

Original paper

# Missed opportunities for diagnosing viral hepatitis C in Poland. Results from routine HCV testing at the Emergency Department in the Hospital for Infectious Diseases in Warsaw

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## Abstract

**Aim of the study:** Current statistics indicate that approximately 150,000 (0.5%) people in Poland suffer from active hepatitis C virus (HCV) infection, but only 20% among them are aware of their status. This project is based on the concept that screening based on the presence of HCV-related risks (a patient's individual history and behavioural risk factors) is more effective than obligatory testing of the whole population. This study investigates prevalence of serological markers for HCV among patients with a risk of exposure to HCV infection.

**Material and methods:** The prospective study concerning patients of 18 years and older was conducted at the Emergency Department (ED) of the Hospital for Infectious Diseases in Warsaw (from 15 September 2016 until 23 July 2018). The inclusion criteria were: a blood transfusion before 1992, more than three hospitalizations in the lifetime, suspected liver disease, elevated aminotransferase activity, imprisonment, patient's own initiative, history of injecting drug use. The rapid HCV test was performed on all patients who fulfilled inclusion criteria. The statistical analyses included calculating serological positivity rate and comparing risk-group characteristics.

**Results:** Among 1502 patients consulted at the emergency department with risk factors for HCV infection during the study period, the HCV test was performed in 1487 cases. New diagnoses were confirmed in 25 cases, HCV seroprevalence was 1.68%, all patients were linked to care, 21/25 (84.0%) were HCV RNA positive.

**Conclusions:** The study confirms that routine rapid testing in certain risk groups constitutes an essential tool for identifying new HCV infections and might have an important role for public health.

**Key words:** Poland, HCV, prevalence, rapid test, risk factors.

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## Introduction

Undiagnosed hepatitis C virus (HCV) is globally recognized as a serious problem because it may be spread and lead to morbidity decades after HCV infection. Current statistics indicate that among the approximately 71 million HCV-infected individuals living around the world, most of such cases occur in Eastern Europe and Central Asia. It is estimated that

less than one out of five infected people know they carry the infection, which results in significant levels of late diagnosis and transmission across the globe [1]. Over 14 million adults are living with hepatitis C in the European region, which translates to the fact that one in every 50 is chronically infected with HCV. The prevalence of chronic hepatitis C infection is diverse due to the inadequate surveillance infrastructure in many European countries and varies among regions

from 0.1% in Belgium, Ireland and the Netherlands to 5.9% in Italy [2]. Strategies aimed at preventing new infections should be tailored to address the most common modes of transmission in each region. Rates of testing and diagnosis for hepatitis C are low, due to the lack of national programmes of testing and, secondly, because a majority of chronically infected people are asymptomatic until the late stage of liver disease [3].

Recent studies show that approximately 150,000 (0.5%) people in Poland are living with active HCV infection, but only 15-20% among them are aware of their status, which has an influence on the dynamics of the HCV epidemic in Poland [4]. Currently, the tests for the detection of anti-HCV antibodies are not routinely performed, which may result in the development of late disease consequences such as cirrhosis or liver cancer (hepatocellular carcinoma). Lack of systemic solutions leads to lower rates of HCV detection in the general population [5]. It is well known that late diagnosis is associated with increased morbidity and mortality, poorer response to treatment, increased healthcare costs and obviously with increased transmission rates [6]. Therefore, there are many benefits of diagnosing HCV at an early stage, and this is why early diagnosis should be a key public health strategy.

In the last decades, the progress in HCV therapy results in the fact that the basic role in the treatment is played by the identification of the target population – especially people who are most likely to be infected with HCV and who present late for care. However, eradication of HCV infection seems to be achievable – it would not be possible without a significant improvement in screening effectiveness. An overview of the European region countries' statistics shows that testing individuals at risk is far from optimal and it is a great challenge to improve testing strategies so that they succeed in identifying the undiagnosed population [7]. In such a situation, the development and implementation of an innovative, rapid testing strategy such as screening based on the presence of HCV-related risks have a decisive significance and might constitute an additional element of the national HCV testing strategy.

Our project is based on the concept that screening dependent on the presence of HCV-related risks (a patient's individual history and behavioural risk factors) is effective in detecting HCV infection [8].

The aim of the study was to estimate the prevalence of HCV infection among all patients who present with risk factors for HCV infection in the Emergency Department of the Hospital for Infectious Diseases in Warsaw, as well as to assess the cascade of care for those tested positive.

## Material and methods

This study was designed as a prospective, one-centre, non-intervention study. Within the programme, routine screening of anti-HCV antibodies was offered to all patients with risk factors for HCV infection within the past 22 months (from 15 September 2016 until 23 July 2018). The rates of serological positivity were calculated and further analysis was performed to examine the association between each risk group's characteristics and seroprevalence.

The inclusion criteria were the following: reaching 18 years of age, granting consent in a written form and fulfilment of the questionnaire regarding the presence of risk factors for transmission of the HCV infection. Patients without HCV infection risk factors were excluded from the study.

The following data were included in the study: age, sex, presence of risk factors for HCV infection, results of rapid serological HCV antibody test, HCV RNA test to confirm the presence of viraemia (PCR HCV) and linkage to care to the out-patient clinic.

We used the Anti-HCV Rapid Test, which is based on solid-phase immunochromatographic technology. The Anti-HCV Test can detect antibodies generated against proteins that are encoded by conserved sequences of CORE, NS3, NS4, NS5 parts of the HCV genome. In order to perform the test, we need two drops of drawn whole blood and 2 drops of diluent. This type of test is simple to perform and can produce a result within less than 15 minutes. The sensitivity of the test is 100%, and Predictive Value is 100%. Serological screening for HCV infection requires an HCV RNA test to confirm the presence of viraemia.

A protocol was developed to link patients with a positive HCV antibody test result to care with an infectious disease specialist for confirmatory testing at a follow-up appointment at the out-patient clinic or depending on health conditions by admission to hospital.

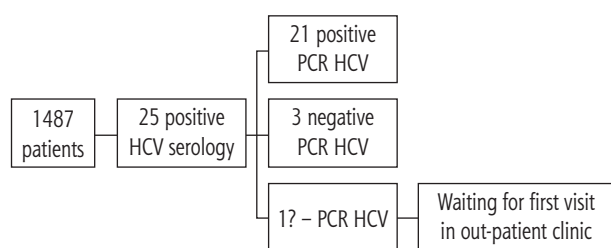
The study has been approved by the Bioethical Committee of the Medical University of Warsaw (Nr KB/123/2017).

## Results

Among 1502 patients consulted at the emergency department with risk factors for HCV infection during the study period, the HCV test was performed in 1487 cases, and 15 patients did not express consent to be tested. Among those tested patients, there were 712 (47.9%) women, with median age 38 years; 288/1487 (19.4%) patients were hospitalized, and there were 56/288 (19.4%) with confirmed acute hepatitis A.

**Table 1.** Characteristics of analysed population according to risk factors

	Number of persons (% of the sample)	Median (min-max)	HCV positive test	Prevalence (95% CI)	Significance of binomial test against the estimated population prevalence of 1%
All tested patients	1487 (100)	38 (18-93)	25	1.68% (1.09-2.47)	0.016
History of injecting drug use	19 (1.3)	31 (20-64)	3	15.8% (3.4-39.6)	0.001
A blood transfusion before 1992	43 (2.9)	57 (25-93)	3	7.0% (1.5-19.1)	0.009
Imprisonment	15 (1.0)	40 (26-87)	1	6.7% (0.2-31.9)	0.140
Suspected liver disease	337 (22.7)	42 (18-90)	13	3.9% (2.1-6.5)	< 0.001
Elevated aminotransferase activity	543 (36.5)	35 (18-93)	16	2.9% (1.7-4.7)	< 0.001
More than three hospitalizations in the lifetime	573 (38.5)	55 (18-93)	11	1.9% (1-3.4)	0.035
Patient's own initiative	516 (34.7)	32 (18-78)	7	1.4% (0.5-2.8)	0.372



**Fig. 1.** Cascade of linkage to care and diagnosis

**Table 2.** Relationship between number of risk factors and HCV prevalence

Number of risk factors	n	Prevalence (%)
1	1056	1.0
2	331	1.8
3	80	6.3
4	16	6.3
5	2	50.0
7	2	50.0

Among 1487 patients who were screened, the HCV antibody was detected in the blood in 25 cases, and the prevalence observed in the study was 1.68%. The highest serological positivity rate was for patients with a history of injecting drug use – 15.8%, a blood transfusion before 1992 – 7.0%, imprisonment – 6.7%, suspected liver disease – 3.9%, elevated aminotransferase activity – 2.9%, more than three hospitalizations in a lifetime – 1.9%, patient’s own initiative testing for HCV/HIV – 1.4%. The general characteristics of the group are presented in Table 1.

Median age of HCV antibody positive patients was 49 (min = 27, max = 82) and was significantly higher ( $p = 0.025$ ) than for the remaining patients, where the median score was 38 (min = 18, max = 93). There was no significant difference in the percentage of female patients between groups (36.0% in the antigen-positive group and 47.3% in the negative).

The median age of HCV antibody positive patients was 49 years (59 for women and 37 for men). New diagnoses were confirmed by the detection of HCV RNA in 87.5% out of 24 patients who underwent a confirmatory RNA test. One patient is still waiting for the first visit to the out-patient clinic. The availability of confirmation testing with an RNA test is limited due to the long waiting time for admission to the out-patient clinic (mean 168 days, from 21 to 288 days). All patients were linked to care, in 96% of cases patients were after their first visit in the out-patient clinic and in 4% of cases they were signed up and waiting for an appointment at the infectious disease specialists. The cascade of linkage to care and diagnostics is presented in Figure 1.

Seven (50%) were hospitalised because of the health conditions (decompensation of liver function: ascites, encephalopathy and thrombocytopenia).

The number of risk factors was significantly related to the probability of HCV infection (OR = 2.2,  $p < 0.001$ ), indicating that the probability of infection increases with the number of risk factors characterizing the patient. Importantly, in follow-up analysis using a multivariate logistic regression model including sex and age, number of risk factors remained the only significant predictor of the presence of HCV antibodies (Table 2).

## Discussion

The performed study showed that the local HCV seroprevalence was higher (1.68%) than the national average (1%), which means that the routine testing for HCV infection based on risk factors is an efficient form of screening for HCV infection [9]. Moreover, in our study, current infection was confirmed by the presence of HCV RNA in 1.27%, which means that it was two times higher than in the general population [10, 11].

Furthermore, this strategy is deemed to be cost-effective and might be a highly effective way of identifying individuals with undiagnosed HCV infection.

Finally, it should be emphasised that all patients with HCV infection detected during the study were linked to the out-patient clinic.

Recently, data regarding estimation of the frequency of HCV infection among working-age population representatives (obtained from the electronic medical records of an outpatient clinic network operating on a countrywide level) have been published in Poland. This study estimates that the anti-HCV seroprevalence in the working age population is 1.5% and provides evidence that screening people born before 1965 could be beneficial [12].

On the basis of the review of publications and studies regarding the prevalence of HCV infection in the Polish population, one remark may be made – the ongoing studies were conducted on small, selected groups of patients. The percentage of persons with HCV antibodies in various social groups ranged from 0.5% to 2.93%. The lowest percentage of the frequency of the occurrence of HCV antibodies was in the group of first-time blood donors (0.5%), then among employees of the public healthcare system (1.7%), pregnant women (2.02% vs. 0.73%), persons exposed to professional and non-professional risks (2.1%), organ donors (2.6%), and the highest percentage of anti-HCV positive patients was found among those aged 50 years and older (2.93%) [13-21].

Moreover, it is still difficult to estimate which groups of patients are most exposed to HCV infection in Poland. A lack of the identified risk groups extracted from the population results in a lack of the possibility to identify patients with undiscovered HCV infection.

An analysis of the estimated number of people aware of the fact of HCV infection in Poland indicated 15-20%, which is a lower result than in other European countries such as France (68%) or Germany (57%) [20, 22].

The main risk factor for HCV infection in Poland is still contact with health care, while in Western Europe it is intravenous drug use [23]. So far, the studies carried out have shown that a Polish patient infected with HCV is a person who has been diagnosed or treated in a health care facility in the past. The majority of infections are related to medical treatments, at about 80-84%, during surgery, endoscopy, dialysis, dental or blood transfusions, or blood products before 1992, due to the use of non-sterile medical equipment, especially reusable equipment. In addition, relatively often, it is a person who has undergone tissue-invasive procedures outside of medical facilities such as tattoo salons, spas or cosmetic salons (which constitute 3% of infections).

As far as the place of the residence is concerned, almost twice as often the infection was detected among the rural population, as well as among people aged 44 years and older [12]. Often, the HCV infections are detected in people who have injected drugs (which constitute 10% of the infections) [24]. More frequently, newly detected HCV infections occur among men having sex with men [25]. Moreover, people who live with HIV infection constitute one of the better-studied populations in Poland, thanks to the comprehensive care. In this group of patients, the HCV coinfection rate is 33% [26].

To date, the significant influence on the dynamics of the HCV infection in Poland was due to the introduction of the control for candidate blood donors since 1992, donors and recipients of organs for transplant and dialysis patients [27]. Furthermore, in 2012, screening for HCV antibodies was incorporated for the first time in Poland into the mandatory recommended package of diagnostic tests and medical consultations for pregnant women [28]. So far, the epidemiological data regarding estimation of the frequency of HCV infection in the group of pregnant women in Poland from 2008 estimated the prevalence of 2.02% (554 patients). However, this type of obligatory screening has been proven less effective than expected (0.73% vs. 2.02%) according to the results shown in the research from 2016 based on a large group of pregnant women (16 130 patients) [21]. On the basis of the analysis of these groups of patients it is shown that this type of testing is more effective in countries where the prevalence of HCV infection is high or mothers are co-infected with HIV [29].

The tests for HCV are also performed as routine screening of health care workers, after occupational or non-occupational exposures, in drug treatment facilities (during harm reduction programmes among injecting drug users), in prisons and sometimes as part of the routine tests before planned surgery [27].

Poland is among the countries with low seroprevalence; thus the whole population-based screening strategy is too expensive and not cost-effective.

The lack of accurate epidemiological data, low awareness regarding the potential sources and risks of infection and a lack of system solutions constitute the leading causes of the low rates of HCV detection in the general population in Poland [30]. Regulations within the national legislation, specially tailored to the population exposure risk or behaviours, might become one of the most important issues that allow Poland to overcome the difficulties.

In addition, many studies indicate that in Poland, the detection of HCV infection is usually accidental or related to the late symptomatic phase of infection.



Considering the very high percentage of undiagnosed infections and the low detection, this situation may be caused by systemic HCV diagnostic limitations. There is currently no national screening programme for the detection of HCV infection. The second important reason is probably the inability to carry out an anti-HCV test in the Primary Care Physician Clinics, because this was not included in the catalogue of medical laboratory diagnostics – the so-called “guaranteed benefits basket”. Moreover, the problem may have to wait long for the diagnostics and qualification for treatment in the specialist out-patient clinics.

Therefore Rapid tests might be an acceptable solution to the problem. These tests do not require laboratory infrastructure and experts in their operation and are very cheap and easy to use [31]. To be acceptable for screening Anti-HCV Rapid tests need to meet the high standards of classical enzyme immunoassays (EIA) tests in terms of analytical performance for sensitivity and specificity [32]. Comparisons of classical enzyme immunoassays tests vs. the Anti-HCV Rapid test have shown significant variability depending on the pre-analytical conditions, manufacturer and sample type (fingerstick whole blood, oral fluids, etc.) [33].

In addition, new Anti-HCV Rapid antibody tests have shown better positive and negative predictive values in studies conducted in developed countries vs developing countries [34]. For example, the evaluation (producer declaration) indicates that the Turklab Anti-HCV Rapid test has demonstrated equivalent performance in the diagnostic sensitivity compared to the CE-marked EIA assay [35].

Recent research has demonstrated that different solutions are adopted in other countries to find people unaware of their HCV infection. For example, in developed countries such as the United States Centers for Disease Control and Prevention (CDC) recommends that all persons born between 1945 and 1965 should get tested for HCV infection one time without prior ascertainment of HCV risk. In addition, an estimated high prevalence is visible among immigrants from high prevalence countries, among individuals who have higher rates of risk behaviours (people with a history of injection drug use, the homeless, prisoners, victims of sexual assault, HIV-infected) or have a history of traditional risk factors such as blood transfusion, blood products, or organs before 1987, or elevated liver enzyme levels [36].

Screening rates of HCV infection vary by region in Europe. For example, France has one of the best prevention and treatment rates, thanks to the implementation of the three national action plans for prevention implemented by the French Ministry of Health since

1999, which started the implementation of the risk-based testing strategies [7]. In parallel, the currently available prevalence studies have classified the United Kingdom as a very low prevalence country for HCV. In the United Kingdom, it is thought that around 214,000 people are living with chronic HCV [37]. According to the Hepatitis C report in the UK available since 2017, such factors as injecting drug use, being black or coming from minority ethnic populations having close links to countries with a high prevalence of the HCV infection continue to be the most important risk factors for infection. It shows that HCV infection affects populations that have poorer access to healthcare. Other less frequently reported exposure risks in England are similar to those observed in most of the countries like the United States, Canada, France and Poland, such as recipients of unscreened blood and untreated blood products, patients exposed to renal units, the injecting drug users and infants born to infected mothers.

Summing up, numerous studies have explored the potential impact of HCV testing based on the screening of persons with identified HCV infection risk factors (based on individual risk assessment), screening of risk groups (injecting drug users, users of psychoactive substances), screening of people living in places where the HCV prevalence is very high (immigrants), and screening based on specific age groups (people over 50 years). Considering the results of our study and the epidemiological situation in Poland, the most important indications for the HCV test are injection drug users (even only once in a lifetime), recipients of blood before 1992 and individuals over 45 years.

According to the project “Prevention of hepatitis C virus (HCV) infections” prepared by the National Institute of Public Health in 2017 in Poland, it is estimated that 65% of injecting drug users have HCV antibodies, which means that they have had contact with HCV [24]. It is worth stressing that the majority of the HCV-positive drug users are not aware of their infection. This problem is of course complex and points out the various causes of this phenomenon, both on the patients’ side – lack of awareness of the infection, a lack of elementary knowledge of the transmission routes, as well as a lack of systemic solutions prepared by the government (the inclusion of the serological tests for HCV in the Polish Primary Care Services) [20]. Probably, we should implement new solutions, such as “mobile medical clinics” in urban settings, which can effectively reach the injecting drug users in the places where they live/exist.

Currently, the most important challenge is to find an answer to the question: Who is the person with the highest risk of HCV exposure and late presentation of HCV infection in Poland?

## Conclusions

The study highlights that the implementation of routine rapid testing is an essential tool for identifying new HCV infections and might have an important role in the population's health. Our findings suggest that using a risk-based strategy is an effective and low-cost method of detection of undiagnosed patients in the Emergency Department and this diagnostic strategy should be adopted in other medical settings.

## Disclosure

The authors report no conflict of interest.

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