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Complex intervention to promote human papillomavirus (HPV) vaccine uptake in school settings: A cluster-randomized trial

Cristyn Davies [a,b,c,*], Helen S. Marshall [d], Julia M.L. Brotherton [e,f,g], Kirsten McCaffery [h], Melissa Kang [i], Kristine Macartney [a,g], Suzanne M. Garland [j,k], John Kaldor [l], Gregory Zimet [m], S. Rachel Skinner [a,c], The HPV.edu Study Group

[a] Specialty of Child and Adolescent Health, Faculty of Medicine and Health, The University of Sydney, NSW, Australia
[b] Sydney Infectious Diseases Institute, The University of Sydney, NSW, Australia
[c] Wellbeing, Health and Youth National Health and Medical Research Council Centre for Research Excellence in Adolescent Health, Sydney, Australia
[d] Women's and Children's Hospital and School of Medicine and Robinson Research Institute, The University of Adelaide, SA, Australia
[e] Australian Centre for the Prevention of Cervical Cancer, Victoria, Australia
[f] Melbourne School of Population and Global Health, The University of Melbourne, Victoria, Australia
[g] National Centre for Immunisation Research and Surveillance, NSW, Australia
[h] Sydney Health Literacy Lab, School of Public Health, Faculty of Medicine and Health, The University of Sydney, NSW, Australia
[i] General Practice Clinical School, Sydney Medical School, Faculty of Medicine and Health, The University of Sydney, NSW, Australia
[j] Centre Women's Infectious Diseases Research, The Royal Women's Hospital, Melbourne, Victoria, Australia
[k] Reproductive and Neonatal Infectious Diseases, Department of Obstetrics and Gynaecology, University of Melbourne, Murdoch Children's Research Institute, Victoria, Australia
[l] The Kirby Institute for Infection and Immunity in Society, Faculty of Medicine, UNSW Sydney, NSW, Australia
[m] Department of Pediatrics, Division of Adolescent Medicine, Indiana University, Indianapolis, USA

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ABSTRACT

Using a cluster-randomized trial design, we aimed to evaluate a complex intervention to increase uptake of human papillomavirus (HPV) vaccination in schools. The study was undertaken in high schools in Western Australia and South Australia between 2013 and 2015 with adolescents aged 12–13 years. Interventions included education, shared decision-making, and logistical strategies. The main outcome was school vaccine uptake. Secondary outcomes included consent forms returned and mean time to vaccinate 50 students. We hypothesised that a complex intervention would increase 3-dose HPV vaccine uptake. We recruited 40 schools (21 intervention, 19 control) with 6, 967 adolescents. There was no difference between intervention and control (3-dose mean 75.7% and 78.9%, respectively). Following adjustment for baseline covariates, absolute differences in coverage in favour of the intervention group were: dose 1, 0.8% (95% CI, −1.4,3.0); dose 2, 0.2% (95% CI, −2.7, 3.1); dose 3, 0.5% (95% CI, −2.6, 3.7). The percentage of returned consent forms in intervention schools (91.4%) was higher than in control schools (difference: 6%, 95% CI, 1.4, 10.7). There was a shorter mean time to vaccinate 50 students at dose 3. The difference for dose 3 was 110 min (95% CI, 42, 177); for dose 2, 90 min (95% CI, −15, 196); and dose 1, 28 min (95% CI, −71, 127). Logs revealed the inconsistent implementation of logistical strategies. The intervention had no impact on uptake. Inadequate resourcing for logistical strategies and advisory board reluctance toward strategies with potential financial implications impacted the implementation of logistical components.

Trial registration: Australian and New Zealand Clinical Trials Registry, ACTRN12614000404628, 14.04.2014. The study protocol was published in 2015 before data collection was finalised (Skinner et al., 2015).

The HPV.edu study group: We would like to acknowledge the contributions to this study by members of the HPV.edu Study Group, including: Professor Annette Braunack-Mayer: Australian Centre for Health Engagement, Evidence and Values, School of Health and Society, Faculty of Arts, Social Sciences and Humanities, University of

Abbreviations: HPV, human papillomavirus; HPV.edu, a cluster-randomized trial, known as HPV.edu, to evaluate a complex multi-component intervention of educational and logistical strategies; WA, Western Australia; SA, South Australia; CFIR, Consolidated Framework For Implementation Research.

* Corresponding author at: Specialty of Child and Adolescent Health, Faculty of Medicine and Health, University of Sydney, Clinical School, Children's Hospital Westmead, Locked Bag 4001, Westmead, NSW 2145, Australia.
E-mail address: Cristyn.Davies@sydney.edu.au (C. Davies).

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Wollongong, NSW, Australia; Dr. Joanne Collins: Women's and Children's Health Network and School of Medicine and Robinson Research Institute, University of Adelaide, SA, Australia; Associate Professor Spring Cooper: School of Public Health, City University of New York (CUNY), New York, NY, USA; Heidi Hutton: Telethon Kids Institute, University of Western Australia, WA, Australia; Jane Jones: Telethon Kids Institute, University of Western Australia, WA, Australia; Dr. Adriana Parrella: Women's and Children's Health Network and School of Medicine and Robinson Research Institute, University of Adelaide, SA, Australia; and South Australian Health and Medical Research Institute (SAHMRI), Adelaide, Australia; Associate Professor David G. Regan: The Kirby Institute for Infection and Immunity in Society, Faculty of Medicine, UNSW Sydney, NSW, Australia; Professor Peter Richmond: Perth Children's Hospital, Child and Adolescent Health Service, Western Australia, Wesfarmers Centre of Vaccines and Infectious Diseases, Telethon Kids Institute, WA, Australia, and School of Medicine, University of Western Australia, Perth, WA, Australia; Dr. Tanya Stoney: Telethon Kids Institute, University of Western Australia, WA, Australia. Contact for the HPV.edu study group: Cristyn.Davies@sydney.edu.au or Rachel.Skinner@sydney.edu.au.

1. Introduction

Schools are ideal settings for administration of vaccines: they enable access to large numbers of age cohort, particularly for years in which attendance is compulsory; are convenient for families, promote peer support and social norms, assist in reducing inequitable access to vaccination and thereby facilitate high coverage (Davies et al., 2021a; Davies et al., 2017; Davies et al., 2021b; Gallagher et al., 2016; Perman et al., 2017). Interventions designed to improve school vaccination programs and coverage are important to ensure that delivery in this context is optimised (Abdullahi et al., 2020; Burns et al., 2021; Davies and Burns, 2014; Selvey et al., 2020). As part of the World Health Organization's cervical cancer elimination strategy, the objective is to have 90% of people with a cervix vaccinated against HPV by age 15, including all minority sub-groups (WHO, 2020).

Completed HPV course coverage in Australia (defined as 3 doses until 2017 and reduced to 2 from 2018) for 15-year-old females in 2020 was 81.5% and for males 78.6% (Brotherton et al., 2022). In Australia, HPV vaccination is Commonwealth government subsidised and free to eligible adolescents through the National Immunisation Program, which also offers diphtheria, tetanus and pertussis [dTpa] booster at the same time as HPV dose 1 (Davies and Skinner, 2021; Davies and Skinner, 2022). HPV vaccination commenced in 2007 for girls aged 12 to 13 years in the first year of high school using the quadrivalent HPV vaccine and was extended to male adolescents in 2013. In 2018, the program transitioned to the 9-valent HPV vaccine (Markowitz et al., 2022).

Adolescents are primarily vaccinated via state and territory-based programs through schools (including government, Catholic, and independent sectors) delivered on designated 'vaccination days' on school grounds after obtaining parental or guardian (hereafter 'parent') consent. Government schools are primarily subsidised by the state government, while Catholic and independent schools require payment of fees from families. Known associations with lower uptake in Australian schools include smaller schools, schools with a higher proportion of Indigenous adolescents, and lower student attendance rates (Vujovich-Dunn et al., 2022). Logistical and organisational factors can influence the successful implementation of school-based vaccination. These factors may include: program leadership and governance; organisational models for vaccination delivery and intersectoral relationships; workforce capacity and roles; communication with parents and students; methods for obtaining consent; organization of vaccination day clinics, and methods for catch up of missed doses (NCIRS, 2021).

To investigate the impact of addressing these issues collectively, we undertook a cluster-randomized trial, known as HPV.edu, to evaluate a complex multi-component intervention of educational and logistical strategies in 40 Australian schools, and have previously reported on secondary outcomes (Davies et al., 2021a; Davies et al., 2017; Davies et al., 2021b). We found solid gains in adolescent knowledge and attitudes related to HPV vaccination (Davies et al., 2017) and small improvements in decisional involvement and vaccine-related confidence and reduced vaccination-related fear and anxiety maintained throughout the vaccine course (Davies et al., 2021a).

Our primary hypothesis was that a complex intervention would increase 3-dose HPV vaccine uptake. We also hypothesised that implementation of logistical components of the intervention would improve vaccination day processes and consent form returns. Further, we hypothesised that implementation of logistical components would improve uptake.

2. Methods

2.1. Design

This study was a community-based cluster-randomized controlled trial of a complex multi-component intervention, with schools as clusters (Skinner et al., 2015). We also undertook a process evaluation, including a qualitative study (Skinner et al., 2015). We followed the CONSORT guidelines (Schulz et al., 2010) for reporting on clinical trials. To guide the development of the logistical intervention and study design, we employed an ecological framework and the United Kingdom's Medical Research Programme Council's Evaluation Framework to understand multiple levels of influence within a complex system (Campbell et al., 2000; Craig et al., 2008; Richard et al., 2011). We also used the Consolidated Framework For Implementation Research (CFIR) to interpret our findings, as this structure helps understand real-world intervention's complex, interacting, and multi-level dimensions (Damschroder et al., 2009). The intervention and data collection spanned 2013 to 2015.

2.2. Changes to protocol post-publication

Advisory board guidance precluded additional in-school vaccination catch-up visits and non-monetary rewards for consent form return. Therefore, we could not systematically implement several planned strategies.

2.3. Participants and recruitment

Schools (clusters) in Western Australia (WA) and South Australia (SA) were recruited as per protocol (Skinner et al., 2015) in 2013–2014. State health department immunisation teams and school personnel were responsible for delivering health department-directed vaccination program activities and the intervention's logistical components. Principals, school personnel and immunisation staff consented to participate in the study.

2.4. Intervention

Control schools conducted the vaccination program as per their usual practice. Vaccination consent forms, vaccination room set-up and catch-up vaccinations followed standard procedures described in state guidelines (Government of Western Australia Department of Health,

2008, 2022; SA Health: Government of South Australia, 2013, 2014).

Intervention schools delivered an intervention including three components (Davies et al., 2021a; Davies et al., 2017). The intervention and proposed mechanisms of action are represented in Fig. 1.

1) Adolescent in-class education and vaccination-day guidelines were designed to improve vaccination literacy, psychosocial outcomes, and vaccination experience.
2) Decisional support tool booklet was designed to promote shared parent-adolescent decision-making;
3) Logistical component comprised consent form return strategies, in-school catch-up of missed doses, vaccination-day guidelines to improve organisational processes, and student vaccination experience was designed to improve uptake (Skinner et al., 2015).

In intervention schools, research staff packaged the decisional support tool with the standard vaccination consent package sent to parents, where possible. Vaccination-day guidelines for the intervention schools intended to improve processes and experience of vaccination. The guidelines included: 1) instructions about optimal vaccination clinic room set-up to minimise student anxiety, maximise privacy and assist with the efficiency of vaccination-day processes, and 2) distraction strategies to directly reduce adolescent anxiety (Davies et al., 2018; Skinner et al., 2015). Immunisation teams were encouraged to provide in-school catch-up vaccinations in intervention schools where appropriate. Study staff offered training to school personnel and their immunisation teams. During this training session, a fidelity log of study activities was provided to immunisation staff (Appendix 1) and school personnel to complete (Appendix 2).

2.4.1. Outcomes

The primary outcome was 3-dose HPV immunisation completion. Secondary outcomes relevant to logistical components' impact (secondary outcomes 2a and 2b) included a) the time to vaccinate students in intervention and control groups and b) the proportion of consent form returns between intervention and control (Skinner et al., 2015). We calculated the group differences for these primary and secondary outcomes (Appendix 3).

Vaccination uptake data were obtained from de-identified records from each state's health department at the end of the school year. Vaccination consent form return rate was calculated using the data provided by the vaccination nurses on the fidelity log completed after HPV dose 1 and the time taken to vaccinate students for each dose (Appendix 1).

2.5. Sample size

The sample size was calculated to detect an increase in 3-dose vaccination uptake of 10%, from 70% to 80%, at 0.05 significance and with a power of 80%, assuming an intraclass correlation coefficient (ICC) of 0.05 (Skinner et al., 2015). To allow for dropout, we increased the sample by 10% to 40 schools (Skinner et al., 2015).

2.6. Randomization

We recruited a stratified random sample of schools, then randomly allocated to intervention or control (Skinner et al., 2015). This process and allocation concealment occurred per the protocol (Skinner et al., 2015).

2.7. Statistical analysis

Primary outcome: analysis compared mean school vaccination uptake percentage using the Mantel-Haenszel method, in a two-step process as per protocol: 1) taking into account stratification by year, state and school sector and adjusted for clustering, 2) logistic regression models adjusting for baseline vaccination rates (average of the previous 2 years), school type (single-sex, or mixed), school size and Socio-Economic Indexes for Areas using generalized estimating equations with robust standard errors (Skinner et al., 2015). Secondary outcomes: (2a) the vaccination consent form return rate was calculated as the number of vaccination consent forms returned divided by the total number of students eligible for vaccination in the school year group. The proportion of consent form returns before dose 1 was compared between

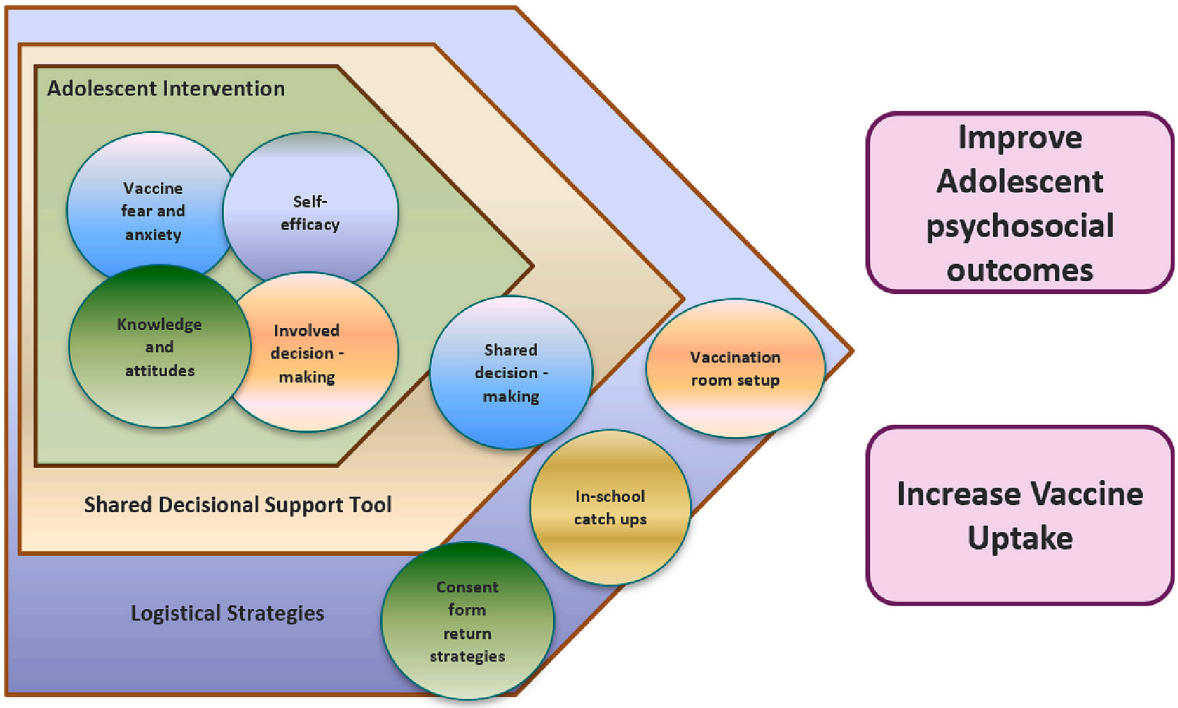

Fig. 1. Multi-component intervention logic model.

groups using a Chi-square test with appropriate adjustment for clustering. (2b) Time taken to vaccinate an average of 50 students in each school was calculated using the reported total number vaccinated during the session, the total time between the start and end of the vaccination session (minus pre-specified breaks) and the number of nurses vaccinating. Significance was set at $P < 0.05$. Statistical analyses were performed with SAS statistical software version 9.4 (SAS Institute).

2.8. Process evaluation

We conducted a process evaluation in all schools. Using data from the fidelity logs (Appendices 1 and 2), we scored compliance with immunisation day guidelines, based on four activities considered essential for improving processes and student experience: ≤30 students waiting to be vaccinated, students occupied pre-vaccination, a separate entry and exit door, and student privacy. Mean implementation scores across all 3 doses (maximum score 12) were calculated for each school by group. Control schools followed similar processes in relevant guidelines (Government of Western Australia Department of Health, 2008; SA Health: Government of South Australia, 2013, 2014).

Within the main study, we conducted a qualitative study based on 11 schools (5 control and 6 intervention). In semi-structured interviews, immunisation nurses were asked about vaccination program logistics. Interviews took place after HPV dose 2 or 3 had been offered in the school program, and were digitally recorded and transcribed verbatim. Participants were recruited until no new relevant knowledge was obtained. Recruitment stopped once thematic saturation was achieved.

The first author (C.D.) performed all analyses and was blinded to the study group. Transcripts were coded in NVivo9, and data were subject to thematic analysis (Braun and Clarke, 2006). Inductive and deductive approaches were used to generate thematic codes. C.D. developed codes with input from the research team and two student assistants: coding was undertaken line by line, with team members' identifying and discussing themes. Conceptual saturation was reached when no new codes were generated. C.D. performed an overall analysis to ensure that diverse themes emerging from the data set were represented. Data analysis was conducted from January 2017 to October 2022.

2.9. Advisory board

We established an advisory board with representatives from the health department and immunisation teams in WA and SA, and the government, Catholic school, and independent education sectors. The board provided input on all aspects of the study.

2.10. Ethics

The study was approved by the following ethics committees: Department of Health Western Australia, Women's and Children's Health Network South Australia, South Australian relevant government authorities, and the University of Sydney, Australia.

3. Results

The 40 study schools (21 intervention; 19 control) included 6967 students in the target year groups (mean age = 13.70 years; SD = 0.45 years) (Table 1) (Davies et al., 2021a).

The socio-demographic characteristics of study schools were similar across groups, with good representation of schools across all socio-economic groupings. Mean HPV vaccination uptake in intervention schools in the year before the study was similar to control schools (77% versus 79%, respectively). In WA, where 24 schools were recruited, the proportion of study schools from each sector (government, Catholic, independent) was similar to that of schools from each sector in the state. (Appendix 4). In SA, the proportion of government schools recruited was slightly less than that in the state (38% versus 44%).

All schools remained enrolled throughout the study (Fig. 2).[3]

3.1. Number and proportion of students who received each vaccination (primary outcome)

There was a small, non-significant difference in favour of the intervention group for each HPV vaccine dose: dose 1, 0.8% (95% CI, −1.4,3.0); dose 2, 0.2% (95% CI, −2.7, 3.1); dose 3, 0.5% (95% CI, −2.6, 3.7) (Table 2).

3.2. Vaccination consent forms returned (secondary outcome 2a)

Sufficient data were collected at dose 1 in 18 (of 21) intervention schools and 17 (of 19) control schools to calculate HPV consent form return rate. Intervention schools had a significantly higher return rate than controls (91.4% intervention versus 87.9% control; difference, 6.0, 95% CI, 1.4, 10.7) (Table 3 *Time to vaccinate 50 students (secondary outcome 2b)*.

Sufficient data were recorded by 18 (out of 21) intervention schools and 17 (out of 19) control schools to calculate time to vaccinate for HPV dose 1; 17 intervention schools and 17 control schools for dose 2, and 14 intervention schools and 16 control schools for dose 3. The mean time to vaccinate 50 students was shorter in intervention schools than in control for all HPV doses but only significant for dose 3. HPV dose 1: 226 versus 310 min (adjusted difference 90; 95% CI, −15, 196; $p = 0.089$); HPV dose 2: 228 versus 257 min (adjusted difference 28; 95% CI, −71, 127; $p = 0.57$) and HPV dose 3: 137 versus 248 min (adjusted difference 110; 95% CI, 42,177; $p = 0.0027$).

3.3. Implementation of consent form return strategies

Eighteen of the thirty-three schools (8 intervention and 10 control) participating in the study in 2014 reported actively reminding students and parents to return the vaccination consent form, suggesting that there was no increase in the systematic implementation of reminders in intervention schools. Strategies used included daily reminders to students, email/letters to parents, phone calls, and school newsletter notices.

3.4. Vaccination clinic set-up

Based on the four essential immunisation day guideline recommendations, intervention schools had a higher average implementation score (7.3 out of 12) for compliance with guidelines than controls (5.9 out of 12) across all 3 doses of HPV vaccine (Table 4).

3.5. In-school catch-up visits

In WA, where in-school catch-up visits were part of standard practice, fidelity logs revealed that eight schools (4 control with 16 visits, and 4 intervention with 12 visits) reported participating in HPV vaccine catch-up clinics. The average number of in-school catch-up visits for the intervention and control groups were 3 and 4, respectively.

3.6. Qualitative findings

Ten interviews with eleven immunisation nurses were conducted across jurisdictions (Appendix 5).

3.6.1. Consent form return barriers and facilitators

Immunisation nurses reported the following barriers to vaccination regarding consent forms: incorrect/incomplete consent forms; no consent form is "not the same as a 'no' consent" (INWA003) to vaccination; consent form couriered by the adolescent is not fool proof; calling parents to attain verbal consent on vaccination day slows down clinic processes; and consent forms expire impeding administration of catch-

Table 1
Summary of participating schools and students completing HPV 3 doses.

		Intervention			Control			Total		
		Schools (n (%))	Students enrolled in participating years (n (column %))	Students received all 3 vaccinations (n (row %))	Schools (n(%))	Students enrolled in participating years (n (column %))	Students received all 3 vaccinations (n (row %))	Schools (n(%))	Students enrolled in participating years (n (column %))	Students received all 3 vaccinations (n (row %))
Total		21	3805	2870 (75.4)	19	3162	2483 (78.3)	40 (100)	6967 (100)	5353 (76.8)
Year	2013	4 (19)	554 (15)	463 (83.6)	3 (16)	450 (14)	363 (80.7)	7 (17.5)	1004 (14.4)	826 (82.3)
	2014	17 (81)	3251 (85)	2407 (74.0)	16 (84)	2712 (86)	2120 (78.2)	33 (82.5)	5963 (85.6)	4527 (75.9)
State	South Australia	8 (38)	1162 (31)	880 (75.7)	8 (42)	1054 (33.0)	817 (77.5)	16 (40)	2216 (31.8)	1697 (76.6)
	Western Australia	13 (62)	2643 (69)	1990 (75.3)	11 (58)	2108 (67.0)	1666 (79.0)	24 (60)	4751 (68.2)	3656 (77)
Sector	Government	9 (43)	2042 (54)	635 (81.0)	8 (42)	1488 (47)	841 (82.0)	17 (42.5)	3530 (50.7)	1476 (41.8)
	Independent	7 (33)	979 (26)	1461 (71.5)	5 (26)	648 (20)	1110 (74.6)	12 (30)	1627 (23.4)	2571 (158)
	Catholic	5 (24)	784 (21)	774 (79.1)	6 (32)	1026 (32)	532 (82.1)	11 (27.5)	1810 (26)	1306 (72.2)
Co-educational	Yes	16 (76)	3082 (81)	2266 (73.5)	15 (79)	2530 (80)	1955 (77.3)	31 (77.5)	5612 (80.6)	4221 (75.2)
	Female only	2 (10)	245 (6)	205 (83.7)	2 (11)	248 (8)	227 (91.5)	4 (10)	493 (7.1)	432 (87.6)
	Male only	3 (14)	478 (13)	399 (83.5)	2 (11)	384 (12)	301 (78.4)	5 (12.5)	862 (12.4)	700 (81.2)
Total enrolled in school	< 800	2 (10)	196 (5)	633 (64.9)	4 (21)	401 (13)	207 (76.7)	6 (15)	597 (8.6)	840 (140.7)
	800 to 999	10 (48)	1557 (41)	721 (77.2)	3 (16)	442 (14)	627 (76.2)	13 (32.5)	1999 (28.7)	1348 (67.4)
	1000 to 1299	2 (10)	343 (9)	499 (74.9)	9 (47)	1763 (56)	1066 (77.2)	11 (27.5)	2106 (30.2)	1565 (74.3)
	1300 and over	7 (33)	1709 (45)	1017 (82.7)	3 (16)	556 (18)	583 (84.6)	10 (25)	2265 (32.5)	1600 (70.6)
ICSEA group	< 1000	4 (19)	975 (26)	161 (82.1)	2 (11)	270 (9)	316 (78.8)	6 (15)	1245 (17.9)	477 (38.3)
	1000 to 1049	6 (29)	934 (25)	1152 (74.0)	5 (26)	823 (26)	306 (69.2)	11 (27.5)	1757 (25.2)	1458 (83)
	1050 to 1099	4 (19)	666 (18)	263 (76.7)	7 (37)	1380 (44)	1415 (80.3)	11 (27.5)	2046 (29.4)	1678 (82)
	1100 and over	7 (33)	1230 (32)	1294 (75.7)	5 (26)	689 (22)	446 (80.2)	12 (30)	1919 (27.5)	1740 (90.7)
Previous year's vaccination rate	$\leq 70\%$	5 (24)	999 (26)	701 (70.2)	3 (16)	417 (13)	273 (65.5)	8 (20)	1416 (20.3)	974 (68.8)
	71% to 80%	8 (38)	1736 (46)	1287 (74.1)	5 (26)	958 (30)	752 (78.5)	13 (32.5)	2694 (38.7)	2039 (75.7)
	81% to 85%	5 (24)	719 (19)	583 (81.1)	6 (32)	1051 (33)	860 (81.8)	11 (27.5)	1770 (25.4)	1443 (81.5)
	$> 85\%$	2 (10)	247 (6)	208 (84.2)	4 (21)	563 (18)	465 (82.6)	6 (15)	810 (11.6)	673 (83.1)
	No previous vaccinations at school	1 (5)	104 (3)	91 (87.5)	1 (5)	173 (5)	133 (76.9)	2 (5)	277 (4)	224 (80.9)

ICSEA: Index of Community Socio-Educational Advantage.

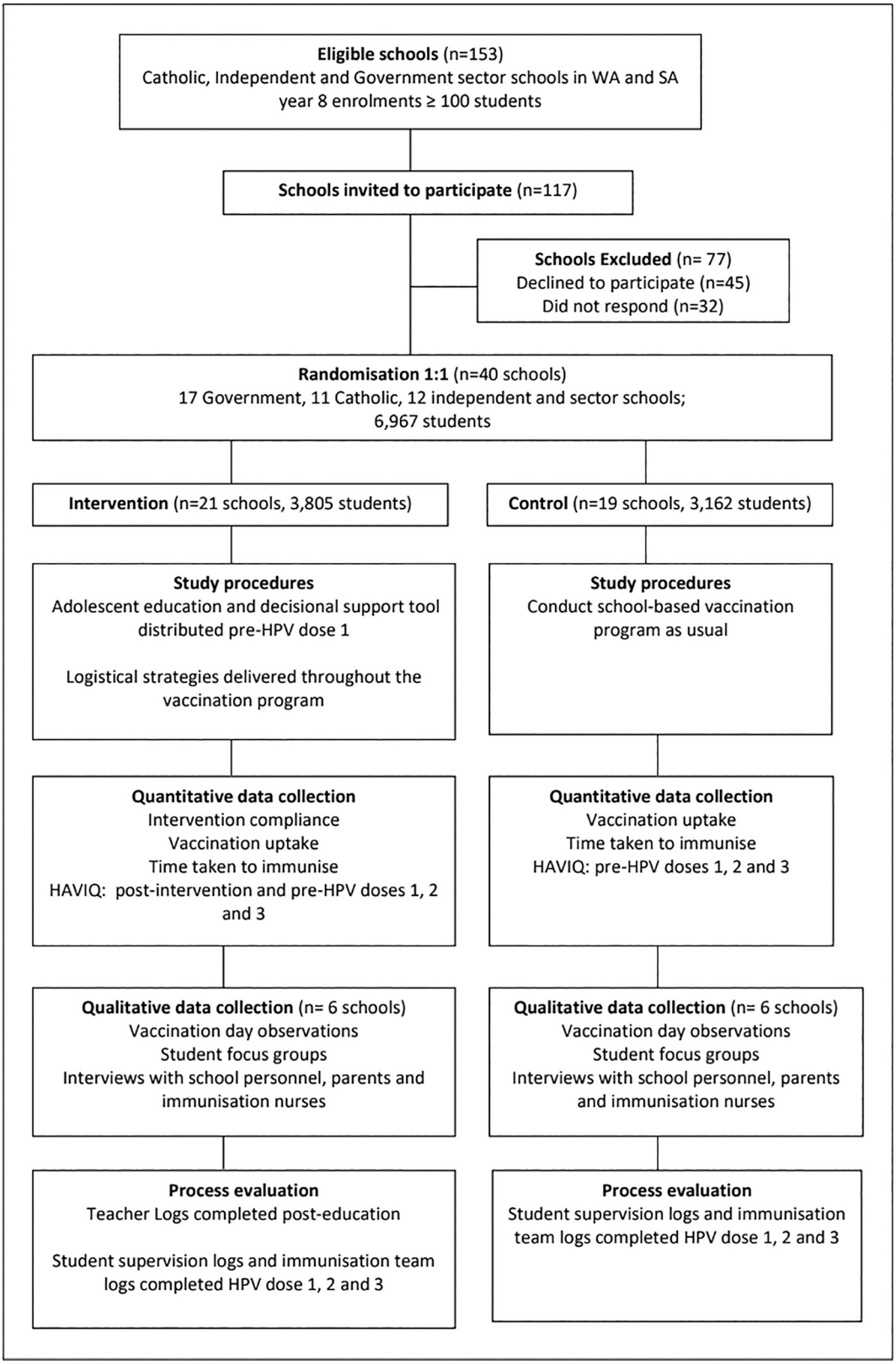

Fig. 2. CONSORT HPV.edu study design.

up vaccines. Common consent form errors included parents not marking correct boxes for all vaccines or having a person without legal guardianship of the adolescent complete the form.

Facilitators included two-week time-limited turn-around for consent form return; a good relationship with the school coordinator; 'conscientious' school personnel; calling parents improves consent rates; and immunisation guidelines outlining roles and procedures (Table 5).

3.6.2. *Catch-up HPV vaccine doses barriers and facilitators*

Immunisation nurses reported the following barriers to vaccine

Table 2
Number and proportion of students receiving each vaccination.

Vaccine dose (1,2,3)	Group (I/C)	Schools (n)	Students enrolled (n)	Students vaccinated (n)	Mean percentage of students vaccinated (%)	Difference (95% CI)*	P-value*	Difference (95% CI)	P-value**
1	I	21	3805	3272	86.0	0.0	0.96	0.8	0.47
	C	19	3162	2705	85.6	(−2.8, 2.9)		(−1.4, 3.0)	
2	I	21	3805	3184	83.7	−0.3	0.88	0.2	0.89
	C	19	3162	2649	83.8	(−3.4, 2.9)		(−2.7, 3.1)	
3	I	21	3805	2881	75.7	−2.5	0.20	0.5	0.74
	C	19	3162	2494	78.9	(−6.4, 1.4)		(−2.6, 3.7)	

* Adjusted for year, state, sector, co-educational status and clustering of students within schools.
** Additionally adjusted for total enrolments group, ICSEA group and previous vaccination rate group.

Table 3
Percentage of vaccination consent forms returned.

Group	Consent forms returned	Adjusted difference* (95% CI)	P-value
Intervention (n = 18)	91.4% (3015/3297)	6.0 (1.4, 10.7)	0.0025
Control (n = 17)	87.9% (2497/2842)		

* Adjusted for year, state, school type.

catch-up: inability to perform in-school catch-ups due to program restraints; adolescent vaccine refusal despite parental consent; adolescents requiring catch-up not vaccinated promptly in the community; catch-up doses administered in a primary care setting may incur a fee; GPs not recording doses, and school not prepared for catch-up clinics. Community catch-up vaccination clinics were likelier to be near the school than the local area where families resided.

Facilitators of vaccine catch-up included: in-school catch-up clinics for missed doses; and processes were optimised where schools partnered with immunisation nurses to deliver the program (Table 5).

4. Discussion

For the primary outcome of this cluster randomized trial, the complex intervention had no impact on HPV vaccine uptake. However, the process evaluation showed that logistical components designed to improve consent form returns and in-school catch-up vaccinations were not systematically implemented in intervention schools; these strategies may be essential for high uptake in school-based vaccination. Another possible explanation for the lack of effect is a high baseline first-dose mean uptake. The 15% of adolescents who did not receive the first dose in this study may require an individually tailored approach. Despite the lack of impact on uptake, the intervention also increased consent form returns by 6 percentage points.

We identified barriers and facilitators to implementing the logistical intervention in several key domains of the CFIR framework (Damschroder et al., 2009) (Table 6).

These included long-term cost (domain 1, cost), given that the intervention included modest financial compensation to resource additional in-school vaccination catch-ups (domain 3, available resources). Due to longer-term financial implications, the advisory board did not support funding additional in-school catch-ups in one jurisdiction. In the other jurisdiction, in-school catch-ups were not part of the school program policy (domain 2, external policies) and were not considered feasible. Therefore, in-school catch-up visits were not systematically implemented in intervention schools. The evaluation found that intervention schools implemented in-school vaccination day strategies to a greater extent than control schools. These in-school strategies were compatible with the goals outlined in the existing state school-based immunisation guidelines (domain 3, compatibility).

The intervention recommended non-monetary rewards to encourage student consent form return. The advisory board was not supportive as they believed this strategy would be ineffective (domain 1, relative advantage), informed by a study undertaken in WA (Mak et al., 2011). The study's goal of 90% consent form return rate was likely too high. Forster and colleagues demonstrated the feasibility of a modest financial incentive to increase consent form returns with HPV vaccine-eligible adolescent girls (87% consent form returns in the intervention group compared with 67% in the control) (Forster et al., 2017). Working with an advisory board requires understanding all members' positions and multiple levels of accountability and influence. Further consultation with additional decision-makers may be required to foster support for an effective strategy. The small increase in consent form return did not eventuate in more vaccination completions. While surprising, there are other required steps between consent return and receipt of vaccination that impact uptake, such as the adolescent being present on vaccination day, which are not influenced by consent return.

There are several issues impacting consent form returns that may undermine the success of the school-based program. Interviews with immunisation nurses showed that barriers to obtaining consent are process-driven (domain 4, knowledge and beliefs about the intervention). Clearly defined guidance on the steps necessary to overcome these barriers could assist. For example, consent forms could be delivered electronically to parents in addition to hard copy (Australian Centre for the Prevention of Cervical Cancer, 2022; NCIRS, 2021); consent form design could be inclusive of people with low literacy and non-English speaking background (Davies and Burns, 2022; NCIRS, 2021; Netfa et al., 2021); resourcing for obtaining verbal consent from parents could be allocated before vaccination day, and the school-based program could consider verbal consent for young people after competency assessment (Chantler et al., 2019; Ferrer et al., 2014; Fisher et al., 2021; Fisher et al., 2020; Zimet et al., 2021) (domain 5, planning and engaging).

Implementation of the logistical study guideline strategies in

Table 4
Average implementation scores for the set-up of the in-school vaccination clinic.

Group	HPV dose 1 average score (max. = 4)	HPV dose 2 average score (max. = 4)	HPV dose 3 average score (max. = 4)	Average total score (max. = 12)	Adjusted difference* (95% CI)	P-value
Intervention (n = 21)	2.48	2.33	2.48	7.29	1.4 (0.03,2.8)	0.046
Control (n = 19#)	1.74	1.89	2.26	5.89		

* Adjusted for year, state, school type.
\# School 113 did not return either the immunisation nurse log or the pre-vaccination supervision log for HPV dose 3, therefore an average of the HPV dose 1 and 2 scores was used to allocate school 113 an implementation score for HPV dose 3.

Table 5
Illustrative quotes from interview findings with immunisation nurses.

Theme	Illustrative quotes from interview findings with immunisation nurses ($n = 11$)
Consent form return	
Barriers	
Incorrect or incomplete vaccination consent forms	With this year's consent form the way it was set out there was a thing at the top that says, "I consent", and people would tick that. […] underneath it says "I do not consent" but they would sign there. So, they were ticking "I consent" [and then] signing "I do not consent" (INSA005). You might get a small batch that a carer has signed. Or a grandmother. Or – One came back that the brother had signed. You know - and that not's legitimate; it has to be a legal guardian (INSA001).
No consent form return does not equal no consent	Not returned consent forms [are] not the same as a "no" consent (INWA003).
Role of adolescent in consent form return	If the boys said they wanted it themselves then they would come back with it – So like educating the boys who hadn't returned the forms had better influence in getting the forms back (INWA001).
Phoning parents	We will be calling parents on the day, and it will take a lot longer (INSA002).
Expiry date	We have to re-consent them because their consents have expired (INWA2006).
Facilitators	
Time-limited turn-around for consent form return	We usually give them a two-week turnaround. […] the longer parents have um, the more likely those forms are going to get lost or waylaid (INSA003).
Phoning parents	[phoning parents on vaccination to obtain verbal consent] is when we got the bulk of the forms back (INSA002).
Relationship with school coordinator	At the beginning of the year […] we provide a list, a guideline for the coordinator as far as them dispensing the consent forms to the class teachers. We advise them that they should have a manila folder, that they should have a student list so that they can keep a track of the consent forms that have been returned, and then they need to have them back by a certain day, so they've got them all together for us to collect them a few days later on an already arranged date for collection (INSA004). The teachers are conscientious […] some schools will give it attention. They make it obvious to the child that they should get it [the vaccine]. And then you will get some private schools that will actually phone the parents– Or send an email or a text – Or whatever they do – To say, your child hasn't returned his/her consent form. And if they were all like that, that would make our life much easier (INSA005).
Implementation of immunisation guidelines: Consent	The guidelines are useful for our work because they clarify queries, they clarify our role. Particularly around consent and policy procedure regarding gaining legal consent to dealing with the form and what to do with the form afterwards and how to deal with a sick child, what our role is with that. And it also helps with relaying, or having something, a piece of paper, something "official" to float in front of the school to say, well this is our role, that is not our role (INSA003).
Missed HPV vaccine doses	
Barriers	
Some jurisdictions cannot implement catch-ups due to program restraints	We don't go back to school. Our schedule is run really tight, so we have got very limited time between one lot of schools and the next lot of visits (INSA003).
Parent consent, and adolescent vaccine refusal	There is not a lot. You can try and talk to them; you can say to them: 'Go away and come back at recess or lunchtime.' Often, they will then. They have seen that their friends have been okay. Sometimes one of their friends will bring them back (INSA005).
Timing of catch-up doses administered in community	You are going back another time to vaccinate them again four weeks later or whatever, or 12 weeks later depending on the dose, but little Johnny missed it at school, and he has had it at the GP four weeks later in the school holidays and now we are fronting up and like you know what we then have to liaise with the parent when did he have it? The timing needs to fit with other doses when we visit the school (INWA005).
Vaccine payment	They would get them [HPV vaccine] for free, but the doctor may well charge a consult. So, with us they are free and it is convenient for parents for the children to be done (INSA004). We have heard some horrific stories about people fronting up with their children to be vaccinated and they have been given a script and told to go to the chemist and the chemist is saying that will be $150 please, and they have just gone what?! I don't think so, and back away, and they give us a call. And we go, no that is wrong (INWA003).
Recording doses	Some doctors don't enter anything on the database, which doesn't help (INWA003).
School not prepared for vaccine catch-up clinics	Sometimes you arrive at the school to catch up students who have missed a dose, and the kids are not organised and ready, and we are left waiting for 20 minutes or more (INWA005).
Facilitators	
Some jurisdictions can implement in-school catch-up clinics	We vaccinated about 170 kids who didn't finish their vaccination schedule last year (INWA004).
Effective partnerships between schools and immunisation teams	They knew where those kids were at all times and they knew what kids we needed to see. There was no point in … … catch up if those kids weren't brought down. And um … … they knew exactly where every kid was and why they weren't there. And I don't – I just think some schools are more organised than other schools (INWA001).

intervention schools, combined with the adolescent intervention, was the likely reason for the reduced time to vaccinate adolescents. The guidelines were intended to provide an environment whereby student anxiety was minimised, and vaccination processes were streamlined. The adolescent intervention improved vaccination literacy, which in turn improved self-efficacy and reduced fear and anxiety (Davies et al., 2021a; Davies et al., 2017). This clearly impacted student wellbeing, behaviour and compliance on vaccination day (Davies et al., 2021a).

5. Limitations

There were some limitations in this study. First, although this was a stratified random sample of schools, one-third of schools approached agreed to participate. This may have biased the sample toward schools with higher vaccination rates, which may have had an impact on the ability of the intervention to have an effect. Second, schools were not blinded to group allocation. Third, insufficient information was reported in the logs to calculate vaccination timing for all three HPV doses in all study schools. Fourth, a smaller proportion of schools contributed timings for HPV dose 3. This may have introduced bias to the time-to-completion result. The data from this study were collected at a time when a three-dose schedule was required, whereas now only one dose is required. A one-dose schedule from 2023 is likelier to be easier to implement and may overcome some of our identified challenges in delivering a school-based program.

6. Conclusion

Our intervention had no significant impact on vaccine uptake, but a slightly higher rate of consent form returns and time savings for third-dose delivery, which may have cost savings for future program planning. Changes to school-based vaccination requires consideration of the

Table 6
Implementation of HPV.edu logistical strategies to promote vaccine uptake organised by CFIR domains.

CFIR domain	CFIR construct	Strategies
1. Intervention characteristics	Cost	Intervention included modest financial compensation to resource additional in-school vaccination catch-ups. Advisory board recognised short-term benefit but was concerned about long-term financial implications.
	Relative advantage	The intervention recommended non-monetary rewards to encourage student consent form return. Advisory board not supportive as they believed this strategy would be ineffective.
2. Outer setting	External policies and incentives	In one jurisdiction, in-school vaccine catch-ups were not part of the school program policy and were unlikely to be implemented.
3. Inner setting	Implementation climate:	Intervention in-school vaccination day strategies were compatible with goals outlined in existing state school-based immunisation guidelines.
	o Compatibility	More intervention schools than control implemented these strategies.
	o Available resources	Intervention included modest financial compensation to resource additional in-school vaccination catch-ups. Advisory board recognised short-term benefit but was concerned about long-term financial implications.
	o Organisational incentives and rewards	The intervention recommended non-monetary rewards to encourage student consent form return. Advisory board not supportive as they believed this strategy would be ineffective.
4. Characteristics of individuals	Knowledge and beliefs about the intervention	The advisory board member from health worked within a restricted budget. Therefore, the board vetoed logistical strategies that may have had longer term financial implications for the school-based immunisation program beyond the duration of the intervention (in-school vaccine catch-ups), and also strategies they believed would not be effective (non-monetary rewards to encourage consent form return). Immunisation nurses identified other consent form barriers than simply higher returns. Immunisation nurses identified program restraints to implementing additional in-school catch-ups, and barriers to out of school catch-ups. Where in-school catch-ups were resourced, they were viewed favourably.
5. Process	Planning and engaging	The intervention was developed prior to the study based on formative work. The advisory board was consulted and supported or vetoed components. School personnel and immunisation teams were briefed and trained about the components of the complex intervention by study staff.

Abbreviations: CFIR: Consolidated Framework for Implementation Research; HPV: human papillomavirus.

organisational model and multiple levels of influence. Inadequate resourcing for logistical strategies, such as funding direct mail-out of consent forms, and advisory board reluctance about strategies with potential financial implications impacted implementation. Working with stakeholders at all levels is crucial to successfully implementing complex interventions.

Ethics approval and consent to participate

The study was approved by the following ethics committees: Department of Health Western Australia, Women's and Children's Health Network South Australia, South Australian relevant government authorities, and the University of Sydney, Australia.

Consent for publication

All authors consent to submission for publication.

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Authors' contributions

CD and SRS had full access to all the data in the study and take responsibility for the integrity of data and the accuracy of the data analysis.

Conceptualization: CD, HM, GZ, KMc, JMLB, SG, SRS.

Investigation, methodology, data curation, acquisition, formal analysis, or interpretation, validation, visualization: CD, HM, JMLB, KMc, MK, JK, GZ, SRS.

Writing - original draft: CD, SRS.

Critical revision of the manuscript for important intellectual content: All authors.

Funding acquisition: HM, JMLB, KMc, MK, SG, JK, GZ, SRS.

Project administration, resources, software: CD, HM, SRS.

Supervision: SRS, GZ, MK, KMa.

Declaration of Competing Interest

Davies reported receiving personal fees from Pfizer to conduct education for primary care physicians outside the submitted work. Dr. Marshall reported receiving grants from GlaxoSmithKline outside the submitted work. Dr. Zimet reported receiving personal fees and grants from Merck and personal fees from Moderna and Pfizer outside the submitted work. Dr. Garland reported receiving grants and personal fees from Merck and serving on the Merck Global Advisory Board HPV outside the submitted work. Dr. Skinner reported that her institution received honoraria from GlaxoSmithKline and Seqirus. No other disclosures were reported.

Data availability

HPV.edu study data includes immunisation data that belongs to state jurisdictions and cannot be shared.

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Appendices. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ypmed.2023.107542.

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