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ORIGINAL ARTICLE

Identifying missed opportunities for hepatitis C virus antenatal testing and diagnosis in England

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Abstract

New case-finding opportunities are needed to achieve hepatitis C virus (HCV) elimination in England by the year 2030. HCV antenatal testing is not offered universally in England but is recommended for women with risk factors for HCV (e.g. injecting drug use, being born in a high-prevalence country). The aim of this analysis was to investigate the missed opportunities for HCV antenatal testing among women who had given birth and were subsequently diagnosed with HCV at some time after childbirth. By linking data on live births (2010–2020) to laboratory reports of HCV diagnoses (1995–2021), we identified all women who were diagnosed with HCV after the date of their first childbirth. This group was considered to potentially have experienced a missed opportunity for HCV antenatal testing; HCV-RNA testing and treatment outcomes were also obtained for these women. Of the 32,295 women who gave birth between 2010 and 2020 with a linked diagnosis of HCV (median age: 34 years, 72.1% UK-born), over half ($n = 17{,}123$) were diagnosed after childbirth. In multivariable analyses, the odds of being diagnosed with HCV after childbirth were higher in those of Asian Bangladeshi, Black African or Chinese ethnicity and among those born in Africa. Over four-fifths (3510/4260) of those eligible for treatment were linked to treatment, 30.7% (747/2435) of whom had a liver scarring level of at least moderate and 9.4% (228/2435) had cirrhosis. Given the potential opportunity to identify cases of HCV with targeted case-finding through antenatal services, universal opt-out testing should be considered in these settings.

KEYWORDS
antenatal testing, hepatitis C virus, late diagnosis, linkage to treatment, opt-out testing

Abbreviations: ESLD, End-Stage Liver Disease; HBV, Hepatitis B Virus; HCV, Hepatitis C Virus; IDU, Injecting Drug Use; ONS, Office of National Statistics; UKHSA, UK Health Security Agency; WHO, World Health Organization.

1 | INTRODUCTION

England has committed to the World Health Organization's (WHO) strategy to eliminate viral hepatitis as a public threat by the year 2030.[1] Internationally, it is estimated that 95% of deaths from viral hepatitis are attributable to hepatitis B (HBV) and C (HCV) viruses.[1] People with HCV in England often present at a late stage of HCV infection, as over one in five people have liver cirrhosis at initiation of treatment, and around half of those with liver cirrhosis were diagnosed with HCV in the previous 2 years.[2] Additionally, 17% of those with HCV-associated end-stage liver disease (ESLD) presented with ESLD prior to their HCV diagnosis.[3] While England has surpassed WHO targets to reduce HCV-related mortality and progress has been made reducing the prevalence of HCV-related morbidity, continued prevention and new case-finding approaches are needed to increase the number of people living with HCV who are aware of their infection and referred to treatment, to reduce the number of people diagnosed at a late stage of infection and ultimately improve the health outcomes of people living with HCV.[2]

Antenatal screening in the UK routinely offers syphilis, HIV and HBV testing,[4] and acceptance of antenatal HBV screening is high (99.8% in 2019/20).[5] Routine universal HCV testing is not currently recommended as part of antenatal screening, due to a low risk of mother-to-child transmission, lack of trial evidence on the efficacy of treatment for HCV in pregnancy and uncertainty about the prevalence of HCV infection among pregnant women.[6] National guidance recommends opportunistic risk-based HCV testing within antenatal services for women with risk factors for HCV such as injecting drug use (IDU) or being from a country with a high HCV prevalence.[7] Although, there is evidence to question how well this is implemented, with local guidance on testing for HCV antenatally varying across care providers.[8,9] Research in London has found that nearly three-quarters (73%) of women who were newly diagnosed with HCV through universal opt-out antenatal screening would have been missed through risk-based screening.[9] Additionally, universal opt-out testing for HCV in antenatal settings has been deemed to be cost-effective in areas where HCV prevalence was 0.1% or higher.[10]

Therefore, the aim of this analysis was to investigate the potential missed opportunity for HCV testing and diagnosis in antenatal services in England by assessing the proportion of women who were diagnosed with HCV after childbirth and evaluating sociodemographic factors associated with post-childbirth diagnosis.

2 | METHOD

The Office of National Statistics (ONS) registry of live births, a dataset of all women who gave birth in England (2010–2020), was linked to routine laboratory reports of HCV diagnoses in England (1995–2021), using a combination of mother's surname, soundex (coding based on a person's surname) and mother's date of birth. For those women with linked records, we considered that there had been a missed opportunity for HCV antenatal testing if the woman was only diagnosed after their first child was born. This assumes that women had acquired HCV prior to pregnancy, consistent with findings that most people diagnosed with HCV tend to be diagnosed at a late stage of infection.[2]

Due to insufficient reporting of HCV-RNA testing in laboratory reports, data pertaining to women who were diagnosed with HCV after childbirth were linked to the sentinel surveillance for blood borne viruses to obtain additional HCV-RNA testing results.[11] Those who were HCV-RNA positive and thus eligible for treatment were also linked to the HCV treatment database (2015–2022) using a combination of NHS number, soundex, date of birth and gender in order to assess fibroscan results and uptake and outcomes of treatment. Fibroscan results were categorised using the European Study of Liver Disease guidance for HCV treatment.[12]

Univariable logistic regression analyses were conducted to describe associations of age, ethnicity and region of birth with post-childbirth diagnosis. Factors, where global p-values were <.1 in bivariable analyses, were included in the multivariable model. Due to the inability to determine when a person acquired HCV in relation to their antenatal screening, a sensitivity analysis was also conducted between those diagnosed prior to childbirth and those diagnosed within 3 years of childbirth. Three years was chosen as a compromise so as to exclude the group of women who would have had the greatest opportunity to have acquired HCV post-childbirth while still permitting a sufficiently powered analysis. To help reduce the risk of including women who acquired HCV after childbirth, those who had evidence of a potential spontaneous clearance (a negative HCV-RNA test following a positive HCV-RNA test with no evidence of treatment) within 6 months of their initial diagnostic test were excluded. A period of 6 months was chosen as the majority of spontaneous clearance occurs during the acute stage of infection (i.e. within the first 6 months after acquisition of HCV).[13,14]

A chi-square analysis was conducted for Fibroscan results to indicate scarring level between women diagnosed with HCV less than 3 years after childbirth and those diagnosed after 3 years or more.

Ethical approval was not obtained for this study as laboratory diagnosis data with personal identifiable information are collated and processed by UKHSA as part of surveillance of HCV infection and disease. These data collections are covered by Health Service (Control of Patient Information) Regulations 2002 (regulation 3) which makes provisions for the recognition, control and prevention of communicable diseases and other risks to public health. Caldicott approval was obtained for the linkage between live births dataset and laboratory reports, as well as the linkage to the sentinel surveillance for blood borne viruses testing and the treatment dataset.

3 | RESULTS

There were 76,956 women with a laboratory report of an HCV diagnosis between 1995 and 2020, 42% of whom (32,295) were linked to the dataset of women who gave birth between 2010 and 2020. Among those not linked to the ONS registry of live births,

58% (26,311/44,661) had the minimum information reported that was required for linkage. The median age of women at the birth of their first child was 34 years (range 14–59 years), and 23,293 (72.1%) had been born in the UK. After excluding women who had evidence of a potential spontaneous clearance within 6 months of diagnosis ($n = 257$), 16,866 (52.6%) received their initial HCV diagnosis after their first child was born. Among this sub-group, the median time between childbirth and being diagnosed with HCV was 1724 days (4.7 years) (inter-quartile range 894–2616 days [2.4–7.2 years]).

Table 1 displays the results of univariable and multivariable logistic regression analyses for the associations of age, ethnicity and region of birth with post-childbirth diagnosis. In univariate analyses, significant associations were seen for each factor, with associations generally remaining similar after adjustment. In particular, those who were older were less likely to receive their HCV diagnosis after childbirth. When compared to women of White British ethnicity, women of Asian Bangladeshi and Chinese ethnicity were most likely to be diagnosed after childbirth, with the odds of post-childbirth diagnosis also being higher in women of other non-Pakistani Asian, Black (African, Caribbean or other) or non-British/Irish White ethnic groups. Whereas those born in Africa were more likely to be diagnosed with HCV post-childbirth (relative to those born in the UK), those born in other European countries were less likely to be diagnosed post-childbirth. A sensitivity analysis limited to women diagnosed within 3 years of their antenatal screening produced similar results, except being of Black Caribbean ethnicity was no longer significantly associated with increased odds of being diagnosed after childbirth compared to White British ethnicity, and being of mixed ethnicity was significantly associated with increased odds of being diagnosed after childbirth.

Among the women diagnosed after childbirth, 10,403 (61.7%) had a linked RNA test, and 5393 (51.8%) had a positive HCV-RNA test result. Of these, 1133 (21%) had a subsequent negative HCV-RNA test result with no evidence of treatment, with the remaining 4260 (79%) being eligible for treatment. Over four-fifths (3510, 82.4%) of those eligible for treatment were linked to treatment data, of whom 3268 (93.1%) initiated treatment between 2015 and 2022. Two-fifths of women linked to treatment data had no history of IDU (1307, 40%); among this group, 101 (7.7%), 254 (19.4%) and 112 (8.6%) were born in Africa, Asia and eastern Europe, respectively.

Fibroscan results were available for 2435 (69.4%) of the women linked to treatment data (Table 2). In this group, most (2206, 90.6%) had a scarring level of at least normal to mild (≥2 kPa), with 747 (30.7%) having a scarring level of at least moderate (>7 kPa), and 228 (9.4%) having cirrhosis (≥12.5 kPa). There was no significant difference in scarring level between women who were diagnosed less than 3 years after childbirth and those diagnosed 3 years or more ($p = .163$). The median time between childbirth and initiating treatment among those diagnosed after childbirth was 2542.5 days (7 years) (inter-quartile range 1901–3171 days [5.2–8.7 years]). Among those who initiated treatment, 2489 (76.2%) achieved a sustained virologic response (SVR).

4 | DISCUSSION

This study highlights the potential missed opportunity for HCV diagnosis in antenatal settings in England, as between 2010 and 2020 over half of women who had given birth and had a reported diagnosis of HCV were diagnosed after childbirth. A limitation of this study is that the timing of acquisition of HCV could not be determined; therefore, we cannot say with certainty that women who were diagnosed after childbirth would have already been living with HCV and thus diagnosed if tested antenatally. However, as acute HCV infection is mostly asymptomatic and people often present at a late stage of HCV infection in England,[2,3] we believe it is reasonable to assume that a significant majority of these women could have been diagnosed antenatally. Additionally, a sensitivity analysis was conducted where time to diagnosis after childbirth was limited to less than 3 years, which produced similar findings. To further increase the sensitivity that our study group contained only women who acquired HCV prior to childbirth, any women who had evidence of spontaneous clearance within 6 months of diagnosis were excluded from analyses. Spontaneous clearance, when occurs, generally does so within 6 months of acquisition of HCV.[13,14] The 6-month period used in this analysis started at the time of diagnosis and therefore likely covers a longer period of time than would be needed to see any cases of spontaneous clearance.

Women who were older were less likely to be diagnosed after childbirth. It is unclear if this is due to these women not having contracted HCV at the time of antenatal screening, thereby only being able to be diagnosed after childbirth, or whether these women were not in a risk category for antenatal testing.

The odds of being diagnosed with HCV after childbirth varied by ethnicity and region of birth, with women of most Black or Asian ethnicities being more likely to be diagnosed after childbirth than White British women. This supports findings from a survey of maternity services in England, which found that the implementation of national guidance for risk-based testing using ethnicity and country of birth varied at a local level.[8] Black and ethnic minority women experience a number of health inequalities during maternal care,[15] such as missed (or fewer) opportunities for testing. Given concerns that targeted testing based on ethnicity, country of birth, and migration status may be perceived as discriminatory or stigmatising, opt-out testing could be a more appropriate and acceptable alternative to risk-based testing. Among those diagnosed after childbirth with no history of IDU, some were born in high-prevalence countries suggesting that they could have been diagnosed antenatally. Moreover, women with a history of IDU could have been diagnosed antenatally, further supporting the case for antenatal opt-out testing.

TABLE 1 Univariable and multivariable logistic regression analyses for ethnicity and region of birth associations with being diagnosed with hepatitis C virus after childbirth.

	Diagnosed prior to childbirth *N* = 15,172 Mean (SD)	Diagnosed after childbirth *N* = 16,866 Mean (SD)	Row (%)	Univariable OR (95% CI)	*p*-value
Age	34.8 (6.3)	32.1 (7.1)	–	0.94 (0.94, 0.94)	<.0001
Ethnicity					<.0001
White British	8712	8341	49	ref.	
White Irish	77	64	45	0.87 (0.62, 1.21)	
Any other White ethnicity	1324	1918	59	1.51 (1.40, 1.63)	
Mixed	207	238	53	1.20 (0.99, 1.45)	
Asian Indian	107	178	62	1.74 (1.36, 2.21)	
Asian Pakistani	879	867	50	1.03 (0.93, 1.14)	
Asian Bangladeshi	16	45	74	2.94 (1.64, 5.20)	
Any other Asian ethnicity	177	252	59	1.49 (1.22, 1.81)	
Black African	177	270	60	1.59 (1.32, 1.93)	
Black Caribbean	64	76	54	1.24 (0.89, 1.73)	
Any other Black ethnicity	68	109	62	1.67 (1.23, 2.27)	
Chinese	51	134	72	2.74 (1.99, 3.79)	
Other	231	224	49	1.01 (0.84, 1.22)	
Unknown	3082	4150	57	–	
Region of birth					<.0001
UK	11,036	12,059	52	ref.	
Western and Southern Europe	809	781	49	0.88 (0.80, 0.98)	
Eastern Europe	830	874	51	0.96 (0.87, 1.06)	
Africa	610	892	59	1.34 (1.20, 1.49)	
Asia	1489	1905	56	1.17 (1.09, 1.26)	
Central and Southern America	155	150	49	0.89 (0.71, 1.11)	
North America	109	104	49	0.87 (0.67, 1.14)	
Oceania	121	97	44	0.73 (0.56, 0.96)	
Unknown	13	4	44	–	

TABLE 2 Fibroscan results for women who were diagnosed with hepatitis C virus less than 3 years and greater or equal to 3 years after childbirth.

Fibroscan results	Diagnosed <3 years after childbirth (*N* = 844) (Col %)	Diagnosed ≥3 years after childbirth (*N* = 1591) (Col %)	Total (*N* = 2435) (Col %)
<2	79 (9.4)	150 (9.4)	229 (9.4)
Normal to mild (≥2 and <7)	515 (61)	944 (59.3)	1459 (59.9)
Moderate (≥7 and <9.5)	121 (14.3)	238 (15)	359 (14.7)
Severe (≥9.5 and <12.5)	45 (5.3)	115 (7.2)	160 (6.6)
cirrhosis (≥12.5)	84 (10)	144 (9.1)	228 (9.4)

Linkage to treatment and treatment initiation among those who were eligible for treatment was high but could be improved. Treatment is not recommended while pregnant and breastfeeding,[16] and therefore, if a women has subsequent children, this may delay treatment initiation. However, ongoing work is needed to ensure women testing positive antenatally are not lost to follow-up. Among the sub-group where Fibroscan data were available, 91% of women had some degree of scarring, around a third had at least moderate scarring, and 10.1% had scarring that was indicative of cirrhosis. This suggests that these women would have had HCV diagnosis if tested during antenatal care as time to cirrhosis from HCV infection is generally decades (37 years for a 20 year old and 29 years for a 30 year old).[17] Although the Fibroscan results are from linkage to treatment and therefore include any delays in treatment initiation after

Multivariable aOR (95% CI)	*p*-value	Diagnosed < 3 years after childbirth *N* = 5233 Mean (SD)	Row %	Univariable OR (95% CI)	*p*-value	Multivariable aOR (95% CI)	*p*-value
0.95 (0.94, 0.95)	<.0001	32.6 (6.9)	–	0.95 (0.94, 0.95)	<.0001	0.95 (0.95, 0.96)	<.0001
	<.0001				<.0001		<.0001
ref.		2645	24	ref.		ref.	
1.01 (0.71, 1.39)		26	29	1.11 (0.71, 1.74)		1.27 (0.81, 1.99)	
1.65 (1.52, 1.80)		696	27	1.73 (1.56, 1.92)		1.79 (1.59, 2.02)	
1.17 (0.97, 1.42)		90	27	1.43 (1.11, 1.84)		1.40 (1.09, 1.81)	
1.76 (1.37, 2.26)		66	27	2.03 (1.49, 2.77)		1.99 (1.45, 2.75)	
1.08 (0.96, 1.21)		370	30	1.39 (1.22, 1.58)		1.43 (1.22, 1.66)	
2.90 (1.62, 5.20)		16	26	3.29 (1.64, 6.60)		3.27 (1.61, 6.63)	
1.53 (1.25, 1.87)		91	27	1.69 (1.31, 2.19)		1.69 (1.38, 2.22)	
1.48 (1.21, 1.82)		83	24	1.54 (1.19, 2.01)		1.38 (1.04, 1.83)	
1.41 (1.00, 1.98)		22	22	1.13 (0.70, 1.84)		1.19 (0.73, 1.95)	
1.62 (1.19, 2.22)		34	24	1.65 (1.09, 2.49)		1.55 (1.01, 2.36)	
2.66 (1.91, 3.72)		33	20	2.13 (1.37, 3.31)		1.92 (1.22, 3.02)	
1.05 (0.86, 1.27)		76	25	1.08 (0.83, 1.41)		1.06 (0.81, 1.39)	
–		985	19	–		–	
	<.0001				<.0001		.0002
ref.		3608	23	ref.		ref.	
0.71 (0.63, 0.81)		283	27	1.07 (0.93, 1.23)		0.78 (0.66, 0.92)	
0.62 (0.54, 0.70)		339	28	1.25 (1.10, 1.43)		0.74 (0.63, 0.88)	
1.36 (1.19, 1.56)		273	23	1.37 (1.18, 1.59)		1.29 (1.07, 1.55)	
0.96 (0.87, 1.06)		609	24	1.25 (1.13, 1.38)		0.96 (0.84, 1.11)	
1.16 (0.89, 1.50)		49	25	0.97 (0.70, 1.38)		1.07 (0.74, 1.56)	
0.91 (0.67, 1.25)		35	25	0.98 (0.67, 1.44)		1.05 (0.69, 1.60)	
0.91 (0.67, 1.24)		36	27	0.91 (0.63, 1.32)		1.26 (0.85, 1.86)	
–		1	27	–		–	

diagnosis, the impact of HCV on these women's health may have been reduced if they were tested antenatally for HCV. Additionally, these findings are similar to another study conducted in London, where all women diagnosed with HCV antenatally had mild liver disease.[18]

A limitation of this study is that disease progression could not be obtained for the majority of women who were diagnosed with HCV after birth. An attempt to assess disease progression with fibroscan results was made, but a result was not available for all women linked to treatment, and other co-morbidities associated with liver scarring could not be accounted for. Other factors associated with acquiring HCV, in particular IDU, could not be included in analyses, as IDU status was not reported in the live births dataset with this information only being available among those who were subsequently diagnosed with HCV and then, only at the time of HCV diagnosis. Additionally, the number of women diagnosed after childbirth who are HCV-RNA positive may differ than what is reported, due to the underreporting of HCV-RNA test results in laboratory results and the linkage between a national diagnoses dataset and the sentinel surveillance dataset, where coverage is around 40% of the GP registered population.[11]

In conclusion, this analysis provides evidence that there is a potential opportunity to identify more cases of HCV with targeted case finding in antenatal testing and that opt-out testing may be one option to remove heterogeneity in testing practice and identify those with chronic HCV infection to care earlier. Identifying these cases earlier may not only reduce morbidity for women with HCV, but also reduce potential further transmission of HCV with successful linkage to treatment and treatment completion.

AUTHOR CONTRIBUTIONS

MH linked the datasets, carried out the analysis and drafted the manuscript. MH, SM, MD, CS and RS conceived the initial concept. SM, MD, RS and CS provided critical input into the methodological and analytical approach, and all authors reviewed and approved all revisions.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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