

BMJ Open Relationship between receipt of substitutable for-fee vaccines and completion of the expanded programme on immunisation: a cross-sectional study in Fujian, China

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ABSTRACT

Objective The aim of this study was to evaluate the relationship between receipt of the substitutable-for-fee vaccines (SFV) and completion of the expanded programme on immunisation (EPI).

Design and settings A cross-sectional study was conducted in Fujian province, China.

Participants Children who were born from 1 September 2009 to 31 August 2011, and who had been residing in the township for at least 3 months, were randomly recruited from 34 townships.

Main outcomes measures Outcomes were completion rate of the EPI and coverage rate of the SFV.

Results The study included 1428 children, of whom 1350 (94.5%) finished the EPI and 282 (19.7%) received at least one dose of the SFV. Administration of the SFV was associated with an increased likelihood of completing the EPI (OR=3.2, 95% CI 1.3 to 7.6 in the total sample and OR=4.0, 95% CI 1.7 to 9.6 in the subsample of children in regions with the SFV accessibility). The impact of the SFV administration on completion of the EPI was larger among children whose parents have junior school education or less (97.8% and 97.9% vs 92.5% and 91.9%, both $p<0.001$) and among those with a timely hepatitis B vaccine first dose (98.5% vs 94.0%, $p<0.001$).

Conclusions Receipt of SFV is associated with increased likelihood of completion of the EPI in Fujian, China.

INTRODUCTION

China has an expanded programme on immunisation (EPI) which includes one dose of Bacille Calmette-Guerin vaccine (BCG), three doses of hepatitis B vaccine (HepB), four doses of oral live attenuated polio vaccine (OPV), four doses of acellular pertussis diphtheria tetanus vaccine (DTaP), two doses of measles-containing vaccine (MCV), two doses of group A meningococcal polysaccharide vaccine (MPSV-A), two doses of live-attenuated Japanese encephalitis vaccine (JE-L), one dose of live-attenuated hepatitis A vaccine (HepA-L), one dose of diphtheria

Strengths and limitations of this study

- This is the first study exploring the association between substitutable for-fee vaccines (SFV) administration and the expanded programme on immunisation completion in China.
- The subjects were selected randomly by lot quality assurance sampling from townships which were randomly extracted by the probability proportional to size sampling method, as well as a high response rate (100%) in the survey; therefore, the sample had a good representation.
- The findings may help target vulnerable children and improve the implementation of the SFV policy in China.
- The sample size was not large enough, and we were not able to control all potential confounding factors in the analyses, both may limit the interpretation of some results.

tetanus vaccine (DT) and two doses of meningococcal A+C polysaccharide vaccine (MPSV-AC).¹ The EPI vaccines are mostly produced by state-owned pharmaceutical companies and are provided to the public as free vaccines. In addition, parents can choose to purchase variants that are for-fee vaccines, which are mostly manufactured by private enterprises based in China or are imported from abroad. The for-fee vaccines can be further divided into two types, normal and substitutable for-fee vaccines (SFV).^{2 3} For example, pneumococcal conjugate vaccine is a normal for-fee vaccine, while inactivated polio vaccine (IPV) is an SFV and can be a substitute for OPV.

Whether to carry out service of the SFV for children has been controversial in China. On the one hand, given worries that the SFV service may cause social injustice and affect the completion of the EPI, the National Health and Family Planning Commission of

the People's Republic of China (China NHFPC) opposed the SFV service.⁴ In some areas, the Health Bureau even prohibited staff in immunisation clinics (IC) from administering the SFV vaccination to children. On the other hand, parents always think the SFV was better than EPI vaccines (eg, safer and more effective), the opinions have been strengthened since the adverse events after the EPI immunisation was reported.^{5,6} Hence, parents may select the SFV once they can afford the fee, and/or they think it is necessary (eg, children are not in good condition for EPI vaccines). Moreover, vaccine providers may recommend the SFV once they thought the SFV was safer than EPI vaccines, worried about the troubles caused by adverse events following immunisation (AEFI) (eg, vaccine-associated paralytic poliomyelitis after OPV immunisation)⁷ and were under pressure to create income for the unit.⁸ Therefore, the SFV immunisation was widely performed in China. It was estimated that 18.05% of children had received at least one dose of the SFV nationally, and the coverage of the SFV was higher among children in eastern areas than that in western regions.²

Previous studies primarily focused on describing coverage of normal for-fee vaccines (such as pneumococcal conjugate vaccine and influenza vaccine) and their determinants,^{8–10} and investigating coverage of the SFV and/or its substitution rate to the EPI vaccines.^{2,11,12} However, no studies to date were conducted to probe the relationship between the SFV vaccination and the EPI completion. Knowing the relationship is important for guidance and management of the SFV service, such as, if the SFV were conducive to complete the EPI for children, the China NHFPC may improve the policy of SFV and encourage vaccination with the SFV for children who can afford the vaccine fee.

Furthermore, parents who choose to have their children received the SFV might not only show a greater disposable income (because the SFV requires an out-of-pocket payment)² but also have higher awareness of immunisation (because they chose the SFV instead of the EPI vaccines). Better economic capacities and higher vaccination awareness were significantly related to completion of the EPI vaccine series.^{13,14} Moreover, previous studies had revealed that children who had initiated a delayed first dose of HepB¹ and whose parents have lower educational levels were less likely to complete the EPI.¹⁵ Therefore, it is reasonable to hypothesise that (1) children receiving the SFV might promote their completion of the EPI and (2) the relationship between the SFV administration and the EPI completion might be modified by parents' education level and initiation time of the HepB first dose. We aimed at assessing coverage rates of the SFV and verifying the hypotheses.

METHODS

Participants and design

The cross-sectional study was part of a national EPI coverage rate investigation and was conducted in

December 2013 in Fujian, China. Details of the national survey have been described elsewhere.^{16,17} In brief, Chinese children aged 2–4 years at the time of the survey (born from 1 September 2009 to 31 August 2011) and who had been residing in the township for at least 3 months were included as target subjects and were randomly selected for the survey. First, a township with a population less than 10 000 was combined with an adjacent township to ensure adequate sample for survey, resulting in 1004 combined townships with a population of $\geq 10\,000$ from the 1058 townships in Fujian province. Second, 34 townships were randomly selected by the probability proportional to size sampling method from the 1004 townships. For each township sampled, five villages (the village where the township government was located and another four randomly selected villages) were sampled as village-level survey sites. Finally, at the village-level survey sites, lot quality assurance sampling was used to sample households for survey.

Parents or guardians of the children were interviewed by a standardised questionnaire which was set by China Center for Disease Control (CDC). The questionnaire contained two major items, including basic information and vaccination history. Measures of family socioeconomic situations (home address, types of living areas and education level of the parents) and child's information (name, gender, birth date, place of delivery, ethnicity and types of household register) were collected and included in the analyses as potential confounding factors. Records on vaccination certificates kept by parents or vaccination cards kept in IC, rather than parents' memories of vaccination, were extracted as evidence of vaccine immunisation to avoid possible recall bias. Children were considered unvaccinated if both the vaccination certificate and vaccination card were absent. It took about 10 min to complete a questionnaire. Newborns who received a HepB in the first and second day of birth were deemed to finish the vaccine within 24 hours and have a timely HepB first dose in our analysis,¹ because it is hard to calculate the exact hours that the babies receive the vaccine.

A total of 42 children were surveyed in each township, including 10 from the village where the township government was located and 8 each from the remaining four villages. Ultimately, a total of 1428 children were selected in the province. Because this was part of regular national public health evaluation of EPI coverage by the township level, all selected subjects should be surveyed, therefore the response rate in our study was 100%.¹⁸ The sampling method was identified as a suitable method for evaluation of the EPI coverage rate by the township level and the sample (42 children) of each township had a power of 90% to detect whether the coverage rate of EPI reached 90% with a 0.05 significance level.¹⁸ The study was part of a national activity which was organised by the China NHFPC to evaluate whether the EPI coverage by the township level meets the requirements of the 12th Five Year Plan of Health Development and was exempt from ethical review.¹⁶

Outcomes

The primary outcome was completion rate of the EPI, which was defined as the percentage of children who had finished the EPI. Completion of the EPI was defined as children completing the EPI according to the recommended immunisation schedule. Children aged 2–3 years should finish one dose of BCG, three doses of HepB, three doses of OPV, four doses of DTaP, two doses of MCV, two doses of MPSV-A, one dose of HepA-L and the first dose of JE-L and an additional second dose of JE-L was demanded for children of 3–4 ages. Vaccination earlier than the initiation schedules time of vaccines and with incorrect intervals between different doses of vaccines was defined as ineffective vaccination.

Children who had received the SFV in accordance with immunisation schedule were identified as completing the corresponding EPI vaccines. The equivalences between SFV and EPI vaccines were as follow¹⁹: (1) For HepB, DTaP, OPV and MPSV-A, one dose of SFV was equivalent to one dose of EPI vaccine. (2) For JE-L, two doses of inactivated Japanese encephalitis vaccine (JE-I) should be vaccinated to 3-year-old children and a third JE-I dose be given to 4-year-old children, which were equal to the first dose and second dose of JE-L, respectively. (3) For HepA-L, one dose of inactivated hepatitis A vaccine (HepA-I) was equal to one dose of HepA-L for children aged below 3 years. However, children who had received a dose of HepA-I should accept another HepA-I dose by 4 years of age, which was identified as completion of the HepA-L for children aged 3–4 years.

The secondary outcome was the coverage of SFV, which was defined as the percentage of children who had accepted one or more doses of the SFV. In this study, the SFV included IPV (substitute for OPV), DTaP and *Haemophilus influenzae* type B (HIB) conjugate vaccine (substitute for DTaP), DTaP/IPV/HIB conjugate vaccine (substitute for OPV and DTaP), group A/C meningococcal conjugate vaccine (substitute for MPSV-A), hepatitis A and B combination vaccine (substitute for HepA-L and HepB), HepA-I (substitute for HepA-L) and JE-I (substitute for JE-L).

Statistical analyses

Data were double entered using EpiData V.3.1 to ensure the consistency and avoid information bias. Multivariate logistic regression models were fitted to estimate the ORs and their 95% CIs for completion of the EPI, after controlling for the potential confounding factors. Pearson's correlation coefficient was evaluated to intuitively reflect the correlation between the EPI completion rate and the SFV coverage rate in regions with the SFV supply.

Due to the implementation of different policies, SFV for children were banned in some areas. To compare completion rates among children in regions with SFV access to Fujian as a whole, we also ran a multivariate logistic regression analysis in the regions of Fujian with access to the SFV. Children were further divided into three groups, including children living in areas without

SFV access (these children did not receive SFV because there was no SFV in the areas), children without history of SFV vaccination in areas with SFV access and children who received the SFV in areas with SFV access. Logistic regression models were remodelled to compare the EPI coverage rates among the three groups.

To examine whether the relationship between receipt of the SFV and completion of the EPI was modified by parents' education level and initiation time of the HepB first dose, we performed cumulative completion rate stratification analysis based on parents' education level (junior school or less vs high school or above) and initiation time of the HepB first dose (> vs ≤24 hours) by Cox proportional hazards analyses, in which the EPI completion time (months) was set as 'survival time'.

All statistical tests were conducted using SPSS V.19.0. A p value of <0.05 was considered statistically significant.

RESULTS

Characteristics of the study population

In total, 1428 children of an appropriate age were surveyed, of whom 1350 (94.5%) finished the EPI, and 282 (19.7%) received at least of one dose of the SFV. Most of the children were of Han ethnicity (97.8%) and were local children (89.6%). More than half of the children were boys (54.0%) and aged 2 years (56.2%); and most children (85%) were born in hospitals at the county level and above.

Table 1 shows the population characteristics of the entire sample and the selected children in regions with the SFV access, stratified by children with and without completion of the EPI. Children who had a history of the SFV were more likely to complete the EPI than those who had not received the SFV (97.9% vs 93.7%) in total sample, as well as in the selected sample (97.9% vs 92.1%).

Receipt of the SFV and completion of the EPI

Compared with children who did not receive the SFV, children who had administrated the SFV were more likely to complete the EPI (unadjusted OR 3.1, 95% CI 1.3 to 7.2 and adjusted OR 3.1, 95% CI 1.3 to 7.4; p=0.009) in the total sample. The adjusted OR rose to 3.9 (95% CI 1.6 to 9.4) in the subgroup of children in regions with the SFV supply (table 2). Children of 3 years old and with timely initiation of the HepB first dose (<24 hours after birth) were more likely to complete the EPI than those of 2 years old and with a delayed HepB first dose. The minority children were less likely to complete the EPI than the Han children (table 2). Educational level of the child's father also affected the completion of EPI in the total sample but insignificant in the subgroup sample (table 2). The SFV coverage was correlated with the EPI completion rate in children from regions with the SFV access (correlation coefficient=0.689; p=0.059) (figure 1).

After controlling for potential factors (child's gender, age and nationality, parents' education level, etc),

Table 1 Base characteristics of children in groups with and without completion of the EPI in total and selected sample

Characteristics	Total sample (n=1428)		Population in regions with the SFV access (n=1008)	
	Did not complete EPIN (%)	Did complete EPIN (%)	Did not complete EPIN (%)	Did complete EPIN (%)
History of the SFV administration				
No	72 (6.3)	1074 (93.7)	57 (7.9)	669 (92.1)
Yes	6 (2.1)	276 (97.9)	6 (2.1)	276 (97.9)
Gender				
Male	40 (5.2)	731 (94.8)	32 (5.8)	517 (94.2)
Female	38 (5.8)	619 (94.2)	31 (6.8)	428 (93.2)
Age at survey (years)				
2 ~	56 (7.3)	746 (92.7)	45 (8.2)	502 (91.8)
3 ~	22 (3.4)	634 (96.6)	18 (3.9)	443 (96.1)
Nationality				
Han	70 (5.0)	1327 (95.0)	55 (5.6%)	922 (94.4)
Minority	8 (25.8)	23 (74.2)	8 (25.8)	23 (74.2)
Place of birth				
County hospital or above	65 (5.4)	1149 (94.6)	54 (6.5)	777 (93.5)
Township hospital	12 (5.7)	197 (94.3)	8 (4.6)	165 (95.4)
Home	1 (20.0%)	4 (80.0%)	1 (25.0%)	3 (75.0%)
Household registration				
Local registration	69 (5.4)	1211 (94.6)	54 (6.2)	819 (93.8)
Outside or no registration	9 (6.1)	139 (93.9)	9 (6.7)	126 (93.3)
Mother's educational level				
Junior school or less	68 (6.6)	967 (93.4)	56 (7.9)	652 (92.1)
High and technical school	8 (3.2)	240 (96.8)	6 (3.1)	189 (96.9)
College or higher	2 (1.4)	143 (98.6)	1 (1.0)	104 (99.0)
Father's educational level				
Junior school or less	69 (6.9)	925 (93.1)	55 (8.0)	629 (92.0)
High and technical school	7 (2.6)	261 (97.4)	7 (3.4)	197 (96.6)
College or higher	2 (1.2)	164 (98.8)	1 (0.8)	119 (99.2)
Initiation time of the hepatitis B vaccine first dose				
>24 hours	9 (13.2)	59 (86.8)	9 (17.6)	42 (82.4)
≤24 hours	69 (5.1)	1291 (94.9)	54 (5.6)	903 (94.4)

EPI, expanded programme on immunisation; SFV, substitutable-for-fee vaccines.

compared with children in regions without the SFV access, children who had received the SFV were more likely to complete the EPI (OR 1.8; 95% CI 0.7 to 4.8, $p=0.25$), while those without the SFV administration were less likely to complete the EPI (OR 0.5; 95% CI 0.2 to 0.8, $p=0.01$) in regions with the SFV supply.

Stratified analyses

We observed significant differences of EPI coverage rates between groups of children with and without the SFV administration by stratifications of parents' educational level (junior school or less vs high school or above) and initiation time of the HepB first dose (> vs ≤24 hours

after birth). Children with the SFV receipt had a significantly higher cumulative completion rate than those without the SFV administration in the subgroup of children whose parents with education level of junior school or less (97.8% vs 92.5% for mother's education level and 97.9% vs 91.9% for father's education level, both $p<0.001$) (figure 2B, D). Similarly, children with timely initiation of a HepB first dose were more sensitive to the SFV vaccination, the cumulative EPI completion rate was higher among children receiving the SFV than that among those without the SFV administration (98.5% vs 94.0%, $p<0.001$) (figure 2E). No significant result was

Table 2 ORs and 95% CIs for completion of EPI

Characteristics	Total sample (n=1428)		Population in regions with the SFV access (n=1008)	
	ORs (95% CI)	p Value	ORs (95% CI)	p Value
History of the SFV administration				
No	Reference		Reference	
Yes	3.1 (1.3 to 7.4)	0.009	3.9 (1.6 to 9.4)	0.002
Gender				
Male	Reference		Reference	
Female	0.8 (0.5 to 1.4)	0.48	0.8 (0.5 to 1.4)	0.46
Age at survey (years)				
2 ~	Reference		Reference	
3 ~	2.5 (1.5 to 4.2)	0.001	2.5 (1.4 to 4.5)	0.002
Nationality				
Han	Reference		Reference	
She	0.2 (0.1 to 0.4)	<0.001	0.2 (0.1 to 0.5)	0.001
Place of birth				
County hospital or above	Reference		Reference	
Township hospital	1.1 (0.6 to 2.2)	0.74	1.9 (0.9 to 4.2)	0.10
Home	0.5 (0.05 to 5.8)	0.60	0.7 (0.06 to 9.2)	0.79
Household registration				
Local registration	Reference		Reference	
Outside or no registration	0.8 (0.4 to 1.6)	0.46	0.9 (0.4 to 1.9)	0.71
Mother's educational level				
Junior school or less	Reference		Reference	
High and technical school	1.1 (0.5 to 2.5)	0.83	1.4 (0.5 to 3.8)	0.50
College or higher	1.7 (0.3 to 9.4)	0.55	2.7 (0.3 to 25.8)	0.38
Father's educational level				
Junior school or less	Reference		Reference	
High and technical school	2.4 (1.0 to 5.7)	0.054	1.9 (0.7 to 4.7)	0.18
College or higher	4.5 (0.8 to 24.8)	0.09	6.5 (0.7 to 62.4)	0.10
Initiation time of the hepatitis B vaccine first dose				
>24 hours	Reference		Reference	
≤24 hours	2.7 (1.2 to 6.0)	0.016	3.9 (1.7 to 9.3)	0.002

EPI, expanded programme on immunisation; SFV, substitutable-for-free vaccines.

observed for children whose parents have education of high school and above and who had received a delayed HepB first dose (figure 2A, C, F).

DISCUSSION

We found that children who had received SFV were more likely to complete the EPI, where the association may be offset by high parents' education level and the delayed initiation of the HepB first dose. In China, frequent reports of AEFI, such as the Shanxi vaccine incident⁵ and the Conde HepB event,⁶ had further

solidified the parents' views of 'cheap is dear, and dear is cheap', they would choose the SFV even if they have to pay an extra cost (each dose costs ¥18 to ¥630 mean: ¥156/dose, approximately US\$24.6/dose²⁰). Moreover, receiving the SFV may create revenue and reduce the incidence of AEFI caused by the EPI vaccines,^{11 21} therefore, children who chose the SFV might be treated more enthusiastically by the staff in the IC than those who chose the EPI vaccines. Hence, receiving the SFV may be an indicator of the economic conditions and vaccination awareness of children's families, and might

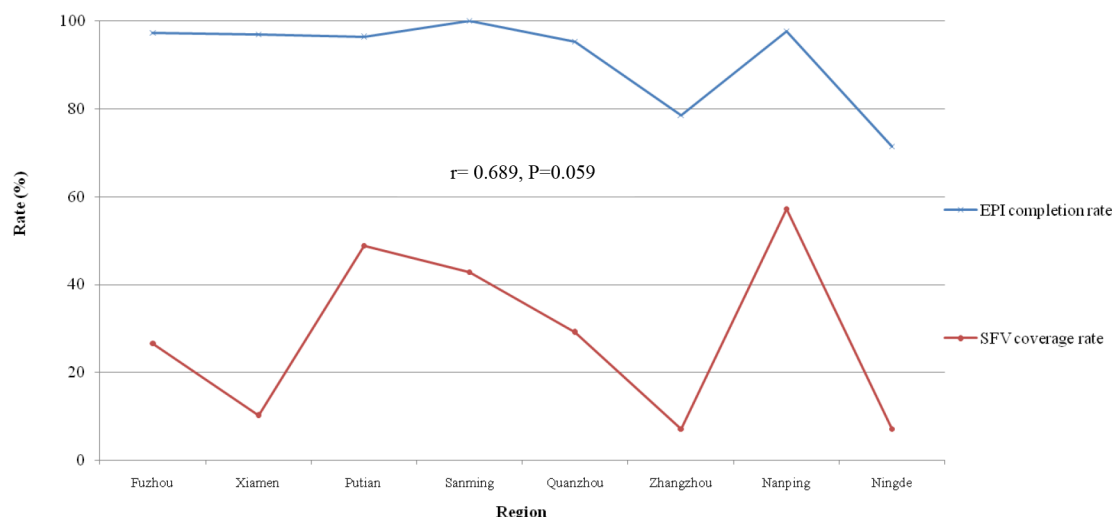


Figure 1 The correlation analysis between the EPI completion rate and the SFV coverage rate in regions with the SFV supply. EPI, expanded programme on immunisation; SFV, substitutable-for-free vaccines.

ensure better service from the staff of the IC, resulting in children having better compliance with immunisation and being more likely to complete the EPI.^{1 2 9 22–26}

Parents with lower education level have certain characteristics (earn less, lack of knowledge and have multiple children) that are not conducive to complete the EPI for their children^{27 28}; they might be more sensitive to the price of the SFV.^{27–29} Whether to receive the SFV may further reflect their economic situation and immunisation awareness, which leads to the difference of the EPI completion between the two groups. The HepB first dose are often delayed as a result of contraindications for children born in hospitals or of low medical accessibility for those born at home,^{1 30 31} which might affect their catch-up vaccination of the EPI vaccines even if they had received the SFV, resulting in a significantly lower completion of the EPI than those with timely initiation of the HepB first dose.

Interestingly, we found that the supply of the SFV may play a ‘double-sword’ role in the EPI completion. Vaccine providers may differentiate children who had received the EPI vaccines from those with the SFV, which may lead to a decline in the enthusiasm of the completion of the EPI.³² Moreover, the difference of completion rate of the EPI between regions with and without the SFV supply may be partly explained by the percentage of non-local children, which was proved as an impact factor for the EPI completion.^{24 31} In our study, the percentage of non-local children was significantly lower in regions without SFV supply than that in regions with the SFV access (3.1% vs 13.4%, $p<0.001$).

We also found that the EPI completion rate was higher in children aged 3 years, which differed from findings of a previous study.³¹ This inconsistency may be explained due to the fact that the age of 3 is usually the start to attend kindergartens, which are required to examine the vaccination certificate of children under regulations,

therefore prompting children to receive their missing vaccinations³³ and effectively improving the completion of the EPI in 3-year-old children. Minority children were less likely to complete the EPI, which may be related to poor economic conditions of their families³⁴ and the lack of vaccination awareness of their parents.³⁵ Similar to previous studies,^{36 37} we confirmed that timely HepB first dose initiation improved the EPI completion in children, possibly because receiving a timely HepB first dose might help emphasise the importance of vaccination to the parents and promote their children’s completion of the EPI.¹

Our study has several limitations. First, we included the SFV, but not normal for-free vaccines, such as the varicella vaccine and the influenza vaccine, which might introduce certain information bias. However, most normal for-free vaccines are not administered until children are 2 years old, this bias might not affect the results of this study. Second, the moderate sample size of this study may limit the interpretation of some results. Finally, other factors, such as access to healthcare, knowledge, attitudes and the practices of parents and providers, regional vaccination policy, the level of regional economic development, will also affect the SFV vaccination. In addition, sociodemographic variables, such as the number of children, parent age, family income and so on, might be better indicators of the willingness to receive SFV than the parents’ education level. Unfortunately, we were not able to include all these factors in the current study.

To the best of our knowledge, this is the first study exploring the association between the SFV administration and the EPI completion in Fujian, China. The association between the SFV administration and the EPI completion was more obvious among children whose parents have lower education level and among those with a timely HepB first dose. Vaccine providers should focus on these vulnerable children and take measures to help

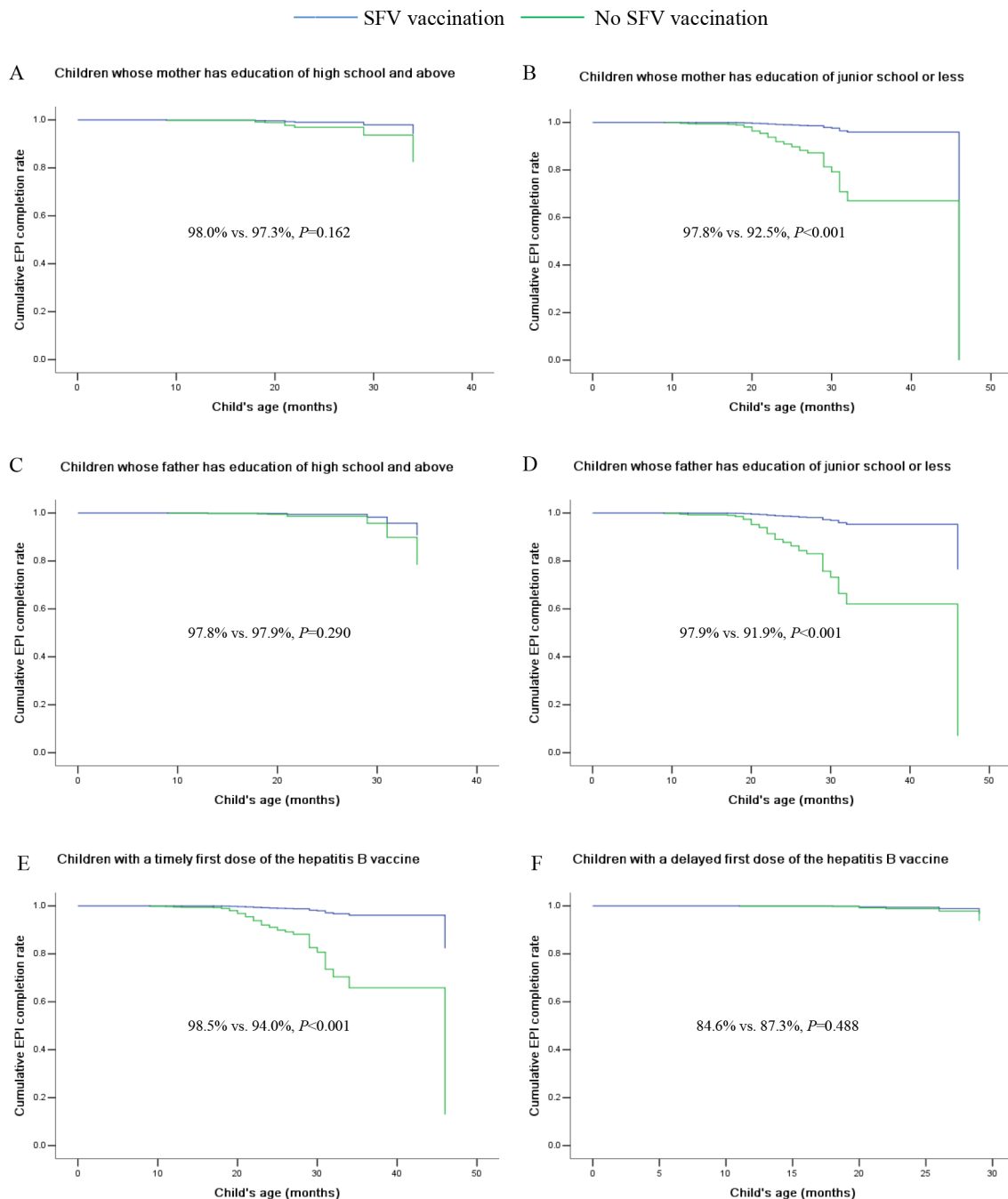


Figure 2 Cox proportional hazards models estimates of the EPI cumulative completion rate according to the receipt of the SFV, stratified by parents' education level and initiation time of the hepatitis B vaccine first dose. A, B, C and D show the difference of cumulative EPI completion rate between groups of children with and without the SFV vaccination by parents' education level (high school and above vs junior school or less), as well as by initiation time of the hepatitis B vaccine first dose (timely vs delayed initiation) in E and F. EPI, expanded programme on immunisation; SFV, substitutable-for-free vaccines.

them complete the EPI on time. The generalisability of the results should be further studied.

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Contributors JNW, YZ and DJL had the initial idea for the study and designed the survey. JNW, MRD and HLP collected and analysed the data for this study. JNW wrote the first draft of the manuscript. All authors critically revised the manuscript and approved the final version.

Competing interests None declared.

Patient consent Obtained.

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