

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email editorial.bmjopen@bmj.com

BMJ Open

The impact and acceptability of self-consent procedures for the schools-based human papillomavirus vaccine: a mixed-methods study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-021321
Article Type:	Protocol
Date Submitted by the Author:	20-Dec-2017
Complete List of Authors:	Audrey, Suzanne; University of Bristol, Population Health Sciences Batista, Harriet; University of Bristol, Population Health Sciences Ferrie, Jo; South West, Public Health England., Screening and Immunisations Evans, Karen; School Nursing (South Gloucestershire) and Specialist Nursing Services. Bell, Michael; Bristol Biomedical Research Centre and NIHR CLAHRC West Yates, Julie; Public Health England, South West Roderick, Marion; Bristol Children's Hospital, Department of Paediatric Immunology Macleod, John; University of Bristol Hickman, M; University of Bristol, Population Health Sciences
Keywords:	Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Paediatric infectious disease & immunisation < PAEDIATRICS, SEXUAL MEDICINE

SCHOLARONE™
Manuscripts

1
2
3 **The impact and acceptability of self-consent procedures for the schools-based human**
4 **papillomavirus vaccine: a mixed-methods study protocol**
5
6
7
8

9 Suzanne Audrey, Population Health Sciences, Bristol Medical School, University of Bristol.

10
11 Harriet Batista Ferrer, Population Health Sciences, Bristol Medical School, University of
12
13 Bristol.

14
15 Joanne Ferrie, Screening and Immunisations Coordinator, South West, Public Health
16
17 England.

18
19 Karen Evans, Head of School Nursing (South Gloucestershire) and Specialist Nursing
20
21 Services.

22
23 Michael Bell, Bristol Biomedical Research Centre and NIHR CLAHRC West.

24
25 Julie Yates, Lead Consultant for Screening and Immunisation, South West, Public Health
26
27 England.

28
29 Marion Roderick, Department of Paediatric Immunology, Bristol Children's Hospital.

30
31 John MacLeod, Population Health Sciences, Bristol Medical School, University of Bristol.

32
33 Matthew Hickman, Population Health Sciences, Bristol Medical School, University of
34
35 Bristol.

36
37
38
39
40
41 **Corresponding author:**

42 Dr Suzanne Audrey

43
44 Senior Research Fellow in Public Health

45
46 Population Health Sciences, Bristol Medical School

47
48 Whatley Road

49
50 Bristol BS8 2PS

51
52 Email: suzanne.audrey@bristol.ac.uk
53
54
55
56
57
58
59
60

1
2
3 Telephone: +44 (0) 117 928 7273
4
5
6
7

8
9 **Total word count:** 3846
10

11 **Main text word count:** 2753
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

Abstract

Introduction. The human papillomavirus (HPV) vaccine, administered in early adolescence, can substantially reduce cervical cancer incidence and mortality. However, lack of written parental consent is a key reason why some young women do not receive the vaccine. The national legal framework allows girls to be vaccinated without parental consent provided they are deemed Gillick competent, but there is some reticence about vaccinating without written parental consent. Self-consent procedures are being implemented in Bristol and South Gloucestershire. This study will examine the implementation, acceptability and impact of these new procedures.

Methods and analysis. Statistical analyses of routine data from Public Health England and the Child Health Information System will test if there has been an increase in HPV vaccination uptake in two ways: is there an increase when comparing before and after the change in our intervention sites, and; does the percentage change in our intervention sites differ from comparison sites (similar to our intervention sites in terms of initial HPV uptake, ethnicity and deprivation levels) in England where no such intervention took place, and how? For the process evaluation we will develop a logic model and use questionnaires, observations and audio-recorded interviews with young women, school nurses, school staff and parents to examine the context, implementation of self-consent, and response to the new procedures.

Ethics and dissemination. The University of Bristol Faculty of Health Sciences Research Ethics Committee and the National Health Service (NHS) Health Research Authority provided approvals for the study. We will produce a report with recommendations about self-consent procedures in conjunction with key stakeholders. At least two papers will be written for publication in peer-reviewed journals and for conference presentations. A summary of

1
2
3 results will be shared with participating immunisation nurses, school staff, young people and
4
5 parents as requested.
6

7 **Registration details.** ISCTRN registration applied for.
8
9

10 11 12 13 **Strengths and limitations of this study**

- 14
15 • The study addresses the lack of evidence about the impact and acceptability of self-
16 consent procedures for the schools-based HPV vaccination programme.
17
- 18 • The study will examine new self-consent procedures as they are implemented in routine
19 practice.
20
- 21 • Although not a trial, the proposed statistical analyses of routine data will provide
22 evidence of the impact of self-consent procedures on vaccine uptake.
23
- 24 • The process evaluation will identify barriers and enablers to self-consent for adolescent
25 vaccinations.
26
- 27 • Findings from this mixed-methods study will inform recommendations for future
28 practice, and may be relevant to other adolescent vaccination programmes.
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Introduction

Inequalities in uptake of the HPV vaccine

High coverage of human papillomavirus vaccination (HPV) programmes in early adolescence can substantially reduce cervical cancer incidence and mortality [1,2]. In the United Kingdom (UK), the HPV immunisation programme, predominantly delivered through schools, is achieving overall high coverage, and estimates suggest it will save 400 women each year from developing cervical cancer [3]. However, research suggests lower socio-economic status (SES) and some ethnic groups are associated with lower uptake of HPV vaccination [4,5]. The incidence of cervical cancer has been found to be higher in lower socioeconomic groups [5] and women are also less likely to access screening programmes than higher socioeconomic groups contributing to a higher mortality rate [6]. Inability to access vaccination adds a further layer of health inequality. Furthermore, students in special schools or pupil referral units are much less likely to receive the vaccine [6] and may require additional efforts by healthcare professionals to ensure they are vaccinated [7].

Because of the preferred age for HPV vaccination (12/13 years), written parental consent tends to be sought. However, previous research examining facilitators and barriers to uptake of the HPV vaccine has shown that a lack of written parental consent is a key reason why some young women do not receive the vaccine [8,9]. Furthermore, it is a barrier with potential to reinforce health inequalities since lack of written parental consent may also be related to lower SES and some ethnic groups [8,9].

Self-consent for HPV vaccination

In the UK, the legal framework allows girls to be vaccinated without parental consent provided they are deemed Gillick competent [10]. However, the World Health Organisation

(WHO) has acknowledged difficulties over consent for HPV vaccination because of the age of the target group, and suggests, at the very least, parents should be informed of the planned vaccination to provide an opportunity for the child to 'opt out' of the procedure [11]. In England, National Health Service (NHS) information about HPV vaccination states: 'Although, as a parent, you're asked to sign a consent form, it is up to your daughter whether she has the vaccine or not' [12] and in Public Health England (PHE) guidance for healthcare professionals there is a lack of a clear directive about whether parental consent is necessary [13].

This lack of clarity has implications for the vaccination process. Parental consent may be missing because of problems in returning paperwork, or because a parent is unwilling to allow their daughter to be vaccinated. In both cases, there may be young women who wish to receive the vaccination. However, some immunisation nurses and school staff appear reluctant to allow girls to make their own decisions about HPV vaccination because of concerns about generating antagonism between parents and the school or healthcare providers [8].

The issue of vaccination without written parental consent needs clarification, and guidance about self-consent procedures is required. However, there is a paucity of peer reviewed published research on the topic of self-consent for adolescent vaccinations. A study undertaken in the USA concluded that the inability of minors to consent for vaccines is a likely barrier to vaccination, and that interventions to increase adolescent vaccination should consider strategies that increase the ability of unaccompanied minors, particularly older minors, to receive vaccines within the context of legal, ethical, and professional guidelines [14]. Also in relation to the USA, Dempsey *et al* suggest the debate over whether adolescents

1
2
3 should be legally allowed to self-consent to vaccination is unresolved and could have a
4
5 substantial impact on vaccination rates [15].
6
7

8
9 In her doctoral thesis Batista Ferrer [16] examined consent for the HPV vaccine in schools in
10
11 Bristol, UK. Reasons recorded for why eligible girls did not receive the first dose of the HPV
12
13 vaccine course revealed that lack of a signed parental consent form was the main reason
14
15 (45.9%), while active refusal by parents occurred much less frequently (11.9%).
16
17 Nevertheless, research indicates that immunisation nurses and school staff were unwilling to
18
19 be held accountable if young women presented for HPV vaccination without parental consent
20
21 [7, 16].
22
23

24
25
26 PHE data for 2014/15, shows some areas in the south-west of England with low uptake of
27
28 HPV vaccination. For example, Bristol was ranked 112th of 119 English local authorities
29
30 (excluding London) and South Gloucestershire was 106th. Because of concerns about low
31
32 uptake rates, staff at PHE (South West) developed a ‘South West Template Pathway on Self
33
34 Consent for School Aged Immunisations’. The aim is to support provider organisations in
35
36 implementing a self-consent process to support young people to easily access vaccines,
37
38 support immunisers to feel confident about self-consent, and to improve the uptake of
39
40 immunisations.
41
42
43

44
45
46 The current research will focus on the practicality and acceptability of implementing the new
47
48 self-consent procedures, and the potential impact on overall uptake and health inequalities.
49
50 This will involve a systematic review of evidence relating to consent procedures for
51
52 adolescent vaccinations, a process evaluation examining new self-consent procedures in two
53
54 local authorities in the south-west of England, and an assessment of the impact of self-
55
56
57
58
59
60

1
2
3 consent on overall uptake levels and in relation to socio-economic status, ethnicity and type
4
5 of school.
6
7

8 9 **Methods and analysis**

10
11 The full study comprises three key elements: a mixed methods systematic review of the
12
13 literature relating to adolescent self-consent for vaccines; process evaluation establishing a
14
15 logic model for self-consent and examining the context, delivery and response to self-consent
16
17 procedures for the HPV vaccination programme, and; statistical analyses of routinely
18
19 collected data relating to HPV vaccination uptake. A protocol for the systematic review will
20
21 be published elsewhere. Here we focus on the statistical analyses of routine data and the
22
23 process evaluation in Bristol and South Gloucestershire local authorities (LAs).
24
25
26
27

28 29 **The new self-consent procedures**

30
31 Information about the HPV vaccine, together with forms requesting parental consent, are
32
33 distributed to young women at school to take home to their parents or carers. Previously,
34
35 young women who had not returned a written parental consent form were not administered
36
37 the vaccine at school. Under the new arrangements, information and parental consent forms
38
39 are still provided by the school for the young women to take home to their parents or carers.
40
41 Those who return a completed parental consent form agreeing for vaccination to take place
42
43 are included in the school-based vaccination session, but in addition those who do not have a
44
45 signed parental consent are also asked to attend the session where an attempt is made by the
46
47 immunisation nurse to gain verbal parental consent over the telephone. Where this is
48
49 achieved, the young women are offered the HPV vaccine. If the parent cannot be contacted,
50
51 the immunisation nurse assesses the young woman's competence using a checklist and
52
53 records this in a form. If the young woman is deemed competent and wants to receive the
54
55
56
57
58
59
60

1
2
3 vaccine, she is asked to sign the form. If she is not deemed competent, or there is reason to
4 believe that it would cause problems at home if she received the vaccine without parental
5 consent, the young woman is not given the vaccine. These young women are given
6 information about alternative options to receive the vaccination, such as such as through a
7 community-based clinic run by the immunisation team: a letter with information about dates
8 is given to the young women at the school-based session.
9
10
11
12
13
14
15

16 17 18 **Statistical analysis of routine data**

19
20 Statistical analyses will examine whether the intervention (implementation of self-consent) is
21 associated with an increase uptake overall and whether it has the potential to reduce health
22 inequalities.
23
24
25
26
27

28
29 Routine PHE surveillance reports HPV uptake by geographical area but does not provide data
30 on uptake by other factors such as ethnic group, social position or type of school. We will
31 examine HPV uptake by these factors by extracting information from the Child Health
32 Information System (CHIS) [17]. Following on from our previous work [5], we will examine
33 data in relation to the programme years 2014/15 until the 2018/19 to compare uptake since
34 the two dose HPV vaccination programme has been implemented. The data will be
35 anonymised and transferred in an encrypted format from the host organisation to the
36 University of Bristol where it will be will be securely stored according to the Data Protection
37 (Amendment) Act 2003 and University of Bristol requirements.
38
39
40
41
42
43
44
45
46
47
48
49

50
51 The following variables will be available from PHE through extracting anonymous aggregate
52 information from routine immunisation systems and CHIS: number of young people offered
53 HPV vaccination; HPV uptake by source (school, primary care, other); consent (parental
54
55
56
57
58
59
60

1
2
3 written, parental verbal, young women's self-consent); ethnic group; index of multiple-
4 deprivation [18]; childhood vaccinations; school year; year of birth; school; local government
5 area. These data can then be used in analyses of HPV uptake. Measures of effect will be
6 expressed as Odds Ratios and risk differences (i.e. % HPV uptake before intervention - %
7 HPV uptake during intervention).
8
9
10
11
12
13
14
15

16 We will test whether there has been an increase in the uptake of the HPV vaccination
17 programme before and after the intervention in terms of risk difference (difference in two
18 proportions and tests of null hypothesis that there has been no change in uptake). Initiation of
19 HPV vaccination uptake is 84.5% in Bristol and 86.4% in South Gloucester. Each year,
20 approximately 1,900 and 1,300 (overall 3,200) are invited to participate [19]. Therefore, there
21 will be an 80% power to detect an increase in HPV vaccine uptake to the average in England
22 (89.4%) and over 90% power to detect an increase to 95%. In addition, we will examine
23 whether uptake among young people from less affluent areas, minority ethnic groups and in
24 alternative educational settings has increased and whether there has been any unintended
25 increase or reduction in health inequalities in relation to HPV uptake. We also will examine
26 uptake for specific schools exposed to the intervention and assess whether there is an
27 association between the intensity of implementation of self-consent procedures (as examined
28 in the process evaluation) and HPV vaccine uptake.
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45

46 The observational data will test whether there has been an increase in HPV vaccination
47 uptake in two ways. First, is there an increase before and after the change in our intervention
48 sites? Second, is there evidence that the % change in our intervention sites is different from
49 other sites in England where no such intervention took place? In the second set of analyses
50
51
52
53
54
55
56
57
58
59
60

1
2
3 we will seek to select comparison sites that are similar to our intervention sites in terms of
4
5 ethnic diversity and social position.
6
7

8 9 **Process evaluation**

10
11 The process evaluation will be conducted in line with the MRC guidance on process
12
13 evaluation of complex interventions [20]. An initial logic model will be developed, in
14
15 consultation with health professionals, to show the hypothesised links between planned
16
17 activities and inputs (self-consent procedures) and the sequence of short- and medium-term
18
19 outcomes (HPV vaccine implementation and uptake) that lead to desired longer-term
20
21 outcomes (increased uptake, reduction in health inequalities). The initial logic model will be
22
23 refined through experience and discussion as the study progresses, leading to an agreed logic
24
25 model at the end of the study.
26
27

28
29
30
31 Context will be considered in relation to the socioecological model and will include
32
33 examination of policy, organisational, interpersonal (family and peers) and intrapersonal
34
35 factors. Questionnaires will be sent to a key contact in all secondary schools and relevant
36
37 immunisation nurses in the two LAs. These will include questions about policies and
38
39 procedures for HPV vaccination within schools. In addition, the researchers will compile
40
41 fieldnotes when conducting observations and interviews in a sample of schools. Context will
42
43 also be explored through interviews with a sample of immunisation nurses, school staff,
44
45 young people and parents.
46
47

48
49
50 Similarly, the implementation and response to the new consent procedures will be examined
51
52 through: questionnaires sent to a key contact in all secondary schools (including alternative
53
54 educational settings) (n=58) and relevant immunisation nurses (n=5) in the two LAs; audio-
55
56
57
58
59

1
2
3 recorded interviews (face-to-face or telephone) with relevant immunisation nurses, and more
4 detailed qualitative research in eight schools (two mainstream and two alternative educational
5 settings in each LA) purposively sampled in relation to type of school, HPV uptake, free
6 school meal entitlement and percentage of students from minority ethnic groups). In these
7 schools, more in-depth research will entail: audio-recorded focus groups or interviews (as
8 preferred by participants) with approximately six young women; audio-recorded interviews
9 with key school staff with responsibility for organising HPV vaccination sessions (one per
10 school); observations of the process and setting for HPV vaccination, and; audio-recorded
11 interviews or focus groups (as preferred by participants) with a purposive sample of
12 approximately six parents per school.

13
14
15
16
17
18
19
20
21
22
23
24
25
26
27 Questionnaire responses will be reported descriptively, showing frequencies and percentages,
28 and further illuminated by relevant free text responses. All focus group and interview
29 recordings will be transcribed verbatim and any potentially identifying information removed.
30
31 Familiarisation with the data will involve two researchers reading and discussing the
32 transcripts to compare and begin to code and categorise the data. Thematic analysis will be
33 undertaken, assisted by the Framework approach to data management [21]. Primary charts
34 will be created using sections of the text relating to the context, views and experiences of
35 self-consent. Streamlined versions of primary charts will be produced as the process of
36 summarising and coding the data progresses. Key terms and phrases will be retained while
37 repetition and extraneous text will be removed. Overarching themes will be identified within
38 which similarities and differences will be explored.

39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 **Ethics and dissemination** 54 55 56 57 58 59 60

1
2
3 The University of Bristol Faculty of Health Sciences Research Ethics Committee and the
4 National Health Service (NHS) Health Research Authority, have provided ethical approvals
5 for the study. In addition, management permission from the Research and Development
6 offices will be sought from each participating Clinical Commissioning Group prior to
7 obtaining the dataset.
8
9
10
11
12

13
14
15 The Bristol Young People's Advisory Group (YPAG) comprises young people aged ten to 17
16 years who are interested in healthcare and research. They meet regularly to help researchers
17 with their projects. Bristol YPAG have been consulted about the design of the study and
18 participant materials. They will also be invited to an event at the end of the study to consider
19 findings and recommendations with the young people, parents, immunisation nurses and
20 school staff involved in the study.
21
22
23
24
25
26
27
28
29

30
31 We will produce a report with recommendations in relation to self-consent in conjunction
32 with key stakeholders. This will be presented at events for relevant healthcare practitioners.
33 At least two papers will be written for publication in peer reviewed journals, and for
34 presentation at academic conferences. We will also summarise the results to share with
35 participating immunisation nurses, school staff, young people and their parents as requested.
36
37
38
39
40
41
42
43

44 **Summary**

45
46 There is currently a paucity of research into the impact of self-consent for adolescent
47 vaccinations. In relation to the HPV vaccination programme, statistical evidence suggests
48 young women from socially disadvantaged groups are less likely to receive the vaccine, and
49 qualitative evidence suggests that the requirement for written parental consent acts as a
50 barrier. This could lead to increased health inequalities. Written parental consent is not a
51
52
53
54
55
56
57
58
59
60

1
2
3 requirement for many of these young women, although self-consent procedures for younger
4 adolescents is not without controversy. School staff and immunisation nurses appear more
5 comfortable with the vaccine being administered following receipt of a signed parental
6 consent form. An opportunity has arisen in the south-west of England for academic
7 researchers and public health practitioners to work together to examine the process and
8 impact of new self-consent procedures as they are developed and implemented, and to
9 produce recommendations for good practice. Although this research focuses on the HPV
10 vaccination programme, the findings may be relevant to other vaccines that are offered to
11 adolescents in school settings.
12
13
14
15
16
17
18
19
20
21
22
23

24 **Authors' contributions**

25 All authors were involved in the conception and design of the research. SA is Principal
26 Investigator; H B-F is study manager and lead researcher; MB facilitates PPI; JF, JY and KE
27 developed and advise on the self-consent procedures and the HPV vaccination process; MR
28 advises on local immunisation strategy; JM advises on health inequalities; MH advises on
29 statistical methods. SA wrote the first draft and all authors contributed to the final version of
30 the manuscript.
31
32
33
34
35
36
37
38
39
40
41

42 **Funding statement**

43 This work is supported by the National Institute for Health Research Research for Patient
44 Benefit (NIHR RfPB) programme (project number PB-PG-0416-20013). The views and
45 opinions expressed therein are those of the authors and do not necessarily reflect those of the
46 NIHR RfPB Programme or the Department of Health.
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Acknowledgments

The study is partly supported by the NIHR Health Protection Research Unit in Evaluation of Interventions at University of Bristol. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, the Department of Health or Public Health England.

Competing interests statement

The authors declare there are no competing interests.

References

1. Paavonen J, Jenkins D, Bosch FX *et al*: Efficacy of a prophylactic adjuvanted bivalent L1 virus-like-particle vaccine against infection with human papillomavirus types 16 and 18 in young women: an interim analysis of a phase III double-blind, randomised controlled trial. *Lancet* 2007;369(9580):2161-2170.
2. Garland SM, Hernandez-Avila M, Wheeler CM *et al*: Quadrivalent vaccine against human papillomavirus to prevent anogenital diseases. *New England Journal of Medicine* 2007;356(19):1928-1943.
3. National Cancer Intelligence Network. Cancer incidence and survival by major ethnic group, England, 2002-2006. Available from http://publications.cancerresearchuk.org/downloads/product/CS_REPORT_INCSURV_ETH_NIC.pdf, 2009
4. Shack L, Jordan C, Thomson CS *et al*. Variation in incidence of breast, lung and cervical cancer and malignant melanoma of skin by socioeconomic group in England. *BMC Cancer* 2008;8(1):271.
5. Fisher H, Audrey S, Mytton J *et al*. Examining inequalities in the uptake of the school-based HPV vaccination programme in England: a retrospective cohort study. *Journal of Public Health* 2013; doi: 10.1093/pubmed/fdt042.

1
2
3 6. Tanton C, Soldan K, Beddows S *et al*. High-Risk human papillomavirus (HPV) Infection
4 and cervical Cancer prevention in Britain: evidence of differential uptake of interventions
5 from a Probability survey. *Cancer Epidemiol Biomarkers Prev* 2015;24:842–53.
6
7
8
9

10
11 7. Boyce T, Holmes A. Addressing health inequalities in the delivery of the human
12 papillomavirus vaccination programme: Examining the role of the school nurse. *PLoS ONE*
13 2012;7(9):e43416.
14
15
16
17
18
19

20 8. Batista Ferrer H, Trotter C, Hickman M, Audrey S. Barriers and facilitators to HPV
21 vaccination of young women in high-income countries: a qualitative systematic review and
22 evidence synthesis. *BMC Public Health* 2014;14:700.
23
24
25
26
27
28

29 9. Batista-Ferrer H, Trotter C, Hickman M, Audrey S. Barriers and facilitators to uptake of
30 the school-based HPV vaccination programme in an ethnically diverse group of young
31 women. *Journal of Public Health* 2015. doi: 10.1093/pubmed/fdv073 First published online:
32 June 7, 2015
33
34
35
36
37
38

39 10. Gillick v West Norfolk and Wisbech Area Health Authority and Department of Health
40 and Social Security. London, House of Lords, 1985.
41
42
43
44
45

46 11. World Health Organisation, Chapter 4: HPV Vaccination. Comprehensive Cervical
47 Cancer Control: A guide to essential practice (C4 GEP). 2013: Geneva, Sweden.
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 12. National Health Service, How is the HPV vaccine given? Available from
4 [http://www.nhs.uk/Conditions/vaccinations/Pages/how-is-hpv-vaccine-cervarix-gardasil-](http://www.nhs.uk/Conditions/vaccinations/Pages/how-is-hpv-vaccine-cervarix-gardasil-given.aspx)
5 [given.aspx](http://www.nhs.uk/Conditions/vaccinations/Pages/how-is-hpv-vaccine-cervarix-gardasil-given.aspx), 2014.
6
7
8
9
10
11 13. Public Health England. Changes to the human papillomavirus (HPV) vaccine schedule
12 2014/15. Advice for healthcare professionals. Available from
13 [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/318686/PHE_](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/318686/PHE_HP)
14 [HPV_Q_A_health_professionals.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/318686/PHE_HP).
15
16
17
18
19
20
21
22 14. Ford C, Skiles MPH, English A *et al*. Minor Consent and Delivery of Adolescent
23 Vaccines. *Journal of Adolescent Health* 2014;54(2):183-189.
24
25
26 DOI: 10.1016/j.jadohealth.2013.07.028
27
28
29
30
31 15. Dempsey A, Mendez D. Human papillomavirus vaccine and adolescents. *Current*
32 *Opinion in Obstetrics & Gynaecology* 2008;20(5):447-454. DOI:
33 10.1097/GCO.0b013e3283086719
34
35
36
37
38
39 16. Batista-Ferrer H. Factors Influencing the Uptake of the Human Papillomavirus (HPV)
40 Vaccination Programme. PhD Thesis. University of Bristol, November 2014.
41
42
43
44
45
46 17. Public Health England. Output-Based Specification for the Child Health Information
47 System, March 2015. Available from
48 [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/417076/Child_](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/417076/Child_Health_Information_240315.pdf)
49 [Health_Information_240315.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/417076/Child_Health_Information_240315.pdf)
50
51
52
53
54
55
56
57
58
59
60

1
2
3 18. Department for Communities and Local Government. English Indices of Deprivation.

4
5 September 2015. Available from

6
7 <https://www.gov.uk/government/statistics/english-indices-of-deprivation-2015>

8
9
10
11 19. Public Health England. Annual HPV vaccine coverage in England: 2014-15. HPV
12 coverage data of first and second dose for the routine cohort at 31 August 2015, by LA and
13 Area Team.
14
15
16
17
18
19

20 20. Moore G, Audrey S, Barker M *et al* *Process evaluation of complex interventions:*
21 *Medical Research Council guidance*. MRC Population Health Science Research Network,
22 London, 2014.
23
24
25
26
27
28

29 21. Ritchie J, Lewis J. *Qualitative research practice: A guide for social science students and*
30 *researchers*. London: Sage, 2003.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

BMJ Open

The impact and acceptability of self-consent procedures for the schools-based human papillomavirus vaccine: a mixed-methods study protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-021321.R1
Article Type:	Protocol
Date Submitted by the Author:	18-Jan-2018
Complete List of Authors:	Audrey, Suzanne; University of Bristol, Population Health Sciences Batista, Harriet; University of Bristol, Population Health Sciences Ferrie, Jo; South West, Public Health England., Screening and Immunisations Evans, Karen; School Nursing (South Gloucestershire) and Specialist Nursing Services. Bell, Michael; Bristol Biomedical Research Centre and NIHR CLAHRC West Yates, Julie; Public Health England, South West Roderick, Marion; Bristol Children's Hospital, Department of Paediatric Immunology Macleod, John; University of Bristol Hickman, M; University of Bristol, Population Health Sciences
Primary Subject Heading:	Infectious diseases
Secondary Subject Heading:	Health policy, Immunology (including allergy), Public health, Sexual health
Keywords:	Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Paediatric infectious disease & immunisation < PAEDIATRICS, SEXUAL MEDICINE

SCHOLARONE™
Manuscripts

1
2
3 **The impact and acceptability of self-consent procedures for the schools-based human**
4 **papillomavirus vaccine: a mixed-methods study protocol**
5
6
7

8
9 Suzanne Audrey, Population Health Sciences, Bristol Medical School, University of Bristol.

10
11 Harriet Batista Ferrer, Population Health Sciences, Bristol Medical School, University of
12
13 Bristol.

14
15 Joanne Ferrie, Screening and Immunisations Coordinator, South West, Public Health
16
17 England.

18
19 Karen Evans, Head of School Nursing (South Gloucestershire) and Specialist Nursing
20
21 Services.

22
23 Michael Bell, Bristol Biomedical Research Centre and NIHR CLAHRC West.

24
25 Julie Yates, Lead Consultant for Screening and Immunisation, South West, Public Health
26
27 England.

28
29 Marion Roderick, Department of Paediatric Immunology, Bristol Children's Hospital.

30
31 John MacLeod, Population Health Sciences, Bristol Medical School, University of Bristol.

32
33 Matthew Hickman, Population Health Sciences, Bristol Medical School, University of
34
35 Bristol.

36
37
38
39
40
41
42 **Corresponding author:**

43
44 Dr Suzanne Audrey

45
46 Senior Research Fellow in Public Health

47
48 Population Health Sciences, Bristol Medical School

49
50 Whatley Road

51
52 Bristol BS8 2PS

53
54 Email: suzanne.audrey@bristol.ac.uk

1
2
3 Telephone: +44 (0) 117 928 7273
4
5
6
7

8
9 **Total word count: 3839**
10

11 **Main text word count: 2753**
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

Abstract

Introduction. The human papillomavirus (HPV) vaccine, administered in early adolescence, can substantially reduce cervical cancer incidence and mortality. However, lack of written parental consent is a key reason why some young women do not receive the vaccine. The national legal framework allows girls to be vaccinated without parental consent provided they are deemed Gillick competent, but there is some reticence about vaccinating without written parental consent. Self-consent procedures are being implemented in Bristol and South Gloucestershire. This study will examine the implementation, acceptability and impact of these new procedures.

Methods and analysis. Statistical analyses of routine data from Public Health England and the Child Health Information System will test if there has been an increase in HPV vaccination uptake in two ways: is there an increase when comparing before and after the change in our intervention sites, and; does the percentage change in our intervention sites differ from comparison sites (similar to our intervention sites in terms of initial HPV uptake, ethnicity and deprivation levels) in England where no such intervention took place, and how? For the process evaluation we will develop a logic model and use questionnaires, observations and audio-recorded interviews with young women, school nurses, school staff and parents to examine the context, implementation of self-consent, and response to the new procedures.

Ethics and dissemination. The University of Bristol Faculty of Health Sciences Research Ethics Committee and the National Health Service (NHS) Health Research Authority provided approvals for the study. We will produce a report with recommendations about self-consent procedures in conjunction with key stakeholders. At least two papers will be written for publication in peer-reviewed journals and for conference presentations. A summary of

1
2
3 results will be shared with participating immunisation nurses, school staff, young people and
4
5 parents as requested.
6

7 **Registration details.** ISRCTN49086105.
8
9

10 11 12 13 **Strengths and limitations of this study**

- 14
15
16 • The study addresses the lack of evidence about the impact and acceptability of self-
17 consent procedures for the schools-based HPV vaccination programme.
- 18
19
20 • The study will examine new self-consent procedures as they are implemented in routine
21 practice.
22
- 23
24 • Although not a trial, the proposed statistical analyses of routine data will provide
25 evidence of the impact of self-consent procedures on vaccine uptake.
26
- 27
28 • The process evaluation will identify barriers and enablers to self-consent for adolescent
29 vaccinations.
30
- 31
32 • Findings from this mixed-methods study will inform recommendations for future
33 practice, and may be relevant to other adolescent vaccination programmes.
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Introduction

Inequalities in uptake of the HPV vaccine

High coverage of human papillomavirus vaccination (HPV) programmes in early adolescence can substantially reduce cervical cancer incidence and mortality [1,2]. In the United Kingdom (UK), the HPV immunisation programme, predominantly delivered through schools, is achieving overall high coverage, and estimates suggest it will save 400 women each year from developing cervical cancer [3]. However, research suggests lower socio-economic status (SES) and some ethnic groups are associated with lower uptake of HPV vaccination [4,5]. The incidence of cervical cancer has been found to be higher in lower socioeconomic groups [5] and women are also less likely to access screening programmes than higher socioeconomic groups contributing to a higher mortality rate [6]. Inability to access vaccination adds a further layer of health inequality. Furthermore, students in special schools or pupil referral units are much less likely to receive the vaccine [6] and may require additional efforts by healthcare professionals to ensure they are vaccinated [7].

Because of the preferred age for HPV vaccination (12/13 years), written parental consent tends to be sought. However, previous research examining facilitators and barriers to uptake of the HPV vaccine has shown that a lack of written parental consent is a key reason why some young women do not receive the vaccine [8,9]. Furthermore, it is a barrier with potential to reinforce health inequalities since lack of written parental consent may also be related to lower SES and some ethnic groups [8,9].

Self-consent for HPV vaccination

In the UK, the legal framework allows girls to be vaccinated without parental consent provided they are deemed Gillick competent [10]. However, the World Health Organisation

(WHO) has acknowledged difficulties over consent for HPV vaccination because of the age of the target group, and suggests, at the very least, parents should be informed of the planned vaccination to provide an opportunity for the child to 'opt out' of the procedure [11]. In England, National Health Service (NHS) information about HPV vaccination states: 'Although, as a parent, you're asked to sign a consent form, it is up to your daughter whether she has the vaccine or not' [12] and in Public Health England (PHE) guidance for healthcare professionals there is a lack of a clear directive about whether parental consent is necessary [13].

This lack of clarity has implications for the vaccination process. Parental consent may be missing because of problems in returning paperwork, or because a parent is unwilling to allow their daughter to be vaccinated. In both cases, there may be young women who wish to receive the vaccination. However, some immunisation nurses and school staff appear reluctant to allow girls to make their own decisions about HPV vaccination because of concerns about generating antagonism between parents and the school or healthcare providers [8].

The issue of vaccination without written parental consent needs clarification, and guidance about self-consent procedures is required. However, there is a paucity of peer reviewed published research on the topic of self-consent for adolescent vaccinations. A study undertaken in the USA concluded that the inability of minors to consent for vaccines is a likely barrier to vaccination, and that interventions to increase adolescent vaccination should consider strategies that increase the ability of unaccompanied minors, particularly older minors, to receive vaccines within the context of legal, ethical, and professional guidelines [14]. Also in relation to the USA, Dempsey *et al* suggest the debate over whether adolescents

1
2
3 should be legally allowed to self-consent to vaccination is unresolved and could have a
4
5 substantial impact on vaccination rates [15].
6
7

8
9 In her doctoral thesis Batista Ferrer [16] examined consent for the HPV vaccine in schools in
10
11 Bristol, UK. Reasons recorded for why eligible girls did not receive the first dose of the HPV
12
13 vaccine course revealed that lack of a signed parental consent form was the main reason
14
15 (45.9%), while active refusal by parents occurred much less frequently (11.9%).
16
17 Nevertheless, research indicates that immunisation nurses and school staff were unwilling to
18
19 be held accountable if young women presented for HPV vaccination without parental consent
20
21 [7, 16].
22
23

24
25
26 PHE data for 2014/15, shows some areas in the south-west of England with low uptake of
27
28 HPV vaccination. For example, Bristol was ranked 112th of 119 English local authorities
29
30 (excluding London) and South Gloucestershire was 106th. Because of concerns about low
31
32 uptake rates, staff at PHE (South West) developed a ‘South West Template Pathway on Self
33
34 Consent for School Aged Immunisations’. The aim is to support provider organisations in
35
36 implementing a self-consent process to support young people to easily access vaccines,
37
38 support immunisers to feel confident about self-consent, and to improve the uptake of
39
40 immunisations.
41
42
43

44
45
46 The current research will focus on the practicality and acceptability of implementing the new
47
48 self-consent procedures, and the potential impact on overall uptake and health inequalities.
49
50 This will involve a systematic review of evidence relating to consent procedures for
51
52 adolescent vaccinations, a process evaluation examining new self-consent procedures in two
53
54 local authorities in the south-west of England, and an assessment of the impact of self-
55
56
57
58
59
60

1
2
3 consent on overall uptake levels and in relation to socio-economic status, ethnicity and type
4
5 of school.
6
7

8 9 **Methods and analysis**

10
11 The full study comprises three key elements: a mixed methods systematic review of the
12
13 literature relating to adolescent self-consent for vaccines; process evaluation establishing a
14
15 logic model for self-consent and examining the context, delivery and response to self-consent
16
17 procedures for the HPV vaccination programme, and; statistical analyses of routinely
18
19 collected data relating to HPV vaccination uptake. A protocol for the systematic review will
20
21 be published elsewhere. Here we focus on the statistical analyses of routine data and the
22
23 process evaluation in Bristol and South Gloucestershire local authorities (LAs).
24
25
26
27

28 29 **The new self-consent procedures**

30
31 Information about the HPV vaccine, together with forms requesting parental consent, are
32
33 distributed to young women at school to take home to their parents or carers. Previously,
34
35 young women who had not returned a written parental consent form were not administered
36
37 the vaccine at school. Under the new arrangements, information and parental consent forms
38
39 are still provided by the school for the young women to take home to their parents or carers.
40
41 Those who return a completed parental consent form agreeing for vaccination to take place
42
43 are included in the school-based vaccination session, but in addition those who do not have a
44
45 signed parental consent are also asked to attend the session where an attempt is made by the
46
47 immunisation nurse to gain verbal parental consent over the telephone. Where this is
48
49 achieved, the young women are offered the HPV vaccine. If the parent cannot be contacted,
50
51 the immunisation nurse assesses the young woman's competence using a checklist and
52
53 records this in a form. If the young woman is deemed competent and wants to receive the
54
55
56
57
58
59
60

1
2
3 vaccine, she is asked to sign the form. If she is not deemed competent, or there is reason to
4 believe that it would cause problems at home if she received the vaccine without parental
5 consent, the young woman is not given the vaccine. These young women are given
6 information about alternative options to receive the vaccination, such as such as through a
7 community-based clinic run by the immunisation team: a letter with information about dates
8 is given to the young women at the school-based session.
9
10
11
12
13
14
15
16
17

18 **Statistical analysis of routine data**

19
20 Statistical analyses will examine whether the intervention (implementation of self-consent) is
21 associated with an increase uptake overall and whether it has the potential to reduce health
22 inequalities.
23
24
25
26
27

28
29 Routine PHE surveillance reports HPV uptake by geographical area but does not provide data
30 on uptake by other factors such as ethnic group, social position or type of school. We will
31 examine HPV uptake by these factors by extracting information from the Child Health
32 Information System (CHIS) [17]. Following on from our previous work [5], we will examine
33 data in relation to the programme years 2014/15 until the 2018/19 to compare uptake since
34 the two dose HPV vaccination programme has been implemented. The data will be
35 anonymised and transferred in an encrypted format from the host organisation to the
36 University of Bristol where it will be will be securely stored according to the Data Protection
37 (Amendment) Act 2003 and University of Bristol requirements.
38
39
40
41
42
43
44
45
46
47
48
49

50 The following variables will be available from PHE through extracting anonymous aggregate
51 information from routine immunisation systems and CHIS: number of young people offered
52 HPV vaccination; HPV uptake by source (school, primary care, other); consent (parental
53
54
55
56
57
58
59
60

1
2
3 written, parental verbal, young women's self-consent); ethnic group; index of multiple-
4 deprivation [18]; childhood vaccinations; school year; year of birth; school; local government
5 area. These data can then be used in analyses of HPV uptake. Measures of effect will be
6 expressed as Odds Ratios and risk differences (i.e. % HPV uptake before intervention - %
7 HPV uptake during intervention).
8
9
10
11
12
13
14
15

16 We will test whether there has been an increase in the uptake of the HPV vaccination
17 programme before and after the intervention in terms of risk difference (difference in two
18 proportions and tests of null hypothesis that there has been no change in uptake). Initiation of
19 HPV vaccination uptake is 84.5% in Bristol and 86.4% in South Gloucester. Each year,
20 approximately 1,900 and 1,300 (overall 3,200) are invited to participate [19]. Therefore, there
21 will be an 80% power to detect an increase in HPV vaccine uptake to the average in England
22 (89.4%) and over 90% power to detect an increase to 95%. In addition, we will examine
23 whether uptake among young people from less affluent areas, minority ethnic groups and in
24 alternative educational settings has increased and whether there has been any unintended
25 increase or reduction in health inequalities in relation to HPV uptake. We also will examine
26 uptake for specific schools exposed to the intervention and assess whether there is an
27 association between the intensity of implementation of self-consent procedures (as examined
28 in the process evaluation) and HPV vaccine uptake.
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45

46 The observational data will test whether there has been an increase in HPV vaccination
47 uptake in two ways. First, is there an increase before and after the change in our intervention
48 sites? Second, is there evidence that the % change in our intervention sites is different from
49 other sites in England where no such intervention took place? In the second set of analyses
50
51
52
53
54
55
56
57
58
59
60

1
2
3 we will seek to select comparison sites that are similar to our intervention sites in terms of
4
5 ethnic diversity and social position.
6
7

8 9 **Process evaluation**

10
11 The process evaluation will be conducted in line with the MRC guidance on process
12
13 evaluation of complex interventions [20]. An initial logic model will be developed, in
14
15 consultation with health professionals, to show the hypothesised links between planned
16
17 activities and inputs (self-consent procedures) and the sequence of short- and medium-term
18
19 outcomes (HPV vaccine implementation and uptake) that lead to desired longer-term
20
21 outcomes (increased uptake, reduction in health inequalities). The initial logic model will be
22
23 refined through experience and discussion as the study progresses, leading to an agreed logic
24
25 model at the end of the study.
26
27

28
29
30
31 Context will be considered in relation to the socioecological model and will include
32
33 examination of policy, organisational, interpersonal (family and peers) and intrapersonal
34
35 factors. Questionnaires will be sent to a key contact in all secondary schools and relevant
36
37 immunisation nurses in the two LAs. These will include questions about policies and
38
39 procedures for HPV vaccination within schools. In addition, the researchers will compile
40
41 fieldnotes when conducting observations and interviews in a sample of schools. Context will
42
43 also be explored through interviews with a sample of immunisation nurses, school staff,
44
45 young people and parents.
46
47

48
49
50 Similarly, the implementation and response to the new consent procedures will be examined
51
52 through: questionnaires sent to a key contact in all secondary schools (including alternative
53
54 educational settings) (n=58) and relevant immunisation nurses (n=5) in the two LAs; audio-
55
56

1
2
3 recorded interviews (face-to-face or telephone) with relevant immunisation nurses, and more
4 detailed qualitative research in eight schools (two mainstream and two alternative educational
5 settings in each LA) purposively sampled in relation to type of school, HPV uptake, free
6 school meal entitlement and percentage of students from minority ethnic groups). In these
7 schools, more in-depth research will entail: audio-recorded focus groups or interviews (as
8 preferred by participants) with approximately six young women; audio-recorded interviews
9 with key school staff with responsibility for organising HPV vaccination sessions (one per
10 school); observations of the process and setting for HPV vaccination, and; audio-recorded
11 interviews or focus groups (as preferred by participants) with a purposive sample of
12 approximately six parents per school.
13
14
15
16
17
18
19
20
21
22
23
24
25

26 Questionnaire responses will be reported descriptively, showing frequencies and percentages,
27 and further illuminated by relevant free text responses. All focus group and interview
28 recordings will be transcribed verbatim and any potentially identifying information removed.
29 Familiarisation with the data will involve two researchers reading and discussing the
30 transcripts to compare and begin to code and categorise the data. Thematic analysis will be
31 undertaken, assisted by the Framework approach to data management [21]. Primary charts
32 will be created using sections of the text relating to the context, views and experiences of
33 self-consent. Streamlined versions of primary charts will be produced as the process of
34 summarising and coding the data progresses. Key terms and phrases will be retained while
35 repetition and extraneous text will be removed. Overarching themes will be identified within
36 which similarities and differences will be explored.
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51

52 **Ethics and dissemination**

53
54
55
56
57
58
59
60

1
2
3 The University of Bristol Faculty of Health Sciences Research Ethics Committee and the
4 National Health Service (NHS) Health Research Authority, have provided ethical approvals
5 for the study. In addition, management permission from the Research and Development
6 offices will be sought from each participating Clinical Commissioning Group prior to
7 obtaining the dataset.
8
9
10
11
12

13
14
15 The Bristol Young People's Advisory Group (YPAG) comprises young people aged ten to 17
16 years who are interested in healthcare and research. They meet regularly to help researchers
17 with their projects. Bristol YPAG have been consulted about the design of the study and
18 participant materials. They will also be invited to an event at the end of the study to consider
19 findings and recommendations with the young people, parents, immunisation nurses and
20 school staff involved in the study.
21
22
23
24
25
26
27
28
29

30
31 We will produce a report with recommendations in relation to self-consent in conjunction
32 with key stakeholders. This will be presented at events for relevant healthcare practitioners.
33 At least two papers will be written for publication in peer reviewed journals, and for
34 presentation at academic conferences. We will also summarise the results to share with
35 participating immunisation nurses, school staff, young people and their parents as requested.
36
37
38
39
40
41
42
43

44 **Summary**

45
46 There is currently a paucity of research into the impact of self-consent for adolescent
47 vaccinations. In relation to the HPV vaccination programme, statistical evidence suggests
48 young women from socially disadvantaged groups are less likely to receive the vaccine, and
49 qualitative evidence suggests that the requirement for written parental consent acts as a
50 barrier. This could lead to increased health inequalities. Written parental consent is not a
51
52
53
54
55
56
57
58
59
60

1
2
3 requirement for many of these young women, although self-consent procedures for younger
4 adolescents is not without controversy. School staff and immunisation nurses appear more
5 comfortable with the vaccine being administered following receipt of a signed parental
6 consent form. An opportunity has arisen in the south-west of England for academic
7 researchers and public health practitioners to work together to examine the process and
8 impact of new self-consent procedures as they are developed and implemented, and to
9 produce recommendations for good practice. Although this research focuses on the HPV
10 vaccination programme, the findings may be relevant to other vaccines that are offered to
11 adolescents in school settings.
12
13
14
15
16
17
18
19
20
21
22
23

24 **Authors' contributions**

25 All authors were involved in the conception and design of the research: SA is Principal
26 Investigator; H B-F is study manager and lead researcher; MB facilitates PPI; JF, JY and KE
27 developed and advise on the self-consent procedures and the HPV vaccination process; MR
28 advises on local immunisation strategy; JM advises on health inequalities; MH advises on
29 statistical methods. SA wrote the first draft and all authors contributed to the final version of
30 the manuscript.
31
32
33
34
35
36
37
38
39
40
41

42 **Funding statement**

43 This work is supported by the National Institute for Health Research Research for Patient
44 Benefit (NIHR RfPB) programme (project number PB-PG-0416-20013). The views and
45 opinions expressed therein are those of the authors and do not necessarily reflect those of the
46 NIHR RfPB Programme or the Department of Health.
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Acknowledgments

The study is partly supported by the NIHR Health Protection Research Unit in Evaluation of Interventions at University of Bristol. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, the Department of Health or Public Health England.

Competing interests statement

The authors declare there are no competing interests.

References

1. Paavonen J, Jenkins D, Bosch FX *et al*: Efficacy of a prophylactic adjuvanted bivalent L1 virus-like-particle vaccine against infection with human papillomavirus types 16 and 18 in young women: an interim analysis of a phase III double-blind, randomised controlled trial. *Lancet* 2007;369(9580):2161-2170.
2. Garland SM, Hernandez-Avila M, Wheeler CM *et al*: Quadrivalent vaccine against human papillomavirus to prevent anogenital diseases. *New England Journal of Medicine* 2007;356(19):1928-1943.
3. National Cancer Intelligence Network. Cancer incidence and survival by major ethnic group, England, 2002-2006. Available from http://publications.cancerresearchuk.org/downloads/product/CS_REPORT_INCSURV_ETH_NIC.pdf, 2009
4. Shack L, Jordan C, Thomson CS *et al*. Variation in incidence of breast, lung and cervical cancer and malignant melanoma of skin by socioeconomic group in England. *BMC Cancer* 2008;8(1):271.
5. Fisher H, Audrey S, Mytton J *et al*. Examining inequalities in the uptake of the school-based HPV vaccination programme in England: a retrospective cohort study. *Journal of Public Health* 2013; doi: 10.1093/pubmed/fdt042.

1
2
3 6. Tanton C, Soldan K, Beddows S *et al.* High-Risk human papillomavirus (HPV) Infection
4 and cervical Cancer prevention in Britain: evidence of differential uptake of interventions
5 from a Probability survey. *Cancer Epidemiol Biomarkers Prev* 2015;24:842–53.
6
7
8
9

10
11 7. Boyce T, Holmes A. Addressing health inequalities in the delivery of the human
12 papillomavirus vaccination programme: Examining the role of the school nurse. *PLoS ONE*
13 2012;7(9):e43416.
14
15
16
17
18

19
20 8. Batista Ferrer H, Trotter C, Hickman M, Audrey S. Barriers and facilitators to HPV
21 vaccination of young women in high-income countries: a qualitative systematic review and
22 evidence synthesis. *BMC Public Health* 2014;14:700.
23
24
25
26
27

28
29 9. Batista-Ferrer H, Trotter C, Hickman M, Audrey S. Barriers and facilitators to uptake of
30 the school-based HPV vaccination programme in an ethnically diverse group of young
31 women. *Journal of Public Health* 2015. doi: 10.1093/pubmed/fdv073 First published online:
32 June 7, 2015
33
34
35
36
37

38
39 10. Gillick v West Norfolk and Wisbech Area Health Authority and Department of Health
40 and Social Security. London, House of Lords, 1985.
41
42
43
44

45
46 11. World Health Organisation, Chapter 4: HPV Vaccination. Comprehensive Cervical
47 Cancer Control: A guide to essential practice (C4 GEP). 2013: Geneva, Sweden.
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 12. National Health Service, How is the HPV vaccine given? Available from
4 [http://www.nhs.uk/Conditions/vaccinations/Pages/how-is-hpv-vaccine-cervarix-gardasil-](http://www.nhs.uk/Conditions/vaccinations/Pages/how-is-hpv-vaccine-cervarix-gardasil-given.aspx)
5 [given.aspx](http://www.nhs.uk/Conditions/vaccinations/Pages/how-is-hpv-vaccine-cervarix-gardasil-given.aspx), 2014.
6
7
8
9
10
11 13. Public Health England. Changes to the human papillomavirus (HPV) vaccine schedule
12 2014/15. Advice for healthcare professionals. Available from
13 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/318686/PHE
14 [HPV_Q_A_health_professionals.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/318686/PHE).
15
16
17
18
19
20
21
22 14. Ford C, Skiles MPH, English A *et al*. Minor Consent and Delivery of Adolescent
23 Vaccines. *Journal of Adolescent Health* 2014;54(2):183-189.
24
25 DOI: 10.1016/j.jadohealth.2013.07.028
26
27
28
29
30
31 15. Dempsey A, Mendez D. Human papillomavirus vaccine and adolescents. *Current*
32 *Opinion in Obstetrics & Gynaecology* 2008;20(5):447-454. DOI:
33 10.1097/GCO.0b013e3283086719
34
35
36
37
38
39 16. Batista-Ferrer H. Factors Influencing the Uptake of the Human Papillomavirus (HPV)
40 Vaccination Programme. PhD Thesis. University of Bristol, November 2014.
41
42
43
44
45
46 17. Public Health England. Output-Based Specification for the Child Health Information
47 System, March 2015. Available from
48 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/417076/Child_
49 [Health_Information_240315.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/417076/Child_)
50
51
52
53
54
55
56
57
58
59
60

1
2
3 18. Department for Communities and Local Government. English Indices of Deprivation.

4
5 September 2015. Available from

6
7 <https://www.gov.uk/government/statistics/english-indices-of-deprivation-2015>
8
9

10
11 19. Public Health England. Annual HPV vaccine coverage in England: 2014-15. HPV
12 coverage data of first and second dose for the routine cohort at 31 August 2015, by LA and
13 Area Team.
14
15
16
17

18
19
20 20. Moore G, Audrey S, Barker M *et al* *Process evaluation of complex interventions:*
21 *Medical Research Council guidance*. MRC Population Health Science Research Network,
22 London, 2014.
23
24
25
26
27

28
29 21. Ritchie J, Lewis J. *Qualitative research practice: A guide for social science students and*
30 *researchers*. London: Sage, 2003.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60