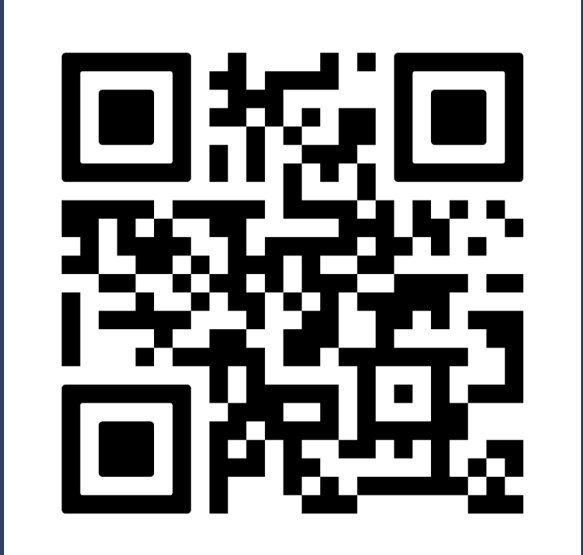


Evaluating the National and Regional Prevalence and Incidence Rates of Hepatitis Delta Virus Among Patients With Hepatitis B Virus Infection in Italy

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Conclusions

- The overall national prevalence and incidence of hepatitis delta virus (HDV) among people with hepatitis B virus (HBV) in Italy were 6.7% and 5.9%, respectively, between 2010 and 2021
- HDV prevalence was higher in the southern region of Italy in both the inpatient and outpatient populations compared with the northern and central regions
- These data highlight the importance of addressing both national and regional needs for early screening, diagnosis, and treatment of HDV

Plain Language Summary

- Hepatitis delta virus (HDV) infection causes the most severe form of hepatitis
- Between 2010 and 2021, 6.7% of people living with hepatitis B virus (HBV) in Italy also had HDV
- The rate of new cases of HDV among people with HBV was 5.9% from 2010 to 2021
- The number of people with HDV was higher in the southern region of Italy compared with the northern and central regions

References: 1. Lempp FA, et al. *Nat Rev Gastroenterol Hepatol*. 2016;13(10):580-9. 2. Huang C, et al. *World J Gastroenterol*. 2014;20(40):14589-97. 3. Da BL, et al. *Gastroenterol Rep*. 2019;7(4):231-45.

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INTRODUCTION

- HDV is a defective RNA virus that completes replication and transmission in the presence of hepatitis B surface antigen^{1,2}
 - HDV causes a more severe form of viral hepatitis than does HBV mono-infection (HBV only)^{1,2}
- Chronic HDV infection results in more rapid progression to cirrhosis, and an increased risk for hepatocellular carcinoma and liver disease–related death, compared with HBV only³

OBJECTIVE

- This retrospective study evaluated national and regional prevalence and incidence of HDV infection among adults with HBV in Italy

METHODS

- This study was conducted using administrative databases from local health units that covered approximately 12 million people across Italy
- Study period: Patients with ≥1 inpatient or outpatient claim (using ICD-9-CM or exemption codes, respectively) between Jan 1, 2009, and Jun 30, 2022
- Identification period: Patients aged ≥18 years with an HDV or HBV only diagnosis between Jan 1, 2010, and Dec 31, 2021, with no prior HDV diagnosis, and who were alive as of Dec 31, 2021, were identified
- The index date was defined as the date of a patient's first claim

Figure 1. Patient Identification

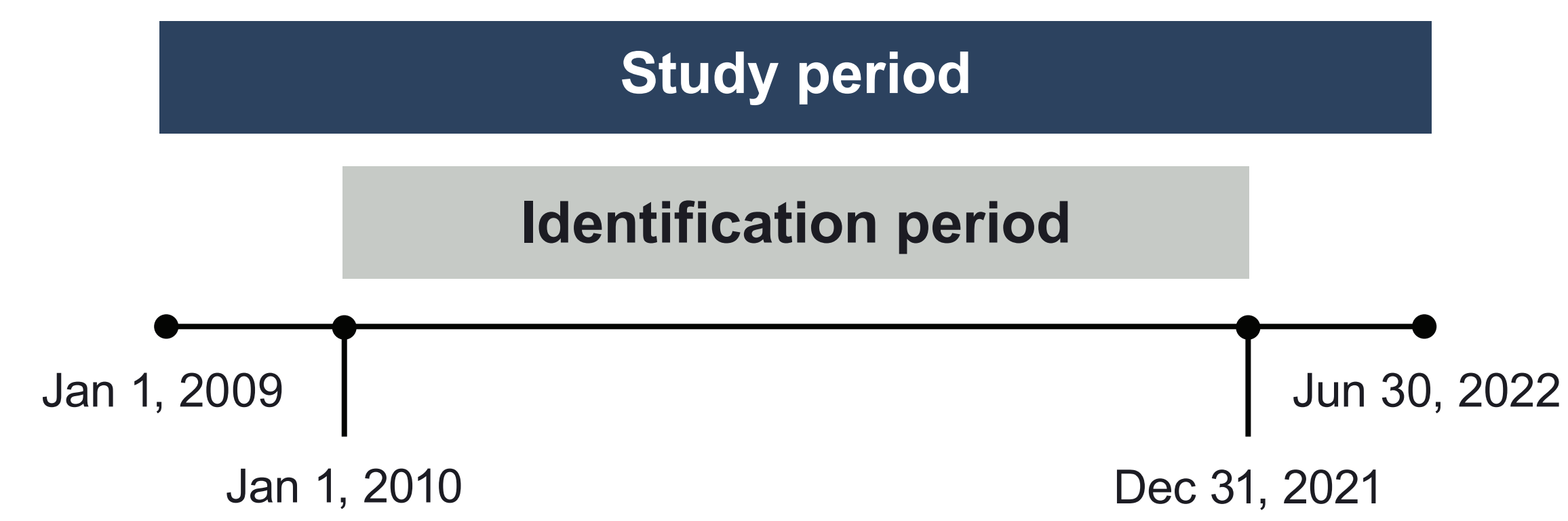
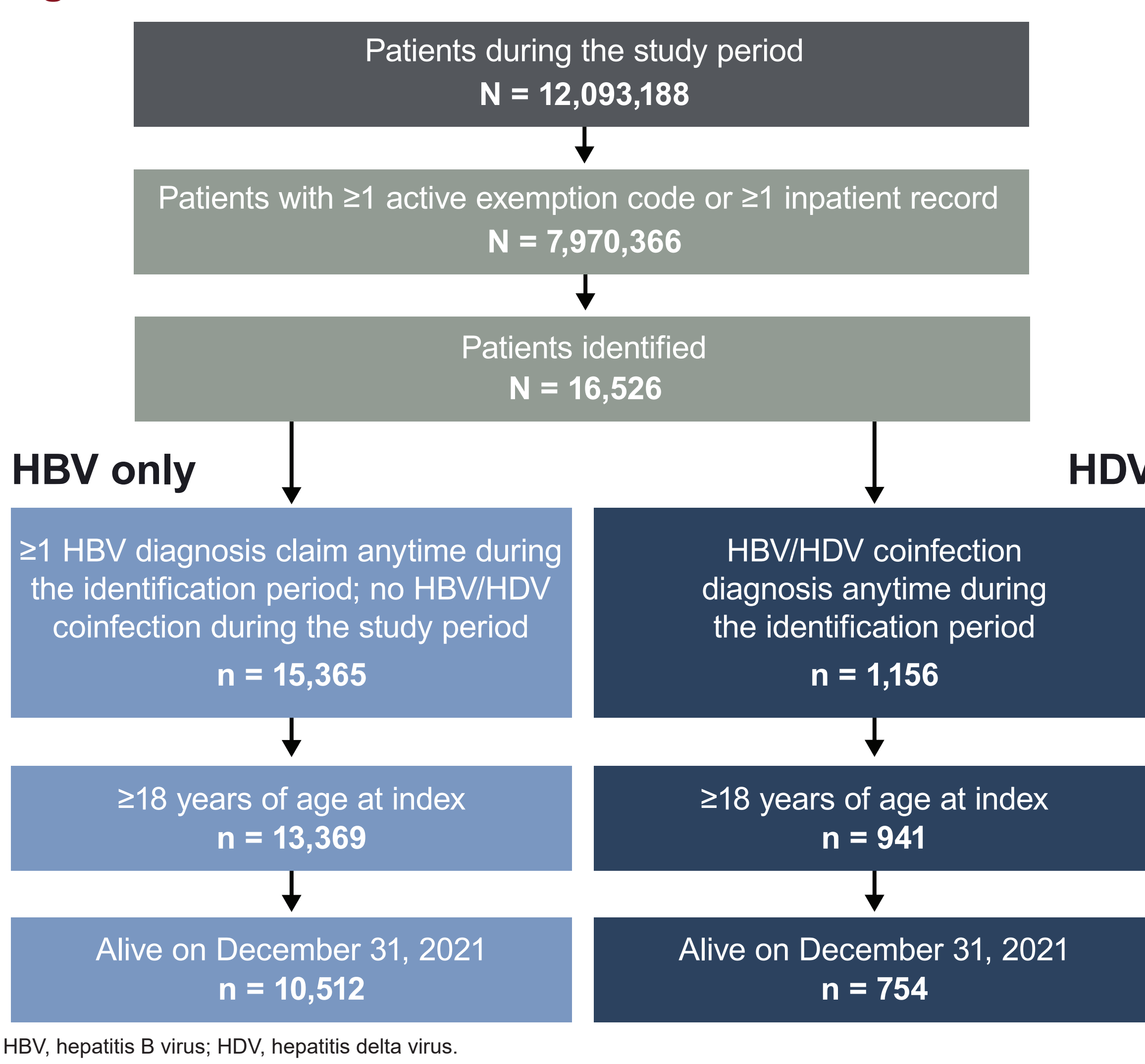


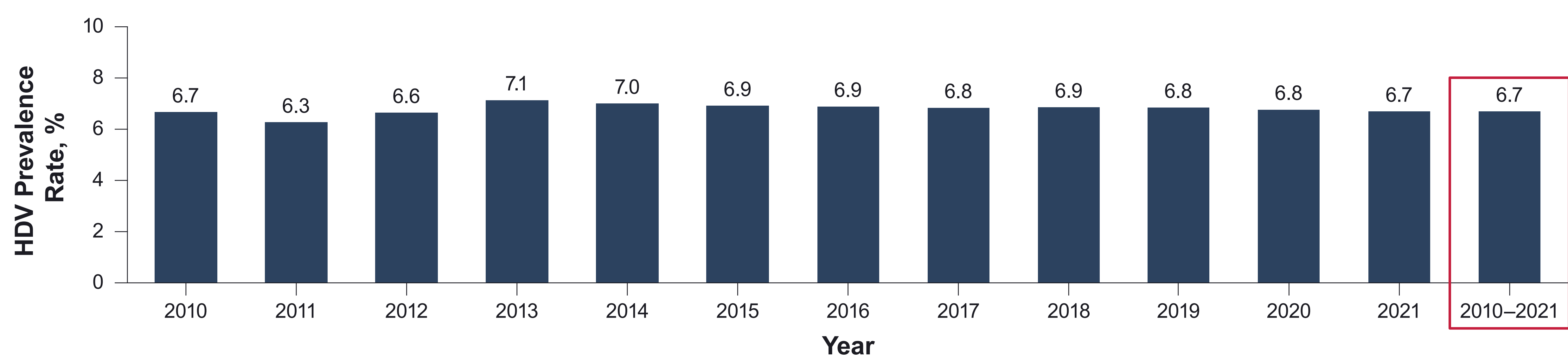
Figure 2. Patient Attrition Flow Chart



- Among the 16,526 patients identified, 10,512 met inclusion criteria for the HBV only cohort, and 754 met inclusion criteria for the HDV cohort

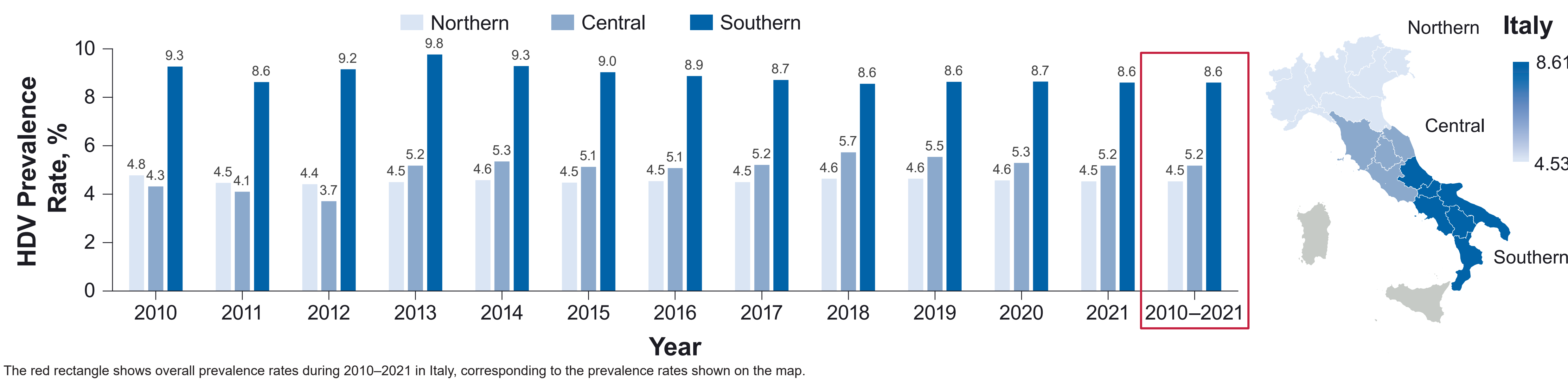
RESULTS

Figure 3. National Prevalence Rates of HDV in Italy, 2010–2021



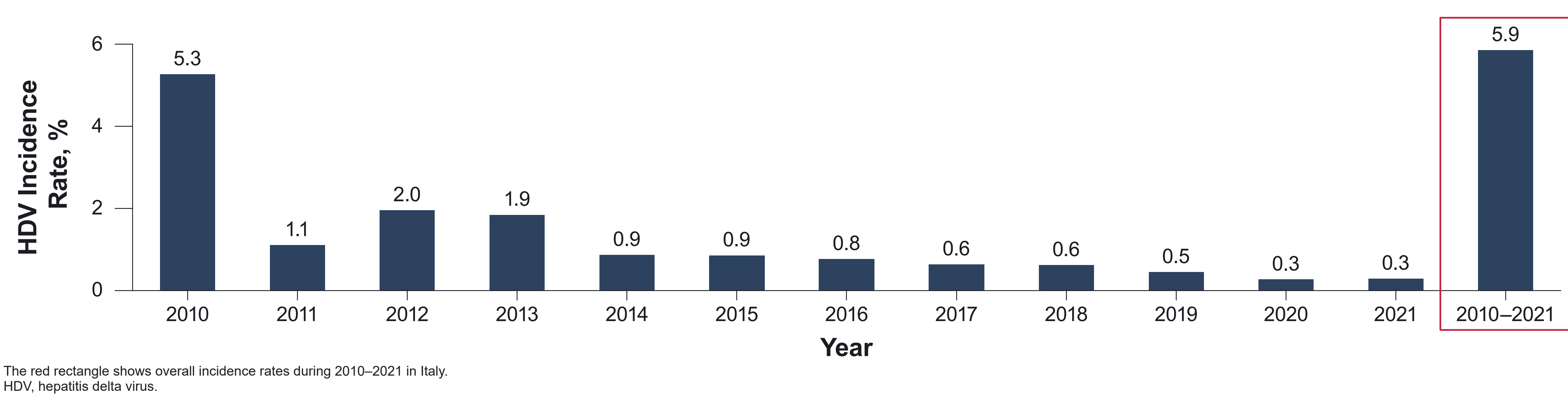
- In Italy, HDV prevalence was 6.7% (range, 6.3%–7.1%) during 2010–2021

Figure 4. Regional Prevalence Rates of HDV in Italy, 2010–2021



- In the northern, central, and southern regions, HDV prevalence was 4.5%, 5.2%, and 8.6%, respectively
- Moreover, HDV prevalence was higher in the southern region for both outpatient (north, 3.9%; central, 3.9%; south, 12.9%) and inpatient (north, 4.6%; central, 5.4%; south, 7.4%) populations

Figure 5. National Incidence Rates of HDV in Italy, 2010–2021



- National HDV incidence was 5.9% (range, 0.3%–5.3%)
- The national HDV incidence rate declined from 5.3% in 2010 to 0.3% in 2021

LIMITATIONS

- The limitations of any retrospective claims study apply. Diagnoses made via ICD-9-CM codes are subject to miscoding and can lead to misclassification bias, and time of diagnosis may not correspond to the time of infection; therefore, results may reflect delayed recognition of infection
- Incidence was defined as a new diagnosis without prior diagnosis, which may not necessarily reflect new infection
- This study may have underestimated the actual number of individuals with HDV and/or HBV infection due to a lack of approved assays and suboptimal screening practices to determine HDV and HBV status; thus, a large group of undiagnosed patients may not be captured in this analysis