Hepatitis Monthly 2009; 9(3): 189-195

ORIGINAL ARTICLE

Mass Vaccination Campaign against Hepatitis B in Adolescents in Iran: Estimating Coverage Using Administrative Data

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Background and Aims: Hepatitis B vaccination has been part of the EPI of Iran since 1993. To extend HBV immunization to 25-year-old adolescents, HBV mass vaccination has been planned for adolescents born from 1989 to 1992. The first 3-round campaign in Iran covered 1989-born adolescents and was implemented in 2007. This study was conducted to estimate vaccination coverage of the campaign using administrative data at the provincial level.

Methods: To assess the campaign vaccination coverage we divided the number of adolescents vaccinated in the campaign by the total number of 17-year-old adolescents who resided in a given province. For the number of vaccinated cases we used administrative data as reported from universities of medical sciences and for the basic population we used the data from the last national population census (2007).

Results: After the 3 rounds of the campaign, a total of 3,983,291 doses of vaccine were administered. At the end of the third round, 70.0% (from 44.2% to 96.1% in various provinces) of the target population received full doses of the HBV vaccination. Moreover, 74.5% (51.3% to 99.9% in various provinces) received at least two doses and 78.3% (from 52.9% to 100% in various provinces) received at least one dose of the vaccine. Nineteen out of 30 provinces achieved acceptable full-dose coverage of higher than 70%. Low coverage (less than 50%) was reported from 3 provinces. Vaccination coverage was significantly higher in girls compared with boys (83.3% vs. 68.7% for full-dose coverage; $P<0.001$). In addition, vaccination coverage was significantly higher in rural areas than urban areas (84.1% vs. 68.7% for full-dose coverage; $P<0.001$).

Conclusions: The campaign reached acceptable coverage in the majority of the provinces. Higher coverage for women and rural areas, two known vulnerable populations in most health care systems, was attained within the campaign.

Keywords: Hepatitis B, Vaccination, Adolescent, Iran

Introduction

Hepatitis B is the main cause of chronic liver disease in Iran [1, 2]. The epidemiology of hepatitis B virus (HBV) infection in Iran has been changing over the last two decades [1]. The prevalence of hepatitis B surface antigen (HBsAg) in the country was reported to be between 2.5% and 7.2% in 1979 [3]. In the 1980s, almost 3% of the Iranian population was affected, varying from 1.7% to 5% in various provinces [1, 2]. A recent systematic

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Received: 1 Oct 2008 **Revised:** 14 Dec 2008
Accepted: 18 Apr 2009

Hepat Mon 2009; 9 (3): 189-195

review indicated that a reasonable estimate of HBsAg seroprevalence in the country in the last 5 years based on data from seven provinces was 2.14% (95% CI; 1.92% to 2.35%) [4].

Given the importance of HBV infection in Iran, the HBV vaccination has been included in the extended program of immunization (EPI) since 1993 [5]. In 2002 the "National Committee of Hepatitis" in Iran revised the program and recommended to extend HBV immunization to 25-year-old adolescents. Thereafter, the Ministry of Health and Medical Education (MOHME) planned to implement a mass HBV vaccination campaign for adolescents who were born from 1989 to 1992 [5]. The first 3-round campaign of the series covering 1989-born adolescents in Iran was implemented in 2007. In order to evaluate the output of the campaign, this study was conducted to estimate the vaccination coverage of the 2007 HBV vaccination campaign using administrative data at the provincial level.

Materials and Methods

The campaign was implemented in three rounds in 2007 to administer three doses of HBV vaccine to the target population (Months 0, 1, 6). The first round was implemented from March 5th to March 18th. The second round was implemented from April 4th to April 19th, and the third round was implemented from August 5th to September 21st. The current health network in Iran provided a suitable infrastructure to implement the campaign [6]. The main approach in the campaign was passive. Prior to each round, MOHME promoted the campaign primarily through announcements, interviews, and educational programs via radio and television. Paper materials such as posters and pamphlets were used for publicity as well. Through these promotional activities, all 17-year-old Iranian adolescent boys and girls born from March 21, 1989 to March 19, 1990 were invited to visit public healthcare provider centers (i.e., Health Houses and Rural Health Centers in urban areas as well as Health Posts, Urban Health Centers, and some extra vaccination stations in urban areas) to receive the hepatitis B vaccine. In addition, as an active approach, a number of outreach teams from each university of medical sciences were sent to hard-to-reach areas to provide vaccination service in the field.

In each round, the adolescents received 20 µg of a recombinant-DNA-derived hepatitis B vaccine (Euvax B®, LG Life Sciences, Jeonbuc-do, South Korea), administered intramuscularly in the deltoid muscle. Vaccinators recorded the vaccinee's name and birth date, vaccination date, and serial number of vaccine vial both on the vaccination card and report sheets. The vaccination card was delivered to the vaccinee and the record sheet was given to upper-level staff at the university. Report sheets were compiled at the next level of administration up to the university's highest level staff, and a final compiled report disaggregated by gender (girl/boy) and living area (urban/rural) was sent from each university to the Center for Disease Control in MOHME. In Rounds 2 and 3, not only were the second and the third doses of vaccine administered, respectively, but also the previous doses were administered to adolescents who had not received the vaccine in previous rounds.

Prior to the start of the campaign, a comprehensive guideline booklet was distributed among university staff contributing to the campaign and included the directions for vaccine transport and storage, proper vaccine administration (aseptic injection technique and injection safety), potentially adverse reactions to the vaccine, how to manage adverse reactions, and the reporting process. The maintenance of a cold chain was verified at all stages from the time the vaccine left the manufacturer until it reached the vaccination posts. Vaccines were transported to the university of medical sciences by cars with refrigerators, which kept the temperature at 2-8°C. Storage fridges in the universities were equipped with emergency electricity, a thermograph, and an alarm system. To deliver vaccines to health houses and health posts, which were the most peripheral vaccination stations, cold boxes that maintained an inner temperature of 2-8°C with ice bags were used. At the vaccination stations, vaccines were kept on the bottom shelf of the refrigerator at 2-8°C to keep them from being frozen. Any frozen vaccines were excluded immediately.

All aspects of vaccine safety were emphasized during the campaign. According to the abovementioned guidelines, the vaccine was not to be administered to individuals with a history of allergic reactions to vaccines. In addition, in the second and third rounds of the vaccine were not to be administered to individuals who experienced anaphylaxis after receiving the vaccine in any of the previous rounds. All vaccinees were asked to remain in the vaccination posts for at least 20 minutes after vaccination to be monitored for any immediate, serious, adverse reactions. Management and executive coordination of the campaign was done by coordination committees at three levels including the country level in MOHME, the provincial level at medical science universities, and the district level in

district house centers. In addition, supervisors from two levels, including MOHME and universities of medical science, were appointed to monitor the implementation process of the campaign in the field.

To assess campaign vaccination coverage, we used a simple formula that divided the number of adolescents who received the vaccine in the campaign in a province by the number of 17-year-old adolescents residing in that same province (i.e., the total target population). This method described by World Health Organization (WHO) [7], also called "administrative estimates of immunization coverage," was believed to provide a good measure of the relative performance by geographic area [8,9]. For the number of adolescents receiving the vaccine in the campaign, we used the reports from the university of medical sciences and the combined data from the provincial level. For the total target population in each province, we used the data from the last National Population and Housing Census in Iran, which was conducted in Oct 2006 [10]. The number of vaccinated adolescents was reported from the universities, disaggregated by sex (boy/girl) and living area (rural/urban). In the third round, disaggregated data were not available in 10 provinces, including Tehran, Charmahal-Bakhtyari, Khorasan.R, Khorasan.N, Semnan, Sistan-Baloochestan, Fars, Kohkilooyeh-Boyerahmad, Gilan, and Lorestan. Therefore, disaggregated coverage for the third dose of the vaccine was calculated based on the other 20 provinces in the country. To compare vaccination coverage between groups, a Chi-square test was applied. The statistical software STATA (version 8.0) and Arc View (version 3.2) were used to analyze and graph the data.

Table 1. ! ! ! ! ! "
! ! # !

Girls	583,403	291,893	875,296 (49.0)
Boys	608,437	304,085	912,522 (51.0)
Total (%)	1,191,840 (66.7)	595,978 (33.3)	1,787,818

Results

A total of 1,787,818 seventeen-year-old adolescents were the target population of the campaign. The basic characteristics of this target population according to the last national population census in 2006 [10] are summarized in Table 1. Within three rounds of the campaign, a total of 3,983,291 doses of vaccine were administered. As Table 2 shows, at the end of the third round, 70.0% (SD=45.8%) of the target population had received full doses of the HBV vaccination. In addition, 74.5% (SD=43.6%) of the target population received at least two doses of the vaccine, and 78.3% (SD=41.2%) received at least one dose.

The number of vaccinated individuals and the vaccination coverage in each province at the end of the third round has been summarized in Table 3. As the table shows, vaccination coverage varied among provinces. Full-dose coverage in provinces such as Charmahal-Bakhtyari, Gilan, Markazi, and Zanjan was reported to be higher than 90%. On the other hand, low coverage (less than 50%) was reported from three provinces: Kohkilooyeh-Boyerahmad, Qom, and Tehran. Looking at Figure 1, most of the provinces (19 out of 30) achieved an acceptable coverage rate of over 70%. Lower coverage was mostly seen in the provinces in the south and southeast of the country, in addition to a couple of central provinces.

As Table 3 indicates, despite acceptable coverage in most provinces, a relatively wide difference was observed between the two extremes. Coverage for the first dose varied from 52.9% to 100%. Likewise, coverage for the second and third doses ranged from 51.3 to 99.9% and 44.2 to 96.1%, respectively. It was observed that the difference between the highest and lowest values widened gradually, from 47.1% in the first dose to 51.9% in the third dose. The vaccination coverage for each dose of the vaccine was disaggregated by sex and living area and is summarized in Table 4. For all three doses, a significantly higher percentage of girls than boys received the vaccine (P<0.001). In addition,

Table 2. ! # ! "! % ! # !
! % " #

First round of campaign	1,320,822 (73.9%)		
Second round of campaign	1,390,738 (77.8%)	1,292,486 (72.3%)	
Third round of campaign	1,399,594 (78.3%)	1,332,294 (74.5%)	1,251,403 (70.0%)

* Data in each cell are expressed as the number of vaccinated persons (percent of coverage).

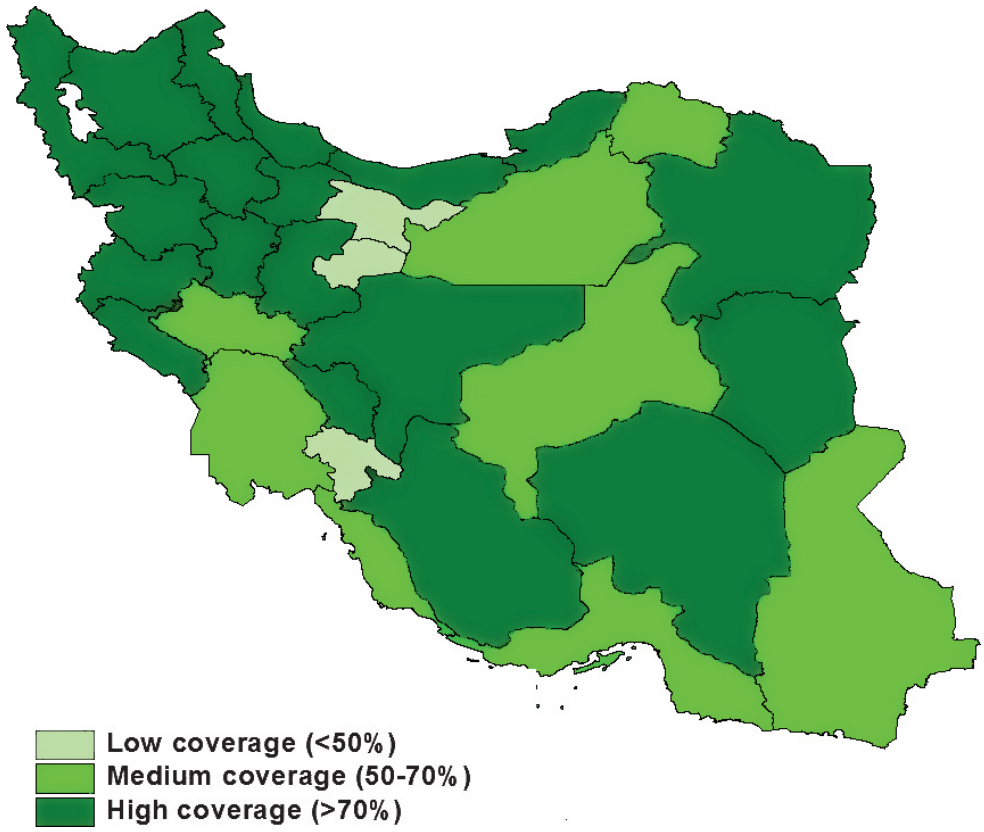

Figure 1. " # ! # # ! # !

vaccination coverage was significantly higher in rural areas than in urban areas (P<0.001).

Discussion

The current study indicates that at the end of the third round, 70.0% of the target population had received the full dose of the HBV vaccination. In addition, 74.5% and 78.3% received at least two doses and one dose of the vaccine, respectively. The achievement of a 70% coverage rate in the campaign is truly exceptional for a large country such as Iran, which is around 1,648,000 square kilometers wide, and considering that nearly 1,800,000 people were eligible to be covered in the campaign.

There have been similar campaigns in the other countries that have been able to achieve higher coverage rates, but they were mostly implemented in countries with limited coverage areas and populations. For instance, in an HBV vaccination program covering all 11- to 12-year-old pupils attending schools in Glasgow, UK in 2001-2002, around 80% received the full three-dose vaccination [11]. This program covered 81 schools with fewer than 11,000 eligible children. Another HBV vaccination program targeting the entire cohort of around 46,000 sixth-grade students in British Colombia, Canada, could achieve 92% coverage for three doses [12]. However, in another experience in Denver (Colorado, USA), when the target population increased to nearly 500,000, the coverage rate dropped. In this school-based HBV vaccination program, which was offered to students in sixth grade in 1996-97, only 61.2% of eligible students completed the vaccine series [13]. A retrospective study in 1997-1998 in Lazio, Italy that evaluated HBV immunization coverage of children reported that 50% of 11-year-old children completed the vaccination [14].

In addition to country coverage of 70% in the campaign, provincial coverage was almost acceptable

Table 3. # ! # # ! # ! % #

28941(86.1)	30043(89.3)	31168 (92.7)	Ardebil
74278(87.2)	78844 (92.5)	78027 (91.6)	Azarbaijan.E
59435 (79.7)	61277 (82.1)	66586 (89.2)	Azarbaijan.W
15365 (66.1)	15721 (67.7)	17824(76.7)	Booshehr
22939 (91.9)	22469 (90.1)	22070 (88.5)	Charmahal-Bakhtyari
93128 (78.9)	94810 (80.3)	96734 (81.9)	Fars
33476 (74.1)	36130 (80.0)	38325 (84.9)	Golestan
49051 (92.1)	48927 (91.9)	50773 (95.3)	Gilan
36482 (78.8)	38182 (82.5)	40365 (87.2)	Hamedan
19135 (50.8)	19754 (52.4)	19929 (52.9)	Hormozgan
12245 (74.7)	12388 (75.5)	13611 (83.0)	Ilam
90432 (80.5)	90941 (80.9)	85869 (76.4)	Isfahan
50281 (71.6)	49551 (70.5)	52416 (74.6)	Kerman
39367 (76.2)	38193 (73.9)	40137 (77.7)	Kermanshah
32180 (77.7)	34064 (82.3)	32415 (78.3)	Kordestan
9029 (44.2)	12032 (58.9)	14245 (69.8)	Kohkilooyeh-Boyerahmad
14464 (88.3)	13405 (81.8)	14330 (87.5)	Khorasan.S
107180 (71.9)	120852 (81.1)	127426 (85.5)	Khorasan.R
11543 (51.6)	16737 (74.7)	20076 (89.7)	Khorasan.N
79634 (66.8)	85155 (71.5)	87878 (73.8)	Khoozestan
32870 (66.1)	37228 (74.9)	41338 (83.2)	Lorestan
53427 (75.4)	52911 (74.6)	55314 (78.0)	Mazandaran
30280 (90.1)	31024 (92.3)	32733 (97.3)	Markazi
25963 (86.1)	26548 (88.1)	26655 (88.4)	Qazvin
11957 (44.8)	13689 (51.3)	17951 (67.2)	Qom
8004 (57.3)	10647 (76.3)	11270 (80.7)	Semnan
36600 (59.8)	42406 (69.3)	45337 (74.1)	Sistan-Baloochestan
132297 (46.0)	155620 (54.1)	174717 (60.7)	Tehran
15404 (61.5)	15691 (62.7)	16725 (66.8)	Yazd
26016 (96.1)	27055 (99.9)	27350 (101.0)	Zanjan
1251403 (70.0)	1332294 (74.5)	1399594 (78.3)	Country

* Data in each cell are expressed as the number of vaccinated persons (percent of coverage).

Table 4. " ! % # ! # ! ! # ! ! % $ #

Girls	732,729 (83.7)	703,386 (80.4)	401,924 (83.3)
Boys	666,865 (73.1)	628,908 (68.9)	346,838 (68.7)
P value	< 0.001	< 0.001	< 0.001
Urban	900,284 (75.5)	846,402 (71.0)	438,034 (68.7)
Rural	499,310 (83.7)	485,892 (81.5)	310,728 (84.1)
P value	< 0.001	< 0.001	< 0.001

* Data in each cell are expressed as the number of vaccinated persons (percent of coverage).

**For 10 provinces, only the combined data of the third dose of the vaccine are available. Therefore, disaggregated coverage by sex and living area for the third dose were calculated based on the data of the other 20 provinces. The provinces excluded from the disaggregated coverage calculation include Tehran, Charmahal-Bakhtyari, Khorasan.R, Khorasan.N, Semnan, Sistan-Baloochestan, Fars, Kohkilooyeh-Boyerahmad, Gilan, and Lorestan.

as well. As Figure 1 shows, most of the provinces (19 out of 30) achieved a coverage rate of over 70%. In 8 provinces, coverage was between 50% and 70%, and coverage rates lower than 50% were seen in three provinces: Kohkilooyeh-Boyerahmad, Qom, and Tehran. It should be noted that the target population in these last three provinces comprised around 19% of the total target population in the country. On the other hand, as shown in Table 3, despite acceptable coverage in most provinces, a relatively wide difference (ranging from 47% to 52%) was observed between the two extremes. This difference widened gradually from the first dose to the third dose.

According to Table 3, coverage of the first round of the campaign in one province (Zanjan) slightly exceeded 100%. This could have been due to some people living in one province and getting vaccinated in another. This is probable as the first round of the campaign was run near the Nowrooz holidays. Furthermore, in some provinces, such as East Azarbaijan, Charmahal-Bakhtyari, Isfahan, etc., the coverage rate in the first or second round was reported to be lower than those of later rounds. There are two possible explanations for this. Firstly, as mentioned before, an adolescent may have received the first dose of the vaccine in one province but got the second dose in another province. Secondly, an adolescent may have been informed of the campaign too late, after the first round had

ended. Such individuals would have had to receive the first dose of the vaccine in a private center and then could have participated in the campaign in further rounds to receive the second and third doses. Despite these logical possibilities, reporting errors cannot be overlooked as a potential cause of the data anomalies.

The Glasgow program was run in three main phases: three doses of the vaccine as well as two extra cleanup phases, which were implemented between Rounds 2 and 3 and after Round 3, respectively [11]. In the Iran campaign, the third round was extended by 47 days, whereas each of the two previous rounds had lasted just 14-16 days. In fact, the last 30 days of the third round were considered to be cleanup. In addition, if someone who would have been eligible for the vaccination during the campaign was referred to a vaccination station in the month after the campaign ended, he/she got vaccinated. We have no comprehensive valid statistics for that time span.

The vaccination coverage reported in the current study was based on the number of adolescents who received the vaccine throughout the campaign. However, the real percentage of target adolescents in Iran who received the HBV vaccine may be higher than that reported from the campaign as some adolescents had already been vaccinated from other sources such as private centers and therefore did not participate in the campaign. According to a brief survey conducted by the Center for Disease Control prior to the campaign on a sample of nearly 10,000 17-year-old adolescents across the country, 10.4% of adolescents had already received an HBV vaccine, of whom only 22.4% (which is equal to 2.3% of the total population studied) had received all three doses of the vaccine [15]. It should be noted that the results of this quick survey should be interpreted conservatively as there are shortcomings in the sampling and data-analysis procedures.

Our findings reveal that coverage for all three doses of the vaccine was significantly higher among girls than boys and among people living in rural areas compared with people living in urban areas (Table 4). In fact, the health network in Iran is more active in rural areas than in urban areas in terms of providing health services. Further, public health services in the rural areas have a significant presence for the whole population, so we observed high percentages of people who participated in the campaign in rural areas. An alternative explanation is that the adolescents in urban areas were more likely to have been vaccinated already and thus not participate in the campaign. This could potentially explain the low coverage observed in Tehran given it is the capital and largest city in the country. The area of residence was found to be a determinant of vaccination coverage in an Italian study as well. Specifically, complete HBV immunization in 11-year-old children in Italy was associated with living in small cities [14].

HBV vaccination has been demonstrated to reduce the prevalence of chronic HBV infection and the incidence of hepato-cellular carcinoma (HCC) dramatically in various countries. In Italy, the first western country to adopt an HBV mass immunization campaign, an HBV vaccination was made compulsory among newborns and 11-year-old children in 1991. Consequently, hepatitis B incidence declined from 5.4 per 100,000 in 1990—before introduction of compulsory HBV vaccination—to 2.9 per 100,000 in 1997 in the country [16]. Similar reductions of the chronic HBV carrier prevalence in immunized cohorts of infants and children have been demonstrated in Gambia, Taiwan, Indonesia, Senegal, and Thailand [17-19]. In addition, a study in Taiwan demonstrated that the incidence of HCC among children declined from 0.70 to 0.36 per 100,000 after implementation of a universal infant hepatitis B vaccination in the country [20]. The impact of the vaccination program in Iran was illustrated by two studies in 1991 and 1999—before and after the infant vaccination program. The studies were conducted on a representative, 1/1000 sample of the Iranian population and indicated that the prevalence of HBsAg in 2- to 14-year-old children had significantly decreased from 1.3% to 0.8% [21]. Moreover, because chronic HBV infection has been shown to be the main cause of HCC in Iran [22], it is predicted that HCC incidence will decrease in future years following the expected decrease in HBV infection incidence and prevalence.

In addition to the information about campaign coverage, policymakers need other information, such as associated costs of the campaign, because the campaign series will be implemented for three other age cohorts of adolescents [5]. According to the most recent study conducted on cost estimation and analysis of the present campaign, the total cost was estimated at 2.3 USD (21,000 IR Rial) per dose administered [23]. The costs for the planned campaign are much lower than has been spent on similar programs in developed countries [11-13]. We used administrative data to estimate campaign coverage in the present study. Administrative data are valuable because they are comprehensive and easy to obtain. They also provide useful logistical information for planning of future immunization activities. However, a comparison of vaccination

coverage estimates obtained from administrative data and surveys in various campaigns has shown that administrative data may overestimate or underestimate vaccination coverage [9]. There are other methods, such as cluster surveys, to assess mass vaccination campaign coverage. In some campaigns two methods were applied together to verify the results derived from administrative data [9]. Relying merely on administrative data may provide false reassurance that the coverage objective has been met. When a country conducts a large-scale campaign, conducting cluster surveys at the provincial or national level can provide a more accurate validation of the coverage, although doing so will require additional effort and expense.

Conclusions

Four age cohorts of Iranian adolescents will be vaccinated against hepatitis B in 4 consecutive years. The 2007 HBV vaccination campaign was the first campaign in the series, and full-dose coverage in the country was 70.0%, while most provinces achieved a coverage rate of over 70%. The campaign was able to achieve higher coverage rates for female adolescents and rural areas, two known vulnerable populations in most healthcare systems.

References

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.76.;6 .?7216F.125 $.?52:6 F:6 $.7./6 &
$6?8 3.0@<>? 3<> 52=.@<0299A9.> 0.>06;<:. 6; %<A@52>; >.;
%
.7.>6F.125 $.?5616.; .451<<?@ 9.B6.; %
<?@ .;.9E?6? <3 @52 :.?? B.006;.@6<; 0.:=.64; .4.6;?@
52=.@6@6? 6; .1<92?02;@? 6; >.; , /?@>.0@& " #
%A==92:2;@