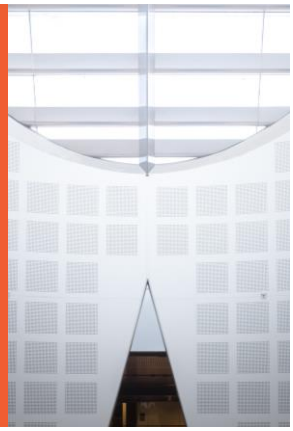
RANDOMISED CONTROLLED TRIAL OF A COMPLEX INTERVENTION TO IMPROVE SCHOOL-BASED HPV VACCINATION FOR ADOLESCENTS: THE HPV.EDU STUDY



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Introduction

- Few countries have SBIPs; mechanisms for building success of SBIPs not established
- School programs rely on good will of education sector, prevailing positive attitudes to vax, support of individual schools- consent forms, vaccination day set up[1,2].
- Our systematic review - education (student), logistics: consent form returns, incentives and mop up strategies (few previous controlled trials)[3]
- **Qualitative research in NSW and SA – student knowledge, discussion with parents, vaccination anxiety; certain vaccination day processes can support experience for adolescents [1,4-7]**

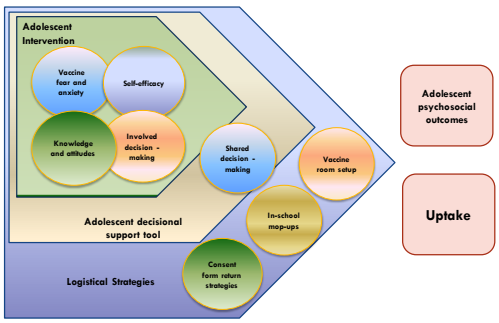
[1]Braunack-Mayer et al, Am J Public Health 2015 (Health Bridges study); [2]Ward et al, CDI 2013; [3] Cooper-Robbins, Vaccine 2011, [4]Cooper Robbins Vaccine 2010, [5]Cooper Robbins Sexual Health 2011; [6]Bernard MJA 2011; [7]Marhsall et al, Vaccine 2014

The HPV.edu Study

Aims

- **To improve outcomes for students**
  - Promote student knowledge about HPV vaccination
  - Improve psycho-social outcomes
- **Promote vaccination uptake**

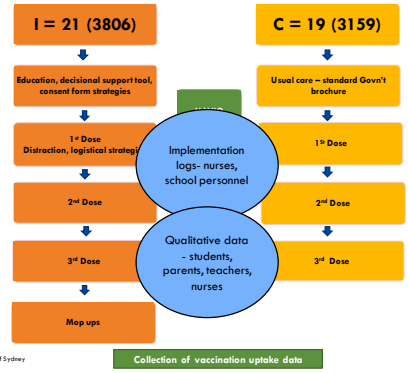
Complex intervention



Complex intervention

- **Adolescent intervention:**
  - In-school teaching with resources and teacher training
  - Animated film with 7 chapters (DVD)
  - Take home magazine
  - Website and app for iphone/ipad/android **www.takechargehpv.org**
  - Distraction/relaxation strategies for use on vaccination day (via ipad app, teaching materials)
- **Decisional support tool**
- **Logistical interventions:** Consent form returns, incentives and in-school mop up strategies

40 Schools (6965 year 8 students)



Qualitative evaluation

- **6 intervention and 6 control schools** (purposive selection as **'case studies')**
  - **15 Student focus groups** (9 control, 6 intervention; 111 students; 63 girls & 48 boys)
  - 22 Parent interviews (3 males, 19 females)
  - 11 School personnel interviews
  - 10 Immunisation team interviews
  - 20 school observation logs

Questionnaire: HAVI-Q

- **Validated questionnaire with 4 domains:**
  - HPV Knowledge and attitudes (6 items)
  - Involvement in decision-making (8 items)
  - Vaccination Fear/Anxiety (6 items)
  - Vaccination self-efficacy (5 items)

RESULTS

Sample demographics

		Intervention		Control	
		Schools (n=21)	Students (n=3806)	Schools (n=19)	Students (n=3162)
State	SA	8	1162	8	1054
	WA	13	2644	11	2108
Sector	Government	9	2042	8	1488
	Independent	7	979	5	648
	Catholic	5	785	6	1026
Co-	Yes	16	3083	15	2530
Educational	Female only	2	245	2	248
	Male only	3	478	2	384

Student knowledge gain

		Schools (n)	Valid Q'naire data (n)	Correct answers	Difference (95% CI)*	P-value*
Pre- dose 1	Intervention group	21	1641	65%	32 (27, 36)	<0.0001
Pre- dose 3	Intervention group	21	1677	53%	20 (17, 24)	<0.0001

Involvement in decision making

		Schools (n)	Valid Q'naire data (n)	Mean score+	Difference (95% CI)*	P-value*
Pre- dose 1	Intervention group	21	1682	3.7	0.11 (0.06, 0.16)	<0.0001

*adjusted for year, state, sector, co-educational status and clustering of students within schools

Improved knowledge and understanding of HPV and HPV vaccination

Intervention	Control
Students had good knowledge: 'It causes cancer', 'Boys and girls can get it'.	Students had limited /no knowledge: 'I'm not sure', 'Is it like one of those infectious kind of things?'
Students were confident about diseases that HPV causes: 'It can cause cervical cancer', '[It can cause] genital warts', '[It can cause] genital cancer'.	Students were less confident about this: 'Is it like vaginal cancer?' [Is it something] 'to do with the reproductive system or something like that?'
Most students understood that mode of transmission was through sexual contact.	While some students understood this, others believed HPV was an 'airborne disease'.
Students knew how many does were required to complete their vaccine course.	Students had varied responses: some thought that two [sic.] doses were required.
Students had consistent understanding about how the vaccine works: the vaccine 'injects small doses of HPV into your body and then like it teaches your body how to like fight it off .'	Students had limited/inconsistent understanding of this: the vaccine 'gives you more good antibodies or something', '…it prevents it from happening.'
Many students said they had the vaccine because of its benefits: 'One of the reasons I wanted to get it was just like I know in the future I am like protected by it.', 'Everyone like learns the process so they know exactly what they need to do.'	Students referred rather to trust of government or health professionals: 'I don't think there would be much of a risk with taking vaccinations because the people who made them know what they are doing.'
Students learned about HPV vaccine from teachers: 'we had a lot of lessons about it'; and from their parents.	Some students said they learned about HPV vaccine at school, but also the Internet; friends; the news media; parents. Information was inconsistent: 'Yeah, we got told about it., '[…]I didn't get told anything.'

Student vaccination-related anxiety

		Schools (n)	Valid Q'naire data (n)	Mean score+	Difference (95% CI)*	P-value*
Pre-dose 1	Intervention	21	1713	2.6	-0.11 (-0.19, -0.02)	0.0075
Pre-dose 2	Intervention	21	1795	2.4	-0.18 (-0.26. -0.10)	<0.0001
Pre-dose 3	Intervention	21	1729	2.3	-0.18 (-0.24, -0.11)	<0.0001

Student vaccination self-efficacy

		Schools (n)	Valid Q'naire data (n)	Mean score+	Difference (95% CI)*	P-value*
Pre-dose 1	Intervention	21	1727	74	4 (1, 7)	0.0061
Pre-dose 2	Intervention	21	1802	81	4 (2, 6)	<0.0001
Pre-dose 3	Intervention	21	1757	84	3 (1, 5)	0.0023

*adjusted for year, state, sector, co-educational status and clustering of students within schools
+ Mean score is mean of 6 fear/anxiety questions. Responses to questions on a Likert scale from 1 = Strongly disagree to 5 = Strongly agree. Lower scores better (less fear/anxiety).

Knowledge linked to positive attitudes and greater confidence with vaccination

Intervention	Control
Students appreciated their knowledge, as it made them feel confident: '…most injections you get, I don't know half the things that I'm getting, I'm like, okay stick my arm … it is probably good for me, but it's not a freedom of choice… even though it is not our choice of whether we get it or not, it is still like you feel more independent about it, like you actually know what it is.'	Students wanted information to feel confident: 'I think that for me, because I personally get like scared of having injections. If I knew it was actually something that was like helpful then it would make me think differently about it and feel more like better about having an injection.'
Students reported less concern about rumours. Greater understanding of the benefits of the vaccine appeared to assist in overcoming anxiety: 'One of the reasons I wanted to get it [HPV vaccination] was just like to know in the future I am like protected by it.'	Students reported concern about rumours and misinterpreted these. Lack of knowledge and uncertainty appeared to contribute to student fear and anxiety: 'I didn't know that like the HPV and HPV vaccine were different things. I thought HPV and HPV vaccine were both the vaccine. And so…did you know that HPV can cause cancer? And I got really scared about it…' 'I get scared when I watch other people get needles.'
Students reported less anxiety due to the vaccination day procedures: '…the kids that were sitting in the chairs with nothing to do you could just see on their faces that they were actually anxious, but the students that had used the iPads were distracted…they were smiling and chatting…'.	Students described how the physical vaccination environment could increase anxiety: 'I don't like it if you see other people coming out of the room, and you can see like they are all red faced or like crying or something…that makes you feel quite…nervous'.

Difference in vaccination uptake between groups

Dose	Mean intervention school uptake (%)	Mean % diff between groups (95% CI)**	P-value**
HPV1	86.0	0.8 (-1.4,3.0)	0.47
HPV2	83.7	0.2 (-2.7,3.1)	0.89
HPV3	75.7	0.5 (-2.6,3.7)	0.74

* Total children enrolled = 3806

** Additionally adjusted for total enrolments group, ICSEA group and previous vaccination rate group

Limitations

- Inability to implement all elements of the complex intervention
  - Consent form reminders, in school mop up vaccination were not implemented and have a direct impact on uptake rates
  - Reasons for non-implementation were varied: challenges with time frame of school based vaccination programs, limited resources with inclusion of males in program, many stakeholders involved, Advisory Board not necessarily aware of what happens at the school level
- Education of students in a school based vaccination program cannot be expected to increase uptake
  - Due to the way the program is implemented.
  - It is difficult for education to have an impact on uptake when we already have a high baseline, 3 dose vaccination coverage (71% national average; 75.7% control, for three doses).

Conclusions

- **Students were more informed about HPV and vaccination, had a better experience on vaccination day**
  - **This was maintained throughout the vaccination course**
  - **This may have longer term effects**
- **Effective education about HPV in SBIP setting can be achieved**
  - In school education was well implemented
  - Student questions were varied and teachers were able to respond to students
- **Qualitative data was useful in providing a more detailed picture of students' experience**

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