Chantler, 2020

Bibliographic Reference	Chantler T; Pringle E; Bell S; Cooper R; Edmundson E; Nielsen H; Roberts S; Edelstein M; Mounier-Jack S; Does electronic consent improve the logistics and uptake of HPV vaccination in adolescent girls? A mixed-methods theory informed evaluation of a pilot intervention.; BMJ open; 2020; vol. 10 (no. 11)

Study Characteristics

Study design	Mixed methods Quantitative: Cluster non-randomised controlled trial (Schools were divided into low, medium or high based on the proportion of pupils receiving free school meals and with English as an additional language. Each e-consent school was matched, as closely as possible, to a paper consent school in the same terciles for both characteristics) Qualitative: Semi-structured interviews
Aim of study	To assess whether an electronic consent form increased consent form return and the uptake of the first dose of HPV vaccine in adolescent girls. Qualitative analysis captured how year experience of the intervention in year 1 informed adaptations to the intervention prior to reuse in year 2.
Behavioural model used	Theory of change
Study location	UK
Study setting	14 secondary schools in South London boroughs
Study dates	June 2018 - July 2018 (year 1) and June 2019 - July 2019 (year 2)
Sources of funding	National Institute for Health Research Health Protection Research Unit in Immunisation in partnership with Public Health England
Inclusion Criteria	Schools in 7 South London boroughs Purposive sampling with the aim of including schools that differed in terms of denomination (private, state, grammar), type (mixed, single sex), sociodemographic, size, vaccination uptake and level of support to the programme. All girls eligible for vaccination were given consent forms
Exclusion criteria	None reported
Intervention details	Electronic consent form developed by Hounslow and Richmond Community Healthcare NHS Trust. Consisted of an online portal with an e-consent form and with information about the vaccination programme where parents could register their child and agree or decline the HPV vaccination. The intervention aimed to: 1. give parents to an online portal with information about the vaccination programme, where they could register their child and agree or decline the vaccination. 2. give nurses electronic access to the portal to facilitate screening and enable them to update records during immunisation sessions. 3. enable automatic updating of central vaccination record databases. Parts of the online portal and data platform (those related to nurse access and automatic updating of databases) were not fully functioning before the intervention

	was first used in June 2018 and so the way that nurses screened students' information and consent forms before and during immunisation sessions was modified.
Comparator details	Limited information. A standard paper consent form was issued for parental consent for the vaccine
Quantitative outcome measures	Vaccine uptake Number of children who received the vaccination at the scheduled school vaccination session
Number of participants	28 schools (14 e-consent and 14 paper). 1733 girls in paper consent (control) group, 1486 in e-consent group
Duration of follow-up	Until next scheduled school vaccination session
Study methods	Mixed-methods theory-informed evaluation study which used a 'Theory of Change' as an evaluation framework. Participants were recruited using purposive sampling with the aim of including schools that differed in terms of denomination (private, state, grammar), type (mixed, single sex), sociodemographic, size, vaccination uptake and level of support to the programme. Schools were divided into low, medium or high based on the proportion of pupils receiving free school meals and with English as an additional language. Each e-consent school was matched, as closely as possible, to a paper consent school. Quantitative methods: Nurses completed a 'tally sheet', with details of the consents received prior to or during the session, any absences and the number of vaccinations given. For both paper and e-consent schools, the proportion of the pupils who did not return a consent form, the proportion vaccinated at the planned session, and the proportion who received consent for the vaccination was calculated. Qualitative methods: Year 1 data collection followed the first year of the e-consent intervention. Year 2 data collection examined the use of e-consent in a different subset of schools. Members of the evaluation team observed the immunisation sessions to evaluate implementation and school staff involved in implementation were asked to complete a feedback form with questions about the organisation of immunisation sessions and the usability and acceptability of e-consent and paper consent. Semi-structured interviews (individual for the programme manager and in groups of 2-4 for immunisation teams) were conducted for Trust staff. In year 1, interviews were also conducted with parents and children either in family homes, by phone, or via Skype. Data was analysed using a thematic approach based on the Theory of Change, and inductive coding was used to capture themes.
Qualitative population and perspective	28 schools (14 paper and 14 e-consent schools) were included with 3219 girls (1733 in paper consent and 1486 in e-consent schools) taking part. In year 1, 15 members of Trust staff who delivered the intervention were interviewed, 12 parents and 5 children were interviewed (9 vaccine acceptors and 3 decliners). In year 2, 14 members of Trust staff were interviewed and 8 children took part in a focus group (all from a single school).
Relevant themes	1. Accessibility - Accessing and using the 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", "my dad said I should have the vaccine, but he did not understand the whole google business about it" 2. Decision making - Student awareness and involvement in decision making '…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"

	3. Implementation - Speed of implementation, effects on workload "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." 4. Sources of information - Amount of information, recommended-recommended vaccines "I think because it's like by the NHS—it kind of gives it validation."
Additional information	Quantitative results only available for year 1 of the pilot intervention. Qualitative results are available for both years (results not separated by year)

Risk of bias (quantitative – modified checklist: combined ROBINS-I and Cochrane cluster 2.0)

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(No randomisation: e-consent schools were matched to a paper consent school based on proportion receiving free school meals and number with English as an additional language)*
1b. Bias arising from the timing of identification and recruitment of individual participants in relation to timing of randomisation	Risk of bias judgement for the timing of identification and recruitment of individual participants in relation to timing of randomisation	Low
2. Bias due to confounding	Risk of bias judgement for confounding	Serious *(Limited information about confounding and analysis methods)*
3. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Moderate *(No information about correcting for selection bias)*
4. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Low
5. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low
6. Bias due to missing data	Risk of bias judgement for missing data	Serious *(Participants were excluded where outcome data was unavailable. No information about the proportion of missing data for each group)*
7. Bias in measurement of outcomes	Risk of bias judgement for measurement of outcomes	Low
8. Bias in selection of the reported result	Risk of bias judgement for selection of the reported result	Low
Overall bias	Risk of bias judgement	Critical *(Study was non-randomised, provided limited information on analysis methods and confounding variables. No information about the proportions of missing data in each group)*

Section	Question	Answer
	Directness	Directly applicable

Risk of bias (qualitative - CASP qualitative checklist)

Section	Question	Answer
Aims of the research	Was there a clear statement of the aims of the research?	Yes
Appropriateness of methodology	Is a qualitative methodology appropriate?	Yes
Research Design	Was the research design appropriate to address the aims of the research?	Yes
Recruitment Strategy	Was the recruitment strategy appropriate to the aims of the research?	Yes
Data collection	Was the data collected in a way that addressed the research issue?	Yes
Researcher and participant relationship	Has the relationship between researcher and participants been adequately considered?	Can't tell
Ethical Issues	Have ethical issues been taken into consideration?	Can't tell *(Study received ethics approval but no information about how the research was explained to participants)*
Data analysis	Was the data analysis sufficiently rigorous?	Yes
Findings	Is there a clear statement of findings?	Yes
Research value	How valuable is the research?	The research is valuable
Overall risk of bias and relevance	Overall risk of bias	Moderate *(No information about how the study was explained to participants and no clear consideration of the relationship between researchers and participants)*
	Relevance	Highly relevant *Views on e-consent forms* Relevant *Views from nursing staff on the online portal for screening and updating records (not fully functioning for the pilot but was implemented later)*