italy.

OBJECTIVES

The objective of the Italian Workshop in Pharmacoeconomics (WEF), born as a practical application of HTA, is to validate an innovative experience that aims at being recognized by Institutions as a national and independent HTA assessor, thus supporting both national and regional healthcare decision-makers. This experience consists of a multi-stakeholder working group that, in the field of new technologies proposed for critical clinical areas, discusses and develops guide-lines and decision rules and comparatively examines local real practice data, directly collected by the members of the Scientific Board.

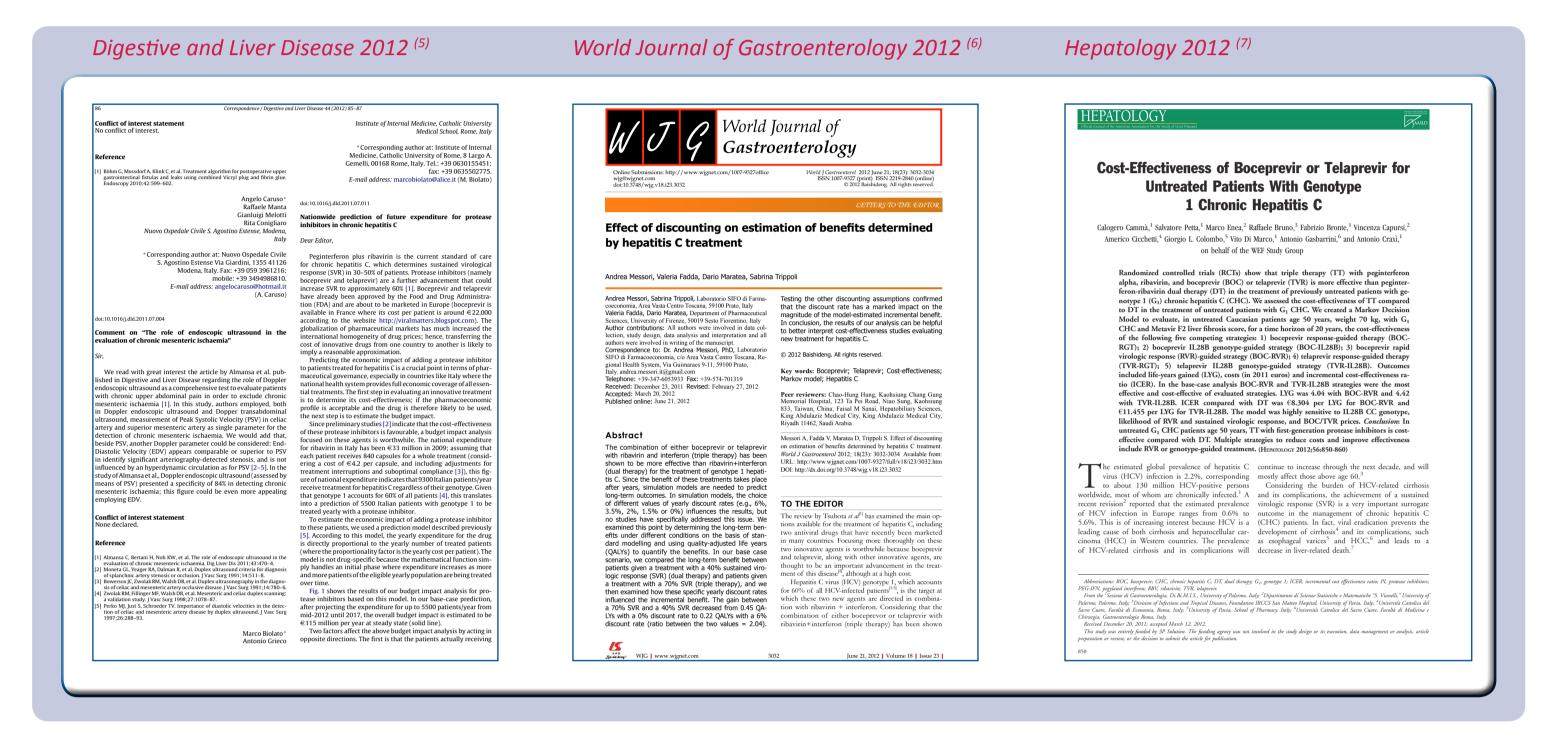
METHODS

The working method consists of a series of meetings (at least 4 per year) of the Scientific board (composed by high-profile experts covering all HTA domains: clinicians, pharmacoeconomists, experts in organizational aspects, bioethicists, patients, Institutions) that carries out a nationwide analysis of the topic under examination and focuses on the main clinical, economic, organizational, social, and ethical features. Questionnaire-based surveys and Delphi panel are the main operational tools. WEF adopts standard HTA procedures according to the EUnetHTA Core Model and to avoid any conflict of interests, no fee is paid to any member.

RESULTS

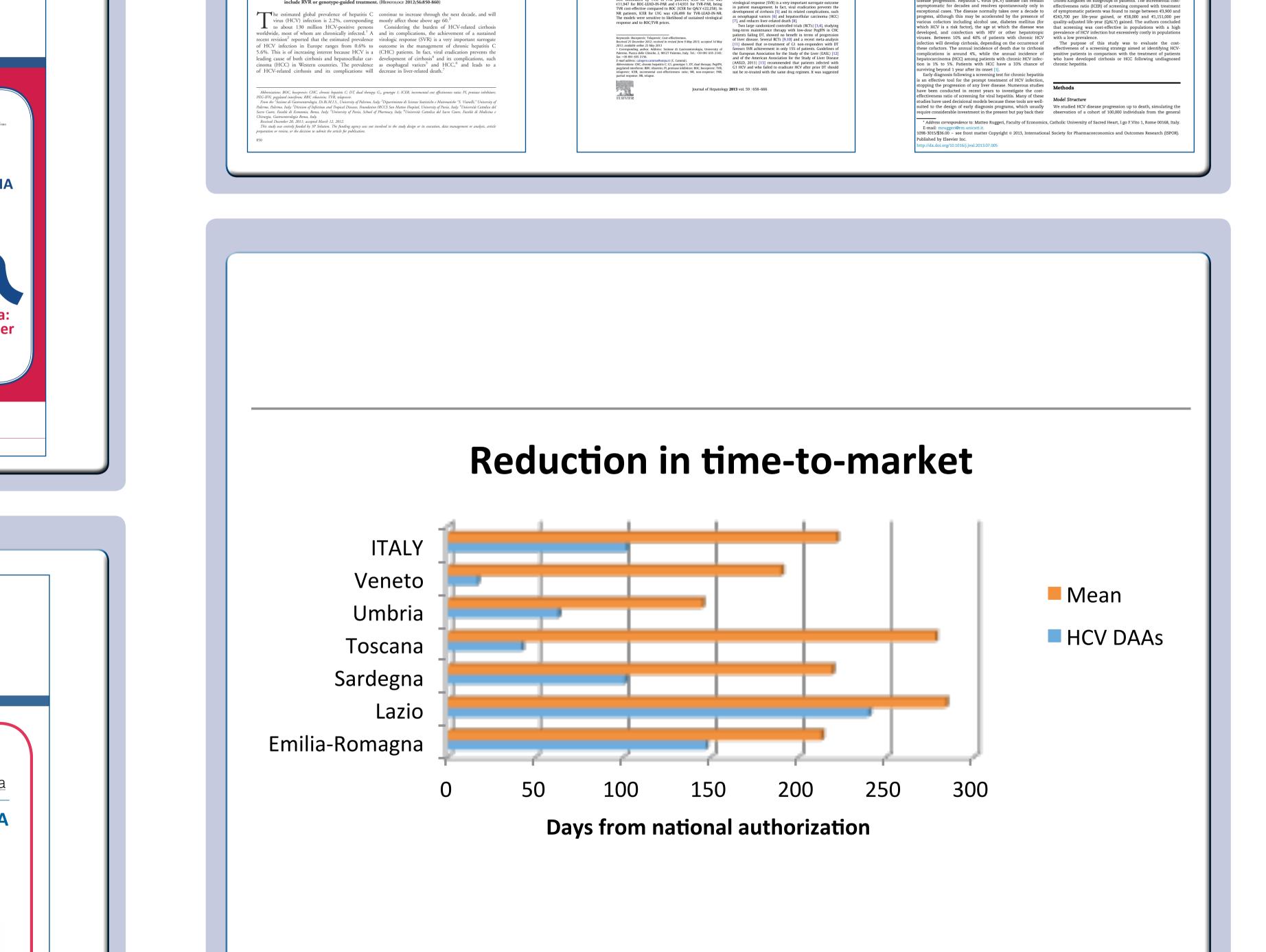
Since 2011, three HTA reports have been produced on hepatology, focusing in 2011 and 2012 respectively on HBV/HCV screening strategies and HCV new Direct Antiviral Agents (DAA)-based therapies and extending in 2013 to hepatocellular carcinoma. In 2013 a second therapeutical area was assessed, dealing with gastroenterology and inflammatory bowel diseases (IBDs), in particular with Crohn's disease and its treatment with biological high-cost drugs. For 2014, a fourth edition on hepatology and a second on IBDs are being developed. A first WEF edition on HIV is also coming up next year.





patology 2013 ⁽⁸⁾	Journal of Hepatology 2013 ⁽⁹⁾	Value in Health 2013 ⁽¹⁰⁾
Cost-Effectiveness of Boceprevir or Telaprevir for <i>Data and the second stress of Boceprevir or Telaprevir for <i>Data and Patients With Genotype Data and the second stress of the second stress </i></i>	Proprietor Proprietor Proprietor P	<section-header><image/><image/><image/><image/><image/><image/><image/><image/><image/><section-header><section-header><image/><image/><section-header><section-header>2<section-header><table-row><image/><section-header>2</section-header></table-row></section-header></section-header></section-header></section-header></section-header></section-header>
of the following five competing strategies: 1) boccprevir response-guided therapy (BOC- RGT); 2) boccprevir IL28B genotype-guided strategy (BOC-IL28B); 3) boccprevir rapid virologic response (RVR)-guided strategy (BOC-RVR); 4) telaprevir response-guided therapy (TVR-RGT); 5) telaprevir IL28B genotype-guided strategy (TVR-IL28B). Outcomes included life-years gained (LYG), costs (in 2011 euros) and incremental cost-effectiveness ra- tio (ICER). In the base-case analysis BOC-RVR and TVR-IL28B strategies were the most effective and cost-effective of evaluated strategies. LYG was 4.04 with BOC-RVR and 4.42 with TVR-IL28B. ICER compared with DT was (8.304 per LYG for BOC-RVR and €11.455 per LYG for TVR-IL28B. The model was highly sensitive to IL28B CC genotype, likelihood of RVR and sustained virologic response, and BOC/TVR prices. Conclusion: In untreated G, CHC patients age 50 years, TT with first-generation protease inhibitors is cost- effective compared with DT. Multiple strategies to reduce costs and improve effectiveness include RVR or genotype-guided treatment. (HENTOLOG 2012;56:850-860)	 (RR), partial response (RR), we asses the cost-effectiveness of TI compared to no therapy in the treat- ment of patients previously treated with G1 CHC. Methods: The valiable published literature provided the data source. The target population was made up of previously treated caucasian patients with G1 CHC. Methods: The valiable published literature provided the data source the target population was made up of previously treated caucasian patients with G1 CHC. Methods: The valiable published literature provided the data source. The target population was made up of previously treated caucasian patients with G1 CHC. Methods: The valiable published literature provided the data form the perspective of the taliable National Health Service. Out- comes included discounted costs (in euro at 2012 value). Methods: The value table year (AUV) and incre- mental cost-effectiveness ratio (ICER) The robustness of the results was evalueted by one-way deterministic and multivari- able probabilistic sensitivity analyses. Results: In RR patients, ICER per VAC compared to no therapy was e9555 for BOC-LEAD-IN-RR and e7101 or 178-LEAD-IN-RR, being BOC dominated by TVR. In PAR patients, ICER for IVG AR, and e11947 for BOC-LEAD-IN-RA and e14951 for 178-RA and e14951 for 178-RA and e14951 for 178-RA and e14951 for 1895 a very important surrogate outcome e11947 for BOC-LEAD-IN-RA and e14951 for 178-RA and e14951 for 1895 a very important surrogate outcome 	Health Service perspective. Methods: We built a Markov model made up of two arms. The "Test Strategy" arm involves a screening program is a valid health-related invest- manipulation with research of HCV RNA as second-level detection. patients with positive test results are treated with peg-interferon affin in combination with ribavrine. Parameters were derived from the literature and validated through experts' opinion. Costs and benefits Introduction Viral hepatitis is a chronic condition with a latent, nonlinear disease progression. Hepatitis C virus (HCV) disease can remain asymptomatic for decades and resolves spontaneously only in the treatment of the intercond and the and the addit relation to combination with can be addited through experts' opinion. Costs and benefits the spontaneously only in the spontaneously only in the spontaneously only in the treatment of the intercent of the program is arried out in France, Great Britain, and the diffectiveness ratio (ICER) to force programs carried of the intercond of the program is a valid bealth related invest- ance and the anti-HCV screening program is a valid health related invest- tions and the other indication and the anti-HCV screening program is a valid health related invest- texpenditure increase for the National Health Bevice. Copyright c 2013, International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Published by Elsevier Inc.





Along with 6 publications in international journals (mean impact factor 7,1), there have also been auditions at the Italian Drug Agency (AIFA) and at the Healthcare Commission in Parliament that have facilitated the approval of new HCV drugs. Furthermore, the analysis of available data about delays in approvals by regional formularies have been reduced by about 55% (from 221 days after national marketing authorization to 101 days; Farmindustria data).

1) Primo Workshop Nazionale di Economia e Farmaci in Epatologia WEF-E 2011 - Roma, 27-28 aprile 2011. I quaderni di medicina II 24 ore Sanità. Giugno 2011 2) Secondo Workshop Nazionale di Economia e Farmaci in Epatologia WEF-E 2012 - Roma, 2 febbraio 2012. I quaderni di medicina II 24 ore Sanità. Aprile 2012 3) Terzo Workshop Nazionale di Economia e Farmaci in Epatologia WEF-E 2013 - Roma, 7-8 febbraio 2013. I quaderni di medicina II 24 ore Sanità. Luglio 2013 4) Primo Workshop Nazionale di Economia e Farmaci per le Malattie Infiammatorie Croniche Intestinali -WEF-IBD 2013 - Roma, 6 febbraio 2013. I quaderni di medicina Il 24 ore Sanità. Giugno 2013

5) Maratea D, Messori A, Fadda V; WEF-E Study Group. Nationwide prediction of future expenditure for protease inhibitors in chronic hepatitis C. Dig Liver Dis. 2012 Jan;44(1):86-7.

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CONCLUSIONS

This new multidisciplinary and multistakeholder approach proved to be well-accepted, and the "WEF method" is already recognized as a milestone in the Italian HTA landscape, by Institutions (e.g. AIFA and Italian MoH), Scientific Societies and pharma industries, thus helping payers in making rational decisions based on HTA methods.

This is the proof that HTA, if well built and following a scientific evidence-based process, is a very useful tool that, considering all aspects concerning the healthcare system, may pragmatically improve prescriptive appropriateness of drugs/technologies and facilitate access to cures.

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10) Ruggeri M, Coretti S, Gasbarrini A, Cicchetti A. Economic assessment of an anti-HCV screening program in Italy. Value Health. 2013 Sep-Oct;16(6):965-72.





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