# 'Just that Little Bit of Doubt': Scottish Parents', Teenage Girls' and Health Professionals' Views of the MMR, H1N1 and HPV Vaccines

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Published online: 3 October 2013

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#### Abstract

Background Parental decision making about childhood vaccinations is complex and the vaccination schedule everchanging. Vaccination may be controversial even in countries with historically high vaccination rates such as Scotland. Health behaviour models have aided understanding of individual vaccine intentions for specific vaccines. These are limited in explaining actual behaviours and are divorced from the impact of socio-cultural contexts on vaccination decision making.

*Purpose* To explore vaccination views in Scotland amongst parents, teenage girls and health professionals across three controversial vaccines: the Measles, Mumps, Rubella (MMR), the Human Papilloma virus (HPV) and the Influenza A (H1N1) vaccine.

Method We used qualitative interviews and focus group discussions in a purposive sample of health professionals (n=51), parents (n=15) and teenage girls aged 12–15 years (n=8) about their views of these vaccines. Discussions were analysed using thematic analysis.

Results Two main themes are highlighted: 'vaccine risks revisited' in which we explored how the MMR legacy resurfaced and how worries about vaccine safety permeated the data. 'Vaccine responsibilities' indicated tensions regarding roles and responsibilities for vaccines. An overarching

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notion of 'just that little bit of doubt' referred to lingering doubts and uncertainties interwoven across the vaccines. *Conclusions* Public health authorities should remain alert towards pervasive vaccine concerns. It is important for authorities to clarify vaccine roles and responsibilities in the face of new and existing vaccines and to acknowledge public concerns regarding vaccine safety.

**Keywords** Qualitative · MMR vaccine · H1N1 vaccine · HPV vaccine · Parents · Young people · Health professionals

## Introduction

Vaccination is considered to be a successful and cost-effective public health intervention in the developed world through the virtual eradication of infectious diseases [1]. Children and adolescents are the largest groups targeted in vaccination programmes [1, 2]. Developed countries have different vaccination programmes; however, there are a number of common diseases targeted. The childhood and adolescent vaccination schedule is ever-changing and new vaccines continually introduced. Following international trends, Scotland introduced the Human Papilloma virus (HPV) vaccine in 2008 in a national school-based campaign amongst preadolescent girls. This protects against common strands of the sexually transmitted HPV virus which can lead to cervical cancer [3]. In 2010, the Influenza A (or Swine Flu) vaccine was also introduced to the vaccination schedule and recommended for children aged 6 months to 5 years of age.

Historically Scotland, the site of the present study, compares favourably with other countries in the developed world and the rest of the United Kingdom (UK) in terms of vaccination rates. For example, the World Health Organisation's recommended 95 % uptake rate was achieved for the primary dose of the Measles Mumps and Rubella (MMR) vaccine [4].



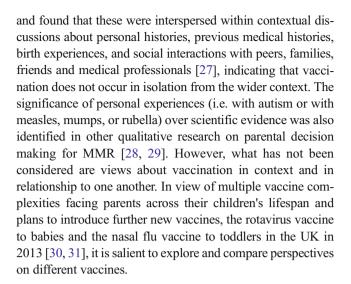
Furthermore, the 80 % uptake rate required for three doses of the HPV vaccine amongst 12–13 year olds was also met [5]. Despite the general success of these vaccination programmes, rates for particular vaccines such as the MMR booster vaccine or HPV vaccine can vary across geographical areas with lower uptake in both deprived [4, 6] and affluent communities [4]. Disease outbreaks in under-immunised sections of the population, serve as reminders of the threat of diseases [7–9].

Historically, vaccine scares involving the MMR vaccine controversy in the UK, linked the vaccine with the development of autism and bowel disease [10]. This had a detrimental effect on uptake rates nationally and internationally and affected public confidence [11]. Yet public health debates about new vaccines emerge in respective contexts. Stöckl's [12] comparison of public health discourses about the introduction of the HPV vaccine in the UK, Germany, Austria and Italy indicated that the MMR controversy had a significant impact on parents' initial perceptions of the safety of the new HPV vaccine in the UK [13]. The introduction of the HPV vaccine in the UK was also associated with an extensive government campaign and positive and compelling media coverage of the vaccine as effective against cervical cancer [14, 15].

Health professional recommendation is important for promoting vaccination [16, 17]. Conversely, ambivalent health messages from health professionals at the time of the MMR scare indicated low staff confidence in promoting vaccination [18, 19]. A study in the UK highlighted the role of the school nurse in targeting health inequalities relating to the HPV vaccine [20]. Despite the success of this vaccine in the UK, small but significant groups remain at risk of not being vaccinated with three doses [6, 20], particularly those outside the education system and school nurses make specific efforts to target these groups [20].

Health behaviour models have been influential in explaining vaccination behaviour but have focused on individual decision making for specific vaccination intentions. In childhood vaccinations, parents are the decision makers, while for vaccinations offered during adolescence, both parents and young people can contribute to decision making. New vaccines can be problematic for parental acceptance [21]. Omission bias was shown to underlie parental decision making for the H1N1 vaccine. Parents preferred to omit having the vaccine and thereby risk exposing their child to the disease rather than actively choose the vaccine which they considered might be harmful [22]. Perceptions of risks regarding vaccinations, as opposed to risk of the disease, have been consistently identified as barriers to uptake of novel and combined vaccines [21, 23, 24]. These studies have yielded important insights, although the focus on intention is problematic, given the weak links between intention and behaviour.

In contrast, others have recognised the broader sociocultural contexts of vaccination decisions [25, 26]. An ethnographic study in England explored mothers' talk about MMR



# Aim

Our aim was to explore parents', teenage girls' and health professionals' views about three vaccines in Scotland: the previously controversial MMR vaccine and two newly introduced vaccines at the time of the study, the H1N1 vaccine and the HPV vaccine. The purpose was to determine views across the three vaccines and consider contextual influences on decision making.

# Method

We used qualitative semi-structured interviews and focus group discussions to explore vaccination views across the three vaccines. We sought parents', teenage girls' and health professionals' views about the MMR vaccine and the two new vaccines. Our findings come from data which was collected from one health board in Scotland<sup>1</sup> during 2008–2010.

## **Participants**

A total of 74 participants took part in the study. Purposive sampling was used to recruit health professionals (n=51), parents (n=15); all mothers) and young people (n=8); schoolgirls aged 12–15 years). Clinical leads in the health service advertised and invited health staff to take part. Posters advertised for parent participants in mother and toddler groups, community and health centres and through clinical leads. In



<sup>&</sup>lt;sup>1</sup> There are 14 national health boards in Scotland, each with its own responsibility for provision of health services.

two high schools that had volunteered to take part in the study, posters advertised the study and information packs were sent home to parents of interested young people.

Ethics approval was granted for the study by the university ethics committee, local health research and development office and the education department. Confidentiality was assured through removing all personally identifiable information and using participant numbers.

#### **Data Collection**

Methods were pragmatic and offered to participants flexibly according to their preference in order to encourage participation. We conducted 15 interviews with mothers, two focus group discussions with girls and 12 interviews and seven focus group discussions with health professionals. Interviews and focus groups were conducted by CGB, a female research psychologist who was not known to the participants. She introduced herself as a social science researcher interested in peoples' views about vaccination but who was not a health professional and hence could not advise regarding different vaccines.

A number of 15 mothers were included: eight had babies or toddlers and seven had teenage girls. No fathers were recruited. Mothers represented a range of socio-economic areas including areas where the MMR vaccine uptake had been lowest [4] and different vaccination histories. These included two mothers who had either refused the MMR vaccine or had paid privately to have the vaccines administered as single doses; seven mothers who were uncertain about accepting the H1N1 vaccine and two mothers with teenage girls who had either refused the HPV vaccine or who had not completed three doses. Fourteen were of white British ethnicity and one was Polish. Following parental consent, eight teenage girls aged 12-15 years (mean=13) took part in two focus group discussions. They were from two high schools where school nurses had recently delivered the HPV vaccine and represented mixed socioeconomic backgrounds. All girls had received at least one dose of the HPV vaccine.

Seven focus group discussions and 12 interviews were held with a range of health professionals including managers involved in the organisation of the three vaccines (n=8), general practice nursing (n=7), health visiting (n=9) and school nursing (n=27) teams.<sup>2</sup> Health staff worked in a range of socio-economic areas including urban and semi-urban areas.

Staff differed in their involvement with administering vaccinations ranging from 'catch-up campaigns' to target those who had been missed; vaccinating specific groups (i.e., preschoolers or teenagers), shared vaccinations between practice nurses and health visitors and/or general practitioners, sole responsibility for vaccination. All school nurses were involved in the HPV vaccine delivery. Topics covered during discussions focused on eliciting participants' views and experiences of the MMR, H1N1 and HPV vaccines. These were digitally recorded and transcribed verbatim.

## **Analysis**

We followed standard methods for conducting a thematic analysis [32]. Analysis was an iterative process. Initially, CGB coded individual transcripts for emerging categories, which she then compared and contrasted across transcripts amongst the same and different groups of participants until themes were refined and verified. Rigour was enhanced through discussion of emerging themes with other members of the research team and a study steering group.

#### Results

We derived two central themes from the analysis: 'vaccine risks revisited' and 'vaccine responsibilities', which are explored below with illustrative data extracts.<sup>3</sup> We identified an overarching notion of 'just that little bit of doubt' which indicated persistent vaccine concerns which were interwoven throughout the data.

## Vaccine Risks Revisited

Despite the context of high primary vaccination rates overall, participants expressed widespread anxieties about vaccines. Concerns about vaccine safety for the MMR vaccine were also evident for the newer vaccines.

The MMR Legacy: 'Just that Little Bit of Doubt'

Over a decade since the controversy, the MMR vaccine emerged as a contentious vaccine. This is illustrated below by a mother who explains why she had opted for the single MMR vaccines due to lingering concerns about the combined

<sup>&</sup>lt;sup>3</sup> Coding identifiers appear as follows: participant number and data collection method.



<sup>&</sup>lt;sup>2</sup> In Scotland, a range of health professionals is involved in the delivery of vaccinations including general practitioners and community nurses. Practice nurses are attached to general practitioner surgeries. Health visitors primarily work with babies and toddlers, whereas school nurses work with school-aged children.

MMR vaccine<sup>4</sup>; this is epitomised in what she called just 'that little bit of doubt':

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They're now saying there's no side-effects, that the MMR doesn't have any bearing on the autism, but there's still that risk factor if you couldn't say for 100% sure that it didn't cause autism, so, but it was just mainly that little bit of doubt (Mother, interview 3)

Caution was also echoed amongst some health staff surrounding the MMR vaccine. This practice nurse explained how she adopted a cautious approach in advocating the vaccine in specific circumstances:

I have said to a mother in the past when the child was quite small just to wait maybe another month or so — not put [MMR vaccine] off drastically ... I don't have any scientific basis for that apart from talking to another medical person whose child had autism after the MMR vaccine (Practice nurse1, interview 1)

The above example indicates lingering doubts regarding the safety of the MMR vaccine where the nurse admits delaying recommendation for the MMR vaccine in a specific case. She identifies that personal and social influences were paramount and gives the personal example of the medical colleague 'whose child had autism after the MMR vaccine' rather than the influence of science or statutory health recommendations. Given the importance of health professional recommendations for vaccinations [16, 17], it is unclear how the mother in the above example would have interpreted this delay and caution and indicates the lasting impact of the MMR controversy on both lay and professional views.

# New Vaccine Worries

In parallel to lingering concerns over safety for the MMR vaccine, participants also expressed concerns over vaccine safety for the two new vaccines. One teenage girl who had refused the HPV vaccine after receiving the first dose at school, talked about personal discomfort:

My arm went really sore and I felt really sick (Schoolgirl 6, focus group 2)

In addition, she talked about more serious worries over the effects of the vaccine:

There's always going to be...someone...that doesn't react properly and I... want to know about that as well and what happened to the people that got sick...not just they felt a wee bit sick but there was actually a reaction to it

<sup>&</sup>lt;sup>4</sup> At the time of the MMR controversy, some parents paid privately to have separate, single doses of the MMR vaccine in the belief that this would minimise potential risks.



These views were endorsed by her mother but included concerns over the longer term:

Have they tested it enough? Can they guarantee that it's not going to have long-term effects when you're 40? (Mother, interview 13)

School nurses expressed mostly favourable views about the public health benefits of the HPV vaccine but acknowledged their own underlying concerns as parents:

Is it going to have long-term side effects? (School Nurse 1, focus group 3)

There were similar worries about the long-term effects of the H1N1 vaccine. These worries, however, were more widely expressed as many parents in our sample remained undecided about this vaccine. For example, as seen by a mother who was also a nurse:

It's [swine flu] actually not turned out to be such a big issue so there is a bit of me now wavering whether I want to put her through [the vaccine] ... [I] would like them to consider researching it a bit more (Mother, interview 7)

## **Vaccine Responsibilities**

Due to pervasive vaccine concerns, we consider different roles and responsibilities for vaccine decision making and for managing doubts. We identify three tensions surrounding vaccine roles: teenage girls' empowerment and the HPV vaccine, mothers' vaccine roles, and health professional strategies to promote vaccination.

Teenage Girls, Empowerment and the HPV Vaccine

Girls emphasised their capability for decision making for the HPV vaccine. This was echoed by mothers and school nurses who considered that girls had adequate knowledge about HPV transmission and sexual health education to make informed decisions. This conviction contrasted with girls' own views. One girl identified gaps in her knowledge about cervical cancer and screening which, she implied, should have been addressed at school:

They [Social Education classes] don't actually like tell you about smear stuff and cancer and that they just go on about smoking, drugs, alcohol and sex (Schoolgirl 5, focus group 2)

Several girls said that information about the HPV vaccine was insufficient and inconsistent, with only some receiving health leaflets. Some criticised the available information for being 'imbalanced', with only positive information provided

rather than the negative effects of the vaccine (i.e., side effects as seen earlier). Girls also said they would have preferred information highlighting personal and social experiences with the HPV vaccine from other girls to supplement official health information. They pointed out that group school assemblies were inappropriate and intimidating for asking personal questions which could be embarrassing. Having to publicly leave the classroom to seek out the school nurse to ask questions was also unacceptable. This indicates the sensitivity of the topic amongst schoolgirls and points to limited opportunities to dispel vaccine worries.

School nurses shared some of the girls' views. Nurses described some available information, for example, a DVD about the vaccine, as incongruent with youth needs. One school nurse considered that the wide publicity campaign and a celebrity death in the UK from cervical cancer provided important messages regarding the severity of the disease and the importance of the vaccine, but the format of the publicity was questioned:

There needs to be more actually online, on social networking sites...And they're less likely to look at TV or pamphlets, it will be social networking sites, twitter (School Nurse 5, focus group 2)

## Mothers' Vaccine Roles

Mothers assumed ultimate responsibility for decision making for childhood vaccines. This could be problematic, as explained by a mother who had two boys diagnosed with autism:

Like the swine flu vaccination and any other vaccinations [my friends who have children with autism] are very nervous of giving them anything else just in case, even though they're like me and pretty much convinced that there isn't a link, there's still that: but what if? (Mother, interview 6)

All vaccination, in the above case, is seen as particularly controversial considering the incriminating role of the MMR vaccine in causing autism. The implication is that children with autism have enough health problems without mothers introducing another potential harm to their children. This is reminiscent of omission bias [22] although works at a much broader level, because concerns about one problematic vaccine (the MMR vaccine) are then extended to other newer vaccines. Hence, the swine flu vaccine appears problematic for this mother (and extended to peers) as: 'nervous of giving them anything else just in case'. Despite professing to be convinced in the lack of evidence for the MMR controversy, clearly unresolved uncertainties remain as evidenced with the inevitable question 'but what if?'.

Despite the original Wakefield report being retracted from the scientific domain [33], this mother also referred to media coverage of the General Medical Council's investigation of the lead authors and subsequent conclusion that they had acted unethically and inappropriately [34]. Hence, underlying and unresolved vaccine concerns were apparent in vaccine decision making where concerns about one vaccine could be extrapolated to other vaccines and refused on that basis.

Despite consenting to all her children's vaccinations, another mother recognised the precarious process of vaccination for parents. This involved an ultimate sense of faith to suspend control which was difficult for first-time anxious mothers generally and in relation to worries about the MMR vaccine:

You just think 'what on earth am I doing with this creature' and then you're willingly handing it over to a medical person to stick some drug in it (Mother, interview 11)

In one case, a mother who had refused all childhood vaccinations for her children recounted a pivotal experience in pregnancy where she was required to have a caesarean section and anaesthetic but had been concerned about the effects of the anaesthetic on her baby:

Lucky I didn't actually believe it because of course it did, she was born very sleepy, not breathing properly and she ended up in special care for 24 h I mean she wasn't seriously ill but I just felt if I'd believed them that she wouldn't have been affected I'd have been very surprised [laugh] at what happened and that just left me thinking well maybe they're not always that truthful, maybe they just tell you what they think you need to hear (Mother, interview 2)

She cited this experience as instrumental in undermining her faith in health authorities and extended this to statutory information about vaccinations which 'didn't feel honest' and failed to report side or long-term effects.

In contrast to childhood vaccines where mothers took ultimate control for decisions and sometimes refused vaccines, the HPV vaccine represented a tension for mothers' roles. Girls as young as 12–13 years can consent to the vaccine themselves, without parental consent, as long as professionals are satisfied that informed consent procedures are undertaken in accordance with supporting guidelines. In practice, parental consent is still sought by health professionals. When questioned by the interviewer about who made the ultimate decision for the HPV vaccine, mothers emphasised collaborative discussions with their daughters and shared decision making. Mothers held the belief that their daughters would make 'the right decision' (i.e., opt for the vaccine). In the event that their daughter made an 'inadequate' choice due to fears of needles, mothers said they would intervene and offer guidance. Mothers' awareness over who made the ultimate decision for this vaccine, however, appeared mixed with some considering it 'ambiguous' or 'dishonest'. One mother whose



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daughters had both received the vaccines in the school programme, considered the lack of consultation as remiss:

Certainly with my younger daughter who was only 13 at the time...I would think well I ought to have been consulted on that (Mother, interview 11)

School nurses recognised that the issue of parental consent for the HPV vaccine was poor and that public education was needed to address this issue.

# Health Professionals' Strategies

Health professionals reported specific strategies to manage vaccination and vaccine concerns. Health staff acknowledged vaccine concerns and, in some cases, shared these concerns.

Staff viewed some groups as more difficult to engage in vaccination than others. One practice nurse from a deprived area summarised her perception of parents' views as follows:

We don't get much objection to MMR or anything like that...very few refuse MMR whereas perhaps in another area...where the parents are a bit more informed or a bit more into pre-reading more, take more interest, then they probably have more questions (Practice Nurse 1, focus group 1)

The nurse distinguished parents from deprived socioeconomic area with parents from, by implication, more affluent socio-economic areas. In affluent areas, parents were perceived to be more questioning of the MMR vaccine, to seek information online and to be influenced by 'alternative health beliefs'. Accordingly, staff related how they were required to adopt different strategies in managing different groups. In deprived areas, staff sent out reminders and undertook opportunistic vaccinations in order to promote vaccination as they were under the impression that parents there were not specifically opposed to vaccination, but were simply 'forgetful' but essentially 'compliant'.

Strategies for managing questioning parents, however, appeared more challenging as 'sometimes we don't have that information to give' (Practice Nurse 1, focus group 2). The internet could be a 'thorn in our side' (Health Visitor 1, focus group 1) because the sheer volume of questionable information available made vaccination decisions challenging for parents and for staff. In some cases, staff acknowledged that there was little they could do:

There's one parent recently that would not under any circumstances get it done [MMR vaccine] — very fixed views and you have to wonder, what's the point really? (Practice Nurse 2, focus group 2)

Managing the emotional aspects of vaccination, not just the technical side, was also widely recognised by parents, girls and staff as an important strategy. The wide emotional distress associated with large-scale HPV vaccination in schools or 'hysteria' related to girls' fears and phobias about needles. In such instances, staff echoed the importance of knowledge and relationship building with their clients to provide reassurance and foster trust. School nurses indicated knowledge of girls' misconceptions and their own roles in allaying fears:

We use larger and larger needles each time we come and the vaccine is about five times as strong each time! We have to reassure quite a lot it's the same (School Nurse 2, focus group 3)

Health staff recognised the sense of trust that vaccination entailed on the part of parents and girls in the face of these heightened emotions. However, they also recognised that trust was fragile, dynamic and could easily be undermined. New media controversies, for example, could suddenly appear and threaten faith in vaccines as one school nurse illustrated:

There was that death [reported in the media]<sup>5</sup> and we were immunising at the same time. So there was a lot of concern that we had to deal with (School Nurse 4, focus group 2)

Such scares largely centred on worries over vaccine safety and effects, reminiscent of the MMR vaccine controversy. In the face of such 'crises' of faith, staff emphasised the importance of timely, clear and unanimous health messages about safety from senior management.

## Discussion

This study is novel in considering parents, girls and professionals' perspectives about three vaccines, the MMR, H1N1 and HPV vaccines, in relationship to one another and within a Scottish context where vaccination is generally high. Previous emphasis on vaccination intentions is divorced from actual behaviours and the context within which vaccination occurs. Our analysis gives credence to the role of qualitative approaches which consider vaccination, not as specific and isolated events, but occurring in relation to one another and shaped by social and personal experiences rather than science, previous medical encounters such as in pregnancy, the influence of peers and the media.

Our analysis demonstrated how vaccine concerns about one vaccine (i.e., the MMR vaccine) could be extrapolated to decisions about newer vaccines (i.e., H1N1 vaccine) and sometimes refusal. The analysis suggests that vaccination was problematic, involved suspending control and an ultimate sense of faith. Our overarching notion of 'just that little bit of doubt' referred to underlying and pervasive vaccine



<sup>&</sup>lt;sup>5</sup> Reference to media reporting of a death in Conventry, UK, which was later reported to be unrelated to the HPV vaccine.

concerns which underscored vaccine decisions and were widely present across the data. This points to previous research about vaccine anxieties surrounding the MMR vaccine [35] but also highlights the lasting impact of the MMR legacy [12] on lay and professional views in a Scottish context. It is significant that vaccine concerns were evident amongst both mothers who refused vaccines, mothers who had previously consented [36] and amongst staff, across the vaccines. Vaccine acceptance, therefore, should not be assumed by public health authorities on the strength of previous vaccine adherence. Rather, it is important to acknowledge and engage with these concerns. Vaccine views could, for example, be actively explored in staff training prior to the implementation of new vaccines and in client consultations.

Our findings indicate areas where tensions in roles and responsibilities exist for vaccines. Despite high HPV vaccine rates in Scotland for the target group [5], girls' sense of empowerment appeared undermined through limited information [37] as well as opportunities to dispel vaccine concerns. Efforts at further engaging girls should be sought for the HPV vaccine which could include directing girls towards social media, as well as official information. Social blog analysis, for example, have proven promising in other contexts and allows public health authorities to engage with vaccine concerns directly [38, 39]. This appears apt given poor public understandings about HPV more generally [40]. Further, mothers were confused about their roles and responsibilities for the HPV vaccine, unlike the childhood vaccines where they assumed complete responsibility. Such changes in responsibilities for consent over the child's lifespan need greater clarity.

It is important to foster confidence in parental decision making for vaccinations. There are tensions, however, between vaccine behaviour, information seeking and confidence. One study [41] showed that parents with positive and decided views about vaccination were less likely to search for information and to feel confident about their decisions. Likewise, in our study, staff perceived mothers from deprived areas to be 'compliant' and 'forgetful'. This assumption, however, may be questionable in terms of how likely such mothers are to be informed and confident about their decisions. At the other extreme, affluent and questioning parents were difficult for staff to engage with. These two groups are particularly significant given previously reported lower uptake rates for the MMR booster vaccine in these areas [4]. Communitybased and health staff literacy initiatives may be significant for confidence building in vaccination.

Finally, our study is novel in emphasising health professional roles in managing emotions in vaccination encounters. In health behaviour models, the inherent assumption of the logical and rational decision maker [26] is challenged here as opposed to someone who makes decisions in the midst of heightened emotions. Greater emphasis should thus be given in recognition of the health professional–client relationship,

and future studies could explore the associated emotional labour required in order to manage such emotions in greater detail [42]. It is important that wider health service management practices support frontline staff in the event of 'crises' of faith and to deliver clear messages about safety.

The findings come from one area in Scotland and relied on volunteers so cannot be generalised to other settings. Perspectives provided by mothers, girls and health professionals, however, offer rich descriptions of how personal and social experiences about vaccine anxieties overlap within a specific context and may be relevant to other contexts with similar vaccine programmes. Triangulation of findings was ensured through the use of multiple viewpoints.

## Conclusion

Public health authorities need greater understandings of local vaccine concerns as embedded with specific socio-cultural and historical contexts in order to engage more directly with these concerns [43] and should clarify vaccine roles and responsibilities. In view of the ever-changing vaccination schedule and imminent introduction of two new vaccines in the UK, the rotavirus and flu vaccines [30, 31], such pervasive doubts are likely to be influential and shape future decision making. Health staff play a significant role in managing emotions and, with support, can play a key role in targeting vulnerable groups.

# **Informed Consent**

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

Acknowledgments This study was funded in part through the NHS Lothian Health Service Research Programme and in part through funding from Edinburgh Napier University. Thanks to Patricia McIntosh for facilitating this work and also to the clinical leads and parents, young people and health professionals who participated in this study. We also thank the study steering group for guidance during the conduct of this study.

## Conflict of Interest None

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