



# Vaccination Refusal in Children under 2 Years of Age in Malaysia 2016-2019

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## Authors' contributions

This work was carried out in collaboration among all authors. Authors XJL and SJ was involved in the conception & design, acquisition of data, analysis and interpretation of data, writing the research report, drafting and revising it critically for important intellectual content and final approval of the version to be published. Authors LEA and ABMK was involved in the conception & design, the proposal development, data collection, write-up of the full report and writing for the publication. All authors read and approved the final manuscript.

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## ABSTRACT

**Aims:** This study will explore the incidence rate of childhood vaccination refusal in Malaysia as well as the reasons for this refusal over a four-year period (2016–2019). Given the complexities and dynamic nature of vaccine refusal, this research is essential for defining the target group, identifying the vaccine types they commonly refuse, and comprehending their vaccination concerns.

**Study Design:** This is a retrospective review study.

**Methodology:** This study used a nationally representative secondary data set from the Malaysian Ministry of Health's Family Health Division for the years 2016 to 2019. We included vaccination refusals involving children younger than 24 months of age. Data was extracted from the mothers' immunization refusal form includes information of the ethnicity, citizenship, religion, occupation, the

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type of vaccine they refused, and the reason for their refusal. The annual incidence rates of childhood vaccination refusal, the types of vaccines and the refusal reason were summarized by percentage, with 95% confidence intervals.

**Results:** There was a decline in incidence rates of vaccination refusal from 3.2 in 2016 to 2.3 in 2019 ( $P<0.001$ ). The refusal rate is highest in the states of Terengganu (15.9%), Kedah (14.1%), and Perak (12.2%). Of the 4052 mothers who refused to vaccinate their children, the majority were Muslims (99.0%) who had secondary education (53.7%) and were housewives (65.3%). Furthermore, most mothers refused to vaccinate their children due to religious beliefs (37.5–39.0%), safety concerns (26.3–34.0%), or belief in complementary and alternative medicine (11.4–15.8%). The reasons of refusal are associated with the mothers' religion, socioeconomic class, and education level ( $P<0.001$ ). Muslims have refused vaccinations due to religious beliefs, as they were concerned about the vaccine's halal status. Meanwhile, mothers from a higher socioeconomic class and with a higher educational level were apprehensive about the vaccine's safety.

**Conclusion:** Consolidated strategies are required to increase vaccination uptake, combined with a concerted effort to comprehend, analyse, and overcome vaccine refusal.

*Keywords: Vaccination refusal; childhood vaccinations; reasons; Malaysia; incidence rate.*

## 1. INTRODUCTION

Vaccination is a cost-effective and preventive health intervention. The World Health Organization (WHO) launched the Global Smallpox Eradication Program in 1959, and smallpox eradication is regarded as one of the greatest achievements in international public health [1]. South America was the first region to be polio free (1971), followed by Asia (1975) and then Africa (1977). Vaccination saves around three million lives every year from vaccine-preventable diseases (VPD) [2]. In 1977, the WHO began the Expanded Program on Immunization to protect children against six childhood diseases: polio, measles, neonatal tetanus, diphtheria, pertussis, and tuberculosis [3].

Vaccine hesitancy, which the WHO defines as a "delay in accepting or refusing vaccines notwithstanding the availability of immunization services," has been observed in more than 90% of the countries in the world [4]. In 2019, the WHO recognized vaccine hesitancy as one of the top 10 global health threats. In 2017, global coverage for the first dose of the measles vaccine was estimated to be 85%, whereas coverage for the second dose was substantially lower, at just 67% [5]. The immunization coverage fell far short of the 95% threshold required to prevent VPD outbreaks, leaving many people vulnerable to the disease in many regions. As a result, measles resurfaced in the European region (EUR), with large-scale outbreaks in Ukraine, Serbia, and several countries that had achieved elimination. Measles incidence in EUR increased fourteen fold from

5.8 per 1 million population (5,273 cases) in 2016 to a peak of 89.5 (82,596 cases) in 2018 [6].

Vaccination services for children are provided free of charge in all Ministry of Health facilities in Malaysia [7]. The National Immunisation Programme (NIP) for children in Malaysia has been initiated in the early 1950s with the immunisation coverage is considered high at >95% since year 1994 [8]. However, in recent years, the incidence of VPD has increased. Malaysia has seen a significant increase in the number of measles cases recorded, with 195 confirmed cases in 2013 compared to 1,981 cases in 2018 [9]. Additionally, reported pertussis cases have increased steadily, from 41 cases in 2010 to 892 cases in 2018 [9]. Malaysia was declared polio free in 2000; nevertheless, a polio case was reported in Malaysia in December 2019 [10]. To date, poliomyelitis has no treatment, and only a vaccine can prevent it. The increased recurrence of VPD that had believed to be eliminated should draw public attention to vaccination coverage gaps.

Malaysia should achieve herd immunity in order to safeguard children from VPD. Vaccinated individuals are not only protected against illness but also help prevent the virus from spreading to other people [11]. However, vaccination refusal has grown more prominent and vocal in recent years worldwide. Individual, group, and contextual factors, as well as vaccine-specific issues, may all contribute to vaccination refusal. It is critical to comprehend the magnitude and nature of refusal at the local level. A variety of studies have been conducted to investigate the reasons why parents refuse, delay, or are

reluctant to vaccinate their children [12–14]. The reasons given by parents vary greatly, but the most prevalent are safety concerns, mistrust of medical professionals, and personal health perceptions.

To the best of our knowledge, only a few studies have evaluated the incidence of vaccine refusal in Malaysia and the reasons that drive childhood vaccination refusal among Malaysia's vaccine refusal groups [15,16]. According to Chan et al.'s study [15], the incidence rate of vaccine refusal in Kedah state, Malaysia, has decreased from 10.51 per 1000 newborns in 2015 to 5.02 in 2016. However, the existing evidence is only applicable to a few states in Malaysia and does not reflect the actual status of vaccine refusal across the country. Since local refusal might result in a rapid fall of vaccination coverage in various contexts, it is critical for all nations to conduct regular assessments of the extent and reasons for local refusal. This study will provide an overview of the annual vaccine refusal incidence rate in Malaysia over a four-year period (2016–2019) and the reasons for parental refusal. The findings of this study will help policymakers understand the trend of vaccination refusal and the barriers parents face in getting their children vaccinated, helping them take the necessary steps to strengthen the country's immunization program.

## 2. METHODOLOGY

### 2.1 Study Design and Eligibility Criteria

This study used secondary data from the Family Health Division of the Malaysian Ministry of Health, which was a nationally representative cross-sectional data set for the years 2016–2019. The analysis included all reported vaccine refusal cases that met the study's inclusion criteria. We included cases involving children younger than 24 months of age that were reported between 2016 and 2019. We excluded cases with missing or incomplete data.

### 2.2 Data Sources

An immunization refusal form was provided to mothers who chose to skip one or more vaccines for their child. Mothers provided their name, age, citizenship, ethnicity, religion, home address, occupation, the type of vaccine they refused, and the reason for their refusal on the form. This form was then compiled and sent on a monthly basis to the State Health Department. The MOH's

Family Health Development Division then gathered data from 13 states and three federal territories in Malaysia (Appendix 1).

## 2.3 Operational Definition

### 2.3.1 Non-immunized and incomplete vaccination

Vaccine refusal is described as an individual's rejection to get vaccinated despite the availability of immunization services. Incomplete vaccination is defined as the lack of any of the vaccinations included on the Malaysian National Immunization Schedule children among children up to 12 months of age [17]. Non-immunized children were classified as those who had not received any of the required vaccines by the time they reached the age of 12 months.

### 2.3.2 The vaccines that mothers refused for their children

We evaluated vaccine doses that were included in the National Immunization Program (NIP) for children under the age of two. Vaccination is provided free of charge to all children as part of the NIP, which covers ten major childhood illnesses: Hemophilus influenza type B (HIB), hepatitis B, diphtheria, measles, mumps, pertussis, poliomyelitis, rubella, tetanus, and tuberculosis (Appendix 2).

### 2.3.3 Reasons for vaccination refusal

- a) **Religious reasons:** Most of the Muslim parents refuse immunization, as they believe that the existing vaccines contain porcine DNA, which is prohibited in Islam [18].
- b) **Safety concerns:** Parents who refuse vaccinations for their children also have concerns over the safety of the vaccines [19]. Parents have questions about the production and composition of the vaccines [20]. Media reports highlighting issues with vaccine components (such as thimerosal) and claiming that vaccinations can cause autism, brain damage, or behavioural disorders encourage parents to be more cautious and concerned about vaccination safety [21]. Such reports raise doubts about both the short-term adverse reactions as well as the possibility of long-lasting negative effects of having the vaccine [22].
- c) **Influence from internet/social media:** Many parents obtain anti-vaccination

information from various sources; the internet was the most popular source of information [23,24]. The sources can be categorized into two groups: informal sources with mostly peer-to-peer content (e.g., internet websites and online groups) and formal sources with more authoritative (or even medical) content (e.g., doctors, books, and public forums on vaccination).

- d) **Belief in complementary and alternative medicine:** Parents also refuse to vaccinate their children for personal or philosophical reasons. Some parents believe that homeopathic medicine is better for their children than the immunity acquired through vaccinations [24].
- e) **Influence from family members/friends:** Studies show that the social environment can influence the parents' choice concerning vaccine refusal. Parents often cite family members and friends as a trusted information source for immunization decision-making [25,26].
- f) **Low VPD susceptibility:** Some parents seem to think that their children are not likely to contract infectious diseases and that infections are not likely to be transmitted to their child; therefore, they are reluctant to vaccinate their child [25].

## 2.4 Statistical Analysis

Analysis was carried out using SPSS software version 21. Annual incidence rates of childhood vaccination refusal were summarized in number per 1000 newborns in Malaysia. The types of vaccines that mothers refused and their reasons for doing so were summarized by number and percentage, with 95% confidence intervals. Chi-square tests were used to examine the association between sociodemographic profiles of the mothers and their reasons for refusing vaccination.

## 3. RESULTS

### 3.1 Incidence Rate and Distribution of Vaccination Refusal in Malaysia

The total numbers of refusal cases in Malaysia throughout the four-year period were 4052, with an overall incidence rates (per 1000 newborns) of 2.3. The results reveal a reduction in annual incidence rates from 3.2 in 2016 to 2.4 per 1000 newborns in 2019 (Table 1). Over the four-year period, Terengganu state had the highest number of vaccination refusal cases (644), followed by Kedah (570 cases), Perak (493 cases), and Kelantan (423 cases) (Table 2).

### 3.2 Demographic and Immunisation Profile

Table 3 shows the social-demographic profile of the mother in relation to vaccination refusal. The majority of the mothers who refused to have their children vaccinated were Malay (94.9%), Muslim (99.0%), had a secondary education (53.7%), and were housewives (65.3%). Among the 4052 children, 504 (12.4%) were aged 12 months and above. Of those 504, 400 (79.4%) were partially immunized, 72 (14.3%) were non-immunized, and 32 (6.3%) refused booster doses. The most refused vaccines were the first and second doses of MMR, the third dose of hepatitis B, and the third dose of DTAP/IPV/Hib (Table 4).

### 3.3 Reasons for Refusing Vaccination

The reasons for refusing vaccination are listed in Table 5. Religious reasons (37.5–39.0%) and safety concerns (26.3–34.0%) remained the most common reasons for refusing vaccination over the four-year period. Meanwhile, there is an increasing trend of mothers who believed that their children had low susceptibility to VPD in 2019 (7.8%), as compared with previous years (3.6–6.4%).

However, reasons for refusing vaccination varied across subpopulations. There is a statistically significant difference between Muslims and non-Muslims for why they refuse to vaccinate their children ( $\chi^2(6) = 23.9, P < .001$ ). For Muslims, religious beliefs and safety concerns are the top reasons for refusing vaccination, whereas non-Muslims do not vaccinate their children due to concerns about vaccine safety as well as influences from family, relatives, or friends.

Interestingly, the reasons for refusing vaccination also differed among mothers in terms of socioeconomic class ( $\chi^2(6) = 42.7, P < .001$ ). Religious beliefs were somewhat more important factor for unemployed mothers and those from the lower social class. Mothers from higher socioeconomic classes are more concerned about vaccine safety compared to other social classes. Notably, unemployed mothers are more likely than other socioeconomic classes to refuse vaccination due to influences from their family, relatives, or friends (Table 6). Furthermore, mothers with a higher level of education are more likely to refuse vaccination because of safety concerns as compared to other groups ( $\chi^2(6) = 64.80, P < .001$ ). In this study, the reasons for refusing vaccination did not differ among children with varying vaccination statuses ( $\chi^2(6) = 14.25, P = .28$ ).

**Table 1. Annual incidence rates of vaccination refusal from year 2016 to 2019 in Malaysia**

Year	Number of children 2 years and below refused vaccination	Number of newborns	Incidence rates (per 1000 newborns)	P value (2016 vs 2019)
2016	1424 <sup>a</sup>	446591	3.2	<0.001
2017	858 <sup>b</sup>	447658	1.9	
2018	727 <sup>c</sup>	446598	1.6	
2019	1043 <sup>d</sup>	441462	2.4	
<b>Total</b>	<b>4052</b>	<b>1782309</b>	<b>2.3</b>	

<sup>a</sup> Incomplete data for state of Sabah and Melaka.

<sup>b</sup> Incomplete data for state of Negeri Sembilan and Pahang.

<sup>c</sup> Incomplete data for state of Perak, WPKL, Selangor, Pahang, Terengganu, Kelantan, Sabah.

<sup>d</sup> Incomplete data for state of Pahang.

**Table 2. Distribution of childhood vaccination refusal across the states in Malaysia**

State/ Year	2016 (n=1424) n (%)	2017 (n=858) n (%)	2018 (n=727) n (%)	2019 (n=1043) n (%)	Total (N=4052) n (%)
Terengganu	232 (16.3)	116 (13.5)	165 (22.7)	131 (12.6)	644 (15.9)
Kedah	170 (11.9)	121 (14.1)	128 (17.6)	151 (14.5)	570 (14.1)
Perak	235 (16.5)	134 (15.6)	0 (0.0)	124 (11.9)	493 (12.2)
Kelantan	90 (6.5)	120 (14.0)	102 (14.0)	109 (10.5)	423 (10.4)
Penang	132 (9.3)	79 (9.2)	71 (9.8)	72 (6.9)	354 (8.7)
Selangor	103 (7.2)	68 (7.9)	68 (9.4)	110 (10.5)	349 (8.6)
Johor	84 (5.9)	82 (9.6)	62 (8.5)	102 (9.8)	330 (8.1)
Pahang	170 (11.9)	2 (0.2)	0 (0.0)	78 (7.5)	250 (6.2)
N. Sembilan	60 (4.2)	6 (0.7)	33 (4.5)	49 (4.7)	148 (3.7)
Perlis	45 (3.2)	32 (3.7)	27 (3.7)	33 (3.2)	137 (3.4)
Melaka	36 (2.5)	29 (3.4)	23 (3.2)	44 (4.2)	132 (3.3)
Sabah	23 (1.6)	43 (5.0)	24 (3.3)	16 (1.5)	106 (2.6)
Sarawak	23 (1.6)	14 (1.6)	13 (1.8)	9 (0.9)	59 (1.5)
WPKL	12 (0.8)	10 (1.2)	8 (1.1)	13 (1.2)	43 (1.1)
WP Putrajaya	6 (0.4)	0 (0.0)	2 (0.3)	2 (0.2)	10 (0.2)
WP Labuan	1(0.1)	2(0.2)	1(0.1)	0(0.0)	4(0.1)

#### 4. DISCUSSION

Under the NIP, Malaysia has achieved more than 95% vaccination coverage among infants and children [8]. However, the resurgence of VPD has sparked concerns about a potential surge in vaccine refusal in Malaysia. To the best of our knowledge, this is Malaysia's first national study on vaccine refusal trends. Given the complexity and dynamic nature of vaccine refusal, this study is critical for defining the target population, identifying the vaccine types they frequently refuse, and understanding their vaccination concerns.

According to the findings of this study, the incidence rate of vaccine refusal declined between 2016 and 2019. This change was most likely triggered by the interventions carried out by the Ministry of Health, which spearheaded the National Immunization Promotion Campaign between 2016 and 2020 to address the issue of vaccination refusal [28]. Several interventions were rolled out, including the dissemination of immunization awareness leaflets to the general

population and healthcare workers as well as a robust advertising effort, including continued press reporting and write-ups on vaccines. Despite this success, there is still room to reduce the incidence of vaccine refusal even more.

The reasons for refusal do not change over the years; more than 60% of mothers still refused to vaccinate their children throughout the four-year period (2016–2019) owing to religious reasons and vaccine safety concerns. Consequently, a more targeted strategy should be developed to address the public's concerns [29]. This study showed that Muslim mothers from a lower socioeconomic class and with an educational level refused vaccination mainly due to religious beliefs. Muslims may refuse vaccination due to concerns that the vaccine may contain porcine DNA, violating stringent religious laws [18]. There is a difference of opinion among Islamic scholars, but the majority consensus is that the pork gelatin used in vaccines is permissible under Islamic law, since refusing vaccination will result in greater harm.

**Table 3. Social-demographic of mothers who refused vaccination**

Characteristics	Frequency (%)
<b>Mother</b>	
Ethnicity	
Malay	3844 (94.9)
Chinese	31 (0.8)
Indian	6 (0.1)
Bumiputera Sabah	45 (1.1)
Bumiputera Sarawak	29 (0.7)
Orang Asli	9 (0.2)
Others	88 (2.2)
Nationality	
Malaysian	3942 (97.3)
Non-Malaysian	110 (2.7)
Religion	
Muslim	4010 (99.0)
Buddha	21 (0.5)
Christian	10 (0.2)
Unknown	11 (0.3)
Level of Education	
No schooling	35 (0.9)
Primary education	246 (6.1)
Secondary education	2174 (53.7)
Tertiary education	1597 (39.4)
Socioeconomic class <sup>a</sup>	
Higher managerial, administrative and professional occupations	88 (2.2)
Lower managerial, administrative and professional occupations	907 (22.4)
Intermediate occupations	78 (1.9)
Small employers and own account workers	82 (2.0)
Lower supervisory and technical occupations	25 (0.6)
Semi-routine occupations	194 (4.8)
Routine occupations	34 (0.8)
Never worked and long-term unemployed	2644 (65.3)
<b>Children</b>	
Mean Age in month (SD)	4 (5.3)

<sup>a</sup> The National Statistics Socio-economic Classification rebased on Standard Occupational Classification 2010 (SOC2010) [27]

**Table 4. Types of vaccine refused by mother (for children 12 months and above)**

Type of vaccines	Refusal (N=504) n(%)
BCG	77 (15.3)
Hepatitis B dose 1	90 (17.9)
Hepatitis B dose 2	222 (44.0)
DTaP dose 1; Hib dose 1; IPV dose 1	269 (53.4)
DTaP dose 2; Hib dose 2; IPV dose 2	289 (57.3)
DTaP dose 3; Hib dose 3; IPV dose 3	320 (63.5)
Hepatitis B dose 3	322 (63.9)
MMR dose 1	426 (84.5)
MMR dose 2	452 (89.7)
DTaP booster; Hib booster; IPV booster	177 (35.1)

**Table 5. Reasons for refusing immunisation over the 4 year period**

Reason*	2016 n (%)	2017 n (%)	2018 n (%)	2019 n (%)
Religious	591 (37.5)	374 (38.2)	322 (39.0)	458 (37.7)
Safety	478 (30.3)	257 (26.3)	237 (28.7)	413 (34.0)
Belief in complementary and alternative medicine	226 (14.3)	155 (15.8)	102 (12.4)	139 (11.4)
Influence by the family/relative/friend	144 (9.1)	96 (9.8)	108 (13.1)	83 (6.8)
Low VPD susceptibility	73 (4.6)	63 (6.4)	30 (3.6)	95 (7.8)
Influence from Internet/Social Media	38 (2.4)	33 (3.4)	23 (2.8)	28 (2.3)
Cost	27 (1.7)	-	3 (0.4)	-

\*multiple reason are allowed

**Table 6. Association between characteristics of mothers, vaccination status of the child and reasons for refusing immunisation**

Variables	Religious	Safety	Belief in complementary and alternative medicine	Influence by the family / relative/ friend	Low VPD susceptibility	Influence from Internet/ Social Media	Cost	X <sup>2</sup>	P value
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
<b>Religion</b>									
Muslim	1741(38.3)	1362 (30.0)	615(13.5)	421(9.3)	258(5.7)	121(2.7)	29(0.6)	23.9	< .001
Non-Muslim	4(8.2)	10 (46.9)	7(14.3)	10(20.4)	3(6.1)	1(2.0)	1(2.0)		
<b>Socio-economic class<sup>#</sup></b>									
Unemployed	1151(38.4)	872 (29.1)	390(13.0)	304(11.5)	181 (6.0)	76(2.5)	24(0.9)	42.7	< .001
Routine	156 (42.0)	111(29.9)	39(10.5)	33(8.9)	19(15.1)	8(2.2)	5(1.5)		
Intermediate	27 (30.7)	24(27.3)	15(17.0)	9(10.2)	7(8.0)	6(6.8)	0(0.0)		
Higher and management	411 (36.1)	378(33.2)	178(15.6)	85(7.5)	54(4.7)	32(2.8)	1(0.1)		
<b>Education</b>									
Secondary and below	1123 (40.9)	759 (27.6)	355(13.0)	274(10.0)	148(5.4)	56(2.0)	30(1.1)	64.8	< .001
Tertiary and higher	622(33.6)	626(33.8)	266(14.4)	157(8.5)	113(6.1)	66(3.6)	0(0.0)		
<b>Vaccination status</b>									
Non-immunised	24(32.4)	25(33.8)	17(23.0)	7(9.5)	6(8.1)	4(5.4)	0(0.0)	14.2	0.28
Partially	153(38.4)	137(34.4)	51(12.8)	43(10.8)	36(9.0)	14(3.5)	10(2.5)		
Immunised									
Booster refusal	12(37.5)	13(40.6)	3(9.4)	2(6.2)	0(0.0)	1(3.1)	2(6.2)		

\* Multiple reason are allowed<sup>#</sup> The National Statistics Socio-economic classification rebased on standard Occupational Classification 2010 (SOC2010) [26]

To address these religious concerns, the Malaysian government talked with religious authorities, and an Islamic legal verdict (fatwa) in favor of vaccination was issued. Messages from religious leaders were more effective than ones from political or medical experts in generating favorable public opinion regarding vaccination [30]. Trusted figures like Imams were using Friday sermons to dispel myths about vaccine safety. These strategies boosted vaccination confidence, which led to a significant rise in COVID-19 vaccine uptake among Somali Muslims in Minnesota [31].

Since all of the vaccinations currently on the NIP schedule are supplied by overseas pharmaceutical companies, the halal certification process may not meet the expectations and preferences of Muslims at large. As a result, the government intends to begin manufacturing halal vaccines in the country to meet public demand for halal-certified vaccine. In addition to the government's initiatives, Muslim organizations should aggressively advocate for vaccinations to increase public acceptance. The Islamic Advisory Group for Polio Eradication (IAG), for example, was established in February 2014, and its eradication efforts have shown to be effective in Pakistan, Afghanistan, and Nigeria [32]. In conclusion, a culturally competent healthcare delivery system is critical in providing health services to populations with diverse values, beliefs, and behaviours by tailoring delivery to meet the social, religious, and cultural needs of the community.

Our findings also show that vaccine refusal due to safety concerns increased between 2016 and 2019. Moreover, vaccine safety is the most important reason among the mothers with a high educational level and socioeconomic status who refuse to vaccinate their children. Hak E et al.'s study also shows that highly educated parents and healthcare workers had negative attitude towards vaccination programs [33]. The most prominent concerns include vaccination ingredients like aluminum, mercury, or formaldehyde as well as the sheer number of vaccines children are expected to take, which may overwhelm, weaken, or disrupt the immune system. As a result, some people are concerned that vaccinations can cause autism, developmental delays, hyperactivity, and attention deficit problems [34]. One scientifically flawed journal article, which speculated on the MMR-autism relationship, has caused widespread concern regarding the safety of MMR vaccination. The influence of this misinformed

article is still strong [35] which may explain why MMR is the most common vaccine that Malaysian mothers reject. The growing concern over vaccine safety should alarm Malaysia's healthcare authorities, and further action is required to address this issue. The existing evidence indicates that the quantity of vaccination information distributed by healthcare providers is insufficient to assist parents in deciding whether or not to vaccinate their children and that they need comprehensive data on vaccine safety to help them reconsider vaccination [36]. According to the research, parents seek vaccination information before, during, and after pregnancy as well as at each subsequent clinic visit for their children [36]. Additionally, it has been shown that giving vaccination information in stages or at various times increases children's chance of getting vaccinated.

A limitation of this study was the lack of a feedback mechanism for vaccination refusal cases for those who followed up in a private clinic and for those living in remote areas with limited access to healthcare; hence, the reported vaccine refusal cases in this study may be underestimated. Furthermore, we only asked the mother to provide vaccination refusal reasons, but the father may also play an important role in vaccination decision-making. Due to incomplete data from the immunization refusal form as well as the absence of the form in certain states, the results do not fully reflect the incidence of refusal cases in Malaysia.

Using nationally representative data, we identified the incidence and causes for refusal of vaccination in Malaysia and its geographical variation in recent years, which is crucial because incidence and causes for vaccination refusal differ by country, region, and time. It is important to identify significant local and context-specific causal factors before strategic responses are developed.

## 5. CONCLUSION

The mean incidence of childhood vaccine refusal was 2.3 per 1000 newborns. Remarkably, the rate of vaccination refusal decreased between 2016 and 2019. In Malaysia, religious beliefs and vaccine safety concerns are the key reasons for mothers to refuse to vaccinate their children. A tailored immunization strategy should be developed to increase vaccine uptake by understanding the reasons for vaccine refusal, which is an evolving issue that should be



revisited on a regular basis. As a result, existing strategies may not be sufficient to turn the tide.

## CONSENT

It is not applicable.

## ETHICAL APPROVAL

The study proposal was registered with the National Medical Research Register, Malaysia (NMRR-20-178-53068) and was approved by the Medical Research Ethics Committee, Malaysia. This study did not involve any interaction with subjects. Thus, informed consent procedure was irrelevant.

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## COMPETING INTERESTS

The views, interpretations, implications, conclusions and recommendations expressed in this paper are those of the authors alone and do not necessarily represent the opinions, views and policy of the Ministry of Health Malaysia. The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article and this study was self-funded.

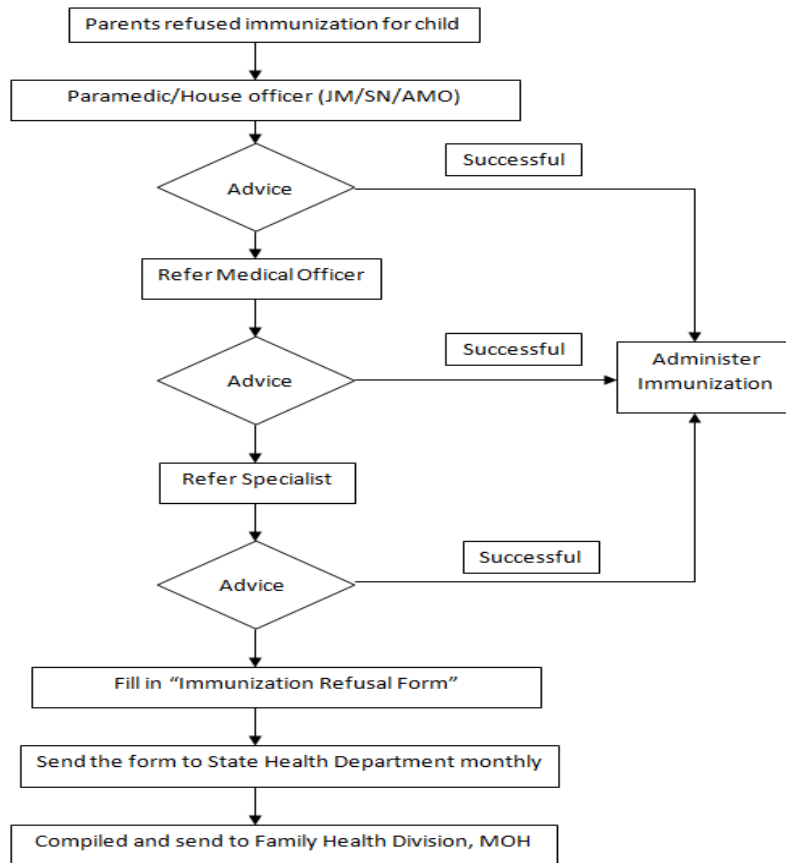
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**APPENDIX 1**



**Fig. 1. Management process for immunization refusal case**

**APPENDIX 2**

Age	At Birth	1 month	2 months	3 months	5 months	6 months	9 months	12 months	18 months	21 months	7 years	13 years	15 years
Types of immunization	BCG Dose 1	Hep B Dose 2	DTap Dose 1	DTap Dose 2	DTap Dose 3	Hep B Dose 3	MMR Dose 1	MMR Dose 2	Dtap Booster	JE Dose 2 (Sarawak only)	MR Dose 2	HPV Dose 1&2	Tetanus Booster
	Hep B Dose 1		Hib Dose 1	Hib Dose 2	Hib Dose 3	Measles Dose 1 (Sabah only)	JE Dose 1 (Sarawak only)		Hib Booster		DT Booster		
			Polio(IPV) Dose 1	Polio(IPV) Dose 2	Polio(IPV) Dose 3				Polio Booster				

**Fig. 2. National Immunization Program for year 2016-2019**

Source data: Ministry of Health Malaysia [18]

**Definition:**

1. **BCG** stands for Bacille Calmette-Guerin, which is the vaccine to protect against tuberculosis.
2. **DTaP** is the combination vaccine that protects against diphtheria, tetanus and pertussis. This vaccine is given together with the Hib and polio vaccines.
3. **IPV** stands for inactivated polio vaccine.
4. **Hib** stands for Haemophilus influenzae type b.

5. **MMR** stands for measles, mumps and rubella.
6. **MR** stands for measles and rubella, given to those born before July 2015.
7. **DT** is a booster dose given to protect against diphtheria and tetanus.
8. **HPV** stands for Human Papillomavirus. The vaccine is available to 13-year-old girls in 2 doses over a period of 6 months.
9. **JE** stands for Japanese Encephalitis. The vaccine is only given in Sarawak

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