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Limited access to hepatitis B/C treatment among vulnerable risk populations: an expert survey in six European countries

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Background: To investigate access to treatment for chronic hepatitis B/C among six vulnerable patient/population groups at-risk of infection: undocumented migrants, asylum seekers, people without health insurance, people with state insurance, people who inject drugs (PWID) and people abusing alcohol. **Methods:** An online survey among experts in gastroenterology, hepatology and infectious diseases in 2012 in six EU countries: Germany, Hungary, Italy, the Netherlands, Spain and the UK. A four-point ordinal scale measured access to treatment (no, some, significant or complete restriction). **Results:** From 235 recipients, 64 responses were received (27%). Differences in access between and within countries were reported for all groups except people with state insurance. Most professionals, other than in Spain and Hungary, reported no or few restrictions for PWID. Significant/complete treatment restriction was reported for all groups by the majority in Hungary and Spain, while Italian respondents reported no/few restrictions. Significant/complete restriction was reported for undocumented migrants and people without health insurance in the UK and Spain. Opinion about undocumented migrants in Germany and the Netherlands was divergent. **Conclusions:** Although effective chronic hepatitis B/C treatment exists, limited access among vulnerable patient populations was seen in all study countries. Discordance of opinion about restrictions within countries is seen, especially for groups for whom the health care system determines treatment access, such as undocumented migrants, asylum seekers and people without health insurance. This suggests low awareness, or lack, of entitlement guidance among clinicians. Expanding treatment access among risk groups will contribute to reducing chronic viral hepatitis-associated avoidable morbidity and mortality.

Introduction

Infection with hepatitis B (HBV) virus and C virus (HCV) affects the liver and can result in a broad spectrum of disease outcomes. People with chronic hepatitis B (CHB) and/or C virus infection remain infectious and are at risk of serious liver disease such as cirrhosis or hepatocellular cancer (HCC). Worldwide, chronic viral hepatitis infection is responsible for over 70% of deaths due to HCC and nearly 60% of deaths due to cirrhosis.[1,2] Around 480–520 million people are estimated to be chronically infected with HBV/HCV, although there are strong regional differences in burden of disease. The largest burden of HCV is found in Central/Eastern Asia and the Middle East whereas HBV prevalence is highest in Sub-Saharan Africa and Asia.[3] There is also some geographical variation in HBV and HCV prevalence in Europe.[4] Most CHB infections in Europe are detected among migrants from HBV-endemic areas. Chronic hepatitis C is also more common among migrants (due to non-sterile health care, dental and shaving practices and equipment in low-and middle-income countries of origin), although a large proportion is found among current/past injecting drug users.[5] Differences in the proportion of chronic hepatitis C cases detected among migrants compared with people who inject drugs (PWID) are reported in Europe; in the United Kingdom (UK), e.g. PWID account for over 90% of cases,[6] whereas migrants from endemic areas account for most infections in the Netherlands, Germany, Italy and Spain.[7,8]

Chronic infections are mostly asymptomatic and progress over a period of 20–30 years towards cirrhosis and HCC. Effective treatment exists for both chronic hepatitis B and C and, from 2014, highly effective direct-acting antivirals that can cure chronic hepatitis C are available.[9,10] Early identification, before decompensation and/or development of HCC, is strongly associated with improved treatment outcome.[11] Therefore, screening for chronic infection among a range of risk groups, but particularly among people born in hepatitis B/C endemic areas and PWID, is recommend as a form of secondary prevention.[6,12] Screening among migrants from areas with >2% viral hepatitis prevalence has also been shown to be cost-effective.[13] Although incident cases

are decreasing, models predict that the peak mortality for HCV-related causes is ahead of us and a large undiagnosed burden of disease exists; that the proportion of people infected that are unaware, undiagnosed and not in treatment is considerably larger than the proportion diagnosed and in treatment.[8] For example, a large screening study in primary care in Germany found that 85% of HBsAg and 65% of anti-HCV positive individuals were unaware of their infection.[14] However, there are few published studies of migrant-specific viral hepatitis screening programmes in Europe.[15–18] PWID-specific studies are more common although screening among this high-risk group is not systematic in any European country, due to both health system and patient-group characteristics, including criminalisation.[19] The literature also suggests that migrant populations experience difficulties in accessing health care and experience worse health outcomes as a result.[20–22] Little is known about access to treatment across Europe among marginalised groups at risk of hepatitis B/C infection.

We aimed to investigate access to treatment for chronic hepatitis B/C in six EU countries (Germany, Hungary, Italy, the Netherlands, Spain and the United Kingdom (UK)) among six patient/population groups. These included undocumented migrants, asylum seekers, people without health insurance, people with state insurance, PWID and people who abuse alcohol. This study is part of *HEPscreen*,[23] an EU Health Programme-funded project focused on screening for chronic viral hepatitis among migrants in Europe.

Methods

A semi-quantitative online survey was developed, pilot tested and translated into the national languages of the study countries and uploaded into Lime Survey™ open source online survey software. The aim of the survey was to understand care pathways in clinical services for patients diagnosed with chronic viral hepatitis in the six study countries using nominal, ordinal and qualitative questions. We report here the results focused on access to treatment among specific patient/population groups; the more clinically focused questions about the use of diagnostics, referral and the role of different clinical specialists are to be reported elsewhere. The survey was sent to experts in hepatology, gastroenterology and infectious diseases based in six EU countries: Germany, Hungary, Italy, the Netherlands, Spain and the UK. We identified experts via board membership of clinical and professional associations, leadership of hepatology treatment and research centres, and authors of relevant scientific articles. Our objective was to reach a sample of 5–10 knowledgeable experts from each country rather than develop a representative sampling frame. In recognition of the low response rate to surveys among practising clinicians, we identified a large sample of 243 recipients.

We asked whether treatment for chronic hepatitis was restricted for each of the six patient/population groups and developed a four-point ordinal scale to measure this: 'no restrictions', 'some restrictions', 'significant restrictions' and 'completely restricted'. An 'unsure' option was also available. We collected respondent data by asking for organisation type and whether they were involved in the care of patients/had a clinical role. Among those with a clinical role, we asked for their medical specialism and used a three-point ordinal scale to gather data on frequency of seeing chronic hepatitis B/C patients (weekly, monthly and annually). Recipients were contacted via e-mail in July 2012 and further reminded twice during data collection. The survey closed in September 2012. Data was exported from Lime Survey to SPSS 19.0.2 for descriptive analysis of frequencies and proportions.

Results

Respondents

Eight of 243 recipients actively opted out after receiving the invitation. From the remaining 235 recipients, a total of 64 responses were received (27%). The response rate differed across the six study countries: 11% in Germany, 24% in the UK, 25% in Spain, 27% in Hungary, 48% in the Netherlands and 60% in Italy. In five of the six countries, Spain being the exception, we achieved the target of between 5 and 10 experts. Three of these 64 respondents had not completed the whole survey and were excluded. All but three of the 61 are currently involved in the care of patients and 95% of these see chronic hepatitis patients on a weekly basis. Due to the clinical nature of the topics, analysis was restricted to only data supplied by those with a clinical role ($n = 58$). Of these, the majority (77%) are specialists in gastroenterology or hepatology, a fifth are specialists in infectious disease, and a small number ($n = 3$) are community/practice nurses. The respondent profile pattern in all countries was similar to this overall pattern except in Italy and the Netherlands; in Italy, nearly half (44%) are specialists in infectious disease and in the Netherlands, a larger proportion (81%) are gastroenterologists/hepatologists. Most are based in academic (61%) or general hospitals (28%).

Access to treatment for undocumented migrants

Most respondents in all countries but Italy reported that antiviral treatment for chronic viral hepatitis is completely or significantly restricted for undocumented migrants. This is especially so in Hungary where three quarters reported treatment to be completely restricted, in the UK where two thirds indicated significant or complete restriction, and in Spain where three quarters selected significant or complete restriction. Over three quarters in Italy reported that there are no or some restrictions in place. Opinion was divided in the Netherlands and Germany (table 1).

Access to treatment for asylum seekers

Two-thirds of those in Hungary and half in Spain reported significant or complete restrictions in treatment for chronic hepatitis patients with asylum seeker status. In contrast, all but one respondent in Germany, over half in the UK, and three quarters of those in the Netherlands and Italy reported no or few restrictions for asylum seekers. However, there are some in the UK, Germany and the Netherlands who indicated that significant restrictions are in place (table 2).

Access to treatment for people without health insurance and people with only state insurance

Over 75% in Italy reported no or few restrictions for those without health insurance whereas significant or complete restrictions were reported by the majority of respondents in Hungary (75%), Spain (75%), the UK (56%) and the Netherlands (46%). Opinion was divided in Germany (table 3). We included the group 'state insurance only' to further explore the influence of (private) health insurance on access to treatment and found that the vast majority of respondents indicated that there are no restrictions (table 3). In the UK, Germany, the Netherlands and Italy, nearly all respondents selected no restrictions. Although 50% in Hungary indicated that no restrictions exist for this group, one quarter selected significant restrictions.

Access to treatment for PWID and patients who abuse alcohol

The majority of respondents in the UK, Germany, the Netherlands and Italy indicated no or few restrictions in antiviral treatment for PWID infected with chronic hepatitis (table 4). In contrast, three quarters of professionals in Hungary reported significant or complete restrictions, with half reporting complete restrictions. Half in Spain reported there to be significant restrictions in place, although others indicated no or some restrictions. As with PWID, the majority of respondents in the UK, Germany, the Netherlands

Table 1 Reported treatment restrictions among undocumented migrants

	UK (*n*=9) (%)	DE (*n*=6) (%)	NL (*n*=22) (%)	HU (*n*=8) (%)	IT (*n*=9) (%)	ES (*n*=4) (%)
No restrictions	11	17	14	0	33	25
Some restrictions	0	17	27	13	44	0
Significant restrictions	44	17	27	0	0	25
Complete restrictions	22	33	23	75	11	50
Unsure	22	17	9	13	11	0

Table 2 Reported treatment restrictions among asylum seekers?

	UK (*n*=9) (%)	DE (*n*=6) (%)	NL (*n*=22) (%)	HU (*n*=8) (%)	IT (*n*=9) (%)	ES (*n*=4) (%)
No restrictions	56	33	50	0	56	25
Some restrictions	0	50	23	0	22	0
Significant restriction	22	17	18	38	0	0
Complete restriction	0	0	0	25	11	50
Unsure	22	0	9	38	11	25

and Italy reported no or few restrictions in treatment to be in place for chronically infected patients who abuse alcohol. It was the opposite in Hungary, as over 75% reported complete or significant restrictions. Opinion was divided in Spain but suggests the existence of restrictions in access to treatment for patients who abuse alcohol.

Discussion

Although effective treatment for chronic hepatitis B/C exists and even cure for chronic hepatitis C, results from this study show that access to treatment is limited for a number of vulnerable populations at risk of chronic infection in most countries we studied. Restrictions were most often reported by experts in Hungary and Spain, while as a group, undocumented migrants have the most limited access to treatment. We also found discordance of opinion about restrictions within countries, especially for groups for whom the health care system defines access to treatment, such as undocumented migrants, asylum seekers and people without health insurance.

For screening to be considered ethical and appropriate and to result in health gain, there should be treatment available for diagnosed patients.[24] The Wilson and Jungner criteria list availability of effective treatment and an agreed policy on who to treat as two of 10 principles that should be met to conduct screening. Treatment availability and eligibility are often seen from a biomedical perspective, in terms of clinical or prognostic factors only. As the six study countries organise their health care differently, eligibility and availability can also be understood from a health system perspective. We were interested to find out whether there are population-group specific restrictions in place as understood by clinicians most involved in providing it. The profile of our respondents indicates that this aim was fulfilled; nearly all respondents are clinical specialists in gastroenterology, hepatology or infectious diseases and see infected patients on a weekly basis.

As in many parts of the world, there are differences in health system organisation between EU countries that make it an interesting environment in which to conduct health systems and health services research; in our EU-funded project, we adopted a European perspective and sought to compare six Member States. In Bismarckian-based welfare states, like the Netherlands and Germany, citizens must 'buy' health insurance provision from insurance companies who cannot discriminate on the basis of individual health conditions or risk factors and contributions depend on an individual's financial resources.[25,26] It is, therefore, not surprising that we do observe some or significant restrictions in access to treatment among people without health insurance here (table 3). In Beveridge-style welfare states, like Italy, Spain and the UK, the notion of national insurance as collective contributions towards social and health service provision is familiar and a national health service with associated universal free access is in place.[27] Other than a small minority who purchase private health insurance coverage, the concept of 'buying' health insurance as a means to entitlement in these universal health systems is undesirable and alien to most. This universalism is mirrored in responses from Italy where no or only some restrictions exist for all six patient/population groups. It is, however, somewhat surprising that restriction to treatment among those without insurance is reported in Spain and the UK, countries with health systems where insurance is not expected to play a role. However, both systems rely on some form of registration to receive social support, such as a National Insurance/NHS number in the UK or a residence permit in Spain. Access to health care would be limited without this registration, not because patients do not have health insurance coverage but because those without state insurance cover are effectively considered undocumented migrants or persons for whom health care entitlement is uncertain.[28] As a result of the financial crisis affecting Spain from 2008, various austerity and cost-containment measures were introduced into the health and social welfare system. One change, introduced after our survey was conducted, was the restriction of access to health care among undocumented migrants (and others considered to be uninsured under the universal, residence permit-based system) to emergency and ante- and post-natal care only.[29] The implication is likely to be more severe restrictions than the already significant restrictions we observe in our results. In Hungary, the health care system is a hybrid of a Semashko-style Soviet system and a Bismarckian-influenced model where (social) health insurance coverage is key to access but the legacy of out-of-pocket payments remains.[30] In fact, respondents from Hungary reported the most restrictions among population groups, especially among undocumented migrants, asylum seekers and people without insurance.

Another surprising finding was the discordance about restrictions within each country, especially for population groups for whom the health care system or policy context defines access to treatment, such as undocumented migrants, asylum seekers and people without health insurance. We suggest that this lack of consensus about restrictions in access to treatment may either be an important explanation of, or in fact caused by, the limited existence of screening programmes that target these higher risk populations. Undocumented migrants and asylum seekers are rarely screened for viral hepatitis and, if found chronically infected, do not actually reach secondary care.[31] Previous studies also found lower

Table 3 Reported treatment restrictions among people with no/state insurance

	UK (*n*=9) (%)		DE (*n*=6) (%)		NL (*n*=22) (%)		HU (*n*=8) (%)		IT (*n*=9) (%)		ES (*n*=4) (%)	
	No	State	No	State	No	State	No	State	No	State	No	State
No restrictions	11	78	0	100	18	82	0	50	44	89	25	50
Some restrictions	11	0	50	0	18	9	16	25	33	11	0	50
Significant restriction	56	0	33	0	32	0	0	25	11	0	25	0
Complete restriction	0	0	0	0	14	0	75	0	11	0	50	0
Unsure	22	22	17	0	18	9	13	0	0	0	0	0

Table 4 Reported treatment restrictions among PWID and people who abuse alcohol (Alc.)

	UK (*n*=9) (%)		DE (*n*=6) (%)		NL (*n*=22) (%)		HU (*n*=8) (%)		IT (*n*=9) (%)		ES (*n*=4) (%)	
	PWID	Alc.	PWID	Alc.	PWID	Alc.	PWID	Alc.	PWID	Alc.	PWID	Alc.
No restrictions	22	22	33	17	55	36	0	13	44	33	25	0
Some restrictions	56	56	50	67	36	59	25	13	33	44	25	50
Significant restriction	11	11	17	17	5	5	25	38	11	0	50	25
Complete restriction	0	0	0	0	5	0	50	38	11	22	0	25
Unsure	11	11	0	0	0	0	0	0	0	0	0	0

preventative health care usage and poorer health outcomes from viral hepatitis among migrant groups.[32,33]

This lack of consensus also suggests that specific guidance about health care entitlement is either not available, unclear or not known to medical professionals most involved in treating viral hepatitis. In the absence of clear guidance about access to specific services/provision in the health care system, professional discretion when treating patients is likely to be applied.[34] To deal with ambiguous health care entitlement criteria, two professional coping strategies have been suggested: 'functional ignorance' where the legal status of somebody who needs health care is neither asked for nor monitored; and 'partial acceptance', where, e.g. specific sub-groups of migrants without permission to stay may have the right to certain limited hospital and outpatient treatment in the case of sickness or accidents, as well as to preventive care.[35] The extent to which the adoption of either strategy influences health outcomes, in terms of screening and referral to specialist care for treatment, warrants further investigation.

Discordance of opinion could be explained by other health system factors. For example, within the Dutch health care system, there are only a selected number of hospitals that are able to provide antiviral treatment to patients without health insurance.[36] The regional organisation of municipal and other public services in Germany (*Länder*) and Spain (*Comunidad Autónoma*) may also be reflected in differing arrangements of health care including entitlement, especially for marginalised groups like undocumented migrants. In the case of Spain, regional authorities define the benefits package for the local population according to local preferences and needs and are responsible for public health service planning.[37]

For PWID patients and patients who abuse alcohol, restricted treatment is less likely to be explained by the health system or policy context and more likely due to associated clinical implications.[9,10] Most professionals in most study countries, other than in Spain and Hungary, reported no or few restrictions for PWID. Case detection, treatment and clinical management of PWID is an important public health issue given the high risk of HCV transmission associated with injecting drug use as well as the large proportion of current/past injecting drug users among the burden of chronic hepatitis C cases in the European population.[4,7] However, previous studies suggest that many PWID remain undetected and if screened, do not reach specialist secondary care.[19,32,38] Over half in all study countries (table 4) reported the existence of some restrictions for patients who abuse alcohol. Alcohol use among people infected with chronic viral hepatitis affects disease progression and increases the risk of cirrhosis and HCC. Alcohol intake is, therefore, undoubtedly a key treatment consideration among chronic viral hepatitis patients and although it is not an explicit contraindication for treatment,[9] alcohol and drug use are identified as the reason for ineligibility of treatment by 83% of treating clinicians in the UK.[39]

The current climate of economic austerity has led to restrictions access to both health and social welfare provision among vulnerable populations and to the effective new treatments that can potentially cure chronic hepatitis C infection.[40] It is, therefore, possible that access to treatment among the populations investigated here has become more restricted since the time of this study. The significant health gains possible through our expanded understanding of viral hepatitis and the scope for secondary prevention can only be realised through expanded access to screening and antiviral treatment to urgently find those most affected.[8]

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Key points

- Discordance of opinion found about access to antiviral treatment for chronic hepatitis B/C across and within six European countries suggests differences both in

interpretation of health care entitlement guidance and in health systems.

- Treatment is significantly or completely restricted for undocumented migrants in all six countries but Italy. Access among asylum seekers differs considerably across the study countries.
- Restriction to treatment among people without insurance was reported in universal national health systems (Spain and the UK).
- Most professionals in most countries, other than in Hungary and Spain, reported no or few restrictions for people who inject drugs.
- Without improved access to screening and treatment, especially among marginalised and vulnerable at risk populations, the potential health gains from advances in secondary prevention cannot be realised.

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