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    Title:
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    What determines uptake of pertussis vaccine in pregnancy?
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    A cross sectional survey in an ethnically diverse population of pregnant women in
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     London
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64 **ABSTRACT**

65 Introduction

Following the major outbreak of pertussis and 14 infant deaths across England in 2012, the Department of Health (DH) introduced the UK's first maternal pertussis vaccination programme. Data published by Public Health England (PHE) suggest uptake of the vaccine varies considerably across the country. The reasons for this heterogeneity need to be addressed to optimise the impact of the program.

71 Objective

- To assess uptake of antenatal pertussis and influenza vaccine in a leading NHS Trust in
- London and to explore awareness and attitudes of pregnant women towards the pertussis
- vaccination programme.

75 Design

A cross sectional survey was conducted in an ethnically diverse group of 200 pregnant women accessing antenatal care at Imperial Healthcare NHS Trust. Quantitative data was tabulated and content analysis was carried out on the free text. Qualitative data was

⁷⁹ divided into themes for accepting or declining the vaccine.

80 Results

Awareness of the program was 63% (126/200) with actual uptake of the vaccine only 81 26.0% (52/200). Women had received information from multiple sources, primarily 82 General Practitioners (GP) and midwives. 34.0% (68/200) of women were offered the 83 84 vaccine at their GP practice, but only 24% reported a meaningful discussion with their GP about it. Uptake differed by up to 15.0% between ethnicities. Qualitative data showed 85 that uptake could be significantly enhanced if vaccination was recommended by a familiar 86 healthcare professional. Feeling uninformed, lack of professional encouragement and 87 uncertainties of risk and benefit of the vaccine were the greatest barriers to uptake. 88

89 Conclusion

Vaccine uptake in this cohort of pregnant women was poor. Understanding the target audience and engaging with key groups who influence women's decision-making is essential. Knowledgeable health care professionals need to recommend the vaccine and provide accurate and timely information to increase success of this important program.

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97 **1. INTRODUCTION**

Pertussis (whooping cough) is a highly contagious, acute bacterial infection of the respiratory tract caused by *Bordetella pertussis*. This exclusively human pathogen can affect people of all ages. Whilst adolescents and adults often display relatively mild symptoms, in unimmunised newborn infants the disease may run a severe course resulting in a high rate of complications and death, [1,2]. Pertussis persists as an infection of significant global public health importance leading to 126,000 deaths worldwide in children up to the age of 5 years in 2013,[3].

Fortunately, wide-scale childhood vaccination programmes have been influential in reducing the morbidity and mortality associated with pertussis, [4, 5, 6, 7]. However, despite high vaccine coverage, a sharp increase in cases has been observed over the past decade, [8,9,10,11] in several countries in Europe, North America and Australia, most likely due to waning immunity after the introduction of the acellular pertussis vaccine, [12]. In the UK, pertussis currently remains the most common cause of hospitalisation and deaths in infants from a vaccine-preventable disease, [5,13].

In late 2011 the UK witnessed a remarkable resurgence of confirmed pertussis cases to a 112 level not seen for almost 20 years. By 2012, infected cases had risen tenfold and the 113 outbreak was extending to infants too young to be protected through routine vaccination. 114 115 Sadly, a total of 14 infant deaths were reported in England in that year. Consequently, an urgent review by the UK Joint Committee on Vaccination and Immunisation (JCVI) 116 recommended to the Department of Health (DH) that pregnant women should be offered 117 routine vaccination with a five component acellular-pertussis containing vaccine, and this 118 program was initiated in October 2012, and was offered to all pregnant women between 119 120 28 and 38 weeks of pregnancy within the UK National Health Service (NHS)[14]

A subsequent Public Health communications campaign to inform women about the need 121 for vaccination and to stimulate uptake ran for approximately 5 months, including 122 123 publication of a range of printed materials, available on order. Communication with healthcare professionals used DH and NHS channels and relied upon Heads of 124 Profession to convey key messages and clinical information about pertussis. The Primary 125 Care Trusts (PCTs) were asked to establish vaccination services quickly using local GP 126 Practices, [15]. Vaccine stocks were delivered to GP practices and the hospital pharmacy 127 held only a limited stock of vaccine for women who were long-term antenatal inpatients. 128

The intervention aims to minimise morbidity and prevent further infant deaths by boosting pre-existing maternal immunity and protect newborns indirectly via transplacentally transferred protective antibody, prior to receiving their own vaccines within the infant immunisation schedule,. During the summer of 2014 the upper gestation recommended

- for receiving the vaccine was reduced to 32 weeks, in light of recent evidence, [16] to
 ensure sufficient antibody transfer from mother to baby prior to birth.
- Despite measures taken to promote pertussis vaccination, monthly figures published by Public Health England (PHE) since the start of the campaign have revealed varied vaccine uptake across England with London achieving 53.3% coverage at best in February 2013,[17].
- In 2013 and 2014, a further 10 deaths in infants occurred with nine of these infants born
 to non-vaccinated mothers. In light of these data and the recent announcement that the
- vaccination programme will continue for a further five years, [18], evaluation of the current pertussis vaccination programme in pregnancy is, therefore, timely and essential to inform
- the long-term strategy for optimising pertussis control.
- We undertook a cross sectional survey to evaluate women's awareness, attitudes towards and acceptance of the current pertussis vaccination programme in order to identify potential barriers that could be addressed in order to improve implementation.

147 2. MATERIALS AND METHODS

148 2.1 Study design

- This study adopted qualitative and quantitative research techniques in the form of a cross-sectional questionnaire survey. Self–reported qualitative information on attitudes to
- vaccines and experiences was gained from the analysis of the free text.

152 **2.2 Ethical considerations**

153 Ethical approval was granted by the London-Hampstead Research Ethics Committee 154 reference:13/LO/1712.

155 **2.3 Theoretical framework and questionnaire development**

- A four part, anonymised questionnaire was developed based upon the Precaution Adoption Process Model and the Health Belief Model of health behavior [19,20,21]. Consideration was given to the potential for inaccuracy in self-reported vaccination status,[22,23,24] and questions were phrased in order to highlight any discrepancy and allow further questions to be asked.
- A pilot survey was conducted with six pregnant women from the target population to optimise the questionnaire to ensure that the 'instrument' was logical and comprehensive for the domain that it was intended to measure. A convenience sampling strategy was adopted.
- 165 **2.4 Study population**

The questionnaire was administered to an ethnically diverse sample of pregnant women who were over 18 years old, at least 27 weeks pregnant and attending for routine pregnancy care over a one year period from May 2013 to June 2014.

When approached by the Research Midwife in the antenatal clinic waiting area,each woman was given a full explanation of the survey, supported by an information leaflet and sufficient time to ask questions before making an informed decision to participate. All questionnaires were returned to the Research Midwife in a sealed envelope prior to leaving the clinic.

174 2.5 Data analysis

Questionnaires were collated and data was entered into an Access database, doublechecked for accuracy and subsequently exported into Microsoft Excel. Descriptive statistics such as percentages and means were calculated. Content analysis was applied to the free text and used to summarise recurring patterns across respondents. Quotes from the questionnaires were tabulated and repeated words and phrases were highlighted according to categories. Themes were derived from these to discern factors influencing women's decisions to accept or decline vaccine, [25].

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183 **3. RESULTS**

¹⁸⁴ 205 questionnaires were distributed to eligible women. Five questionnaires were excluded

due to insufficient response to multiple questions. 200 were completed and analysed (97.0% response rate).

187 **3.1 Respondent characteristics**

The average age of the respondents was 31.4 years (median, 31: range 18 - 34), the average gestation was 32 weeks (range 27 - 41weeks) and 46.0% (93) of the respondents were nulliparous. The respondents were of diverse ethnicities. Demographic details are summarised in Table 1.

To assess cohort representativeness, the demographic data of the respondents was compared with key data extracted from the Ciconia Maternity Information System (CMIS) of all women booking for routine care at the same NHS antenatal clinic. This comparison showed no significant differences between the groups and was representative of the pregnant population attending the hospital Trust.

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Table 1. Characteristics of pregnant women participating in survey

Characteristic	Survey participants N=200	CMIS data comparison N=5877
Average age (years)	31.4years	31.57years
Range:	18-43years	16-52years
Parity (P)	-	-
0	93(46.5%)	
≥1	107(53.5%)	
Parity range:	P0 – P8	
Average gestation	32 weeks	
Range:	27- 41weeks	
Ethnicity		
Asian (British, Bangladeshi, Indian, Pakistani including Chinese)	40 (20.0%)	14%
Black (British, African, Caribbean)	37 (18.5%)	18%
White (British, various other nationalities)	88 (44.0%)	48.5%
Mixed	9 (4.5%)	3.3%
Other ethnicities	19 (9.5%)	15.4%
Did not want to say or not stated	7 (3.5%)	
London postcodes		
NW2	26 (13%)	458 (7.8%)
W2	22 (11%)	602 (10.2%)
NW6	21 (10.5%)	520 (8.8%)
NW10	19 (<u></u> 9.5%) ´	822 (13.9%)

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202 **3.2 Uptake of pertussis vaccine**

Of the 200 respondents, 26.0% (52/200) had been vaccinated during their current pregnancy. 72.0% (144/200) had not received the vaccine and four women (2.0%) could not remember. Of the 144 women who had not been vaccinated, 79 (54.8%) stated that they were undecided about accepting the vaccine during this pregnancy but may consider it in the future (Fig.1).

Uptake differed by ethnicity with the highest uptake amongst 'White women' with 29.5% (26/88) vaccinated. Within this group the highest uptake was in the "White – Other" ethnic group (predominantly Polish) with 36.0% (18/50) vaccinated. The lowest uptake of 18.9% (7/37) was in the "Black/Black British group with the poorest uptake being 7.1% (1/14) in Black Caribbean women. Women who did not state their ethnicity had an uptake of 14.3% (1/7).

3.3 Reasons for accepting pertussis vaccine

Vaccinated women were asked to describe their reasons for accepting the pertussis vaccination with four themes emerging.

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3.3.1 The importance of encouragement and understanding

- The predominant reason given by 78.8% (41/52) of women for accepting the vaccine was encouragement or recommendation by a healthcare professional known to them.
- 221 When asked about their knowledge and understanding of the pertussis vaccine only 16 of
- the 52 vaccinated women could name the vaccine they had received or provide any detail in their response. This suggested that while women had opted to take the vaccine perhaps the information given was difficult to interpret or the discussion around this
- process had been limited.

226 **3.3.2 Keeping me and my baby safe**

Women believed that by receiving the vaccine they were acting in the best interests of their unborn baby by protecting themselves and reducing the risk of their baby developing pertussis in the early weeks following birth.

230 3.3.3 Risk avoidance and precaution

Other reasons given for accepting the vaccine included preventing the disease and preventing any damage caused to the baby as a result of pertussis infection.

233 **3.3.4** How experience influenced decision-making

Identifying with the disease by knowing someone who had experienced pertussis,
 influenced women's decisions to accept the vaccine. Personal experience of vaccine–
 preventable illness also had a positive influence on decision-making.

237 **3.4 Impact of complications in pregnancy on decision making**

- 238 Forty three of the 200 respondents (21.5%) reported complications in their current
- pregnancy with 13 (6.5%) reporting gestational diabetes and 7 (3.5%) with pre-eclampsia.
- Of these women, 30.2% had received the pertussis vaccine. In contrast, only 22.9% of
- the 157 women with uncomplicated pregnancies had been vaccinated.

242 **3.5 Attitudes to vaccination in future pregnancies**

- 47.5% (95/200) of all the respondents expressed a willingness to accept the pertussis vaccine in their next pregnancy. Over one third (38.5%) were undecided, but only 8.0%
- stated they would not wish to take up the vaccine and 6% did not answer this question.

3.6 Reasons for declining pertussis vaccine

- Unvaccinated women were asked to describe their reasons for declining the pertussis vaccination during pregnancy and gave a number of different reasons for declining the
- pertussis vaccine, as summarised in Table 2. Five women gave more than one reason.
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253 Table 2. Reasons for declining vaccine

Question: If you have decided not to have the whooping cough vaccination, why did you take this decision?	N=144
Not aware and never informed about the vaccine Insufficient information about the vaccine Safety concerns as we need more research evidence to show efficacy/safety Trust in natural immunity and lifestyle Breastfeeding gives baby enough immunity Had whooping cough as a child so have enough immunity Religious reasons Other reason	51.3% (74) 32.6% (47) 12.5% (18) 4.1% (6) 0.6% (1) 0.6% (1) 0.6% (1) 0.6% (1)

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255 Content analysis was applied to the free text and was used to summarise recurring 256 patterns across respondents in four emerging themes.

257 3.6.1 Lack of information, awareness and professional encouragement

The main reasons for declining the vaccine were the lack of information and awareness 258 of the vaccine combined with a lack of encouragement from familiar healthcare 259 professionals. The vast majority (91.0% (182/200)) of women believed that their 260 healthcare professional should provide them with more information about the 261 recommended vaccinations during pregnancy. They requested that this information 262 should be given in a timely manner supported by a meaningful discussion in order to 263 make an informed decision about accepting or declining the vaccine within the optimal 264 timeframe. Women who were undecided about accepting the vaccine also considered 265 that it was important to be fully informed and that information should be more accessible. 266

267 It was also apparent that women who sought advice wanted detailed information about 268 the causes, symptoms, side-effects and significance of the disease in order to support 269 their decision-making.

Other important sources of information included discussions with relatives and friends, utilising media sources such as printed material and radio and actively seeking information on the internet. Just 3.0% (6/200) of women indicated the public health campaign as their primary source of information. Of these, only one woman had received the vaccine.

275

276 3.6.2 Natural is better

Women thought that over-medication could be a hazard during pregnancy and that 'natural was better'. There was a firm belief that 'nature would take care of things'.

279 **3.6.3** Perceived risks and safety concerns

Some women worried about the side-effects of the vaccine on their unborn baby and to themselves. Others felt that there was insufficient evidence to support the use of the vaccine at this present time. Women's perceptions of risk about vaccination both for themselves and their unborn baby influenced how they felt about accepting any vaccines during pregnancy.

285 **3.6.4** Not needed as low perceived susceptibility

The vaccine was also considered unnecessary by some women who did not perceive that they were at sufficient risk of contracting the disease. Women were associating their healthy lifestyle with being at 'low risk' of getting the disease. Furthermore, some women believed that breastfeeding provided all the immunity their baby would need to prevent them from developing the infection.

3.7 Awareness of recommendations for vaccines in pregnancy in general

In order to assess whether the attitude towards pertussis vaccine might also influence the uptake of other vaccines recommended in pregnancy, we included questions that related to both pertussis and influenza vaccine. Overall, 63.0% (126/200) of respondents were aware that the pertussis vaccine is recommended in pregnancy compared with 69.5% (139/200) aware of the maternal influenza vaccine programme (Fig.2)

While 34.0% (68/200) of the respondents had been offered pertussis vaccination at their GP practice, only 24.0% (48/200) reported that they had discussed the issue with their GP. Some women had approached their GP and asked for the pertussis vaccine or for further information, nevertheless, 61.5% were not offered the vaccine and 4.5% could not remember. Of the 126 women who had been informed of the pertussis vaccination programme by their healthcare professional, 38.8% (49/126), nevertheless declined to take the pertussis vaccine.

In contrast, 48% (96/200) of the respondents had been offered the influenza vaccine at their GP practice. Of the 139 women who were informed of the influenza vaccination programme by their healthcare professional, 50.3% (70/139) were vaccinated during pregnancy.

308 **3.8 Preferred sources of information**

When women were asked to report all known sources of information about the pertussis programme available to them, 16.6% (21/126) indicated the GP and midwife as the

- 311 primary sources. Other sources of information included friends and the internet. Seventy
- four women(37.0%) were not aware of the vaccination programme.
- 313 When asked about receiving information about vaccination programmes in the future,
- 314 91.0% (182/200) of women said that it would be helpful to receive more information in a
- timely manner accompanied by a meaningful discussion and the opportunity to ask
- guestions. Table 3 summarises the sources accessed and preferred sources of
- 317 information for all future communications about vaccination in pregnancy.
- 318

Table 3. Sources of information accessed by respondents

Question: How were you informed about the whooping cough vaccination program?	N=126
Source of information:	
GP	24.0% (48)
Midwife	13.0% (26)
Antenatal clinic	10.0% (20)
Other source (internet etc.)	9.0% (18)
Media (newspaper, radio)	4.0% (8)
Public health campaign	2.5% (5)
Obstetrician	0.5% (1)
maternal vaccination in the future? (more than 1 answer allowed)	
Antenatal clinic	60.0% (120)
GP	59.0% (118)
Midwife	35.0% (70)
Personal letter sent out in post	22.0% (44)
Online website	20.5% (41)
Leaflet or poster in clinic or surgery	19.0% (38)
Text or email	15.0% (30)
Maternity helpline	1.0% (2)
Other	1.0% (2)
Would prefer not to have any additional information	5.0% (10)
Did not respond to question	4.0% (8)

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4. DISCUSSION

323 Despite an ongoing public health campaign to promote pertussis vaccination during

324 pregnancy in the UK and new cases in infants in the community, uptake has varied

325 considerably across the country and has remained comparatively low in London.

We assessed the awareness and attitudes to pertussis vaccination in pregnancy using 326 327 both quantitative and qualitative tools. Only 26.0% of women in our cohort had received the vaccine, considerably less than the 62.3% national coverage recently reported by 328 329 PHE,[17] and fell short of the reported London coverage which ranged from 33.5% at worst to 53.3% in February 2013, [26]. PHE have suggested that the published coverage 330 data should be interpreted with caution due to inherent problems identified in data capture 331 and reporting,[17]. Nonetheless, our findings are a source of concern since they indicate 332 a generally lower than average uptake of pertussis vaccination by pregnant women 333 attending our busy, acute NHS Trust. 334

It would appear that making decisions about accepting vaccine during pregnancy is a complex process and women will utilise their own beliefs, attitudes and values about vaccination in general when balancing perceived risks and benefits to themselves and their baby,[27]. However, consistent with similar studies our findings also highlight the importance of encouragement and recommendation by a familiar healthcare professional in this process,[27,28,29, 30].

Despite recommendation from the UK Department of Health, awareness of the need for 341 maternal vaccination was comparatively low at 63.0%, which, in itself represents a barrier 342 343 to uptake. Lack of awareness combined with a lack of encouragement by professionals were the main reasons given for not accepting the vaccine. Being informed was 344 important, also noted in previous studies, [31,32] and being aware of the disease 345 increases women's probability of accepting the vaccine,[33]. Many women were sceptical 346 of vaccine safety and efficacy despite published evidence,[34] and 91% wanted more 347 348 information about vaccines in general.

The main sources of information for pregnant women were GPs and midwives and yet women displayed misconceptions about the vaccine. This suggests that the information received was limited and difficult to interpret and only 24% of the women questioned reported a meaningful discussion with their GP. A study examining postpartum vaccine acceptance in a diverse sample of 815 Australian women also noted that access to information was significantly associated with uptake,[35].

From the contrasting comments in this study -see supplementary document- it was obvious that women's needs around obtaining and retaining information are very diverse. The experience reported here was one of disempowerment which ultimately impacted decision-making and maternal choice.

Uptake varied across ethnic groups with only 7.1% of Black Caribbean women being vaccinated. This finding is consistent with prior studies on racial disparity in vaccination

practice which showed that black women are more likely to reject vaccination because 361 they doubted the effectiveness, distrusted the healthcare system and feared they may 362 become ill from the vaccine [36, 37, 38, 39]. This was an important finding given the 363 significant number of women with Black/Black British ethnicity booking for care at this 364 Trust (18%). Understanding the target audience and engaging with key groups who 365 influence women and parents in vaccination decision-making is important and might be 366 influenced by ethnicity and possible disparities in access to PH materials or use of GP's. 367 Our questionnaire did not capture such details, but our subsequent focus group activities 368 will be able to explore these issues in more depth. 369

- The latest enquiry into maternal deaths, *Saving Lives, Improving Mothers' Care* [40] reports that between 2009-2012, 357 women died during pregnancy or within six weeks of the end of their pregnancy. One in 11 of these women died from influenza and more than half of the influenza deaths could have been prevented by a flu vaccination. Compared with pertussis, reported uptake of Influenza vaccine in our study was 9% higher. This difference may be attributed to greater awareness of the influenza vaccine during pregnancy and better availability at their GP practice.
- Women were dissatisfied with the extent of information they received and resorted to 377 378 researching information online as an alternative. There is little doubt that the development of new media such as the Internet and facilities such as NHS Direct have created easier 379 access to 'medical' knowledge about pregnancy and childbirth, but, without professional 380 help to explain the importance and relevance, misconstrued information may have caused 381 women to reject the vaccination. This may be helped by emphasising the importance of 382 383 maternal vaccination early in pregnancy at the first antenatal appointment then following this up at each subsequent clinic attendance and support this discussion with the 384 385 inclusion of the DH leaflets in the 'booking pack'. Ideally, maternal vaccination should form part of the recommended information provided in the routine schedule of antenatal 386 care and should be included in the National Institute for Health and Care Excellence 387 (NICE) Antenatal Care Guidelines. 388

A number of women expressed concerns about the safety and efficacy of the vaccine. Previous studies have shown that perception of harm to the baby or pregnant woman is directly related to vaccine refusal,[35,36,41,42,43]. An observational study of over 20000 pregnant women who participated in the maternal vaccination programme in the UK, concluded that there were no safety concerns,[34]. The data also show that maternal immunisation with an acellular-pertussis-containing vaccine can provide 90% protection against infant disease,[16]. Our results underline the critical role of healthcare professionals in advising and informing women in pregnancy. Only 24% of the women had engaged in a discussion with their GP about the vaccine. Other studies conducted during the H1N1 epidemic reported similar findings [31].

In recognition of the need for accurate information which targets misconceptions we have recently developed a vaccination information telephone APP, and we are using a mobile vaccination information 'hub' which is 'rolled out' and displayed in the antenatal clinic area and manned by the research midwives. This allows women and professionals direct access to current information, is interactive and achieves better visibility than leaflets.

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With a growing body of evidence supporting the safety of the vaccine, weekly/monthly email shouts to healthcare professionals to update and increase awareness of current pertussis activity in the community would ensure staff are equipped to deal with queries efficiently.This type of information can be provided via text message and adapted for pregnant women and healthcare professionals alike, utilising the existing NHS text messaging service.

412 Our study acknowledges some limitations. This was a cross-sectional study of only 200 413 women at a single large NHS TRUST in London. However the sample was representative 414 of the diverse population of women attending this Trust and our findings are likely to be 415 applicable to many other settings caring for a similar population of women.

We relied upon self-reported vaccine status and while this is recognised as a suitable alternative to medical record audit for determining vaccine uptake in adults, [44], there is potential for some reporting bias in our estimates of vaccine uptake.

It could be argued that surveying women at 27 weeks gestation might have been too early. However, since the vaccine can be administered from 28 weeks onwards, women should ideally be made aware of the vaccine at least one week in advance and the average gestation in our study was 32 weeks.

At the start of the DH pertussis campaign, pertussis-containing vaccine stocks were 423 supplied to GP practices. With hindsight vaccine stocks may have been better placed in 424 antenatal clinics where women could be informed about the vaccination programme and 425 receive the vaccine without an additional visit to their GP practice. Both information and 426 427 vaccines should be available at any point of contact with health services during pregnancy, with knowledgeable staff promoting their use. Comparative studies might be 428 warranted to analyse where vaccination of pregnant women could be delivered with the 429 highest success rates, and the opinion of pregnant women should be sought as part of 430

this process. Some GP practices are likely to have much higher rates of uptake andpathways to success could be shared.

In this campaign, communication of information used a top-down approach which, in this particular care setting was ineffective in delivering the key messages to staff in direct contact with pregnant women. In any future campaign it will be essential that PHE and DH engage directly with the staff delivering the care. In addition, although appropriate resources were developed to inform professionals and pregnant women, these are only provided on demand and not issued routinely to areas such as antenatal clinics.

In summary, the main barriers to uptake of the maternal immunisation program were lack 439 of awareness and the lack of accessible information about safety and rationale for the 440 program. Healthcare professionals with GP's and midwives in particular need to be more 441 engaged in delivering these important messages to women in their care in an accessible 442 and timely fashion. Practically, a four-pronged approach should be employed, which 443 delivers education for expecting parents, support for healthcare professionals with up to 444 date knowledge, enhanced media coverage promoting the benefits of vaccination and 445 increased understanding of the consequences of poor vaccine uptake for individuals and 446 society. 447

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459 Author's contributions

The study was conceived by BK, BD and LR. The questionnaires were developed and implemented by BD and PJ with critical input from BH, LR and BK. The database was designed by BK and BL. The data entry and analysis of results was conducted by BD, PJ and BK. The first draft of the manuscript was developed by BD and BK and subsequent versions had input from all authors. The final submission has been approved by all authors. We affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained. BK is the guarantor of the paper.

469 **Competing interest statement**

- 470 All authors declare that no support from any organisation for the submitted work has been
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