

Does electronic consent improve the logistics and uptake of hpv vaccination in adolescent girls? A mixed methods theory informed evaluation of an intervention

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Abstract

Background Technological solutions may improve the logistics of obtaining parental consent in school-based immunisation programmes. In 2018/19 a health care organisation in London, England, piloted an electronic consent intervention in the adolescent girls' HPV vaccination programme. We conducted a mixed-methods evaluation to examine the usability and acceptability of the intervention and assess its impact on consent form returns and HPV vaccine uptake.

Methods The intervention was implemented in 14 secondary schools in seven South London boroughs. Each e-consent school was matched with a school that used standard paper consent. Matching was based on location and the proportion of students: i. with English as a second language, ii. receiving free school meals (socio-economic status proxy). Consent form return rates and HPV vaccine uptake were compared quantitatively between intervention and matched schools. Data from immunisation session observations (n=7), school feedback forms (n=14), individual and group interviews with implementers (n=8), parents and adolescents (n=12) and a focus group discussion with adolescents was analysed thematically to document user's experiences investigate the implementation of the intervention.

Results HPV vaccination uptake did not differ between e-consent and matched paper consent schools, but timely consent form return was significantly lower in the e-consent schools (73.3% (n=11) vs 91.6% (n=11), p=0.008). The transition to using the system was not straightforward, whilst schools and staff understood the potential benefits, they found it difficult to adapt to new ways of working which removed some level of control from schools. Part of the reason for lower consent form return in e-consent schools was that some parents found the intervention difficult to access and use. Adolescents highlighted the potential for e-consent interventions to by-pass their information needs.

Conclusions The e-consent intervention did not improve consent form return or vaccine uptake due to challenges encountered in transitioning to a new way of working. New technologies require embedding before they become incorporated in everyday practice. The intervention is undergoing further iterative development to improve its usability, ensure schools are appropriately involved and adolescents receive tailored immunisation information. A re-evaluation once stakeholders are accustomed to e-consent may be required to understand its impact.

Background

Vaccination against human papilloma virus (HPV) provides long-term protection against cervical and other cancers and genital warts (1, 2). In England HPV vaccination (2 doses 6 months apart) is offered to 12-14 year olds in the school-based immunisation programme; a delivery model that is widely accepted by parents and students (3). There are logistical challenges associated with this model related to obtaining parental consent prior to adolescent immunisation. Students are typically given a paper consent form that their parents/legal guardians need to sign. The passage of the form from teachers to students to parents and back again can result in low rates of form return and have a detrimental effect on vaccine uptake (4-7). Follow-up by school staff and immunisation teams can help improve uptake but is resource intensive (8, 9). In the context of the drive towards a "paperless NHS" (10), there is increasing interest in the potential for technological solutions such as electronic consent (e-consent) to streamline this process. Evidence from evaluations of adolescent immunisation programmes using e-consent is required to inform programme planning. This paper documents results from a mixed-methods theory-informed evaluation of an e-consent intervention. We evaluated the usability and acceptability of the test of concept intervention for school-based immunisations from the perspective of parents and adolescents, health professionals and schools, and assessed its impact on consent form returns and HPV vaccine uptake.

The electronic consent intervention

The e-consent intervention was developed by Hounslow and Richmond Community Healthcare NHS Trust with the support of a software development company in 2017/18 and used as a test of concept in their adolescent girls' vaccination programme in June/July 2018. HRCH is responsible for administering this vaccination programme in secondary schools across eight boroughs in South London. At the time of the study four immunisation teams consisting of nurses and administrative assistants covered two boroughs each and were based in offices within these areas.

The e-consent intervention comprised an online portal with an e-consent form and a data platform and related implementation procedures (Figure 1). Functionally the intervention aimed to: 1) provide parents with access to an online portal (via a weblink) where they could find out more about the vaccination programme and type in basic health and personal information about their adolescent and state whether they agreed to or declined HPV vaccination; 2) provide nurses with electronic access to this form through the data platform to facilitate screening and enable them to update vaccination records in real-time during immunisation sessions; 3) enable automatic updating of central vaccination record databases. Parts of the online portal and data platform (specifically those relating to points 2 & 3) were not fully functioning before the intervention was first used in June 2018. Hence modifications had to be made to the way nurses screened students' information and consent forms before and during immunisation sessions. Figure 1 differentiates what happened in Year 1: June/July 2018 and in Year 2: June/July 2019 (blue text). In this evaluation we focused primarily on Year 1, especially in the quantitative measurement of outcomes and impacts, however we were also able to capture how Year 1 experience informed adaptations to the intervention before it was reused in Year 2.

Methods

Study design

We used a mixed-methods theory-informed study design to evaluate the e-consent intervention its implementation. Before the study started the lead implementers and evaluators developed a 'Theory of Change' (ToC) for the intervention (Figure 2), which served as an evaluation framework. The ToC depicts the inputs planned for operationalising the intervention, implementation activities, and the pathways expected to lead to defined outputs, outcomes and impact.

Quantitative methods were used to assess whether the intervention increased consent form return and the uptake of the first dose of HPV vaccine in adolescent girls in June/July 2018. The steps involved in implementing the e-consent system, people's experiences of these, the interactions between inputs, activities, pathways and outputs, outcomes and impacts were investigated using qualitative methods between June 2018-July 2019.

School selection

The e-consent intervention was introduced as part of the adolescent girls' HPV vaccination programme in 14 secondary schools in seven South London boroughs in June 2018. The selection of e-consent schools was purposive with the aim of including schools that differed in terms of denomination (private, state, grammar), type (mixed, single sex), socio demographic, size, vaccination uptake, and level of support to the programme.

Each e-consent school was matched with a paper consent school from the same borough. Schools were divided into low, medium or high in terms of the proportion of pupils receiving free school meals and the proportion of pupils with English as

an additional language, based on national tertiles. Each e-consent school was matched, as closely as possible, to a paper consent school in the same tertile for both characteristics.

Quantitative methods & analysis

Data collection

At each vaccination session nurses completed a handwritten “tally sheet”, with details of the consents received prior to the session, any consents obtained on the day, any absences and the number of vaccinations given. These tally sheets were completed for e-consent and paper consent schools.

In addition, for e-consent schools, we extracted the name of the school, date and time of consent form completion and type of consent (agreement by parent or adolescent self-consent or decline) for each consent form in the e-consent system. No identifiable information was accessed. This information was combined with tally sheet data, which was manually transcribed into MS Excel. Where there were discrepancies or missing data this was checked with the immunisation teams and in the case of the e-consent schools the e-consent data was used in preference to the tally sheet data.

Data analysis

Characteristics of the paper and e-consent schools were described in terms of proportion of pupils receiving free school meals, speaking English as an additional language, ethnicity and characteristics of the schools (religious affiliation and state/private funded), using data from the Office of National Statistics. (REF: <https://www.gov.uk/government/statistics/schools-pupils-and-their-characteristics-january-2018>).

For both paper and e-consent schools, we calculated: (i) the proportion of the pupils for whom a consent form had not been returned prior to the vaccination session, (ii) the proportion of pupils vaccinated at the planned session and (iii) the proportion of pupils for whom a “yes” consent was received (prior to or on the day of the planned vaccination session).

We compared e-consent schools with paper consent schools in terms of timely form return, outcome of consent and vaccination uptake using Kruskal Wallis tests for statistical significance. Where data was missing from a school that school and its matched pair were excluded from the analysis. All analyses were done in MS Excel and Stata 15.

Qualitative methods & analysis

Data collection

Data was collected over two time periods: June-December 2018 and June-July 2019. The first period coincided with and followed the implementation of the first year of intervention, and the second period occurred during the second year of

implementation in a subset of schools.

June-July 2018

Observations of e-consent school HPV immunisation sessions

Members of the evaluation team (RC, TC, SMJ) accompanied immunisation teams during seven e-consent school HPV immunisation sessions to obtain a contextual understanding of the implementation of the intervention. The evaluators documented (field notes) what worked well and what if any problem-solving was applied during sessions.

School feedback forms from paper and e-consent schools

School staff involved in organising immunisation sessions were asked to complete a feedback form after the HPV immunisation sessions (see Additional file 1). They included questions about the organisation of immunisation sessions and the usability and acceptability of e-consent and paper consent. Seven e-consent and seven paper consent schools completed these forms.

Individual and peer group interviews with HRCH staff

These semi-structured interviews (SSIs) involved HRCH staff who were responsible for implementing the intervention. The programme manager was interviewed individually, the two data specialists together and the four immunisation teams in peer-groups of 2-4 participants (12 interviewees) at their respective offices. In total 15 members of staff took part in interviews which lasted about one hour.

Interviews with parents and adolescents from e-consent schools

These SSIs involved parents and adolescents who had used the e-consent system and took place after the HPV immunisation sessions (Sept-Nov 2018). Parents/legal guardians were asked to indicate their willingness to be contacted by researchers in the e-consent form (ticked a statement). A sample of those who responded positively were invited to take part in an interview to discuss their experience of using the e-consent system. A total of 12 interviews were conducted, nine with families who had accepted the HPV vaccination and three with families who had declined it. Four of the interviews were conducted face to face in family homes, seven by telephone, and one by Skype video. Adolescents participated in five of the interviews.

June-July 2019

The analysis of data collected in 2018 informed revisions to the e-consent intervention before it was implemented again in some schools as part of the 2018/19 HPV vaccine programme. Additional data was collected in June-July 2019. This consisted of two group interviews with HRCH staff (one with nine and the other with five members of staff) and one focus group discussion (FGD) with eight adolescent girls, who had recently received an HPV vaccine at an e-consent school. The FGD was facilitated by (TC/SB) and took place in a quiet room at the school during lunchtime.

The topics covered in the staff, parent and adolescent SSIs and adolescent FGD are summarised in Text Box 1 (Topic guides provided in Additional File 2).

Text box 1: Topics covered in interview

Staff interviews

- Experience of managing the administration of the school-based vaccination programme
- Experience of obtaining consent in school-based vaccination programme
- Acceptability and usability of the e-consent system
- Interaction between schools and immunisation teams
- Adolescent self-consent
- Reflections on use of the e-consent system

Parent and adolescent interviews

- Views on adolescent vaccination
- Understanding of adolescent vaccination
- Experience of providing consent for the HPV vaccine
- Acceptability and usability of the e-consent system
- Teenagers experience of immunisation in school
- Vaccine programme communication
- Views on adolescent self-consent

Data analysis

The interviews and FGD were audio recorded with participant's permission and transcribed anonymously. Transcripts, observational field notes and school feedback forms were downloaded into a qualitative data analysis management software programme (NVivo 12). We adopted a thematic analytical approach which combined semi-deductive mapping of data to the 'input', 'activities', 'pathways', 'outputs', 'outcomes' and 'impacts' depicted in the ToC and inductive open coding to capture emerging themes(11). We sought to account for the interdependence of ToC categories and real-life experience of managing organisational change, which do not always progress from inputs – impacts in a seamless linear manner.

Results

Quantitative

Participants

Twenty-eight schools (14 e-consent and 14 paper consent schools) comprising 3219 girls (1733 in paper consent and 1486 in e-consent schools) were included in the study. Of those schools, 26 were state and 2 were private schools. Twenty-one of the schools had no religious affiliation, 3 were Roman Catholic (all paper consent), 3 Church of England (2 e-consent, 1 paper consent) and 1 was another Christian faith school (paper consent).

The proportion of pupils eligible for free school meals, with English as an additional language and students' ethnicity profile was similar between the e-consent and paper consent schools (Table 1).

Return of consent forms ahead of session

Overall 83% of consent forms (paper or e-consent) were returned prior to the vaccination session. However, compared with paper schools timely (prior to the planned session) return was lower in the e-consent schools (73.3% (n=11) vs 91.6% (n=11), $p=0.008$). We could only measure this difference in 22 matched schools.

Outcome of consent

There was no statistically significant difference in the proportion of pupils for whom a "yes" consent was received (prior to or on the day of the session) between the paper (n=14) and e-consent (n=14) schools (85% in e-consent schools, 83% in paper consent schools, $p=0.89$).

Vaccination uptake

There was no statistically significant difference in the proportion of pupils that were vaccinated at the scheduled vaccination session between the paper (n=14) and e-consent (n=14) schools (80.6% vs 81.3%, $p=0.93$). These figures did not include those who were absent on the day and vaccinated later. The final vaccine uptake across all the schools was over 86%.

Qualitative

Thematic mapping and participants

The results of the ToC thematic analytical mapping are presented under relevant headings ('input', 'activities', 'pathways', 'outputs', 'outcomes') followed by an overarching theme on managing change. In this analysis we drew on data collected from participants between June-Dec 2018 (seven observations of immunisation sessions in e-consent schools, 14 school (seven e-consent, seven paper) feedback forms, four immunisation team interviews, 12 interviews with parents/adolescents who used the intervention) and June-July 2019 (two group interviews with HRCH staff, one FGD with eight adolescent girls from an e-consent school).

Inputs

Resources and Training

There was a 'buzz' about the development of the e-consent intervention and its potential to streamline the consent process and facilitate safer data collection. Programme commissioners had provided financial support and the HRCT wanted to pilot it during the 2017/18 HPV vaccine programme. Immunisation team members were positive but expressed some reservations about the implications for practice (e.g. not able to review paper consent forms prior to immunisation) and the speed of change. Due to tight deadlines only one main orientation/training session took place before the e-consent intervention was introduced, which meant that the bulk of learning happened on the job.

"I think as well, it was probably four days before our first session, we didn't know what we were doing. ...so I do feel we are running before we can walk." (Immunisation Team 2)

Intervention not fully operational

The data platform component of the online portal was not operational prior to implementation. Parents were able to access and complete the e-consent form, but the immunisation teams could not use the portal's data platform to review student's consent forms or upload data during immunisation sessions. Instead large (A3) paper sheets with information about who had provided consent were provided by the data management team for nurses to record immunisation details and subsequently upload to recording systems. The sheets were difficult to decipher during busy sessions and nurses were less able to prepare cohort figures and tally sheets in advance.

"It was an anti-climax not being able to use the laptops and still have a paper sheet in front of me." (Immunisation Team 4)

Mobilizing and resourcing schools

There was limited time to engage with schools prior to the start of the vaccination programme, although all e-consent implementing schools were provided guidance on how to disseminate the weblink. A few schools declined to use the intervention due to concerns about barriers to electronic communication with parents (e.g. lack of email addresses). These concerns were more pronounced in city centre schools which served many families for whom English was not their first language.

School immunisation liaison staff (school-link) reported a 'loss of control' associated with the change in their access to consent forms. They could no longer see 'who had said yes, and who had said no', which restricted their ability to follow-up unreturned forms. Paper-consent schools could monitor this directly by counting forms, but with e-consent schools immunisation teams had to check parental responses and tell schools which families had not replied.

"Because it is all down to the link person, because if that link person is more pro e-things, they will just go 'Oh great, you saved my life, no more paperwork', but if that link person is kind of old fashioned, 'I want my pen and paper, I want my hard copy'". (Immunisation Team 3)

Activities

Dissemination of the online e-consent portal weblink to parents

E-consent schools used different electronic means (parent mail, email, school website, newsletters, letters) to send parents the weblink to the online portal. Blanket reminders were mainly sent electronically, unless immunisation teams provided schools with details of non-responders. In this case follow-up could be more targeted and involve text messages and phone calls as well as emails. One school used a translator to engage parents who did not understand the consent process due to language barriers. Another school was not willing to send out emails and asked the immunisation team to provide them with printed letters referring to the weblink to send to parents.

Of the seven e-consent schools who completed the feedback form, four were positive about the intervention and how it had been implemented stating that it had reduced their workload. Another school was mainly positive but noted that some parents had found the e-consent form difficult to access, another reported that their parent cohort had found the system very difficult to access and use, and the last school was the one who had used letters to disseminate the weblink.

Pathways

Navigating the e-consent form and related information

The e-consent form included links to an HPV vaccination leaflet. However, none of the interviewees had downloaded or read this leaflet for the following reasons: accessed information elsewhere, already sufficiently informed, older daughter vaccinated, positive about vaccination.

Proactive information seeking was more common in families who were vaccine hesitant. Parents who were more confident about vaccines restricted their information seeking to NHS sources but suggested that a 'road map' to adolescent vaccination could be useful since they lacked information about this.

Adolescents reported a variety of information seeking behaviours. Some just accepted HPV vaccination as '*something that needs to be done*' and felt reassured that it was recommended by the NHS: "*I think because it's like by the NHS - it kind of gives it validation.*" (Adolescent 9 - Yes). Others wanted the HPV vaccine leaflet to include more information about HPV and related health risks and vaccine side-effects, so that they did not panic if they experienced any of these.

In the FGD students expressed a preference for paper leaflets and discussed how the e-consent could bypass them: "*... because like if it's emailed, like your mum doesn't have to share it with you. And like if I have something done like an injection, I'd like to know what's going on and when. But like she filled out the form without like telling me, so like if they'd been given out in school then I could have read it and see what's happening.*"

Parental and adolescent HPV vaccine decision-making processes

Interviews with parents and adolescents suggested that communication about vaccine decision-making varied between - *very limited discussion - to a heads up as what to expect - to parents offering to answer questions - to more in-depth discussions*. Some parents thought they did not need to talk to their daughters in detail since it was their responsibility to decide and others did not want to talk too much in case this induced anxiety, particularly if their daughters were needle phobic.

The 'heads up' approach was about making sure adolescent knew what to expect and this exchange usually occurred shortly prior to the scheduled immunisation session. Offering to answer questions was part of this and depended mainly on the adolescents' desire to find out more. More in-depth discussions involved parents and adolescents discussing the vaccine programme, sometimes looking for more information and deciding whether to take part.

"I had done my own research and we'd looked at it together...so, we talked about what it was, why it was important." (Parent 10 – declined vaccination)

Adolescent FGD participants reflected on the locus of responsibility for vaccine decision-making and concurred that they would like their parents to decide. Where they differed was whether they wanted to discuss the vaccination with their parent.

"I wouldn't like to be given the option to like not to have the injection done...so I'm kind of glad that my mum just decided, but I would have liked her to talk it through with me..." (FGD participant)

Using the e-consent intervention

The parents who were interviewed found the system easy to use and usually completed the form as soon as they received it. A few parents would have liked an email confirmation after they had completed the e-consent form.

"I thought it was very easy. I think you're probably going to get more responses that way from parents in this day and age. However, the downside is obviously you may not get that chance to discuss it. (Parent 5 – Yes)

According to feedback from nurses and schools not all parents found the intervention easy to access or use with language barriers accounting for some difficulties. The key issue however related to the receipt and use of the online portal weblink. In some cases, students told nurses that their parents had not signed up for the school parent mail system and therefore did not receive the weblink. Nurses also received a significant number of calls from parents asking for guidance; some reported that the weblink would not open or that webpages would freeze making it difficult to complete and submit the form. Other parents had limited access to the internet or were less confident about using technology. During an immunisation session one student stated: *"my dad said I should have the vaccine, but he did not understand the whole google business about it"*. In some instances, the weblink closed a few days prior to an immunisation session to give immunisation teams time to screen student information prior to sessions. Some parents who had missed the last sign-up date sent notes to school on the session date to confirm their consent/non-consent for vaccination.

Outputs

Nurses access to e-consent forms and student information

The immunisation sessions at e-consent schools were affected by the low return of consent forms and nurses not being able to access information about students and their consent status electronically during sessions. Instead they had to review student details and their consent status on A3 paper lists created by the HRCH data management team. The nurses found this more difficult than reviewing individual paper consent forms in the way they were used to. They understood that this was an interim measure and were looking forward to the opportunity to be able to access and input real-time data electronically in the future.

The low return of consent forms in e-consent schools resulted in administrative and logistical challenges (e.g. predicting cohort numbers and tallying consents received before and during sessions). To manage these challenges immunisation teams increased the number of nurses and administrative assistants who attended e-consent school immunisation sessions.

The lower return of consent forms in e-consent schools resulted in nurses reporting that they had to contact more parents than usual during immunisation sessions to obtain verbal consent. This had implications for the nurses' workload distribution and the length of sessions.

"...we had 80 consent forms outstanding at a big school. But, normally, if you only have a couple it's fine. It meant us was making calls all morning, it took a nurse out of immunising to be able to do that, so that did have a big impact."
(Immunisation Team 2)

Conducting phone calls during sessions was not straightforward. Firstly, nurses had to rely on students (if they had phones with them) or staff to help them access correct contact details. Secondly, immunisations sessions were busy and noisy which impeded communication and privacy. Thirdly, it was not always possible to reach parents who were at work or out of the house during day-time hours. If parents were uncontactable the nurses assessed if students who wanted to be vaccinated had sufficient maturity and intelligence to understand and appraise the nature and implications of the proposed vaccination(12, 13). This process was time-consuming and not all nurses felt comfortable about vaccinating without verbal or written parent permission.

Transition: adapting to change and iterative development

The initial 'buzz' about the e-consent intervention decreased over time amongst some staff within the four immunisation teams. Whilst some staff remained positive and receptive to the implementation coordinators enthusiasm and vision, others expressed a sense of half-heartedness about having to adapt quickly from a known way of obtaining consent, albeit with flaws (e.g. cost of paper, mileage clocked up in collection paper consent forms from schools), to a new technology enabled way with some functional limitations in Year 1 (see Figure 1).

"Change is always difficult isn't it...it was the initial meetings that we went to, and nothing seemed to be concrete. Everything was like, "Well, we'll look into that." Time, as we all know, goes so quickly. It didn't feel prepared, it felt really rushed..."
(Immunisation Team 2)

In the HRCH staff group interviews conducted in July 2019 members of the immunisation teams reflected on lessons learnt from their experience of transitioning to a 'brand new way of working' over the past year. Key learning points from an internal organisational perspective were: (i) adopt right pace of progress when introducing new interventions with have several components, (ii) be clear about which part of a multi-component intervention is being piloted and implemented (e.g. in Year 1

it was primarily about the e-consent form), (iii) importance of timely communication, quick thinking, and flexibility when things do not quite go to plan.

In terms of school engagement HRCH staff emphasised the importance of close collaboration with schools to establish appropriate means of consent in different educational and social contexts. The right balance of responsibility between schools and immunisation teams needs to be negotiated to maintain positive working relationships and ensure that adolescents can access essential vaccines.

"I would also say the idea of just changing to e-consent... schools need different things... it is really important to work with the school and a make sure that they are happy with everything and it suits that school, because some schools it might just not suit right now. It might suit them in a couple of years, but right now it just doesn't work." (HRCH immunisers group interview, July 2019)

HRCH made several changes to the implementation of the e-consent intervention in Year 2 (2018/19) based on the Year 1 (2017/18) experience and evaluation findings that were shared at several stages during the study (Text Box 2). These changes mainly related to the inputs, activities and pathways parts of the ToC and distribution of the e-consent form and related information. The data platform component of the intervention was undergoing further iterative development as part of the Year 2 implementation in 22 schools across South London.

Text Box 2: E-consent intervention implementation changes between Yr1 and Yr2

- Taking more time to engage (emails, phone calls and meetings) with schools in preparations to find the right level of involvement
- Ensuring students receive a paper copy of the HPV adolescent programme leaflet produced by Public Health England in addition to information provided in the e-consent form
- Pushing more for assemblies and contact with adolescent girls prior to the immunisation sessions
- Providing ongoing training and mentoring of immunisation teams on use of the intervention

Discussion

The e-consent intervention and related implementation strategy had no detected impact on vaccine uptake and did not improve the return rate of consent forms in its first year of implementation. This could be interpreted as a negative result, however this would fail to account for the embedding process required before new technologies become (or do not become) routinely incorporated in the everyday practice of individuals and groups(14). Our findings indicate that the transition from paper to e-consent was not straightforward, and that staff and schools, though mainly open to change, took time to adapt. The transition was hampered by the reduced functionality of the IT capability (intervention fidelity), limited staff training and engagement of schools. It is likely that this e-consent intervention would need to be used for more than one year to achieve any benefits to process efficiency and vaccine uptake.

In the 'Normalisation Process Theory' (NPT) it is argued that practices become routinely embedded or normalized as the result of people working, individually and collectively, to enact them. Enactment is promoted or inhibited through the operation of four mechanisms; coherence (sense-making), cognitive participation (individual buy-in), collective action (joint effort) and reflexive monitoring (user appraisal)(15).

Sense-making requires users to have a shared understanding concerning the purpose of an intervention, their responsibilities in its implementation, its potential benefits and the differences to existing practice (16). In our study, immunisation teams recognised the potential value of the intervention but were not clear about their specific responsibilities. This was due to the swift implementation and the fact that parts of the intervention were not operational from the start. The latter was discouraging for HRCH staff, who had hoped the intervention would help them input immunisation data during sessions.

From the school perspective the main change in role they had to make sense of related to their degree of involvement in and control for consent forms collection and follow-up.

User buy-in is defined in NPT as user's agreement to try out a new way of completing a task and their willingness to drive and sustain the implementation of a new intervention (15). HRCH coordinators encouragement, ability to adapt when problems arose was critical to sustaining momentum throughout the implementation phase. Most schools bought into the concept of technology-enabled consent yet their willingness to sustain this change could have benefited from earlier collaboration between immunisation teams, head teachers, and liaison staff. Parents and student's engagement with the e-consent intervention was variable. Parent interviewees accessed the online portal and were able to complete and submit the e-consent form with ease. The significant difference in consent form return rate between e-consent and paper consent schools (73.3% (n=11) vs 91.6% (n=11), p=0.008) response rate (73.3%) indicated however that this was not the case for all parents. Of additional concern was that the e-consent intervention inadvertently bypassed some adolescents' information needs and related opportunity to talk to their parents about HPV vaccination. This was an important finding that was acted on by HRCH in Year 2. The solution was to ensure that students still receive a paper NHS information leaflets about the adolescent HPV vaccination programme in school, where possible as part of interactive sessions with nurses and teachers. Moving forward there is scope to co-develop additional multi-media information materials with adolescents. This could help answer teenager's questions in adolescent friendly language using communication channels they trust(17).

In our study collective action with regards to the intervention was evidenced when immunisation teams and schools worked together to make the follow-up of e-consent form non-response more targeted. Reflexive monitoring occurred at different stages of the intervention implementation, partly facilitated by this real-time evaluation. A limitation of these activities was the lack of a forum for face to face interactions between different user's (HRCH staff, Parents, school liaison staff and adolescents). The evaluators shared their analysis of parental and adolescent data with implementers confidentially, but more co-production activities need to be integrated in the subsequent evaluation of this intervention. There is an increasing interest in how co-production activities and related theory complement and extend NPT (18, 19).

The implementation coordinators were reassured that despite the introduction of a significant change to practice HPV vaccine uptake had not declined. In an urban conglomerate where achieving high vaccine uptake is inherently difficult this was a good achievement. The critical issue for them was to continue to improve the intervention to ensure it was user-friendly, efficient and achieved the goal of simplifying consent logistics. There was a recognition that one size does not fit all and that in some schools, paper and e-consent systems may need to run side by side. In this instance flexibility gains will need to be balanced against a potential increase in burden resulting from running two parallel systems. HRCH received a Public Sector Paperless Award in 2019 in recognition of their efforts in pioneering digital consent approaches (20).

Implications for policy

There is a need to streamline consent processes for adolescent immunisation and ensure that parents and adolescents are fully informed about these preventative measures. Electronic consent could be an effective option to achieve this. However, it needs to be tailored to specific contexts, and parents, schools and adolescents need to provide input in the development, implementation and evaluation of such technological interventions. Evaluations also need to factor in the time needed for new working practices to be fully integrated. Our experience suggests that to gain a complete and accurate assessment of the impact of new interventions evaluations need collect data over more than one cycle of implementation. Finally our findings suggests that parents and adolescents would value more information about adolescent vaccination. School-based immunisation programmes could be a platform for helping young people assume more responsibility for their own health with parental support(21).

Study strengths and limitations

There is limited published evidence on this subject hence this study addresses a gap in the literature. It also shows how real-time evaluation can support the iterative and reflexive development of interventions which is essential for their longer-term integration. Formal randomised controlled intervention trials with baseline and end line data points could be conducted subsequently in new areas to test for effectiveness. Key limitations include the lack of interviews with school staff to complement the feedback forms and not being able to access and interview parents who found the intervention more challenging to use.

Conclusions

Obtaining electronic consent from parents could help streamline school-based adolescent immunisation programmes. This study demonstrates the value of theory-informed real-time evaluation in the iterative development of interventions. The results showed no impact, positive or negative, of an e-consent intervention on the delivery of the HPV vaccination programme. Hence at this stage we would advise caution against dismissing the intervention because it did not improve consent form return rates in a single year. The reasons for this are multi-faceted and are being addressed in improvements to the intervention and the implementation strategy. A re-evaluation in schools using the e-consent intervention for several years in a row may be required to truly understand its impact. Given that the change associated with the transition from paper to e-consent was not straightforward the fact that HPV vaccine uptake remained stable was encouraging. Introducing change that affects different actors requires all stakeholders to understand, buy in and work together in refining and co-producing complex behavioural interventions.

Abbreviations

FGDs:	Focus group discussions
HPV:	Human Papilloma Virus
HRCT:	Hounslow and Richmond Community Health Trust
NPT	Normalisation Process Theory
ToC:	Theory of Change
SSI's:	Semi-structured interviews

Declarations

Ethics approval and consent to participate

The research published in this manuscript was approved by the PHE Research Support & Governance Office (Ref: NR0131) and the London School of Hygiene and Tropical Medicine Observational/Interventions Research Ethics Committee (Ref: 15839). Participants who took part in the qualitative component of this research received study information letters and were provided the opportunity to ask questions before they agreed to take part. Written informed consent was obtained from all research participants prior to interviews (individual, peer-group, parent adolescent dyad) and the FGD. For the latter parental and adolescent informed consent was obtained and school or immunisation staff were not present during the discussion. All participants were told that their participation was voluntary, and their data was stored and presented in a manner that seeks to protect their confidentiality.

Consent for publication

Not applicable

Availability of data and materials

Data collection tools and some anonymised data are available on request via the LSHTM public repository.

Competing interests

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. Michael Edelstein, Rosie Cooper and Ellen Pringle worked for Public Health England for the duration of this research.

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Authors' contributions

TC and SMJ designed the study with input from SR, ET, HN, ME and RC. EP led the quantitative data analysis with support from RC and SB. TC collected and led the analysis of the qualitative data with support from SB. All authors discussed the preliminary findings and contributed to and critically reviewed the manuscript.

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Table 1

Table 1: Characteristics of paper and e-consent schools ^[1] ^[2]

	Paper consent schools (n=13)	E-consent schools (n=13)	P-value*
% (range) of children eligible for free school meals	17.3 (1.5-52.1)	17.3 (1.5-43.2)	0.84
% (range) of children with English as additional language	30.9 (5.5-53.6)	32.4 (9.1-59.2)	0.72
% (range) of children of white British ethnicity	30.9 (1.5-69.6)	34.6 (6.3-65.7)	0.63

*Refers to comparison of each characteristic using Kruskal-Wallis test

[1] Characteristics information was not available for the two private schools

[2] Data from Schools, pupils and their characteristics: January 2018, Department of Education.

Figures

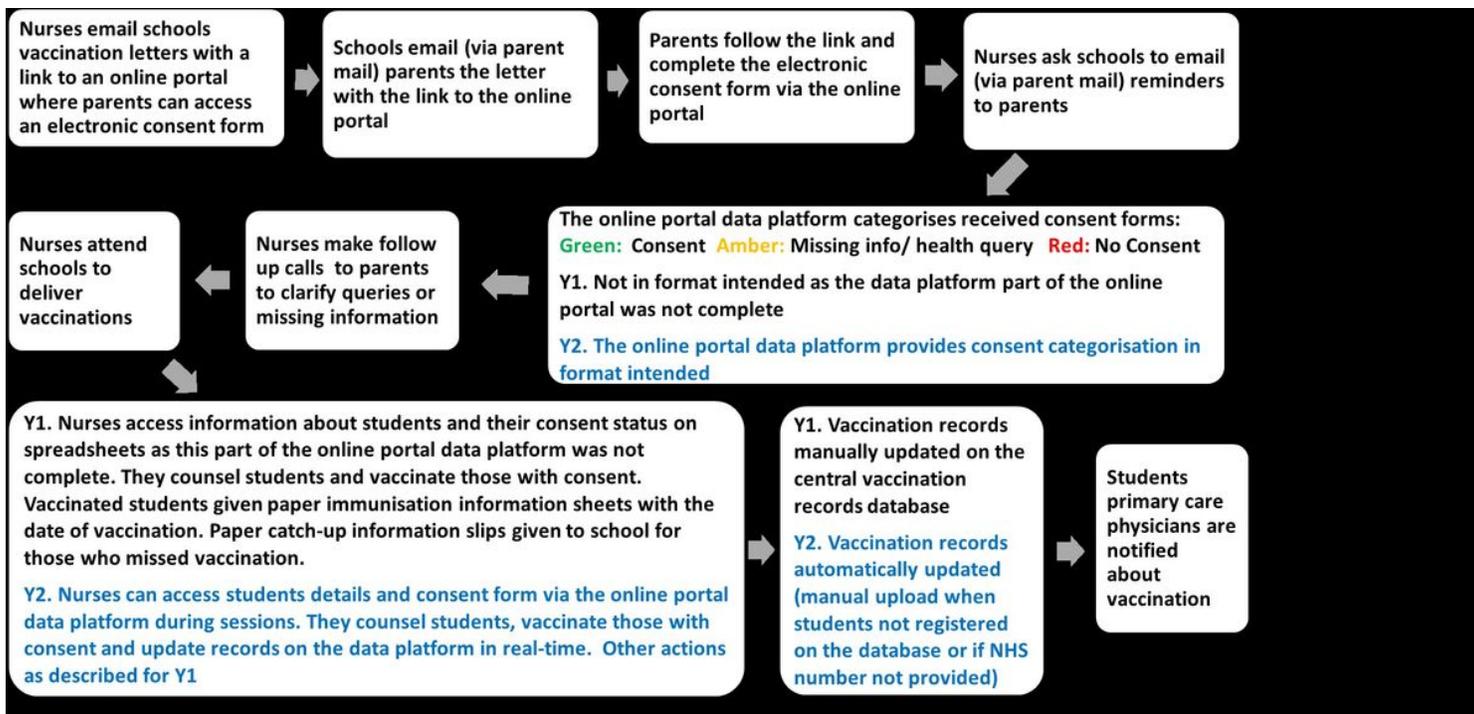


Figure 2

The Electronic consent intervention

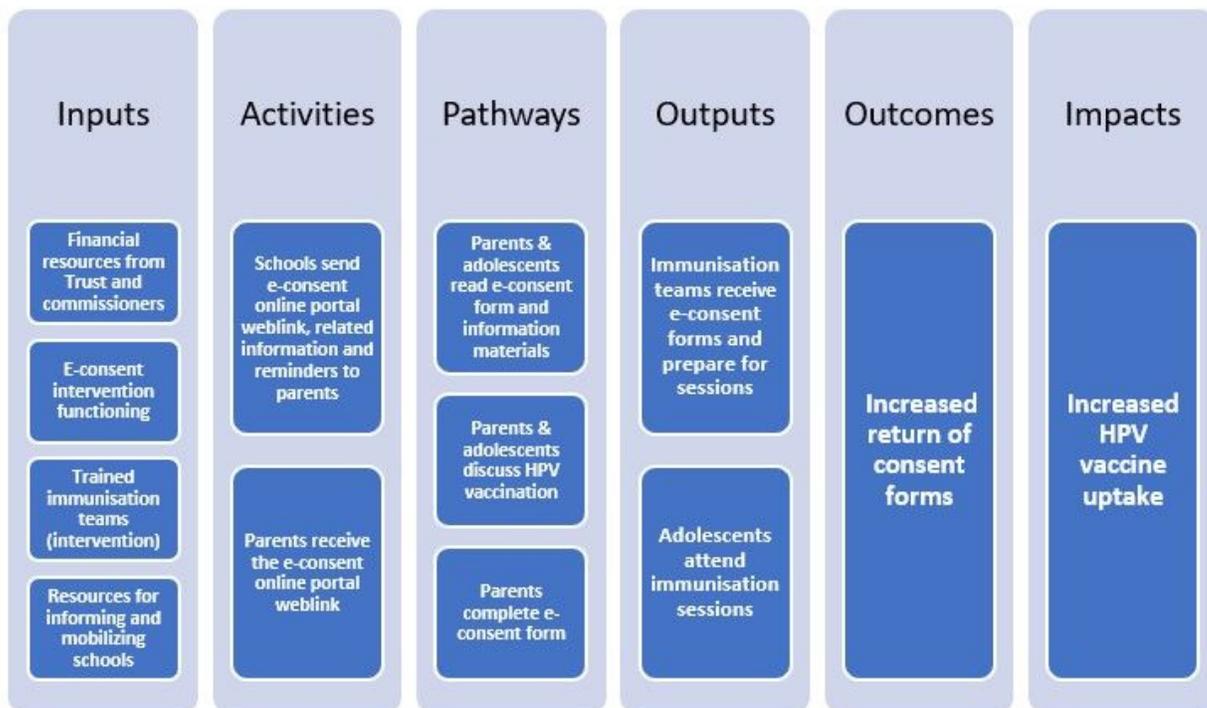


Figure 3

Theory of Change for the e-consent intervention

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