

# HBsAg detection in blood donors in Poland, 1995–2004

## Wykrywanie HBsAg u polskich dawców krwi w latach 1995–2004

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### Summary

**Background:** *At the end of the 1980s the incidence rate of hepatitis B in Poland was one of the highest in Europe. The aim of our study was to analyse HBsAg detection rates in Polish blood donors in the years 1995–2004.*

**Materials and methods:** *Between 1 January 1995 and 31 December 2004, 4,669,435 donors were screened for HBsAg: 1,896,770 first time donors and 2,772,665 repeat donors.*

**Results:** *HBs antigen was detected in 0.35% of all Polish blood donors; in 0.79% of the first time donors and 0.06% of the repeat donors. The HBsAg detection rate decreased during the analysed period, from about 1% in 1995 to 0.67% in 2004 for first time donors, and from 0.088% to 0.017% in repeat blood donors. The relative decline rate was greater for repeat donors than for first time donors (20.7% per year and 5.4 % per year, respectively). A wide range of trends for HBsAg prevalence was observed in different regions of the country. For repeat donors it ranged from a 33.5% decrease per year in the southwest to a stable level (about 0%) in the northeast. In most regions, a decreasing tendency was observed for first time donors (max 10.9% per year) although a 3.4% per year increase was observed in the central region (łódzkie).*

**Conclusions:** *In 1995–2004 the frequency of HBV infection marker in Poland was higher than in most European countries. A decreasing tendency for HBsAg detection in blood donors was observed. Such a trend was found both in repeat and first time donors. In one region, however, an inverse tendency was observed.*

**Key words:** HBV, HBsAg, blood donors, screening

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### Streszczenie

**Wstęp:** *Pod koniec lat 80 zapadalność na WZW typu B w Polsce była jedną z najwyższych w Europie. Celem pracy była analiza wykrywania HBsAg u polskich dawców krwi w latach 1995–2004.*

**Materiały i metody:** *Od 1 stycznia 1995 do 31 grudnia 2004 w badaniach przeglądowych w kierunku HBsAg wykonywanych metodami immunoenzymatycznymi (EIA) przebadano 4 669 435 dawców: 1 896 770 pierwszorazowych i 2 772 665 wielokrotnych.*

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**Wyniki i wnioski:** HBsAg wykryto u 0,35% dawców krwi: u 0,79% dawców pierwszorazowych i 0,06% wielokrotnych. Częstość wykrywania HBsAg malała w analizowanym okresie czasu: od około 1% w 1995 do 0,67% w 2004 wśród dawców pierwszorazowych i od 0,088% do 0,017% u dawców wielokrotnych. Tempo spadku częstości wykrywania HBsAg było większe wśród dawców wielokrotnych niż pierwszorazowych (20,7%/rok vs. 5,4 %/rok). Tempo spadku częstości wykrywania HBsAg w poszczególnych częściach kraju było bardzo zróżnicowane. Wśród dawców wielokrotnych wahało się od 33,5%/rok na południowym-zachodzie do poziomu stabilnego (bez zmian, ok. 0%) na północnym wschodzie. W większości regionów u dawców pierwszorazowych obserwowana była tendencja spadkowa (maksymalnie 10,9%/rok), wyjątek stanowił region łódzki, gdzie zarejestrowano wzrost o 3,4%/rok. Częstość wykrywania HBsAg u dawców krwi w Polsce w latach 1995–2004 była większa niż w innych krajach europejskich. W tym okresie czasu obserwowano tendencję spadkową zarówno wśród dawców pierwszorazowych, jak i wielokrotnych. W jednym regionie zarejestrowano wzrost częstości wykrywania HBsAg u dawców (łódzkie).

**Słowa kluczowe:** HBV, HBsAg, dawcy krwi, badanie przeglądowe

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## Background

The HBsAg screening of all Polish blood donors, introduced in 1972, is still a very important HBV transmission-preventing procedure. In Poland, 1 million donations, on average, are collected from 250,000 donors per year. The results of viral marker testing in such a wide donor population are a valuable source of epidemiological data, particularly useful for investigating long-term trends in low risk populations.

In Poland at the end of the 1980s, the reported hepatitis B incidence rate was one of the highest in Europe [1], with approximately 45 cases per 100,000 inhabitants per year. After implementation of a comprehensive public health program, the incidence rate dropped to 4.1 cases per 100,000 in 2004 [2]. The program improved sterilization of medical equipment (in 1986), introduced HBsAg screening for pregnant women, and vaccination of children born to infected mothers (after 1989), as well as the vaccination of some other population groups at the beginning of the 90s. The aim of our study was to analyse the results of HBsAg screening in Polish blood donors from 1995 to 2004 and to evaluate the new epidemiological trends in the country previously ranked as having intermediate seroprevalence (2–8%) [3], with high HBV infection incidence, in which a wide HBV spread-reducing campaign was undertaken. We hope the results may prove helpful for future blood service policy, aimed at limiting HBV epidemics.

## Materials and methods

Between 1 January 1995 and 31 December 2004, 4 669 435 donors (1 896 770 first time donors and 2 772 665 repeat donors) were screened for HBsAg. All donors were voluntary and non-remunerated, aged 18–65 years. A repeat donor was defined as one who had donated blood within the last two years. Donors were medically assessed and all of them denied any known risk factors for viral infection listed in the questionnaire.

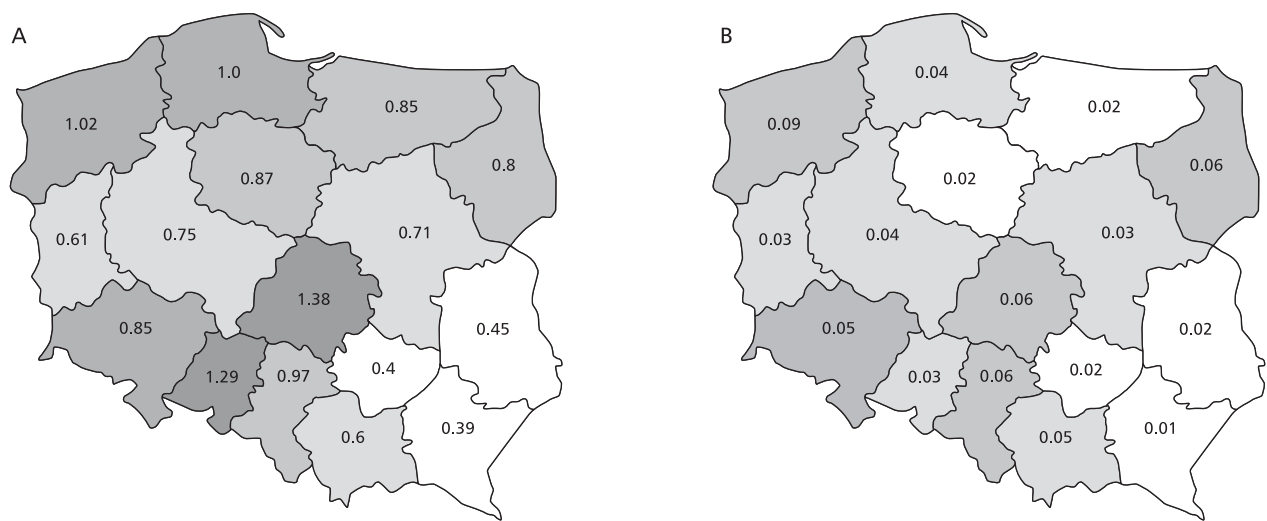
Testing was performed in 22 Regional Blood Transfusion Centres (RBTC) with EIA assays according to the manufacturers' instruction: 1995–1997 HBs Auszyme II Monoclonal EIA (Abbott), Monolisa AgHBs EIA (Sanofi Diagnostics Pasteur); 1996–2004 HBs Hapanostika Uniform II (Organon, since 2002 BioMerieux); 1997–2004 HBsAg EIA system 3 (Ortho Diagnostics). All reactive samples were retested in duplicate and only repeatedly reactive samples were considered positive. In all donors, the neutralization test was used for HBsAg confirmation. Positive donors were excluded from the donor registry. The number of HBsAg positive donors was annually reported by each RBTC to the Institute of Haematology and Transfusion Medicine for data analysis.

Statistical analysis was performed with SAS Software version 9.1. (SAS Institute, Cary, NC). Poisson regression was used for frequency comparison.

**Table 1.** HBsAg positive frequency in Polish first time and repeat donors

**Tabela 1.** Częstość wykrywania HBsAg u dawców pierwszorazowych i wielokrotnych w Polsce

Donors	Observation period	HBsAg — positive frequency (%)	Relative risk (95% confidence interval)	P value	First time/repeat donors
First time	1995–2004	0.799%	18.6 (15.3–22.7)	< 0.0001	18.6:1
Repeat		0.043%	Reference level		
First time	1995	0.982%	10.6 (8.2–13.8)	< 0.0001	11.1:1
Repeat		0.088%	Reference level		
First time	2000	0.845%	25.1 (19.8–31.9)	< 0.0001	26.4:1
Repeat		0.032%	Reference level		
First time	2004	0.672%	50.0 (31.4–79.7)	< 0.0001	39.5:1
Repeat		0.017%	Reference level		



**Figure 1.** The average frequency of HBsAg detection in 100 first time (A) and repeat blood donors (B), in the period 1995–2004, distributed according to regions

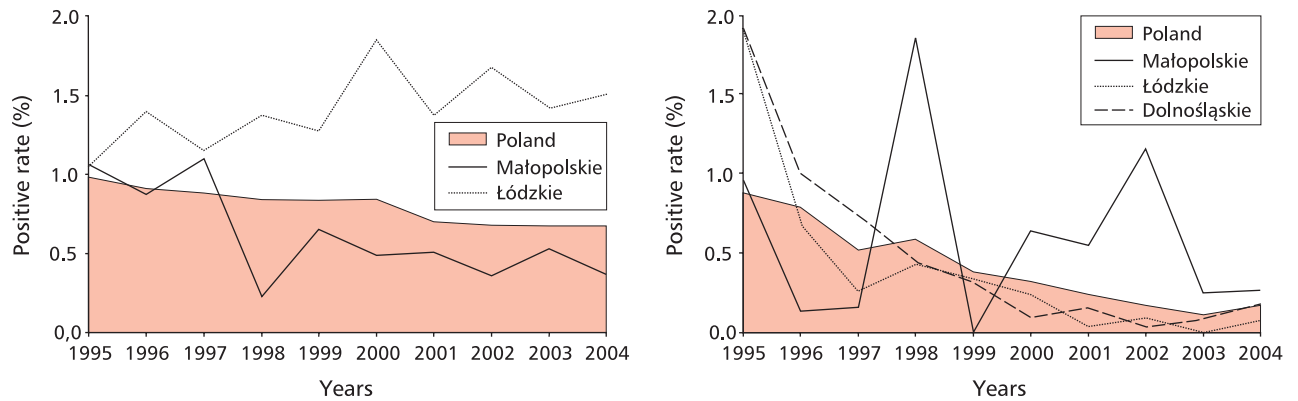
**Rycina 1.** Średnia częstość wykrywania HBsAg na 100 badań wśród dawców pierwszorazowych (A) i wielokrotnych, w latach 1995–2004, według województw

### Results

In the period 1995–2004, HBs antigen was detected in 0.35% of all Polish blood donors — 0.79% first time blood donors and 0.05% repeat blood donors. Within the analysed period, 16,329 blood donors were deferred from blood donation due to repeated reactivity in HBsAg testing (on average — 1633 infected persons per year). Significant differences in HBsAg prevalence were observed in various regions of the country. The lowest frequency was found in the south-eastern districts (podkarpackie, świętokrzyskie, lubelskie), both in first time and repeat donors (below 0.5% and 0.03%, respectively). The highest rate in first time donors was noted in the district of łódzkie (central Poland,

1.4%), in pomorskie and zachodniopomorskie in the north-west (1.0%), and in śląskie, opolskie, and dolnośląskie in the south-west (0.9%). For repeat donors, HBsAg was detected most frequently in zachodniopomorskie (0.11%) and śląskie (0.07%) (Figure 1).

A significant difference in HBsAg positivity rates between first time and repeat blood donors was observed. In general, the prevalence of this marker was 18-fold higher in the former than in the latter group (Table 1). The differences between both groups, however, changed over time. At first (in 1995), HBsAg was identified about 11-fold more frequently in first time than in repeat blood donors, but in 2004 the antigen was detected almost 40-fold more frequently (the differences were statistically



**Figure 2.** HBsAg prevalence rates for Polish first time and repeat donors in 1995–2004 (A and B respectively). Both figures present regions of significant differences as compared to the trend for the whole country (within the same period of time)

**Rycina 2.** Wykrywanie HBsAg u pierwszorazowych i wielokrotnych dawców krwi w Polsce (odpowiednio ryciny A i B). Na obu rycinach na tle trendów dla całego kraju przedstawiono zmiany częstości wykrywania HBsAg w regionach kraju, gdzie występowały skrajne tendencje w analizowanym okresie czasu

significant in both cases  $p < 0.0001$ ). The change can be explained by a relatively greater decline rate for repeat donors than for first time donors (20.7% per year, 95% confidential interval 15.1–25.9% vs. 5.4% per year; 95% confidential interval 3.9–6.8%). A wide range of trends for HBsAg prevalence was observed in different regions of the country (Figure 2). For regular donors it ranged from an annual decrease of 33.5% in the dolnośląskie district (southwest) (95% confidential interval 21.8–43.5%) and 36.9% per year (95% confidential interval 22.7–48.5%) in the north (pomorskie district) to a stable level in the northeast (podlasie district). For first time donors the annual decrease was 10.9% (95% confidential interval 6.3–15.2%) in the south (małopolska region). However, in the central region (łódzkie), an annual increase of 3.4% (95% confidential interval 0.1–6.9%) was observed.

## Discussion

The HBsAg prevalence in first time and repeat blood donors is several-fold higher in Poland than in most West European Countries [4, 5] and the United States [6]. Our results are comparable to the data previously reported for some southern European countries [7] and Japan [8]. In the 80s, 1.98% of Italian blood donors were found to be HBsAg positive, as were 0.68% of Japanese blood donors in the 90s. Significantly higher values were reported for blood donors in some hyperendemic countries like Ghana, with a HBsAg prevalence of 16% [9]. Our findings are consistent with the results

reported for earlier studies, which assessed another serological marker of exposition for HBV infection. Anti-HBc was identified in 7–8% of Polish donors, several-fold more frequently than in other European countries [10, 11].

However, the results from the present study clearly indicate the declining trend for HBV prevalence rate among blood donors in the period 1995 to 2004. This trend can at least partly be explained by the vaccination campaigns for hepatitis B as well as the improvement of sanitary conditions in hospitals. This explanation is supported by the faster decline among repeat donors than among first time donors. In the former group, recent infections were observed, but the prevalence of this infection marker in the latter group reflects the number of newly acquired and chronic infections in the general population.

Prevention and control of HBV infection in Poland comprises: screening of all pregnant women and vaccination of babies at risk of acquiring perinatal HBV infection (since 1989), vaccination of health service workers and students at increased risk due to professional exposure and people in contact with HBsAg carriers (since 1990), persons with chronic illness requiring frequent parenteral procedures and prior to planned surgical procedures (since 1993). With the improvement of epidemiological data, obligatory vaccination prior to planned surgery was discontinued in 2002, although it is still recommended. Finally, the routine immunization program for infants was launched progressively in the period 1993–1996, depending on the epidemio-

logical status of the region, and in 2000 it was followed by a catch-up immunization program for fourteen-year-olds. By 2004, about 32% of the total population had been vaccinated with the vaccination-coverage ranging from 27.6% to 38.2%, depending on the voivodeship [12].

A similar, but not as marked, tendency for HBsAg prevalence in blood donors after the introduction of a vaccination programme was shown for other European countries [4, 5] and the United States [6], although no significant changes were observed for countries like the Netherlands with initially low hepatitis B incidence [13]. Our results are in accordance with WHO data that indicate the greatest HBV vaccination impact in countries with higher hepatitis B incidence and prevalence in the population [14].

Others factors may also have contributed to the reduction of HBsAg prevalence: greater awareness of factors associated with increased infection risk and voluntary deferral by potential high-risk donors; improvement in donor recruitment procedures, donor deferral, as well as donation screening and retention.

The differences in the rate of decline between first time and repeat donors may also have been related to the efforts of the blood service to reduce infection risk. In the case of repeat donors, they involve, in particular, screening tests and pre-donation interviews promoting health awareness and self-deferral criteria for donors with increased HBV infection risk. It should also be noted that the decreasing tendency does not refer to all regions. The increasing tendency for first time donors in central Poland may have been an echo of the HBV outbreak among children in that region in the mid-eighties [2], which then spread to the territory of eastern Poland and could only be held in check after routine immunization of infants in 1993.

Our data confirm significant regional differences in the epidemiological status of HBV in Poland and should be considered an important indicator both for local epidemiological service and for doctors in Regional Blood Transfusion Centres responsible for the deferral of high-risk HBV infection blood donors. It is worth noting that an elevated HBV prevalence was found in regions of high unemployment and worse social and economic living conditions.

According to WHO reports, in Western European countries with a low HBV prevalence in the general population, a mounting HBV incidence level has been noted in recent years (a marked in-

crease was reported in 2004). New infections were observed among people who had not been vaccinated or who had emigrated from countries of high HBV prevalence [14]. In addition, evidence from Taiwan shows that after introducing vaccination against hepatitis, there was a significant increase in the proportion of HBV surface *a* determinant mutants missed by HBsAg screening but capable of infecting vaccinated people [15].

As a result of the epidemiological situation in Poland, a national program of nucleic acid testing (NAT) for the hepatitis B virus has become obligatory since the beginning of 2005. The main aim is to further limit the HBV epidemic through a system of identifying donors infected in the pre-seroconversion window period and with the so-called "occult infection", as well as to prevent blood transfusion from such donors. Our previous results confirmed the presence of vaccine resistant mutants in the general population [16]. The data we found, together with the results from other European regions such as Spain, Italy, and Japan, where the HBV prevalence used to be high, point to the fact that the frequency of HBV surface gene mutants in those regions is higher than in countries with lower epidemiological status [16–18]. The epidemiological trends in Poland still need careful observation. For this purpose, the data from HBsAg and HBV DNA screening of blood donors and polymorphism analyses may prove useful. The significant decrease in HBV prevalence observed after the extensive vaccination campaign in Poland is now being followed by a period of stabilization. The question is whether increasing trends will be observed in the Polish population after we reach the European average level.

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