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In reply to: Confirmation of antibodies against hepatitis C virus by recombinant immunoblot: Is it really an improvement to abandon it?



En respuesta a: Confirmación de anticuerpos frente al virus de la hepatitis C mediante inmunoblot recombinante: ¿es realmente una mejora abandonarlo?

Dear Editor,

In spite of the high efficacy of antiviral treatment, for the first time in infectious diseases and in the absence of a vaccine, there is an opportunity to eliminate an infection, namely hepatitis C. WHO sets year 2030 as the target for HCV elimination,¹ and Spain is estimated to achieve WHO goals for elimination by 2024.² One of the barriers to elimination is appropriate screening: as EASL guidelines³ state, “most laboratories use a two-step approach (phlebotomy and antibody test in step 1, and phlebotomy and a test for HCV RNA in step 2), resulting in a substantial fraction of patients with anti-HCV antibodies never receive confirmatory HCV RNA testing”. For this reason both EASL and AASLD⁴ guidelines, currently recommend that “if anti-HCV antibodies are detected, the presence of HCV RNA in serum or plasma should be determined to identify patients with ongoing infection (A1)”. In addition, EASL guidelines recommend “Reflex testing for HCV RNA in patients found to be anti-HCV antibody-positive should be applied to increase linkage to care (B1)”. Several Spanish studies have already reported the benefits of reflex testing on linkage to care^{5,6} and on health economics.⁷ Reflex testing is supported by all Spanish scientific societies involved in HCV care.⁸

We believe that the reasons for continuing supplementary antibody confirmation testing proposed by Avellón et al. may be out of scope for clinical management and may hamper the elimination goals of hepatitis C. First, a 20% of false positive tests is not acceptable for any screening test in the clinical laboratory, and is far beyond the specificity of 3rd and 4th generation FDA cleared and CE marked immunoassays to detect anti-HCV. Second, the statement “the decision to exclude confirmation by RIBA from diagnostic algorithms is partially based on the assumption that a test detecting viremia following a reactive result on an anti-HCV screening test will effectively discard false positive results” is misleading. Reflex testing is not intended to discard any false positive result of anti-HCV; it is intended to diagnose active infection by HCV and to identify and link to care those patients that need and may benefit from treatment. This is the clinical need for clinicians, and is the need to achieve elimination goals. With reflex testing patients, and clinicians, will receive the clinical information they really need, it is not a case of reporting false or true positive results on HCV antibodies. The only room for discrimination between false positive results and cleared HCV infections is clinical and epidemiological research. There is no need of it in clinical practice and with elimination purposes. In our opinion, it is unclear how “false positive result may have significant consequences for the patient in terms of time and cost”, nor “if previous contact with HCV is confirmed, the patient would require prevention advice and continuous monitoring since reinfection could occur”, as this is already recommended by clinical guidelines with annual HCV-RNA testing for all patients with ongoing risk fac-

tors for HCV acquisition. Dr. Avellón states that “legitimate demand from all patients to receive information of equal quality on the results obtained with laboratory diagnostic tests that have been prescribed and performed”. However, we believe that the demand of the patient is to be cured, and the goal for Public Health System is to achieve the elimination of hepatitis C, rather than start a debate on if prevalence data are or not “quite far from reality due to the false positive results”.

In conclusion, there is sufficient data to support that using supplementary methods for the confirmation of anti-HCV antibodies should be abandoned in clinical practice in the Spanish network of diagnostic laboratories, as it results in a barrier for appropriate clinical management and for linkage to care, and hampers HCV elimination in Spain.

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