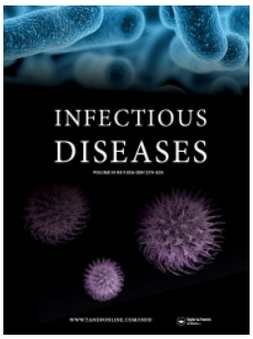

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Diagnosis and treatment coverage among hepatitis C infections in Denmark, 2022: a capture-recapture study using national registers

Signe Freja Storgaard[a,b], Inge Petersen[a], Gordon Hay[c], Signe Bollerup[d,e], Maria Wessman[f], Nina Weis[d,g], Lars Haukali Omland[g,h,i], Birgit Røge[j], Alex Lund Laursen[k], Lone Hagens Mygind[l], Henrik Krarup[m,n], Toke Seierøe Barfod[e,g], Lone Galmstrup Madsen, Anders Koch[f,g,h], Sandra Dröse[a], Anne Øvrehus[a] and Peer Brehm Christensen[a,b]

[a]Department of Infectious Diseases, Odense University Hospital, Odense, Denmark; [b]Department of Clinical Research, Faculty of Health Sciences, University of Southern Denmark, Odense, Denmark; [c]School of Public and Allied Health, Liverpool John Moores University, Liverpool, UK; [d]Department of Infectious Diseases, Copenhagen University Hospital, Hvidovre, Denmark; [e]Department of Internal Medicine, Zealand University Hospital, Roskilde, Denmark; [f]Department of Infectious Disease Epidemiology and Prevention, Statens Serum Institut, Copenhagen, Denmark; [g]Department of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark; [h]Department of Infectious Diseases, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark; [i]Department of Bacteria, Parasites and Fungi, Research Unit for Reproductive Microbiology, Statens Serum Institut, Copenhagen, Denmark; [j]Department of Internal Medicine, Kolding Hospital, Kolding, Denmark; [k]Department of Infectious Diseases, Aarhus University Hospital, Aarhus, Denmark; [l]Department of Infectious Disease, Aalborg University Hospital, Aalborg, Denmark; [m]Department of Molecular Diagnostics, Aalborg University Hospital, Aalborg, Denmark; [n]Department of Clinical Medicine, Aalborg University, Aalborg, Denmark

ABSTRACT

Background: Following the introduction of direct-acting antivirals (DAAs), elimination of hepatitis C virus (HCV) became a target of the World Health Organisation (WHO) in 2016. Denmark had a HCV prevalence of 0.21% in 2016, and in 2018, unrestricted access to DAAs was introduced together with intensified testing strategies.

Aim: To estimate adult HCV diagnostic and treatment coverage in Denmark by the end of 2022.

Methods: Four national HCV source registers (laboratory reports, surveillance notifications, treatment database and hospital diagnoses) were merged. Capture–recapture analysis was used to estimate diagnosed individuals not identified in the registers, and estimates were adjusted for treated patients. The undiagnosed population was estimated using HCV testing data among high-risk individuals recorded in the Register for Treatment of Drug Use and compared with Danish studies on the diagnosed fraction of newly detected HCV cases.

Results: Across the four registers, 1,649 valid records of HCV-infected adults alive and resident in Denmark were identified. Capture–recapture analysis estimated a total of 1,700 (95% CI: 1,677–1,739) diagnosed individuals. With an undiagnosed fraction of 22–32%, the total HCV-infected population was estimated at 2,471–2,582 individuals, corresponding to a prevalence of 0.05–0.06% by the end of 2022. Compared to the 2016 baseline 82% had been diagnosed and 77% of diagnosed patients had been treated for HCV.

Conclusion: HCV prevalence in Denmark has declined substantially, and with ongoing national initiatives to test and treat the remaining HCV patients we are likely to achieve WHO targets of diagnostic coverage and treatment before 2030.

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Hepatitis C; elimination; epidemiology; register-based study; Denmark; prevalence

Introduction

Hepatitis C virus (HCV) infection remains a major cause of liver-related morbidity and mortality. The majority of infections (62–80%) progress to chronic infection and may potentially lead to cirrhosis and/

CONTACT Signe Freja Storgaard signe.freja.storgaard@rsyd.dk Department of Infectious Diseases, Odense University Hospital, Odense, Denmark.

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or hepatocellular carcinoma [1,2]. Since 2014, direct-acting antivirals (DAA) have enabled highly effective curative treatment, offering realistic prospects for global elimination. In 2016, the World Health Organization (WHO) set ambitious targets for elimination of HCV as a public health threat by 2030, aiming for 90% diagnosis coverage and treatment of 80% worldwide [3]. Denmark endorsed these targets, introduced unrestricted DAA access in 2018, and launched a national elimination strategy in 2023 [4]. Treatment can only be prescribed by specialists in infectious disease and gastroenterology, but the treatment may be delegated to other doctors and nurses. Treatment is free of charge for patients.

Accurate estimation of the number of people living with HCV – including those undiagnosed – and identification of populations at the highest risk are central to monitoring elimination progress [3–5]. Previous Danish estimates using nationwide registry linkages and capture–recapture methods reported 16,888 individuals living with HCV in 2007 and 9,975 in 2016 [2,6]. Despite Denmark's long-standing tradition of comprehensive national registries, no complete registry of HCV exists, limiting systematic monitoring of HCV trends. However, Denmark offers a unique opportunity to link existing national registries through the 10-digit personal identification number (PIN) assigned to all individuals with permanent residency.

People who inject drugs (PWID) remain the primary risk group for HCV in the developed countries and in Denmark, where 85% of the reported cases are related to injecting drug use[2,6–9]. Reduction of HCV transmission among PWIDs in high-income countries is estimated to decrease incidence by 79% [10].

Since 2018, the removal of treatment restrictions has fundamentally changed the treatment landscape in Denmark and led to several outreach projects [11]. The major interventions have been introducing dry blood spot testing for HCV, establishing out-reach HCV test and treatment in drug treatment facilities and mobile clinics, and personal evaluation for treatment to 4,000 diagnosed untreated HCV patients based on the 2016 estimate. Estimating how this has affected the HCV-infected population is therefore essential for the elimination strategy.

The aim of this study was to estimate the prevalence of diagnosed and undiagnosed active hepatitis C infections and treatment coverage among those diagnosed to assess progress toward related WHO elimination targets in Denmark at the end of 2022.

Method

Study design and study population

We conducted a nationwide, registry-based study to estimate the prevalence of HCV infection in Denmark as of 31 December 2022. The study was set in Denmark, where the adult population was estimated to be 4.7 million individuals (aged $\geq$ 18 years) by the end of 2022 [12]. All individuals with a valid PIN who had been registered with HCV infection in one of four national health registers before 31 December 2022 were included.

Individuals aged $<$18 years, deceased, emigrated and patients treated with DAA for HCV and/or with evidence of viral clearance were excluded.

Data sources and variables

We combined four national incomplete registers of HCV, using the PIN to link individuals across registers. The four source registers were as follows (for details, Supplementary):

Laboratory register (LAB)

LAB contains information on viral hepatitis tests and results from the mid-nineties to 2022. Data is reported by all laboratories in Denmark performing HCV tests.

Clinical database (CLIN.)

Information on patients receiving specialized care for HCV in Denmark, registered by physicians at Infectious Disease Departments throughout Denmark. This database contains data on both laboratory HCV-RNA tests and HCV treatments, from 2002 to 2022 [13].

Communicable diseases register (REPORT)

Since May 2000, mandatory reporting of acute and chronic HCV has been required in Denmark (recommended since 1994). Reporting is done by diagnostic physician. REPORT is managed by Statens Serum Institut, auspices of the Danish Ministry of Health.

Hospital register (HOSP.)

The HOSP captures all public hospital contacts in Denmark and has been in operation since 1977. Since 1994, ICD-10 codes had been reported. HOSP is managed by the Danish Health Data Authority.

Moreover, we extracted data from three additional registers to further form and characterize the HCV population:

Register for treatment of drug use (DRUG)

National register since 1996 contains information about all individuals referred to treatment for drug addiction, with data reported by drug treatment centres. Information includes patterns of drug use, drug intake and treatment. This register was used to characterise the HCV-infected population with regard to drug use patterns and validate the coverage of the source registers in the drug using population – as >85% of Danish HCV patients have been exposed by drug use [7].

Danish Civil Registration System (CPR)

Established in 1968, this register contains information on vital status, sex, age, current residence and immigration/emigration for all Danish residents registered with a PIN.

Hospital pharmacy register

All medications, administered in public hospital settings, recorded when prescriptions are entered into electronic patient journal systems. This source was used to supplement information on HCV treatment. The register was established on 15 May 2018.

Case definition

This study defines an individual infected with chronic HCV as: (i) a positive HCV-RNA test, or (ii) recorded in the CLIN as HCV infected, or (iii) ICD-10 code B18.2 (chronic HCV in HOSP) or (iv) reported to REPORT. Cases were not simultaneously recorded in all registers, and lag time was noted especially for HOSP and REPORT leading to a proportion of patients entering in these registers after treatment initiation (CLIN) or documented cure (LAB). To distinguish 're-diagnosis' from reinfection after HCV cure we included individuals if they were i (re)entering in one of the four sources registers $\geq$ 365 days after treatment or a negative test. Patients who were HCV-RNA positives in LAB after last treatment completion were included regardless of time since last treatment (Supplementary Figure S1).

Outcome and statistical methods

To estimate the prevalence of HCV infection and the diagnostic coverage in Denmark, it is necessary to account for both the diagnosed and the undiagnosed populations. The target for diagnosis coverage (90%) and treatment (80%) was evaluated using WHO guidance from 2023 with 2016 as baseline year (9,975 HCV infected) [14].

Diagnosed population

As no registry in Denmark completely captures all diagnosed HCV cases, a capture–recapture analysis was applied. This statistical method is commonly used to estimate the true size of a population when only incomplete data from overlapping sources are available [15]. In this context, the method provided an estimate of how many should have been found diagnosed with HCV in the four sources registries, but were not recorded, called the 'non-identified' population. The method assumes independency between the sources used; however this assumption is rarely met in clinical medicine. To account for potential dependencies, a Poisson regression model including interaction between the four source

registers was applied. Additionally, the method assumes equal catchability across individuals, also unlikely to be met; to minimize the bias introduced by this the variables sex, age and region of residence were included in the Poisson regression, similar to previous stratified estimates [2,6]. Sex was categorized into two categories, men and women. Age was categorized in three groups: 18–49, 50–59 and older than 60 years. Current residency was categorized in the five health system regions in Denmark. Akaike information criterion (AIC) with the lowest value was used to choose the best-fitting model among the 113 models that were fitted to the data. If multiple models have an AIC difference less than two (due to the rule of thumb that such models have equal substantial support), the most simple model was chosen (with the fewest interactions terms), to avoid overfitting [16]. We present all models with an $\Delta AIC < 2$ in Supplementary. In all analyses, non-parametric bootstrapping procedures with 1,000 repetitions were implemented for the estimation of confidence intervals (CI).

Sensitivity analyses assessed a crude model, not adjusting for interactions between registers, nor sex, age or region of residence. Furthermore, a three-source capture–recapturing excluded one of the sources at a time, to assess the effect of each register. Additionally, the robustness of the Poisson regression model was assessed, with negative -binomial as well as zero-inflated negative binomial regression models, trying to take into account the datasets many empty cells (147/450).

Undiagnosed population

To determine the undiagnosed fraction we used DRUG. Individuals at high risk for HCV infection – defined as those reported to ever have been injecting drugs or receiving opioid substitution therapy (OST) – in this register were identified. Their HCV testing status and results were assessed through linkage with the four source registers (restricted to 31.12.2022). Assuming the untested individuals had the same HCV prevalence as the tested, the presumed number of untested individuals infected by HCV was estimated. The undiagnosed fraction was then estimated by dividing the number of untested drug users, presumably HCV infected with the total number of HCV-positive individuals in the high-risk. See Figure S2 in Supplementary for elaboration.

To validate the undiagnosed fraction derived from DRUG, we analyzed 10 Danish HCV screening initiatives conducted between 2016 and 2024 ($n = 6{,}407$), including individuals from high-risk populations [17–21] and personal communication SFS, Sandra Dröse, Jonas Demant, Martin Petri Bækby].

The 95% CI for the total HCV prevalence estimate was done using parametric bootstrapping (1,000 repetitions), combining the identified population with the capture–recapture estimate of the non-identified population and simulating cases in the undiagnosed population assuming a binomial distribution.

Treatment coverage

According to WHO recommendations, the treatment coverage was calculated as the number of treatments prescribed among patients diagnosed in the period since baseline (2016–2022) [14].

All data management and statistical analyses were conducted within the secure research environment hosted by the Danish Health Data Authority (Sundhedsdatastyrelsen). Statistical analyses and graphical work were carried out using Stata version 19.5 and R version 4.4.3 [22–24].

Results

Identified diagnosed population

In total, 17,888 individuals were ever registered with a HCV diagnosis in any of the four source registers, with HOSP being the register contributing with most identified individuals (15,148) and REPORT with the fewest (7,408) (Figure 1).

After assessing inclusion and exclusion criteria, 2,074 individuals were identified with HCV infection as of 31 December 2022 (Figure 1). Of the 2,074, 26% (536/2,074) were classified as reinfected and 79% (425/536) of these were identified solely through HOSP. We excluded the 425 from the study population. The total identified population of HCV-infected individuals was hereby 1,649 individuals.

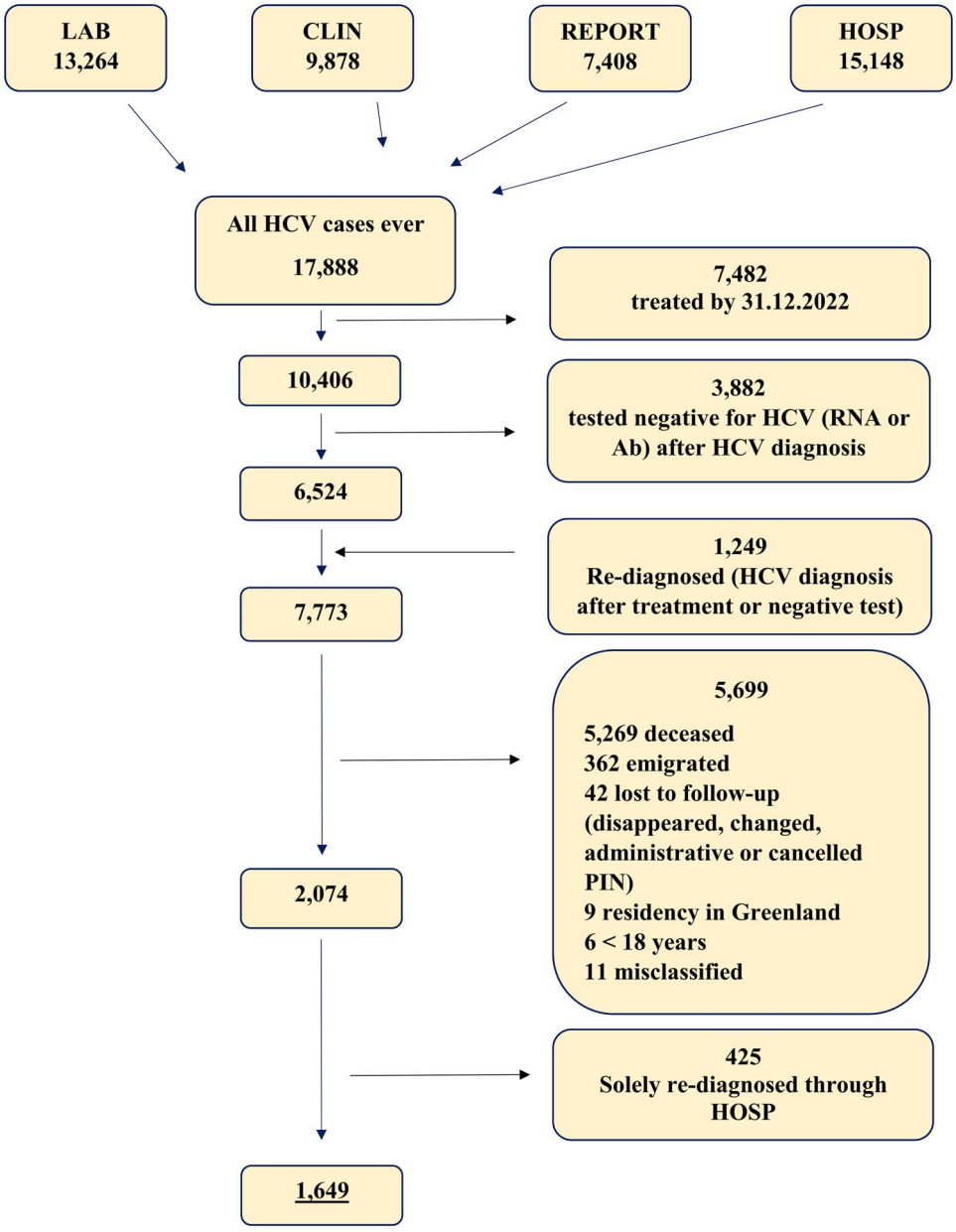

Figure 1. Flowchart of the study population (the identified population).

The median age of the identified study population was 55 years, and 62% were men. A large proportion had drug-related risk factors; 55% were registered in DRUG, and of these, 91% met criteria for high-risk of HCV infection (Table 1).

Venn diagram on the distribution and overlap between the four sources is shown in (supplementary Figure S2).

'Non-identified' population

Applying the capture–recapture method to the identified population, we found that the Poisson model was overdispersed, but the differences between the three models were small (Tables S1-3). The negative binomial regression was therefore applied and estimated that 51 (95% CI: 28–90) additional individuals diagnosed with HCV were not found in the four source registers (Supplementary Table S2).

The combined identified and 'non-identified' population was therefore estimated at 1,700 individuals (95% CI: 1,677–1,739).

Table 1. Identified diagnosed population characteristics.

	LAB	CLIN	REPORT	HOSP	Total
Number of individuals	57% (938)	35% (583)	28% (464)	72% (1,181)	100% (1,649)
Sex, % women	34% (318)	33% (192)	31% (146)	40% (477)	38% (623)
Age, median (IQR)	54 (46–63)	54 (46–63)	54 (47–62)	55 (46–63)	55 (46–63)
Regions					
Region North	13% (126)	13% (74)	9% (42)	11% (135)	11% (184)
Region Central	23% (212)	20% (117)	18% (82)	19% (219)	18% (297)
Region South	20% (188)	26% (152)	25% (118)	26% (307)	25% (408)
Region Zealand	12% (116)	14% (82)	19% (88)	18% (214)	18% (293)
Region Capital	32% (296)	27% (158)	29%(134)	26% (306)	28% (467)
Registered in DRUG	63% (587)	62% (364)	75% (350)	69% (813)	66% (1,081)
Reinfected*	4% (42)	9% (50)	8% (37)	4% (50)	7% (111)

*Cases re-entering register more than one year after treatment or negative HCV test.

Using the crude model including the four source registers, the estimated 'non-identified' population was 110 (95% CI: 15–789) (Supplementary Table S1). Comparing Poisson negative binomial and zero-inflated negative binomial models showed minimal differences (Supplementary Tables S1–S3). Estimates from the three-source capture–recapture analysis were of similar magnitude, except for the model without HOSP and that were 24% lower than the main model (Supplementary Table S4).

Undiagnosed population

In DRUG we identified 17,455 individuals alive by 31.12.2022; living in Denmark and at high-risk for HCV infection. Of these, 11,954 (68%), had been tested for HCV (HCV Ab or HCV RNA, incl. 102 individuals diagnosed through CLIN, REPORT or HOSP) with an HCV-positive prevalence of 31%. Assuming the same HCV prevalence among the 5,501 who had never been tested nor registered in any of the four source registers, we estimated 1,708 of these to be infected by HCV, corresponding to an undiagnosed fraction of 32% (95%CI: 30%–33%) among high-risk patients with HCV in DRUG (Supplementary Figure S3).

In comparison, the contemporary Danish screening initiatives had an undiagnosed fraction of 22% (95% CI: 18%–26%) (Supplementary Table S5).

Overall estimated chronic HCV prevalence in 2022

The total estimate comprises three components (Figure 2): 1) The identified diagnosed population from the four source registers ($n = 1{,}649$). 2) The 'non-identified' population (diagnosed but not in registers) is derived from the capture–recapture analysis, $n = 51$ (95% CI: 28–90). 3) The undiagnosed population, 32% (95% CI: 30%-33%), $n = 851$ (95% CI: 780–888). Together, these correspond to an estimated 2,551 (95% CI: 2,471–2,582) individuals living with HCV in Denmark as of 31 December 2022. If the undiagnosed fraction was in fact only 22%, the total estimate decreased to 2,179 individuals. Including the statistical variation and possible bias we think it is more correct to say that the total estimate is likely to be in the range of 2,471–2,582 persons (0.05–0.06% of the adult population).

Calculated according to WHO guidance Denmark have achieved a diagnostic coverage of 82% since 2016 (Supplement Table S6) [14].

Treatment coverage

We identified 3,042 diagnosed with HCV in the period 2015–2022 of whom 14% (418) had died or left the country and 16% (491) had cleared the virus without treatment. Among the remaining 2,134 77% (1,636) had been treated, compared to the WHO target of 80% treated among the diagnosed in the period.

Discussion

Key results

This nationwide register-based study shows that chronic HCV prevalence in Denmark has declined to historically low levels. By 31 December 2022, there were an estimated 2,471 – 2,582 individuals living with

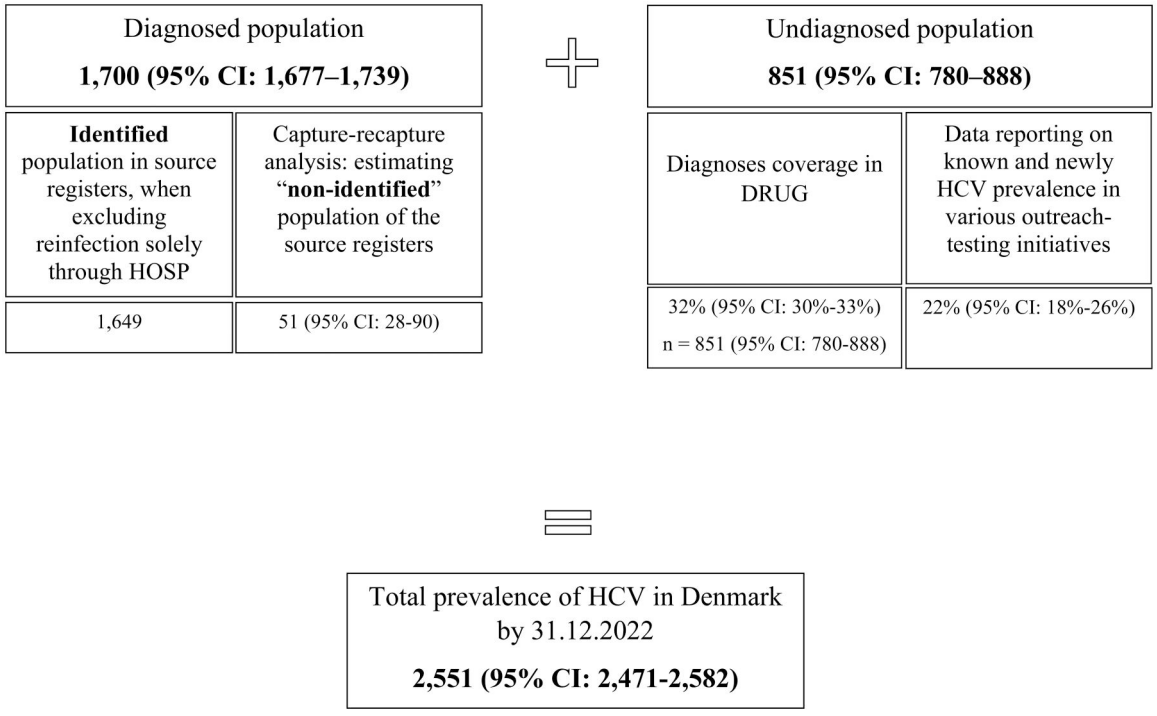

Figure 2. Study set-up with results.

chronic HCV, corresponding to a prevalence of 0.05–0.06%. This represents an approximately 86% reduction from the first estimate in 2007 (0.38%) and 76% reduction compared to 2016 (0.21%) and aligns well with the sustained decline in reported HCV cases over the past two decades (Figure 3). This is in agreement with a range of published results from Scandinavia and other European countries: In Norway, the number of new cases was estimated to fall from 726 in 2000 to 30 in 2022, and the estimated population from 11,000 in 2011 to 3,202 in 2022 [25]. In Iceland, the HCV population was 760 in 2016 of whom >95% were treated over 3 years during the TraP-HepC initiative [26]. In Switzerland, the estimated prevalence of HCV decreased from 0.5% (40,000) in 2015 to <0.1% (6–9,000) in 2020 [27].

Limitations and strengths

There are several limitations and uncertainties present in this study.

Underestimation of the 'non-identified' population due to positive dependency between source registries. Dependency between registers strongly influences the capture–recapture estimate of the 'non-identified' population. In 2022, the non-identified population was only 3% compared to 24% in 2007 and 19% in 2026, suggesting that the completeness of registers increased [2,6]. Positive dependence may lead to underestimation of the hidden population, and although this is adjusted for in the model, it may be insufficient, especially as the number of cases decreases. In our data, 27% of cases were identified only in HOSP, while cases only present in one of the other three registers were much smaller (5–14%). A higher-than-expected number of individuals were present in all four registers, suggesting mild positive dependency and a potential underestimation of the 'non-identified' population.

Data validity. A key assumption of capture–recapture analysis is accurate case identification and linkage. In Denmark, accurate linkage across the registries is largely ensured by the unique PIN system, although data validity varies across registers. The LAB and CLIN registers include HCV-RNA results and are therefore the most valid indicators of current infection. Incomplete/incorrect reporting may bias estimates in either direction. Treatment was recorded as prescriptions, and we do not know if the medicine was consumed. We assumed a 100% cure rate among treated patients but especially among drug uses, this may be lower. Among 7,482 patients treated, we had a post-treatment negative HCV test for 51% (3,828) in LAB. To support the assumption that the majority of treated patients are in fact cured, the national report for Western Denmark in 2020 observed 97.6% SVR [28]. REPORT primarily relies on

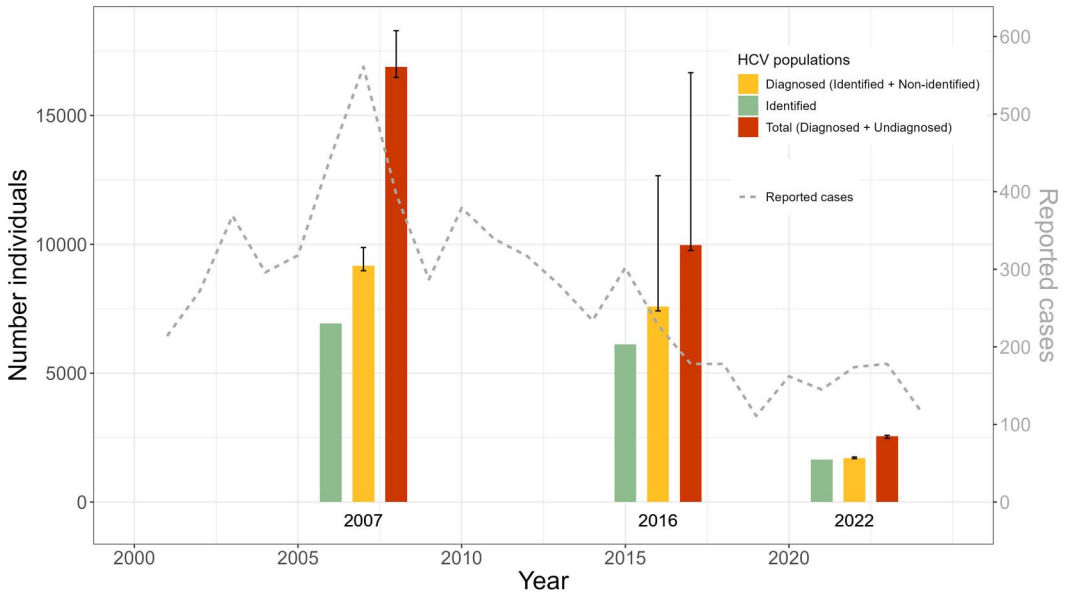

Figure 3. Trends of HCV prevalence in Denmark.

physician-based mandatory reporting and has historically had low coverage (<50%) [29]; also reflected in our findings, only 28% of diagnosed cases were notified, potentially leading to underestimation. From 2026, REPORT is expected to be supplemented with laboratory-based reporting, a change expected to improve reliability in the future [30]. HOSP represents the largest uncertainty. The validity of HOSP for gastroenterological diseases is known to be limited [31], and the ICD-10 classification system does not include a specific code for resolved HCV infection. Previous validation from the estimate conducted in 2016 found that fewer than 10% of the individuals only presented in HOSP had confirmed chronic HCV (PBC personal communication). As this group accounted for 27% of identified cases, the register likely inflates the prevalence estimate. Changes in HOSP coding practices in 2019 may also explain the observed increase in diagnoses, which was not mirrored in the other registers (Supplementary Figure S4).

The uncertainty of the undiagnosed fraction. We estimated that 32% of individuals in DRUG were undiagnosed, corresponding to 851 individuals of the diagnosed population. This assumes that HCV prevalence among untested individuals is similar to the prevalence among those tested. However, high-risk drug users may be more frequently in contact with treatment and health services and therefore more likely to be tested, so assuming the same HCV prevalence among tested and not tested drug users potentially lead to an overestimation of the undiagnosed population. The tested population was significantly older and with a higher proportion of females, and this supports that the HCV prevalence among the non-tested may be lower. So the 22% undiagnosed fraction among across the 10 Danish screening initiatives may be more correct (Supplementary Table S5). Additional uncertainty relates to the size of the PWID population. The most recent national estimate from 2009 identified approximately 13,000 PWID in Denmark, of whom half to two-thirds were not enrolled in treatment [32]. In agreement with this, only 55% of identified HCV cases were recorded in DRUG, despite that 85% of HCV transmissions in Denmark are related to drug use. Many PWIDs are probably not captured in DRUG and this contributed to the uncertainty of the true number of individuals living with undiagnosed HCV.

Finally, our registers were connected by PIN and therefore we were not able to examine the influence of HCV-positive migrants, who do not receive a PIN until they are granted residence permit. Among identified cases since 2016 the proportion of patients from outside Western Europe was 20% with no increase over the years. A recent international review estimated the chronic HCV prevalence among migrants to 0.7% (15 times higher than the current Danish HCV estimate) and as the yearly number of immigrants from outside Western Europe is in the order of 50.000/year this could mean an influx of 350 HCV positive persons in Denmark per year – of whom most will receive a permanent PIN within one year [33], but this group is not systematically offered HCV testing. In Norway, the proportion of migrants

among HCV was estimated to 7–16% in several studies but as the prevalence of HCV among PWIDs continue to decrease up to 1/3 of the total HCV infected population in Norway could be immigrants in 2022 [25]. This suggests that the HCV prevalence in Denmark including migrants could be higher than our estimate.

A major strength of this study is the ability to compare results with national estimates from 2007 [2] and 2016 [6] using similar methodology. Furthermore, Denmark's longstanding tradition of comprehensive registry data and linkage *via* the unique PIN system substantially strengthens the analysis.

Interpretation

The substantial reduction in HCV prevalence over recent decades likely reflects a combination of expanded treatment access and high mortality in the affected population (Supplementary Figure S5). Similar declines in prevalence, alongside increased treatment uptake, have been observed in Norway and Sweden following the removal of treatment restrictions and implementation of outreach programs [25,34]. In addition, HCV transmission may have decreased, as injecting drug use appears to have declined in Denmark, reflected by a reduced proportion of new treatment entrants reporting heroin injection [32,35].

As a result of this study, a major initiative approaching elimination is currently ongoing. The initiative contacts all untreated individuals with HCV identified in this study to ensure testing and treatment are offered (Call-In Project). Based on similar initiatives in Europe, 25–50% of individuals contacted with HCV will respond and be cured [36]. In addition, the Ministry of Health has endorsed that the 5,501 untested individuals we identified in DRUG – with an estimated 22–32% risk of untreated HCV – will be contacted and offered HCV testing and linkage to care in 2026 (Test and Treat Project). The framework for monitoring and supporting HCV elimination efforts is also applicable to other countries with comprehensive national health registers, such as the Scandinavian countries. Expanding testing in high-risk groups is crucial not only to increase diagnostic and treatment coverage, but also to prevent disease progression and reduce transmission within vulnerable communities.

In conclusion, our study demonstrates a substantial decline in HCV prevalence in Denmark by 2022. Although the WHO diagnostic coverage of 90% and treatment coverage of 80% for HCV were not reached, the public health initiatives that this study have started suggests that we will reach these target before 2030.

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Author contributions

CRediT: **Signe Freja Storgaard**: Conceptualization, Formal analysis, Methodology, Project administration, Visualization, Writing – original draft; **Inge Petersen**: Data curation, Formal analysis, Methodology, Writing – review & editing; **Gordon Hay**: Methodology, Validation, Writing – review & editing; **Signe Bollerup**: Resources, Writing – review & editing; **Maria Wessman**: Resources, Writing – review & editing; **Nina Weis**: Resources, Writing – review & editing; **Lars Haukali Omland**: Resources, Writing – review & editing; **Birgit Røge**: Resources, Writing – review & editing; **Alex Lund Laursen**: Resources, Writing – review & editing; **Lone Hagens Mygind**: Resources, Writing – review & editing; **Henrik Krarup**: Resources, Writing – review & editing; **Toke Seierøe Barfod**: Resources, Writing – review & editing; **Lone Galmstrup Madsen**: Resources, Writing – review & editing; **Anders Koch**: Resources, Writing – review & editing; **Sandra Dröse**: Resources, Supervision, Writing – review & editing; **Anne Øvrehus**: Resources, Supervision, Writing – review & editing; **Peer Brehm Christensen**: Conceptualization, Data curation, Funding acquisition, Project administration, Resources, Supervision, Writing – review & editing.

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ORCID

Signe Bollerup http://orcid.org/0000-0001-9604-4582
Maria Wessman http://orcid.org/0000-0002-9417-5594

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