BMC Infectious Diseases

https://doi.org/10.1186/s12879-026-13931-1

Article in Press

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Received: 17 February 2026

Accepted: 29 June 2026

Published online: 07 July 2026

Cite this article as: D'Aquila V., Biliotti E., D'Abramo A. *et al.* Hepatitis B virus prevalence, susceptibility and care engagement among vulnerable migrant populations in Rome. *BMC Infect Dis* (2026). https://doi.org/10.1186/s12879-026-13931-1

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Hepatitis B Virus Prevalence, Susceptibility and Care Engagement Among Vulnerable Migrant Populations in Rome

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WORD COUNT: 3757

TABLES and FIGURES: 2 Tables and 2 Figures

Abstract

Background: Hepatitis B virus (HBV) remains a leading cause of morbidity and liver-related mortality globally. Vulnerable migrant populations often experience challenges with accessing testing, vaccination and care, both before and after arrival.

Methods: Asylum seekers and undocumented migrants hosted in six reception facilities in metropolitan Rome were prospectively offered

screening for hepatitis B surface antigen (HBsAg), surface antibodies (anti-HBs) and core antibodies (anti-HBc). Individuals with HBsAg positivity were assisted in accessing a specialist referral service, with support available throughout the screen-and-link pathway to reduce administrative, linguistic and logistic barriers.

Results: Between February 2024 and August 2025, 435 individuals from 38 countries underwent screening (median age 28 years; 86.7% male). Most (273; 62.8%) were non-immune (HBsAg/anti-HBc/anti-HBs negative), 88 (20.2%) had prior infection (HBsAg negative/anti-HBc positive, usually with anti-HBs), and 51 (11.7%) had vaccine-induced immunity (anti-HBs positive only). HBsAg was detected in 23 (5.3%; 95% CI 3.6-7.8), including 16/149 (10.7%) participants from the African region and 7/160 (4.4%) from South-East Asia (all from Bangladesh); none had hepatitis delta, hepatitis C or HIV coinfection. Overall, 20/23 (87.0%) were successfully engaged in care; 5/20 (25%) met immediate treatment indications based on virological, biochemical and/or liver fibrosis criteria.

Conclusions: This study highlights the dual public health challenge of chronic HBV infection and lack of HBV immunity among asylum seekers and undocumented migrants in Rome. The initially high linkage to care demonstrates the effectiveness of integrated screen-and-link approaches. Strengthened HBV testing, vaccination and care pathways should be proactively embedded within health services for vulnerable migrant populations.

Introduction

Hepatitis B virus (HBV) infection remains a major global public health challenge, accounting for an estimated 1.1 million deaths annually from cirrhosis and hepatocellular carcinoma (HCC) [1]. Despite the substantial impact of universal childhood vaccination programmes, which have markedly reduced HBV incidence and prevalence in many settings, a high burden of chronic infection persists, particularly in parts of Africa and Asia: in 2022, the

World Health Organization (WHO) estimated that approximately 65 million people in the African region and 61 million in the South-East Asian region were living with HBV infection [2]. Yet, fewer than 5% have been diagnosed worldwide [2], a gap that continues to undermine HBV control efforts.

Between January and October 2024, nearly 160,000 migrants reached Europe via the Mediterranean and Northwest African maritime routes [3], with Italy a major point of arrival. Following the introduction of universal HBV vaccination in 1991, Italy is now classified as a low-endemicity country [4]. Migration has important implications for HBV epidemiology in low-endemicity countries, as a substantial proportion of migration flows originates from regions with high or intermediate HBV endemicity: HBV prevalence has been estimated at 8.8% for individuals originating from Sub-Saharan Africa and 5.7% for those from East and South-East Asia and Oceania [5]. In 2024, the most frequently reported nationalities among people arriving in Italy by sea were Bangladeshi (20%), Syrian (19%), Tunisian (13%), Egyptian (7%) and Guinean (6%) [3].

Italy operates a universal national health system, and documented migrants are entitled to the same healthcare coverage as Italian citizens [6]. Asylum seekers and undocumented migrants are legally guaranteed access to urgent and essential care, including infectious disease prevention, although implementation varies across regions [7]. In practice, it is recognised that multiple structural, administrative and social barriers often limit access to healthcare for asylum seekers and undocumented migrants across Europe [8]. In Italy, in the absence of a nationwide implementation programme, HBV screening initiatives, although supported by national guidelines [9], remain fragmented. Local initiatives focused on asylum seekers and undocumented migrants have consistently reported a high prevalence of hepatitis B surface antigen (HBsAg) positivity, typically exceeding 5% [10-18]. Even more strikingly, more than half of individuals screened lack serological evidence of HBV immunity, presumably because they are unvaccinated [10,13,18].

Furthermore, early loss to follow-up across the cascade of care has been repeatedly documented, thereby limiting the individual- and population-level impact of screening efforts [10,13].

Against this background, given the paucity of data from central Italy, this prospective study aimed to evaluate the outcomes of a screen-and-link programme that offered HBV testing, combined with rapid, supported referral to specialist care, to asylum seekers and undocumented migrants hosted in reception facilities in metropolitan Rome. The findings are intended to inform the design of effective strategies for HBV testing and linkage to vaccination and care in this population.

Methods

Study population

In February 2024, the Lazzaro Spallanzani National Institute for Infectious Diseases (hereafter referred to as INMI) in Rome launched an INMI-based outpatient service for migrants, called “Ambulatorio Popolazioni Mobili” (Mobile Populations Outpatient Service, hereafter referred to as APM), with a specific focus on providing infectious disease screening and clinical evaluation upon migrants' arrival at reception facilities. Within this context, the study population comprised individuals aged ≥16 years who, between February 2024 and August 2025, were residing in six hosting facilities for asylum seekers and undocumented migrants located in metropolitan Rome. These included four Extraordinary Reception Centres (Centri di Accoglienza Straordinaria [CAS]: Ciampino, Villa Troili, Amarilli, Casilina) and two other hosting facilities (Community of Sant’Egidio, Casa Approdo). The facilities provide temporary housing for individuals applying for international protection in Italy and have dedicated staff to support administrative processes, including supporting engagement with health care in this study. The facilities differ in size, ranging from small accommodation services to larger reception centres. Nominal capacity ranges approximately from 30 to 500 individuals across facilities, with a combined nominal capacity in the

order of 1,000 individuals. However, this estimate should be interpreted cautiously, as nominal capacity does not reflect actual occupancy, which may vary widely and fluctuate over time because of new arrivals, transfers and departures. The total number of individuals hosted in the participating reception facilities during the study period could not be reliably ascertained, as administrative records, including precise legal status, were not accessible for research purposes.

The study was approved by the Ethics Committee of the Lazio Area 4 (n. 44-2025). Written informed consent was obtained from all participants, with assistance from translators when necessary. The study was conducted in accordance with the Declaration of Helsinki.

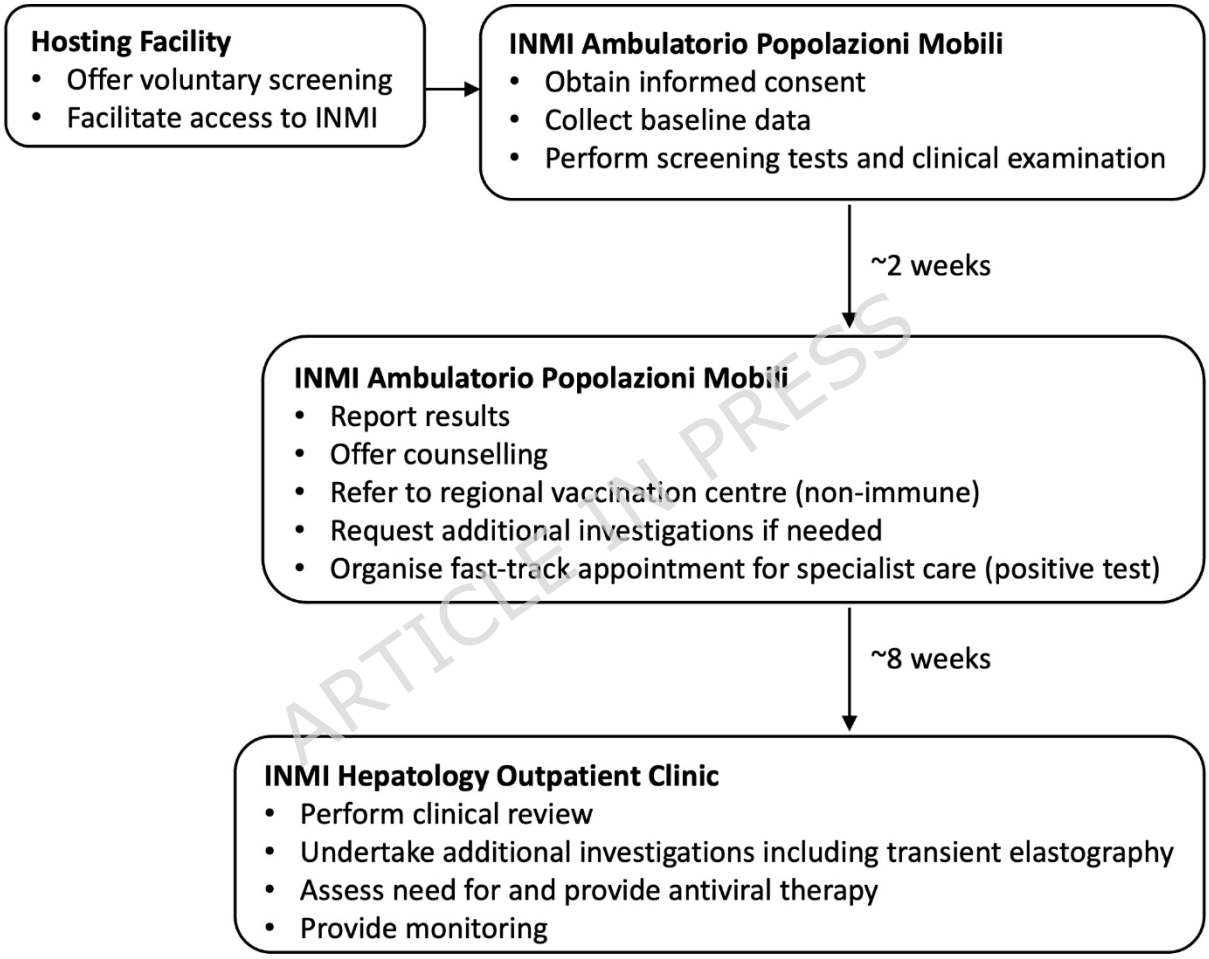
Screening procedures and care pathway

We adopted a structured pathway, centralised at INMI, designed to minimise loss to follow-up between the offer of screening, testing, result reporting, and any required specialist assessment (Figure 1). The hosting facility staff offered voluntary screening to all residents of the participating centres, organised the screening visit for those who accepted screening (first APM visit), and accompanied them to the screening and follow-up visits. At the first APM visit, following consent and baseline data collection (demographics, migratory route and time since arrival in Italy), participants underwent clinical examination and sampling for laboratory investigations. A second APM visit was arranged for result reporting, approximately 2 weeks after the first. At the second APM visit, participants with a positive result underwent further laboratory investigations to complete the assessment and received fast-track appointments within approximately 8 weeks for specialist review and any required imaging, including abdominal ultrasound, all of which were INMI-based (Figure 1). Cultural mediators were available throughout the pathway when required.

At the time of the study, a structured, free-of-charge HBV vaccination pathway was not available within either the participating reception facilities

or the INMI. HBV vaccination was available at regional vaccination centres, requiring a referral and self-arranged appointment. Vaccination was recommended by the APM's medical team to non-immune participants, with information provided on how to access the regional vaccination centres, but uptake was not measured during the study period.

Figure 1. Cascade of care



Laboratory methods

Blood samples collected at the APM were tested in the INMI diagnostic laboratory. Samples were tested for HBsAg, antibodies to hepatitis B surface (anti-HBs), hepatitis B core (anti-HBc) and hepatitis C (anti-HCV), and HIV antigen/antibody using the Alinity assays (Abbott Diagnostics, Abbott Park, Illinois, United States). Anti-HCV positive samples were tested for HCV RNA

by the Aptima HCV Quant Dx Assay (Hologic Inc, San Diego, California, United States). Samples with detectable HBsAg were tested for hepatitis e antigen and antibody (HBeAg and anti-HBe) by the Alinity assay (Abbott Diagnostics) and for HBV DNA by the Aptima HBV Quant assay (Hologic Inc) with a lower limit of quantification (LLOQ) of 10 IU/mL. They were also tested for hepatitis delta antibodies (anti-HDV) by the LIAISON XL Murex Anti-HDV assay (DiaSorin SPA, Saluggia [VC], Italy) and for HDV RNA (regardless of anti-HDV results) by the AltoStar HDV RT-PCR assay (Altona Diagnostics, Hamburg, Germany) with a LLOQ of 20 IU/mL.

HBV serological categories were defined as follows:

- HBsAg-positive: Active HBV infection;

- Non-immune: Negative HBsAg, anti-HBs, anti-HBc;

- Prior infection: Negative HBsAg, positive anti-HBc, with or without anti-HBs;

- Vaccine-induced immunity: Negative HBsAg and anti-HBc, with anti-HBs ≥ 10 IU/L.

Clinical evaluation of individuals with HBsAg positivity

Individuals with a positive HBsAg test result who attended the hepatology service referral underwent clinical examination and additional investigations, including transient elastography. FibroScan® was used to measure liver stiffness as a non-invasive indicator of liver fibrosis and the Controlled Attenuation Parameter (CAP) as an indicator of liver steatosis. Liver stiffness measurement (LSM) interpretative cut-offs were >7 kPa for significant fibrosis (≥F2), >8 kPa for advanced fibrosis (≥F3) and >11 kPa for cirrhosis (F4) [19]. CAP thresholds, extrapolated from validation studies largely conducted in metabolic liver disease rather than in chronic HBV infection, were ≥248 dB/m for mild steatosis (S1), ≥268 dB/m for moderate steatosis (S2) and ≥280 dB/m for severe steatosis (S3) [20]. HBV status was classified based on alanine aminotransferase (ALT), HBV DNA levels and LSM [19]. ALT levels were considered raised if >35 U/L regardless of sex. HBV DNA levels

≥2000 IU/mL were considered clinically significant [19,21]. Indications for antiviral therapy and the frequency of monitoring were assessed in accordance with the latest European Association for the Study of the Liver (EASL) guidelines [19], considering biochemical, virological, and LSM-based criteria, as well as individual risk factors for HCC (including age, sex, and region of origin).

Statistical analysis

Analyses were restricted to individuals who agreed to undergo screening. This was not necessarily the total eligible population, as we were unable to obtain the number of individuals hosted at each participating centre during the study period. Data were analysed descriptively using proportions for categorical variables and medians with interquartile ranges (IQR) for continuous variables. Prevalence was described as proportions with 95% confidence intervals (CI). The country of origin was classified according to the WHO's regional grouping [22]. The chi-test or Fisher's test compared categorical variables; the Mann-Whitney U test (two-sided) was used for comparison of continuous variables. Adjusted models were not explored due to the small sample size and collinearity among available variables. Significance was defined as a p-value <0.05. Analyses were performed using STATA 19.0 (StataCorp LP, TX, USA).

Results

Study population

A total of 435 individuals underwent voluntary screening between February 2024 and August 2025 (Table 1). They were predominantly males (86.7%) with a median age of 28 years. By WHO region, participants originated mainly from South-East Asia (36.1%), Africa (34.5%), and the Eastern Mediterranean (28.3%). All participants reported arriving in Italy by sea.

Among participants from the African region, most were from West Africa (96/137, 70.1%; Burkina Faso, Côte d'Ivoire, Gambia, Mali, Nigeria, Benin,

Guinea, Senegal, Sierra Leone, Ghana and Liberia), followed by East/Northeast Africa (33/137, 24.1%; Sudan, Eritrea, Ethiopia, Uganda and Kenya) and Central Africa (8/137, 5.8%; Cameroon, Congo, Central African Republic, Chad and Angola). Participants from the Eastern Mediterranean region were mainly from Asia (51/121, 42.1%; Afghanistan and Pakistan), North Africa (43/121, 35.5%; Egypt, Libya, Tunisia and Somalia) and the Middle East (27/121, 22.3%; Syria, Palestine, Saudi Arabia and Iraq [including Kurdistan]). Participants from South-East Asia were all from Bangladesh. The median interval between arrival in Italy and screening was 5 months (Table 1).

Table 1. Characteristics of the study population at screening

[a]74/88 (84.1%) had anti-HBs.

		Total population	HBV status			
			Current infection	Non-immune	Prior infection	Vaccine-induced immunity
			HBsAg +	HBsAg - Anti-HBc - Anti-HBs -	HBsAg - Anti-HBc + Anti-HBs +/-[a]	HBsAg - Anti-HBc - Anti-HBs +
Total		435 (100)	23 (5.3)	273 (62.8)	88 (20.2)	51 (11.7)
Sex at birth, n (%)	Male	377 (86.7)	22 (5.8)	237 (62.9)	72 (19.1)	46 (12.2)
	Female	58 (13.3)	1 (1.7)	36 (62.1)	16 (27.6)	5 (8.6)
Age, median years (IQR)		28 (22-35)	30 (23-36)	27 (22-34)	30 (25-39)	24 (20-29)
Age stratum, n (%)	≤24	164 (37.7)	7 (30.4)	109 (39.9)	22 (25.0)	26 (51.0)
	25-34	161 (37.0)	5 (21.7)	103 (37.7)	33 (37.5)	20 (39.2)
	35-44	84 (19.3)	9 (39.1)	48 (17.6)	22 (25.0)	5 (9.8)
	>45	26 (6.0)	2 (8.7)	13 (4.7)	11 (12.5)	0 (0)
WHO Region of origin, n (%)	South-East Asia	160 (36.1)	7 (4.4)	117 (73.1)	26 (16.3)	10 (6.3)
	Africa	149 (34.3)	16 (10.7)	67 (45.0)	54 (36.2)	12 (8.1)
	Eastern Mediterranean	121 (27.8)	0	84 (69.4)	8 (6.6)	29 (24.0)
	Europe	2 (0.5)	0	2 (100)	0 (0)	0 (0)
	Americas	2 (0.5)	0	2 (100)	0 (0)	0 (0)
	Western Pacific	1 (0.2)	0	1 (100)	0 (0)	0 (0)
Time since arrival, median months (IQR)		5 (1-15)	6 (4-18)	3 (1-13)	9 (2-20)	4 (1-14)

HBV serological profile

Most participants (273, 62.8% [95% CI, 58.0-67.3]) tested negative for all three HBV markers, indicating no evidence of immunity from prior infection or vaccination (Figure 2). A further 88 (20.2% [95% CI 16.6-24.3]) had evidence of prior infection (HBsAg-negative and anti-HBc-positive; 74/88 [84.1%] also showed anti-HBs), whereas 51 (11.7% [95% CI 8.9-15.1]) had

anti-HBs only, consistent with vaccine-induced immunity. A total of 23 participants had a positive HBsAg test (5.3% [95% CI 3.6-7.8]).

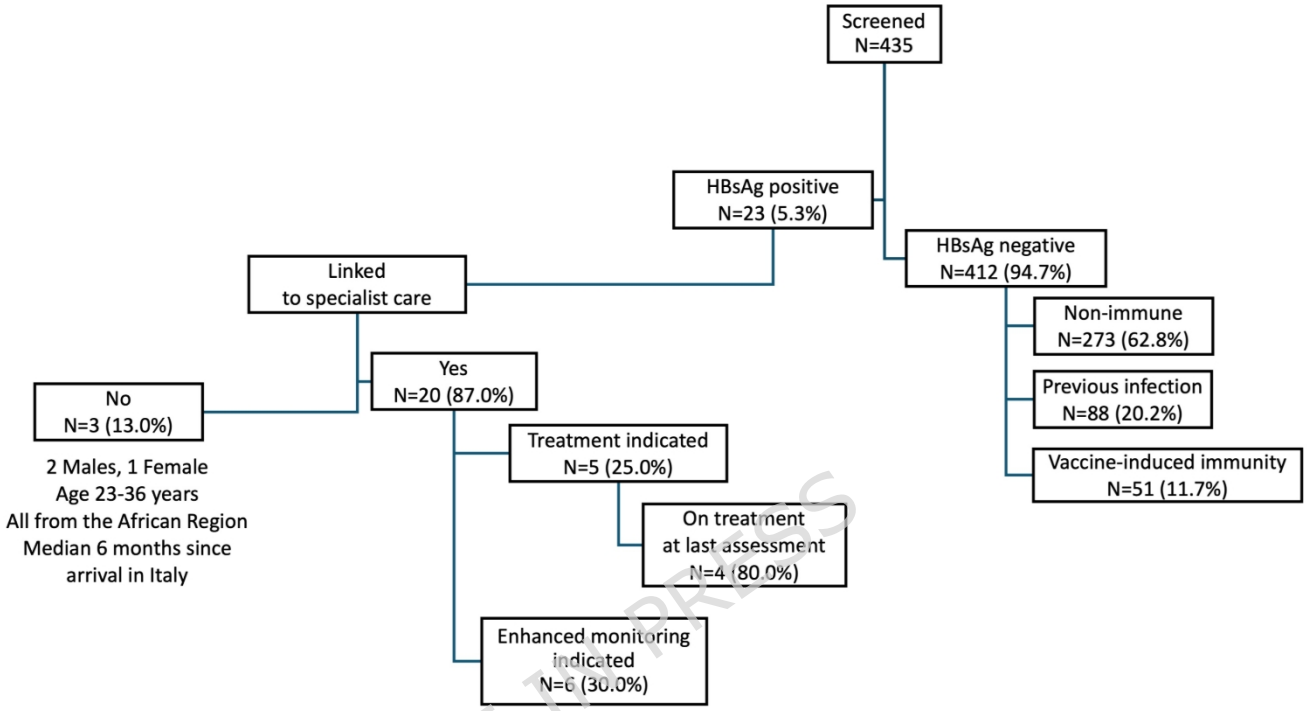
Participants with results indicative of vaccine-induced immunity were younger (median age 24) than individuals in the other three groups (Table 1), including those with detectable HBsAg (median age 30), those with prior infection (median age 30) and those lacking immunity (median age 27) ($p<0.01$). Proportions of participants with vaccine-induced immunity also differed significantly across WHO regions (Table 1). They were higher among individuals from the Eastern Mediterranean region (29/121, 24.0% [95% CI 16.7-32.6]) than among those from the African region (12/149, 8.1% [95% CI 4.2-13.6]) or Bangladesh (10/160, 6.3% [95% CI 3.0-11.2]) ($p<0.01$). There were no sex differences between participants with vaccine-induced immunity compared with the other three groups ($p=0.52$).

Proportions with a positive HBsAg test result similarly differed across regions (Table 1), with the highest rates among individuals from the African region (16/149, 10.7% [95% CI 6.3-16.9]) and Bangladesh (7/160, 4.4% [95% CI 1.8-8.8]) whereas no cases were detected among participants from the Eastern Mediterranean (0/121 [95% CI 0-3.0]) or among the five participants from other regions) ($p<0.01$). Overall, 14 individuals with HBsAg positivity originated from West Africa, with the largest representation from Burkina Faso (4/16, 25.0%). Whereas individuals with HBsAg positivity were older than those with vaccine-induced immunity (Table 1), they showed no significant age difference with those who were non-immune ($p=0.18$) or had prior infection ($p=0.62$). The point estimates suggested that HBsAg seroprevalence was higher among men (22/377, 5.8% [95% CI 3.7-8.7]) than among women (1/58, 1.7% [95% CI 0.04-9.2]) (Table 1), but numbers were insufficient to draw conclusions ($p=0.34$).

A total of 4/418 individuals (1.0%; 95% CI 0.3-2.4), two from the African region and two from the Eastern Mediterranean region, had a positive HIV test, whereas 3/427 (0.7%; 95% CI 0.2-2.0), one each from the European,

African and Eastern Mediterranean regions, had anti-HCV, all without HCV RNA. No HBV co-infections with HIV, HCV or HDV were detected.

Figure 2. Participants' disposition



Clinical characteristics of individuals with HBsAg positivity who attended hepatology referral

Of the 23 individuals with a positive HBsAg test result, 20 (87.0%) attended the hepatology referral (Figure 2). The median time from the screening visit (first APM visit) to specialist evaluation was 59 days (IQR 28-82). At the initial evaluation, most (17/20, 85.0%) had detectable HBV DNA (≥ 10 IU/mL), including 8/20 (40.0%) with levels ≥ 2000 IU/mL; ALT levels were >35 U/L in 5/20 (25.0%) (Table 2). Among 19 individuals with available results, LSM findings were compatible with significant fibrosis (≥ F2) in two (10.5%) (7.3 kPa and 7.4 kPa, respectively), advanced fibrosis (≥F3) in one (5.3%) (9 kPa) and cirrhosis in one (5.3%) (19 kPa). In three (15.8%) individuals, CAP values were suggestive of mild (S1) (256 dB/m), moderate (S2) (275 dB/m) and

severe (320 dB/m) steatosis, respectively. With one exception, there was no overlap between fibrosis and steatosis. One HBeAg-negative individual with a history of alcohol abuse had readings consistent with both cirrhosis (19 kPa) and severe steatosis (320 dB/m), with ALT 33 U/L, AST 24 U/L, undetectable HBV DNA and HBsAg 70 IU/mL.

According to EASL criteria [19], a total of 5/20 (25.0%) individuals met immediate treatment indications based on HBV DNA ≥2000 IU/mL + ALT >35 IU/mL (n=3); HBV DNA ≥2000 IU/mL + ALT >35 IU/mL + ≥ F2 fibrosis (n=1); or detectable HBV DNA + ≥ F3 fibrosis (n=1). At the last assessment, treatment had been initiated in four individuals using tenofovir disoproxil fumarate or entecavir. Follow-up was arranged for all individuals, with 6/20 (30.0%) participants requiring enhanced monitoring, including the individual with cirrhosis (HBV reactivation risk and follow-up for liver-related complications); one HBeAg-negative individual with ALT 11 U/L, HBV DNA 1100 IU/mL, HBsAg 23000 IU/mL and LSM 7.4 kPa (≥F2) (suspected disease activity); one individual with HBeAg, emerging anti-HBe, ALT 19 U/L, HBV DNA 22,200 IU/mL and LSM 5.0 kPa (suspected phase transition; transmission risk); and three HBe-Ag-negative individuals of African origin aged 20-31 years with HBV DNA ≥2000 IU/mL (2020-16,335), ALT <35 U/L (20-31) and LSM <7 (3.7-5.4) (disease risk; transmission risk).

An abdominal ultrasound scan was scheduled for all individuals; to date, 15/20 (75.0%) have attended for examination, and no HCC cases have been detected.

Table 2. Characteristics of the population with HBsAg positivity who attended hepatology referral

Total population, n		20
Sex at birth male, n (%)		20 (100)
Age, median years (IQR)		30 (22-37)
WHO Region of origin, n (%)	South-East Asia	7 (35.0)
	Africa	13 (65.0)
Time since arrival, median months (IQR)		6 (4-17)
HBeAg positive, n (%)		3 (15.0)
HBV DNA detected (>10 IU/mL), n (%)		17 (85.0)
HBV DNA stratum (IU/mL), n (%)	<10	3 (15.0)
	10 - 499	5 (25.0)
	500-999	3 (15.0)
	1000-1999	1 (5.0)
	≥ 2000	8 (40.0)
HBV DNA, median IU/mL (IQR)		639 (166-17,801)
ALT, median U/L (IQR)		29 (19-35)
ALT >35 U/L, n (%)		5 (25.0)
AST, median U/L (IQR)		28 (25-32)
HBsAg, median IU/mL (IQR)		7100 (851-19,134)
Liver stiffness measurement, median kPa (IQR) (n=19)[a]		5.1 (4.5-6.3)
Liver CAP, median dB/m (IQR) (n=19)[a]		197 (189-225)
HBV profile, n (%)		
HBeAg-negative		
HBV DNA <2000 IU/mL, ALT <35 U/L		11 (55.0)
HBV DNA ≥ 2000 IU/mL, ALT <35 U/L		3 (15.0)
HBV DNA ≥ 2000 IU/mL, ALT >35 U/L		2 (10.0)
HBV DNA <2000 IU/mL, ALT >35 U/L		1 (5.0)
HBeAg-positive		
HBV DNA ≥ 2000 IU/mL, ALT >35 U/L		2 (10.0)
HBV DNA ≥ 2000 IU/mL, ALT <35 U/L		1 (5.0)
Indications for immediate antiviral treatment[b], n (%)		5 (25.0)
Indications for enhanced monitoring, n (%)		6 (30.0)

[a]One individual had not yet been tested; [b]Based on EASL guidelines 2025 [19].

Discussion

Targeted interventions are crucial for enhancing access to HBV screening, vaccination and specialist care in underserved, vulnerable populations; however, significant gaps persist in provision [23]. European [19] and Italian [9] guidelines recommend HBV screening for migrants coming from regions with intermediate or high HBsAg prevalence (≥2%) or with other risk factors for infection, and referral to specialist care for those with detectable HBsAg. The guidelines also acknowledge that effective implementation depends on consistent access to services across the pathway. In this prospective study of asylum seekers and undocumented migrants in metropolitan Rome, we

identified a substantial burden of chronic HBV infection alongside a large proportion of individuals lacking serological evidence of HBV immunity. In the absence of a coordinated national framework [10], our study evaluated the feasibility of a structured screen-and-link programme designed to minimise administrative, linguistic and logistic barriers that commonly hinder access to testing and care in migrant populations.

The study provides an overview of HBV epidemiology in this setting, highlighting a substantial prevalence of chronic HBV infection and an even larger pool of non-immune individuals. Overall, HBsAg seroprevalence (5.3%) was higher than estimates for the general Italian population (<1%) [4], and substantially higher than the most recent estimate of diagnosed chronic HBV infection in Italy derived from national exemption data (0.22% of adults) [24]. In previous studies in similar cohorts, HBsAg prevalence was 5-11% in cities in northern Italy in 2006-2024 [10-12,18], 7-10% in southern Italy (2012-2018) [13-17] and 10% in a study from a single reception centre in Rome in 2012-2013 [16]. The high prevalence we observed among African participants (~11%) is also consistent with findings from similar cohorts in Italy [11,12,14-18] and elsewhere in Europe [25], and mirrors HBV epidemiology in countries of origin [26,27], which, while heterogeneous, were predominantly in West Africa.

Previous studies of similar populations in Italy (2012-2024) reported seropositivity of 0.3-3.5% for HIV and 0.5-4% for HCV [10,11,14-16,18]. In our study, HCV seropositivity (0.7%) was at the lower end of previous estimates, with no HCV RNA positivity, whereas HIV seropositivity was 1%. No HBV co-infections with HIV, HCV or HDV were detected. There was also no HBV co-infection with HDV, as evidenced by negative anti-HDV and HDV RNA. Among general populations with detectable HBsAg, HDV seroprevalence has been estimated at ~6% in the African region and ~4% in Bangladesh [28]. However, marked heterogeneity has been reported: seroprevalence ranges from ~0.2% to 40% in West Africa [28]. Thus, the

absence of HDV co-infections in our cohort may reflect a small sample size and heterogeneity in HDV epidemiology across regions of origin.

More than 60% of screened individuals lacked evidence of HBV immunity. There was evidence of greater vaccine-induced immunity among younger individuals and participants from the Eastern Mediterranean region. In contrast, vaccine-related evidence of immunity was less common among participants from the African and South-East Asian regions, the latter represented exclusively by Bangladesh. These patterns are consistent with global data showing uneven childhood vaccination coverage and incomplete multi-dose schedules in many high-endemicity settings, as well as limited adolescent and adult catch-up programmes globally [2,29]. Despite national immunisation policies that prioritise equity and explicitly include migrants and other vulnerable populations [30], the absence of easily accessible vaccination pathways during the study period underscores a persistent gap between policy intent and operational delivery in Italy.

Screening and care models for migrant populations show heterogeneity across Europe, but reports consistently highlight multiple structural, legal and cultural or linguistic barriers that substantially impede engagement with specialist services for people with HBV: many individuals are never referred, fail to reach specialist services or disengage from follow-up [5]. There is a recognised lack of comprehensive evaluations of existing community-based interventions and an absence of an established framework [23]. At the same time, evidence suggests that context-tailored approaches can improve linkage to prevention and care [14,22,31-33]. A key finding of this study was the high attendance rate (87%) at the initial specialist appointment following HBsAg detection. This outcome likely reflects the integration of screening into an active referral pathway, rather than relying on individuals navigating complex healthcare systems independently. Our programme combined close collaboration between reception facilities and the centre of clinical care, staff-assisted navigation, pre-scheduled appointments and access to cultural

mediation, with the aim of addressing logistic and communication barriers at multiple points along the screen-and-link pathway. Whilst a longer follow-up is needed to confirm the durability of our findings, similar observations have been reported from community-based HBV programmes in other European countries and North America [23]. Active referral models, culturally tailored interventions, and point-of-care and other rapid testing strategies have been associated with improved linkage to specialist care among migrant populations [23,27,31-33]. By contrast, standard care pathways based on passive referral and autonomous healthcare navigation remain vulnerable to substantial loss to follow-up across the care cascade. We elected to assist participants in attending the centralised screening and care site, rather than perform point-of-care testing, which would have required trained personnel at each hosting facility. Importantly, this visit offered the opportunity to perform a clinical examination, expand the range of investigations (e.g., malaria, Schistosoma) and offer counselling.

From a clinical perspective, participants with a positive HBsAg test result presented with heterogeneous profiles. One in four (25%) met European guideline indications for immediate antiviral therapy based on either HBV DNA ≥2000 IU/mL with elevated ALT or advanced fibrosis with detectable HBV DNA [19]. An additional 30% required enhanced monitoring to characterise HBeAg-negative infection and overall status, and to determine treatment eligibility, considering risk factors for disease progression, transmission risk and individual preferences. Interpretation of transient elastography findings warrants caution. In this study, elastography was performed at a single time point to support clinical decision-making. Nevertheless, the low prevalence of significant fibrosis observed is consistent with the cohort's young age. There was a single case of cirrhosis accompanied by severe steatosis, which was linked to alcohol abuse rather than HBV, an observation warranting holistic clinical assessment beyond viral parameters.

This study has limitations. First, despite approximate nominal capacity estimates, the absence of reliable denominator data for the participating reception facilities precluded estimation of screening uptake and associated factors, and limited formal assessment of selection bias. As noted in previous studies [16], factors such as health awareness, perceived risk, fear and stigma might have influenced voluntary participation. However, screening was offered universally across centres, without preselection based on nationality, age, sex or clinical characteristics, and the observed seroprevalence and immunity profiles are consistent with data from comparable migrant cohorts in Italy and elsewhere in Europe. In 2012-2013, a study from a single reception centre in Rome reported that among just over 300 screening participants, proportions with HBV, HCV and HIV were 9.9%, 3.4% and 3.5%, respectively [16]. Whilst our findings extend these data, further studies are needed to confirm patterns and trends across central Italy. We also currently lack verifiable records of HBV vaccination for the non-immune population. Although vaccination was recommended for those without evidence of seroprotection, we acknowledge that navigating complex booking systems is likely to lead to limited uptake. Importantly, our centre has planned to establish a dedicated vaccination centre to facilitate access. Finally, the study was not powered to identify independent predictors of HBsAg positivity or linkage to specialist care.

This is, to our knowledge, the first report in central Italy and one of the first in Italy to describe the clinical profile of people with HBsAg positivity among asylum seekers and undocumented migrants, using harmonised data collection and comprehensive characterisation. Our findings have direct implications for HBV elimination goals. WHO targets for 2030 include diagnosing 90% of chronic HBV infections and ensuring 90% of patients with detectable HBsAg undergo assessment of treatment eligibility [34]. Our findings provide practical evidence that integrating screening and facilitated

linkage to care is feasible in vulnerable migrant populations and is essential to advance HBV elimination efforts.

DECLARATIONS

Abbreviations

ALT Alanine aminotransferase
APM Ambulatorio Popolazioni Mobili (Mobile Populations Outpatient Service)
anti-HBc Hepatitis B core antibodies
anti-HBs Hepatitis B surface antibodies
anti-HCV Hepatitis C virus antibodies
anti-HDV Hepatitis delta antibodies
ALT Alanine aminotransferase
AST Aspartate aminotransferase
CAP Controlled Attenuation Parameter
CAS Centri di Accoglienza Straordinaria (Extraordinary Reception Centres)
CI Confidence interval
EASL European Association for the Study of the Liver
F2 / F3 / F4 Fibrosis stages (Significant, Advanced, Cirrhosis)
HBeAg Hepatitis B e antigen
HBV Hepatitis B virus
HBsAg Hepatitis B surface antigen
HCC Hepatocellular carcinoma
HCV Hepatitis C virus
HDV Hepatitis delta virus
HIV Human immunodeficiency virus
INMI Istituto Nazionale per le Malattie Infettive (Lazzaro Spallanzani National Institute for Infectious Diseases)
IQR Interquartile range
IU/mL, IU/L International units per millilitre/litre
kPa Kilopascals (unit for liver stiffness)
LLOQ Lower limit of quantification
LSM Liver stiffness measurement
RT-PCR Reverse transcription polymerase chain reaction
S1 / S2 / S3 Steatosis grades (Mild, Moderate, Severe)
U/L Units per litre
WHO World Health Organization

Ethics approval and consent to participate

The study was approved by the Ethics Committee of the Lazio Area 4 (n. 44-2025). Written informed consent was obtained from all participants, with assistance from translators when necessary. The study was conducted in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable

Availability of data

De-identified data may be made available from the corresponding author on reasonable request, subject to approval by the study investigators and applicable ethical and data protection requirements.

Competing Interests

EB, GdO: Personal fees from Abbvie and Gilead and research funding (to institution) from Gilead, for unrelated work.

CT: Personal fees from Abbvie and Gilead, for unrelated work

AMG: Personal fees from Abbott, Gilead, Roche and GSK; research funding (to institution) from Gilead and Roche for unrelated work.

EN: Personal fees from Roche, Gilead, Valneva and Takeda and research funding (to institution) from Takeda, for unrelated work

VdA, ADA, DK, FF, SV, AP, ARG: None.

Funding

This study was supported by funds allocated to the National Institute for Infectious Diseases “Lazzaro Spallanzani”, IRCCS, 00149, Rome (Italy), from the Italian Ministry of Health (Linea 1 and Linea 2 Progetto 5b).

Authors’ contribution

Study ideation: EN, AD, EB, GD, FF, SV

Data collection: DK, EB, VdA, CT, ARG, AP, CT

Data analysis: AMG, EB, VdA

Writing of the manuscript: AMG

Revision of the manuscript: AMG, GdO, EB, VdA, EN

All authors reviewed and approved the final manuscript.

Acknowledgements

The authors are grateful for the support received from the staff of the reception facilities and the INMI Ambulatorio Popolazioni Mobili (Elena Boschiavo, Patrizia De Marco, Maria Letizia Giancola, Alessandra Lamonaca,

Andrea Mariano, Claudia Palazzolo, Sara Pantanella, Giuseppa Tarabù, Maria Virginia Tomassi).

REFERENCES

1. World Health Organization. Hepatitis B. 2025. Available at: https://www.who.int/news-room/fact-sheets/detail/hepatitis-b (accessed Dec 2025).
2. World Health Organization. Global Hepatitis Report 2024: Action for access in low- and middle-income countries. Available at: https://www.who.int/publications/i/item/9789240091672 (accessed Dec 2025).
3. Operational Data Portal. Europe situations: data and trends - arrivals and displaced populations - October 2024. Available at: https://data.unhcr.org/en/documents/details/112944 (accessed Dec 2025).
4. Sagnelli C, Sica A, Creta M, Calogero A, Ciccozzi M, Sagnelli E. Epidemiological and clinical aspects of hepatitis B virus infection in Italy over the last 50 years. World J Gastroenterol. 2022;28:3081-3091.
5. Razavi-Shearer DM, Kondili LA, Hall S, et al. Estimating the impact of displacement from Ukraine on HBV and HCV prevalence among migrants in the European Union, 2024: A modeling study. Lancet Reg Health Eur. 2025;58:101452.
6. Italian Government. Vivere e lavorare in Italia. Salute. Avallabile at: https://integrazionemigranti.gov.it/it-it/Ricerca-norme/Dettaglio-norma/id/12/Salute (accessed Dec 2025).
7. World Health Organization. Italy: Country Health Profile 2023. Available at: https://eurohealthobservatory.who.int/publications/m/italy-country-health-profile-2023 (accessed Dec 2025).
8. Kim JU, Ingiliz P, Shimakawa Y, Lemoine M. Improving care of migrants is key for viral hepatitis elimination in Europe. Bull World Health Organ 2021;99:280-286.
9. Tosti ME, Marceca M, Eugeni E, et al. Health assessment for migrants and asylum seekers upon arrival and while hosted in reception centres: Italian guidelines. Health Policy 2021;125:393-405.
10. Formenti B, Benoni R, Testa J, et al A. Navigating healthcare pathways: Cascade of prevention and care for chronic viral hepatitis in asylum seekers and refugees. A multicenter analysis in Northern Italy. J Migr Health. 2025;11:100307.
11. Donisi A, Gerna L, Fietta T, Grecchi C. Screening approach among newly arrived asylum seekers: experience in a primary health care setting in Piacenza, Emilia Romagna, Northern Italy. J Prev Med Hyg. 2020;61:E445-E450.

12. El-Hamad I, Pezzoli MC, Chiari E, et al. Point-of-care screening, prevalence, and risk factors for hepatitis B infection among 3,728 mainly undocumented migrants from non-EU countries in northern Italy. J Travel Med. 2015;22:78-86.
13. Mazzitelli M, Greco G, Serapide F, et al. Outcome of HBV screening and vaccination in a migrant population in southern Italy. Infez Med. 2021;29:236-241.
14. Prestileo T, Di Marco V, Dino O, et al. Effectiveness of a screening program for HBV, HCV, and HIV infections in African migrants to Sicily. Dig Liver Dis. 2022;54:800-804.
15. Coppola N, Alessio L, Gualdieri L, et al. Hepatitis B virus, hepatitis C virus and human immunodeficiency virus infection in undocumented migrants and refugees in southern Italy, January 2012 to June 2013. Euro Surveill. 2015;20:30009.
16. Russo, G, Vita S, Miglietta A, Terrazzini N, Sannella A, Vullo V. Health profile and disease determinants among asylum seekers: a cross-sectional retrospective study from an Italian reception centre. J Public Health 2016;38:212-222.
17. Coppola N, Alessio L, Gualdieri L, et al. Hepatitis B virus infection in undocumented immigrants and refugees in Southern Italy: demographic, virological, and clinical features. Infect Dis Poverty 2017;6:33.
18. Ursini T, Bonato L, Zaffagnini A, et al. Screening for infectious and neglected tropical diseases among newly arrived migrants from Africa and Asia: a retrospective study from Verona province, Italy. Trop Med Health 2025;53:119.
19. European Association for the Study of the Liver. EASL Clinical Practice Guidelines on the management of hepatitis B virus infection. J Hepatol. 2025;83:502-583.
20. European Association for the Study of the Liver; European Association for the Study of Diabetes; European Association for the Study of Obesity. EASL-EASD-EASO Clinical Practice Guidelines on the management of metabolic dysfunction-associated steatotic liver disease (MASLD): Executive Summary. Diabetologia 2024;67:2375-2392.
21. World Health Organization. Guidelines for the prevention, diagnosis, care and treatment for people with chronic hepatitis B infection. 2024. Available at: https://www.who.int/publications/i/item/9789240090903 (accessed Dec 2025).
22. World Health Organization. Countries/areas by WHO region. Available at https://apps.who.int/violence-

info/Countries%20and%20areas%20by%20WHO%20region%20-%2012bfe12.pdf (accessed May 2026).
23. Paoletti F, D'Agostino M, De Mattia E, et al. Appraisal of community-based interventions for hepatitis B in underserved populations using the quadruple aim of value-based medicine: a scoping review within the VH-COMSAVAC project. BMC Public Health 2025;25:3901.
24. Loglio A, Gardini I, Conforti M et al. Diagnosed patients with chronic hepatitis B and Delta virus in Italy in 2024: An estimation from a national real-world database. Liver Int. 2025;45:e70336.
25. Bivegete S, McNaughton AL, Trickey A, et al. Estimates of hepatitis B virus prevalence among general population and key risk groups in EU/EEA/UK countries: a systematic review. Euro Surveill. 2023;28:2200738.
26. World Health Organization. Viral Hepatitis Scorecard 2021: African Region. Available at: https://www.afro.who.int/publications/viral-hepatitis-scorecard-2021-african-region (accessed Dec 2025).
27. McNaughton AL, Lourenço J, Bester PA, et al. Hepatitis B virus seroepidemiology data for Africa: Modelling intervention strategies based on a systematic review and meta-analysis. PLoS Med. 2020;17:e1003068.
28. Stockdale AJ, Kreuels B, Henrion MYR, et al. The global prevalence of hepatitis D virus infection: Systematic review and meta-analysis. J Hepatol. 2020;73:523-532.
29. World Health Organization. Immunization Data. Available at https://immunizationdata.who.int/global?topic=&location= (accessed Dec 2025).
30. Italian Ministry of Health (Ministero della Salute). National vaccination plan 2023. (Piano nazionale prevenzione vaccinale. Available at https://www.salute.gov.it/new/it/tema/vaccinazioni/piano-nazionale-prevenzione-vaccinale/ (accessed Dec 2025).
31. Picchio CA, Nomah DK, Rando-Segura A, et al. Community-based screening enhances hepatitis B virus linkage to care among West African migrants in Spain. Commun Med (Lond). 2023;3:182.
32. Ghimire S, Hallett J, Gray C, Lobo R, Crawford G. What works? Prevention and control of sexually transmitted infections and blood-borne viruses in migrants from Sub-Saharan Africa, Northeast Asia and Southeast Asia living in high-income countries: A systematic review. Int J Environ Res Public Health 2019;16:1287.
33. Not A, Ouaarab-Essadek H, Montoro M, et al. Hepatitis B and C screening and linkage to care in migrants from endemic countries in Barcelona through a community action. Liver Int 2025;45:e70126.

34. World Health Organization. Elimination of hepatitis by 2030. Available at: https://www.who.int/multi-media/details/elimination-of-hepatitis-by-2030 (accessed Dec 2025).