Evaluation of a universal hepatitis B vaccination program and antenatal screening for hepatitis B surface antigen: Results from a real-world study

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INTRODUCTION

Infection with hepatitis B virus (HBV), defined as hepatitis B surface antigen (HBsAg) positivity, is a major public health problem. Universal vaccination against HBV in infancy was implemented in Israel in 1992.

AIM

The aim of this study was to evaluate the national HBV vaccination program with antenatal HBsAg screening, among infants and their mothers both epidemiologically and economically.

MATERIAL & METHODS

Using the database of a health maintenance organization with 2 million members, we retrospectively identified, all the infants born in 2015-2016 and their mothers. Maternal data collected included age, ethnicity, country of birth and HBsAg status during pregnancy. HBV vaccination coverage among infants was calculated. A cost-benefit analysis of the HBV vaccination program was conducted based on the actual costs of HBV infection treatments in all HBsAg positive mothers. Mothers born after 1992 were considered vaccinated and those born before 1992 were considered unvaccinated.

CONCLUSION

The Israeli vaccination program against HBV infection is epidemiologically and economically justified. High coverage rates among infants born to HBsAg positive mothers reflect very good adherence to the vaccination program and antenatal screening. Higher HBsAg positivity rates among immigrant mothers identify a high-risk population for HBV infection.

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RESULTS

Our cohort included 72,792 mothers who gave birth to 77,572 live infants. A total of 71,107 (97.7%) mothers were screened for HBV during pregnancy, of them 124 (0.2%), who gave birth to 132 infants were HBsAg positive.

Table 1. Coverage rates of hepatitis B vaccination among newborns in Israel during 2015-2016

Coverage rate		Total births n=77,572	Newborns to HBsAg negative mothers n=75,674	Newborns to HBsAg positive mothers n=132	Newborns to unscreened mothers n=1766
Birth dose coverage within 24 h		87%	87%	95% ^{a b}	81% ^a
Three doses of vaccine within 1y		86%	87%	91% ^b	76% ^a
Vaccine	1st dose	94%	95%	95% °	88% a
Coverage:	2 nd dose	93%	93%	95% ^c	86% ^a
	3 rd dose	89%	90%	95% ^b	81% a
	Unvaccinated	6%	5%	5% ^c	12% ^a

^a P<0.001 vs. newborns to HBsAg negative mothers; ^b P<0.001 vs. newborns to unscreened mothers; ^c P<0.05 vs. newborns to unscreened mothers.

Table 2. HBsAg status according to demographic characteristics of mothers.

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HBsAg status		Total n=72,792	HBsAg negative mothers n=70,983 (97.5%)	HBsAg positive mothers n=124 (0.2%)	Unscreened mothers n=1685 (2.3%)
Birth year < 1992		69,934 (96.1%)	68,378 (96.3%)	120 (96.8%)	1436 (85.2%) a
Ethnicity:	Jewish	66,011 (90.7%)	64,426 (90.8%)	114 (92.0%)	1471 (87.3%) b
	Arab	3,008 (4.1%)	2,921 (4.1%)	6 (4.8%)	81 (4.8%) b
	Unknown	3,773 (5.2%)	3,636 (5.1%)	4 (3.2%)	133 (7.9%) b
Country of birth:	Israel	63,053 (86.6%)	61,526 (86.7%)	65 (52.4%) °	1462 (86.8%)
	Former Soviet Union	6,582 (9.0%)	6,375 (9.0%)	51 (41.1%) °	156 (9.3%)
	Ethiopia	163 (0.2%)	151 (0.2%)	8 (6.5%) ^c	4 (0.2%)
	Other	2,994 (4.1%)	2,931 (4.1%)	0 с	63 (3.7%)

 $[^]a$ $P\!<\!0.001$ vs HBsAg negative mothers or HBsAg positive mothers; b $P\!<\!0.001$ vs HBsAg negative mothers; c $P\!<\!0.001$ vs HBsAg negative mothers or unscreened mothers.

Table 3. Cost analysis of the vaccination program

Treatment		Cost per treatment	Quantit y	Total cost
Vaccination cost *	Vaccine, staff labor, transportation and refrigerated storage	\$3.0	218,753	\$656,259
	0.5% Wastage	\$3.0	1,094	\$3,281
HBIG		\$61.6	132	\$8,131
	Minor required pediatrician or nurse visit	\$31.9	3,506	\$111,990
Adverse events	Major required hospitalization	\$554.3	5	\$2,910
Antenatal HBsAg screening		\$25.8	71,107	\$1,834,561
Total cost of vacc	ination program without antenatal HBsAg			\$782,572
Total cost of vacc screening	ination program with antenatal HBsAg			\$2,617,133

^{*}Vaccination costs were calculated according to the compliance rate of 94%.

Table 4. Cost-Benefit analysis of the vaccination program

	Vaccinated mothers	Unvaccinated mothers	Without a vaccination program		
N	2,609	68,498	71,107		
Mothers needing HBV treatment	4	120	626		
% Mothers needing HBV treatment	0.15%	0.18%	0.88%		
Total HBV treatment costs per	Total HBV treatment costs per				
mother	\$1,239	\$6,428	\$6,428		
Total HBV treatment costs	\$4,957	\$771,326	\$4,022,090		
Total cost of HBV in vaccinated and unvaccinated mothers			\$776,283		
Total cost of vaccination program v	\$782,572				
Total cost of vaccination program v	\$2,617,133				
Benefit to Cost ratio without antenatal HBsAg screening			4.15		
Benefit to Cost ratio with antena	1.24				