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Title

Implementing new consent procedures for the schools-based HPV vaccination programme: a qualitative study

Author names and affiliations

Dr Suzanne Audrey¹

Ms Karen Evans²

Dr Michelle Farr^{1,3}

Joanne Ferrie⁴

Dr Julie Yates⁵

Dr Marion Roderick⁶

Dr Harriet Fisher¹

¹ Population Health Sciences, Bristol Medical School, University of Bristol, Bristol, UK

² Head of School Nursing (Sirona) and Specialist Nursing Services, Bristol and South Gloucestershire, UK

³ The National Institute for Health Research Applied Research Collaboration West (NIHR ARC West) at University Hospitals Bristol NHS Foundation Trust, Bristol, UK

⁴ Screening and Immunisation Manager, Public Health England (PHE) / NHS England and NHS Improvement (NHSEI) – South West, UK

⁵ Lead Consultant for Screening and Immunisation, Public Health England / NHS England and NHS Improvement (NHSEI) – South West, UK

⁶ Consultant Paediatrician, Department of Paediatric Immunology & Infectious Diseases, Bristol Children's Hospital, Bristol, UK

Corresponding author:

Dr Suzanne Audrey

Bristol Medical School, Population Health Sciences

39 Whatley Road

Bristol BS8 2PR

Email: suzanne.audrey@bristol.ac.uk

Abstract (391 words)

Background. The English schools-based human papillomavirus (HPV) programme was offered to young women aged 12-13 years. High coverage was achieved, but variations in uptake across local authorities were apparent. The requirement for written parental consent acted as a barrier to some young women with the potential to exacerbate health inequities.

Objectives. To consider the practicalities and implications of implementing new consent procedures for the schools-based HPV vaccination programme.

Design. Qualitative study.

Settings. Two local authority areas in the south-west of England with relatively lower uptake of the HPV vaccination programme.

Participants. The 53 participants included: the immunisation programme manager, three immunisation nurses, three members of staff in mainstream schools, five members of staff in alternative education provider settings, 19 young women, and 22 parents.

Methods. Digitally recorded, semi-structured interviews were undertaken. All transcripts were fully transcribed and anonymised. Thematic analysis was undertaken, assisted by the Framework approach to data management.

Results. The new consent processes for the HPV vaccination generally worked well. Telephoning parents on the day of the vaccination session was viewed as an acceptable and effective way to reach parents. Adolescent self-consent was rarely undertaken. This can be explained partially by the relative success in gaining parental verbal consent but concerns about disrupting relationships - between healthcare professionals, parents and school staff, or within families – made professionals reluctant to administer the vaccine without some form of parental consent. For young women with special educational needs and disabilities the consent process relied upon close communication between school staff and parents. Other young women whose access to the vaccine, or consent options, were unclear or problematic included: those who were registered with a school but attended an alternative setting for part of their timetable; those educated at home; those in the care of the local authority or living with a foster family, and; young people with gender dysphoria.

Conclusions. Expanding the consent procedures for the schools-based HPV vaccination programme to include parental telephone consent was broadly welcomed by the immunisation nurses, parents, and young women in our study. The requirement for young women to confirm that they had discussed

vaccination with their parents, and that vaccination would not cause difficulties at home, meant adolescent self-consent was rare in this age-group. Greater understanding of the barriers to uptake outside of the mainstream school-based sessions is needed to further address inequalities in uptake.

Main text word count: 6,775

Key words: Adolescent, consent, health inequalities, HPV, qualitative research, vaccines

What is already known about the topic?

- High coverage in the UK's schools-based HPV vaccination programme has been achieved, but variations in uptake across local authorities exist
- The requirement for written parental consent may act as a barrier to vaccination receipt for some young people
- There is a strong preference for written parental consent when administering the HPV vaccine to young adolescents (12/13 years)

What this paper adds

- Widening consent procedures to include telephoning parents for their verbal consent was a practical arrangement welcomed by immunisation nurses, school staff, parents and young women
- Although permitted within the new consent procedures, adolescent self-consent was rare and regarded as problematic for young people aged 12/13 years
- Greater understanding of barriers to vaccination uptake outside of mainstream schools-based sessions is needed to further address inequalities in uptake

INTRODUCTION

The English schools-based human papillomavirus (HPV) programme was initially offered to young women aged 12 to 13 years and has now been expanded to include their male peers. (For this study, we use the World Health Organisation's definition of young people as those aged between 10 and 24 years [1]). High coverage in the programme delivered to young women was achieved, but variations in uptake across local authorities were apparent (range: 70.2-95.8% for the first dose in 2018/19) [2]. In the south-west of England, lower uptake by geographical area, ethnicity and educational setting has been shown [3].

Provided young people demonstrate sufficient understanding of the nature and implications of treatment, often referred to as 'Gillick competence' in the United Kingdom (UK), the legal framework allows young people to be vaccinated without their parents' consent [4]. However, local policies tend to require parental consent for the HPV vaccine to be delivered in the school setting, and may this act as a barrier to receipt of the vaccination for some young people [5,6].

New consent procedures were developed and implemented from 2017 in two local authority areas in the south-west of England with relatively lower uptake [7]. Previously, only young women with written parental consent had been invited to attend the HPV vaccination session. The new procedures allowed all eligible young women to attend the session, irrespective of whether they had returned a consent form signed by a parent or carer. The immunisation team sought verbal parental consent by telephoning parents where written consent had not been received. If parental verbal consent was not achieved, adolescent self-consent was considered for those young women who were assessed as competent.

We undertook a mixed methods evaluation to examine the impact, acceptability and practicality of the new consent procedures [7]. Our statistical analyses showed uptake improved in one of the two local authorities [8]. Further, the additional steps within the procedures addressed some inequalities in uptake by overcoming barriers to vaccination for young women whose families were less likely to respond to paper-based methods of consent [9].

Our previous analysis, examining the acceptability of the new procedures, identified concerns about the ability of younger adolescents to take responsibility for decisions about their healthcare and reluctance to challenge the primacy of parental consent [10]. In this paper, we consider the practicalities of implementing the new consent procedures and implications for schools-based adolescent vaccination programmes.

METHODS

Recruitment

Required approvals for the research activities were provided by the University of Bristol's Faculty of Health Sciences Research Ethics Committee and the National Health Service (NHS) Health Research Authority (references: 57621 & 18/HRA/0367).

The research was undertaken in two local authorities in the south-west of England where the new consent procedures were implemented. School recruitment and data collection took place during the 2017/18 and 2018/19 programme years, before the programme was widened to include males. Mainstream schools in which at least 12 female Year 8 students had not been vaccinated during the 2016/17 programme year were sent information packs about the study and invited to participate. Alternative education providers in the two study areas were also invited to participate: these included schools for young women with special educational needs and disabilities (SEND).

We developed topic guides for interviews with immunisation nurses, mainstream school staff, alternative education providers, parents, and young women. These were adapted to be relevant to each participant group but covered the same key issues: beliefs about the HPV vaccine, views and experiences of the HPV vaccination programme, and opinions about the new consent procedures.

A researcher observed the vaccination session in three of the mainstream schools. Detailed field notes recorded the context and any specific incidents relevant to implementation of the new consent procedures. Initial recruitment for interviews was through participating schools but, as recruitment of sufficient parents and young people proved difficult, we invited relevant community organisations to participate. Depending on individual preferences, young women and parents were interviewed

separately, with their parent/daughter or with a peer/peers. The interviews were conducted by one researcher (HF) and took place within community organisations, schools, homes or workplaces. All participants aged 16 years or older gave written informed consent before participating in the study. For participants aged younger than 16 years, both written parental consent and young women's assent were obtained.

Qualitative analysis

All recordings were transcribed verbatim, checked for accuracy, and anonymised. Thematic analysis [11] was undertaken, assisted by the Framework approach to data management [12]. We used both an inductive and deductive approach to analysis, focusing on our main research questions while identifying issues emerging from the data. Coding of all transcripts was undertaken by one researcher, while a second researcher double-coded a sub-set of 12 transcripts to check for meaning, relevance and reliability, and to agree the coding framework applied to the full set of transcripts. Primary charts were created by extracting sections of text relating to relating to the practicalities of implementing the new consent procedures. Streamlined charts focusing on the practicalities of implementing the new procedures were produced during which key terms and phrases were retained and extraneous text removed, as the process of summarising and analysing the data progressed. Overarching themes were identified within which similarities and differences explored.

RESULTS

Participants

Four of the 15 eligible mainstream schools, and five of the 17 alternative educational settings, consented to take part. Observations of the vaccination sessions took place in three of the mainstream schools. Fifty-three participants took part in digitally recorded, semi-structured interviews. This included interviews with the immunisation programme manager and three immunisation nurses who comprised the permanent team delivering the HPV vaccination programme in the two local authorities, three members of school staff who had involvement with the HPV vaccination programme in the mainstream schools, and a key member of staff from each of the five alternative educational settings in the study. Nineteen young women were interviewed including eight (aged 12 to 13 years) who were recruited at their school and were involved in the new consent procedures, and 11 (aged 13 to 17 years) who were

recruited from community organisations. Eight of the young women were from Black, Asian and minority ethnic groups. All of the young women attended mainstream schools and had been vaccinated against HPV: one had self-consented, six were vaccinated following parental verbal consent gained during the schools-based session, and 12 had returned a signed parental consent form (one of whom had signed the form herself). Interviews were also conducted with 22 parents (21 mothers and one father) in the community setting, of whom five had daughters who participated in the study.

School preparedness for the new consent process

Although schools had been provided with information about the new consent procedures, the immunisation staff indicated that some schools were not fully prepared for inviting all eligible young women to the immunisation session, irrespective of whether they had a parental consent form:

“Some of them [schools] have not read the information that we gave them and emailed to them and gave them hard copies of at every opportunity. They still swear blind that they didn’t know what was happening (laughs)... the consents and what we’re doing, and the fact that we need everybody down, we need to speak to everybody... I think it doesn’t get read. I think people think they’ve been doing it for years, so they don’t need to know.” [Immunisation nurse 3]

Written parental consent

Written parental consent was achieved in the majority in cases but it was also recognised that some parental consent forms would not be returned:

“The vast majority of them [parental consent forms] will come back on or before the deadline and then no matter how much chasing you do with a particular, with a very small group of students thankfully, you will still never get them all returned.” [Mainstream school 2, school staff 1]

A variety of reasons were described as to why parental consent forms were not returned:

“So lots of them will be that they [parents] did sign the form and it’s not made its way back to us. Some will be that they haven’t seen the form at all, it never even made its way home to mum, that she didn’t see the form, and then obviously you do get the parent refusals. It does say on the form that even if it’s a ‘no’ please sign that it’s a ‘no’ and send it back. So, lots of

them will just not send it back at all...and some are just genuinely busy mums that are like ‘Oh my goodness, its sat on the kitchen worktop, I forgot’ [laughs] so it’s just hectic, busy lives and they didn’t send it back in time.” [Immunisation nurse 2]

It was recognised that some households find it more difficult than others to deal with paper-based consent:

“I think the school should provide folders so you could keep all your stuff safe ‘cos some people don’t have the money to buy folders like me.” [Young woman 1, mainstream school 1]

“That difficult-to-get parent could be a parent that’s working three jobs around the week, do you know what I mean, to keep the food on that child’s table, could be someone that’s looking after a sick parent, you know, there’s so much different other reasons.” [School staff, mainstream school 10]

However, in some cases, young people were deliberately avoiding vaccination by not informing their parents that the session was taking place:

“Sometimes its maybe that the kid doesn’t give their parents the letter ‘cos maybe they’ve skimmed it through, they decide that they don’t want it and then they just don’t give it to the parents.” [Young woman 1, community group 6]

The new consent procedures, with additional options, were intended to overcome some of the barriers to vaccination caused by the lack of written parental consent.

Telephone consent

Because of their strong preference for gaining parental consent, the immunisation team attempted to make telephone contact with a parent before considering a young person’s competence for self-consent:

“Initially when we talked about self-consent there were lots of concerns. Certainly, as a team, that’s why we suggested we do parental verbal consents as a step before going to self-consent, so I think we’re quite happy with that.” [Immunisation programme manager]

“The fact that we phone parents on the day is really good because there are a substantial amount of forms, I feel, that are not returned and then when you phone parents they’re very happy still for their child to be immunised.” [Immunisation nurse 1]

School staff, parents and students also appeared satisfied with this arrangement:

“So even though there is a self-consenting process, the school nurses are quite good at phoning the - they’re very good at phoning the parents here and also the girls would generally want to phone the parents as well.” [School staff, mainstream school 10]

“So they were asking me on the phone that if I’m happy for her to have it, I said yes it’s ok...because they said it’s something that is not going to hurt them (laughs) ‘cos I’m just worried that it is something, also like, they say it’s going to be fine.” [Parent 2, community group 5]

“She [mother] didn’t sign the letter, so she had to, the school had to ring her to make sure that she was giving her consent...Because she read the information and she signed it but then she didn’t give it back to me so I couldn’t get it back to school in time.” [Young woman 2, mainstream school 1]

There were initial concerns that the process of telephoning parents would be time consuming, and this was observed during one session in which young women felt they waited too long to receive the vaccine:

“They gave my parents a call but there was a lot of people who were waiting for the parents because they either forgot or they didn’t even give their parents the form and some people just, it was a lot of people on that day and lots of them were like ‘Oh, I want to have it done’ and there weren’t enough adults around, personally I think...I was in a boiling hot room waiting for some vaccination and lots of people were ‘Oh, I really want to have this done quickly and just get this over with. I can’t wait this long. I’m getting even more scared by the minute’” [Young woman 2, mainstream school 9]

“My mum signed it saying yes but I lost my form, so I was waiting for ages like... They did call my mum, but it took a while because they had to call a lot of parents.” [Young woman 5, mainstream school 9]

But the benefits of seeking and gaining telephone consent were seen to outweigh the drawbacks:

“It’s a lot of work and for those schools that you get 30, 40 plus consent forms not coming back in, and you’ve got all those young people with you and you’re trying to make all these phone calls. Yes, it is frustrating but actually the fact that they get a good percentage of those come back as positives, actually that’s good because those young people wouldn’t necessarily have got vaccinated otherwise.” [Immunisation programme manager]

As the programme progressed, some additional funds were allocated to support the process of gaining telephone consent:

“I had a long conversation with our commissioners and we did get a little bit of extra money to allow us, not huge, but to give us a bit more capacity so that we could do it [telephone parents] because we could prove the evidence that it made a significant difference.” [Immunisation programme manager]

The immunisation team also realised that parents would be more likely to answer the telephone if their child was making the telephone call, which may have improved the process:

“Now quite often we will get the young people to phone their parents because they’ll answer their child’s mobile phone. If they have a mobile number that’s unrecognisable most people don’t tend to answer them.” [Immunisation programme manager]

Although there had been concerns about whether the person giving verbal consent was in fact the parent, these were overcome by the nature and content of the telephone conversation.

“They normally talk to you about their child and like ‘Oh it’s been such a heck of a week, I’m so sorry we haven’t managed to do the form’, do you know what I mean? You normally get more of a feedback as to, you know, and you’re also asking them about allergies and their medical history and things so if I did feel that it wasn’t, and they didn’t have an idea, then I obviously would be concerned in that situation, you know, ask more questions as to decipher that they were a parent or a legal guardian.” [Immunisation nurse 1]

Self-consent

In practice, only a small number of young people self-consented to the vaccine:

“I have only probably done only two self-consents, two or three, not very many. I don’t think we’ve done very many as a group of us to be honest because like I said the majority of people return the form or you phone them and get verbal consent and obviously if we can do that, that’s what we’ll aim to do.” [Immunisation nurse 1]

Because of concerns about disrupting relationships - between healthcare professionals, parents and school staff, or within families – the new procedures included asking young people whether they had discussed the vaccine with their parents and whether administering the vaccine without parental consent would cause difficulties at home:

“I would have a little chat with the girl and find out whether her parents are aware of the day and aware of the form and whether they’ve seen it...we always try and get the girls, if that’s the case, to phone their parents and then they normally pick up with the, you know, a known number up there, so we do that, then obviously get consent from the parents. But if we weren’t able to get consent and the girl had shown the parents the consent form and the parents had said ‘Yes, that’s absolutely fine, I think that’s a great idea’ but not yet actually signed it, then I would be happy to go down obviously the questionnaire assessing for Gillick competency. But the parents have to have said that they have seen the form and they’ve had to have chatted to the child about them wanting to have the immunisation for me to be happy to self-consent them.”

[Immunisation nurse 1]

“I think you should call home, that’s what I did, and if they don’t answer...‘Cos my mum didn’t answer but I signed in a form or something to say if mum actually wanted you to have your vaccine, and my mum wanted, so I filled in some forms, answered some questions.” [Young woman 1, mainstream school 1]

But the requirement for young people to say they had discussed the HPV vaccine with their parents, could act as a barrier to vaccination:

“There was a student that I couldn’t get hold of the parents for a consent form, they met the criteria in the PGD [patient group directive] as in being Year 8 to offer them self-consent but they, I didn’t because they said that they hadn’t shown the form to their parents so they didn’t have a feeling as to whether parents would like them to have it or would not, and so in that case

I just gave them the clinic letter and yes, talked to them about clinic options.” [Immunisation nurse 1]

Assessing competence could also lead immunisation nurses to conclude that self-consent was not appropriate:

“We talk through the leaflet with them, talk about what HPV is and we ask them a few questions afterwards, the form that we go through, ask them a few questions about what is the name of the illness we’re trying to protect, what can happen if you do get HPV virus, how many doses will you have. If they can’t answer, even though you’ve just gone through the information with them, we wouldn’t take their self-consent.” [Immunisation nurse 2]

There was one example of a young woman, assessed as competent, who self-consented to the HPV vaccination against her parents’ wishes and this case was discussed in the interviews by all members of the immunisation team:

“On the letter that was sent out it was clearly explained that if they didn’t return the form then we would be in a position to, and if we couldn’t get hold of them, we would ask the child to self-consent if they were able to, and if they were deemed to be competent to do so within the Fraser guidelines. So in fact we had a Year 8 child who presented to the clinic saying that she hadn’t got the form and because she’d forgotten it, but really wanted to have the vaccination, could she still have the vaccination. So we went through everything. We tried phoning mum, we tried phoning dad, she tried phoning mum and dad, we couldn’t get hold of them, she was very aware of what the vaccination was about, we talked to her about it and we felt she was able to give her consent so we went ahead and gave the vaccination on the basis of self-consent and then had a huge complaint from parents because actually they’d signed the form to say no, but the girl hadn’t handed that in. So, it’s difficult in that situation, but actually the girl was obviously very aware of what she, she’d obviously read the letter and knew that, if the form wasn’t returned, she could then go ahead and have the vaccination.” [Immunisation nurse 2]

Although this was perhaps the clearest example of a young woman self-consenting to health care provision, some of the broader implications of going against parents’ wishes were highlighted.

“I think my only concern was that she never came back for a second vaccine and I have checked that and she didn’t come back for a second, so she has got some protection but she hasn’t got full protection... That’s why we always ask, the first question we ask when we’re doing self-consent is do you feel by you having this vaccination it will, I can’t remember the exact wording, but do you feel it will be detrimental to, has discussion taken place why no consent’s been completed by the family, consider delaying the vaccine if this may lead to any disagreements in the family... We just have to be very mindful that we’re the advocate for that young person ‘cos we want them to have it if they really want to have it done, but we don’t want to be causing them harm within that family and breaking those family relationships.” [Immunisation programme manager]

This young woman was correct in anticipating that if she returned the form in which her parents had declined the vaccination on her behalf, she would not receive the vaccine. Although the immunisation team were willing to telephone the parents of students who had not returned a form at all, they did not try to contact the parents of young women who wanted to be vaccinated but whose parents had indicated refusal on the form.

“If we’ve got a no... then we take that as a no. I think if you start keep phoning parents too much, they see that as harassment, so you kind of have to get that balance...we would get a letter to the parents saying I appreciate you said no this time, here’s some more information, if you change your mind here’s the clinic dates, just give us a ring.” [Immunisation programme manager]

In practice, adolescent self-consent became the role of more experienced members of the immunisation team.

“It isn’t something that we tend to do in health very often, so it was quite a ‘Ooh not quite sure about this’... It is the substantive members of staff in the imms team that would do self-consents ‘cos I felt it was important to have a key group of staff that were aware of the procedures and how to do it, rather than make it open to everybody, and I think that works really well.” [Immunisation programme manager]

Self-consent was less common than the team had anticipated, and it was acknowledged that some young women continued to be disadvantaged, in terms of vaccination coverage, by a system that relies on parental consent.

“I had hoped going into it that it would help us get the more vulnerable girls that may not have the vaccine otherwise, unless we caught them in school, and that their parents haven’t sent consent forms back and probably aren’t going to take them to the doctor’s surgery to have it done or bring them to a clinic. However often those vulnerable girls aren’t deemed competent once we go through the assessment with them unfortunately. Not always, obviously, but on the whole. Or they haven’t spoken to parents about it, they’ve got no idea whether mum wants them to have it done or not.” [Immunisation nurse 2]

As the programme progressed, the immunisation team appeared more comfortable with the new consent procedures but there was still some reluctance to highlight the option of self-consent.

“Whether it would cause more problems because they think ‘Oh it doesn’t matter if I haven’t got my consent form because I can self-consent anyway’ and then obviously we have the problems of not everyone is suitable to self-consent, or if you’ve not discussed it with parents then we are not going to take your self-consent. So obviously I’m not for holding information back from them but I don’t know what we would gain from that information being pushed more to them...I wouldn’t want it to get to the point where actually they think ‘Oh I can just sign my form at the time, don’t worry mum, don’t worry about that, I’ll sign it when I get there’ kind of thing, ‘cos obviously it opens up more cans of worms the more self-consent we do [laughs].” [Immunisation nurse 2]

Catch-up clinics and alternatives

Young women who did not receive the vaccine at the school-based session were given information about other options including catch-up clinics run by the immunisation team:

“It is letting the young people know that there are other options, or they can wait ‘til they’re a little bit older, that they actually absolutely can go to their GP [general practice] and have it done, if they want us to talk to parents we’re more than happy to do that, if they want to come

back to a clinic we run a variety of clinics, they can come back to any of those.” [Immunisation programme manager]

‘If she’s a bit anxious that she doesn’t want a vaccine in front of her friends at school, so parents will bring them to clinic where they can feel more relaxed, people aren’t looking at them having it done. Some of them may well be that they didn’t know about the session at school perhaps so, the route where we would normally do self-consent, but they haven’t even spoken to parents about it, they would then bring them to clinic to have it done there. Or they were absent on the day of the school and it’s not one of the schools that we’re going back to perhaps and they would bring them to clinic.” [Immunisation nurse 2]

However, the convenience of the schools-based system for many parents and young people was contrasted with the need to make an appointment for, and take time out to attend, a catch-up clinic:

“We do find that parents, obviously if you give them the option [of a catch-up clinic], if they phone in and book an appointment, they’ll turn up. The ones that you phone to say ‘Oh we noticed your child hasn’t had this, we sent you, you know, I’m not sure whether you want to come to a clinic’ and you kind of make that agreement over the phone, if people are going to DNA (did not attend) it tends to be the ones that you’ve phoned, not the ones that have made the effort to phone in... It’s quite difficult, if people aren’t going to engage. That’s why it is better if we can go through the young people in schools ‘cos parents, if they’re not going to engage, won’t take them anywhere.” [Immunisation programme manager]

Some schools-based ‘mop up’ sessions also took place for young women who were unable to attend the main vaccination session.

“If we had a school where the school had inadvertently booked a school trip and a number of them were on a school trip, which often happens, and they were say 20 young people that were due a vaccine yet weren’t, then we would go back in and do a school-based session. And if there were other young people who were around at the time who for whatever reason didn’t have a consent form or whatever, then they would be welcome to come to that session.” [Immunisation programme manager]

These additional sessions could be helpful for young people with irregular patterns of school attendance:

'The mop up sessions, now I know they're happening, great...there's lots of different times that our children come in, plus then you've got over in (name of unit) which is the behavioural side, they have their own completely individual timetable, so you could just keep missing the same child over and over again.' [School staff 1, alternative educational setting 3]

Alternative educational settings and additional needs

School staff and parents highlighted the importance of close relationships between schools and the parents of young people with SEND. Under these circumstances consent procedures were predominantly seen as a mixture of written and verbal parental consent:

"We all work together to earn the trust and support of the parents, so we'd have a much, we'd have a good chance of speaking to the parents... There's one or two parents who never return anything and then it's just a chase them up job, but because again we're only working with eight students in our class it's not that big a job, so we have the capacity to do that and make sure it all happens." [School staff 1, alternative educational setting 1]

"I always let the school know if I'm not available. Like if I'm on a course, I'll ring the school in the morning or the day before and say 'Look, I'm not available tomorrow, but you can always get hold of my parents or my sister if you need anything'. So, I always let them know in advance if I'm not going to be available... and they are really good with having contact as well. Really, really good." [Parent 1, community group 4]

Parents, school staff, and the immunisation nurses themselves, expressed concerns that nurses who are not based in the schools would be unfamiliar with the complex needs of some young people. Consequently, they would be unwilling or unable to vaccinate without parental consent:

"The special schools that I've seen so far, none of the children I would have thought would have any idea about HPV and be able to talk through back to me about it...they've had serious learning difficulties." [Immunisation nurse 1]

"I think with the type of students we've got I don't think, you know, a nurse would want to make that decision. I don't know [laughs] but I think that would be putting quite a lot of pressure on them as well actually to judge capacity." [School staff 1, alternative educational setting 1]

"I know they're not doing boys yet but my son who has autism probably wouldn't speak to you. He wouldn't. He would just look at you because he's electively mute so, if something is tricky, he just won't talk...he probably would struggle to understand. He probably would just do his 'I'm not going to talk to you', just stand there and look at you so you obviously not be able to assess him...and then he'd come home and tell me 'Some woman tried to stick a needle in me' [laughs]." [Parent 2, community group 4]

But there was also some recognition that not all SEND children were unable to take responsibility for decisions about their health and it is important to support them in this process:

"Maybe we're doing a disservice to the children with special educational needs and autism but...I think you'd have to take it on an individual case because a lot of the children are really bright and switched on and know a lot about a lot of things and it's not saying they wouldn't understand but I think because the extra, the nature of their disability, I think you would have to be a bit more careful with consent." [School staff 1, alternative educational setting 1]

"My worry has always been because I'm autistic that I might be discounted based on my disability and not - basically my biggest fear is having my agency taken away from me based on me being disabled and thus perceived as not being able to make a decision, but I can." [Young woman 2, community group 4]

There were other settings and circumstances that could act as barriers to implementing the HPV vaccination programme. Some young people were registered with a school but attended an alternative setting for part of their timetable:

"Their movement around is quite hard to keep track of. One of the schools we went into, we didn't even realise that actually they had further satellite units...so they're on the roll at [name of pupil referral unit] but actually they're educated in satellite units which are more suitable for their needs." [Immunisation nurse 2]

There was uncertainty about uptake of the vaccine for young people who are educated at home:

"We also send out the consent forms to children who are on home tuition. It's only once have we had a parent bring their child in, who's on home tuition. And I do, I wonder what the uptake is for them. I've no idea whether that parent or any other parent are then thinking 'Right, I'm not going into school so therefore I'll take them to the GP'. I don't know what the uptake is on that."

[School staff 1, alternative educational setting 3]

The consent process for vaccinating young people in the care of the local authority, or living with a foster family, was also considered a barrier to uptake:

"Their foster carers are not allowed to sign it, but actually the foster carer is there with them, talking to them about it. So actually, you know, it should be I think a joint decision, particularly as I say we've had so many problems getting hold of social workers. But we have got a policy in place for that for September so hopefully that might improve...Just that we let social workers know at the beginning of the academic year and get consent at the beginning of the year... 'Cos actually they're the most vulnerable children and so really they're the ones that really need to have it." [Immunisation nurse 3]

The issue of gender identity and HPV vaccination was raised in relation to one student, although this may be partially resolved (at least in relation the HPV vaccine) when the programme is implemented irrespective of gender:

"We've only had the one child that we've kind of had to sort that with. But we haven't got any further than, you know, trying to speak with him and say even though he identifies, he still has all the- but it's really difficult isn't it, because he's going through - plus suffers with anxiety anyway." [School staff 1, alternative educational setting 3]

DISCUSSION

Our results suggest the new consent processes for the HPV vaccination generally worked well. Some schools needed to be reminded that all eligible young women were invited to the vaccination session irrespective of whether they had returned a form with parental consent, illustrating the importance of good communication between school staff and immunisation teams for schools-based vaccination

programmes. But, once the new system became clear, there appeared to be broad agreement that the requirement for written parental consent was a barrier to some young women receiving the vaccine that could be overcome by adjusting the consent procedures.

Implications for practice: Parental verbal consent

Telephoning parents on the day of the vaccination session was viewed as an acceptable and effective way to reach parents and confirm their wishes regarding vaccination of their adolescent daughter. There were initial concerns that the process of telephoning parents would be time consuming, and this was observed during one session. However, additional funds were allocated to support the process of gaining telephone consent and this expenditure was considered worthwhile. The immunisation team also realised that parents would be more likely to answer the telephone if their adolescent daughter made the initial contact. Concerns about whether the person giving verbal consent was the parent could be overcome by the subsequent conversation between the immunisation nurse and parent.

With appropriate resource for immunisation nurse time, this approach could be easily and routinely implemented more widely in different local authorities and across other schools-based adolescent vaccination programmes. Resources could be helpfully targeted to schools known to have lower uptake to ensure maximum capacity of the immunisation team to be able to reach parents without disruption to delivery of the vaccination session.

Implications for practice: Adolescent self-consent

Adolescent self-consent was rarely undertaken. This can be explained partially by the relative success of the immunisation team in gaining parental verbal consent. But other factors, specific to the principle of adolescent self-consent were evident.

Because of concerns about disrupting relationships - between healthcare professionals, parents and school staff, or within families – the new procedures included asking young people whether they had discussed the vaccine with their parents and whether administering the vaccine without parental consent would cause difficulties at home. This could act as a barrier to vaccination but was considered important by the immunisation team. The example of a young woman, assessed as competent, who

self-consented to the HPV vaccination against her parents' wishes was raised by all members of the team. It was perhaps the clearest example of a young woman making her own decision about whether to receive the vaccine, but it may have reinforced the strong preference amongst the immunisation nurses to clarify parental consent. The belief in the primacy of parental consent was also evident in the policy of telephoning parents where no consent form had been returned, but not if a competent young woman said she wanted to receive the vaccine despite her parents returning the form indicating their refusal.

A consent process which adopts a 'young person-centred' approach to obtaining adolescent self-consent could help promote young people's rights to take responsibility for decisions affecting their health. The first step could centre on understanding the young person's wishes as to whether their parents should be contacted, rather than prioritising seeking parental verbal consent. This approach is routinely adopted in the UK for provision of contraception to young people under the age of 16, both in healthcare and school settings. However, the predominant view of the adults and young women we interviewed was to seek some form of parental consent for the HPV vaccine administered to young people aged 12-13 years. A young person-centred approach may be more acceptable for other vaccination programmes delivered to older adolescents, such as the TDap and MenACWY programmes, that are usually given to young people aged 14-15 years.

Implications for practice: Beyond the mainstream

Young women who did not receive the vaccine at the main school-based session were given information about other options including catch-up clinics in the community or requesting the vaccine through GP surgeries, but the convenience of the schools-based system for most parents and young people was contrasted with the need to make an appointment and take time out to attend alternative settings. Some schools-based 'mop up' sessions took place where, for example, timetabling had resulted in a relatively large number of young women unable to attend the main vaccination session. These sessions also offered an additional opportunity to access the vaccine for young women whose parental consent had been unclear at the main session.

For young women with SEND the consent process relied upon close communication between school staff and parents, and predominantly involved a mixture of written and verbal parental consent. Immunisation nurses, parents and school staff highlighted the importance of understanding the complex needs of SEND students, especially in assessing competence. Despite some recognition that not all SEND children were unable to take responsibility for decisions about their health, self-consent appeared to be precluded in practice. Other young women whose access to the vaccine, or consent options, were unclear or problematic included: those who were registered with a school but attended an alternative setting for part of their timetable; those educated at home; those in the care of the local authority or living with a foster family, and; young people with gender dysphoria.

Vaccination uptake outside of the mainstream school-based sessions remained substantially lower than in other settings [8]. This is of concern as these young people are often considered more vulnerable and may experience adverse outcomes across multiple health and social domains. This remains an under-researched area and greater understanding of the barriers to uptake of the HPV vaccination programme for these young women is needed to further improve access and address inequalities in uptake.

Limitations

Our data relate to implementation of new consent procedures in the south-west of England and findings may be less applicable to schools-based vaccination programmes elsewhere. Recruitment of Year 8 students and their parents proved difficult through the school system, although we increased the number of interviewees by recruiting through community organisations. At the time of the research, the HPV vaccine was only being offered to young women and a male perspective is not included in our study.

Conclusions

Expanding the consent procedures for the schools-based HPV vaccination programme to include parental telephone consent proved to be a successful and pragmatic adaptation that was broadly welcomed by the immunisation nurses, parents, and young women in our study. The requirement for young women to confirm that they had discussed vaccination with their parents, and that vaccination

would not cause difficulties at home, meant adolescent self-consent was rare in this age-group. Greater understanding of the barriers to uptake outside of the mainstream school-based sessions is needed to further address inequalities in uptake.

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DECLARATIONS

Ethics approval and consent to participate

The University of Bristol's Faculty of Health Sciences Research Ethics Committee and the National Health Service (NHS) Health Research Authority provided the required approvals (references: 57621 & 18/HRA/0367). All participants aged 16 years or older gave written informed consent before participating in the study. For participants aged younger than 16 years, both parental consent and affirmative young women's assent were required prior to participation.

Availability of data and materials

The datasets generated and analysed during the current study are not publicly available as consent from study participants was not obtained for the use of the data in this way. Anonymised datasets may be made to available to other researchers with permission from the Principal Investigator of the study on reasonable request.

Competing interests

There are no competing interests declared.

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Authors' contributions

SA, KE, JF, JY, MR and HF were involved in the conception and design of the research. SA was principal investigator, contributed to data analysis, and wrote the first draft of the manuscript; HF was study manager, undertook data collection, and contributed to data analysis; MF contributed to data analysis; KE, JY and JF developed and advised on the new consent procedures and the HPV vaccination process; MR and KE advised on local immunisation strategy and assisted with recruitment. All authors contributed to important intellectual content to the manuscript and have given approval of the final version to be submitted.

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