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Abstract

Background: One of the major factors contributing to parental refusal of vaccinations is the perception that vaccines cause side-effects. While symptoms are commonly reported following vaccinations, their causes are not always straightforward. Although some may be directly attributable to the vaccine itself, others may reflect pre-existing or coincidental symptoms that are misattributed to the vaccine.

Purpose: To investigate psychological factors associated with parental report of side-effects following vaccination with the child influenza vaccine, and parental intention to re-vaccinate one's child the following year.

Methods: A prospective cohort study was run in primary care practices in London in the 2016/17 influenza season (ClinicalTrials.gov number NCT02909855). 270 parents from fourteen practices completed a questionnaire before their child's vaccination. Follow-up questionnaires were completed three days after vaccination and one month after vaccination. Parental report of side-effects and vaccination intention for the subsequent year were measured.

Results: Parental report of side-effects was strongly associated with pre-vaccination expectation of side-effects. Suggestions received from the media, NHS vaccination leaflet and health care workers, as well as uncertainty-related beliefs, perceived sensitivity of the child to medicines, pessimism and anxiety were also associated with reporting side-effects. Side-effect report was associated with lower vaccination intention for the following influenza season.

Conclusions: Side-effect perception following vaccination is influenced by psychological factors, in particular expectations. Perceiving side-effects reduces future vaccination

intention. Future public health communications should aim to decrease unrealistic expectations of side-effects in order to increase vaccine uptake.

Key words: influenza, child vaccination, attitudes, symptom, psychological factors

Introduction

In England, routine vaccination of children for influenza began in 2013 (1). Although the vaccine is provided for free, uptake remains low, with vaccination targets of 40% in two to four year olds set by Public Health England not being reached in the 2015/16 and 2016/17 influenza seasons (2, 3). There has been much research conducted on factors associated with vaccine uptake, with a number of systematic reviews consistently finding the perception that the vaccine causes side-effects to be associated with vaccination refusal (4-7).

Although side-effects from the influenza vaccine are mostly “mild in nature and short term” (8), research by our group indicates that parents who perceived side-effects in their child following vaccination for influenza in the 2015/16 season were less likely to intend to re-vaccinate their child the following year (9). This issue is particularly problematic for the child influenza vaccine as clinical trial data indicate that 47.9% of children will experience side-effects following vaccination (8), yet children need to be re-vaccinated each year.

To date, there has been little research exploring the factors that contribute to parental perception of side-effects in one’s child. Understanding what determines whether parents perceive symptoms in their child has implications not just for our understanding of how their attitudes towards vaccinations develop, but also for our understanding of treatment decisions made on behalf of the child more generally (10) and on the burden to health care services if parents overestimate the presence or severity of a symptom (9, 11).

Research has identified associations between a number of psychological factors and symptom perception in oneself. One study, investigating the incidence of side-effects following travel vaccinations, found that adults who were already symptomatic at the time of vaccination reported more symptoms following vaccination (12). Symptom perception in oneself has also been associated with perceived sensitivity to medicines (12, 13), modern health worries (14-

19) and personality traits such as anxiety (20) and negative affect (12, 21, 22). Increases in symptom reports have been shown following news coverage about the side-effects of a medication (23) and following observation of symptoms in others (24), something which may be more apparent in females than in males (24, 25). Negative beliefs about medicines are associated with higher expectations of side-effects (26) and misattribution of nonspecific symptoms to medications (27). For some of these factors, the potential for a vicious circle exists. For example, if perceived sensitivity to medicines facilitates the development of symptoms after a medicine is taken, this may reinforce a patient's view of themselves as sensitive.

In contrast to what we know about perception of symptoms in oneself, limited, mainly poor quality research exists investigating parental perception of symptoms in one's child. Studies suggest that some factors associated with symptom perception in the self may also be implicated in parental perception of symptoms. For example, parental symptom perception has been associated with an expectation for medication to cause side-effects (28, 29), and social observation of symptoms in others (9). General attitudes, such as being concerned about the safety of a vaccine and not liking vaccinations for the child have also been associated with parental symptom perception (9, 30). Parents are more likely to perceive symptoms in their child if the child has a history of symptoms, or is currently experiencing nonspecific symptoms (31-37), or if the child has a chronic health problem (9, 35, 38-41). Parents with increased anxiety report more symptoms in their child (32-34, 42). However, almost all research investigating factors associated with the perception of symptoms in the child is cross-sectional, limiting our ability to infer causality.

Although parents may perceive side-effects in their child immediately following their influenza vaccination (43), their decision to re-vaccinate their child occurs one year later. Recall of symptoms is often inaccurate, and may be influenced by different factors to

immediate perception, including expectation, previous experiences and symptom severity (44).

In this study, we sought to: a) assess whether pre-vaccination symptoms, parental expectation, previous history of symptoms following vaccination, parental psychological traits, parental perceptions about medicines and other technologies, attitudes towards influenza and the vaccine, and personal and clinical characteristics are associated with parental report of side-effects following child influenza vaccination both immediately after and one month after vaccination; b) identify whether the influence of significant predictors on perception of side-effects is mediated by parental expectations; and c) assess whether perception of a side-effect, worry about and perceived severity of side-effects, suggestion of side-effects from a health care worker, and change in the child's perceived sensitivity to medicines is associated with vaccination intention for the following influenza season. We also hypothesised that perception of side-effects might affect parental perception of their child's sensitivity to medicines.

Methods

Design

Participants in this prospective cohort study completed questionnaires before their child received the influenza vaccine for the 2016/17 influenza season (T1), three days after their vaccination (perception, T2) and one month after their vaccination (recall, T3).

Sample size calculation

We based our sample size calculation on the ability to detect a small odds ratio of 1.6 (45) for symptom perception between parents with high and low expectation of symptoms. Clinical trial data suggest that 47.9% of children who received the Fluenz tetra vaccine report a symptom (46). Survey data by our group suggested that we could assume equal sample sizes

between those who do and do not expect symptoms (47). To detect this difference as significant at the 5% level with 85% power requires a total sample size of 180. We therefore aimed to recruit 300 people at T1, to allow for a 40% attrition rate.

Participants and recruitment

Participants were eligible for the study if they: had a child aged two to four on 31st August 2016; were 18 years or over; and spoke fluent English.

Potential participants were identified by eleven primary care practices in South London and were sent letters informing them about the study. Parents were then approached upon arrival at the practice for their child's influenza vaccination by LS or a research nurse. Additional participants from other practices participated online.

Study materials

Full study materials can be found in the supplementary materials.

Outcome measures

We asked parents at T2 and T3 if they thought their child had “experienced any of the following side-effects because of their latest child flu vaccine.” For our list of side-effects, we used an adapted parent-report form of the patient health questionnaire (48), to which were added potential side-effects of the vaccine listed in the patient information leaflet (46) and a more general non-specific symptom (the child being “not themselves”) that was recommended when the materials were piloted with 11 parents. This symptom list has been used in a previous nationally-representative study by our group (9).

Intention to vaccinate in the 2017/18 influenza season was measured at T2 and T3 by two items adapted from Payaprom et al. (49) (“I **want** [child] to be vaccinated for flu next year”

and “I **intend** [child] to be vaccinated for flu next year”) which were rated on a five-point Likert scale from “strongly disagree” to “strongly agree.”

Symptoms prior to vaccination

A child’s existing symptoms at the time of vaccination were measured by asking parents if their child had “shown signs of any of the following symptoms in the last 24 hours.” The list of symptoms provided was the same as that used in our outcome measure.

Expectation

A direct measure of expectation asked parents how likely it was that their child would “get short term side-effects from the flu vaccine” on a five-point Likert scale of “very unlikely” to “very likely.” Parents were also asked how likely five different sources (friends and family, official websites and departments, the media, the NHS influenza vaccination leaflet, and the health care worker) had said side-effects were from the vaccine, and their trust in these sources of information. Parents were also asked whether they knew “any children who have experienced side-effects from the flu vaccine.” All expectation questions were asked at T1 apart from those relating to the suggestion of side-effects from the health care worker as these could not be asked until after the vaccination appointment had taken place, at T2.

Symptoms following previous vaccinations

At T1, parents were asked if the child had “ever had side-effects” from previous influenza vaccinations and other routine vaccinations. Parents who indicated their child had experienced side-effects from previous influenza vaccinations were asked how severe the side-effects were and how worried they had been. Parents who indicated their child had experienced side-effects from other routine childhood vaccinations were asked how worried they had been.

Psychological traits

Participants completed four personality measures at T2. Participants' trait anxiety was measured by the short form of the State-Trait Anxiety Inventory (STAI-T) (50). Trait affect was measured using the short form Positive and Negative Affect Schedule (PANAS) (51). Participants' neuroticism was measured using the neuroticism items from an abbreviated form of the Eysenck Personality Questionnaire – Revised (EPQR-A) (52). Optimism and pessimism were measured using the revised Life Orientation Test (LOT-R) (53).

Perceptions about other medicines and technologies

Participants' perception of their child's sensitivity to medicines was measured at both T1 and T3 using an adapted parental report version of the Perceived Sensitivity to Medicines questionnaire (PSM) (13).

The Modern Health Worries Questionnaire (MHW) (54) and the Beliefs about Medicines Questionnaire, general section (BMQ-G) (55) were both completed at T2.

Attitudes towards influenza and the vaccine

Attitudes towards influenza and the child influenza vaccine were measured at T1 by a series of fifteen statements used in a previous study by our group (9). Parents were also asked how much it would impact their daily life if their child were to catch influenza.

Personal and clinical characteristics

Participants were asked for their age and gender. Personal characteristics relating to the index child included age, gender and whether they were the parent's first child. Clinical characteristics, such as whether the parent or child had a long-term health condition and whether there were any people 'at risk' for influenza in the child's household were also asked. Participants were asked whether the child was up-to-date on other routine vaccines.

Procedure

Ethical approval for the study was granted by the NHS Research Ethics Committee

(Reference: IRAS ID: 192325, REC reference: 16/LO/1003).

Participants were recruited into the study between 1st October 2016 and 16th December 2016.

Prior to completing T1 materials, consent was obtained from all parents following standard practice from our research ethics committee.

Parents completed T1 materials in the waiting room at the primary care practice immediately prior to their child's vaccination appointment, or online before their child's vaccination appointment. One item in T1, asking whether the child had experienced any symptoms in the past 24 hours, was excluded from the online version; participants were contacted on the day of their child's vaccination appointment to answer this.

Three days after the vaccination appointment, parents were contacted via email with a link to T2 materials, which were available online. One month after the vaccination appointment, parents were emailed a link to T3 task materials. If participants did not have access to email, T2 and T3 materials were completed by telephone.

Protocol registration

The protocol for the study was registered in advance on clinicaltrials.gov (identifier: NCT02909855).

Data analysis

Predictors of side-effect report

We recoded report of a symptom at T2 or T3 and in the 24 hours prior to vaccination into binary variables (reported at least one symptom versus no symptoms reported).

We recoded data where parents indicated that they had not received information from a particular source as missing. A composite measure of symptom suggestion from each

information source was created by multiplying the suggestion of side-effects from that source by the participant's trust in that source. We treated knowing another child who had experienced side-effects following vaccination for influenza as a binary variable (yes, no). General attitude questions were recoded to binary variables (agree, disagree); as with previous research using these items, we treated "neither agree nor disagree" as missing data. Separate logistic regressions were used to determine whether pre-existing symptoms; expectation for the child to develop side-effects; previous experience of side-effects; personality traits; perceptions; attitudes; and personal and clinical characteristics predicted perception of side effects at T2 and T3.

Expectations as a mediating variable

Zero-order correlations were run to identify factors that were correlated with direct expectations of the child developing side-effects and side-effect report at T2 and T3. Factors that were correlated with both direct expectations and side-effect report at either T2 or T3 were entered into mediation analyses using the method described in Mackinnon (56). Mediation using standardised coefficients was run to see whether the report of side-effects was mediated by expectation. 95% confidence intervals were computed using bootstrapping (2000 repetitions) and were bias-corrected. Personal and clinical characteristics were entered into the model as covariates.

Predictors of vaccination intention

Answers to vaccination intention questions were dichotomised, with participants coded as 'definitely intending' to vaccinate their child (answered "agree" or "strongly agree" to both questions) or 'not definitely intending' to vaccinate (answered "neither agree nor disagree," "disagree" or "strongly disagree" to one or both questions). We then used intention at both T2 and T3 to create a single overall intention score. Where participants only completed one follow-up questionnaire we used the data available to us to classify their response as either

‘definitely intend’ or ‘do not definitely intend’ to vaccinate. Where participants completed both T2 and T3 and had concordant intentions, we classified them as either ‘definitely intend’ or ‘do not definitely intend’ as appropriate. If conflicting intentions were given at T2 and T3 we classified participants as ‘do not definitely intend.’

We computed the difference between perceived sensitivity to medicines at T3 and T1 by subtracting T1 scores from T3.

Logistic regression analyses were used to identify whether report of a side-effect at T2 or T3; worry about and perceived severity of these side-effects; suggestion that the child would experience side-effects by a health care worker; and change in the child’s perceived sensitivity to medicines, predicted intention to re-vaccinate the child in the next influenza season.

Predictors of change in perceived sensitivity

We used linear regression analyses to identify whether reporting side-effects at T2 or T3 was associated with an increase in perceived sensitivity to medicines. For these analyses, perceived sensitivity to medicines at T1 was controlled for (57).

Sensitivity analyses

We ran sensitivity analyses to identify whether clustering by primary care practice affected the significance of any of the results. We used mixed models, including primary care practice as a random effect in the regressions. For mediation analyses, we followed the same approach to see if clustering affected pathways.

All analyses controlled for personal and clinical characteristics and were run in SPSS version 22 (58), apart from mediation analyses which were run in STATA 12 (59). The binary_mediation macro was used, which allows for dichotomous outcomes as well as taking covariates into account.

Results

Participants

270 participants were recruited from fourteen primary care practices. 233 participants initiated T2 follow-up, with 202 (74.8%; 185 mothers) participants completing all items. 200 participants initiated T3 follow-up, with 195 (72.2%; 164 mothers) completing all items. 167 participants (61.9%) completed both follow-ups. Participants' personal characteristics can be found in Table 1.

Side-effect reporting

At T2, 98 people out of 227 who completed the question (43.2%, 95% CI [36.7, 49.7]) reported at least one side-effect. At T3, 72 people (out of 200, 36.0%, 95% CI [29.3, 42.7]) recalled at least one side-effect. Associations between personal characteristics, predictor variables and side-effect report can be found in Tables 1 to 3.

At T2, parents were more likely to report side-effects in boys, if they had expected their child to experience side-effects and if they had perceived a suggestion of side-effects from the media, NHS vaccination leaflet or health care worker during their vaccination appointment. When taking into account both trust and suggestion, only suggestions from health care workers increased the odds of reporting side-effects.

At T3, parents were more likely to recall that their child had experienced side-effects if they had expected side-effects; perceived a suggestion of side-effects from the NHS vaccination leaflet; had high trait anxiety; high pessimism; and if they perceived their child to be sensitive to medicines. Perceiving oneself not to know enough about the vaccine and feeling that the vaccine is not safe were also associated with the recall of side-effects at T3.

Expectation as a mediator

When controlling for personal and clinical characteristics, there was an indirect effect of suggestion of side-effects from the media ($\beta=.103$, 95% CI [.005 to .251]; see Table 4) through expectation on side-effects reported at T2. There was also an indirect effect of suggestion of side-effects from the NHS vaccination leaflet ($\beta=.143$, 95% CI [.033 to .307]) through expectation on side-effects reported at T2. At T3, there was no evidence for an indirect effect of suggestion of side-effects from the NHS vaccination leaflet or pessimism through expectation, on recall of side-effects. There was, however, an indirect effect of perceived sensitivity to medicines through expectation on side-effects recalled ($\beta=.098$, 95% CI [.020 to .210]); the total effect of the mediation model was significant ($\beta=.269$, 95% CI [.060 to .460]), with 36.6% of the effect mediated.

Intention to vaccinate

204 (83.6%, 95% CI [78.9, 88.3]) parents indicated that they definitely intended to vaccinate their child in the next influenza season (2017/18), while 40 (16.4%, 95% CI [11.7, 21.1]) indicated that they did not definitely intend to vaccinate their child. Associations between personal characteristics, predictor variables and vaccination intention can be found in Tables 5 and 6.

Parent age was associated with intention, with parents aged 35 to 44 having higher vaccination intention. Parental worry about side-effects at T2 and perceived severity of side-effects at T2 were also associated with decreased intention to vaccinate. At T3, parental recall that one's child experienced a side-effect and worry about the side-effects were associated with decreased intention.

Perceived sensitivity to medicines

At T1, the overall mean PSM score was 10.03 (SD=3.34, n=270), while at T3 it was 9.40 (SD=3.36, n=194) ($t(193)=1.264, p=.21$).

While there was no association between reporting side-effects at T2 and change in PSM score, a significant association was found at T3 ($\beta=.20, t(183)=2.79, p=.006$; see Table 7), with parents who recalled that their child experienced side-effects tending to increase their rating of their child's perceived sensitivity to medicines.

Sensitivity analyses

Sensitivity analyses indicated that there were no substantial differences to the results when taking into account the effect of clustering by primary care practice. Only two results were changed: worry about side-effects at T3 was no longer significantly associated with intention to vaccinate; and side-effects recalled at T3 was no longer significantly associated with change in parental perceived sensitivity to medicines. For the mediation analyses, there was no difference to the strength or the significance of any of the main pathway effects. Thus, clustering should not change the results of the binary_mediation analysis macro.

Discussion

Concern about side-effects is a common reason for declining vaccination (4). This is a potential problem for the influenza vaccine for which side-effects are common and yearly vaccination is recommended. As might be expected in a cohort of parents who have already vaccinated their child once (5), most of our participants intended to vaccinate their child again the following year. However, one in six parents were less than certain in their intentions. Factors that strongly predicted being uncertain were the perceived severity and worry about side-effects three days after vaccination and recalling one month later that the child had experienced side-effects. These findings suggest that providing reassurance to

parents about the typically transitory and non-harmful nature of side-effects may be a useful strategy in reducing long-term attrition among parents who initially vaccinate their child.

Pre-vaccination expectations were strongly associated with side-effect reporting both three days and one month after vaccination, indicating the stability of expectations as a predictive factor over time. These results confirm previous findings from cross-sectional research (28) and are in line with a substantial body of work suggesting that expectations make symptom perception in oneself more likely (24), at least partly because of the increased monitoring for symptoms that can occur as a result of increased expectation. To our knowledge, this is the first time the role of expectation has been demonstrated for the perception of side-effects in someone else, presumably as a result of a similar monitoring-related mechanism.

Parents who thought that the NHS vaccination leaflet, health care workers or the media had suggested the vaccine causes side-effects were also more likely to report side-effects three days after vaccination. Surprisingly, when taking into account parental trust about the source of information, only suggestion from the health care worker remained significant. This indicates that parents' immediate perception of side-effects may be influenced by the number and recent nature of suggestions of side-effects received, in line with the availability heuristic (60). The effect of suggestion from both the media and the NHS vaccination leaflet were mediated by direct expectation. Only suggestion of side-effects from the NHS vaccination leaflet was associated with side-effect reporting at one month, however, implying that while suggestions are important for immediate perception of symptoms, they may be less important in the longer-term recall of those symptoms.

In terms of practical implications, these results suggest that reducing expectations may help limit the perception of side-effects. In particular, influential sources, such as the NHS vaccination leaflet and health care workers could aim to minimise their suggestion of the

incidence of side-effects. Although these sources have an obligation to inform patients about potentially serious adverse effects of medication, research has shown that the phrasing currently used by information sources causes people to substantially overestimate the likelihood of side-effects (9, 26). Our findings add weight to calls for this to be corrected (26).

Interestingly, although learning and social observation are associated with the nocebo response (24), we found no effect of having seen other children experience side-effects from the vaccine or having previously perceived side-effects from vaccination in one's own child, on reporting of side-effects. One possible reason for this may be that symptom perception is not happening in the self, as in previous research, but in one's child. In this situation, parents are unable to access bodily cues and sensations, but must attend to and interpret their child's behaviour (61). It is possible that social observation specifically affects bodily sensations.

We also found a gender difference in perception of side-effects, with parents being more likely to report side-effects in boys than girls three days after vaccination. The reasons for this are unclear. In contrast to our results, one previous study found that three days following their child's diphtheria, pertussis and tetanus vaccination, a higher proportion of mothers who contacted health care workers did so about their female child's side-effects (62). However, these results may not be directly comparable, as they relate to parental behaviour in response to side-effects, rather than perception of side-effects per se (63).

Exclusively associated with recall of side-effects at T3 were uncertainty-related beliefs such as believing the vaccine had not been tested enough and feeling that one did not know enough about the vaccine, as well as personality traits such as anxiety and pessimism. The effect of uncertainty-related beliefs and personality traits should be taken with caution as confidence intervals for the effect of the former were wide, and the effect sizes of the latter were small.

However, these results suggest that different factors are more influential for the medium-term recall of side-effects compared to the immediate perception of side-effects, and is consistent with findings that general negative affect is associated with negative memory bias (64).

The perception that one's child is particularly sensitive to medicines was also associated with recall of side-effects at T3. This effect was found to be mediated by direct expectation.

Again, this is consistent with evidence suggesting that such perceptions can prompt people to monitor for evidence that is in line with their expectations (13). We also found evidence that a feedback loop might be in operation – parents who recalled symptoms at T3 also tended to have elevated perceptions of their child's sensitivity to medicines. However, these results should be taken with caution as there was no longer an association when taking into account clustering by primary care practice. Whether this effect persists in the long term is unknown.

Limitations

Several limitations should be considered for this study. First, our sample may not be fully representative of the wider population of vaccinating parents. However, rates of side-effect perception identified in this study (43.2%) are close to those found in clinical trial data (47.9%) (46) and a previous demographically representative survey (41.0%) (9) suggesting that no systematic bias exists with regards to our main outcome. Our sample is mostly made up of mothers and we cannot say whether these findings would hold in a population of fathers. Second, not all potential predictors were measured at T1, due to time constraints as parents completed materials before their child's vaccination appointment. However, only variables which should not change between time points, including demographics and personality traits, were asked at T2. Third, the interpretation of some results should be taken with caution due to low numbers and resulting wide confidence intervals. Results should be interpreted with caution due to the large number of analyses run, which increases the likelihood of type 1 errors.

Conclusions

Our study suggests that in order to decrease side-effect perception and recall, and increase vaccination intention, parental expectations of side-effects following vaccination should be minimised, and that parents should be reassured about the generally mild nature of these side-effects. This could be achieved through different avenues, but influential sources, such as the NHS vaccination leaflet and health care workers, should disseminate this message. By managing parents' expectations about the incidence, severity and associated concern about side-effects, more parents may decide to re-vaccinate their child.

Compliance with Ethical Standards

Disclosure of potential conflicts of interest

The authors declare that they have no conflict of interest.

Research involving human participants

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Prior to completing T1 materials, consent was obtained from all parents following standard practice from our research ethics committee.

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Table 1. Participants' personal characteristics and associations with side-effect reporting

Participant characteristics	Level	Side-effects recalled at T2			Side-effects recalled at T3		
		Side-effects perceived	No side-effects perceived	Adjusted odds ratio (95% CI) ^a	Side-effects perceived	No side-effects perceived	Adjusted odds ratio (95% CI) ^a
Parent gender	Male	17 (40.5)	25 (59.5)	0.812 (0.309 to 2.133)	15 (41.7)	21 (58.3)	1.288 (0.465 to 3.563)
	Female	81 (43.8)	104 (56.2)	Reference	57 (34.8)	107 (65.2)	Reference
Parent age	45+	8 (50.0)	8 (50.0)	1.441 (0.426 to 4.876)	4 (30.8)	9 (69.2)	0.770 (0.193 to 3.066)
	35-44	41 (40.2)	61 (59.8)	1.007 (0.461 to 2.201)	34 (36.6)	59 (63.4)	1.068 (0.456 to 2.501)
	18-34	20 (39.2)	31 (60.8)	Reference	15 (34.1)	29 (65.9)	Reference
Parent chronic illness	Present	18 (36.7)	31 (63.3)	0.572 (0.231 to 1.416)	15 (34.1)	29 (65.9)	0.998 (0.389 to 2.563)
	None	72 (43.9)	92 (56.1)	Reference	47 (35.3)	86 (64.7)	Reference
Other 'at risk' people in child's household	Yes	33 (40.7)	48 (59.3)	0.987 (0.472 to 2.064)	23 (34.3)	44 (65.7)	0.865 (0.390 to 1.916)
	No	50 (44.6)	62 (55.4)	Reference	33 (35.5)	60 (64.5)	Reference
Child gender	Male	56 (51.4)	53 (48.6)	2.232 (1.139 to 4.374)*	38 (38.0)	62 (62.0)	1.176 (0.570 to 2.429)
	Female	42 (35.9)	75 (64.1)	Reference	34 (34.3)	65 (65.7)	Reference
First-born child	Yes	53 (40.2)	79 (59.8)	0.783 (0.383 to 1.598)	35 (30.7)	79 (69.3)	0.914 (0.418 to 1.995)
	No	38 (46.3)	44 (53.7)	Reference	27 (42.2)	37 (57.8)	Reference
Child age	Range 1 to 5	N=98, M=3.04, SD=0.930	N=127, M=3.13, SD=0.917	0.921 (0.630 to 1.346)	N=72, M=3.15, SD=1.016	N=126, M=3.08, SD=0.900	1.297 (0.873 to 1.927)
Child chronic illness	Present	9 (50.0)	9 (50.0)	2.250 (0.635 to 7.970)	6 (33.3)	12 (66.7)	0.965 (0.261 to 3.567)
	None	82 (41.8)	114 (58.2)	Reference	56 (35.0)	104 (65.0)	Reference
Child up-to-date with other routine vaccines	Not fully UTD	5 (50.0)	5 (50.0)	1.157 (0.236 to 5.679)	3 (50.0)	3 (50.0)	1.418 (0.207 to 9.724)
	UTD	86 (42.6)	116 (57.4)	Reference	59 (34.5)	112 (65.5)	Reference

^a Adjusting for all other personal characteristics (both parent and child, apart from child up-to-date vaccine status for other routine vaccines)

* $p \leq .05$

Abbreviations. UTD = up-to-date

Table 2. Psychological predictors and associations with side-effect reporting

Category	Perception statement	Level	Side-effects recalled at T2		Adjusted odds ratio (95% CI) ^a	Side-effects recalled at T3		Adjusted odds ratio (95% CI) ^a
			Side-effects perceived	No side-effects perceived		Side-effects perceived	No side-effects perceived	
Presence of pre-existing symptoms	Symptom in last 24 hrs	No	59 (41.8)	82 (58.2)	Reference	45 (37.5)	75 (62.5)	Reference
		Yes	35 (44.3)	44 (55.7)	1.059 (0.501 to 2.241)	23 (31.1)	51 (68.9)	0.723 (0.321 to 1.627)
Direct measure of expectation	Expectation for child to get side-effects	5 point Likert ('very likely' to 'very unlikely')	N=98, M=3.13, SD=0.833	N=128, M=2.62, SD=0.940	2.085 (1.349 to 3.221)*	N=72, M=3.06, SD=0.870	N=127, M=2.65, SD=0.972	2.093 (1.325 to 3.306)*
Suggestion of symptoms - expectation	Suggestion of causing side-effects – friends/family/relatives	4 point Likert ('very likely' to 'very unlikely')	N=61, M=2.44, SD=0.719	N=83, M=2.41, SD=0.750	1.315 (0.730 to 2.371)	N=47, M=2.43, SD=0.773	N=83, M=2.39, SD=0.746	1.544 (0.796 to 2.993)
	Suggestion of causing side-effects – Official websites/helplines/departments/agencies	4 point Likert ('very likely' to 'very unlikely')	N=65, M=2.09, SD=0.701	N=94, M=2.12, SD=0.746	1.366 (0.759 to 2.458)	N=44, M=2.18, SD=0.620	N=96, M=2.05, SD=0.745	1.803 (0.922 to 3.526)
	Suggestion of causing side-effects – Media	4 point Likert ('very likely' to 'very unlikely')	N=49, M=2.51, SD=0.794	N=73, M=2.42, SD=0.865	1.869 (1.011 to 3.456)*	N=34, M=2.53, SD=0.861	N=72, M=2.38, SD=0.846	1.635 (0.836 to 3.197)
	Suggestion of causing side-effects – NHS vaccination leaflet	4 point Likert ('very likely' to 'very unlikely')	N=68, M=2.26, SD=0.745	N=98, M=2.09, SD=0.801	1.790 (1.018 to 3.148)*	N=45, M=2.33, SD=0.739	N=100, M=2.04, SD=0.790	2.146 (1.139 to 4.046)*
	Suggestion of causing side-effects – HCW suggestion in vaccine appointment	4 point Likert ('very likely' to 'very unlikely')	N=61, M=2.64, SD=0.708	N=69, M=2.39, SD=0.691	2.273 (1.152 to 4.487)*	N=41, M=2.61, SD=0.542	N=69, M=2.42, SD=0.736	1.703 (0.845 to 3.430)
	Suggestion of causing side-effects – friends/family/relatives	by Trust (range 2 to 16)	N=60, M=8.52, SD=3.192	N=80, M=8.20, SD=2.826	1.128 (0.977 to 1.304)	N=47, M=8.38, SD=3.274	N=81, M=8.42, SD=2.974	1.082 (0.932 to 1.256)
	Suggestion of causing side-effects – Official websites/helplines/departments/agencies	by Trust (range 2 to 20)	N=65, M=8.62, SD=3.436	N=91, M=8.79, SD=3.501	1.023 (0.910 to 1.149)	N=44, M=8.68, SD=3.483	N=93, M=8.87, SD=3.630	1.023 (0.899 to 1.165)
	Suggestion of causing side-effects – Media	by Trust (range 2 to 20)	N=49, M=8.14, SD=3.606	N=70, M=7.56, SD=3.010	1.130 (0.976 to 1.309)	N=34, M=8.00, SD=3.822	N=69, M=7.83, SD=3.148	1.046 (0.887 to 1.233)

	Suggestion of causing side-effects – NHS vaccination leaflet	by Trust (range 1 to 20)	N=68, M=9.84, SD=3.831	N=95, M=9.14, SD=3.869	1.094 (0.978 to 1.224)	N=44, M=10.09, SD=4.022	N=97, M=9.24, SD=3.960	1.090 (0.967 to 1.229)
	Suggestion of causing side-effects – HCW suggestion in vaccine appointment	by Trust (range 1 to 20)	N=61, M=11.52, SD=3.581	N=69, M=10.19, SD=3.919	1.151 (1.016 to 1.303)*	N=41, M=11.29, SD=2.571	N=69, M=10.38, SD=4.236	1.074 (0.949 to 1.214)
Social observation - expectation	Knowing another child with side-effects	No	82 (42.5)	111 (57.5)	Reference	61 (35.3)	112 (64.7)	Reference
		Yes	16 (47.0)	18 (53.0)	1.546 (0.614 to 3.889)	11 (40.7)	16 (59.3)	2.041 (0.763 to 5.462)
	Severity of side-effects observed in other children	5 point Likert ('very mild to very severe')	N=16, M=2.06, SD=0.680	N=18, M=2.06, SD=0.539	2.240 (0.197 to 25.486)	N=11, M=2.09, SD=0.302	N=16, M=1.94, SD=0.443	3.344 (0.021 to 525.680)
Previous symptoms following vaccination	CHILD having side-effects from flu vaccine previously	No	27 (43.5)	35 (56.5)	Reference	18 (29.0)	44 (71.0)	Reference
		Yes	9 (37.5)	15 (62.5)	0.840 (0.219 to 3.229)	8 (36.4)	14 (63.6)	2.097 (0.541 to 8.134)
	Worry about CHILD's previous side-effects	4 point Likert ('not at all' to 'very worried')	N=9, M=1.78, SD=0.667	N=15, M=1.60, SD=0.828	†	N=8, M=1.88, SD=0.641	N=14, M=1.64, SD=0.929	†
	Severity of CHILD's previous side-effects	5 point Likert ('very mild' to 'very severe')	N=9, M=1.89, SD=0.601	N=15, M=1.33, SD=0.488	†	N=8, M=1.75, SD=0.463	N=14, M=1.29, SD=0.469	16.704 (0.446 to 626.152)
	CHILD side-effect from other routine vaccines	No	37 (34.9)	69 (65.1)	Reference	27 (28.4)	68 (71.6)	Reference
		Yes	49 (50.5)	48 (49.5)	2.103 (0.997 to 4.434)	34 (40.5)	50 (59.5)	1.842 (0.807 to 4.206)
Worry about side-effect from other routine vaccine	4 point Likert ('not at all' to 'very worried')	N=49, M=1.82, SD=0.697	N=48, M=1.75, SD=0.601	0.915 (0.369 to 2.267)	N=34, M=1.75, SD=0.463	N=50, M=1.64, SD=0.598	2.747 (0.975 to 7.738)	
Psychological traits	Neuroticism (EPQR-A)	Range 0 to 6	N=91, M=1.54, SD=1.377	N=120, M=1.72, SD=1.685	0.940 (0.755 to 1.170)	N=62, M=1.69, SD=1.421	N=114, M=1.64, SD=1.652	1.050 (0.830 to 1.328)
	Positive affect (PANAS)	Range 5 to 22	N=88, M=15.39, SD=3.978	N=119, M=15.32, SD=3.505	0.946 (0.862 to 1.038)	N=62, M=14.90, SD=4.179	N=113, M=15.51, SD=3.368	0.933 (0.846 to 1.029)
	Negative affect (PANAS)	Range 5 to 18	N=88, M=7.92, SD=2.780	N=119, M=7.45, SD=2.727	1.051 (0.929 to 1.188)	N=62, M=7.77, SD=2.439	N=113, M=7.58, SD=2.856	1.024 (0.889 to 1.166)
	Anxiety (STAI-T)	Range 6 to 19	N=91, M=12.47, SD=2.651	N=120, M=12.87, SD=2.634	0.993 (0.861 to 1.146)	N=62, M=13.08, SD=2.491	N=114, M=12.67, SD=2.523	1.192 (1.011 to 1.406)*

	Optimism (LOT-R)	Range 1 to 12	N=85, M=7.53, SD=1.817	N=115, M=7.26, SD=1.920	0.942 (0.783 to 1.134)	N=61, M=7.30, SD=1.856	N=111, M=7.40, SD=1.997	0.843 (0.688 to 1.032)
	Pessimism (LOT-R)	Range 0 to 12	N=85, M=4.29, SD=2.109	N=115, M=4.18, SD= 2.134	1.147 (0.966 to 1.363)	N=61, M=4.51, SD=1.776	N=111, M=3.89, SD=2.213	1.254 (1.035 to 1.518)*
Perceptions about medicines and other technologies	Perceived sensitivity to Medicines at T1 (PSM – T1)	Range 5 to 25	N=98, M=10.48, SD=3.253	N=129, M=9.40, SD=3.404	1.074 (0.970 to 1.189)	N=72, M=10.51, SD=2.722	N=128, M=9.30, SD=3.476	1.150 (1.030 to 1.285)*
	Modern Health Worries (MHW)	Range 28 to 126	N=88, M=67.32, SD=22.696	N=118, M=67.53, SD=20.288	0.987 (0.969 to 1.005)	N=62, M=68.34, M=21.907	N=113, M=66.25, SD=19.386	1.004 (0.985 to 1.024)
	Beliefs about Medicines Questionnaire-general, harm subscale (BMQ-GH)	Range 4 to 20	N=91, M=8.73, SD=2.539	N=121, M=8.59, SD=2.728	1.016 (0.889 to 1.161)	N=62, M=8.55, SD=2.559	N=115, M=8.45, SD=2.722	1.015 (0.881 to 1.169)
	Beliefs about Medicines Questionnaire-general, overuse subscale (BMQ-GO)	Range 5 to 19	N=91, M=10.84, SD=2.391	N=121, M=10.72, SD=2.742	1.032 (0.905 to 1.176)	N=62, M=10.79, SD=2.593	N=115, M=10.49, SD=2.716	1.079 (0.939 to 1.240)

^a Adjusting for all personal characteristics (both parent and child, apart from child up-to-date vaccine status for other routine vaccines)

* $p \leq .05$

† Adjusted calculations unable to be run due to lack of cases in some groups.

Abbreviations. NHS = National Health Service, HCW = health care worker

Table 3. General attitudes and associations with side-effect reporting

Perception statement	Level	Side-effects recalled at T2			Side-effects recalled at T3		
		Side-effects perceived	No side-effects perceived	Adjusted odds ratio (95% CI) ^a	Side-effects perceived	No side-effects perceived	Adjusted odds ratio (95% CI) ^a
The child flu vaccine has not been tested enough for me to feel it is safe	Agree	9 (60.0)	6 (40.0)	1.188 (0.248 to 5.690)	8 (66.7)	4 (33.3)	6.466 (1.083 to 38.586)*
	Disagree	58 (40.0)	87 (60.0)	Reference	42 (30.2)	97 (69.8)	Reference
The child flu vaccine can cause unpleasant short-term side-effects	Agree	23 (57.5)	17 (42.5)	1.549 (0.566 to 4.235)	11 (36.7)	19 (63.3)	1.354 (0.438 to 4.184)
	Disagree	36 (39.6)	55 (60.4)	Reference	26 (28.6)	65 (71.4)	Reference
The child flu vaccine can cause long-term health problems	Agree	1 (50.0)	1 (50.0)	0.000 (†)	2 (66.7)	1 (33.3)	†
	Disagree	72 (42.9)	96 (57.1)	Reference	48 (31.4)	105 (68.6)	Reference
The child flu vaccine does not suit my religious or cultural beliefs/values	Agree	6 (85.7)	1 (14.3)	4.811 (0.464 to 49.858)	3 (75.0)	1 (25.0)	2.043 (0.115 to 36.171)
	Disagree	76 (42.2)	104 (57.8)	Reference	53 (32.3)	111 (67.7)	Reference
I don't like [child] having vaccinations in general	Agree	6 (75.0)	2 (25.0)	2.926 (0.393 to 21.762)	3 (60.0)	2 (40.0)	4.227 (0.320 to 55.808)
	Disagree	81 (44.5)	101 (55.5)	Reference	61 (37.7)	101 (62.3)	Reference
I don't know enough about the child flu vaccine	Agree	24 (49.0)	25 (51.0)	1.414 (0.555 to 3.605)	20 (50.0)	20 (50.0)	3.014 (1.033 to 8.797)*
	Disagree	48 (44.9)	59 (55.1)	Reference	36 (35.3)	66 (64.7)	Reference
The vaccination campaign is just about making money for the manufacturers	Agree	3 (42.9)	4 (57.1)	0.275 (0.014 to 5.229)	4 (66.7)	2 (33.3)	4.940 (0.367 to 66.515)
	Disagree	73 (43.2)	96 (56.8)	Reference	52 (32.9)	106 (67.1)	Reference
The flu vaccine would interact with other medications that [Specified Child] is currently taking	Agree	0	0	†	1 (100.0)	0 (0.0)	†
	Disagree	129 (59.2)	89 (40.8)	Reference	52 (34.4)	99 (65.6)	Reference
Vaccinating [Specified Child] against flu each year will overload his/her immune system	Agree	9 (69.2)	4 (30.8)	1.377 (0.267 to 7.095)	5 (50.0)	5 (50.0)	2.363 (0.417 to 13.388)
	Disagree	72 (41.9)	100 (58.1)	Reference	53 (33.8)	104 (66.2)	Reference

Vaccinating [child] against flu each year is too much of an ongoing time commitment	Agree	3 (33.3)	6 (66.7)	1.161 (0.146 to 9.220)	2 (28.6)	5 (71.4)	1.099 (0.088 to 13.705)
	Disagree	82 (42.7)	110 (57.3)	Reference	64 (37.0)	109 (63.0)	Reference
Having the child flu vaccine is an effective way of preventing [Specified Child] from catching flu	Agree	81 (43.3)	106 (56.7)	0.673 (0.173 to 2.612)	63 (37.0)	107 (63.0)	2.455 (0.481 to 12.531)
	Disagree	7 (46.6)	8 (53.3)	Reference	3 (23.1)	10 (76.9)	Reference
If I don't vaccinate [child], then [child] is likely to catch flu	Agree	28 (52.8)	25 (47.2)	1.198 (0.477 to 3.006)	23 (44.2)	29 (55.8)	1.858 (0.688 to 5.018)
	Disagree	33 (45.2)	40 (54.8)	Reference	18 (30.0)	42 (70.0)	Reference
Flu would be a serious illness for child	Agree	55 (40.4)	81 (59.6)	0.705 (0.254 to 1.954)	41 (33.9)	80 (66.1)	0.896 (0.303 to 2.647)
	Disagree	14 (41.2)	20 (58.8)	Reference	8 (32.0)	17 (68.0)	Reference
Flu would be a serious illness for self	Agree	42 (41.2)	60 (58.8)	0.821 (0.348 to 1.940)	32 (36.4)	56 (63.6)	1.377 (0.536 to 3.534)
	Disagree	24 (42.1)	33 (57.9)	Reference	12 (27.3)	32 (72.7)	Reference
Flu would be a serious illness for someone in child's household	Agree	54 (44.3)	68 (55.7)	1.094 (0.456 to 2.621)	38 (36.2)	67 (63.8)	1.108 (0.426 to 2.883)
	Disagree	18 (38.3)	29 (61.7)	Reference	11 (31.4)	24 (68.6)	Reference
If [child] were to catch flu, how much, if at all, would it impact your daily life?	4 point Likert ('not at all' to 'a great extent')	N=91, M=3.41, SD=0.683	N=122, M=3.41, SD=0.586	0.915 (0.514 to 1.628)	N=162, M=3.339, SD=0.636	N=115, M=3.50, SD=0.598	0.814 (0.441 to 1.500)

^a Adjusting for all personal characteristics (both parent and child, apart from child up-to-date vaccine status for other routine vaccines)

* $p \leq .05$

† Adjusted calculations unable to be run due to lack of cases in some groups

Table 4. Mediation analyses for effect of direct expectation as a mediator on perception of side-effects at T2 and T3

Independent Variable	Mediator	Dependent Variable	Total indirect effect (95% CI) ^a	Direct effect (95% CI)	Total effect (95% CI) ^a	Proportion of effect mediated
Suggestion of causing side-effects – Media	Direct expectation	Side-effects recalled at T2	.103 (.005 to 0.251)*	.158 (-.196 to .408)	.261 (-.092 to .496)	39.48%
Suggestion of causing side-effects – NHS vaccination leaflet	Direct expectation	Side-effects recalled at T2	.143 (.033 to .307)*	.080 (-.220 to .368)	.223 (-.054 to .467)	64.14%
Suggestion of causing side-effects – NHS vaccination leaflet	Direct expectation	Side-effects recalled at T3	.095 (-.039 to .273)	.208 (-.106 to .474)	.304 (.026 to .542)*	Not significant
Perceived sensitivity to Medicines at T1 (PSM – T1)	Direct expectation	Side-effects recalled at T3	.098 (.020 to .210)*	.170 (-.050 to .380)	.269 (.060 to .460)*	36.61%
Pessimism (LOT-R)	Direct expectation	Side-effects recalled at T3	.038 (-.014 to .125)	.210 (-.057 to .406)	.248 (-.018 to .447)	Not significant

^a Adjusting for all personal characteristics (both parent and child, apart from child up-to-date vaccine status for other routine vaccines)

* $p \leq .05$

Abbreviations. NHS = National Health Service

Table 5. Participants' personal characteristics and associations with intention to vaccinate

Participant characteristics	Level	Intention to vaccinate child next flu season		
		Do not intend to vaccinate	Intend to vaccinate	Adjusted odds ratio (95% CI) ^a
Parent gender	Female	38 (19.0)	162 (81.0)	0.397 (0.078 to 2.004)
	Male	2 (4.5)	42 (95.5)	Reference
Parent age	45+	1 (6.3)	15 (93.8)	5.277 (0.587 to 47.468)
	35-44	17 (16.5)	86 (83.5)	2.932 (1.049 to 8.196)*
	18-34	12 (23.1)	40 (76.9)	Reference
Parent chronic illness	Present	7 (14.0)	43 (86.0)	2.289 (0.562 to 9.325)
	None	30 (18.2)	135 (81.8)	Reference
Other 'at risk' people in child's household	Yes	14 (17.3)	67 (82.7)	0.597 (0.221 to 1.617)
	No	15 (13.2)	99 (86.8)	Reference
Child gender	Female	21 (16.4)	107 (83.6)	1.714 (0.665 to 4.420)
	Male	18 (15.7)	97 (84.3)	Reference
First-born child	Yes	23 (17.3)	110 (82.7)	0.776 (0.279 to 2.160)
	No	14 (16.9)	69 (83.1)	Reference
Child age	Range 1 to 5	N=39, M=3.23, SD=1.038	N=203, M=3.07, SD=0.890	0.725 (0.432 to 1.216)
Child chronic illness	Present	2 (11.1)	16 (88.9)	2.389 (0.241 to 23.669)
	None	35 (17.7)	163 (82.3)	Reference
Child up-to-date with other routine vaccines	Not fully UTD	1 (10.0)	9 (90.0)	1.421 (0.149 to 13.588)
	UTD	36 (17.6)	168 (82.4)	Reference

^a Adjusting for all other personal characteristics (both parent and child, apart from child up-to-date vaccine status for other routine vaccines)

* $p \leq .05$

Abbreviations: UTD = up-to-date

Table 6. Associations between variables and intention to vaccinate

Category	Perception statement	Level	Intention to vaccinate child next flu season		Adjusted odds ratio (95% CI) ^a
			Do not intend to vaccinate	Intend to vaccinate	
Symptoms following vaccination	Presence of side-effects as recalled at T2	Yes	21 (21.4)	77 (78.6)	0.627 (0.242 to 1.622)
		No	17 (13.2)	112 (86.8)	Reference
	Worry about side-effects as recalled at T2	4 point Likert ('not at all' to 'very worried')	N=21, M=2.19, SD=1.030	N=79, M=1.49, SD=0.575	0.258 (0.076 to 0.874)*
	Severity of side-effects as recalled at T2	5 point Likert ('very mild' to 'very severe')	N=21, M=2.48, SD=0.873	N=79, M=1.70, SD=0.790	0.110 (0.020 to 0.598)*
	Presence of side-effects as recalled at T3	Yes	16 (22.2)	56 (77.8)	0.272 (0.090 to 0.825)*
		No	13 (10.2)	115 (89.8)	Reference
Worry about side-effects as recalled at T3	4 point Likert ('not at all' to 'very worried')	N=15, M=2.00, SD=0.926	N=55, M=1.55, SD=0.662	0.165 (0.029 to 0.923)*	
Severity of side-effects as recalled at T3	5 point Likert ('very mild' to 'very severe')	N=14, M=2.29, SD=0.914	N=52, M=1.75, SD=0.789	0.310 (0.084 to 1.144)	
Psychological predictors	HCW suggestion in vaccine appointment	4 point Likert ('very likely' to 'very unlikely')	N=21, M=2.48, SD=0.873	N=111, M=2.50, SD=0.686	1.821 (0.670 to 4.950)
	HCW suggestion in vaccine appointment	Suggestion by Trust, range 1 to 20	N=21, M=9.57, SD=5.316	N=11, M=10.97, SD=3.528	1.297 (1.052 to 1.598)*
	Change in perceived sensitivity to medicines	Range -20 to 8	N=28, M=-0.18, SD=2.749	N=166, M=-0.33, SD=3.449	1.002 (0.868 to 1.170)

^a Adjusting for all personal characteristics (both parent and child, apart from child up-to-date vaccine status for other routine vaccines)

* $p \leq .05$

Abbreviations: HCW = health care worker

Table 7. Associations between reporting side-effects at T2 and T3 and parents' perceived sensitivity of their child to medicines

Side-effect reporting	Level	Perceived sensitivity to medicines						
		N, mean, SD	Adjusted B ^a	Standard Error B	β	<i>t</i>	<i>p</i>	Adjusted R ²
Side-effects recalled at T2	Side-effects perceived	N=73, M=-0.29, SD=3.10	0.422	0.533	.061	0.793	.430	.291
	No side-effects perceived	N=104, M=-0.28, SD=3.33	Reference					
Side-effects recalled at T3	Side-effects recalled	N=71, M=-0.47, SD=3.40	1.466	0.526	.204	2.786	.006*	.342
	No side-effects recalled	N=123, M=-0.01, SD=3.27	Reference					

^a Adjusting for all personal characteristics (both parent and child, apart from child up-to-date vaccine status for other routine vaccines, and perceived sensitivity to medicines at T1)

* $p \leq .05$