Master's thesis

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Hepatitis C testing uptake among hospitalized people who inject drugs

Opportunities to enhance the hepatitis C care cascade

Master's thesis in Public Health
Supervisor: Håvard Midgard
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Abstract

Title: Hepatitis C testing uptake among hospitalized people who inject drugs: Opportunities to enhance the hepatitis C care cascade

Background: Hepatitis C virus (HCV) infection is a major cause of chronic liver disease. The World Health Organization has committed to the goal of eliminating viral hepatitis as a public health threat by 2030. Untreated chronic HCV infection can lead to progressive liver fibrosis, cirrhosis, liver failure and hepatocellular carcinoma. Unless tested most people are unaware of their disease. In Norway, 80% of the people with HCV are infected through injecting drug use. People who inject drugs are often hospitalized for injection-related infectious diseases, drug-related complications, and mental health disorders. Hospitalization can therefore be an opportunity for HCV testing among people who use drugs. The OPPORTUNI-C study gave health care personnel lectures presenting key aspects of HCV epidemiology and care to increase HCV testing uptake.

Aim: The primary aim of this study is to describe the hepatitis C testing cascade and compare HCV testing uptake among people who inject drugs who were admitted for inpatient care in a Medical and Psychiatric Department at Lovisenberg Diaconal Hospital before and after an HCV educational campaign. Secondary aims are to assess the prevalence of HCV RNA among those tested and to examine if patient characteristics are associated with the probability of being tested.

Method: This is a quality assurance project assessing clinical activities regarding HCV testing in hospitalized people who inject drugs. This is done using retrospectively collected data from medical records in a random sample of individuals with a history of injecting drug use admitted for inpatient care at Lovisenberg Diaconal Hospital in 2018 and 2020.

Results: Testing uptake during hospitalization increased from 35% in 2018 to 56% in 2020 following lectures given to health care personnel in 2019. HCV RNA prevalence among tested individuals decreased from 23% in 2018 to 13% in 2020. In 2018 current opioid agonist treatment was associated with an increased likelihood of being tested for HCV, while in 2020 an increasing number of hospital admissions that year, and recent injecting drug use was associated with an increased likelihood of being tested. Improved testing was prominent among amphetamine users, increasing from 24% in 2018 to 52% in 2020.

Conclusion: From 2018 to 2020 the HCV testing uptake increased among hospitalized people who inject drugs. Hospitalization represents an excellent opportunity to improve HCV testing uptake among people who inject drugs.

Keywords: Hepatitis C virus, screening, people who inject drugs

Sammendrag

Tittel: Hepatitt C-testopptak blant sykehusinnlagte personer som injiserer rusmidler. Muligheter til å forbedre hepatitt C-behandlingskaskaden

Bakgrunn: Hepatitt C virus (HCV)-infeksjon er en viktig årsak til kronisk leversykdom. Verdens helseorganisasjon har forpliktet seg til et mål om å eliminere viral hepatitt som en trussel mot folkehelsen innen 2030. Uten behandling kan kronisk HCV-infeksjon føre til progressiv leverfibrose, skrumplever, leversvikt og leverkreft. HCV-smitte gir sjelden symptomer og uten å bli testet er de fleste uvitende om sykdommen. I Norge er 80% av de som har HCV smittet gjennom sprøytebruk. Personer som injiserer rusmidler blir ofte innlagt på sykehus for injeksjonsrelaterte sykdommer, rusrelaterte komplikasjoner og psykisk sykdom. Sykehusinnleggelse kan derfor representere en mulighet for HCV-testing blant personer som injiserer rusmidler. OPPORTUNI-C-studien gjennomførte undervisning for helsepersonell om HCV epidemiologi og behandling med mål om å øke HCV testopptaket.

Hensikt: Hovedmålet med denne studien er å beskrive HCV-testkaskaden og sammenligne HCV-testopptak blant personer som injiserer rusmidler innlagt på medisinsk og psykiatrisk avdeling ved Lovisenberg diakonale sykehus før og etter en HCV undervisningskampanje. Sekundære mål er å vurdere forekomsten av hepatitt C-virus RNA blant de som er testet og undersøke om pasientkarakteristikker er assosiert med sannsynligheten for å bli testet.

Metode: Dette er et kvalitetssikringsprosjekt som vurderer klinisk praksis vedrørende testing av HCV blant personer som injiserer rusmidler innlagt på sykehus. Dette gjøres ved å undersøke retrospektive data i journaler hos et tilfeldig utvalg av personer som injiserer rusmidler innlagt ved Lovisenberg diakonale sykehus i 2018 og 2020.

Resultat: HCV-testopptak under sykehusinnleggelse økte fra 35 % i 2018 til 56 % i 2020, i etterkant av undervisning gitt til helsepersonell i 2019. Prevalensen av HCV RNA blant de testede gikk ned fra 23 % i 2018 til 13 % i 2020. I 2018 var nåværende substitusjonsbehandling assosiert med økt sannsynlighet for testing, mens i 2020 var et økende antall sykehusinnleggelser det året, og nylig injeksjonsbruk assosiert med økt sannsynlighet for testing. Forbedring i testopptak var mest fremtredende blant amfetaminbrukere, og økte fra 24 % i 2018 til 52 % i 2020.

Konklusjon: Fra 2018 til 2020 økte HCV-testopptaket blant sykehusinnlagte personer som injiserer rusmidler. Sykehusinnleggelse representerer en utmerket mulighet til å forbedre HCV-testing blant personer som injiserer rusmidler.

Nøkkelord: Hepatitt C virus, testing, personer som injiserer rusmidler

Preface

This study is conducted as part of a Master of Philosophy in Public Health at the Norwegian University of Science and Technology (NTNU). The Centre for Elimination of Hepatitis (SELIHEP) in Oslo facilitated and made this study possible. All data were collected at Lovisenberg Diaconal Hospital in Oslo during the autumn of 2021.

My reason for choosing this theme is a special interest in hepatitis C because of the many people I have met during 13 years of work as an infectious diseases nurse at St. Olav's University Hospital in Trondheim, and a wish to improve the care for people who inject drugs.

To my supervisors at SELIHEP; Håvard Midgard, Ane Kristine Finbråten and Olav Dalgard, and to my supervisor at NTNU Tom Ivar Lund Nilsen: thank you for all conversations, motivation, and feedback.

Also, a big thank you to family and friends for letting me stay with you during my time in Oslo.

Trondheim, May 2022

Maja Skaland

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1 Introduction

1.1 Hepatitis C

Hepatitis C is an inflammation of the liver caused by the bloodborne hepatitis C virus (HCV) (WHO, 2021a). HCV infection has an important impact on global health at a level comparable to human immunodeficiency virus (HIV), tuberculosis, and malaria, but has despite this largely been ignored as a health priority (WHO, 2016). This seems now to change. Worldwide, an estimated 58 million people have a chronic HCV infection , and in 2019 approximately 290.000 people died of the disease (WHO, 2021a). This makes HCV a major cause of chronic liver disease (Pawlotsky et al., 2018) and a public health threat (WHO, 2018).

The natural history of HCV infection is highly variable (Pawlotsky et al., 2018). Chronic infection can lead to progressive liver fibrosis, cirrhosis, liver failure and hepatocellular carcinoma (Hajarizadeh et al., 2013; Spearman et al., 2019). The life time risk of decompensated cirrhosis and hepatocellular carcinoma is 10-20% in people living with chronic HCV infection over a period of 20-30 years (Spearman et al., 2019). Patients with chronic HCV also have a lower quality of life than the general population, where the driving factors are fatigue, depression, and cognitive impairment (Negro et al., 2015).

HCV is transmitted through percutaneous exposure for infected blood (Den norske legeforening, 2019). I Europe, people who inject drugs are at highest risk of acquiring HCV by sharing needles and equipment (Den norske legeforening, 2019; WHO, 2021a). In Norway 80% of the people living with HCV are infected through injecting drug use (Dalgard et al., 2003).

More than 75% of new HCV infections are asymptomatic (Spearman et al., 2019), and unless tested, infected people are most likely unaware of their disease (WHO, 2018). When symptoms do appear it is often as a sign of advanced liver disease (CDC, 2020). In Norway, 30-40 people develop hepatocellular carcinoma each year because of HCV infection, and just as many develop liver failure. Yearly, 10-20 liver transplantations are performed because of complications related to HCV and approximately 40 people die (Helsedirektoratet, 2019). A Norwegian cohort study found liver disease to be the main cause of death in people who inject drugs dying at an age of 50 years or older (Kielland et al., 2013). A modelling study from 28 European Union countries found only 36% of the people living with HCV infection to be diagnosed (European Union, 2017).

1.2 Treatment

The goal of HCV therapy is to cure infection, and through this prevent complications of HCV related liver disease, improve quality of life, remove stigma, and prevent further transmission of HCV (Pawlotsky et al., 2018; Spearman et al., 2019). In 2014 new direct-acting antiviral therapy was introduced for the treatment of HCV infection (Götte & Feld, 2016; Helse- og omsorgsdepartementet, 2018). Direct-acting antiviral therapy can halt or even reverse progression of liver disease (Helsedirektoratet, 2019; Zhou et al., 2016). The 8-12 weeks oral treatment has very few side effects, is safe and will cure the infection in more than 95% of the treated (Helsedirektoratet, 2019). The new therapy has changed the HCV treatment paradigm and has made elimination a possibility (Martinello et al., 2020). As treatment eligibility expands, the focus is shifting towards screening, diagnosis and linkage to care (Zhou et al., 2016).

1.3 Elimination strategies

In 2016, the World Health Organization (WHO) committed to the goal of eliminating viral hepatitis as a public health threat by 2030 (WHO, 2017). Elimination was defined as an 80% reduction in new infections and 65% reduction in HCV-related mortality compared to the 2015 baseline (WHO, 2017). Achieving the elimination goals requires giving hepatitis a higher priority in public health responses (WHO, 2016). With the WHO's HCV elimination targets and available direct-acting antiviral therapy, many countries have developed national HCV strategies (Scott et al., 2018). In 2018 the Norwegian Ministry of Health and Care Services launched a national viral hepatitis strategy with the ambitious goal of 90% reduction in prevalence by the end of 2023, and that no one should die or become seriously ill because of HCV infection (Helse- og omsorgsdepartementet, 2018; Helsedirektoratet, 2019).

To reach the WHO targets, evidence-based testing strategies will be essential (Scott et al., 2018). In 2021 WHO wrote an interim guidance on validation of the elimination goals using absolute impact targets, with an annual HCV incidence of ≤ 2 per 100 PWID and HCV related annual mortality rate of ≤ 2 per 100 000 people (WHO, 2021b). A Norwegian monitoring plan for the elimination of HCV is under construction (K. Kielland & L. Wüsthoff, personal communication, 09.05.22). As of June 2018, only 12 of 194 countries were on track to meet the elimination targets (Spearman et al., 2019).

Oslo municipality has developed its own plan to eliminate HCV as a health threat to people who inject drugs in Oslo. The main aims are in accordance with the ones stated in the National strategy, but in addition Oslo municipality has a separate goal of a prevalence ≤ 5% among people who inject drugs within 2023 (Velferdsetaten, n.d.).

1.4 Epidemiology in Norway

HCV has been notifiable to the Norwegian Surveillance System for Communicable Diseases (MSIS) since 1990. Different indications for notification have been used since then and the data has some limitations (Kileng et al., 2019). In the period 1990-1992 the presence of anti-HCV antibodies were to be notified, and from 1992-2007 only acute hepatitis C (MSIS, n.d.). From 2008 to 2015 both anti-HCV antibodies and HCV RNA should be notified, and from 2016 only HCV RNA positive cases (MSIS, n.d.). In a Norwegian study of HCV treatment uptake among people who have received opioid agonist treatment, only 57% of the treated patients were notified to MSIS (Midgard et al., 2016). In 2018, 639 cases were reported to MSIS (FHI, 2019). The Public Health Institute plan to strengthen the knowledge about occurrence of HCV in people who inject drugs, both prevalence and incidence, and assess the effect of the measures initiated towards 2023 (Helsedirektoratet, 2019).

Because population-based data is scarce, there are uncertainties regarding the HCV prevalence in Norway (Kileng et al., 2019). According to the Polaris Observatory HCV collaborators (2017), the viremic prevalence in Norway was thought to be 0.4% in 2015. The prevalence among people who inject drugs is however much higher. The prevalence of anti-HCV antibodies in patients enrolled in opioid agonist therapy was estimated at 50% in 2017 (Aas et al., 2020a). In Trondheim the prevalence found among people who use drugs was 61% in the period 2015-2017 (Hannula et al., 2021). Until 2015, the HCV prevalence among people who inject drugs in central Oslo has been stable around 40-50% (Helse- og omsorgsdepartementet, 2018).

Incidence is more difficult to measure than prevalence as most new cases are asymptomatic. The lack of data on incidence makes it harder to make knowledge based preventive decisions. However, one way to calculate incidence and burden of HCV is through modelling, and it has been estimated that the incidence of HCV among people who inject drugs in Norway was 381 new infections in 2015 (Meijerink et al., 2017).

In Norway, the number of people who recently injected drugs has been stable around 9000 individuals (Aas et al., 2020b). In Oslo, the number is estimated to be 2000 individuals (Velferdsetaten, n.d.). Approximately 7000 people who inject drugs both former and currently are estimated to live with hepatitis C (Aas et al., 2020b).

1.5 The hepatitis C care cascade

The HCV care cascade is an illustration of the HCV continuum depicted in steps. The presentation can vary and count up to 10 steps (Pawlotsky et al., 2020). The first step represents the number of people living with HCV infection, the next step the proportion diagnosed, being assessed for treatment eligibility, initiated treatment, completed treatment and finally to cure (Zhou et al., 2016). The function of a cascade of care is to describe how many people have progressed through each step. Cascade of care analyses can be used to identify where intensified efforts are needed to secure retention in the cascade of care. Cascade of care reporting can indicate whether countries are on track with the key targets (Safreed-Harmon et al., 2019). Even with unlimited access to treatment, modelling suggests interventions to improve the HCV cascade of care among people who use drugs are required to reach the elimination goals (Scott et al., 2017).

1.6 Testing, screening, and diagnosis

The steps of the care cascade can be grouped into phases where the first phase is screening and diagnosis (Pawlotsky et al., 2020). Testing is crucial to succeed with the elimination strategy (Helsedirektoratet, 2019) since eliminating HCV infection as a public health threat requires diagnosing 90% of those infected (Helsedirektoratet, 2019; WHO, 2018). Accurate data on prevalence and incidence are needed to analyse the magnitude of infection and design suitable public health interventions accordingly (Pawlotsky et al., 2018). Countries have developed different strategies based on local epidemiology and dominant transmission routes. Screening strategies can be universal, targeted, or a combination of the two. Different strategies include screening of populations at risk of infection, birth cohort screening, and general testing based on intermediate to high seroprevalence (Pawlotsky et al., 2018; Spearman et al., 2019).

According to the Norwegian Public Health Institute people who could have been exposed to HCV should be tested (FHI, 2019).

Table 1. *Indications for HCV screening*

Indication list
People who ever injected drugs
People who have snorted cocaine
People living with HIV
Men who have sex with men
The recipients of blood products before 1992 in Western-Europe (including Norway), North America, Japan, New Zealand and Australia, and recipients of blood products at any time in countries other than those mentioned
Immigrants from countries with a high prevalence of hepatitis C
People subjected to unsafe injections in the health services
People with an elevated alanine aminotransferase level
People subjected to accidental needle-sticks
People in dialysis
People tattooed under unsafe hygienic circumstances
People who have received dental treatment or professional shaving or similar in medium- and high endemic places

(FHI, 2019;Testing for hepatitt C, own translation from Norwegian)

This is an accordance with advices by the Norwegian Directorate of Health which states that everyone who is or has been at risk of contracting HCV must be offered screening (Helsedirektoratet, 2019).

After exposure to HCV, anti-HCV antibodies will be produced within 5-12 weeks. HCV ribonucleic acid (RNA) is often detectable 1-2 weeks after virus transmission (FHI, 2019). Screening is based on the detection of anti-HCV antibodies (Pawlotsky et al., 2018). An anti-HCV test can be positive due to acute, chronic, or resolved infection. To distinguish ongoing infection from previous infection, a test to detect HCV RNA is required (Scott et al., 2018). A person previously successfully treated or spontaneously cleared for HCV RNA will continue to have anti-HCV antibodies. Since anti-HCV antibodies do not protect against future infections, reinfection is possible (Helsedirektoratet, 2019). In most settings, a diagnosis of HCV infection requires two steps (Scott et al., 2018) Most labs test for antibodies in step one and RNA in step two (Pawlotsky et al., 2018). RNA tests are not used as initial screening due to higher associated costs (Scott et al., 2018).

Standard-of-care HCV testing requires serum or plasma by venepuncture but testing for HCV is also possible using other alternatives. Point-of-care testing can detect anti-HCV antibodies through oral fluids and whole blood from finger-stick (Grebely et al., 2017). Point-of-care tests were limited by only measuring anti-HCV antibodies (Grebely et al., 2017), but in 2015 point-of-care diagnostic tests for HCV RNA was launched (Scott et al., 2018). Dried blood spot testing is a method that can be used for testing of anti-HCV antibodies, HCV RNA and genotype testing (Spearman et al., 2019). These methods especially presents a wider opportunity for screening outside the health structures (Trucchi et al., 2016). HCV core antigen is a surrogate of HCV replication and can be used to detect active infection, but the test has a lower analytical sensitivity than PCR (Chevaliez et al., 2014). These tests can be used to facilitate test and treat programmes important for elimination of HCV (Spearman et al., 2019).

1.7 Hospitals as an arena for hepatitis C care

Various arenas are engaged in HCV screening, such as opioid substitution clinics, low threshold services and prisons. Hospitals also constitute a suitable arena for screening, and this is in line with The Norwegian Health Directory, Public Health Institute, and municipalities wish for new ways to increase testing uptake (Helse- og omsorgsdepartementet, 2018). People who inject drugs constitute a marginalized group in society and many people with HCV infection are less engaged with healthcare services (Pawlotsky et al., 2020; Scott et al., 2018). Data from Akershus University Hospital suggests that most people treated for HCV infection are people with former injecting drug use or people infected before immigration to Norway. People who inject drugs are less likely to make use of the treatment offer, than the remaining population (FHI, 2019). In Australia, assessment and treatment for HCV RNA positive individuals was studied in people admitted to the hospital for other reasons. The study included people previously lost to follow-up from other services, illustrating the opportunities in reaching those who do not access care elsewhere (Chiong & Post, 2019). Especially young people who inject drugs and not receiving opioid agonist therapy may be hard to reach, even with low threshold services (Midgard et al., 2020). However, this population is at risk of emergency hospitalization due to diseases associated with their drug use (Midgard et al., 2020).

1.7.1 Care bundle for mental health and substance use

In September 2018, the Norwegian Directorate of Health launched a care bundle for mental health and substance use. In the care bundle it is emphasized that people who inject drugs should be examined for complications of their injection practice and tested for bloodborne infections on all occasions they are in contact with health services (Helsedirektoratet, 2018b). The overall aims of the care bundle is to contribute to a better health, increased quality of life and increased life expectancy for this patient group, in addition to a coherent and coordinated patient processes (Helsedirektoratet, 2018b). Patients could be referred to the care bundle from January 2019 (Helsedirektoratet, 2018b).

1.7.2 OPPORTUNI-C

In 2019, OPPORTUNI-C was initiated in several hospitals in the Oslo region. OPPORTUNI-C is a pragmatic stepped wedge cluster randomized trial comparing the efficacy of immediate HCV treatment initiation with the current standard of care, referral to outpatient care at discharge, among people who inject drugs admitted for inpatient care (Midgard et al., 2020). As a part of the introduction phase of the study, health care personnel were given lectures presenting key aspects of HCV epidemiology and care, as well as the content of the care bundle. The key point was to increase testing uptake with education on who and when to test for HCV, according to guidelines. Information was also distributed to health care personnel via e-mail, newsletters, flyers and posters (Appendix 1) (Midgard et al., 2020).

1.7.3 Prior research

Globally, similar studies have been performed. Systematic reviews from 2015 (Aspinall et al., 2015) and 2016 (Zhou et al., 2016) identified 23 studies on improving HCV testing uptake in various settings. Of these, only one study came from a hospital setting. This was a study from Australia which found HCV testing in psychiatric inpatients to increase after an educational and counselling program targeting patients (Lacey et al., 2007). In three studies from the United States, clinician reminders have been shown to increase

HCV testing, compared to no reminders (Zhou et al., 2016). These studies were performed in a primary care setting and the target population was patients from a high-prevalence birth cohort or HCV associated risk behaviours (Zhou et al., 2016). Because local epidemiology and health care systems vary, data from a Norwegian hospital setting is of value.

1.8 Aim and objectives

The primary aim of this study is to describe the hepatitis C testing cascade and compare HCV testing uptake among people who inject drugs who were admitted for inpatient care in a Medical and Psychiatric Department at Lovisenberg Diaconal Hospital before and after an HCV educational campaign. Secondary aims are to assess the prevalence of HCV RNA among those tested and to examine if patient characteristics are associated with the probability of being tested.

2 Methods

2.1 Study design

This is a quality assurance project assessing clinical activities regarding testing of HCV in hospitalized people who inject drugs. This is done using retrospective data from medical records.

2.2 Setting

Data was collected from September to December 2021 at Lovisenberg Diaconal Hospital. Lovisenberg Diaconal Hospital is situated in central Oslo and provides medical services for the districts Gamle Oslo, Sagene, Grünerløkka and St. Hanshaugen (Byleksikon, n.d.). Lovisenberg Diaconal Hospital offers treatment within internal medicine, mental health and interdisciplinary specialized drug treatment (Lovisenberg Diakonale Sykehus, 2022). The Department of Medicine and Department of Psychiatry at Lovisenberg Diaconal Hospital were both clusters in the OPPORTUNI-C trial.

2.3 Study population

The study population consists of people who inject drugs, or people with drug administration methods associated with risk of contracting HCV, who were admitted to the Medical Department and Psychiatric Department at Lovisenberg Diaconal Hospital during 2018 and 2020. The study population was identified as shown in Figure 1, using relevant International Statistical Classification of Diseases and Related Health Problems, 10th Edition (ICD-10) codes for injecting drug use and injecting-related infectious disease. If a patient had a relevant ICD-10 diagnosis code, but no indication for HCV testing, they were excluded.

Table 2. *The ICD-10 diagnosis codes used to identify the study population*

ICD-10 codes used as a proxy for (injecting) drug use	ICD-10 codes used as a proxy for injecting-related infectious diseases
F11 Mental and behavioural disorders due to use of opioids	B18.2 Hepatitis C infection
F14 Mental and behavioural disorders due to use of cocaine	I33 Acute and subacute endocarditis
F15 Mental and behavioural disorders due to use of other stimulants	I38 Endocarditis, valve unspecified
F19 Mental and behavioural disorders due to multiple drug use and use of other psychoactive substances	I39 Endocarditis and heart valve disorders in diseases classified elsewhere
R78.1 Finding of opiate drug in blood	I80 Phlebitis and thrombophlebitis
R78.2 Finding of cocaine in blood	L02 Cutaneous abscess, furuncle, and carbuncle
R78.4 Finding of other drugs of addictive potential in blood	L03 Cellulitis
T40 Poisoning by narcotics and psychodysleptics	M72.6 Fibroblastic disorders, necrotizing fasciitis
T43.6 Poisoning by psychostimulants with abuse potential	M86 Osteomyelitis
Z50.3 Drug rehabilitation	
Z71.5 Drug abuse counselling and surveillance	

2.4 Time period

As mentioned above, the time periods of 2018 and 2020 in the study were chosen to be before and after the educational campaign and increased focus on HCV in 2019. The OPPORTUNI-C trial included patients from October 2019, and the first patients could be referred to the care bundle for mental health and substance use from January 2019 (Helsedirektoratet, 2018a).

2.5 Data collection process

The relevant ICD-10 diagnosis codes were selected by specialists in infectious diseases and gastroenterology. The IT-department at Lovisenberg Diaconal Hospital identified the journals of patients admitted to the Medical Department and Psychiatric Department in 2018 and 2020 with the relevant diagnosis codes. An Excel file containing a list of patients was placed in a secure research database at Lovisenberg Diaconal Hospital where only study personnel were given access to the data. The patients on the list were identifiable only by Norwegian Patient Registry-ID. The journals were read one by one using the Norwegian Patient Registry-ID to find the patient in the Distributed Information and Patient Data System in Hospitals (DIPS). If a patient had an indication for HCV testing, data was collected as per protocol, if not, the patient was excluded. The list of patients counted 998 individuals with 1781 episodes of admission. Due to workload, it was necessary to reduce the number of journals to read. To avoid risk of selection bias, the IT-department randomized patients using Qlik random number generator. 313 journals were read in the randomized order and by department and year. When the data collection process was complete, the datafile containing information on testing and exposure variables was moved to Services for Sensitive Data for analysis. Services for Sensitive Data offers a secure project area to store and analyse sensitive research data (University of Oslo, n.d.).

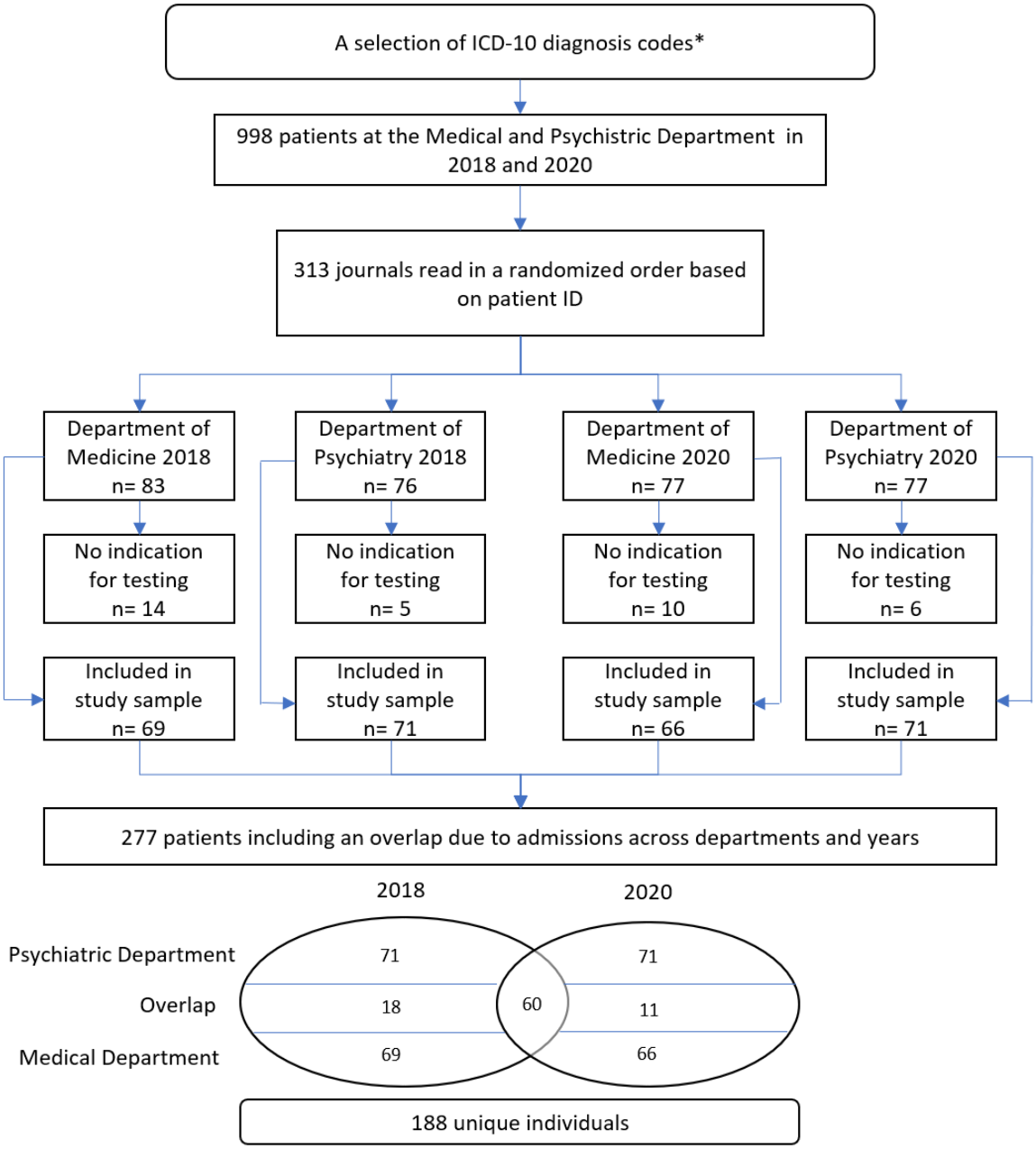

Figure 1. *The data collection process and the distribution of patients in departments and years, as well as the overlapping numbers.*

*Shown in Table 2.

2.6 Variables

The variables recorded are shown in Table 3 and 4. The dependent variable testing was recorded for every hospital admission, while the independent variables were recorded on the baseline admission for every patient in each department and year.

Table 3. *Testing, dependent variable*

Category	Variables	Description	Method of collection
HCV-testing	Indication for testing	As defined by the Norwegian Public Health Department	Recorded manually
	Tested	Yes/no. Counts as yes if tested within the last 12 months	Extracted automatically
	Anti-HCV	If tested; Positive/ Negative	Recorded manually
	HCV RNA	If tested; Positive/ Negative	Recorded manually

Blood samples from Lovisenberg were analysed at Oslo University Hospital. Anti-HCV antibodies are detected by the electrochemiluminescence immunoassay "ECLIA" on the Cobas e801 instrument (Brukerhåndbok i mikroboiologi OUS, 2021). Specificity is measured to be 99.5% in blood donor samples, and a seroconversion sensitivity of 100% (Alborino et al., 2011).

Quantitative detection of HCV RNA was done with real-time polymerase chain reaction (PCR) (Brukerhåndbok i mikrobiologi OUS, 2021). HCV RNA was detected on Roche Cobas AmpliPrep-Cobas TaqMan Version 2.0 until November 2018, when switching to the Roche Cobas 6800 system. The new system is fully automatic and contributes to reduced response time (Klundby & Norrvall, 2018). The lower limit of detection is 15 international units (IU)/ml, as recommended (Pawlotsky et al., 2018).

Table 4. *Independent variables recorded*

Category	Variables	Description	Method of collection
Socio-demographic characteristics	Age	Years at admission	Extracted automatically
	Sex	Male/female	Extracted automatically
	Housing	Own housing/ municipal housing/ institution/ low threshold/ prison/ without permanent residence	Recorded manually
	Nationality	Country of birth, as documented in journal	Recorded manually
	Source of income	Paid work/ sick leave/ work assessment allowance (AAP)/ disability pension/ social benefits	Extracted automatically

	Marital status	Unmarried/married/separated/ divorced	Extracted automatically
Drug and alcohol use	Hazardous alcohol consumption	Yes/ no. Recorded manually. Defined as 21 units or more for men and 14 units or more for women, or by relevant diagnosis code	Recorded manually
	Opioid agonist treatment	Methadone/levomethadone/ buprenorphine/buprenorphine depot/buprenorphine naloxone	Recorded manually
	Main drug	Main drug(s) used as described in journal	Recorded manually
Admissions	Primary diagnosis	The primary ICD-10 diagnosis code for the current admission	Extracted automatically
	Secondary diagnosis	The secondary diagnosis recorded for the current admission	Extracted automatically
	Durance of hospital admission	Reported in days, hours, and minutes	Extracted automatically

To make appropriate categories some values were recoded before statistical analysis. Age was both analysed continuous and classified into categories of 18-40 and ≥40 years. Patients <40 years are in literature described as younger individuals (Spearman et al., 2019). Additionally, this made approximately equally sized categories. Drugs were grouped into stimulants, such as amphetamines and cocaine and depressants such as heroin and morphine. Number of hospital admissions were grouped into 1,2 and ≥3 to examine possible associations with an increasing number of admissions and to separate those frequently in and out of hospital.

Housing was dichotomised into stable and unstable housing. The stable housing category includes own or rented apartment, as well as municipal housing. Unstable housing is typically defined as not being fixed and is an independent risk factor of HCV infection because of high-risk behaviour associated with HCV transmission (Arum et al., 2021). The unstable housing group includes low threshold housing, institution, prison and being without permanent residence.

2.7 Statistical analysis

The data was exported from Excel to Stata using 7-zip encryption and had to be processed to conduct data analysis. Initially every admission had a row in Stata, several for each patient if hospitalized several times. To conduct analysis without accounting for repeated measures, the data was reconstructed to capture all information on each individual in a single row. Patients were defined as tested for HCV if a test had been conducted during any admission in the previous 12 months.

2.7.1 Descriptive statistics

In the baseline characteristics, all data is summarized by department and year and reported as median (range, IQR) or N (%) as appropriate.

In the population studied, some patients are frequently in and out of hospital and therefore appear in both departments and years. To investigate whether those who are admitted in both years differentiate from the other patients, the characteristics of the 60 overlapping patients are displayed in a separate table as well.

2.7.2. HCV-testing cascade

The HCV testing cascade illustrates to what extent those at risk of contracting HCV are tested for HCV, either while admitted for inpatient care or in the previous 12 months. A test performed within 12 months of admission is registered as a success as Norwegian guidelines recommends people at risk to be tested every 6-12 months (Den norske legeforening, 2019; FHI, 2019; Helsedirektoratet, 2019). Lastly, the testing cascade illustrates how many people who have HCV out of those tested.

In the testing cascades the Medical and Psychiatric Department are combined, looking only at the separate years. The patients are counted so that no individual, test, or result is counted twice, and so the bar chart illustrates the cascade without the overlap of patients between departments.

2.7.3 HCV-testing uptake

HCV-testing uptake is presented as the proportion of patients tested in 2018 and 2020, the absolute difference in proportions, as well as the odds ratio between the proportions. Since 60 patients were admitted in both 2018 and 2020 the groups are not fully independent of each other. As this may influence the precision of the estimated proportions and their differences, analysis was done in both the full sample and a restricted sample excluding patients who were admitted in both 2018 and 2019. Data are also presented separately for each department. Statistical precision of all estimates is given as a 95% confidence interval (CI).

2.7.4 Prevalence

When measuring the prevalence of HCV in this specific population, the numerator is the number of people with a positive HCV RNA, and the denominator is the number of people tested for HCV by either anti-HCV or HCV PCR. Counting people with a positive HCV RNA was done manually to ensure that no individual was counted twice due to overlap between departments and years.

2.7.5 Patient characteristics associated with testing

Logistic regression was used to estimate odds ratios with 95% confidence intervals for HCV-testing (yes, no) associated with age, sex, housing status, opioid agonist treatment, recent injecting drug use, drugs used and number of hospitalizations. The analyses were conducted separately for the 2018 and 2020 samples. Regression analysis can be used as a method to deal with confounding (Rothman, 2012). All associations were adjusted for age (years) and sex (woman, man), variables that are thought to be potential confounders in this population (Dalgard et al., 2003; Kileng et al., 2019). The remainder variables were not mutually adjusted since they may partly capture the same phenomena.

As data was recorded retrospectively from the medical journal, some data are missing. The association between testing and variables is therefore based on a varying number of people, and this is displayed in the results, as well as the number of people tested. Age and sex are collected for all patients, and so the number of people included in the crude and adjusted analyses is the same.

2.7.6 Change in testing uptake by variable

Possible changes in the differences in testing uptake according to patient characteristics are displayed as a bar graph showing the percentage tested in 2018 and 2020, stratified by age, sex, recent injecting drug use, opioid agonist therapy and main drug used.

Data analysis was conducted using Stata Statistical Software, release 17.

2.8 Ethics and safety

This study is categorized as a quality assessment project with an overall aim of ensuring the quality of work that has already been carried out. In a guide to the Act of June 20th, 2008 no. 44 on medical and health research (the Health Research Act), it is stated that quality assurance can be defined as projects and evaluations that aims to check that diagnostics and treatment provide the intended results (Regjeringen, 2010). The Law of Health care personnel §26 states that employees in health services can gain access to medical information for quality assurance purposes (Helsepersonelloven, 1999).

The OPPORTUNI-C study is approved by the Regional Committee for Medical Research and Ethics (REK) (reference number 2019–128). Quality assessment projects do not require approval from REK (REK, n.d.). A request was still sent to REK regarding application, but they confirmed that the study could be carried out as planned. An application was submitted to The Data Protection Official at Lovisenberg Diaconal Hospital, who approved the study (Appendix 2). In accordance with a request from the Data Protection Official, all data was collected while situated at Lovisenberg Diaconal Hospital. An application was sent and granted for storage space on the secure servers at Lovisenberg Diaconal Hospital.

To enhance the care to this patient group, assessing the current status is a way to better understand where and how to improve the quality of health care offered.

3 Results

This study included a total of 188 unique patients admitted to Lovisenberg Diaconal Hospital in 2018 and 2020 with a relevant ICD-10 diagnosis code. Of these, 60 patients were admitted in both 2018 and 2020. In 2018, 18 patients were admitted to both departments, and in 2020 11 patients were admitted to both departments. Irrespective of this overlap, 69 patients were admitted to the Medical Department and 71 to the Psychiatric Department in 2018. Corresponding numbers for 2020 are 66 and 71.

3.1 Characteristics of the study population

Table 5 show descriptive statistics of the study population according to year and department.

Table 5. *Baseline characteristics*

	2018		**2020**	
	Medicine	Psychiatry	Medicine	Psychiatry
Sample by department and year, n (%) *	69(49)	71(51)	66(48)	71(52)
Age, median (range)	46 (21-66)	36 (21-61)	48 (21-66)	38 (23-61)
Sex				
Male	47 (68)	45 (63)	46 (70)	46 (65)
Female	22 (32)	26 (37)	20 (30)	25 (35)
Nationality				
Norwegian	58 (84)	53 (75)	53 (80)	50 (70)
Other	9 (13)	18 (25)	10 (15)	20 (28)
Missing	2 (3)	0 (0)	3 (5)	1 (2)
Housing status				
Own accommodation	30 (43)	19 (27)	25 (38)	25 (35)
Municipal housing	5 (7)	11 (15)	9 (14)	15 (21)
Institution	10 (14)	16 (23)	10 (15)	16 (23)
Prison	2 (3)	2 (3)	1 (2)	1 (1)
Low threshold	8 (12)	13 (18)	12 (18)	7 (10)
Without permanent residence	5 (7)	7 (10)	5 (8)	3 (4)
Unknown	8 (12)	3 (4)	3 (5)	4 (6)
Income				
Paid work	3 (4)	1 (1)	2 (3)	5 (7)
Sick leave	1 (1)	1 (1)	1 (1)	1 (1)
Work assessment allowance	10 (14)	19 (27)	7 (11)	15 (21)
Disability pension	19 (28)	33 (46)	22 (33)	34 (48)
Social benefits	9 (13)	10 (14)	7 (11)	9 (13)
Unknown	27 (40)	7 (10)	27 (41)	7 (10)
Injecting drug use in the last 6 months				
Yes	32 (46)	34 (48)	40 (61)	31 (44)
No	25 (36)	14 (20)	8 (12)	25 (35)
Unknown	12 (17)	23 (32)	18 (27)	15 (21)
Main drug				
Heroin	19 (28)	6 (8)	25 (38)	5 (7)
Amphetamines	15 (22)	29 (41)	17 (26)	39 (55)
Heroin and amphetamine	7 (1)	30 (42)	9 (14)	13 (18)
Cocaine	3 (4)	3 (4)	0 (0)	5 (7)
Other	10 (15)	0 (0)	3 (5)	2 (3)
Unknown	4 (6)	3 (4)	12 (18)	7 (10)
Hazardous alcohol consumption				
Yes	15 (22)	21 (30)	14 (21)	19 (27)
No	41 (59)	21 (30)	32 (49)	20 (28)
Unknown	13 (19)	29 (40)	20 (30)	32 (45)
Length of hospitalization median number of days (IQR)	3.1 (0.8-8.9)	25.9 (4.9-48.9)	3.5 (1.0-7.4)	18.6 (5.1-47.2)
Number of times hospitalized during current year	32 (46)	30 (42)	27 (41)	27 (38)

1	12 (17)	11 (15)	21 (32)	20 (28)
2	25 (37)	30 (43)	18 (27)	24 (34)
≥3				
Opioid agonist treatment* (current)	28 (41)	12 (17)	34 (52)	15 (21)
*Opioid agonist treatment				
Methadone	19 (68)	8 (67)	20 (59)	6 (40)
Levomethadone	1 (4)	0 (0)	1 (3)	0 (0)
Buphrenorphine	2 (7)	2 (16)	6 (18)	2 (13)
Buphrenorphine naloxone	6 (21)	2 (16)	5 (15)	6 (40)
Buphrenorphine depot	0 (0)	0 (0)	2 (6)	1 (7)

*Some patients appear in both departments and years

There is a tendency for lower median age in the Psychiatric Department, 36 and 38 years versus 46 and 48 years in the Medical Department in 2018 and 2020, respectively. Heroin is most frequently used in the Medical Department, while amphetamine accounts for the highest numbers in the Psychiatric Department. Accordingly, there is a higher number of opioid agonist therapy in the Medical Department than in the Psychiatric Department. Length of hospitalization, counted as median number of days in the Medical Department, is 3.1 and 3.5 in 2018 and 2020 respectively, and 25.9 and 18.6 days in the Psychiatric Department. For both the Medical Department and Psychiatric Department the number of times hospitalized were higher in 2020 than 2018.

Table 6 shows patient characteristics of the 60 patients admitted in both 2018 and 2020.

Table 6. *Sample with overlap between years*

Patient characteristics of the overlapping sample, n (%)	
Age, median (range)	40.5 (21-64)
Sex	
Male	38 (63)
Female	22 (37)
Recent injecting drug use	
Yes	33 (55)
No	16 (27)
Unknown	11 (18)
Main drug	
Heroin	13 (24)
Amphetamines	17 (31)
Heroin and amphetamine	18 (33)
Cocaine	2 (4)
Other	2 (4)
Unknown	1 (2)
Opioid agonist therapy (current)	16 (27)
Ever tested	
Yes	49 (82)
No	11 (18)

There are no major differences between the full sample and the overlapping sample regarding patient characteristics. Both departments have overlapping patients, and so

the median age of 40.5 years in the overlapping sample is lower than median age in the Medical Department and higher than median age in the Psychiatric Department. The gender proportions are approximately the same. The majority have a history of recent injecting drug use, and heroin and amphetamine accounts for 88% of the drugs used.

3.2 The HCV testing cascade in 2018 and 2020

Figure 2 and 3 illustrates the testing cascades in 2018 and 2020.

In 2018, 122 people with the relevant ICD 10-diagnosis codes had an indication for HCV testing. Out of these, 55 (45%) had recent injecting drug use. The remaining 67 people either had previous injecting drug use without a negative HCV test or information on testing after being at risk, or drug behaviour associated with risk of transmission of HCV. 43 people (35%) were tested for HCV, either with anti-HCV or HCV PCR. Of those with a positive HCV RNA, 8 people (80%) were in the not recent injecting drug use group, while 2 people (20%) had recent injecting drug use.

Stratified by department, 30/69 (43%) of the people with an indication for testing were tested in the Medical Department. In the Psychiatric Department, 19/71 (27%) were tested. Looking only at people with recent injecting drug use, 11/33 (33%) were tested in the Medical Department and 10/34 (29%) in the Psychiatric Department, respectively.

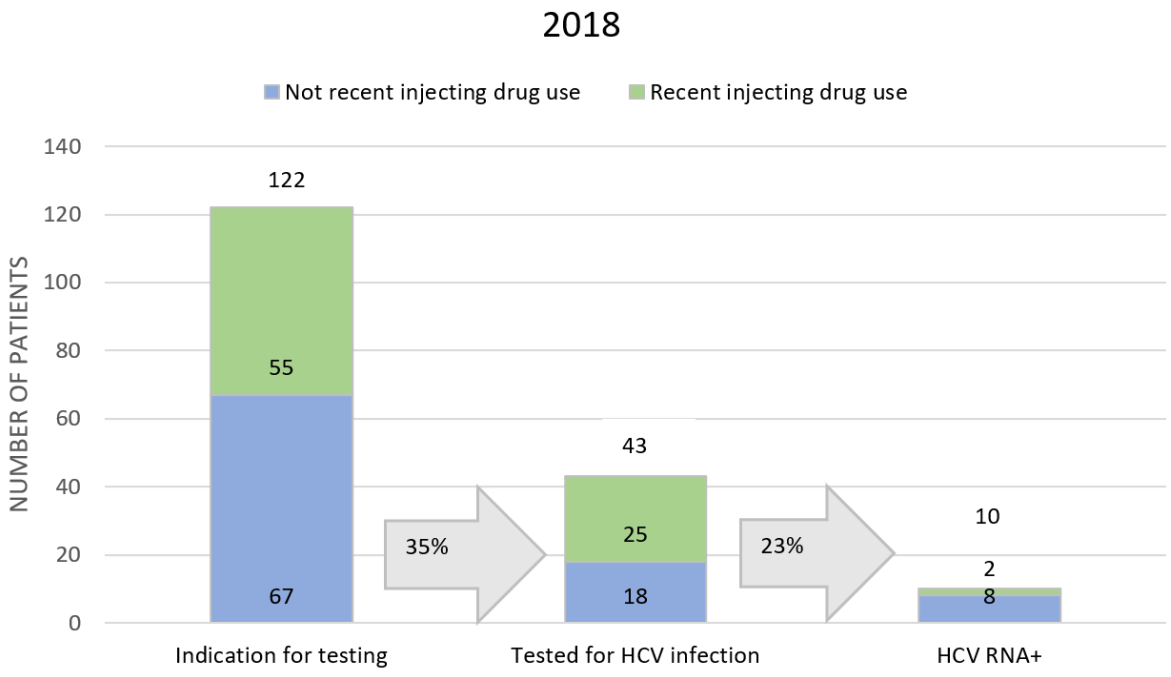

Figure 2. *The 2018 HCV testing cascade*

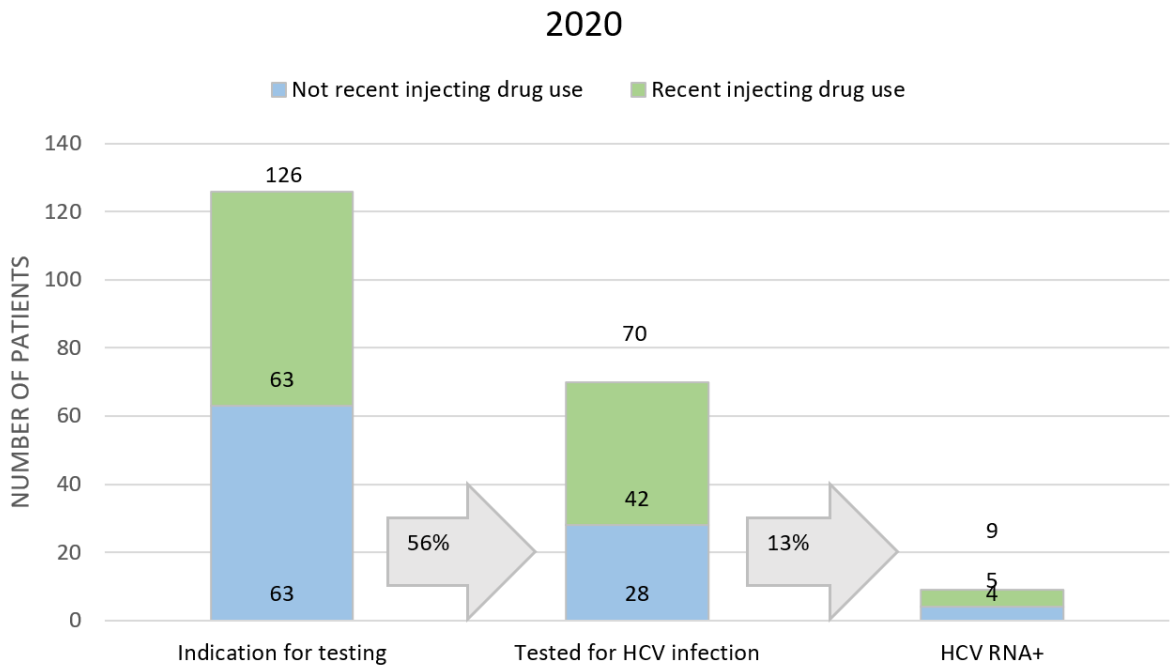

Figure 3. *The 2020 HCV testing cascade*

In 2020, 126 people with the relevant ICD 10-diagnosis codes had an indication for HCV testing. Out of these, 63 (50%) had recent injecting drug use. 70 people (56%) were tested for HCV infection. 9 people had positive HCV RNA, 5 (56%) in the group of recent injecting drug use, and 4 (44%) in the group of not recent injecting drug use.

Stratified by department, 40/66 (61%) of the people with indication for testing were tested in the Medical Department, while 37/71 (52%) were tested in the Psychiatric Department. Of the people with recent injecting drug use, 22/41 (54%) were tested in the Medical Department and 19/31 (61%) were tested in the Psychiatric Department.

3.3 Testing uptake in 2018 and 2020

Table 7 shows the testing uptake in 2018 and 2020. In the full sample the proportion tested was 0.35 in 2018 to 0.56 in 2020. This is a 21% (95% CI 9.5-32.5) increase in proportions and corresponds to an odds ratio of 2.38 (95% CI 1.43-3.98). In the sample without overlap, the proportion tested was 0.25 in 2018 and 0.41 in 2020. This gives a 16% (95% CI 0-32) increase in proportions tested and an odds ratio of 2.37 (95% CI 1.03-5.58). Divided by department, the increase in proportions tested was more pronounced in the Psychiatric Department with a 25% (95% CI 9-41%) difference in proportions and an odds ratio of 2.98 (95% CI 1.40-6.41), compared to the Medical Department with an 18% (95% CI 1-35) increase in tested proportions and an odds ratio of 2.00 (95% CI 0.95-4.21).

Table 7. *The testing uptake*

Sample and year	Number of patients	Number tested for HCV	Proportion tested (95% CI)	Difference in proportions (95% CI)	Odds ratio (95%CI)
Full sample					
2018	140	49	0.35 (0.27-0.43)	0.00 (reference)	1.00 (reference)
2020	137	77	0.56 (0.48-0.64)	0.21(0.095-0.325)	2.38 (1.43-3.98)
Sample without overlap					
2018	62	14	0.25(0.14-0.36)	0.0 (reference)	1.00 (reference)
2020	66	27	0.41 (0.29-0.53)	0.16 (0.00-0.32)	2.37 (1.03-5.58)
Medicine					
2018	69	30	0.43 (0.31-0.55)	0.00 (reference)	1.00 (reference)
2020	66	40	0.61 (0.49-0.73)	0.18(0.01-0.35)	2.00 (0.95-4.21)
Phsychiatry					
2018	71	19	0.27 (0.17-0.37)	0.00 (reference)	1.00 (reference)
2020	71	37	0.52 (0.40-0.64)	0.25 (0.09-0.41)	2.98 (1.40-6.41)

3.4 HCV prevalence

In 2018, 10 patients tested positive for HCV RNA out of 43 patients tested for HCV. This gives a prevalence of 23.3%. In 2020 9 patients tested positive for HCV RNA out of 70 people tested, giving a prevalence of 12.5%. In 2018 and 2020 combined, 17 unique individuals tested positive for HCV RNA out of 90 people tested and thus a prevalence of 18.9%.

3.5 Patient characteristics associated with HCV testing

Table 8 and 9 displays factors associated with HCV testing in 2018 and 2020.

Table 8. *Factors associated with HCV testing in 2018*

2018			Unadjusted		Adjusted*	
Covariate	No.	Test uptake (%)	OR	95% CI	aOR	95% CI
Sex						
Male	80	28 (35)	1.00	reference		
Female	42	15 (36)	1.03	0.47-2.25		
Age, years	122	43 (35)	1.01	0.98-1.05		
Age categories						
18-40 years	62	19 (31)	1.00	reference		
≥41 years	60	24 (40)	1.51	0.71-3.19		
Housing						
Unstable	55	20 (36)	1.00	reference	1.00	reference
Stable	55	17 (31)	0.78	0.35-1.73	0.76	0.34-1.69
Recent injecting drug use						
No	56	17 (30)	1.00	reference	1.00	reference
Yes	66	26 (39)	1.49	0.70-3.17	1.65	0.75-3.60
Opioid agonist therapy						
No	100	30 (30)	1.00	reference	1.00	reference
Yes	22	13 (59)	3.37	1.30-8.72	3.69	1.28-10.68

Main drug						
Amphetamines and similar	41	10 (24)	1.00	reference	1.00	reference
Heroin and similar	55	23 (42)	2.23	0.91-5.44	2.29	0.92-5.68
Others and unknown	14	5 (36)	1.72	0.47-6.35	1.74	0.46-6.63
Number of hospital admissions, continuous	122	43 (35)	1.17	0.99-1.38	1.18	1.00-1.40
Number of hospital admissions						
1	62	18 (29)	1.00	reference	1.00	reference
2	19	5 (26)	0.87	0.27-2.78	0.84	0.25-2.76
≥3	41	20 (49)	2.33	1.02-5.30	2.43	1.06-5.59

*Adjusted for age (continuous) and sex (woman, man). Abbreviations: OR= odds ratio, aOR= adjusted odds ratio, CI= confidence interval.

Table 9. *Factors associated with HCV testing in 2020*

2020			**Unadjusted**		**Adjusted***	
Covariate	No.	Test uptake (%)	OR	95% CI	aOR	95% CI
Sex						
Male	83	49 (58)	1.00	reference		
Female	43	21 (49)	0.66	0.32-1.39		
Age, years	126	70 (56)	1.02	0.99-1.06		
Age categories						
18-40	60	29 (48)	1.00	reference		
≥41	66	41 (62)	1.75	0.86-3.56		
Housing						
Unstable	46	29 (63)	1.00	reference	1.00	reference
Stable	67	34 (51)	0.60	0.28-1.30	0.61	0.28-1.33
Recent injecting drug use						
No	63	28 (44)	1.00	reference	1.00	reference
Yes	63	42 (67)	2.50	1.21-5.15	2.40	1.17-5.08
Opioid agonist therapy						
No	96	50 (52)	1.00	reference	1.00	reference
Yes	30	20 (67)	1.84	0.78-4.34	1.72	0.68-4.35
Main drug						
Amphetamines and similar	48	25 (52)	1.00	reference	1.00	reference
Heroin and similar	52	33 (63)	1.60	0.72-3.55	1.64	0.73-3.70
Other	9	4 (44)	0.74	0.18-3.08	0.81	0.19-3.49
Number of hospital admissions, continuous	126	70 (56)	1.81	1.28-2.56	1.94	1.35-2.79
Number of hospital admissions						
1	54	20 (37)	1.00	reference	1.00	reference
2	37	22 (59)	2.49	1.06-5.88	2.61	1.08-6.30
≥3	35	28 (80)	6.8	2.51-18.40	8.62	3.01-24.68

*Adjusted for age (continuous) and sex (woman, man). Abbreviations: OR= odds ratio, aOR= adjusted odds ratio, CI= confidence interval.

Data from 2018 (Table 8) show those who use opioid agonist therapy to have an odds ratio for HCV testing of 3.4 (95% CI 1.3-8.7), compared to patients not using opioid agonist therapy. There was suggestive evidence of an association between higher age and likelihood of being tested with an odds ratio of 1.51 (CI 0.71-3.19), but as the confidence intervals show, the results are also compatible with no association. The study showed no clear difference in testing uptake related to sex. Females had an odds ratio for HCV testing of 1.03 (CI 0.47-2.25) compared to male patients

In 2020 (Table 9) an increasing number of hospitalizations that year was associated with HCV testing (OR 1.8 per admission; 95% CI 1.3-2.6). Compared to people who did not inject drugs recently, those who had a recent injecting drug use had an odds ratio for HCV testing of 2.5 (95% CI 1.21-5.15). There was suggestive evidence of an association between higher age and likelihood of being tested in 2020 as well, odds ratio 1.75 (CI 0.86-3.56), but as in 2018 the confidence intervals show the results to be compatible with no association as well. Females had an odds ratio for HCV testing of 0.66 (CI 0.32-1.39) compared to male patients, and no clear difference in testing uptake.

Figure 4 illustrates the testing uptake by explanatory variable based on the proportion tested.

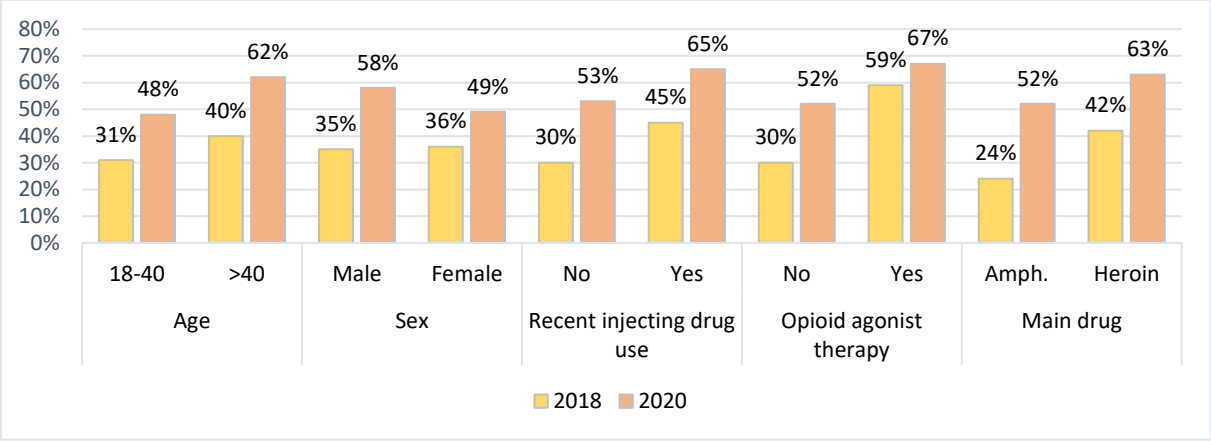

Figure 4. *The testing uptake by explanatory variable*

Improved testing was most prominent among amphetamine users, increasing from 24% (10 out of 41) in 2018 to 52% (25 out of 48) in 2020. Having not recent injecting drug use and being male were the two variables with the second largest increase in testing, with 23%. The variable with the lowest increase in testing uptake (10%) was opioid agonist therapy.

4 Discussion

4.1 Summary of main findings

This study found that testing uptake in people who use and inject drugs increased from 2018 to 2020. The increase in testing was more pronounced in the Psychiatric Department than in the Medical Department. In 2018 opioid agonist therapy was associated with increased likelihood of being tested, while in 2020 injecting drug use and multiple hospitalizations were associated with increased likelihood of testing. The largest increase in the proportion being tested was in the group who use amphetamines.

4.2 Comparison with existing literature and possible explanations for the results

4.2.1 HCV testing cascade

Of the people with an indication for testing in 2018, 55% did not have recent injecting drug use and 42% of those were tested for HCV infection. The majority (80%) of HCV RNA positive people did not have recent injecting drug use. This group includes both people with prior injecting drug use, and people with other drug use associated with risk of HCV transmission. In 2020, 50% of the people with an indication for testing did not have recent injecting drug use, and 40% of those were tested. Of the HCV RNA positive samples, 44% were among those without recent injecting drug use.

There are several possibilities for the relatively high viremic prevalence among those without recent injecting drug use. A systematic review of HCV in self-reported non-injecting drug users found the HCV prevalence of to be higher in the non-injecting drug user group than in the general population (Scheinmann et al., 2007). Still, there are substantial gaps in the research regarding HCV in non-injecting drug users. The evidence regarding risk of HCV infection in people who have never injected drugs remains uncertain (Scheinmann et al., 2007). Sexual transmission of HCV is rare, but higher among those with high-risk sexual activity (Sy & Jamal, 2006). A potential route for transmission of HCV is through sharing contaminated equipment used for sniffing drugs such as cocaine, amphetamines, or other powdered drugs. However, this requires further research, and it is uncertain what role intranasal drug use plays in HCV transmission (Aaron et al., 2008). Some patients may have failed to report the actual route of administration or not identify themselves as injecting drug users (Scheinmann et al., 2007). Some patients in the not recent injecting drug use group have stopped injecting drugs years ago and may now administer drugs in other ways.

The Norwegian authorities agree upon the principles of HCV testing (Den norske legeforening, 2019; FHI, 2019; Helsedirektoratet, 2019). Although the possibility for treatment has changed several times during the last decade, the recommendation for testing has been the same and should be known to health care personnel. The C-SCOPE study investigated barriers to HCV testing, management and treatment among physicians prescribing opioid agonist therapy in USA, Canada, Europe (not Norway) and Australia (Litwin et al., 2019). 86% of physicians reported testing all with injecting drug use for HCV, and 58% reported re-testing regularly. There was reported poor access to on-site HCV testing and point-of-care testing. Physician perceived barriers varied according to country and health system. At a patient level, barriers were most frequently social circumstances, unstable housing, and a marginalized lifestyle (Litwin et al., 2019). While education on the implications of HCV can affect knowledge-based reasons of non-adherence to guidelines, it does not affect external barriers like lack of time, or attitudinal barriers (Southern et al., 2014).

Internationally, different strategies are used to increase screening. Improved access to testing, patient and provider education, and prompts to increase testing by providers are examples of these (Zhou et al., 2016). In the United States, a study investigated the awareness of HCV screening guidelines among physicians (Kallman et al., 2009). To the best of our knowledge, we are not aware of similar surveys examining to what extent Norwegian physicians are familiar with the content of HCV screening guidelines and potential barriers associated with HCV testing.

4.2.2 Testing uptake 2018 and 2020

The HCV testing uptake was 35% in 2018 and 56% in 2020. The higher difference in proportions of people tested in the Psychiatric Department 0.25 versus 0.18 in the Medical Department is partly due to a lower testing uptake in the Psychiatric Department (27%) in 2018, compared to the Medical Department (43%). Before the new direct acting antivirals, HCV treatment was Interferon-based. This treatment had substantial side effects and was contraindicated for many people with psychiatric disorders (Sundberg et al., 2018). This may have led to screening and treatment for HCV being less prioritized in psychiatric wards (Ramachandran et al., 2019), despite research showing psychiatric patients to be at risk of HCV infection (Hughes et al., 2016). In the era of direct acting antiviral treatment, HCV treatment has become possible for patients with psychiatric disorders (Ramachandran et al., 2019). Admissions to a psychiatric department are an opportunity to test and treat patients (Valerio et al., 2021), and patients with psychiatric disorders need to be prioritized for HCV screening and linkage to care (Ramachandran et al., 2019). Psychiatrists have less knowledge of HCV therapy compared to other specialities (Valerio et al., 2021), hence showing the need for educational interventions. Educational sessions have transformed HIV related knowledge among providers in a psychiatry setting and similar interventions may be useful in the HCV field as well (Valerio et al., 2021).

In a primary care clinic, a quality improvement project from the United States aimed to increase HCV screening in a birth cohort group to over 90% over a three-year period. They implemented a "plan, do, study, act" model for improvement and assessed 50 patient records every six months during the study period. Baseline data on provider knowledge were obtained prior to the study, and findings suggests that providers likely posed the greatest barrier to screening (Trinh & Turner, 2018). In their study, improving knowledge alone did not increase screening rates. The interventions most effective were reminders in the electronic medical record and individualized audit of providers screening rates with rewards for those with the highest rates. From a starting point at 24% of the eligible patients screened, this quality improvement project increased screening to 90% in under three years (Trinh & Turner, 2018). Compared to this study, testing uptake at Lovisenberg increased with substantially fewer efforts. It is possible that Lovisenberg Diaconal Hospital would be able to achieve a higher increase in testing uptake with a more structured and comprehensive intervention.

4.2.3 Screening practises

Even though testing uptake increased from 2018 to 2020, with 56% of the patients with indication for testing being tested there is still a need for improvement.

Since testing is a two-step process in most settings, a new blood sample for RNA testing must be collected if anti-HCV antibodies are detected (Grebely et al., 2017). This process has been associated with loss to follow-up (Scott et al., 2018) and as a result, many patients with anti-HCV antibodies never receive confirmatory HCV RNA testing (Grebely

et al., 2017). Studies from Europe show that 69% of patients did not receive a confirmatory diagnosis of HCV infection (Pawlotsky et al., 2020). By reflex testing, HCV RNA is tested by the laboratory whenever anti-HCV antibodies are detected (Pawlotsky et al., 2018). At Oslo University Hospital, HCV RNA is tested reflexively in patients with newly discovered anti-HCV antibodies. As HCV RNA analysis is validated for plasma, while the first screening sample often is serum, a possible obstacle to reflex testing is the lab asking for a new sample.

Previously treated or spontaneous cleared HCV infection does not give protective immunity and people with risk behaviour are therefore at risk of reinfection (Helsedirektoratet, 2019). As more people are treated, more people will have a positive anti-HCV antibody test in combination with negative HCV RNA(Scott et al., 2018). In time there might be a need to rethink the screening strategy. One strategy is to screen for current infection by testing for HCV RNA (Scott et al., 2018). Suppose first-time infection, screening by RNA would also reduce the diagnostic window as antibody response occurs slowly after transmission (Geretti et al., 2018). This is, however, a more costly strategy than anti-HCV antibody screening (Scott et al., 2018).

A risk factor-based strategy has been a key element in guidelines, but such a strategy has limitations as well. There is stigma associated with HCV infection. Patients may be reluctant to disclose being at risk, and providers do not always collect risk information (Pawlotsky et al., 2020). There might be an underreporting of injecting drug use if a patient does not recall, understand or report being at risk (Lyons et al., 2016). After HCV screening in a general adult population in Tromsø, researchers suggested that the risk-based screening strategy is suboptimal after 69% of the previously undiagnosed individuals had a history of injecting drug use, and theoretically should have been detected by the strategy (Kileng et al., 2019). In this study, median estimated time from infection to diagnosis in the group of people with HCV was 30 years (Kileng et al., 2019).

Egypt, a country with a very high HCV prevalence, has changed screening guidelines to recommend a one-time HCV screening for all individuals aged 18 years or older. In regions with a low prevalence this method is costly as many patients need to be screened. However, modelling studies in France and the United States have shown this approach to be cost-effective even in low prevalence settings (Pawlotsky et al., 2020). Some countries recommend screening the general population in areas with a prevalence of ≥2%, while other recommend birth cohort screening (Pawlotsky et al., 2020).

An approach with renewed interest is screening with HCV core antigen. Testing of HCV core antigen is an affordable alternative to HCV RNA. It is less sensitive than HCV RNA testing but performs with adequate sensitivity for detecting chronic infection. It may be an alternative, especially in low- and middle-income countries (Grebely et al., 2017). Point-of-care testing have been shown to increase testing (Grebely et al., 2017), and countries like the United States and France have validated point-of-care testing for HCV infection screening. This method especially presents a wider opportunity for screening outside the health structures (Trucchi et al., 2016). Still, some researchers argue that point-of-care tests need to be implemented in non-traditional settings like emergency departments to meet the goal of identifying 90% of HCV positive people (Pawlotsky et al., 2020). Many patients have difficult venous access after years of injecting drug use and this represents a barrier to obtaining blood samples (Grebely et al., 2017). Some patients does not want to take blood samples, and this was noted in some of the medical journals at Lovisenberg Diaconal Hospital, especially at the Psychiatric Department. A

study from Australia investigated acceptability and preferences for screening by finger-stick and venepuncture among people who inject drugs and found the majority (65%) to prefer finger-stick (Bajis et al., 2018). Another strategy studied is opt-out screening of all patients undergoing venous blood sampling in emergency departments. This has been successful in the United Kingdom where they found a high number of newly diagnosed HCV (Orkin et al., 2016). Blood sampling by venepuncture is the screening method used at Lovisenberg Diaconal Hospital. If the new screening methods have a place in Norwegian hospitals remains unexplored.

4.2.4 Prevalence

Measuring HCV RNA prevalence is an important part of monitoring the health of people who inject drugs. To evaluate the progress towards the National elimination goals, Norway aims to monitor the prevalence in this population (Helsedirektoratet, 2019). This study suggests a declining HCV RNA prevalence from 23.3% in 2018 to 12.5% in 2020. Some studies estimate prevalence based on the number eligible to receive the testing intervention (Aspinall et al., 2015). In this study estimating the prevalence in the combined number of anti-HCV antibody and HCV RNA in the denominator is thought to give the most truthful estimate. HCV RNA testing alone in the denominator would have given a falsely high prevalence and the people with indication for testing a false low result.

The Health Survey among people who inject drugs in Oslo have assessed the prevalence of HCV RNA regularly. In the period 2001-2015 the prevalence was stable around 40-50% (Helse- og omsorgsdepartementet, 2018). In 2018, prices of direct acting antiviral treatment dropped, and where physicians due to high costs previously had to prioritize those with liver fibrosis for treatment (Yousafzai et al., 2021), treatment could now be offered regardless of fibrosis stage. Because treatment was made available for all, many have been treated for HCV during the last years. In Norway, 2945 people were treated for HCV in 2018, 2075 people in 2019 and 1365 people in 2020 (K. Kielland, personal communication, 31.03.2022). 95% of these treatments are estimated to be successful. The last estimates from the Health Survey in Oslo suggest a declining prevalence from 26% in 2018 to 14% in 2021, mainly due to increased treatment uptake (E. Opheim, personal communication, 01.04.2022). These figures are in accordance with the estimates from Lovisenberg Diaconal Hospital. Because more people were tested in 2020, the prevalence found at Lovisenberg Diaconal Hospital in 2020 might be lower because the denominator increases, but the decrease shown from 2018 to 2020 might also be a consequence of increased treatment.

4.2.5 Patient characteristics associated with HCV testing

Several studies have examined factors associated with being tested positive for HCV (Alter, 2002; Dalgard et al., 2003), but this study examining factors associated with being tested contributes to valuable data regarding testing practises.

Of the people with relevant diagnosis codes (Table 2), a large majority had an indication for testing. Lovisenberg is an inner-city hospital, and this is reflected in the patient group. The socio-demographic characteristics of the study population reveal a highly marginalized group with low levels of work-related income and own accommodation. The districts that Lovisenberg Diaconal Hospital provides medical services to have a higher incidence of acute intoxications than the rest of Oslo (Akopian et al., 2015). They also have a higher proportion of people on opioid agonist therapy (Velferdsetaten, 2017). Some studies have shown an association between HCV positivity and sociodemographic

characteristics (Trinh & Turner, 2018). Age, sex, and housing status were not associated with HCV testing at Lovisenberg Diaconal Hospital.

Hospitalization presents an opportunity for HCV care (Valerio et al., 2021), and for some people, medical care is most commonly accessed in hospitals (Enkelmann et al., 2020). In 2018, having three or more admissions to Lovisenberg Diaconal Hospital was associated with increased likelihood of HCV testing, while in 2020 the association was stronger and present from the second visit.

In 2018 opioid agonist treatment was associated with increased likelihood of HCV testing, compared to not being on opioid agonist treatment. This is following the findings from a German study among people who recently started injecting drugs (Enkelmann et al., 2020). Opioid agonist treatment has also been shown to be associated with reduced risk of HCV acquisition (Platt et al., 2017). In 2020 recent injecting drug use was associated with increased likelihood of HCV testing. This association has been found previously as well (Soipe et al., 2018). Injecting drug use is the main route of HCV transmission and perhaps the most crucial screening indication.

4.2.6 Testing uptake by explanatory variable

In the present study, testing uptake among amphetamine users was most pronounced, increasing with 28% from 2018 to 2020. Correspondingly, testing uptake among individuals not engaged in opioid agonist treatment also increased. This increase may be explained by an increase in testing in the Psychiatric Department, where a high proportion of amphetamine users are found. Amphetamines can be smoked, snorted, eaten or injected (FHI, 2016). Oslo University Hospital did a study in collaboration with the Public Health Institute where they analysed the remains of 600 used syringes and needles to investigate what was being injected in Oslo. The results showed that heroin was most frequently injected with approximately 66% of the cases, amphetamines in 60% and almost a third contained both substances (Gjerde, 2021). As users of amphetamines have no options for substitution treatment, nor any antidote, the hospital must treat amphetamine overdoses (FHI, 2016). Amphetamines and other stimulants are most common in the younger age groups (Sandøy, 2022), and the socially marginalized users (Amundsen, 2015).

Testing uptake also increased among males and among those without recent injecting drug use, with an 23% increase in both groups. There were fewer females than males in the study population, slightly more in the Psychiatric Department than the Medical Department. This is approximately in accordance with both the gender proportions of people who inject drugs in literature (Degenhardt et al., 2017), and in other studies of people who inject drugs in Oslo (Langaas & Kjølberg, 2017; Midgard et al., 2021; Velferdsetaten, 2017). The proportion of females admitted to Lovisenberg Diaconal Hospital remained the same in 2018 and 2020, yet females only had an 13% increase in testing. People without recent injecting drug use is probably a heterogeneous group with differences in testing uptake.

One assumption was that hospitalization could be an arena to reach younger people who inject drugs. In the study population, no individuals were below 21 years of age despite an 18-year age limit in both the Medical and Psychiatric Department. It is estimated that 29.8% of the people who inject drugs in Western Europe are younger than 25 years old (Degenhardt et al., 2017). The increase in testing from 2018 to 2020 was largest in the oldest patient group.

4.3 Strengths and limitations

4.3.1 Circumstantial factors

In February 2020 the first patient with Covid-19 was admitted to a Norwegian hospital, and on March 12th, the country was in lock down. It is difficult to say if and how the pandemic influenced testing uptake. There may have been changes from usual behaviour from hospital and patient perspective. According to a covid-19 survey among people who use drugs in Norway, some reported a change in access to drugs, which in turn may affect drug behaviour and intoxication (Kjøs et al., 2021; Welle-Strand et al., 2020). As hospitals were under pressure by numerous covid-19 hospitalizations, this may have affected the threshold of admitting patients to the hospital.

The evaluation of the care bundle for mental health and substance use suggests there is still a way to go regarding improved care for somatic health. The Covid-19 pandemic contributed to putting the implementation of the care bundle on hold for a while (Helsedirektoratet, 2021). In an evaluation performed by Sintef a year after initiating the care bundle, health care personnel express frustration based on a lack of clarification between general practitioners and the health service responsibilities regarding assessment and follow-up of somatic health. 60-80% of health care personnel answered that they did not think the care bundle had contributed to better care of somatic health (Ådnanes et al., 2021).

The increase in testing uptake between 2018 and 2020 can be attributed to several factors including the educational efforts made before commencement of the OPPORTUNI-C study in 2019, and the initiation of the care bundle for substance use and mental health which promotes testing for bloodborne transmittable diseases. Because there is no control group or control department there is no comparison to provide information on the testing uptake without these efforts. The OPPORTUNI-C study included patients from October 2019 until December 2021, and the presence of the study may have led to an increased focus on testing. After the restrictions to direct acting antivirals therapy were removed in 2018, testing may have increased as the possibility for treatment changed.

4.3.2 Methological limitations

When comparing proportions between 2018 and 2020, an assumption is that the groups are independent of each other, or matched (Portney, 2020). As this study had partially overlapping individuals this assumption was not met. To further understand possible implications of this, odds ratios for testing in 2020 versus 2018 in the full sample and the sample without overlap were compared. The odds ratios of testing were similar; 2.38 (95% CI 1.34-3.98) in the full patient sample, and 2.37 (95% CI 1.03-5.58) in the sample without overlap. This indicates that testing in this groups are somewhat the same. The dependency problem regarding the overlap is mainly about the precision becoming too high, and thus giving confidence interval that is narrower than they should be.

One challenge of retrospective studies is incomplete medical records (Portney, 2020). Alcohol consumption is poorly described in medical records, and this gave a high number of missing data in both departments, but especially in the Psychiatric Department (40% and 45%). Although it would have been relevant to examine associations between educational background and being tested for HCV, education in rarely stated in the medical records. It was decided to not collect this data due to the large number of missing observations.

All relevant journals could have been read and all data collected to ensure accurate results. This is, however, time and resource demanding, and was not possible within the scope of this study. When only a proportion of the records were to be examined, this problem was approached by randomizing patients to avoid selection bias.

Some variables that were collected in this study are not clearly stated in the medical records, and there is the chance that another researcher would have evaluated information from the cases which were not straight forward differently. However, these cases were few and would not have affected the overall results.

An English study examining physician nonadherence to a hepatitis C screening program found effects of an educational effort to decline from 59.1% to 13.7% over the weeks following the intervention (Southern et al., 2014). Because the testing uptake at Lovisenberg Diaconal Hospital is calculated as an average score from the whole year, if such a decrease in testing uptake exists in the year following the educational campaign, it is not visible.

4.3.3 Local differences

Findings from this study are not necessarily generalizable to other populations with different epidemiologic background. In Oslo, there are more people with problems regarding living conditions, and more people with drug dependency, than in the rest of Norway (Velferdsetaten, 2017). Even though OPPORTUNI-C only included a few hospitals, the care bundle was introduced throughout Norway. Future studies in Norway should also include data on testing uptake, to know that current guidelines for screening are being followed.

The original coding is done by the physician in charge of the patient, with regular review by administration. It could be that some patients have not gotten a code that would include them on the list giving a selection bias, but there are good internal routines in place to secure adequate coding.

Blood samples from Lovisenberg Diaconal Hospital are analysed at Oslo University Hospital. There are possible limitations with centralized laboratory testing in regards of logistics (Grebely et al., 2017). If a blood sample is collected on a Friday afternoon, the plasma is too old for analysis on Monday. Sometimes there is not enough blood to analyse both anti-HCV antibodies and HCV RNA, and by the time this information reaches the physician, the patient might have been discharged. For this study, it could mean that an intention to test was not counted. However, this would most likely only apply to a few samples.

4.4 Implication of the results

A study investigating the policy response to HCV in the Nordic countries suggests that despite all the resources and strong public health infrastructure, the countries do not fully commit to tackling the HCV epidemic at a policy level (Safreed-Harmon et al., 2018). The Global Health Sector Strategy on Viral Hepatitis 2016-2021 (WHO, 2016) recommends implementing evidence-based national hepatitis plans. National HCV programs rely on epidemiological data and service coverage information to determine what interventions to reinforce in populations and locations (Safreed-Harmon et al., 2018).

Following the Norwegian HCV strategy there is a need to monitor the health sectors efforts regarding diagnosis and treatment of HCV (Helsedirektoratet, 2019). Because

incidence surveillance is demanding when it comes to HCV, regular prevalence studies in high-risk populations are necessary for infection surveillance. This is resource-intensive work, but the best way to provide a picture of the occurrence of HCV in people who inject drugs over time (Helsedirektoratet, 2019). The findings of this study may contribute to decisions on how to best allocate public resources.

Understanding the epidemiology of HCV within a setting is necessary to identify testing strategies to enhance diagnosis (Grebely et al., 2017). Testing uptake reached 56% in 2020. Knowing this it is relevant to consider ways to increase the testing uptake further. It may be valuable investigating why some people with indication for screening are not tested and how to ensure testing of younger patients. Considerations could be made regarding electronic reminders for screening in medical records and point-of-care screening.

5 Conclusions

This study describes the hepatitis C testing cascade among people who inject drugs admitted to the Medical Department and Psychiatric Department at Lovisenberg Diaconal Hospital in 2018 and 2020. It also compares HCV testing uptake between the years.

The HCV testing cascade highlights important steps needed towards treatment and eventually elimination of HCV as a public health threat. From 2018 to 2020 the HCV testing uptake increased among hospitalized people who inject drugs. The increase in testing followed an educational campaign regarding HCV epidemiology and care, and the initiation of a mental health and substance use care bundle.

In addition, the study calculated the prevalence of HCV RNA among the patients tested during 2018 and 2020. This supports the Public Health Institutes aim to strengthen the knowledgebase regarding HCV prevalence in this population.

The patient characteristics associated with the probability of being tested contributes to knowledge on who is currently being tested and where additional efforts may be needed. For future research it would be valuable investigating barriers and reasons for physician non-adherence to HCV guidelines.

Hospitalization represents an excellent opportunity to improve HCV testing uptake among people who inject drugs. This study provides Lovisenberg Diaconal Hospital with relevant groundwork to enhance the care to this patient group.

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Appendix

Appendix 1: OPPORTUNI-C poster.

Appendix 2: Recommendation from the Data Protection Official at Lovisenberg Diaconal Hospital.

OPPORTUNI-
Opportunistic Treatment of HCV Infection:
Immediate vs Outpatient Treatment Initiation

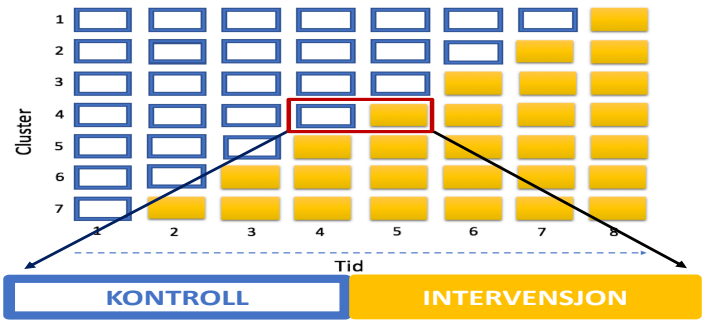
OPPORTUNI-C: UMIDDELBAR VS POLIKLINISK HEPATITT C-BEHANDLING AV PASIENTER INNLAGT I SYKEHUS - EN PRAGMATISK KLINISK STUDIE

BAKGRUNN OG MÅL MED STUDIEN

Til tross for at svært effektive legemidler mot hepatitt C-infeksjon er tilgjengelig, har helsevesenet i liten grad nådd aktivt injiserende rusmiddelbrukere med behandling. Denne pasientgruppen er ofte innlagt for akuttbehandling av rusrelaterte tilstander av somatisk eller psykiatrisk karakter. **Målet med studien er å undersøke effekten av umiddelbar (opportunistisk) behandling av hepatitt C hos pasienter innlagt i sykehus** sammenliknet med "standard of care" henvisning til poliklinisk behandling etter utskrivelse. Det primære endepunktet er andelen pasienter som fullfører behandlingen, målt som uttak av siste pakning fra apoteket.

STUDIEDESIGN

Cluster-randomisert pragmatisk klinisk studie med "stepped wegde" design hvor 7 clustere (avdelinger) trinnvis vil bli randomisert til intervensjon etter en felles initial kontrollperiode.



CLUSTERE

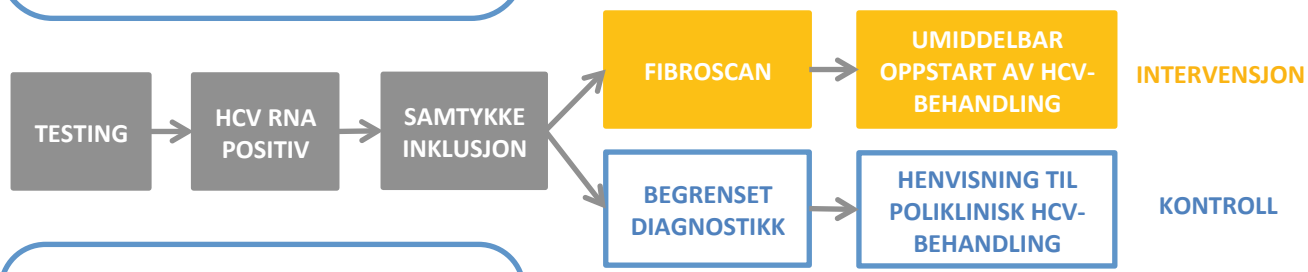
- Seksjon illegale rusmidler AHUS
- Akuttpsykiatrisk avdeling AHUS
- Medisinsk divisjon AHUS
- Rusakuttmottak Aker OUS
- Medisinsk klinikk OUS
- Psykiatrisk akuttmottak LDS
- Medisinsk klinikk LDS

INKLUSJONSKRITERIER

- Alder > 18 år
- HCV RNA positiv
- Innlagt i ett av 7 clustere
- Informert samtykke

EKSKLUSJONSKRITERIER

- Graviditet eller amming
- Ikke samtykkekompetent
- Pågående HCV-behandling



TESTING AV HEPATITT C

Alle pasienter som noen gang har injisert rusmidler testes så raskt som mulig ved innkomst. Ta serum + plasma til anti-HCV og HCV RNA. Genotyping er ikke nødvendig. HCV RNA analyseres daglig.

HAR DU SPØRSMÅL?

- **AHUS**: Professor Olav Dalgard (926 16 800) eller Kristian Nødtvedt Malme (922 09 146)
- **OUS**: Postdoc Håvard Midgard (908 30 071)
- **LDS**: Postdoc Ane-Kristine Finbråten (977 16 892)

AKTUELL PERIODE

KONTROLL

INKLUDERTE PASIENTER HENVISES TIL POLIKLINISK HEPATITT C-BEHANDLING VED UTSKRIVELSE

ALLE HCV RNA POSITIVE PASIENTER

- Informert samtykke innhentes av studiepersonell
- Fyll ut inklusjonsnotat (DIPS-frase OPPORTUNI-C)
- Meld fra til koordinator Ana Urzua (934 67 692)
- Henvis pasienten til lokal infeksjonsmedisinsk eller gastromedisinsk poliklinikk ved utskrivelse

AKERSHUS UNIVERSITETSSYKEHUS
Oslo universitetssykehus
Lovisenberg Diakonale Sykehus

PERSONVERNOMBUDETS TILRÅDING

Til:	Ane-Kristine Finbråten
Kopi:	Forskningsavdelingen LDS, klinikksjef Hallvard Fanebust
Fra:	Personvernombudet
Saksbehandler:	Erling Moldal
Dato:	19.8.21
Sak:	Personvernombudets tilråding til innsamling og behandling av personopplysninger
Saksnummer/ Personvernnummer:	

Personvernombudets tilråding til innsamling og behandling av personopplysninger i samband med kvalitetssikringsprosjekt: Hepatitt C-testopptak og prevalens blant sykehusinnlagte med injiserende rusmiddelbruk: Muligheter for å forbedre HCV-omsorgen

Hjemmelsgrunnlag

Personvernombudets oppgaver er hjemlet i Lov 2018-06-15-38 om behandling av personopplysninger (personopplysningsloven), EUROPAPARLAMENTS- OG RÅDSFORORDNING (EU) 2016/679 av 27. april 2016 om vern av fysiske personer i forbindelse med behandling av personopplysninger og om fri utveksling av slike opplysninger samt om oppheving av direktiv 95/46/EF (generell personvernforordning) GDPR, artikkel 39.
Dette følger blant annet av personopplysningsloven, personvernforordningen artikkel 38 nr 1:

Den behandlingsansvarlige og databehandleren skal sikre at personvernombudet på riktig måte og i rett tid involveres i alle spørsmål som gjelder vern av personopplysninger.

Rettsgrunnlaget for behandlingen av personopplysninger i samband med prosjektet er Personvernforordningen artikkel 9 nr 2, bokstav i.

Bakgrunn

Jeg viser til mottatt dokumentasjon oversendt pr e-post den 10.8.21, samt utfyllende informasjon gitt pr telefon av Finbråten 17. og 19.8.

Personvernombudets vurdering
Det fremgår at prosjektet er et kvalitetssikringsprosjekt som er godkjent av klinikksjef Hallvard Fanebust. Det fremgår videre at uttrekk av helseopplysninger skal utføres av personer med gyldig adgang til dette, at data avidentifiseres og lagres på tilgangsstyrt prosjektområde.

Personvernombudet vurderer at personopplysninger kan behandles på følgende forutsetninger:

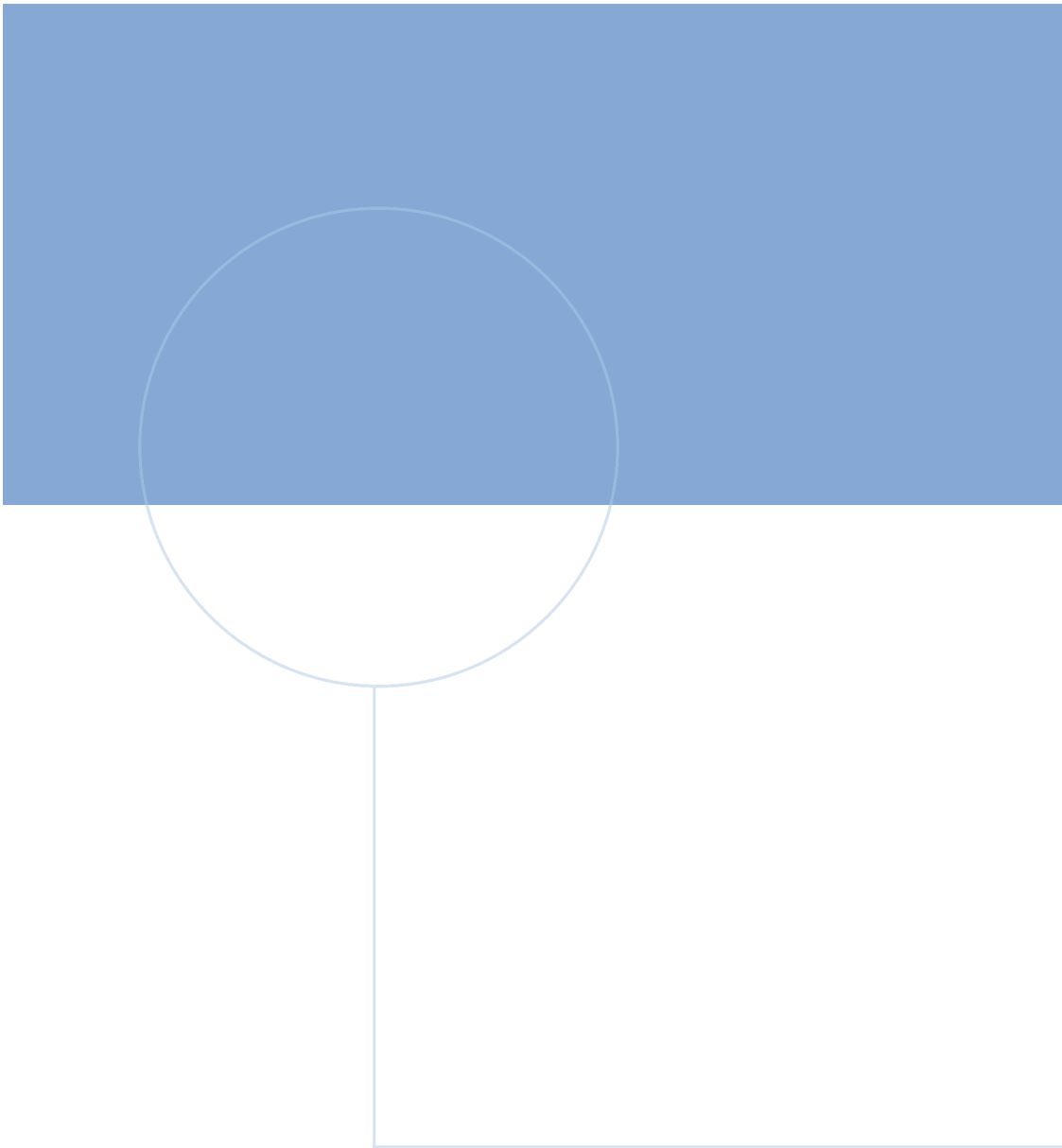
1. Personopplysninger behandles utelukkende for det formål som er angitt i meldeskjema til personvernombudet, med vedlegg.
2. Opplysninger fra pasientjournal **må hentes ut av helsepersonell med lovlig tilgang til opplysningene**, jf pasientjournalloven § 6, samt helsepersonelloven §§ 21 og 21a, og **som er underlagt sykehusets instruksjonsmyndighet gjennom ansettelsesforhold**
3. Personopplysninger lagres som oppgitt i melding til personvernombudet.
4. Ved eventuelle fremtidige endringer som berører **formålet**, utvalget inkluderte eller databehandlingen må endringen forlegges personvernombudet for vurdering før iverksettelse. Behandling av personopplysningene i prosjektet skjer for øvrig i samsvar med mottatt melding til personvernombudet.
5. Data slettes som oppgitt i melding til personvernombudet. Når formålet med databehandlingen er oppfylt sendes melding om bekreftet sletting til personvernombudet

Dette dokumentet og eventuelle senere uttalelser om prosjektet arkiveres i sykehusets saksarkiv.

Med hilsen

Erling Moldal

Personvernombud
Lovisenberg Diakonale Sykehus AS



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