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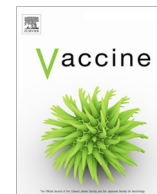
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## Optimising informed consent in school-based adolescent vaccination programmes in England: A multiple methods analysis

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## ABSTRACT

The process of obtaining informed consent for school-based adolescent immunisation provides an opportunity to engage families. However, the fact that parental consent needs to be obtained remotely adds complexity to the process and can have a detrimental effect on vaccine uptake. We conducted a multiple methods analysis to examine the practice of obtaining informed consent in adolescent immunisation programmes. This involved a thematic analysis of consent related data from 39 interviews with immunisation managers and providers collected as part of a 2017 service evaluation of the English adolescent girls' HPV vaccine programme and a descriptive statistical analysis of data from questions related to consent included in a 2017 survey of parents' and adolescents' attitudes to adolescent vaccination. The findings indicated that the non-return of consent forms was a significant logistical challenge for immunisation teams, and some were piloting opt-out consent mechanisms, increasing the proportion of adolescents consenting for their own immunisations, and introducing electronic consent. Communicating vaccine related information to parents and schools and managing uncertainties about obtaining adolescent self-consent for vaccination were the main practical challenges encountered. Survey data showed that parents and adolescents generally agreed on vaccine decisions although only 32% of parents discussed vaccination with their teenager. Parental awareness about the option for adolescents to self-consent for vaccination was limited and adolescents favoured leaving the decision-making to parents. From the interviews and variability of consent forms it was evident that health professionals were not always clear about the best way to manage the consent process. Some were also unfamiliar with self-consent processes and lacked confidence in assessing for 'Gillick competency'. Developing pathways and related interventions to improve the logistics and practice of consent in school-based adolescent immunisation programmes could help improve uptake.

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### 1. Introduction

The number of routine vaccinations offered to adolescents has increased in recent years. In England, three vaccines are offered through schools (HPV, Men ACWY and DTP booster - see [Table 1](#)) [1], which has proved to be effective in achieving high coverage and efficient delivery to larger cohorts in a short time period. The school-based delivery model is used in a wide range of other settings and is being assessed for the United States adolescent immunisation programme [2]. Pupils who are absent can be followed up

in catch-up sessions at schools, community clinics and primary care. Although school-based vaccination is well accepted by parents and students [3], it entails logistical challenges including the return of parental consent forms, which can be a barrier to achieving higher coverage [4,5].

#### 1.1. Informed consent & adolescent immunisation

The World Health Organization (WHO) defines an adolescent as any person aged 10–19 [6] and categorises current vaccination consent practice for 6–17 year olds in three ways [7]:

- (1) Written consent – parent/guardian complete form to give consent

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**Table 1**  
Vaccinations offered routinely to adolescents in England.

Age and gender	Target diseases	Vaccines
Girls aged 12–13 (1st dose school in year 8)*	Cervical cancer caused by human papilloma virus (HPV) types 16 & 18 and genital warts caused by types 6 and 11	HPV Vaccine 2 doses 6–24 months apart
Girls & boys aged 14–15 (School year 9)	Tetanus, diphtheria and polio (a check of MMR status is also made)	Td/IPV (one booster dose) MMR if required (one dose)
	Meningitis caused by serogroups A, C, W and Y	Men ACWY (one dose)

\* The HPV vaccination programme is due to be extended to boys in September 2019.

- (2) Verbal consent – parent/guardian give verbal consent after being informed
- (3) Implied consent – (opt-out) the choice to refuse consent

### 1.1.1. Models for obtaining informed consent

In England, consent for adolescent immunisation programmes is mainly obtained from legal guardians (usually parents). Young people are given a form for their parent to sign and hand back to school before an immunisation session takes place. However, a proportion of consent forms are not returned [8,9], which has implications for vaccine uptake. Achieving high rates of consent is dependent on persistent efforts by schools and immunisation teams to follow up missing forms [4,9,10]. The following resource-intensive strategies have been shown to help improve vaccine uptake: supplementing the distribution of paper consent forms with phone calls to parents, incentivising form returns and offering additional opportunities for catch-up [4,10–13]. Several countries are piloting or using other consent models, such as a streamlined universal consent form which parents complete to indicate approval for all immunisations provided at secondary school [14], and default policies [15]. Initial results indicate that parents prefer opt-in systems [15], and want timely information about vaccines given at different stages during a student's time at school [14].

### 1.1.2. Adolescent self-consent

The age at which adolescents can self-consent for vaccination varies across different contexts and differs from assent, which is when young people are involved in decision-making but do not make an autonomous decision. In England, increased support is being given to the practice of adolescent self-consent, not only for Men ACWY and booster vaccines given to older adolescents (14–16 years) but also for HPV vaccine given from age 12 onwards. In these instances, the role of the health professional is to assess the young person's maturity and understanding of the vaccination programme and judge whether they are 'Gillick competent' i.e. able to consent to vaccination by themselves [16–18]. Previous research suggests that the implementation of adolescent self-consent procedures can be problematic with many nurses tending to delay vaccination rather than vaccinate without parental consent [5,19]. Situations where daughters and parents disagree about the decision to vaccinate can be particularly difficult to manage – especially in school-based programmes, where overriding parents' wishes can have a detrimental effect on the relationship between school and parents [20].

### 1.1.3. Communication & informed consent

It is evident that communication is core to ensuring that parents and adolescents are in a position to make informed decisions about vaccination. Gottvall et al. [21] highlight the importance of adopting a 'relational approach' to obtaining informed consent. This approach recognises that individuals are interdependent and embedded within social contexts (e.g. families and peer groups) which need to be accounted for in communication strategies. This is not straightforward in school-based immunisation programmes,

where health professionals have limited opportunities for face to face interaction with parents and to some extent adolescents. They have to work very closely with schools to promote informed and positive discussion about adolescent immunisation across the school and the home context.

## 2. Aim and methods

This research investigated the process by which consent is obtained in the English school-based adolescent immunisation programme with the aim of understanding existing challenges and identifying pathways for optimising the consent processes. To do this we have combined data from two sources: (1) interviews with immunisation providers/managers and a review of consent forms, (2) analysis of survey data of parents and adolescents in relation to vaccination attitudes. The methods used to collect this data are described in the following sections.

### 2.1. HPV vaccine programme service evaluation

In 2017, we conducted a service evaluation to identify service-related factors which may have contributed to a small decline in HPV vaccine coverage in adolescent girls in England. This decline occurred following the change from a three to a two-dose schedule in 2014 and resulted in completion rates dropping from 86.7% for the three dose course in 2013/14 to 85.1% and 83% for the two-dose course in 2015/16 and 2016/17 respectively [22,23].

The service evaluation involved conducting semi-structured interviews with 39 participants responsible for delivering immunization programmes in six local authorities in the South West (Cornwall, North Somerset, Bristol), North Central Midlands (Lincolnshire, Leicester), and South Central Midlands (Luton). This sampling frame included areas that; (i) delivered both doses of HPV vaccine in school Year 8 and areas that delivered the first dose in Year 8 and the second dose in Year 9. (ii) were geographically and socio-demographically diverse, (iii) had a range of HPV coverage rates, and commissioned different types of providers (e.g. school nurses, and immunization teams). A more detailed description of the methods and overall findings has been published elsewhere [24].

As part of the service evaluation, we also conducted a content evaluation of a sample of adolescent consent forms. We contacted all NHS England local teams in January 2018 (n = 14) requesting copies of the consent forms used by all their service providers in the school-based adolescent vaccination programmes (HPV programme, Men ACWY programme, teenage booster (Td/IPV) programme). We received 36 consent forms for the HPV programme and 35 consent forms for Men ACWY and teenage booster programmes. We extracted data for analysis into Microsoft Excel and reviewed all the consent forms via a content analysis.

### 2.2. Adolescent tracking survey

In 2017 PHE commissioned a survey to explore the attitudes of parents and young people to adolescent vaccines. One objective of

the survey was to understand the decision-making and consent process. Interviews were carried out in 143 randomly selected areas in England, which were stratified by the index of multiple deprivation. The sample of 654 parents and 652 young people was representative of England, within each region, by deprivation, as well as by the age and gender of young people aged 13–15. The majority of interviews with parents and young people took place the same household. Interviews were conducted face-to-face by trained interviewers using Computer Assisted Personal Interviewing. The questions relating to the consent process included: who makes the decision (parent, adolescent or both), whether the immunisation decision was automatic or discussed and explored, and whether there was ever disagreement between the parent and young person.

### 3. Findings

#### 3.1. Logistics of sending and retrieving consent forms

The dissemination and retrieval of consent forms was reported as logistically complex and resource intensive for immunisation teams. The main challenge was handling the non-return of forms, which could not be recorded as ‘positive refusal’ or ‘positive consent’. Form non-return was mainly explained as a bureaucratic failure, although several interviewees suggested that some adolescents may purposely not give forms to their parents. In the absence of returned forms, nurses could not be sure that parents were aware that their daughters have had an offer of HPV vaccine.

*“So, the number of non-returns is our biggest problem. We can deal with refusals because we can evidence those, but what we can’t determine is out of those non-returns, how many people want to have it and how many people don’t.” (NCM, Service provider 2)*

Service providers worked closely with schools to re-issue consent forms and send email or text reminders to non-responders. The active involvement of schools and nominated school staff who supported the programme was described as critical to increase consent form return rates. Other solutions included emailing parents and asking them to print out and return consent forms, parents consenting by emails and setting up electronic consent systems.

One area was piloting an opt-out approach for the school booster and the meningitis vaccines on the basis that most students had already taken up the primary course for these vaccines. Parents were informed that their children would be immunised and asked to contact the immunisation teams if they wanted to opt-out, and students were asked to provide verbal consent during the immunisation session. Service commissioners stated that they were hesitant about extending the opt-out pilot to the HPV vaccine programme, partly because it was a vaccine offered for the first time in adolescence but also because it targeted younger adolescents.

#### 3.2. Communication with parents and adolescents

The primary means of communication between immunisation teams and parents and adolescents was by sending out invitation letters with accompanying consent forms and in some cases an HPV vaccine information leaflet. Some teams complemented this with immunisation information sessions in schools for pupils, but none offered anything similar for parents. Parents were provided with contact details for the immunisation teams so they could ask questions and obtain more information.

*“...we’re [immunisation team] quite happy to take calls at any point, to answer any queries. Because I have had a few [parents]*

*that have been thinking they’re going to say no, but then we’ve had a conversation and it’s actually allayed their fears and it’s been understood more clearly that they actually go ‘okay, yes, we’ll have it’ which is good, because, as I say, we want to encourage them all to have it. So, anything we can do to improve that is time well-spent as far as I’m concerned.” (NCM, Service provider, 4)*

According to service providers the most common parental concern was the perception that if they agreed for their daughter to receive the HPV vaccine, they were indirectly condoning promiscuity. A few service providers also noted a decline in the uptake of the second dose of HPV vaccine in their areas and associated this with increased negative media coverage.

*“There’s a lot of negative press about it, and actually we found this year that quite a few parents have actually withdrawn consent for the second HPV. I think more work needs to be done by Public Health to get that message out that actually, this vaccine is okay, it is a good one to have, it is fine.” (SW, Immunisation team group interview 2)*

Service providers stressed the need for nurses to receive regular training and have access to up to date information materials so that they could be proactive in responding to questions about adolescent immunisation. They also observed that awareness about HPV vaccination had decreased over the last couple of years.

#### 3.3. The practice of obtaining consent

Three approaches to obtaining consent were described: (i) written consent form returned by parents and assent by adolescents during immunisation sessions, (ii) verbal consent from parents via phone calls during sessions, if parental consent forms were not returned, and assent by adolescents, (iii) self-consent in ‘Gillick competent’ adolescents, if parental consent form was not returned and nurses were unable to contact parents during the session. Adolescent self-consent required extra time and resources during immunisation sessions and not all nurses felt confident about assessing for ‘Gillick competency’. Several schools were also not happy about girls aged under 16 being allowed to self-consent.

*“Around the issue of consent in schools, there were some issues flagged this year in some of our schools. We were in [the school] doing the Year 9s and some of them didn’t have consent forms. One of the schools was very unhappy with the fact that we were going to be self-consenting young people.” (SW, Immunisation team group interview 1)*

With regards to self-consent, nurses also needed to negotiate situations where adolescents’ cultural heritage may inhibit their ability to provide self-consent and where parents and adolescents disagree about consent.

*“The difficulty is where you get a cultural mix about who makes decisions in the house /family. This is a learning point of who makes decisions in the family, who gives consent and obviously in certain cultures the young person themselves wouldn’t feel able to give consent to themselves because it would be deemed it’s their parents’ responsibility and they wouldn’t obviously go against a parent’s wishes.” (NCM, Service provider 2)*

In situations where an adolescent did not want to be immunised, nurses would ‘go with the young person’ even if parents had provided consent. In cases where it was evident that the student was fearful, they would book a clinic appointment, and in cases where students provided a clear rationale for not wanting to be immunised, they would respect their wishes and advise them

to get back in contact if they changed their minds. Clinic mop-up sessions were viewed as better places than schools for allaying fears and addressing individual needs.

Managing situations where the young person wanted to be vaccinated but the parents disagreed was more complicated, and the nurses in our sample often advised these students to talk to their parents and then approach the team again when the immunisation team returned for the next set of adolescent vaccinations.

The consent forms content analysis revealed that consent forms varied greatly in their length and content (see [supplementary files](#) for full details). Many included non-specific and open-ended questions about adolescents' medical history, which were not based on contraindications for the vaccine in question. A few forms also asked about pregnancy even though the national guidelines were clear that this is not required and several mentioned that "vaccinations are not normally given in pregnancy", which was inconsistent with ongoing maternal immunisation programmes. Of relevance to vaccine communication, less than half of the forms signposted parents to information sources and many did not encourage parents to discuss the vaccination programme with their teenager.

#### 3.4. Consistency of parental and adolescent decision-making

The tracking survey showed that there was rarely any disagreement between young people and their parents over immunisation decisions. Only five per cent (25/498) of parents reported that they wanted their child to have an immunisation that the young person did not want. Only 1% (5/480) of young people wanted to have an immunisation that their parent preferred them not to have. The majority of parents (70%) said that they automatically (on receipt of the consent form) consented for their child to be immunised, with only a third of young people being involved in this decision-making. If parents had previously seen a leaflet about teenage vaccination (leaflets suggested adolescents should talk to their parents about vaccination), they were more likely to discuss it with their child (39% who had seen at least one leaflet vs 32% overall).

The survey highlighted that only 37% (184/498) of parents whose child had been offered immunisation were aware that their adolescent had the right to make their own decision about immunisation. Only 8% (40/498) of adolescents had self-consented to vaccination with a similar number stating that they would like to give their own permission. Over half of adolescents (58% 278/480) would prefer their parents to decide.

Figures that depict findings from the survey are included as [supplementary files](#).

## 4. Discussion

The process of obtaining informed consent for immunisation provides opportunities for discussion and exchange of information to enhance understanding and strengthen trust in vaccination programmes. The evidence presented in this paper suggests however that logistical (form return) and practical (communicating information, negotiating differences in opinion, and managing uncertainties about self-consent) challenges can have a negative impact on uptake in school-based programmes.

#### 4.1. Logistical challenges and possible solutions

The non-return of consent forms was challenging to manage and of concern to immunisation teams since it could mean that adolescents were not receiving vaccines with significant health benefits. Teams reported that input from school staff helped to achieve high form return rates although not all schools could provide this. Additional follow up by teams on and after the day of

vaccination enhanced uptake but was resource intensive. Some immunisation teams considered other options to improve form return and vaccine uptake including opt-out (although reservations were voiced for the HPV vaccine programme due to age of the target age-group) electronic systems and incentives. The following paragraphs summarise related evidence on these potential solutions.

##### 4.1.1. Opt-out consent models

Research on an opt-out consent model in a low and middle income context indicated that opt-out approaches may help achieve higher vaccine uptake rates, especially in countries like Rwanda, where it is not usual to obtain consent prior to immunisation [25]. Research conducted in the USA however suggests that parents prefer opt-in approaches although they were not unduly opposed to opt-out policies [15]. A two-year service evaluation of the opt-out pilot system for Men ACWY and DTP boosters conducted in one of the evaluation case study areas concluded that: (i) the model was feasible from a legal, financial, and parental acceptance perspective, (ii) that it achieved higher uptake rates in schools over 2 years (e.g. Men ACWY uptake in one school increased by 36% in one school between 2016 and 2018), and (iii) that it should be rolled out more widely in future [26].

##### 4.1.2. Electronic consent systems

The development of electronic systems for obtaining consent for immunisation is gaining momentum in England, although published literature about the effectiveness of these systems remains sparse. Electronic consent systems have been adopted in trials [27] and electronic health interventions are being used to enhance call and recall systems and deliver personalised reminders for vaccination appointments [28–30]. Telephone reminders have also been shown to increase the uptake of vaccinations in school settings [31]. Given the role technological solutions could play in improving vaccine uptake there is a need to promote shared learning by means of communities of practice [32,33] or similar learning forums.

##### 4.1.3. Incentives

Evidence is mixed on the use of incentives to increase rates of parental consent and the return of forms. A cluster randomised feasibility trial [13] which involved the chance to win a £50 shopping voucher in the intervention arm if girls returned consent forms (containing a statement of agreement or refusal) showed that 87% of girls in the intervention arm returned a consent form compared with 67% in the control arm. Previous research on incentives [12,34] was less conclusive, apart from one study which found peer incentives were more effective than individual ones [35]. Classes in which all students returned signed forms received snack coupons. The individual incentives were scholastic credits, school materials (e.g. pencils and folders) and attendance at school social events. These incentives were assessed alongside educational activities which were found most important in motivating students to be vaccinated [36].

#### 4.2. Communication and vaccine-decision making

Findings from the tracking survey showed that parents and adolescents generally agreed on vaccination decisions and that over half of adolescents preferred their parents to lead in the decision-making. Combined with evidence that showed that insufficient information about the HPV vaccine programme amongst parents contributed to lower uptake [37], these findings emphasise the importance of ensuring that parents are well informed about adolescent immunisation.

The qualitative evaluation suggested that awareness about HPV vaccination had declined over the last couple of years and that

wider-reaching promotional activities would be helpful. The review of consent forms also showed that there is a need to ensure that forms refer parents and adolescents to the appropriate information on the vaccine and avoid non-essential questions. Addressing informational needs is however not straightforward, however. Streamlining consent forms by promoting the use of national templates and ensuring that these either reference or are disseminated with information leaflets will help. Although educational programmes have been shown to increase knowledge and improve attitudes towards specific vaccines [38–40], there is limited evidence about which ones work best and whether they result in increased uptake [40,41]. Findings from our research indicated that it can be difficult to find time in school schedules to deliver vaccine education. Creative educational tools like an HPV comic book developed by Katz et al. [39] and a web-based HPV information website [42] may help to overcome these challenges, but these interventions require further evaluation and need to broaden their focus to include other adolescent vaccines.

Evidence about the role of social marketing (a “process that applies traditional marketing principles and techniques to influence target audience behaviours that benefit society as well as the individual” [43] in promoting adolescent immunisation is also limited. Research conducted by Cates et al. [44] assessed the effect of HPV vaccine educational materials targeted at mothers of 11–12 year olds which were designed using social marketing principles. They found that the educational campaign only led to modest increases in vaccine uptake although it did spur parents to ‘take action’ by finding out more about vaccine programmes. Another novel approach for increasing parental and adolescent engagement with immunisation involved forming citizen juries, which were convened separately with adults and young people [45]. Findings from this Australian research indicated that the two groups can form different opinions about immunisation policies, with adolescents supporting compulsory vaccination and parents preferring opt-out systems. Of interest here is that neither of these systems would involve active consent.

#### 4.3. *Managing self-consent*

Obtaining self-consent for immunisation from teenagers has been a longstanding good practice in circumstances where written or verbal consent from the parent is not available at the time of immunisation [16]. Despite this, like Wood et al. [20], we found that health professionals were unfamiliar with the adolescent self-consent processes and lacked confidence in how to assess for ‘Gillick competency’. Furthermore, evidence from the tracking survey suggests that parental awareness of this option is limited and that most young people have not been offered the opportunity to provide self-consent. This is partly explained by other survey results which show that adolescents generally defer to parents in immunisation decision-making, whose views they tend to concur with. This recourse to parental support was also observed by health professionals conducting Meningitis ACWY vaccine catch-up programmes in older adolescents and University students [46].

Independent health care decision-making in adolescence is characterised as something that evolves over time and is dependent on cognitive development, experience and the ability to communicate choices and understand options [47]. Hence, the provision of health care services for young people requires ongoing assessment of their developing autonomy which is not straightforward. There is a need for additional research, training and reflection about how to achieve this in order to help health professionals gain more confidence in supporting adolescents in the process of acquiring the necessary skills and information to make immunisation and other health care-related decisions [48]. Ongoing research aimed at assessing the effectiveness of self-

consent and gaining insights into health professionals’ and adolescents’ experiences of obtaining and providing self-consent will contribute to this agenda [49].

#### 5. **Study limitations**

This study provides insights into challenges and opportunities in the implementation of adolescent immunisation programmes. The use of different methods to gain insights has benefits but there is a clear need for evidence about interventions aimed at improving programme logistics and consent practice. Our findings provide descriptive and quantitative data to support the development of interventions in England and Wales and similar settings. However, we cannot draw any causal inference from the qualitative data although the findings may be transferable in similar settings. The cross-sectional survey results are more generalisable and this type of attitudinal tracking is repeated at regular intervals by Public Health England.

#### 6. **Conclusion**

There is a need to streamline the logistics and enhance the practices involved in communicating information about adolescent vaccination and obtaining consent for adolescents’ participation in school-based immunisation programmes. Most young people rely on parental guidance and resources should be provided to stimulate discussion and enhance immunisation literacy. This may increase adolescents’ capacity to make positive choices as they gain more responsibility for their health. Health professionals also need support in assessing and developing adolescent capacity for making autonomous decisions about vaccination. We have identified pathways that could contribute to improving the effectiveness of the consent process. Many are currently being trialled in small-scale studies in the UK and other countries. To ensure that consenting does not reduce opportunities to vaccinate and lower coverage in adolescent vaccines, we agree with Cooper et al. [41] that there is need for further rigorous evaluation of interventions in order to harness the potential efficiencies of school-based programmes.

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#### **Contributions**

SMJ participated in the design of the study, supported data collection and analyses of the qualitative evaluation, and helped draft the manuscript. TC wrote the manuscript, led the design and analysis of the qualitative study. LL and JY led the design of the survey and the data analysis and wrote the relevant finding section. VS and PP conducted the review of consent forms and wrote the relevant findings section. All authors supported the development of the manuscript and approved the final version.

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### Declaration of Competing Interest

Tracey Chantler, Sadie Bell, and Sandra Mounier-Jack report that they were in receipt of funding from the National Institute of Health Research while conducting this research. Vanessa Saliba, Louise Letley and Joanne Yarwood worked for Public Health England for the duration of this research.

### Appendix A. Supplementary materials

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.vaccine.2019.07.061>.

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