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Infectious screening and vaccination coverage in patients with inflammatory bowel disease: a single-center observational study

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Abstract: Introduction: Patients with inflammatory bowel disease (IBD) are at increased risk of infections due to immune dysfunction and use of immunosuppressive and biologic therapies. Therefore, proper screening for latent infections and vaccinations are important to improve treatment safety. The aim of the study was to assess serological screening for hepatitis B and C virus (HBV, HCV) infections and to evaluate vaccination coverage in patients with IBD in routine clinical practice in a tertiary center.
Materials and Methods: A total of 105 patients with IBD were included (Crohn's disease, n = 56; ulcerative colitis, n = 48; IBD unclassified, n = 1). Data were collected using an original questionnaire and laboratory assessment of HBV and HCV markers. A subgroup analysis evaluated COVID-19 vaccination and adverse events.
Results: All patients reported a negative history of HBV and HCV infection. Anti-HBc total antibodies were detected in 5 patients, while none were HBsAg-positive and none tested positive for anti-HCV antibodies. Among 82 patients vaccinated against HBV, 31 (38%) had nonprotective anti-HBs titers. Current IBD treatment was not associated with impaired vaccine response. Vaccination rates for influenza, pneumococci, and meningococci were low. Only 15% of patients reported receiving information about vaccination from the physicians. In the COVID-19 subgroup, 74.7% of patients were vaccinated, with mostly mild adverse events.
Conclusions: Despite existing recommendations, screening and vaccination coverage in patients with IBD remain insufficient, indicating the need for implementation of immunoprophylaxis in routine clinical practice.

Keywords: inflammatory bowel disease, opportunistic infections, vaccination, immunoprophylaxis, hepatitis B.

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Introduction

Infectious complications represent one of the most common and clinically significant adverse outcomes in patients with inflammatory bowel disease (IBD), with opportunistic infections accounting for a substantial proportion of these events. [1, 2, 3] Evidence from studies conducted in European populations indicates that patients with IBD treated with immunosuppressive agents and biologic therapies particularly when used in combination, are at an increased risk of opportunistic infections. [1, 3, 4, 5] In a large European cohort comprising 6914 patients with IBD, the incidence of serious infections was reported to be 3% in the overall population and 5% among patients receiving immunosuppressive therapy. Comparable findings have been reported in other regions of the world; in a cohort study conducted in China among hospitalized patients with IBD between 2014 and 2019, the prevalence of opportunistic infections was estimated at approximately 4.5%. [6]

Opportunistic infections are caused by microorganisms that are ubiquitous in the environment and typically exhibit limited pathogenic potential in individuals with a competent immune system. However, in patients with impaired immune function such as those with chronic inflammatory conditions including those with IBD, individuals undergoing immunosuppressive therapy, or patients with active malignancies these infections may occur more frequently and be associated with atypical and often severe clinical manifestations. [4, 6, 7, 8]

Established risk factors for opportunistic infections include age over 50 years, high disease activity in IBD, steroid refractoriness, the use of biologic therapies, and combination treatment involving immunosuppressive agents. Additional factors contributing to an increased risk of infection include chronic comorbid conditions such as diabetes mellitus, chronic kidney disease, and liver disease, as well as malnutrition and inadequate implementation of recommended primary and booster vaccinations. [5, 6, 7, 8]

In accordance with European Crohn's and Colitis Organisation (ECCO) recommendations, infection prevention in patients with IBD should be based on an individualized assessment of infectious risk and the performance of appropriate screening procedures prior to and during immunosuppressive therapy. [7] Before initiating immunosuppressive or biologic treatment, screening for chronic and latent infections is recommended, including evaluation for tuberculosis (interferon gamma release assays and chest radiography), viral hepatitis B and C (HBsAg, total anti-HBc and anti-HBs antibodies; anti-HCV antibodies with subsequent HCV RNA testing in seropositive individuals), and human immunodeficiency virus (HIV) infection. [7, 9, 10] In patients without a documented history of varicella infection or vaccination, assessment of immunity to varicellazoster virus by measurement of anti-VZV IgG antibodies is also advised. [7] This structured diagnostic approach enables early identification of high-risk patients and significantly enhances the safety of immunosuppressive treatment in individuals with IBD.

Particular attention should be paid to occult hepatitis B virus (HBV) infection, which is characterized by the absence of detectable HBsAg in the presence of anti-HBc antibodies and low or undetectable levels of HBV DNA in serum or liver tissue. In such cases, total anti-HBc antibodies may represent the sole serological marker of previous HBV exposure. [11, 12] Following HBV infection, viral eradication is incomplete, as the viral genome persists in hepatocytes in the form of covalently closed circular DNA (cccDNA). Under conditions of immunosuppression, reactivation of viral replication may occur, leading to an increase in HBV DNA levels and the development of hepatitis, which may occasionally follow a severe clinical course. [11, 12, 13, 14] Although such

cases are relatively uncommon, they constitute a clinically relevant risk in immunosuppressed patients.

It should be emphasized that existing clinical guidelines do not always fully reflect real-world clinical practice. Therefore, the primary objective of the present study was to evaluate adherence to recommended screening and vaccination strategies in routine care of patients with IBD. Our center is among the largest institutions in the country dedicated to the management of IBD, providing an opportunity to assess real life clinical practice in a representative patient population. This analysis aimed to identify areas requiring improvement and to propose potential strategies for optimizing clinical management, with the goal of enhancing patient safety and quality of care.

Additionally, in the context of the recent SARS-CoV-2 pandemic, COVID-19 vaccination rates in patients with inflammatory bowel disease were evaluated, along with the potential impact of vaccination on disease activity and its tolerability. The influence of ongoing IBD treatment on these outcomes was also assessed.

Materials and Methods

The study population consisted of patients diagnosed with Crohn's disease (CD), ulcerative colitis (UC), or IBD unclassified (IBD-U) who were hospitalized at a tertiary referral center for adult patients in the Greater Poland region, either due to exacerbation of IBD or for scheduled administration of biologic therapy.

Data were collected using an original, structured questionnaire that included items related to demographic characteristics (sex, age), disease course (type of IBD, disease duration, current treatment, and history of surgical interventions), as well as questions regarding the implementation of preventive vaccinations. These included vaccinations covered by the current National Immunization Program in Poland (hepatitis B virus and varicella-zoster virus) and recommended (non-mandatory at the time of patients' inclusion to the analysis) vaccinations, such as those against influenza, pneumococci, meningococci, yellow fever, herpes zoster, and human papillomavirus (HPV). The questionnaire also contained questions addressing whether patients had been informed by physicians about the need to initiate or complete recommended vaccinations and about potential additional vaccinations.

Following completion of the questionnaire, the immunization status against hepatitis B and C viruses was assessed in all patients based on laboratory analyses of venous blood samples, including hepatitis B surface antigen (HBsAg), anti-HBs antibody titers, total anti-HBc antibodies, and anti-HCV antibodies. Laboratory testing was performed using two-step chemiluminescent microparticle immunoassays (CMIA) on the Abbott Alinity analyzer (Abbott Diagnostics), in accordance with the standard procedures applied in the hospital's diagnostic laboratory.

An additional analysis was performed with regard to coronavirus disease 2019 (COVID-19). Information was collected regarding COVID-19 vaccination status (number of vaccine doses received), adverse events following vaccination, and the clinical course of SARS-CoV-2 infection, as well as the potential impact of vaccination on the occurrence or exacerbation of gastrointestinal symptoms. The questionnaire was expanded to include questions concerning whether patients had been informed by physicians about the potential risk of a more severe course of COVID-19 in individuals with IBD and whether they had been encouraged by physicians to receive COVID-19 vaccination.

This study had an observational and retrospective design. Patient participation was voluntary, and all data were analyzed anonymously. The study was conducted in accordance with the Declaration of Helsinki and approved by the Bioethics Committee of Poznan University of Medical Sciences (Resolution No. 363/20).

Results

A total of 105 patients with IBD were included in the analysis, comprising 56 patients with CD (53.3%), 48 patients with UC (45.7%), and 1 patient with IBD-U (1%). The study population included 61 men (58.1%) and 44 women (41.9%). The median age was 35 years (interquartile range [IQR]: 25–46 years), and the median disease duration was 6 years (IQR: 2–9 years).

The most commonly used treatments were mesalazine (86.7%) and glucocorticosteroids (75.2%), with glucocorticosteroids being used significantly more frequently in patients with UC compared with those with CD ($p = 0.01079$). Azathioprine was administered to 43 patients (41%), while 13 patients (12.4%) received biologic therapy, including 12 patients treated with tumor necrosis factor inhibitors and 1 patient treated with vedolizumab.

No patients tested positive for hepatitis B surface antigen (HBsAg) or anti-HCV antibodies. Total anti-HBc antibodies were detected in 5 patients (4.8%). Non-protective anti-HBs antibody titers (<10 mIU/mL) were observed in 38 patients (36.2%) in the entire study population (n = 105), including 31 patients (38%) among the 82 individuals who reported previous vaccination against hepatitis B virus. Among vaccinated patients, those with nonprotective anti-HBs titers tended to be older compared with patients who achieved protective titers (40 ± 15 vs. 35 ± 14 years); however, this difference did not reach statistical significance ($p = 0.08$).

The clinical characteristics of the patients, serological status, and treatments used are summarized in Table 1.

Table 1. Serological status, vaccination uptake and clinical characteristics of IBD patients.

Variable	Results
A. Patient characteristics	
Age, median (IQR), years	35 (25–46)
Sex, n (%) Female Male	 44 (41.9) 61 (58.1)
Type of inflammatory bowel disease, n (%) Crohn's disease, n (%) Ulcerative colitis, n (%) Inflammatory bowel disease unclassified, n (%)	 56 (53.3) 48 (45.7) 1 (1)
Disease duration, median (IQR), years	6 (2–9)
B. Serological status	
HBsAg positive, n (%)	0 (0)
Total anti-HBc positive, n (%)	5 (4.8)
Anti-HBs < 10 mIU/mL, n (%)	38 (36.2)

Table 1. Cont.

Variable	Results
C. Treatment	
5-aminosalicylic acid, n (%)	91 (86.7)
Glucocorticosteroids, n (%)	79 (75.2)
Azathioprine, n (%)	43 (41.0)
Biologic therapy, n (%)	13 (12.4)

No significant associations were found between HBV serological status and age, sex, type of IBD, or disease duration ($p > 0.05$).

Analysis of the relationship between current treatment and hepatitis B vaccination status revealed that patients receiving tumor necrosis factor-α (TNF-α) inhibitors were significantly less likely to have been vaccinated against hepatitis B compared with patients not receiving this therapy (6/12 [50.0%] vs. 76/91 [83.5%], p = 0.0199). This association is illustrated in Figure 1.

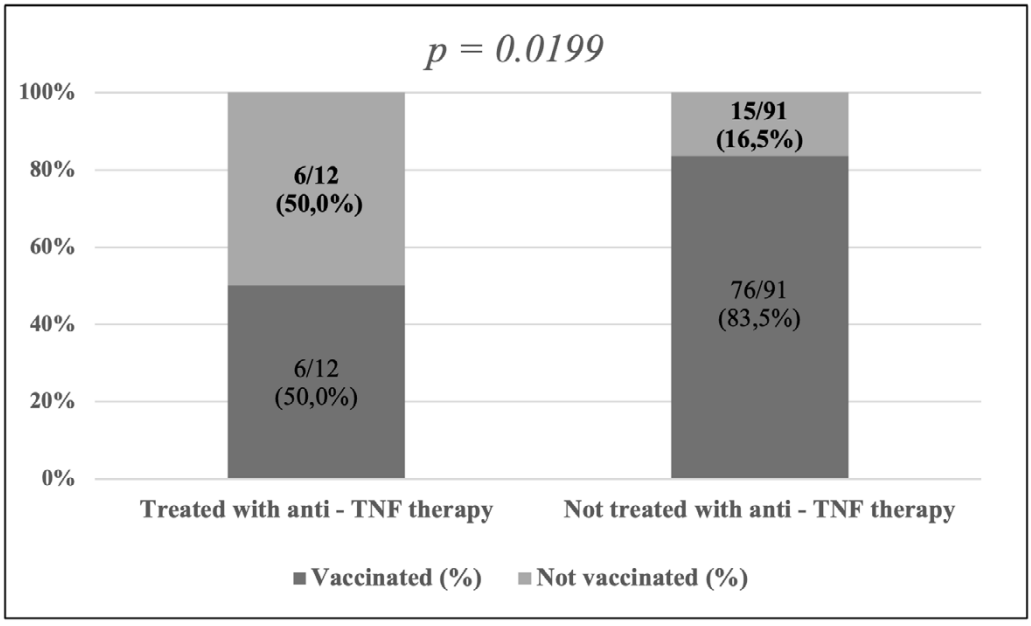

Fig. 1. Hepatitis B vaccination status according to treatment with tumor necrosis factor inhibitors. Patients treated with tumor necrosis factor inhibitors were significantly less frequently vaccinated against hepatitis B compared to patients not receiving this therapy ($p = 0.0199$).

No significant associations were observed between hepatitis B vaccination uptake and the use of other medications (5-aminosalicylic acid, glucocorticosteroids, or azathioprine) or demographic variables ($p > 0.05$).

Analysis of preventive vaccination uptake showed that, despite widespread recommendations for hepatitis B vaccination, 21.9% of patients had not been vaccinated.

Other recommended vaccinations, including those against influenza, pneumococci, meningococci, and varicella-zoster virus (VZV), were administered only sporadically. Detailed data on vaccination uptake are presented in Figure 2.

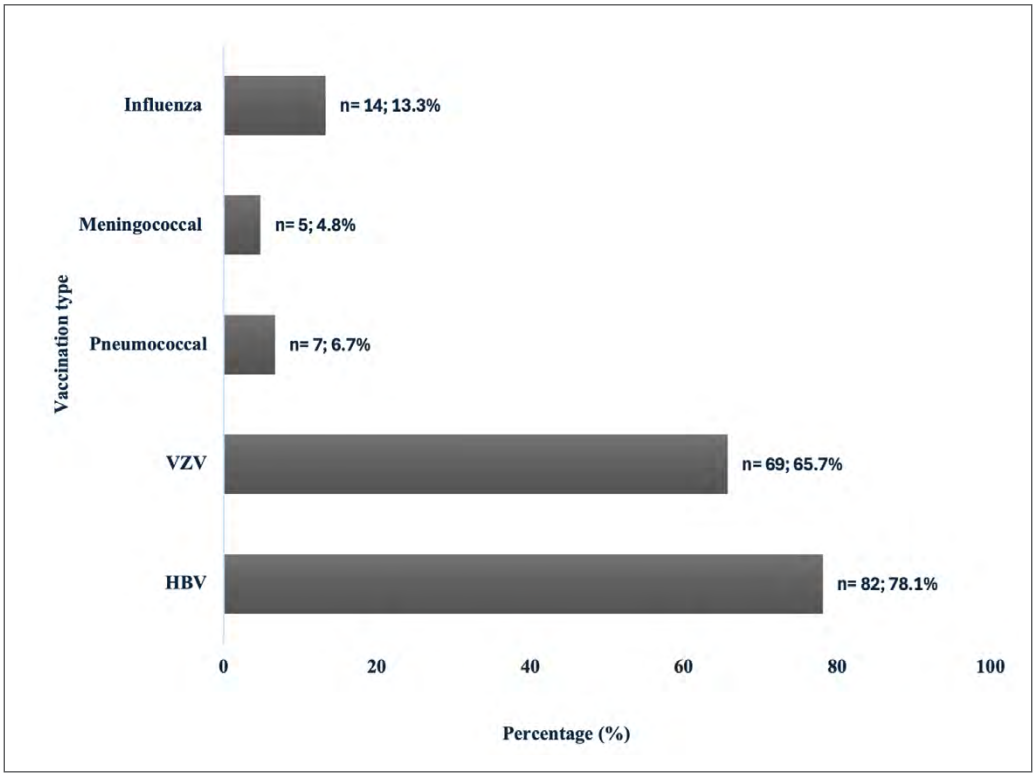

Fig. 2. Uptake of recommended vaccinations among patients with inflammatory bowel disease. Values are presented as percentages with corresponding absolute numbers (n); denominators may differ depending on data availability.
HBV — hepatitis B virus; VZV — varicella-zoster virus.

No significant associations were found between uptake of recommended vaccinations and sex, type of IBD, or current treatment ($p > 0.05$).

According to the collected data, 16 patients (15.23%) reported that gastroenterologists addressed the topic of infectious disease prevention during routine follow-up visits, including active encouragement to receive vaccinations.

In light of the recent COVID-19 pandemic, an additional analysis was performed in a subgroup of 75 patients. In this group, 56 patients (74.7%) reported receiving at least one dose of a SARS-CoV-2 vaccine. The median number of administered vaccine doses was 2 (interquartile range [IQR]: 2–3 doses).

No significant differences in COVID-19 vaccination rates were observed according to age, sex, type of IBD, or ongoing treatment ($p > 0.05$).

Adverse events following COVID-19 vaccination were reported by 12 vaccinated patients (21.4%) and were predominantly mild, including general fatigue (6/56; 10.7%), fever (3/56; 5.4%), and arthralgia (2/56; 3.6%). Transient exacerbation of gastrointestinal symptoms following COVID-19 vaccination was observed in 8 patients (14.3%). No association was found between IBD treatment and the occurrence of adverse events.

Among patients who reported being encouraged by a gastroenterologist to receive COVID-19 vaccination, 18 of 24 individuals (75.0%) were vaccinated, compared with 38 of 51 patients (74.5%) in the non-encouraged group; this difference was not statistically significant ($p > 0.05$).

Discussion

In the present study, we evaluated the practical implementation of immunoprophylaxis in patients with inflammatory bowel disease (IBD). The obtained results indicate that, despite existing guidelines, there remains room for improvement in everyday clinical practice. Diagnostic management in this group of patients should be comprehensive and include multiple aspects, such as the assessment of latent and chronic infections, as well as strategies to prevent infectious complications associated with immunosuppressive and biologic therapies. Immunoprophylaxis should therefore be regarded as an integral component of IBD management rather than merely a pre-treatment step. [1, 2, 3, 4, 5, 6, 7] This is consistent with previous observations highlighting the importance of a comprehensive approach to IBD treatment, including modifiable factors influencing diseases outcomes. [15]

One of the important findings of the present study was the presence of total anti-HBc antibodies in patients without a documented history of HBV infection, suggesting that the risk of occult HBV infection in this population is clinically relevant and should not be overlooked. [9, 10, 11, 12, 16] Furthermore, despite self-reported vaccination against hepatitis B virus, a substantial proportion of patients exhibited anti-HBs antibody titers below the protective threshold. [17] These findings support routine assessment of anti-HBs titers in vaccinated individuals, not only prior to planned initiation of immunosuppressive or biologic therapy but also in patients not currently receiving such treatment. This approach is justified by the possibility of sudden disease exacerbation, the need for urgent hospitalization or surgical intervention, and situations in which there may be insufficient time to complete vaccination. [18, 19]

In our cohort, older age showed a tendency toward lower anti-HBs titers among vaccinated patients, although this association did not reach statistical significance. Previous studies, including those conducted in pediatric populations, indicate that the risk of an inadequate post-vaccination response increases with age, which may represent an additional factor to consider when planning immunization strategies in patients with IBD. [19, 20]

In the present study, no negative impact of immunosuppressive or biologic therapy on the immune response to HBV vaccination was observed. Similar conclusions have been reported in some previous studies, [19, 21] as well as in the meta-analysis by Jiang *et al.*, which demonstrated substantial heterogeneity in the immune response to HBV vaccination among patients with IBD and did not provide conclusive evidence of a dominant negative effect of immunosuppression. [20] At the same time, other reports indicate reduced vaccine efficacy in patients receiving intensive immunosuppressive treatment or anti-TNF therapy, particularly in older age groups,

highlighting the importance of administering vaccination prior to treatment intensification. [19, 20, 21]

We also evaluated the implementation of recommended vaccinations, including those against influenza, pneumococci, meningococci, varicella-zoster virus (VZV), human papillomavirus (HPV), and yellow fever. The results indicate a low level of adherence to these vaccination recommendations despite existing guidelines, which may reflect limited awareness of recommendations and insufficient communication regarding immunoprophylaxis among both patients and physicians. [22, 23, 24] Similarly low vaccination rates have been reported in other observational studies, in which insufficient knowledge among patients and healthcare providers, as well as limited awareness of the risk of opportunistic infections, were identified as major barriers. [22, 23, 24] Available evidence further suggests that even among patients receiving biologic therapy, adherence to recommended vaccinations remains suboptimal, which is consistent with our observations.

In the analysis of COVID-19 vaccination, 74.7% of patients received at least one dose of the vaccine. This finding indicates a relatively high level of vaccine acceptance among patients with IBD; however, approximately 25% remained unvaccinated, which continues to represent an area requiring attention. In a global meta-analysis conducted by Bianchi *et al.*, similar results were reported, with 72% of patients having received at least one vaccine dose. [25, 26] Comparable vaccination rates (70–90%) have been described in other population-based studies and meta-analyses. [27, 28] Vaccination was well tolerated and was not associated with a significant risk of worsening intestinal symptoms. Adverse events were reported in 21.4% of vaccinated patients and were predominantly mild and flu-like in nature (headache, fatigue, myalgia, and arthralgia). Transient exacerbation of intestinal symptoms was observed in 14.3% of patients. Similar cohort studies have demonstrated that the frequency of adverse events in patients with IBD is comparable to that observed in the general population and that vaccination is not associated with an increased risk of disease flare. [29, 30] No association was observed between immunosuppressive or biologic therapy and the frequency of adverse events, which is consistent with findings from other analyses involving patients with IBD. [25, 26]

Patients who reported receiving a vaccination recommendation from their gastroenterologist were not significantly more likely to be vaccinated than those in whom the topic had not been addressed during the visit. This may suggest that vaccination decisions are influenced by multiple factors beyond physician recommendation alone. However, it should be emphasized that the proportion of patients reporting such recommendations was low, which limits the ability to draw definitive conclusions.

Systematic reviews indicate that physician recommendation may facilitate vaccine acceptance; therefore, physicians — particularly gastroenterologists should actively engage in promoting immunoprophylaxis among patients with IBD. [23, 24]

The results of our analysis are consistent with the 2021 ECCO guidelines, which emphasize the need for screening for chronic and latent infections prior to initiation of immunosuppressive therapy in patients with IBD. [7] Similar positions are presented in the guidelines of the World Health Organization (WHO) and other institutions involved in infection prevention, which highlight the importance of systematic assessment of infectious risk in this population. [9, 10]

In our view, one of the key factors limiting vaccination uptake is concern regarding vaccine safety and potential adverse events. This phenomenon may have intensified in recent years due to extensive public debate on vaccination, particularly in the context of COVID-19, potentially contributing to increased scepticism toward other preventive vaccines. [23, 24] An additional challenge

appears to be the lack of clearly defined responsibility for initiating and coordinating vaccinations among physicians of different specialties, which may lead to fragmentation of preventive efforts.

Failure to implement recommended vaccinations is associated with increased and avoidable risk related to immunosuppressive and biologic therapies, including atypical infection courses and reactivation of latent infections. [1, 6, 7] The findings of our study underscore the need for a systematic approach to immunoprophylaxis in patients with IBD. The implementation of simple, standardized tools such as a dedicated vaccination calendar in paper or electronic form could facilitate rapid and reliable verification of vaccination status. Within such a framework, the gastroenterologist, as the specialist planning therapies associated with increased infectious risk, could play a central role in coordinating preventive measures.

This study has several limitations. Its single center design may limit the generalizability of the results. Moreover, part of the data was based on patient completed questionnaires, which may be associated with reporting bias beyond our control. We did not account for the time elapsed since vaccination or for factors such as educational level or socioeconomic status, which may influence both antibody titers and vaccination uptake.

In conclusion, despite existing recommendations regarding immunoprophylaxis of infectious diseases in patients with IBD, gaps in everyday clinical practice remain. The findings of this study highlight deficiencies in infection prevention and may support efforts aimed at improving screening and vaccination strategies in patients with inflammatory bowel disease. Analogous to vaccination schedules used in pediatric populations, consideration should be given to the introduction of a dedicated vaccination calendar for patients with IBD — a population that continues to grow and evolve, partly due to the dynamic development of biologic therapies.

Author Contributions

E.B. and P.E. conceived the study and developed the methodology. E.B. performed the investigation and collected the data. M.R. performed the statistical analysis. E.B. prepared the first draft of the manuscript. P.E. and A.D. critically revised the manuscript for important intellectual content. P.E. supervised the work. All authors have read and agreed to the published version of the manuscript.

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Conflict of interest

The authors declare no conflicts of interest.

Abbreviations

anti-Hbc — antibody to hepatitis B core antigen
anti-Hbs — antibody to hepatitis B surface antigen
HBsAg — hepatitis B surface antigen
IQR — interquartile range
mIU/mL — milli-international units per milliliter

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