

15-year evaluation of changes in the HBsAg positivity rate in pregnant women in Turkey: the prominent effect of national vaccination

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Abstract

Background: The detection of hepatitis B surface antigen positivity in pregnant women before delivery is crucial to preventing mother-to-child transmission of hepatitis B virus.

Aims: This study aimed to evaluate the status and rate of testing for hepatitis B surface antigen, rate of hepatitis B surface antigen positivity, hepatitis B surface antigen positivity distribution rate by age, and changes in hepatitis B surface antigen positivity rate in pregnant women over the study period.

Methods: We conducted a multicentre, cross-sectional, descriptive study covering the period January 2005 to June 2019 for 2 145 668 pregnant women from 27 provinces in all 7 regions of Turkey, collected using Microsoft Excel before statistical analysis.

Results: We found that 1 012 593 (47.1%) pregnant women were tested for hepatitis B surface antigen over the 15-year period, out of which 11 471 (1.1%) were hepatitis B surface antigen-positive. Overall, 97% of the hepatitis B surface antigen positive women were born before 1998, the year that national HBV vaccination was launched in Turkey. The rate of hepatitis B surface antigen positivity in that group was 1.1%, compared with 0.3% among women born after 1998.

Conclusion: There was a downward trend in the hepatitis B surface antigen positivity rate among pregnant women in the younger age groups, especially among those born after universal hepatitis B vaccination was inaugurated, and low rate of HBsAg testing during pregnancy.

Keywords: HBsAg positivity, pregnancy, vaccination, women Turkey

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Introduction

Worldwide, approximately 90% of people with chronic hepatitis are not aware of their illness (1). They may consequently spread the hepatitis B virus (HBV) to others and experience progression of the disease. Perinatal exposure is a significant mode of HBV transmission, resulting in chronic disease in approximately 90% of infected infants. Exposure to HBV in infancy or early childhood is associated with an increased risk of developing cirrhosis and hepatocellular carcinoma (1,2). It is, therefore, crucial to notify HBsAg positive pregnant women and take necessary precautions to prevent mother-to-child transmission of HBV. These precautions include routine prenatal screening for HBsAg in combination with the administration of hepatitis B hyper

immunoglobulin (HBIG) within the first 12–24 hours after delivery, followed by HBV vaccination of infants born of HBsAg positive mothers (3–5). Despite adequate prophylaxis with hepatitis B vaccination and HBIG, HBV transmission may occur at a rate of 5–10% in infants of HBeAg-positive mothers with a detectable HBV DNA level > 10 IU/mL (6,7). Some strategies, especially therapy with antiviral drugs, are therefore recommended in those with high viral load during pregnancy to reduce the amount of virus (viral load) in the blood. This strategy is essential to protect unborn babies from mother-to-child transmission (1,6–8).

Nowadays, even in most countries where HBV is endemic, HBsAg screening using an ELISA test during pregnancy is far below desirable levels. The US Centers

for Disease Control and Prevention recommends that each pregnant woman should be tested for HBsAg during the first prenatal visit in each pregnancy and further recommends HBsAg testing for all pregnant women, even if they had been previously vaccinated or tested (9–12).

The recommendations on the necessity of testing for HBsAg in pregnancy were first defined in Turkey in the antenatal care guidelines published by the Ministry of Health in 2014 (13). A considerable lack of knowledge or awareness of this guideline among physicians led to poor compliance with screening for HBsAg and insufficient requests for HBsAg testing during pregnancy; HBsAg testing, therefore, could not be done among pregnant women at the desired levels throughout the country. There was no legal obligation in Turkey to screen pregnant women for HBsAg during pregnancy until 2018. Thus, until 2018 physicians tested pregnant women for HBsAg only as a recommended option (13).

Turkey is among the moderately endemic countries in terms of HBV, located in the European continent and adjacent to the Asian continent. Its universal HBV vaccination programme started in 1998. Adolescent vaccination campaigns (catch-up campaigns) were carried out in schools between 2005 and 2009. Health workers and adults in the high-risk group are vaccinated free of charge by the Ministry of Health. Children born in 1998 and 1999 who were vaccinated at birth were revaccinated during the catch-up campaign. Catch-up vaccinations have not been administered since 2000. Within the scope of safe injection practices, the use of disposable syringes started in 1985 and safe blood transfusion practices are carried out meticulously. For this reason, the incidence of acute HBV cases in Turkey has decreased over the years, and chronic HBV infection has decreased significantly, especially in children and adolescents (14).

The World Health Organization initiated a programme (the Global Health Sector Strategy) to eliminate viral hepatitis throughout the world by 2030 and to reduce the number of cases and the number of deaths due to this disease (2). In compliance with this programme, the Turkish Ministry of Health created and implemented the Chronic Viral Hepatitis Prevention and Control Programme in October 2018 (14). The programme made it legally obligatory for physicians to order HBsAg testing during pregnancy for all pregnant women, in addition to adopting the strategies included in the Global Health Sector Strategy in Turkey (14).

Since implementation of this programme just began in Turkey, this study assessed the rates of HBsAg screening in pregnant women and the situation before the programme started. We conducted this study to determine the changes in the status and rate of testing for HBsAg and the HBsAg positivity rate among pregnant women during 2005–2019. We especially wanted to do this before the implementation of the Viral Hepatitis Prevention and Control Programme, which will continue for 5 years (14).

Methods

Study design

We performed this multicentre, retrospective, cross-sectional study between 1 July 2019 and 1 July 2020; the data included in the study were obtained between 2005 and 2019. We created an *Excel* form and sent it to all health centres, followed by the agreement of the centres to participate in the study. Data were collected from 50 primary, secondary and tertiary health centres in 27 of the 81 provinces in Turkey (Adana, Aksaray, Ankara, Antalya, Batman, Çanakkale, Denizli, Edirne, Gaziantep, Giresun, Hatay, Iğdır, İstanbul, İzmir, Kahramanmaraş, Kars, Kütahya, Manisa, Mersin, Muş, Rize, Şanlıurfa, Şırnak, Tekirdağ, Trabzon, Uşak, Yozgat), distributed throughout the country.

Each participating centre recorded its data in the *Excel* form and sent it to our centre for each year. The data included: the number of pregnant women admitted to the centres, number of pregnant women tested for HBsAg, number confirmed to be HBsAg-positive and the birth dates of the pregnant women.

We subsequently stratified the data for HBsAg-positive pregnant women by age group and year and analysed the data in terms of the annual rate of HBsAg positivity. The pregnant women in our study were divided into 5-year age groups. Since the mothers who were born in 1998 and 1999 were revaccinated in the catch-up campaign, these and the other mothers who were born in 2000 and after (who were vaccinated at birth only) were evaluated in separate groups. We evaluated all of the data separately for each institution per year of the study. The study physician responsible for each centre deleted duplicate records. The patients' data were anonymized under the privacy policy to prevent disclosing personal information. We recorded only the initial letters of the first and last names, date of birth and test results in the *Excel* form before sending the data for statistical analysis.

Statistical analysis

The data were analyzed using the *JASP* software, version 9.2.0, using descriptive statistical methods (number, percentage, frequency). Simple linear regression analysis was performed to determine changes in the rate of HBsAg positivity over time. $P < 0.05$ was considered statistically significant.

Ethical considerations

We obtained ethical approval from the institutional ethics boards of the University of Health Sciences, Izmir Bozyaka Education and Research Hospital (08.09.2016, No. 430) and the Turkish Public Health Institution Presidency (05.05.2016, No. 45202601).

Results

The data for 2 145 668 pregnant women admitted into 50 primary, secondary or tertiary healthcare centres from 27 provinces and all 7 regions of Turkey were analysed.

Of these women, 3729 (0.2%), 47 1928 (22.0%) and 1 670 011 (77.8%) were followed up in primary, secondary and tertiary health care units, respectively. Among those who received care in primary, secondary and tertiary health care units, HBsAg testing was carried out in 1545 (41.4%), 174 347 (36.9%) and 83 670 (50.1%) pregnant women, respectively.

The rate of testing for HBsAg during pregnancy was reported to be $\geq 90\%$ in 8 centres. The distribution of the status and rate of testing for HBsAg and the rate of HBsAg positivity in pregnant women is shown in Table 1.

In total, 1 012 593 (47.1%) pregnant women were tested for HBsAg; 11 471 (1.1%) were found to be HBsAg positive (Table 1). The largest group of the HBsAg positive patients (35.8%) were in the 29–35 years age group followed by the 36–40 years (22.0%), 25–28 years (15.2%) and 41–45 years (12.3%) age groups (Table 2). Of the 11 471 pregnant women included in our study, 11 138 (97.1%) were born in or before 1997, and only 333 (2.9%) were born in or after 1998 (after the start of the universal HBV vaccination programme).

Turkey comprises 7 geographical regions, and HBsAg positivity rates were determined for these regions: Marmara (1.46%), Black Sea (3.30%), Aegean (1.40%), Central Anatolia (0.28%), Eastern Anatolia (1.51%), Mediterranean (1.10%) and South-Eastern Anatolia (1.63%).

The number of pregnant women attending a health centre, the number of HBsAg tests and the rate of HBsAg positivity in pregnant women in each province are shown in Table 3. HBsAg positivity was partially higher in Eastern Anatolia, South-Eastern Anatolia and Black Sea regions. However, due to internal migration the rates may differ in other regions as well. The centre in the Black Sea region, which participated in our study, is a university hospital that closely monitors HBsAg positivity cases in pregnant women referred from the surrounding area. This region receives immigrants from some countries in the Black Sea region where HBsAg positivity is higher, and from Eastern.

The numbers of pregnant women attending health centres, numbers of HBsAg tests and numbers of HBsAg positivity according to year are shown in Table 4. Accordingly, the rates of HBsAg screening in pregnant women did not change significantly over the years. However, HBsAg positivity in pregnant women tended

to decrease over the years and has decreased below 1% in recent years.

Simple linear regression analysis showed that the rate of HBsAg positivity decreased significantly over the years ($r = -0.798$, standard error of the mean = 0.332, $P < 0.001$) (Figure 1) and the trend is projected to continue over the next 5 years.

Discussion

The HBsAg positivity rate worldwide is estimated to be approximately 3.6% and geographic variations in the natural history of HBV infection are well documented (2,4,6,15,16). There has been a widespread reduction in acute viral hepatitis B cases in recent years. A favourable change in the epidemiology of HBV infection is observed mainly at younger ages – children, adolescents and young adults (1,2). In a 2017 review of studies published during 2005–2015, the rate of HBsAg positivity was estimated to be 1.0–4.4% in the general community in European countries (17). A number of meta-analyses of HBV epidemiological studies from Turkey have reported similar rates and as a common finding of all these surveys, a significant decrease was observed over time in HBsAg positivity rates in the general population (17–20).

Studies published between 2000 and 2016 in the Eastern Mediterranean and Middle Eastern regions were included in a meta-analysis which evaluated HBsAg positivity in pregnant women recruited from the countries in these regions. In that report, data on 89 452 pregnant women were examined in 49 articles; HBsAg positivity was reported to range from 1.0% (Qatar) to 10.8% (Yemen) in 12 countries, including Turkey (2.8%) (21).

The HBsAg positivity rate (1.1%) for pregnant women in our study is comparable to the rates in other studies. In more recent studies performed after 2005 involving pregnant women, the rate was reported to vary between 1.2% and 12.3% (mean 4%) (18). A 2016 review from Turkey that examined 64 studies carried out between 1975 and 2016 found that HBsAg positivity among pregnant women was 1.2%–19.2%; it also emphasized that the rate had decreased over the years (22). Another study from Turkey examining the HBsAg positivity rate in pregnant women found rates of 2.6% ($n = 3010$) between 1995 and 2001, 0.8% ($n = 2995$) between 2002 and 2008 and 0.8% ($n = 1600$) between 2009 and 2015 (23). Araz et al. found

Table 1 Distribution of the status and rate of testing for HBsAg and the rate of positivity in pregnant women according to type of health care unit in 27 provinces of Turkey, 2005–2019

Type of health care unit	Total No. pregnant women admitted No. (%) ^a	Total No. pregnant women tested No. (%) ^b	No. pregnant women HBsAg positive No. (%) ^b
Primary	3 729 (0.)	1 545 (41.4)	25 (1.6)
Secondary	471 928 (22.0)	174 347 (36.9)	3 164 (1.8)
Tertiary	1 670 011 (77.8)	836 701 (50.1)	8 082 (1.0)
Total	2 145 668 (100.0)	1 012 593 (47.1)	11 471 (1.1)

^aColumn percentage.

^bRow percentage.

Table 2 Distribution of HBsAg-positive pregnant women according to age in 27 provinces of Turkey, 2005–2019

Age group (years) (birth year)	No.	%
56 ≥ (1963 and before)	23	0.2
46–55 (1964–1973)	501	4.4
41–45 (1974–1978)	1 413	12.3
36–40 (1979–1983)	2 527	22.0
29–35 (1984–1990)	4 102	35.8
25–28 (1991–1994)	1 745	15.2
22–24 (1995–1997)	827	7.2
20–21 (1998–1999)	236	2.1
17–19 (2000–2003)	97	0.8
Total	11 471	100.0

the rate to be 2% in 11 840 pregnant women (mean age 25.5, range 19–43 years) in Gaziantep, southern Turkey, between 2003 and 2005 (24). Later, Tanrıverdi et al. reported an HBsAg positivity rate of 1.2% among 35 295 pregnant women aged 18–45 years in the eastern region of Turkey between 2013 and 2016 (25). Our findings support this downward trend in the HBsAg positivity rate among pregnant women in recent years. According to the analysis of a survey conducted in the United States of America between 2011 and 2014 that included 819 752 pregnant women aged 10–50 years, the rate of testing for HBsAg was 82% and 0.14% ($n = 1190$) were diagnosed with HBV infection. In comparison with that study, the rate of testing for HBsAg in pregnant women was extremely low (47.1%) in our study (26).

Table 3 Laboratory examination and HBsAg positivity in pregnant women in 27 provinces of Turkey, 2005–2019

Province	No. pregnant women attending a health centre	No. laboratory tests for HBsAg	No. pregnant women HBsAg +ve	Laboratory testing for HBsAg (%) ^a	HBsAg positivity (%) ^a
İstanbul	311 418	125 655	1 879	40.35	1.50
Hatay	47 805	25 471	281	53.28	1.10
Giresun	9 004	6 168	61	68.50	0.99
Kütahya	16 655	15 557	206	93.41	1.32
Tekirdağ	10 843	5 158	68	47.57	1.32
Antalya	120 694	66 100	943	54.77	1.43
Trabzon	35 248	9 208	167	26.12	1.81
Aksaray	22 103	13 175	173	59.61	1.31
Adana	1 435	1 435	15	100.00	1.05
Şırnak	15 267	7 632	83	49.99	1.09
İğdir	38 339	8 474	145	22.10	1.71
Kahramanmaraş	87 345	40 765	499	46.67	1.22
Mersin	62 434	56 432	362	90.39	0.64
Edirne	6 612	6 475	80	97.93	1.24
Batman	140 787	50 608	1 435	35.95	2.84
Şanlıurfa	258 670	111 334	1 327	43.04	1.19
Çanakkale	40 556	8 975	117	22.13	1.30
İzmir	62 172	29 764	505	47.87	1.70
Muş	43 208	13 679	304	31.66	2.22
Ankara	279 066	269 760	600	96.67	0.22
Rize	131 787	16 504	826	12.52	5.04
Yozgat	68 404	20 266	81	29.63	0.40
Denizli	4 013	1 196	15	29.80	1.25
Gaziantep	138 554	28 239	386	20.38	1.37
Kars	122 905	45 734	582	37.21	1.27
Uşak	62 234	21 814	232	35.05	1.06
Manisa	8 110	7 015	99	86.50	1.41
Total	2 145 668	1 012 593	11 471	47.19	1.13

^aRow percentage.

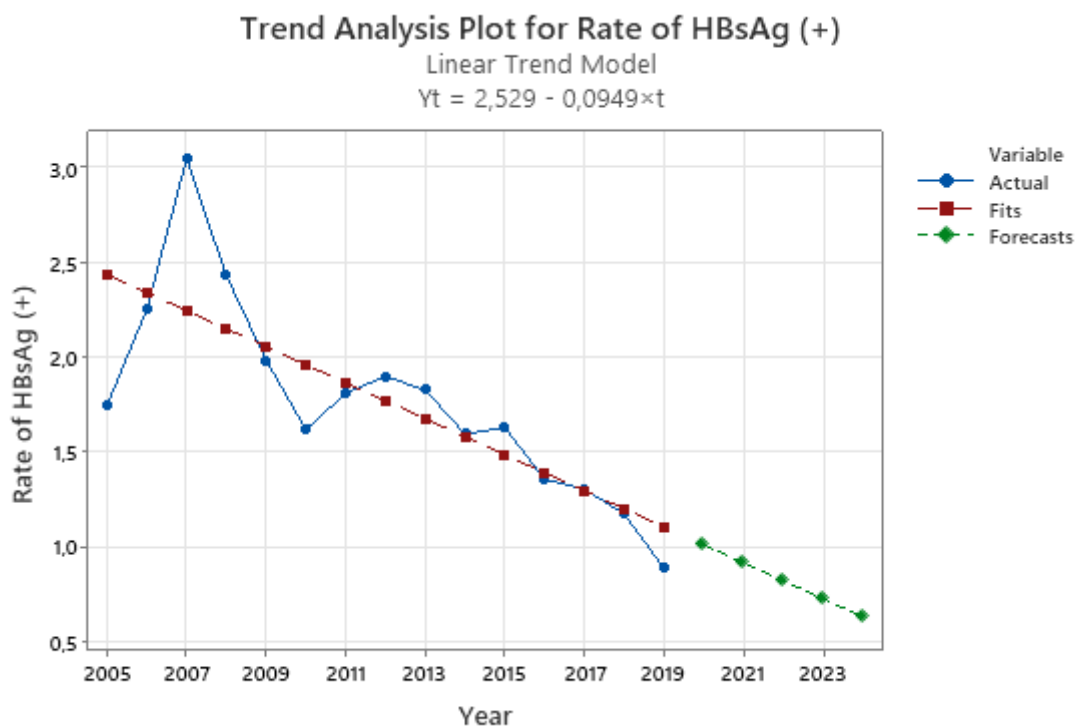
Table 4 Laboratory examination and HBsAg positivity by year in pregnant women in 27 provinces of Turkey, 2005–2019

Year	No. pregnant women attending a health centre	No. laboratory tests for HBsAg	No. pregnant women HBsAg +ve	Laboratory testing for HBsAg (%) ^a	HBsAg positivity (%) ^a
2005	4 500	2 136	36	47.47	1.69
2006	4 500	2 753	62	61.18	2.25
2007	6 635	3 711	113	55.93	3.05
2008	45 929	28 071	238	61.12	0.85
2009	55 402	28 689	350	51.78	1.22
2010	64 409	29 090	331	45.16	1.14
2011	98 914	35 087	470	35.47	1.34
2012	124 525	46 565	670	37.39	1.44
2013	195 141	68 607	975	35.16	1.42
2014	230 663	100 933	1 163	43.76	1.15
2015	219 191	106 220	1 286	48.46	1.21
2016	340 231	150 898	1 642	44.35	1.09
2017	367 187	192 610	2 005	52.46	1.04
2018	320 006	182 425	1 821	57.01	1.00
2019 ^b	68 435	34 798	309	50.85	0.89
Total	2 145 668	1 012 593	11 471	47.19	1.13

^aRow percentage.

^bJanuary–July.

Figure 1 Change in rate of HBsAg positivity among pregnant women tested in 27 provinces of Turkey, 2005–2019 (regression equation $Y_t = 2.529 - 0.0949 \times t$) (using Minitab, trial version: raw data available from corresponding author on request)



Only 8 of the 50 centres included in our study were recorded as having an HBsAg testing rate of $\geq 90\%$. When the data for HBsAg-positive pregnant women were analysed according to age group, the greatest number were in the 29–35 years age group (35.8%), with 22.0% of the 36–40 years age group testing positive. The incidence of acute and chronic HBV infection decreased significantly, especially in children and adolescents, due to the impact of the ongoing national HBV immunization programme since 1998 in Turkey (18,27). According to Public Health Agency data, the rate of vaccination for hepatitis B increased from 64% in 1999 to 98% in 2018 in Turkey (14). As a supplement to the national HBV immunization, children born between 1994 and 1999 and 1991 and 1993 were vaccinated with second doses of hepatitis B vaccine in primary and high schools within the scope of the catch-up vaccination campaign implemented between 2005 and 2009 (28). The catch-up activity was partially implemented for children born between 1991 and 1993. Since the catch-up campaign was applied only to in-school children, it is not clear whether children who did not attend school that day or who were absent for different reasons were vaccinated, nor how many doses they were given. For this reason, it is assumed that students received 1–3 doses of HBV vaccine during this campaign. The lowest rate of HBsAg-positivity in the 16–21 years age group may be an indication of the success of the national and catch-up hepatitis B immunization programmes and support the positive impact of such

immunization programmes in pregnant women. People who are exposed to HBV at a younger age are more likely to develop chronic infection and subsequent cirrhosis and hepatocellular carcinoma; the prevention of HBV transmission at younger ages is, therefore, of great importance. Screening of pregnant women for HBsAg and national immunization against HBV in the newborn in combination with the administration of hepatitis B immunoglobulin at the right time are the easiest and most economical means of preventing hepatitis B. Our study is crucial to ensuring comprehensive and extensive data at the national level, rather than local data in a particular region, on the status and rate of testing for HBsAg and the rate of HBsAg positivity in pregnant women

It is gratifying that, although the rates of HBsAg testing in pregnant women have increased, the rates of HBsAg positivity in pregnant women have decreased significantly over the years. We recommend a new vaccination programme for this population, especially in the national action plan of the Turkish Viral Hepatitis Prevention and Control Programme. We support the creation of a legal obligation to carry out HBsAg testing in pregnant women. Such efforts will help prevent mother-to-child transmission of HBV and lead to a subsequent reduction in the prevalence of HBV infection.

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Quinze ans d'évaluation de l'évolution du taux de positivité de l'AgHBs chez les femmes enceintes en Turquie : l'effet majeur de la vaccination nationale

Résumé

Contexte : La détection d'une positivité à l'antigène de surface de l'hépatite B chez les femmes enceintes avant l'accouchement est cruciale pour prévenir la transmission mère-enfant du virus de l'hépatite B.

Objectifs : La présente étude visait à évaluer le statut et le taux de dépistage de l'antigène de surface de l'hépatite B, le taux de positivité à l'antigène de surface de l'hépatite B, le taux de distribution de l'antigène de surface de l'hépatite B selon l'âge, et l'évolution du taux de positivité de l'antigène de surface de l'hépatite B chez les femmes enceintes au cours de la période d'étude.

Méthodes : Nous avons mené une étude multicentrique, transversale et descriptive couvrant la période allant de janvier 2005 jusqu'à juin 2019 pour 2 145 668 femmes enceintes de 27 provinces dans les sept régions de Turquie, collectée à l'aide de Microsoft Excel avant l'analyse statistique.

Résultats : Nous avons constaté que 1 012 593 (47,1 %) femmes enceintes avaient été testées pour l'antigène de surface de l'hépatite B au cours de cette période de 15 ans, dont 11 471 (1,1 %) étaient positives. Globalement, 97 % des femmes positives à l'antigène de surface de l'hépatite B étaient nées avant 1998, année où la vaccination nationale contre le VHB a été lancée en Turquie. Le taux de positivité à l'antigène de surface de l'hépatite B dans ce groupe était de 1,1 %, contre 0,3 % chez les femmes nées après 1998.

Conclusion : On a constaté une tendance à la baisse du taux de positivité à l'antigène de surface de l'hépatite B chez les femmes enceintes des groupes d'âge plus jeunes, en particulier chez celles nées après le lancement de la vaccination universelle contre l'hépatite B, et un faible taux de dépistage de l'AgHBs pendant la grossesse.

تقييم 15 عاماً من التغييرات في معدل النتائج الإيجابية للمستضد السطحي للالتهاب الكبدي B / المستضد الأسترالي لدى النساء الحوامل في تركيا: التأثير البارز للتطعيم على المستوى الوطني

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الخلاصة

الخلفية: ثمة أهمية كبرى لاكتشاف النساء الحوامل الإيجابيات للمستضدات السطحية للالتهاب الكبدي B اكتشافاً مبكراً في مرحلة ما قبل الولادة، لتَوْقِي انتقال فيروس الالتهاب الكبدي B من الأم إلى الطفل.

الأهداف: هدفت هذه الدراسة إلى تقييم حالة ومعدل اختبار المستضدات السطحية للالتهاب الكبدي B، ومعدل الحالات الإيجابية لهذه المستضدات، وتوزيع الحالات حسب العمر، والتغيرات في معدل النتائج الإيجابية للمستضدات لدى النساء الحوامل على امتداد فترة الدراسة.

طرق البحث: أجرينا دراسة وصفية مقطعية متعددة المراكز عن المدة من يناير/ كانون الثاني 2005 إلى يونيو/ حزيران 2019، وشملت ما مجموعه 2145668 امرأة حاملاً من 27 محافظة في جميع المناطق السبع في تركيا، وجمعت البيانات باستخدام برنامج مابكرو سوفت إكسيل قبل إجراء التحليل الإحصائي.

النتائج: وجدنا أن 1012593 امرأة حاملاً (47.1%) قد خضعن لاختبار المستضد السطحي للالتهاب الكبدي B على مدى 15 عاماً، وجاء بينهن 11471 عينة إيجابية (1.1%) لهذه المستضدات. وإجمالاً، تبين أن 97% من النساء الإيجابيات للمستضدات قد وُلدن قبل عام 1998، وهو العام الذي دُشن فيه التلقيح الوطني ضد فيروس التهاب الكبد B في تركيا. وبلغ معدل الإيجابية تجاه المستضدات السطحية للالتهاب الكبدي B في هذه المجموعة 1.1%، مقارنة بنسبة 0.3% بين النساء اللاتي وُلدن بعد عام 1998.

الاستنتاجات: تبين وجود اتجاه لانخفاض في معدل النتائج الإيجابية تجاه المستضدات السطحية للالتهاب الكبدي B بين النساء الحوامل في الفئات العمرية الأصغر، ولا سيما بين أولئك اللاتي قد وُلدن بعد تدشين التطعيم الشامل ضد التهاب الكبد B، وانخفاض معدل اختبار المستضدات السطحية للالتهاب الكبدي B في أثناء الحمل.

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