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Self-consent for the HPV vaccine

Submission date	Recruitment status	[_] Prospectively registered
19/09/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/01/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/02/2021	Infections and Infestations	

Plain English summary of protocol

Background and study aims
HPV vaccination can reduce the risk of cervical cancer in women. However, girls from lower socio-economic groups, some ethnic groups, and those not attending 'mainstream' schools are less likely to receive the vaccine. It is recommended that HPV vaccination takes place at age 12/13. Because this seems quite young, written parental consent is asked for but it can be difficult for some girls to provide. The law allows girls to consent for themselves if they understand what the vaccine is for and what the side effects might be. The aim of this study is to examine whether it is practical and acceptable for young people to consent for themselves to have the HPV vaccination, rather than their parents giving written consent. The study also looks at the impact of self-consent on the number of young people receiving the vaccine.

Who can participate?
Young women who were involved in the new self-consent procedures for the HPV vaccination programme at a participating school, their parents/carers, healthcare professionals and key school staff

What does the study involve?
The new self-consent procedures are observed in Bristol and South Gloucestershire, and interviews and focus groups are conducted with girls, parents, school nurses and school staff. The uptake rates of HPV vaccination before and after the new self-consent procedures are compared to see if uptake increases overall and in relation to socio-economic status, ethnicity and type of school.

What are the possible benefits and risks of participating?
The researchers cannot say that taking part in this study will benefit participants directly, but it is hoped that the study will result in improvements to the consent procedures for the HPV vaccination programme. No major risks are expected. As HPV is a sexually transmitted infection, topics may arise in the interview that relate to sexual health. Some participants maybe uncomfortable talking about such topics and are free to move on to the next topic or stop the interview at any time if they wish.

Where is the study run from?
Bristol Medical School, University of Bristol (UK)

When is the study starting and how long is it expected to run for?
September 2017 to August 2019

Who is funding the study?
NIHR Research for Patient Benefit Programme (UK)

Who is the main contact?
Dr Suzanne Audrey

Contact information

Type(s)
Scientific

Contact name
Dr Suzanne Audrey

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2790

Study information

Scientific Title
The practicality, acceptability and impact of self-consent procedures for the schools-based Human Papilloma Virus (HPV) vaccination programme

Study objectives
The aim of the research is to examine the implementation, acceptability and impact on uptake, of self-consent procedures for the HPV vaccination programme.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Faculty of Health Sciences Research Ethics Committee at the University of Bristol, 13/11/2017, ref: 57621

Study design
Systematic review, process evaluation and statistical analyses of routine data concerning HPV vaccination uptake in two local authorities with low uptake (Bristol and South Gloucestershire)

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Self-consent for HPV vaccination programme

Interventions
Observations of the implementation of the new-self consent procedures for the HPV vaccination programme; interviews and focus groups to find out views and experiences of the new self-consent procedures for the HPV vaccination programme from the perspectives of young women, their parents/carers, school staff and healthcare professionals; analysis of routinely collected data concerning HPV vaccination uptake in two local authorities.

Intervention Type
Other

Primary outcome measure
% change of HPV vaccination programme uptake before and after implementation of self-consent procedures

Secondary outcome measures
1. % change in HPV vaccination programme uptake in intervention site in comparison to comparison sites
2. Barriers and facilitators to implementation of self-consent procedures from perspectives of young women, parents, immunisation nurses and school staff

Overall study start date
01/09/2017

Completion date
31/01/2020

Eligibility

Key inclusion criteria
1. Young women who were involved in the new self-consent procedures for the HPV vaccination programme at a participating school
2. Parents/carers of young women who were involved in the new self-consent procedures for the HPV vaccination programme at a participating school
3. Healthcare professionals involved in the delivery of the HPV vaccination programme at participating schools
4. Key school staff involved in the delivery of the HPV vaccination programme at participating schools

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
112

Total final enrolment
82

Key exclusion criteria
1. Participants who do not have capacity to provide informed consent/assent
2. Participants who are unable to communicate in English

Date of first enrolment
01/11/2017

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Medical School, University of Bristol
Canynge Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS

Sponsor information

Organisation
University of Bristol

Sponsor details
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+44 (0)117 331 7130
birgit.whitman@bristol.ac.uk

Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists will disseminate this research to the academic community, practitioners and stakeholders.

For the academic community they plan to submit at least two open-access peer reviewed publications including the systematic review of available literature on self-consent for adolescents, and the results of the study. They will also disseminate the results to at least one national and one international conference. For practitioners they will complete a report of their findings and disseminate the results through practitioner conferences and events e.g. the South West Regional public health conference.

The trialists will also hold a stakeholder event to which we will invite school nurses, school staff, parents and young people. This will be an opportunity to discuss self-consent for young people, and the potential barriers and facilitators.

School nurses will be actively encouraged to be involved in the dissemination activities, and findings from the study will also be disseminated through appropriate websites and social media. The final report of the study will also provide an opportunity for further dissemination.

Intention to publish date
31/01/2021

Individual participant data (IPD) sharing plan
The trialists cannot share the full datasets because they are working on an NHS dataset and the interview data is of a sensitive nature. However, they will consider reasonable requests to share anonymised non-sensitive data arising from the study. Requests can be made to Dr Suzanne Audrey.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/03/2018		Yes	No
Results article	qualitative results	10/11/2020	16/02/2021	Yes	No
Results article	qualitative results (2)	03/11/2020	16/02/2021	Yes	No
Results article	results	26/09/2020	16/02/2021	Yes	No