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SHORT COMMUNICATION

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# Laboratory reform counteracts the WHO hepatitis C elimination strategy in Germany

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## Abstract

The World Health Organization and the German government have announced an initiative to eliminate chronic hepatitis C until the year 2030. To reach this goal, one important step is adequate screening and detection of so far undiagnosed infections. The most common initial test is anti-HCV. This parameter was extra-budgetary reimbursed by statuary healthcare insurances in the past. However, this policy has changed after a nationwide laboratory reform which should reduce the laboratory costs of patients insured in the statuary healthcare insurances. We therefore analysed the impact of the laboratory reform on the order of anti-HCV tests in 510 656 anonymized patient data sets before and after the initiation of the reform. The number of anti-HCV tests declined by 9.4% in quarters I-III 2018 in comparison with the same time period of the year 2017. The number of HBsAg tests declined by 7.4%, indicating that the reduced anti-HCV laboratory orders are not parameter-specific, but most likely a surrogate of the intention of the laboratory reform to generally lower the demands of blood samples and laboratory costs. Thus, the scenario is an important example, how political decisions of the medical self-government influence the screening setting for viral hepatitis: if the current policy is not changed, the laboratory reform directly counteracts the WHO hepatitis C elimination strategy in Germany.

**KEYWORDS**
anti-HCV, hepatitis B, hepatitis C, screening

After the invention of direct antiviral agents (DAA) to treat chronic hepatitis C infection, the World Health Organization has announced an initiative to eliminate the infection until the year 2030.[1] This initiative has been adapted to Europe and Germany by the HCV Elimination Manifesto and the national 'BIS 2030 Strategie' of the German Government.[2,3] To eliminate HCV infection, two major principles must be fulfilled: (a) adequate early laboratory testing to detect so far undiagnosed infections and (b) adequate treatment with direct antiviral agents.[4] The latter is already possible in Germany, because the German healthcare system allowed reimbursement of all different DAA regimens after marketing authorization without major restrictions which induced a dramatic decline of patients listed for liver transplantation due to HCV-induced cirrhosis[5] and has shifted the spectrum of HCV-infected patients to early disease stages.[6] However, adequate screening and detection of so far undiagnosed infections still need improvement. Early detection strategies in the primary care setting, which is the most important entry level to the healthcare system in Germany, have recently been evaluated and rely on the testing of anti-HCV in serum as screening parameter.[7] In the past, anti-HCV testing was extra-budgetary reimbursed by statuary healthcare insurances and not taken into account when

  

the laboratory budget of each outpatient physician was estimated. This policy has changed since 1 April 2018: here, a nationwide laboratory reform initiated by the Association of Statutory Health Insurance Physicians ('Kassenärztliche Bundesvereinigung [KBV]') was established which should reduce the demands of blood samples and because of that the laboratory costs of patients insured in the statuary healthcare insurances. The reform determines lower and high laboratory costs per laboratory order for each medical group (eg for primary care physicians, internal medicine doctors and gynaecologists) in the outpatient field. These values are specified by the KBV and fixed for a longer time. If an individual outpatient physician has laboratory costs below the lower value of his peer group (ie a primary care physician in the group of primary care physicians), a gratuity will be paid 100%. If an individual outpatient physician has laboratory costs over the high value of his peer group, a gratuity will not be paid (0%). If the laboratory costs are between the lower and high value, the gratification is paid pro rata. Thus, it is attractive to order a priori as few laboratory tests as possible in order to be below the mean laboratory costs of the peer group at the end of the reference period. In addition to this policy, the reimbursement strategy of the anti-HCV test was changed: now, anti-HCV in serum (code: EBM 32618) is not an extra-budgetary test any more, but is included in the laboratory budget and is therefore relevant for the budget calculation. In contrast to anti-HCV, the status of HBsAg as screening parameter for chronic hepatitis B infection has not been changed, and HBsAg is still extra-budgetary (code: EBM 32781). We therefore analysed the impact of the laboratory reform on the order of anti-HCV tests in large laboratory institutes.

'ALM e.v.' is the professional association of Accredited Laboratories in Medicine in Germany (www.alm-ev.de) and includes >200 medical laboratories. We analysed the number of anti-HCV tests (code: EBM 32618) in 510 656 anonymized patient data sets of the quarters I/2018 (the quarter before the initiation of the laboratory reform), and II and III/2018 (the first two quarters after the initiation of the laboratory reform), in comparison with the number of anti-HCV tests in the quarters I-III of the year 2017. Due to the number of participating laboratories and the number of analysed patient data sets, the results are considered to be representative for Germany.

The number of anti-HCV tests ordered by physicians of the outpatient setting declined by 9.4% in quarters I-III 2018 in comparison with the same time period of the year 2017 (Figure 1). The number of tests declined already in quarter I/2018, because announcements on potential economical disadvantages were released prior to the start of the laboratory reform. The number of ordered HBsAg tests has declined by 7.4% in the same observation period, indicating that the reduced anti-HCV laboratory orders are not parameter-specific, but most likely a surrogate of the intention of the laboratory reform to generally lower the demands of blood samples and laboratory costs.

Thus, the described scenario is an important example, how political decisions of the medical self-government influence the screening setting for viral hepatitis: the laboratory reform impairs successful hepatitis screening strategies and might also affect the regulatory reporting of HCV infections to the National Institute of Infectious Diseases (Robert Koch Institute). The German Society of Gastroenterology (DGVS) has addressed this issue to the Association of Statutory Health Insurance Physicians and demands that at least the anti-HCV test is excluded again from the laboratory reform and re-classified as an extra-budgetary parameter. If the current policy is not changed, the laboratory reform directly counteracts the WHO hepatitis C elimination strategy in Germany.

## CONFLICT OF INTEREST

The authors have nothing to disclose.

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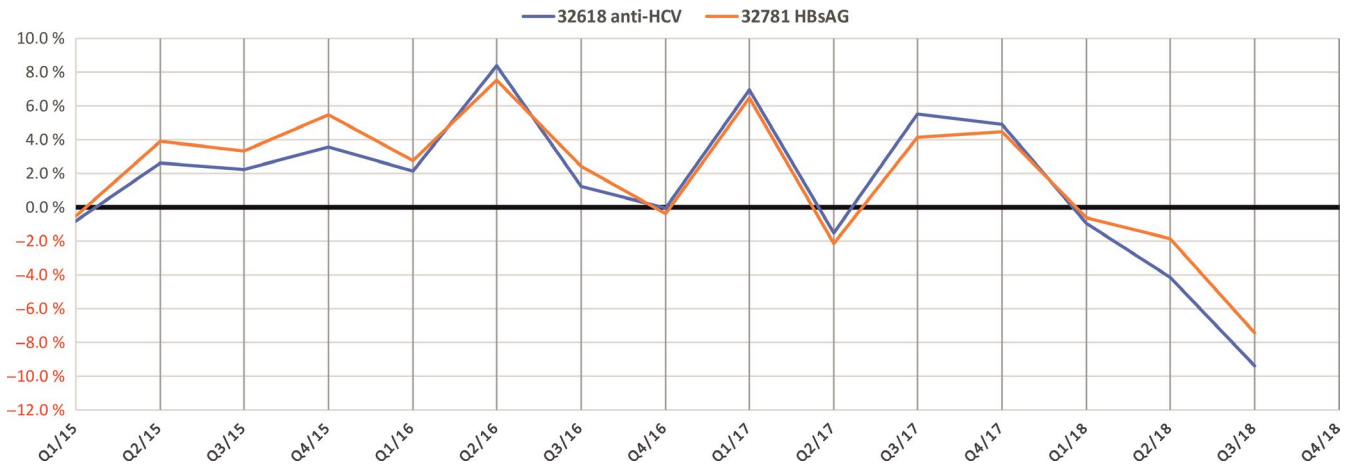


**FIGURE 1** Relative number of anti-HCV (EBM code 32618) and HBsAg (EBM code 32781) laboratory requisitions in comparison with the quarter of the preceding year

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