Fisher, 2020

Bibliographic Reference	Fisher H; Hickman M; Ferrie J; Evans K; Bell M; Yates J; Roderick M; Reynolds R; MacLeod J; Audrey S; Impact of new consent procedures on uptake of the schools-based human papillomavirus (HPV) vaccination programme.; Journal of public health (Oxford, England); 2020

Study details

Secondary publication of another included study- see primary study for details	Audrey 2020
Other publications associated with this study included in review	Audrey 2021, Fisher 2020
Trial registration number and/or trial name	South West Template Pathway on Self Consent for School Aged Immunisations
Study type	Uncontrolled before-and-after studies
Study location	UK
Study setting	Schools in 2 Local Authorities in South West England
Study dates	Pre-intervention: 2015-16 and 2016-2017 Post-intervention: 2017-2018 and 2018-2019
Sources of funding	Joint funding (MR/KO232331/1) from the British Heart Foundation, Cancer Research UK, Economic and Social Research Council, Medical Research Council, the Welsh Government and the Wellcome Trust, under the auspices of the UK Clinical Research Collaboration

Inclusion criteria	Two local authorities in South West England Data provided covered the two local authorities that implemented the new consent procedures and covered urban or rural/urban areas
Exclusion criteria	Individual records were excluded if the school identifying code was absent or invalid, the date of birth was invalid, or partial postcode was missing or invalid
Intervention(s)	Under the new procedures, where written parental consent is not received the immunization team make telephone calls to seek parental verbal consent during the vaccination session. Additionally, if parents cannot be contacted during the vaccination session, young women considered 'Gillick-competent' by the immunization team can self-consent if they confirm that they have discussed the vaccine with their parents and it would not cause a problem at home if they were vaccinated without written or verbal parental consent. Young women who do not receive the vaccine on the day are provided with written information about community catch-up clinics.
Outcome measures	Vaccine uptake By Local Authority
Number of participants	2 Local Authorities
Duration of follow-up	2 years

Study arms

Local Authority 1 (N = 4384)
New HPV vaccination programme with all young people attending vaccination sessions, irrespective of whether they have returned a consent form

Local Authority 2 (N = 2602)
New HPV vaccination programme with all young people attending vaccination sessions, irrespective of whether they have returned a consent form

Risk of bias (GUT EPOC risk of bias)

Section	Question	Answer
Random sequence generation	Was the allocation sequence adequately generated?	NA
Allocation concealment	Was the allocation adequately concealed?	NA
Baseline characteristics	Were baseline characteristics similar?	NA
Incomplete outcome data	Were incomplete outcome data adequately addressed?	Unclear

Knowledge of the allocated interventions	Was knowledge of the allocated interventions adequately prevented during the study?	NA
Protection against contamination	Was the study adequately protected against contamination?	NA
Selective outcome reporting	Was the study free from selective outcome reporting?	Yes
Other risks of bias	Was the study free from other risks of bias?	No *(Study used routinely collected data on vaccinations delivered in school and community settings to all young people registered with a GP and eligible for routine HPV vaccination during the study period. This did not provide information on baseline characteristics, and some records had to be excluded because of invalid data)*
Overall judgements of risk of bias and directness	Overall risk of bias	High risk of bias *(Uncontrolled design with no information about baseline characteristics and some records had to be excluded because of invalid data. The authors reported that different data sources reported different levels of uptake)*
Overall judgements of risk of bias and directness	Overall directness	Directly applicable

Forster, 2017

Bibliographic Reference	Forster, Alice S; Cornelius, Victoria; Rockliffe, Lauren; Marlow, Laura Av; Bedford, Helen; Waller, Jo; A cluster randomised feasibility study of an adolescent incentive intervention to increase uptake of HPV vaccination.; British journal of cancer; 2017; vol. 117 (no. 8); 1121-1127

Study details

Other publications associated with this study included in review	Quantitative outcomes related to Rockliffe 2018
Study type	Cluster randomised controlled trial
Study location	UK
Study setting	Schools in 3 London boroughs (Enfield, Lambeth, Southwark)

Study dates	July 2016 - January 2017
Sources of funding	Cancer Research UK
Inclusion criteria	All secondary schools in the 3 London boroughs Parents of all girls eligible for the vaccine (year 8 girls) were given the option to opt out of the study
Exclusion criteria	None reported
Intervention(s)	Girls were provided with an information leaflet about the HPV vaccine and a consent form from the school, which they were asked to hand deliver to their parents and return before a prescribed date. They were also told by their form tutor and in a letter that they would be eligible to be entered into a prize draw to win a £50 Love2Shop voucher if they returned their consent form, signed by a legal guardian, before a prescribed date. Eligibility for entry into the prize draw was dependent on consent form return only, not vaccine receipt. All girls who returned their consent form were entered into a prize draw for each school, with girls having a 1 in 10 chance of winning. The draw was made following the first dose of the HPV vaccine,
Comparator	Girls were provided with an information leaflet about the HPV vaccine and a consent form from the school, which they were asked to hand deliver to their parents and return before a prescribed date. There was no prize draw or incentive offered for consent form return
Outcome measures	Consent form return
Number of participants	9 schools, 593 female students
Duration of follow-up	Duration of vaccination programme
Loss to follow-up	Intervention: 1 school, 12 girls Control: 2 schools, 6 girls
Additional comments	Outcome was number of consent forms returned, not vaccine uptake (consent form return outcome was used as a proxy for vaccine uptake but quality was downgraded for directness) Outcome was adjusted for clustering effects using the ‘vce’ command in STATA

Study arms

Incentivised consent form return (N = 4) 4 schools, 267 female students
Standard consent form (N = 5) 5 schools, 326 female students

Risk of bias (Cochrane Cluster risk of bias 2.0)

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(Some differences in baseline characteristics for ethnicity, religion and deprivation)*
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 deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Low
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	Low
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(Differences in baseline characteristics)*
	Overall Directness	Partially indirect *(Reported outcome is based on consent form return rather than vaccine uptake)*

Gibson, 2014

Bibliographic Reference Gibson K; Celebrate and Protect: A mixed methods evaluation; 2014; 1-52

Study details

Other publications associated with this study included in review	Quantitative report associated with Lwembe 2016
Study type	Cluster non-randomised controlled trial
Study location	UK

Study setting	Practices in 9 London PCTs (Barking & Dagenham, Bexley, Greenwich, Kensington & Chelsea, Hammersmith & Fulham, Newham, Tower Hamlets, Waltham Forest, Westminster)
Study dates	October 2012 - February 2013
Inclusion criteria	Strategic leads in the PCT, programme management team, healthcare professionals, primary care staff and parents/carers Unclear how these were identified
Exclusion criteria	None reported
Intervention(s)	The Celebrate and Protect programme. A personalised celebration card and an information leaflet with a vaccination schedule, sent out by the GP practice to parents/carers registered at the practice following the birth of a child, or prior to the first or fourth birthday of a child registered at the practice. The card intended to celebrate the birth of a child or a child's birthday and act as a call to action for the parent /guardian to contact the practice and book a vaccination or health check.
Comparator	Control - no reminder card programme. No further information provided
Outcome measures	Vaccine uptake Estimated from charts presented in the report
Duration of follow-up	12 months
Additional comments	Non-peer reviewed report No information about whether the results were adjusted for clustering. We could not adjust them ourselves as the study did not provide sample sizes for the control arm.

Study arms

Celebrate and Protect (N = 56) 16 strategic leads/programme management team, nine providers and 31 parents/carers
Control (N = ?) Number of providers, practices and parents/carers in the control arm not reported

Risk of bias (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 *(Group allocation not randomised. No information about baseline characteristics and unclear how the practices not randomised to the intervention were selected)*
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	Some concerns *(No information about baseline characteristics)*

Section	Question	Answer
2. Bias due to confounding	Risk of bias judgement for confounding	Moderate *(No information about confounding variables and limited information about analysis)*
3. Bias in selection of participants into the study	Risk of bias judgement for selection of participants into the study	Low
4. Bias in classification of interventions	Risk of bias judgement for classification of interventions	Moderate
5. Bias due to deviations from intended interventions	Risk of bias judgement for deviations from intended interventions	Moderate
6. Bias due to missing data	Risk of bias judgement for missing data	Serious *(Data only available for 3 of the 9 PCTs in the intervention because of incomplete data sets. No information about data excluded from the control arm)*
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 *(Data is from a non-peer reviewed report. The study was non-randomised, did not provide information on baseline characteristics and provided limited information on analysis methods. Unclear how practices were selected for the control arm and data from a high proportion of the centres included in the intervention were excluded from the analysis)*
	Directness	Directly applicable

Shourie, 2013

Bibliographic Reference	Shourie, S; Jackson, C; Cheater, F M; Bekker, H L; Edlin, R; Tubeuf, S; Harrison, W; McAleese, E; Schweiger, M; Bleasby, B; Hammond, L; A cluster randomised controlled trial of a web based decision aid to support parents' decisions about their child's Measles Mumps and Rubella (MMR) vaccination.; Vaccine; 2013; vol. 31 (no. 50); 6003-10

Study details

Study type	Cluster randomised controlled trial
Study location	UK
Study setting	Community (participants were at home)

Study dates	May 2009 - September 2010
Sources of funding	National Institute for Health Research, Research for Patient Benefit Programme
Inclusion criteria	First-time parents with a child aged 3–12 months being offered the first dose of the MMR vaccine An email address and sufficient English language skills
Exclusion criteria	None
Intervention(s)	**Intervention 1:** Parents were posted a web link to the MMR decision aid and received usual practice from their GP practice (same as in the usual practice arm). **Intervention 2 (not relevant to this review):** Parents were sent a Health Scotland leaflet titled 'MMR your questions answered' and received usual practice (same as in the usual practice arm).
Comparator	Parents received an invite from their GP practice to have their child vaccinated for the first dose MMR at 12–13 months, usually including a leaflet with facts about the vaccine ('MMR the Facts') and an offer of a consultation if they had any concerns.
Outcome measures	Vaccine uptake
Number of participants	50 GP practices, 230 parents (127 parents in the 2 arms relevant to this review)
Duration of follow-up	When children reached 15 months of age
Additional comments	Intervention 2 (Health Scotland leaflet) was not relevant to this review as no associated qualitative studies were found. Information on this intervention is included in the education review

Study arms

MMR decision aid (N = 50) 14 clusters	
Loss to follow-up	5 GP practices, 6 parents
Usual practice (N = 77) 18 clusters	
Loss to follow-up	6 GP practices, 8 parents

Characteristics

Arm-level characteristics

	MMR decision aid (N = 50)	**MMR leaflet (N = 93)**	**Usual practice (N = 77)**
Mean age of parent *(years)*			
Mean/SD	32.2 (5.51)	33.29 (5.58)	31.43 (5.25)

	MMR decision aid (N = 50)	MMR leaflet (N = 93)	Usual practice (N = 77)
Mean age of child *(Months)*			
Mean/SD	9 (2.35)	8.04 (2.63)	8.33 (2.4)

Risk of bias (Cochrane Cluster risk of bias 2.0)

Section	Question	Answer
1a. Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Some concerns *(At baseline, participants in the decision aid arm had a higher number of people who had decisional conflict than parents in the control arm)*
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 deviations from intended interventions (If your aim is to assess the effect of assignment to intervention, answer the following questions).	Risk of bias judgement for deviations from intended interventions	Some concerns *(Usual practice already involved sending an information leaflet)*
3. Bias due to missing outcome data	Risk of bias judgement for missing outcome data	Low
4. Bias in measurement of the outcome	Risk of bias judgement for measurement of the outcome	Low *(Outcome assessors may have been aware of the intervention but outcomes were objective)*
5. Bias in selection of the reported result	Risk of bias for selection of the reported result	Low
Overall bias and Directness	Risk of bias judgement	Some concerns *(There were differences regarding decisional conflict at baseline between the arms. Usual practice involved sending out a leaflet)*
	Overall Directness	Directly applicable