THE HPV.EDU STUDY: RCT of complex intervention to improve school based HPV vaccination for adolescents

How we could have done it better…

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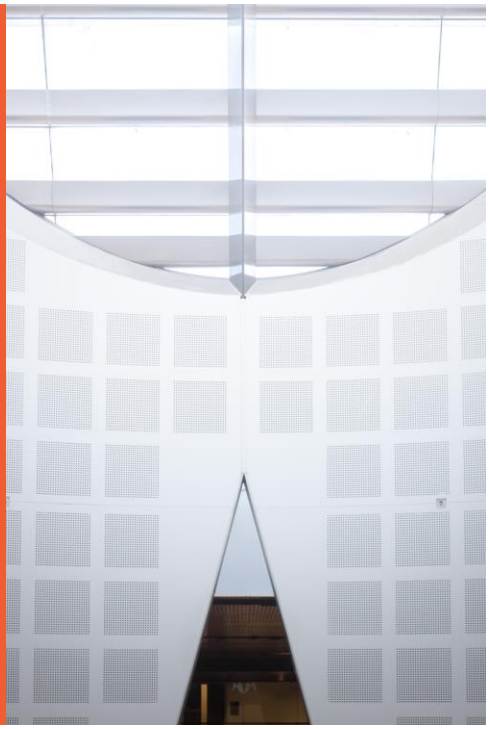
THE UNIVERSITY OF SYDNEY



Co-Investigators

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- P. Whyte, Deakin University
- J.M.L Brotherton, National HPV Vaccine Program Register
- S.M. Garland, University of Melbourne
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Backround

- In-school mass vaccination programs effective in high coverage in adolescent age group *Das, J Adoles Health 2016*
  - What mechanisms achieving high coverage?
  - Need good will of education sector, positive attitudes to vaccination, support of individual schools- consent forms, vaccination day set up [1,2.]
- Systematic review of process evaluations in school vaccination programs *Cooper Robbins et al*[3] - **education** (student), **consent form returns** (in WA resending consent packs *Mak et al 2011*), **incentives** and **catch up** strategies
- Qualitative research in Australia soon after introduction of HPV vaccine in 2007–student knowledge, discussion with parents, vaccination anxiety; vaccination day processes[1,4-7]

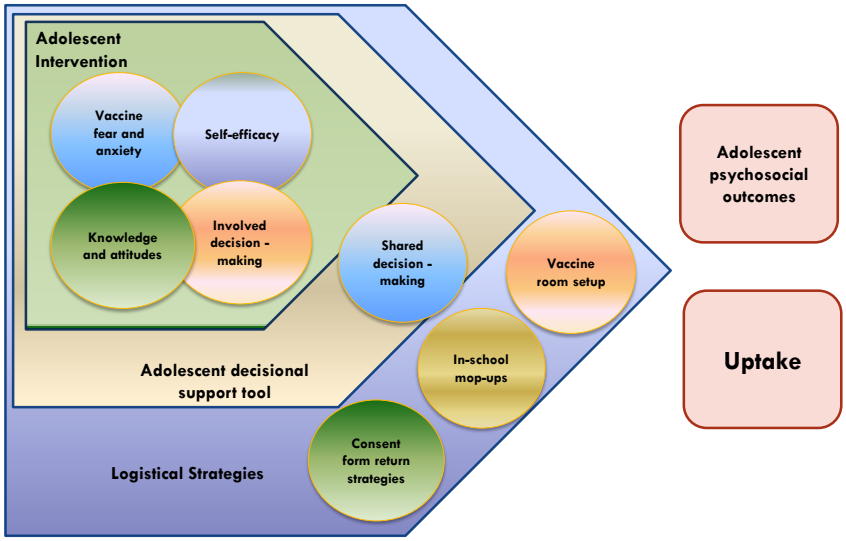
[1]Braunack-Mayer et al, Am J Public Health 2015 (Health Bridges study); [2]Ward et al, CDI 2013; [3] Cooper-Robbins, Vaccine 2011, [4]Cooper Robbins Vaccine 2010, [5]Cooper Robbins Sexual Health 2011; [6]Bernard MJA 2011; [7]Marhsall et al, Vaccine 2014

The HPV.edu Study

Aims

- **To improve outcomes for students**
  - Promote student knowledge about HPV vaccination
  - Improve psycho-social outcomes (d-m, self effic, fear/anx)
- **Promote vaccination uptake**

Multicomponent intervention: hypothesised mechanisms of action



Skinner et al. BMC Public Health (2015) 15:896
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BMC Public Health

STUDY PROTOCOL Open Access

HPV.edu study protocol: a cluster randomised controlled evaluation of education, decisional support and logistical strategies in school-based human papillomavirus (HPV) vaccination of adolescents

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Evaluation design

- Cluster randomised controlled trial
  - Schools in greater metro in SA and WA
  - Stratified random sample of schools (State, school type)
  - Allocated to multi-component intervention/ control (usual practice) arm (allocation concealment)
- Conducted in the 'real world' to inform implementation
  - Advisory Boards: key stakeholders from Education sector, local immunisation providers, State immunisation program
  - Met prior to recruitment of schools and during to inform intervention and processes
  - Modifications to intervention made based on feedback
- Outcomes measures/ tools/ questionnaires for quant outcomes
  - Psychosocial measures needed to be developed/validated (no prior tools for the specific aims)- HAVIQ
  - Approval to collect individual student level data via parental opt-out consent in one locality and not the other
- Evaluation of process (implementation fidelity)

INTERVENTIONS AND MEASURES

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)

Cooper, S.C., Davies, C., McBride, K., Blades, J., Stoney, T., Marshall, H. and Skinner, S.R., 2015. Development of a human papillomavirus vaccination intervention for Australian adolescents. *Health Education Journal*, p.1-11. doi:10.1177/0017896915608884

Parent adolescent decisional support tool

- Initially HPV vaccination parent-adolescent shared Decision Aid
  - To reduce vaccine-hesitancy
  - Qualitative methods, dyad interviews (under review)
  - presentation of data in different ways (word and figures): 'balanced presentation of data to support informed decision making'
- Modified by wider investigator group, advisory group after initial dissemination to 4 schools in first year
  - Concerns that it was impacting decisions against vaccination
- Short information brochure providing brief information in a positive way
  - Disseminated with consent forms and standard information brochure in one state and after in the other

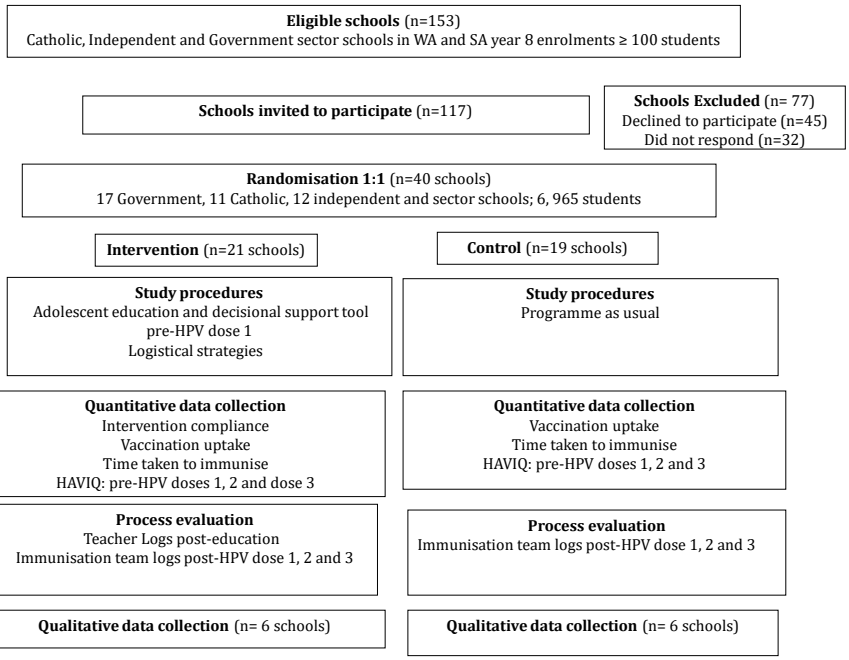
Organisational strategies

- Reminders to return consent forms
  - Re-send packs, reminders, house points to return
- Guidelines for vaccination room set up/ specific strategies to reduce anxiety
- Offering additional in-school catch up doses
  - Letters to parents to attend council clinics was standard practice in one locality
  - Recently introduced as standard practice in other locality

Quantitative evaluation via HAVI-Q

- **Validated questionnaire with 4 domains:**
  - HPV Knowledge and attitudes (6 items- yes/no or don't know)
  - Involvement in decision-making (8 items- Likert scale)
  - Vaccination Fear/Anxiety (6 items- Likert scale)
  - Vaccination self-efficacy (5 items- Confidence scale)

Forster, McBride, Davies, Stoney, Marshall, McGeechan, Cooper, Skinner. Development and validation of a measure to evaluate adolescents' knowledge about human papillomavirus (HPV), involvement in HPV vaccine decision-making, self-efficacy to receive the vaccine and fear and anxiety: the HAVIQ. *Public Health, 147: 77-83*


Eligible schools (n=153)
Catholic, Independent and Government sector schools in WA and SA year 8 enrolments ≥ 100 students
Schools invited to participate (n=117)
Schools Excluded (n= 77)
Declined to participate (n=45)
Did not respond (n=32)
Randomisation 1:1 (n=40 schools)
17 Government, 11 Catholic, 12 independent and sector schools; 6, 965 students
Intervention (n=21 schools)
Control (n=19 schools)
Study procedures
Adolescent education and decisional support tool pre-HPV dose 1
Logistical strategies
Study procedures
Programme as usual
Quantitative data collection
Intervention compliance
Vaccination uptake
Time taken to immunise
HAVIQ: pre-HPV doses 1, 2 and dose 3
Quantitative data collection
Vaccination uptake
Time taken to immunise
HAVIQ: pre-HPV doses 1, 2 and 3
Process evaluation
Teacher Logs post-education
Immunisation team logs post-HPV dose 1, 2 and 3
Process evaluation
Immunisation team logs post-HPV dose 1, 2 and 3
Qualitative data collection (n= 6 schools)
Qualitative data collection (n= 6 schools)

RESULTS

Participant school demographics

		Intervention		Control	
		Schools (n=21)	Students (n=3806)	Schools (n=19)	Students (n=3162)
State	State 1	8	1162	8	1054
	State 2	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

		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

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

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

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

*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).

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).

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

IMPLEMENTATION EVALUATION AND RESPONSE RATES

Education resources used in intervention schools

Educational Resource	Number of schools*
DVD chapter: What is HPV	21
DVD chapter: What is HPV vaccination	20
DVD chapter: Boys and HPV**	20
Magazine	20
DVD chapter: Vaccination on the Day	19
DVD chapter: HPV decision-making	18
DVD chapter: Vaccination in the Future	18
Website	14
In- class activity: Crossword puzzle	12
In- class activity: Talk with your parents	10
In-class activity: HPV Bingo	8
In-class activity: The decision-making process	6
In- class activity: Meditation Exercise	4
In-class activity: Educate the Public	4
In-class activity: Summary	4
In- class activity: Matching Game	3
DVD chapter: Recap	3

Lessons:

- Research with students in schools is challenging
  - Resourcing, support for schools, ethical barriers
- Modifying immunisation procedures also needs time and collaboration
  - Consent form reminders; in-school catch up vaccination
  - Short time frame from start of school year, inclusion of males, multiple layers of stakeholders, complexity around what happens in each school on the ground
- Education of students in a school based vaccination program doesn't increase uptake
  - Consent via parents
  - Already high baseline uptake of 3 dose (75.7% control)

Conclusions

- Effective education about HPV in SBIP setting can be achieved
  - In school education was well implemented, knowledge maintained, flow on effects possible
  - Teachers responded positively
- Consent form returns and catch-up of missed doses are likely key to increased vaccine coverage in school programs
  - Need to work closely with all key stakeholders- RCT design is challenging in real world setting
  - Jurisdictions are implementing strategies
    - we are working with NSW, WA and TAS in NHMRC Partnership Grant: Addressing the gaps in adolescent HPV vaccination

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'Is it like one of those infectious kind of things?' The importance of educating young people about HPV and HPV vaccination at school

Cristyn Davies, Susan Rachel Skinner, Tanya Stoney, Helen Siobhan Marshall, Joanne Collins, Jane Jones, Heidi Hutton, Adriana Parrella, Spring Cooper, Kevin McGeechan, Gregory Zimet & for the HPV.edu Study Group

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