

# Self-consent for the HPV vaccine

<b>Submission date</b> 19/09/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/02/2021	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## 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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**Contact details**  
Bristol Medical School  
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BS8 2PS

## 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**  
Canyng Hall  
39 Whatley Road  
Bristol  
United Kingdom  
BS8 2PS

## Sponsor information

**Organisation**  
University of Bristol

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Bristol  
England  
United Kingdom  
BS8 1TH  
+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?
<a href="#">Protocol article</a>	protocol	03/03/2018		Yes	No
<a href="#">Results article</a>	qualitative results	10/11/2020	16/02/2021	Yes	No
<a href="#">Results article</a>	qualitative results (2)	03/11/2020	16/02/2021	Yes	No
<a href="#">Results article</a>	results	26/09/2020	16/02/2021	Yes	No