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THE IMPACT OF INACTIVATED POLIO VACCINE INTRODUCTION ON THE OVERALL EXPANDED PROGRAM ON IMMUNIZATION COVERAGE AND TIMELINESS IN YOGYAKARTA PROVINCE

DAMPAK DIMULAINYA PEMAKAIAN INACTIVATED POLIO VACCINE TERHADAP CAKUPAN DAN KETEPATAN WAKTU PEMBERIAN IMUNISASI PENGEMBANGAN PROGRAM IMUNISASI DI PROVINSI DAERAH ISTIMEWA YOGYAKARTA

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ABSTRACT

Background: Implementation of the expanded program on immunization (EPI) has been excellent in Yogyakarta Province. Since September 2007 this province has piloted the introduction of inactivated polio vaccine (IPV), instead of oral polio vaccine (OPV). The shifting policy raised concern on the possibility that the new program would compromise the performance of the existing EPI. This study was a part of evaluation study on IPV pilot project in this province 2.5 years after its implementation. It was aimed to assess the impact of IPV introduction on coverage and timeliness of immunizations within EPI.

Method: We conducted a cross sectional study using WHO standard 30-by-7 cluster sampling to evaluate the EPI program in Yogyakarta Province, both in urban and rural areas. The subjects included children aged 12-23 months old and their parents. A questionnaire was used to get information from parents/caregivers on demographic and socioeconomic characteristics. Along with data on status and date of IPV vaccination, we included those of other EPI. The impact of IPV implementation was evaluated by determining the coverage and timeliness of all immunizations within EPI. We compared the current data with those in period before introduction of IPV. We used Epi Info™ 2003 software for data entry and analysis.

Result: Coverage of vaccinations within EPI is in overall ranged from 92-100%. The coverage is similar between urban and rural areas for all vaccines and doses. There is no difference in EPI coverage before and after the introduction of the IPV. Approximately 89% children have received complete immunization. Average age of immunization for each vaccine was very close to the recommended schedule. However, only 69% children received the immunization timely.

Conclusion: The EPI coverage in Yogyakarta Province is excellent and not compromised by the introduction of IPV. The proportion of children received timely immunization is relatively low. We suggest including timeliness, beside the coverage, when evaluating the performance of immunization program.

Key words: immunization, EPI, IPV, coverage, timeliness

ABSTRAK

Latar belakang: Implementasi pengembangan program imunisasi di Propinsi Daerah Istimewa Yogyakarta (DIY) telah berjalan dengan sangat baik. Sejak September 2007 propinsi ini melaksanakan proyek percontohan vaksin polio inaktif (IPV, *inactivated polio vaccine*), sebagai pengganti vaksin polio oral. Perubahan kebijakan ini memunculkan kehawatiran terhadap kemungkinan terganggunya kinerja Pengembangan Program Imunisasi (PPI) yang sudah berjalan. Penelitian ini merupakan bagian dari penelitian evaluasi terhadap pilot project IPV di propinsi ini 2,5 tahun setelah implementasinya. Penelitian bertujuan untuk menilai dampak pemakaian IPV terhadap cakupan dan ketepatan waktu imunisasi yang tercakup dalam PPI.

Metode: Kami melakukan penelitian potong lintang dengan metode standard WHO *"30-by-7"* sampling klaster untuk mengevaluasi PPI di Propinsi DIY baik di wilayah perkotaan maupun pedesaan. Subyek peneliian mencakup anak usia 12-23 bulan dan orang tua/pengasuh mereka. Kuesioner dipakai untuk memperoleh informasi tentang karakteristik demografi dan sosial ekonomi. Serta status dan tanggal imunisasi yang tercakup dalam PPI. Seiring dengan pengambilan data tentang status dan tanggal imunisasi IPV, kami juga mencakup data tersebut untuk semua vaksinasi lain dalam PPI. Dampak pelaksanaan program IPV dinilai dengan menentukan cakupan dan ketepatan waktu pemberian seluruh imunisasi yang tercakup dalam PPI. Kami membandingkan data tersebut dengan data dari periode sebelum pemakaian IPV. Kami menggunakan perangkat lunak Epi Info™ 2003 untuk proses pemasukan dan analisis data.

Hasil: Cakupan imunisasi yang tercakup dalam PPI secara keseluruhan berkisar 92%-100%. Cakupan tersebut serupa di daerah perkotaan dan pedesaan. Tidak ada perbedaan cakupan PPI sebelum dan setelah pemakaian IPV. Sekitar 89% anak telah mendapatkan imunisasi dasar lengkap. Rerata umur pemberian masing-masing vaksin sangat mendekati jadual yang direkomendasikan. Namun, hanya sekitar 69% anak yang mendapatkan imunisasi tepat waktu.

Kesimpulan: Cakupan PPI di Provinsi DIY sangat baik dan tidak terpengaruh oleh pemakaian IPV. Proporsi anak yang mendapatkan imunisasi tepat waktu masih relatif rendah. Kami menyarankan untuk memasukkan ketepatan waktu imunisasi, selain cakupan, ketika mengevaluasi kinerja program imunisasi.

Kata kunci: imunisasi, PPI, IPV, cakupan, ketepatan waktu

INTRODUCTION

The national expanded program on immunization (EPI) in Indonesia includes four doses of hepa-

titis B vaccine (including the so called dose "zero", HB-0, given at birth), single dose of BCG vaccine, 3 doses of diphtheria, whole cell pertussis, and tetanus (DPT) toxoid, 4 doses of oral polio vaccine (OPV, including dose "zero" given at birth) and single dose of measles vaccinations. Since 2004, the hepatitis B vaccine, except for the HB-0, was administered in combined form with DPT (DPT-HB).

In 2007, Indonesian national coverage for complete immunization among children aged 12-23 months was 46.2%.[1] In Yogyakarta Province the coverage was 64.6%, representing the second highest coverage nationally after Bali Province. In more recent survey in 2010[2] the national coverage was 53.8%, whereas in Yogyakarta Province it was 91.1% and being the highest coverage nationally.

In 2007 the Indonesian Ministry of Health chose Yogyakarta Province to pilot the use of inactivated polio vaccine (IPV), instead of OPV, in routine immunization program.[3] This policy remarked that the province has entered the final stage in polio eradication. It was indicated by the absence of wild polio cases within the last several years, supported by high coverage of the 4th dose of OPV and excellent implementation of acute flaccid paralysis (AFP) surveillance system, including a sewage system that allows for environmental surveillance of poliovirus. An independent coverage survey[4] found the coverage for the 1st through 4th doses of the OPV were 100%, 100%, 99.5%, and 98.6%, respectively. The seroprevalence study also indicated that more than 98% children had protective level of antibodies against all type of polio viruses. In such situation, the benefit of OPV has been no longer overweight the risk for possible adverse events of paralysis due to vaccine-associated paralytic poliomyelitis (VAPP) or outbreaks due to circulating vaccine-derived polio virus (VDPV).[5]

While the shifting policy has marked an important step in polio eradication program, the introduction of IPV in routine EPI needs special attention. Any change or implementation of new immunization policy potentially influences the existing immunization. In addition, contrary to the OPV, which is simply given orally, the IPV should be administered by injection. In US, the policy change from OPV to IPV immunization has initially raised many criticisms. There is concern that parents may not permit their children to receive numerous simultaneous injections and the healthcare providers might be reluctant to administer multiple shots at a single visit. Those combined factors would I turn lead to reduced vaccination coverage. Two studies in US show no evidence for this fear.[6-9] However, this concern has not been evaluated in the setting of developing countries.

This present study is a part of evaluation study on IPV pilot project implementation aimed to evaluate the impact of IPV introduction on the overall EP in Yogyakarta Province approximately 2.5 year after the inclusion of IPV in routine immunization program. The evaluation includes coverage as well the timeliness of vaccinations.

METHOD

We conducted EPI survey in Yogyakarta Province according to the World Health Organization (WHO) recommendation using cluster sampling method.[10] The detailed of the method has been described in our previous report.[11] Along with data on IPV, we simultaneously acquired those of overall immunizations within EPI. We evaluated the EPI performance in term of immunization coverage and timeliness. We compared the current data with those in period before introduction of IPV. We used Epi Info™ 2003 software for managing data entry and analysis.

RESULT

Overall, 426 children participated in the study, including 215 in rural area and 211 in rural area. In both urban and rural areas, most of mothers have education level of secondary school and to be housewife.

Table 1 presents the comparison of immunization coverage between the current survey and previous one held in 2004 when OPV remained exist in

Table 1. Comparison of EPI coverage between 2004 and 2010 survey

Vaccines	2004 survey	2010 survey	
	%	%	95%CI
HB-0*	-	99.1	98.1 - 99.9
BCG	97.1	99.8	99.3 - 100.0
HB-1	96.7	98.6	96.6 - 100.0
HB-2	97.1	98.6	96.9 - 100.0
HB-3	96.7	92.7	90.3 - 95.2
DPT-1	97.4	100.0	100.0 - 100.0
DPT-2	96.7	99.8	99.3 - 100.0
DPT-3	96.2	99.5	98.9 - 100.0
Polio-0¶	99.7	-	-
Polio-1	96.7	100.0	100.0 - 100.0
Polio-2	96.4	99.8	99.3 - 100.0
Polio-3	96.4	99.3	98.5 - 100.0
Polio-4	96.0	96.7	95.2 - 98.3
Measles	94.3	98.6	97.5 - 99.7

* Hepatitis 0 (HB-0) vaccine in 2010 survey was comparable to hepatitis 1 (HB-1) vaccine in 2004 survey

¶ In 2004 survey, polio-0 represents oral polio vaccine (OPV) given soon after birth. In 2010 survey, polio-4 represents IPV given at 9 months old simultaneously with measles immunization.

§ No raw data available at present to calculate the 95%CI

the program. Both surveys indicated high coverage for all vaccines and no significant difference in coverage observed in those two surveys.

Table 2 shows the coverage for immunizations included in EPI was all above 91%. The coverage of IPVs has been reported in our previous publication.[11] The 1st dose of DPT and IPV immunization represented the highest coverage, whereas the 3rd dose of hepatitis B vaccine does the lowest one. In fact, the coverage of all vaccines, except for the 3rd dose of hepatitis B, was above 96%. No significant difference in the coverage between urban and rural areas for all vaccines and doses.

In the present EPI program in Yogyakarta Province BCG vaccine should be given by 3 months old. The HB-0 vaccine is recommended to be administered within the first seven days after birth. The 3 subsequent doses of hepatitis B are scheduled at 2, 3, and 4 months old in combination form with DPT (DPT-HB), simultaneously with administration of IPV (IPV-1 through IPV-3). The 4th dose of IPV (IPV-4) is scheduled at 9 months old along with administration of measles vaccine. Table 4 shows the mean age of vaccines administration. Those for IPV may be found elsewhere.[11]

The completeness and timeliness of vaccinations are presented in table 6. Overall, 89.0% (CI95%: 86.0-92.0) children received all vaccines included in EPI. The rate is slightly higher in rural area though this difference is not significant. When timeliness is put into account, only 68.6% (CI95%: 63.6-73.7) children received immunization at proper time for all EPI vaccines. No differences were observed when the data stratified into urban and rural areas. We define overall immunization timelines as the timely administration for all vaccines included in EPI. BCG vaccination is timely when it is administered by 3 months old. Hepatitis B zero dose (HB-0) vaccination is appropriate when it is delivered within the first 7 days after birth, as the recommendation of Indonesian Ministry of Health. The first dose of IPV and DPT vaccines should be given at 6 weeks old or beyond. The timely measles vaccination was defined as its administration at 9-12 months old. For vaccines scheduled at multiple doses (hepatitis B, DPT, and IPV) the interval of administration should be 24 days or more. It is based on general guidelines that the minimum interval of vaccination is 4 weeks (28 days), however, doses given within 4 days before the minimum age for all vaccines are considered acceptable.[12]

Discussion

Immunization program has saved many children from morbidity and mortality associated with vaccine-preventable diseases. The national EPI in Indonesia provides protection against seven target diseases with important public health impact, including tuberculosis, hepatitis B, polio, diphtheria, pertussis, tetanus, and measles.

This is the first study evaluating the performance of EPI in Yogyakarta Province after implementation of IPV pilot project. This survey found that despite of shifting policy of OPV-to-IPV, the EPI coverage in

Table 2. Immunization coverage by urban/rural area and in overall

Vaccines	Urban		Rural		Overall	
	%	(95%CI)	%	(95%CI)	%	(95%CI)
HB-0	98.6	(97.0-100.0)	99.5	(98.6-100.0)	99.1	(98.1- 99.9)
BCG	100.0	(100.0-100.0)	99.5	(98.6-100.0)	99.8	(99.3-100.0)
HB-1	97.7	(93.8-100.0)	99.5	(98.6-100.0)	98.6	(96.6-100.0)
HB-2	98.1	(95.2-100.0)	99.1	(97.7-100.0)	98.6	(96.6-100.0)
HB-3	91.2	(85.9- 96.3)	94.3	(89.2- 99.5)	92.7	(90.3- 95.2)
DPT-1	100.0	(100.0-100.0)	100.0	(100.0-100.0)	100.0	(100.0-100.0)
DPT-2	99.5	(98.6-100.0)	100.0	(100.0-100.0)	99.8	(99.3-100.0)
DPT-3	100.0	(100.0-100.0)	99.1	(97.7-100.0)	99.5	(98.9-100.0)
Measles	99.5	(98.6-100.0)	97.6	(95.6- 99.7)	98.6	(97.5- 99.7)

Table 3. Age of vaccination (HB-0 in days, others in months)

Vaccines	Urban		Rural		Overall	
	Mean	95%CI	Mean	95%CI	Mean	95%CI
HB-0	3.5	1.0- 8.0	0.7	1.0-2.4	5.0	3.3-6.8
BCG	0.7	0- 1.3	0.4	0.1-0.6	0.6	0.5-0.7
HB-1	2.2	1.9- 2.5	2.2	2.1-2.4	2.2	2.1-2.3
HB-2	3.6	2.9- 4.4	3.5	3.1-3.9	3.4	3.3-3.5
HB-3	5.8	3.3- 8.3	4.4	4.0-4.9	4.8	4.6-4.9
DPT-1	2.2	1.9- 2.5	2.2	2.1-2.4	2.3	2.2-2.3
DPT-2	3.6	2.9- 4.4	3.5	3.1-3.9	3.5	3.4-3.6
DPT-3	5.8	3.3- 8.3	4.4	4.0-4.9	4.8	4.6-4.9
Measles	9.8	9.3-10.3	9.2	9.7-9.6	9.5	9.3-9.7

Table 4. Immunization completeness and timeliness

	Urban	Rural	Overall
	% (95%CI)	% (95%CI)	% (95%CI)
Complete immunization			
- all vaccines	86.1 (81.4- 90.7)	91.9 (88.2 - 95.1)	89.0 (86.0- 92.0)
- hepatitis B	88.8 (84.6- 93.1)	93.8 (90.6 - 97.1)	91.3 (88.6- 94.0)
- BCG	100.0 (100.0-100.0)	99.5 (98.6-100.0)	99.8 (98.5-100.0)
- DPT	99.5 (98.6-100.0)	99.1 (97.7-100.0)	99.3 (98.5-100.0)
- IPV	95.8 (93.1- 98.5)	97.2 (94.9- 99.4)	96.5 (94.7- 98.2)
- Measles	99.5 (98.6-100.0)	97.6 (95.6 - 99.7)	98.6 (97.5- 99.7)
Timely immunization			
- all vaccines	65.4 (57.9-72.9)	71.6 (64.7- 78.5)	68.6 (63.6- 73.7)
- hepatitis B	72.0 (65.0-78.9)	75.7 (69.3- 82.2)	73.9 (69.2- 78.6)
- BCG	99.4 (98.3-100.0)	99.4 (98.3-100.0)	99.4 (98.6-100.0)
- DPT	95.9 (92.9-98.9)	96.6 (93.9- 99.3)	96.2 (94.2- 98.3)
- IPV	92.1 (88.0-96.3)	93.2 (89.4- 96.9)	92.67 (89.9- 95.5)
- Measles	95.2 (91.9-98.5)	95.5 (92.3- 98.6)	95.31 (93.1- 97.6)

Yogyakarta Province remains impressive for each dose of all vaccines, ranging from 96-100%. For overall and each vaccine, the coverage is very similar to that of 2004 survey, when OPV was still used in the program. Moreover, the coverage for all vaccines is equally high in both urban and rural areas. The findings suggest that introduction of IPV does not compromise at all the performance of existing immunization program. Introduction of new program into EPI sometimes adversely affects the existing program. For OPV-to-IPV shifting, it is not only about the change of vaccine but also that of mode of administration from oral to the invasive injection methods. The fact that Yogyakarta Province successfully maintains high immunization coverage in the current IPV era may partly reflect excellent socialization of the new policy to the community. It is strongly indicated by the homogeneous high coverage in both urban and rural areas for all vaccines. Dissemination of the new EPI package is facilitated by relatively small area of Yogyakarta Province. Its geographical characteristics also make almost all health facilities are easily accessible by any mode of transportations. On the other hand, this study also suggests that the introduction of IPV into the current EPI has been well accepted by the community. One important reason for children being drop-out from immunization is the frequency of visit. Parents tend to be less complying when they are asked to have more visits to get immunization service. Therefore, any change or addition of vaccine would be more acceptable when it is integrated into the existing schedule without the need of additional visit. This is especially important considering that the IPV should be given by injection, contrary to the OPV. In this sense, the IPV administrations are scheduled at 2, 3, and 4 months old, simultaneously with those of DPT vaccine, and at 9 months old for the last IPV dose, together with measles vaccine. By this arrangement, there is no change at all in number and schedule of immunization visits. Such approach has been also applied in other countries when integrating new vaccine in EPI schedule, such as hepatitis B vaccine.[13, 14] We also consider that the predominantly paternalistic culture of Yogyakarta society may contribute to the acceptance of the program. Under this culture, as long as the health decision maker and providers involve community leaders in socializing the program and persuading the people, the program can be usually accepted well by the community.

Approximately 89% children have complete immunization, meaning they have received all vaccines within EPI, including one dose of BCG, four doses of hepatitis B, 3 doses of DPT, four doses of IPV, and one dose of measles vaccines. This percentage is close to the recent administrative estimate of 91%.[2] This represents the highest complete EPI coverage achievement in Indonesia. The national coverage for complete EPI is approximately 54%. In fact, there is large discrepancy among different provinces, ranging from the lowest 28% in Papua Province to 91% in Yogyakarta. Moreover, there are still 13% children in average who never received any vaccination included in EPI. This percentage is even as high as 35% in Papua Province.[2]

Immunization coverage has been frequently used as the standard measure of immunization program.[15] However, vaccination coverage alone does not take into account the possible inappropriate timeline of vaccine administration. In recent years, there are more concerns on vaccination timeliness as an equally important indicator in assessing the

performance of immunization program. High level immunization coverage does not always imply timely vaccination.[16, 17] Data from several countries indicate that the age-appropriate vaccination is usually much lower than the coverage.[18-20] In USA, approximately 73% children received all standard vaccinations but only 13% of them received all of the vaccinations at the recommended age.[21] More recent data suggested higher percentage but remains as low as 18% for the timely vaccination.[22] Furthermore, about 30 children in USA are undervaccinated for more than 6 months during their first 24 months old and approximately 25% children experience delay for immunization for at least 4 vaccines. Significant delays in immunization are also observed in Australia.[23] Data from 45 low-income and middle-income countries shows large variability among different countries but in general indicate poor immunization timeliness.[24] This study also indicates the same tendency. While 89% children have complete immunization, only 69% received the vaccination timely. It is interesting to note that the average ages of immunization for each vaccine in this study are very close to the recommended schedule. Each vaccine is administered at average age of no more than 1 month within the schedule. This study suggests that relying only on the coverage and average age of immunization can be misleading in term of timely immunization.

Poor immunization timeliness may result from too early administration, too close interval, or delay of administration. The first dose of IPV and DPT should be administered at least at 6 weeks old. Too early administration would result in suboptimal immune response and increase the risk for development of adverse event following immunization (AEFI). The minimum interval between doses for vaccine requiring multiple doses is 4 week but doses given within 4 days before the minimum interval (24 days) are considered acceptable. Too close spacing would result in suboptimal immune response and should be considered as invalid dose and need to be repeated.[25] Unfortunately, we pose difficulty in defining the delay of vaccination. Unlike the recommendation from the American Academy of Pediatrics (AAP), the Indonesian national EPI schedule does not strictly define the longest interval between vaccine doses that remain acceptable (for vaccine with multiple doses administration). Moreover, there is schedule recommended by the Indonesian Pediatrics Society (IPS) that is slightly different with that of national EPI. For DPT and IPV vaccines, IPS recommends an optimal interval of 8 weeks for DPT and IPV vaccinations. Therefore, in IPS recommendation, the first to the third doses of DPT and IPV are administered at 2, 4, and 6 months old, while the fourth dose of IPV at 9 months old, as in national EPI schedule. This difference complicates us in determining the definition of delay of immunization in this study. For this reason, we do not include "delay" in our definition of timeliness.

Special attention should be emphasized for hepatitis vaccine zero dose (HB-0). Despite high level of coverage (91.3%), only 73.9% is given within the first 7 days of life, as recommended by the Indonesian Ministry of Health. Study in Lombok Island (Indonesia) proves that administration of hepatitis B vaccine at age more than 7 days old is associated with higher prevalence of hepatitis B infection compared with those do within the first 7 days old (3.0% versus 1.4%).[26] For countries with high burden of hepatitis B infection, such as Indonesia, immediate administration of hepatitis B vaccine is essential to prevent the perinatal transmission, which leads to high probability for the children getting chronic hepatitis B infection. World Health Organization (WHO)[27] and the Advisory Committee on Immunization Practices (ACIP)[28] suggest earlier hepatitis B vaccination, i.e. within the first 24 hours and 12 hours of life, respectively. Using the WHO recommendation the rate declines into 66%. We are unable to calculate the coverage of the HB-0 within the first 12 hours of life, as ACIP recommendation, since the immunization card record only the date of immunization without additional information on "time". However, it can be expected that the percentage will be further declining. Then, there remain considerably high proportion of newborn babies receive hepatitis B vaccination beyond the ideal period.

To our knowledge, this is the only study in Indonesia so far evaluating comprehensively the performance of all immunizations within EPI in term of immunization coverage, completeness, and timeliness. For area such as Yogyakarta Province where high coverage has been achieved, timely immunization should be the next important goal. The coverage alone would be a poor indicator of the vaccinated fraction of the population. Timely vaccination is essential to generate adequate immunity.[29] Delayed immunization has been proved to be a risk factor for pertussis and measles infection.[30-32] Late administration of BCG vaccine seems to be related with reduced survival.[33] Poor immunization timeliness, despite of high coverage, will place many children in period without or with suboptimum immune protection. Poor timeliness may result in disease

outbreaks. When outbreak occurs in area with high level of both coverage and timeliness, then we may consider other factor such as the quality of cold chain in vaccine transportation. Thus, evaluation of vaccination timeliness will provide positive feedback on the adequacy of immunization program implementation. Recent outbreak of measles in some area of Yogyakarta and that of diphtheria in East Java may necessitate this perspective.

We conclude that the EPI coverage in Yogyakarta Province is not compromised by the OPV-to-IPV shifting program. However, there are still significant proportion of children received vaccinations at inappropriate schedule. We encourage including the timeliness when assessing the performance of immunization program. Nevertheless, it should be noted that the study was carried out in area with stable high immunization coverage. Similar studies in other Indonesian areas with more variable immunization performances would be beneficial.

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