

# Vaccine hesitancy and reported non-vaccination in an Irish pediatric outpatient population

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#### Abstract

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Vaccine hesitancy is defined as a delay in acceptance, or refusal, of vaccines, despite availability. It is a complex and context specific phenomenon, and identified as a global health priority. The 'Parent Attitudes about Childhood Vaccines' (PACV) questionnaire is a validated tool for identifying vaccine hesitancy. Our aim was to use the PACV to assess vaccine hesitancy and its relationship with reported non-vaccination in an Irish population, for the first time. Our participants were parents or caregivers of children attending general paediatric clinics in a tertiary pediatric hospital in Dublin, Ireland between September and December 2018. In total, 436 participants completed the questionnaire. 5.5% of our population reported non-vaccination. Human Papilloma Virus and Measles, Mumps, Rubella vaccines were the most commonly cited vaccines of concern (11.5% and 6.7% respectively) and autism spectrum disorder was the most commonly side effect of concern (4.3%). Mean PACV score was 26.9 (SD 19.1), with a significant difference between non-vaccinators and vaccinators (53.2 vs 25.3, p<0.001). Safety and efficacy concerns were the major contributor to non-vaccination. 14.4% of our population were vaccine-hesitant using the conventional cut-off score, which increased to 22% when using an optimal cut-off which maximized sensitivity and specificity. The accuracy of the PACV score to identify nonvaccination was good (area under the ROC curve = 0.827) and the optimal cut-off had a high negative predictive value (98.5%). Conclusion: PACV identified reported non-vaccination with high accuracy in our population. It may be useful to screen vaccine hesitant parents who could benefit from interventions to improve uptake.

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# **Keywords:**

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vaccine hesitancy, vaccine refusal, childhood vaccinations, vaccine promotion, public health, immunization, vaccine safety, Ireland

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68	SOW conceived the study. SOW and JB designed the study. SOW and LL collected the data. SOW and FM
69	conducted the analysis. All authors interpreted the findings. SOW, FM and KG drafted the manuscript. All
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# What is known?

- Vaccine hesitancy is a leading threat to global health, with falls in vaccine uptake associated with
   disease outbreaks worldwide.
- The Parent Attitudes about Childhood Vaccines (PACV) questionnaire is a validated measure of
   vaccine hesitancy, and correlates with non-vaccination in many populations.

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# What is new?

- This large study in a paediatric outpatient clinic setting represents the first use of the PACV in a Western European population to assess vaccination hesitancy.
- Screening a paediatric clinic population with the PACV and selecting those who score hesitantly
   increases the likelihood of targeting a non-vaccinator from to 1 out of 5 from 1 out of 20 with an
   unselected approach.

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# **Abbreviations**

- 86 ASD Autism spectrum disorder
- 87 CI Confidence interval
- 88 HPV Human papillomavirus
- 89 MMR Measles, mumps, rubella
- 90 PACV Parent attitudes about childhood vaccines
- 91 ROC Receiver operating characteristic
- 92 SD Standard deviation
- 93 STROBE Strengthening the reporting of observational studies in epidemiology

#### Introduction

Vaccination is amongst the most successful public health interventions, second only to the provision of clean drinking water in reducing the burden of infectious diseases [1]. Globally, child mortality from vaccine-preventable diseases has fallen by more than two-thirds in the last three decades, in large part due to the increased availability of vaccinations [2]. While this benefit is preferentially seen in the developing world, it is estimated that childhood vaccination of a single year birth cohort in the United States of America (USA) prevented 42,000 deaths, and 20 million disease cases [3].

Public confidence in vaccination is critical in ensuring continued vaccination uptake, with falls in vaccination rates in recent years in countries including the United Kingdom and Ireland [4, 5], resulting in disease outbreaks [6, 7]. Even modest falls in vaccine uptake have significant public health and economic consequences, with one model suggesting that a 5% reduction in measles, mumps rubella (MMR) vaccine uptake is associated with a 3-fold annual increase in measles cases [8]. This uptake decline is multifactorial, but chief among the causes is vaccine hesitancy, recognized by the World Health Organization (WHO) in 2019 as one of biggest threats to global health [9].

The WHO's Strategic Advisory Group of Experts on Immunization Working Group defines vaccine hesitancy as 'as a delay in acceptance, or refusal of vaccines, despite their availability' [10]. Other groups have created alternative models of vaccine behavior however the common thread through these theories is the concept that a population's attitudes towards vaccination exists on a continuum between demand for all vaccines on one extreme, and rejection of all on the other.

Vaccine hesitant parents are a complex and context specific group, with a wide variety of views which are time, geography and vaccine dependent. Parents may choose to accept some childhood vaccines completely, delay or decline doses of some, and decline others outright. They may make different choices for different vaccines and different children, as their view changes over time. Determinants of vaccine hesitancy have been summarized using the WHO's 3 Cs model – confidence in the vaccines and the system that administers them, complacency regarding the risks of vaccine-preventable diseases, and convenience of physically getting the vaccination [10].

For pediatricians and all healthcare professionals, understanding, targeting and influencing vaccine-hesitant cohorts towards positive vaccination choices is an important role. While clearly a population who need attention from healthcare professionals, identifying vaccine-hesitant parents is challenging. Given the large, varied population it represents, perhaps unsurprising that the label of vaccine hesitancy is variably applied in different studies, impacting the comparability of results between studies [11, 12].

In 2011, Opel and colleagues developed the Parent Attitudes about Childhood Vaccines (PACV) survey, as a tool to assess parental vaccine hesitancy [13]. This has been validated to identify vaccine hesitance, and predict non-vaccination [14, 15]. The PACV has since been adapted for use in other populations [16–18], translated into multiple languages [19, 20] and used as an outcome in experimental studies [21, 22].

Vaccine hesitancy is context-specific, varying across regions and healthcare systems, however the PACV has not been used to assess vaccine hesitancy in a Western European setting to date. Our aim was to administer the PACV to assess vaccine hesitancy and its relationship with reported non-vaccination among parents and caregivers of children attending Irish outpatient clinics. We sought to quantify the rates of vaccine hesitancy and non-vaccination, to investigate vaccination-related concerns, and to assess and optimize the performance of the PACV to predict non-vaccination in our population.

# Methods

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146 Study design, setting, and participants

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This is a cross-sectional study, reported in line with the Strengthening Reporting of Observational Studies in Epidemiology (STROBE) statement. It was conducted from September to December 2018 in the pediatric outpatient clinic of Children's Health Ireland at Temple Street, Dublin, Ireland, a national acute hospital providing secondary and tertiary care to children. These patients are referred for public general paediatric input from birth to 16 years, by their primary care doctor most frequently, or in follow up to an emergency department attendance or hospital admission. They included new and returning patients, and excluded patients attending pediatric subspecialties (neurology, endocrinology etc.) but included those referred to the general pediatric services. A convenience sample of parents and caregivers accompanying a child to a clinic visit who entered the waiting room prior to their appointment were eligible for participation in the study. All parents and caregivers were approached when checking in for their clinic visit and invited to read a participant information leaflet about the study and to complete the questionnaire. If a child was accompanied by two adults, only one was invited to participate. Those who went immediately from check-in to see their health care practitioner without waiting were not included. The questionnaire was completed without assistance unless requested. Exclusion criteria included (i) parent/caregiver under 18 years of age, (ii) attending clinic with an interpreter, or (iii) had previously participated. Completed questionnaires were returned anonymously and were not seen by the attending clinician. This study was approved by the Children's Health Ireland at Temple Street Ethics Research Committee (Reference: 18.071).

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Variables

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The study tool (included in supplementary) was a questionnaire consisting of the 15-item PACV questionnaire, demographic questions, vaccination status/intention for the participant's oldest child, and white-space questions about vaccine-specific and side-effect concerns allowing participants to answer in unformatted free-text. The draft questionnaire was adapted for an Irish population following a pilot among a convenience sample of five parents/caregivers who met the inclusion criteria. All parents who were approached to participate in the pilot did

so. Sociodemographic questions about income level and marital status were removed as these were felt to be overly intrusive by our pilot group and would likely have impacted on levels of participation.

The PACV is a 15-item questionnaire, divided into 3 domains, behavior (2 items), safety and efficacy (4 items) and general attitudes and trust (9 items). There are three response designs in the PACV; dichotomous, a 5-point Likert scale, and an 11-point scale (e.g. ranging from '0 − Not sure at all' to '10 − completely sure''). All items are assigned a numeric score. A simple linear transformation was used to convert raw score to a 0-100 scale, with higher scores indicating increased hesitance. Participants were dichotomized as 'non-hesitant' with a score <50, and 'hesitant' if score was ≥50, in line with previous research [13]. Scores were also calculated for each domain using a similar linear transformation.

The vaccination status of the participant's oldest child was collected by self-report. Participants were invited to disclose specific vaccines and specific side-effects they had concern about. Participants' age, level of educational attainment, and relationship to the child attending, and age of the participant's oldest child were also collected.

Statistical analysis

Statistical analysis was performed using Stata v14.0 with significance set at *P*-value < 0.05. We summarized individual PACV item responses, domain scores, and total PACV score, and compared total score between vaccinators and non-vaccinators using a t-test with unequal variance. Univariate and multivariate linear regression were used to assess the association between participant characteristics (age of the participant, their relationship to the child, their educational attainment, age of their oldest child and whether vaccine/side-effect concerns were report) and PACV score, estimating beta-coefficients with 95% confidence intervals (CIs). We confirmed that assumptions for linear regression were met by assessing post-regression diagnostics on the normality of residuals, homoskedasticity and multicollinearity.

The ability of the PACV to predict reported non-vaccination was assessed. The area under the Receiver Operator Characteristic (ROC) curve was calculated, representing the accuracy with which the PACV score distinguished between non-vaccinators and vaccinators. This ranges from 0.5 (no better than chance) to 1.0

(perfect accuracy). We identified an optimal cut-off point for classifying hesitancy using three approaches: 1) the point nearest the top left corner of the ROC curve (indicating perfect sensitivity and specificity), 2) the point that maximizes the product of the sensitivity and specificity, and 3) the point that maximizes the sum of the sensitivity and specificity. Measures of diagnostic accuracy (sensitivity, specificity, positive and negative predictive values, and likelihood ratios for positive and negative results) with 95% CIs were calculated using the conventional cut-off of ≥50 for the PACV, and the optimal cut-off point identified.

# Results

There were an estimated 564 patients attending clinics which were included for recruitment. Not all were eligible for participation, as some were repeat attenders who had already completed the questionnaire, and some did not enter the waiting room prior to medical review, so an exact study denominator was not available. In total, 436 parents/caregivers participated in the study, giving an estimated response rate of 77.3%. Participant characteristics are shown in **Table 1**. Sociodemographic variables did not significantly differ between reported vaccinators and non-vaccinators. Mean age was 38.1 (SD 7.5) years, the majority were parents (97.3%) and had completed third-level education (65.9%). Twenty-two participants (5.5%) reported their oldest child either had or would not receive some or all vaccines. A childhood vaccine that caused concern was reported by 21.6%, most frequently human papillomavirus (HPV) and MMR (11.5% and 6.7%, respectively). Concerns were reported more frequently among those reporting non-vaccination (72.7% versus 19.9% among reported vaccinators). A total of 16.1% parents/caregivers reported a potential vaccine side-effect that they were concerned about, the most common being autism spectrum disorder (ASD) (4.3%), allergy/anaphylaxis or an unspecified reaction (2.3%) (**Supplementary Figures 1 and 2**).

The mean PACV score was 26.9 (SD 19.1) and the distribution of scores is shown in **Figure 1**. The mean score for the Safety and Efficacy domain was 51.7 (SD 31.4), which was significantly higher than for the General Attitudes and Trust domain (20.0, SD 19.0), which was significantly higher than the Behavior (8.7, SD 24.7) domains (p<0.001 for both, see **Supplementary Figure 3**). Vaccinators had a lower mean PACV score compared to non-vaccinators (25.3 vs 53.2, p<0.001). The scoring of individual questions is shown in **Figure 2**. The question "How concerned are you that your child might get a serious side-effect from a vaccine?" had the highest proportion of hesitant responses at 51.8%, while "All things considered, how much do you trust your child's doctor?" had the lowest proportion of hesitant responses at 3.2%.

Examining factors associated with PACV score (**Table 2**), there was a statistically significant relationship between participant age and lower score, with each year increase in age corresponding to a decrease of -0.75 (95% CI -1.12 to -0.38) in PACV score, independent of other factors. Conversely, each year increase in the age of a participant's oldest child was associated with an increase of 0.69 (95% CI 0.31 to 1.07) in PACV score. Reporting a childhood vaccine of concern was associated with an increase of 10.59 (95% CI 5.02 to 16.17),

240 while reporting a side-effect of concern also had a statistically significant relationship with higher score (8.24, 241 95% CI 1.49 to 14.99). 242 243 The accuracy of the PACV score to identify self-reported non-vaccinators was good, with an area under the 244 ROC curve of 0.827 (Figure 3). The optimal cut-off point was identified 41.67, which also maximized the 245 product and sum of the sensitivity and specificity. This classified 96 (22%) of participants as hesitant, as 246 opposed to 63 (14.4%) identified using the conventional cut-off point of ≥50, and measures of diagnostic 247 accuracy for both are shown in **Supplementary Table 1**. The cut-off point of 41.67 had a sensitivity of 77.3% 248 (95% CI 54.6% to 92.2%) and a specificity of 81.3% (95% CI 77.1% to 85.1%). The positive predictive value of 249 being classed as hesitant was 18.9% (95% CI 11.4% to 28.5%) and the negative predictive value of being 250 classed as non-hesitant was 98.5% (95% CI 96.4% to 99.5%).

#### Discussion

Our study, one of the largest PACV studies to date, and the first in a Western European population, shows that in our population vaccine hesitancy, as defined by a high PACV score, was associated with reported non-vaccination. Concerns regarding safety and efficacy were the predominant driver of vaccine hesitancy in our population.

Nearly 15% of our population was vaccine-hesitant using the conventional PACV cut-off, similar to other populations including Canada, (15%) and Indonesia (15.9%) [23, 24]. The prevalence identified in our study is higher than in Iraq (9.9%) and the United Arab Emirates (12%) [20, 25] and lower than Italy (34.7%) and several USA studies (>20%) [14, 18, 26]. This places Ireland in the middle of vaccine hesitancy estimates, which concurs with the 2018 Wellcome Global Monitor Report [27]. This survey showed 73% of the Irish participants thought vaccines were safe, and 93% of parents reported their child had received one or more vaccines.

We found that older participants had a lower PACV which has been observed previously [19]. It is has been suggested that the higher levels of hesitance in younger parents may be due to increased use and the influence of social media in younger cohorts, where there are strong anti-vaccination narratives easily accessible [28]. We also found that those with younger children were more likely to be vaccine-hesitant, contrasting with the Malaysian study which suggested first-time mothers were more vaccine-hesitant [19].

Our hesitancy rate was three times higher than the reported non-vaccination rate, suggesting there may be a significant proportion of parents who are choosing to vaccinate, but still have significant vaccine concerns. The national trends in vaccination rates in Ireland align with this finding. In Ireland vaccination is not mandatory, and the HPV vaccine was added to the schedule in 2010. HPV vaccine uptake was 85.5% in the 2011/2012 school year, but fell to 51% in 2016/2017, coinciding with a rise in anti-HPV vaccine publicity [29]. This experience has been mirrored internationally [30]. A concerted, multi-modal cross-sectoral alliance was built by Ireland's National Immunisation Office to reverse this trend, resulting in an increase in the vaccination rates to 64.1% in 2017/2018 [31]. This experience illustrates how hesitant parents may be persuaded for or against vaccination, depending on the information they are provided with. More than one in ten participants in this

study were still concerned about HPV vaccination today, emphasizing the need for continued vigilance against future uptake declines.

Our results showed that safety and efficacy is the primary motivator for vaccine hesitance. This result mirrors other PACV research worldwide [17, 24], and safety concerns are the most commonly cited barrier to vaccination [32]. Keeping children healthy is one of the most important considerations for parents, and choices can be based on a complex balancing of risks and benefits [33]. The fraudulent association between vaccines and ASD has been thoroughly debunked, however this side-effect was the single most commonly cited in our population (4.3%). Similar to HPV, MMR vaccination rates declined sharply following this controversy in the late 1990s. In the intervening period, while immunization levels have recovered, parental reservations regarding ASD have remained [34]. Allaying these concerns is important for ensuring continued MMR uptake.

Over 90% of our participants trusted their doctor. Trust in healthcare professionals, and pediatricians in particular, has been consistently described as critical for vaccine uptake [35]. Indeed, some surveys of parents of vaccination aged children suggest that the influence of the pediatrician is the single most powerful factor in vaccine acceptance [36]. This places professionals in a unique position to promote vaccination. Increasing numbers of pediatricians are caring for the children of parents who have refused a vaccine [37], but up to half of these may be convinced to accept vaccination with continued engagement [38]. Therefore, professional guidance for pediatricians advises continuing discussions with vaccine hesitant patients after initial refusal [39].

These consultations can be challenging. The provision of information about the safety of vaccines and the dangers of vaccine-preventable diseases, while important, may not alone be sufficient to reduce hesitancy, change minds and increase vaccine uptake [40]. It is crucial to engage with specific concerns raised by parents about specific vaccines. Evidence-based methods for vaccine promotion amongst parents include using a presumptive, rather than a participatory, approach to vaccine discussion, to make vaccine acceptance rather than refusal the default position [41]. For those who resist vaccination, motivational interviewing techniques have been shown to be effective, as has persistence with positive messaging over the course of the clinical relationship [41].

Some have advocated using personal stories of positive vaccine experiences, or the experiences and negative outcomes of vaccine preventable diseases as a tool to combat the emotional narratives that can contribute to vaccine hesitancy [42]. Caution must be exercised in using this approach however, as some pro-vaccine messages can have the unintended consequence of increasing vaccine hesitancy. A randomized trial using a variety of messaging varieties, including emotional narratives about disease-associated harms, found these messages actually decreased vaccination intent [40], and several studies have. A nuanced balance of corrective facts and narratives, targeted for the individual parent and their concerns and experiences, coming from a trusted source within a strong doctor-patient relationship may be more effective than a universal approach.

Applying these techniques in clinical practice can be time-consuming and daunting, which can have negative outcomes for both parents and healthcare professionals [43]. As such, targeting the interventions to where they are most needed is critical. Our results suggest the PACV is a robust tool to identify parents who are vaccine hesitant, as a focus for targeted vaccine promotion. We identified a novel cut-off point (41) for hesitance to optimize the tool's performance in detecting potential non-vaccinators. Using the PACV with our new cut-off point to target non-vaccinators, rather than an untargeted approach, we increase the likelihood of targeting a non-vaccinator from 1 in 20, to 1 in 5, assuming a non-vaccination rate of 5%, as in our population. In clinical practice, the PACV offers the realistic prospect of engaging parents who are at high risk of non-vaccination, in a timely fashion. Based on the negative predictive value, those identified as non-hesitant have a high probability (98.5%) of being vaccinators and therefore a clinician is unlikely to miss a non-vaccinator. In more time-constrained settings, the higher conventional cut-off point could be used, increasing the specificity at the expense of lower sensitivity, resulting in more non-vaccinators being classified as non-hesitant.

Our study was limited by lack of access to vaccination data and relied on the use of self-reported vaccination, as have many previous vaccine hesitancy studies [19, 20, 24, 44]. In the absence of integrated electronic health records and national life-long registries however, self-report remains the practical option for vaccination information. We used vaccination status of the oldest child in our study, with a mean age of 9.9. This is older than many other PACV studies and may affect recall. However, with the HPV vaccine as a further vaccination choice that parents of these older children will still have to make, evaluating vaccine hesitancy in parents of this age-group is vital. Our population were attending a pediatric clinic, and therefore may not be representative of a general population of children. For instance, there is evidence that children with chronic conditions, more

prevalent in a hospital attending population than the community at large, may be under-vaccinated when compared with their peers [45]. Children with chronic diseases are a heterogenous group, with varied diseases, parent attitudes, and receive different advice from their pediatricians, which has been shown to affect vaccine uptake [46]. We were unable to collect information on chronic conditions affecting our participants to examine the effect of chronic disease on vaccine hesitancy in our population. However, the findings are informative for clinicians who are encountering a population similar to that in this study. Our results may not apply to children attending other settings. We were unable to capture the characteristics of those eligible for inclusion in the study who chose not to participate. Our high rate response rate of 77.3% minimized our response bias, but does not mitigate generalizability. Our non-vaccination rates are lower than national and local averages [5, 31], which may reflect this, as well as social desirability bias. The representativeness of our population (e.g. 79.1% being mothers) may limit the generalisability of our results to others involved in vaccination decisions.

#### Conclusion

In conclusion, we found that the PACV identified reported non-vaccination with high accuracy in our population, therefore it may be a useful tool for pediatricians to effectively screen their clinic for vaccine hesitant-parents and to support vaccination uptake over the course of childhood. Our results suggest that Ireland ranks mid-tier internationally in terms of vaccination hesitancy, with concerns regarding vaccination safety a primary driver.

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**Tables** 

Table 1. Descriptive characteristics of participants

Characteristic	Total (n=436)	Self-reported vaccinators (n=391)	Self-reported non-vaccinated (n=22)
Age of participant (years), Mean (SD)	38.1 (7.53)	38.4 (7.38)	37.0 (8.80)
Relationship, n (%)			
Mother	344 (79.1)	307 (78.5)	19 (86.4)
Father	79 (18.2)	73 (18.7)	3 (13.6)
Other	11 (1.4)	11 (2.8)	0 (0.0)
Educational attainment, n (%)			
Primary	20 (4.7)	19 (4.9)	0 (0.0)
Some secondary	34 (8.0)	30 (7.8)	2 (9.5)
All secondary	91 (21.4)	82 (21.2)	4 (19.0)
Tertiary	280 (65.9)	255 (66.1)	15 (71.4)
Age of oldest child (years), Mean (SD) Concerned by at least one childhood vaccine, n (%)	9.9 (7.01) 94 (21.6)	10.0 (6.94) 78 (19.9)	9.9 (7.32) 16 (72.7)
Reported a side effect of concern, n (%) Reported vaccination status of oldest child, n (%)	59 (13.5)	44 (11.3)	13 (59.1)
Received all vaccinations	348 (84.3)	348 (89.0)	
Intend to fully vaccinate	43 (10.4)	43 (11.0)	
Not received any vaccines	3 (0.7)		3 (13.4)
Not receiving certain vaccines	19 (4.6)		19 (86.6)

Table 2. Association of participant factors with the Parent Attitudes about Childhood Vaccines questionnaire score from univariate (unadjusted) and multivariate (adjusted) linear regression

	Unadjusted		Adjusted	
	Beta coefficient (95% CI)	p value	Beta coefficient (95% CI)	p value
Age of participant, years	-0.16 (-0.42, 0.09)	0.207	-0.75 (-1.12, -0.38)	< 0.001
Relationship				
Mother (reference group)	0.00		0.00	
Father	-3.51 (-8.19, 1.18)	0.142	1.45 (-4.26, 7.16)	0.618
Other	4.23 (-6.79, 15.26)	0.451	9.04 (-10.52, 28.60)	0.364
Educational attainment				
Primary	5.29 (-3.50, 14.07)	0.238	6.42 (-4.87, 17.72)	0.264
Some secondary	1.36 (-5.53, 8.26)	0.697	5.07 (-4.71, 14.86)	0.308
All secondary	0.47 (-4.11, 5.05)	0.841	-0.06 (-5.85, 5.74)	0.984
Third level (reference group)	0.00		0.00	
Age of oldest child, years Concerned by at least one	0.32 (0.02, 0.63)	0.039	0.69 (0.31, 1.07)	< 0.001
childhood vaccine Reported a side-effect of	11.29 (7.04, 15.53)	< 0.001	10.59 (5.02, 16.17)	< 0.001
concern	11.98 (6.84, 17.12)	< 0.001	8.24 (1.49, 14.99)	0.017

Mean variance inflation factor was 1.28, maximum 1.70. For the adjusted model, multiple R-squared value was 0.166.

# 476 Figures

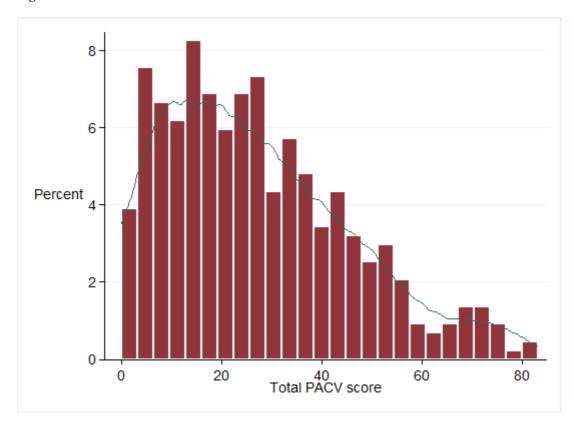


Figure 1. Distribution of Parent Attitudes about Childhood Vaccines questionnaire scores

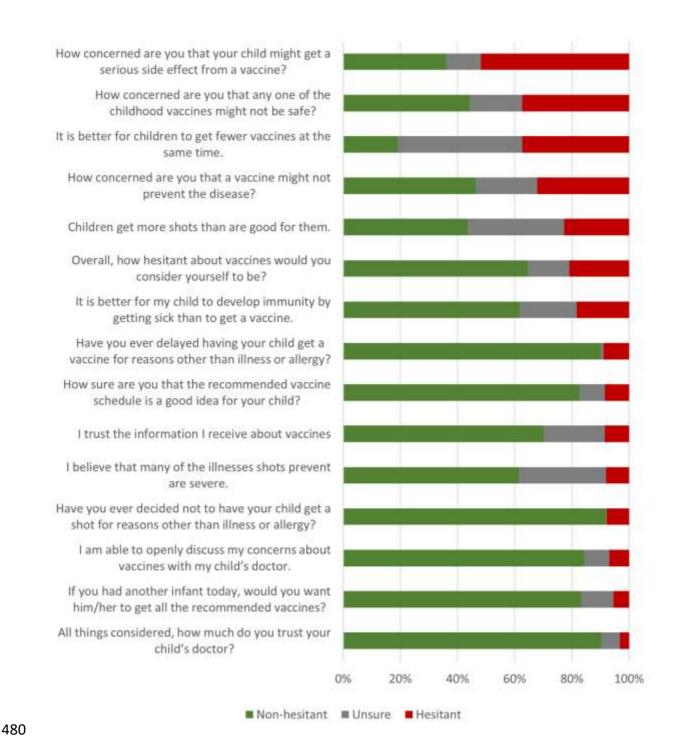


Figure 2. Distribution of responses for each of the 15 items within the Parent Attitudes about Childhood Vaccines questionnaire

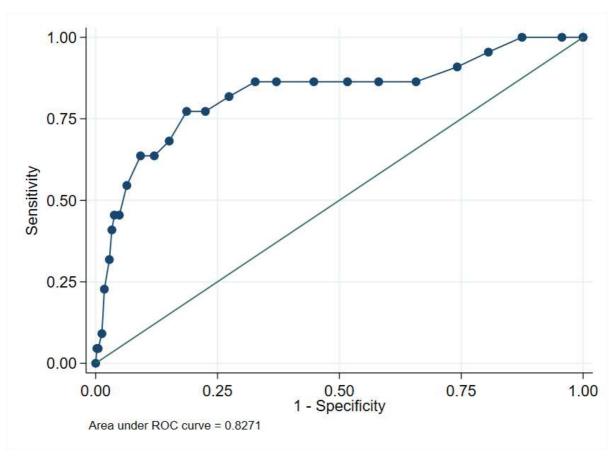


Figure 3. Receiver Operating Characteristic (ROC) curve for the Parent Attitudes about Childhood Vaccines questionnaire score in predicting non-vaccination