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Title of the Study: Pragmatic Cluster Randomised Control Trial using Vaxcards as an age-appropriate tool to incentivise and educate school students about vaccination: a pilot trial.

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Abstract

OBJECTIVES: This trial aimed to determine if return rates of consent forms for vaccination could be improved when Vaxcards was offered as an incentive to school children.

SETTING: Nineteen schools in South East Melbourne participated.

INTERVENTIONS: Students in the experimental arm received a pack of Vaxcards when they returned their government consent form.

OUTCOME MEASURES: Return of 'yes' consent forms for vaccination as part of a local government council vaccine program was the primary outcome for this trial. Return rates were compared between intervention and control schools and to historical return rates.

RESULTS: Secondary school students (n=3087) from 19 schools participated. Compared to historical returns, a small global reduction in 'yes' responses to consent forms was observed across all schools of -4.21% in HPV consent 'yes' responses and -

4.69% for DTPA. No difference between the experimental and control groups was observed.

CONCLUSIONS: Low consent 'yes' rates and reduction in consent rates between 2018 and 2019 for all groups are concerning. This finding highlights the need for behaviour change interventions across all groups to increase vaccine confidence. Lack of effect of incentivization with Vaxcards in this pilot study may have been due to the timing of receiving the cards (after the decision to vaccinate had been made, not before) and the limited intensity of the intervention. Optimizing the timing and the intensity of exposure to Vaxcards could improve the outcome

Strengths and Limitations of this study

- This trial was also conducted in a real world, pragmatic setting. Behavior change interventions are complex in their nature due to the ways in which behaviors develop in different contexts for different individuals.
- A larger study considering all these things is needed to more definitively determine efficacy of Vaxcards as a standalone intervention when delivered as an ethical incentive for vaccination.
– reward of Vaxcards for returning a consent card regardless of response may mean the incentive to return a form consenting 'yes' was diluted, impacting the main outcome measured.
-It may not have been able to effectively control for bias in this study and so there are lessons for future studies of Vaxcards and of vaccine hesitancy in schools for a larger trial. There may have been an unrecorded data-reporting lag by the council if they were still waiting for consent cards to come in retrospectively after following up students within schools.

Background

Vaccines are a safe and efficacious preventive measure for many illnesses. Despite a long history and evidence of safety and effectiveness, vaccination rates are variable depending on geography, socioeconomic status, and confidence in vaccination [1-4]. Education, incentives for vaccination, and engagement with those who are hesitant to vaccinate are critical areas to investigate in order to increase vaccination rates [4].

Vaccination rates vary globally but dip below targeted goals for vaccine coverage in many advanced economies including Australia, where vaccination coverage is around 90–94% [5]. Within Australia, there is variation in vaccine coverage between states. Meanwhile, within states there can be substantial regional variation [5]. Growing understanding from social network analysis shows clustering of vaccine refusal and lowering herd immunity, potentially providing focal points for outbreaks.[6-8]

Incentivizing vaccination is a common practice in population health programs.[9-12] It has been shown that monetary and non-monetary incentives improve vaccination uptake by up to three times[13]. A Cochrane review of strategies to improve vaccine uptake in adolescents showed health education, class-based school vaccine strategy, multi-component provider interventions and targeting parents and financial incentives may all improve uptake [14].

Recent government programs within Australia implemented in 2001 such as 'no jab, no play' and 'no jab, no pay', involve withholding childcare or welfare payments from parents of unvaccinated children. The aim with these programs is to deter vaccination avoidance by withholding financial support to families eligible for these schemes [15]. This strict approach appears to increase catch-up vaccine status, especially in lower socioeconomic groups [16], but the full implication on longer term

vaccine trust and confidence is not understood. Other research has suggested it is unclear whether this punitive approach is effective [15,17]. Three percent of children aged 1-6 years are affected by registered or presumptive (unregistered) vaccination objection, which suggests that the overall impact of vaccination objection on vaccination rates has remained largely unchanged [17].

In Australia, the two main vaccines for adolescents are for HPV and Diphtheria, tetanus and pertussis (DtPa), received at age 12-13. Adolescent HPV vaccine coverage in females for first second and third doses are 86%, 83% and 78% respectively; while rates for males are 78%, 75% and 67%[18]. For older children, such as adolescents who receive vaccinations in Australian secondary schools, the return of the consent form is a major limiting factor in the rate of vaccine uptake [19]. Interventions to incentivize return of this consent form might improve rates of vaccination delivered through this program.

Large vaccination programs, such as in schools, rely on simple systems to provide informed consent to participate in the programs. Ethically, individuals must understand the risks and benefits of vaccination and organisations must gain consent before invasive procedures like intramuscular injections [20]. The informed consent process can be a barrier to participation in these programs and result in missed opportunities for vaccination [21]. Students in the state of Victoria, Australia, are provided a consent card prior to vaccination that their parents must sign and return in order to receive the HPV and DtPa vaccines around age 12, at their school. This occurs in the first year of their secondary schooling. Depending on the local region, students are provided this form from one to six months in advance, determined by their school. This means sometimes they can transition from primary to secondary school during the time period in which they are required to return the consent form. Many forms are lost, forgotten or deprioritised during this transition period and there is little incentive for the student or parent to return the form other

than the benefit of receiving the vaccination [21]. Some vaccine programs monetarily incentivize schools or parents to attain minimum rates of consent form return; however, this school level incentivization has limited impact on target vaccination levels [22].

The school vaccination program is a target area for interventions that can help increase vaccination rates. However, there is no consensus as to what interventions are most effective to incentivize and educate about vaccination in adolescents. The Cochrane review called for more understanding of adolescent specific hesitancy and targeted interventions that are class-based, multimodal, use appropriate incentives and involve health-education delivery [14]. All of these are a potentially modifiable by Vaxcards - a collectable, educational table-top card game.

Collectables and gamification are educational tools that can help children engage with learning, generate discussion, and provide incentive to engage with the content being delivered [23 24]. This medium of education increases motivation and engagement [23]. The collectable card game 'Vaxcards', has cards with characters based on diseases that children are vaccinated against. Vaxcards was launched after a successful crowdfunding campaign in 2016, and its viability as a stand-alone game with educational quality is shown by being listed as a staff pick new games award on Kickstarter and by being selected in the National Serious games working group[25]. Within the health community it has attracted significant interest, being the topic of a top shared and read article on the Bill & Melinda Gates Foundation supported GAVI website and the focus of a feature article in *The Lancet* [26]. The authors write, "Vaxcards appear to be an innovative card game for children, but beneath that they may have the potential to overcome some of the behavioral barriers when incorporated with existing vaccination programs".

The objective of the present trial is to pilot test the use of Vaxcards as an ethical, non-monetary incentive, to support school vaccination programs for secondary school students. It will determine if the return of the consent form for vaccination improves when the card game is offered as an incentive. We hypothesize that students in schools that were incentivised to return the vaccination consent form will show improved vaccination consent form return rates.

Methods

The study will be reported using Consort guidelines and extensions for cluster and pragmatic trials[27].

a) Trial design

A pragmatic, cluster randomised controlled trial [28] involving secondary schools within a large local government area in the outer south east of Melbourne, Australia. Block randomisation was used to allocate participating schools to one of two groups forming experimental and control groups.

b) Participants and setting

The participating local government area is in southeast Victoria, Australia, on the fringes of the state capital city of Melbourne. It encompasses a diverse cultural population of high and low socioeconomic status families as well as being one of the highest growth areas in the state. The vaccination consent rate within the catchment schools in 2018 varied from 64.6% to 91.3%, which is below the WHO and Australian government target of 95% coverage. At this age, children in this area are receiving the Australian Schedule vaccination for HPV and Diphtheria, tetanus and pertussis booster. It is also a target age for collectable card games.

c) Control arm.

The control arm took part in the normal processes of the school-based vaccination program. In this arm, parents of children received information about the vaccination program during term 4 of the preceding school year as usual. They were asked to sign and return a consent form to the school before the vaccination program occurs early in term 1 of the next school year. The local government council records return rates of consent to vaccination forms.

Experimental arm.

Students underwent the normal government vaccination process as above. At the time of consent form distribution, children and their parent/caregiver were provided a handout advising them that children who return the consent form will be given a "basic pack" of the card game Vaxcards. This form contained an explanatory statement about the study and offered the chance for parent or carer to decline participation of their child in the study or to contact the research team for further information.

The school staff member responsible for coordinating the government vaccination program provided one basic pack of Vaxcards to children who returned a vaccination consent form in the intervention schools in February 2019. Consistent with the pragmatic nature of the trial, the school determined which staff member was responsible for this. The card pack was handed to each student who returned his or her vaccination consent form, regardless of response or consent to vaccination. This was done to not exclude non-consenting students from the intervention because they could change their consent status any time prior to vaccination.

Proposed intervention,

Vaxcards packs contain 13 disease character cards that represent the diseases vaccinated against during the routine childhood immunisation schedule in Australia (measles, mumps, rubella, diphtheria, tetanus, pertussis, HPV, rotavirus,

haemophilus B, hepatitis B, meningococcal, pneumococcal, varicella). Each character is designed to anthropomorphise the disease, with traits of symptoms of the disease and information or 'powers' that reflect the microbiology of the disease, the vector or mode of transmission and information on global incidence and mortality that reflect how powerful the character is within the game. Each player collects their own set of disease characters and exchanges addition, subtraction and multiplier game mechanics to influence a sliding scale of 'hit points'. The game is designed so disease characters maintain their scientific names and encourage the use of terminology and symptomatology amongst players. The game play is light-hearted in nature and nonviolent or threatening.

d) Outcomes

The primary outcome was consent to vaccination based on returned council consent forms, routinely collected by local government councils.

e) Procedure for randomisation and blinding

A statistician, blinded to the school characteristics, conducted the randomisation and allocation sequence performed, by assigning clusters to interventions. It was not possible to blind participants to the intervention; however, they were blinded to information about the existence of a control/experimental group until after vaccination. Block randomisation determined allocation of participating schools to one of two groups forming experimental and control groups. To ensure balanced proportions of these school characteristics in each cluster in the test and control groups we stratified the randomisation by school based upon number of year 7 student enrolments ('less than 100' and 'more than 100') and consent return (<90% and ≥90%). After randomisation and allocation to groups, the lead investigator, who was not blinded, consented and recruited schools to participate. The statistician remained blinded.

Initially, two schools included in the randomisation process were not identified as specialised schools for children with intellectual disability (ID 25 and 12). Once identified, these two schools were removed from the original randomisation allocation (as both were randomly allocated to the control group) because a likely confounder was student type. Instead of excluding these two schools, reallocation occurred after creation of another stratification factor (special needs) of one school to the test group and other to control. For pragmatic reasons, the school scheduled to begin the vaccination program later in the year than the other school was assigned to the test group, as this gave the researchers more time to introduce the intervention. The control school was the other school.

f) Sample size and pre-trial power calculation

Within the 31 schools in the local government council, 25 were participating in the 2019 local government vaccination program. Of these, in 2018, there were 12 schools in this council area with enrolments of less than n=100 year 7 students aged 12-13 and n=11 schools with 100 or more. There were eight schools with ahistorical consent return rate of less than 90%.

Of the 31 eligible schools, six schools were not participating in the council vaccination program and were excluded (Figure 1). One school had already returned the council consent forms and was excluded. This school (from the experimental group) was replaced by another school from the same strata, randomly selected from the control group. Of the remaining 24 schools, 19 agreed to participate in the trial and seven were randomised to the experimental arm (n=965 students) and 12 to the control arm (n=2122 students).

A pre-study power calculation was conducted assuming 23 clusters of school involvement. The study had ample power (>95%) to detect a change in proportion of 5%. The power calculation was done using Stata statistical software for a stepped-wedge trial with 23 clusters defined at the level of the school. The primary outcome

measure was the return of the consent form from 120 students per school, significance level set at 0.05, intraclass correlation coefficient (ICC) within schools of 0.3, approximately half the schools receiving the intervention (ie steps=1) , and data examined at two time points (baseline (returns in 2018), year 1 (returns in 2019).

g) Data collection methods, instruments used:

The primary outcome data was de-identified, routinely reported local government council data on consent form returns which was provided to the researchers by the local government council. Return of consent cards and number consenting to vaccination was reported to the researchers for analysis.

h) Patient and Public Involvement

No patients were involved in the study. Stakeholders of teachers and council vaccination services were involved in the design of the trial to best fit in the existing vaccine schedule without disrupting workflow of the current consent card collection and vaccination process.

Data analysis

The main outcomes were the consent rate change (HPV, DaPa, both) for each school, which was calculated by the comparison between the council collected vaccine consent rates from the baseline in 2018 compared to the trial year of 2019.

We used linear regression to investigate each of these three outcomes with three bivariate independent variables of 2018 school students in year 7 (>100; <100), previous 2018 consent form return rates (<90%; >90%), and intervention group allocation (test; control).

We used Stata 16 (Stata Corp, College Station, TX) for the regression analyses.

h) Participant flow

Several schools declined the invitation to be involved in the trial. The most common reasons included they did not participate in the council vaccine program (six) were too busy or had other commitments (two), the research topic was 'too sensitive'(three) and one school requested the investigators seek an additional approval from a Catholic schools research ethics committee which was unable to be attained within the timeframe of the study (one).

Figure 1 PRISMA chart showing the flow of participant's through the RCT

Results

The trial involved a total of 3087 secondary school students in 19 school clusters. Consent forms were returned from n=2754 students. Of those returned n=2081 were marked 'yes' comprising 75.6% of all returned HPV forms (range between schools= 50.3% - 90.6%) and n=2113 (76.7%) of all returned DaPa forms (range between schools= 54.6% – 92.2%) in 2019. There were 327 outstanding consent cards that were not returned according to council data.

Subgroup analysis demonstrated a significant improvement in consent to vaccination between 2018-2019 for students from small schools (<100 students in the year level). The combined increase in returned 'yes' forms for both vaccines in these schools was 4.49% (10.99% better than larger schools, with a coefficient -0.11 for school size on vaccination rate change, p. 0.04 CI(-0.22 - -0.01)). There was no

significant difference on sub-group analysis of prior vaccination rates in schools. (see table 1)

Compared to the historical comparison, there was a mean global reduction in 'yes' responses in returned consent forms across all schools of -4.21% for HPV and -4.69% for DaPa. The average 'yes' response (ie. a positive response consenting to participation in vaccination) across all schools for the previous year (2018) was 79.77% for HPV (range of 56.6% - 90.72%) and 81.42% for DaPa (range of 61.54% – 95.88%). There was no statistically significant difference between the change in proportion of returned consent forms between experimental and control groups with a consent to vaccination. (see table 2)

There was considerable intra-school variation in the proportion responding 'yes' between 2018 and 2019. 'Yes' consent for HPV forms ranged from -21.5% to +34.02%, and yes consent for DaPa ranged from -17.27% to +29.92%.

Table 1: Analysis vaccination consent rate changes between Intervention and sub-strata.

HPV^					
	% change	**Difference**	**Coef.**	**p.**	**95% CI**
	control	**intervention**			
Intervention	-2.05%	-2.74%	0.69%	0.37	-0.05 (-0.16 - 0.07)
	<100 students	100+ students			
Size of school	3.98%	-6.33%	10.31%	0.06	-0.11 (-0.22 - 0.01)
	Low consent school	High consent school			

Previous consent rate	0.44%	-6.65%	7.10%	0.28	-0.06 (-0.17 - 0.05)
DtPa*					
	% change	**Difference**	**Coef.**	**p.**	**95% CI**
	control	**intervention**			
Intervention group	-2.35%	-1.79%	-0.57%	0.43	-0.04 (-0.15 - 0.07)
	<100 students	100+ students			
Size of school	5.00%	-6.67%	11.68%	0.03	-0.12 (-0.23 - -0.01)
	Low consent school	High consent school			
previous consent rate	0.89%	-6.89%	7.78%	0.2	-0.06 (-0.17 - 0.04)
Combined DtPa* + HPV^					
	% change	**Difference**	**Coef.**	**p.**	**95% CI**
	control	**intervention**			
Intervention group	-2.20%	-2.26%	0.06%	0.39	-0.05 (-0.15 - 0.06)
	<100 students	100+ students			
Size of school	4.49%	-6.50%	10.99%	0.04	-0.11 (-0.22 - -0.01)
	Low consent school	High consent school			
previous consent rate	0.67%	-6.77%	7.44%	0.22	-0.1 (-0.17 - 0.04)

^HPV = Human Papilloma Virus vaccine

*DtPa = Diphtheria, Tetanus and Pertussis vaccine

Table 2: Combined intervention and control school consent rate changes

HPV	2018 average consent	2019 average consent	Difference
consent all schools	79.7%	75.6%	-4.2%
range	56.6 - 90.7%	50.3 - 90.6%	-21.5 - 34.0%
DtPa			
consent all schools	81.4%	76.7%	-4.7%
range	61.5 - 95.9%	54.5 - 92.2%	-17.3 - 29.9 %
Combined HPV +DtPa			
consent all schools	80.6%	75.9%	-4.75%
Range	59.4 - 93.3%	52.4 - 91.4%	-19.4 - 32.0%

Discussion

The major finding from this data is the low consent rates and the global reduction in consent rates between 2018 and 2019 for both the control and experimental groups. Consent for vaccination is far below target range specified by the local government council area in which this trial was undertaken of 95%. This highlights the need for interventions to increase these rates and prevent further vaccine hesitancy in the setting of public-school vaccination programs.

In order to improve vaccination rates towards target levels of >95%, we must improve the low consent rates of these students. Consent is required by these school vaccination programs in order to vaccinate the children, so without targeting the barriers to consenting, we will not improve actual rates of vaccinated individuals in the student population.

Vaxcards can be considered a desirable and 'ethical', non-monetary incentive to influence behavior change that is directed toward the adolescents being vaccinated. Collectables and gamification are important educational tools that can help children engage with learning, generate discussion, and provide an incentive to engage with the content being delivered [23]. The theoretical underpinnings of Vaxcards as an intervention is multifaceted. This is represented in our logic model of the theory of change (Figure 2). Initially, the use of receiving Vaxcards as an incentive to return consent forms acts, from a behavioral standpoint, as a reward. As we previously mentioned, rewards have shown good effect in increasing vaccine uptake, but there have been no tangible take-home interventions directly designed for this age group. Secondly, Vaxcards acts as a social tool for students, parents, peers and teachers to interact and lower the barrier to discussing topics around vaccination and diseases. Thirdly, it utilizes these educational points throughout the gameplay to increase knowledge of the infectious diseases in the content of the game, increasing salience of their risks and the benefit of preventative vaccination against them. This requires the buy in of government or organisations to distribute Vaxcards alongside vaccination programs, and school stakeholders to also deliver and engage with the tool. The timely delivery and playing of the game should theoretically result in increased vaccine consent and uptake, conversations around vaccines, knowledge of the diseases and increase vaccine confidence. The intervention drew on principles of use of incentive, and took a pragmatic approach adding to existing council and school strategies to improve consent return rates, but was unable to impact return rates in this trial.

Figure 2: Logic Model (or theory of change) for Vaxcards.

The first limitation to improving consent is reducing the logistical barriers to returning the consent card. The card is provided in some schools the year before the vaccination occurs. This means that some students receive the cards in their last year of primary school, to bring home and have their parent's sign, only to attempt returning the card to the child's school when the new school year begins. Many students change schools during these two years and there is a risk of lost to follow-up when changing school systems.

Smaller schools did show a significant improvement in consent for vaccination, irrespective of previous vaccination consent levels. One explanation may be that smaller schools are better placed to communicate health promotion activities to students and parents given the individual concerns vaccination can generate. It could explain why larger schools are having trouble improving vaccine consent given the large difference between the one-year time difference and the concurrent emergence of hesitancy in the community.

There is also an element of timing in the provision of the incentive and the intensity of the intervention. Perhaps exposure to the intervention earlier will lead to more of an impact. For example, receiving the Vaxcards with the educational packet from the council instead of as a reward for returning consent forms will enable a chance of impacting vaccine hesitancy to those who are most likely to require it, who never returned consent cards and were therefore not exposed to the intervention. It is also likely that the intensity was not enough. In this study we do not know how the participants used the cards, whether they engaged with the information in the cards, or had an opportunity to clarify their understanding to learn more about them. Introduction or integration of the game in science or health classes could reinforce the educational aspects and impact on vaccine uptake, as evidenced in the Cochrane review of adolescent vaccine interventions [14].

In a pragmatic sense it is unlikely a single intervention alone will largely change complex paradigm like vaccine hesitancy. In future trials, we would like to investigate the intervention in combination with other incentives and educational material to determine if a multifaceted approach can shift consent rates.

Strengths and Limitations

The outcomes of this trial were impacted by the unexpectedly large deviation in vaccination consent between the clusters of schools. The sample size was based in part on an estimated effect size, which may have been too optimistic. A larger study considering all these things is needed to more definitively determine efficacy of Vaxcards as a standalone intervention when delivered as an ethical incentive for vaccination. We also do not know the vaccine outcome of children who did not return a consent form, declined school vaccine or ticked 'had elsewhere'. It is possible these students did indeed get vaccinated outside the school program and the 'consent' rates do not infer true vaccine status of the group. Lastly, all students who returned consent cards were given a pack of Vaxcards, regardless of response. This decision was made pragmatically by the schools to not discriminate based on responses and to include all students. It also aligned with incentives of the school, which are measured in total consent card return rate, not consent 'yes' return rates. This is an interesting point to possible consider as a target to increase consent 'yes' rates, to change school performance indicators to align with public health outcomes rather than the return of forms regardless of outcome. Nevertheless, reward of Vaxcards for returning a consent card regardless of response may mean the incentive to return a form consenting 'yes' was diluted, impacting the main outcome measured.

A further limitation of this study includes the insufficient cluster sizes required for statistical assessment. Also, it may not have been able to effectively control for bias in this study and so there are lessons for future studies of Vaxcards

and of vaccine hesitancy in schools for a larger trial. There may have been an unrecorded data-reporting lag by the council if they were still waiting for consent cards to come in retrospectively after following up students within schools.

This trial was also conducted in a real world, pragmatic setting. Behavior change interventions are complex in their nature due to the ways in which behaviors develop in different contexts for different individuals. [29 30]. The design of this trial may also have dilution the effect if the intervention efficacy that may impact the results. For this reason, a much larger trial involving more clusters to account for this dilution effect would be suitable to further assess the intervention.

Conclusions

Vaxcards is a novel intervention that addresses many recommendations made in the recent Cochrane review of effective interventions to improve vaccine uptake in adolescents [14]. These elements include being an ethical incentive that can be incorporated into other health education and health promotion initiatives as part of multi-component approaches to support vaccine uptake amongst school-aged children. This potential requires further investigation to assess impact on vaccine uptake and vaccine confidence. A combination of optimizing the timing and the intensity of the intervention as part of a multimodal approach will be required to significantly shift hesitancy and improve consent rates and ultimately uptake of vaccination.

Conflicts of interest

The lead author is the creator of Vaxcards that supplied the card games for evaluation in this study and this was disclosed to the participating schools and councils involved in the vaccination project. This interest will be disclosed in all subsequent research output.

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Figure legend:

Figure 1 PRISMA chart showing the flow of participant's through the RCT

Figure 2 Logic Model (or theory of change) for Vaxcards.

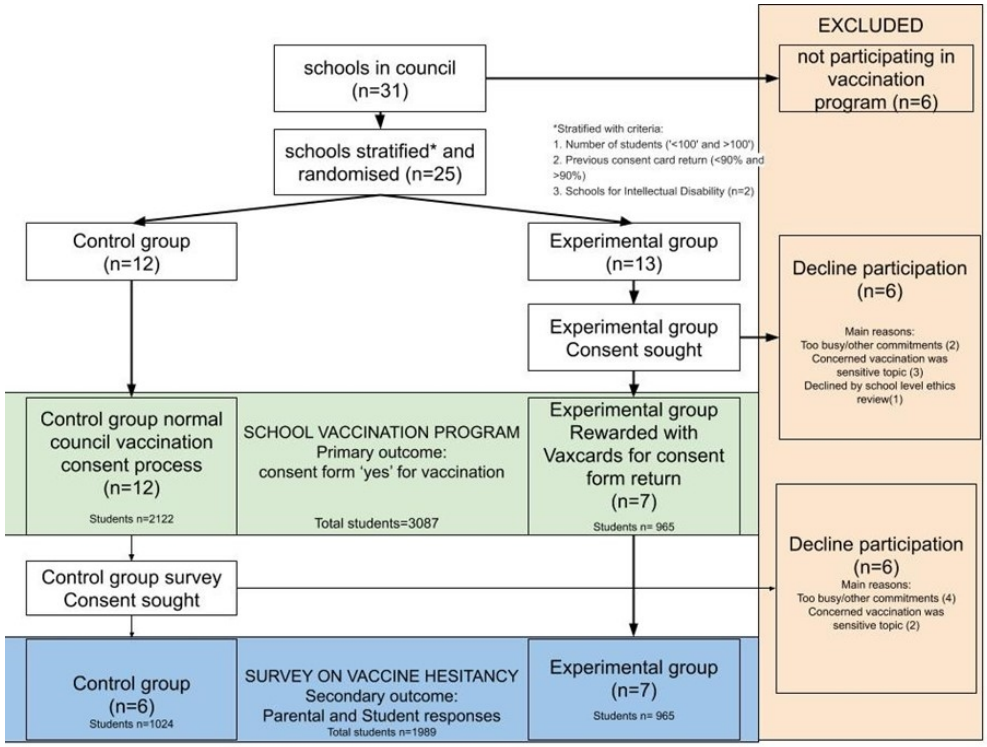

Figure 1 PRISMA chart showing the flow of participant's through the RCT

159x119mm (146 x 146 DPI)

Figure 2 logic model

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	10
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	na
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	9

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	13
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	12
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	13
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	12
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	18
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	18
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Pragmatic Cluster Randomised Control Trial using Vaxcards as an age-appropriate tool to incentivise and educate school students about vaccination

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Title of the Study: Pragmatic Cluster Randomised Control Trial using Vaxcards as an age-appropriate tool to incentivise and educate school students about vaccination

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Abstract

OBJECTIVES: This trial aimed to determine if return rates of consent forms for vaccination could be improved when Vaxcards was offered as an incentive to school children.

SETTING: Nineteen schools in South East Melbourne participated.

INTERVENTIONS: Students in the experimental arm received a pack of Vaxcards when they returned their government consent form.

OUTCOME MEASURES: Return of 'yes' consent forms for vaccination as part of a local government council vaccine program was the primary outcome for this trial. Return rates were compared between intervention and control schools and to historical return rates.

RESULTS: Secondary school students (n=3087) from 19 schools participated. Compared to historical returns, a small global reduction in 'yes' responses to consent forms was observed across all schools of -4.21% in HPV consent 'yes' responses and -4.69% for DTPA. No difference between the experimental and control groups was observed.

CONCLUSIONS: Low consent 'yes' rates and reduction in consent rates between 2018 and 2019 for all groups are concerning. This finding highlights the need for behaviour change interventions across all groups to increase vaccine confidence. Lack of effect of incentivization with Vaxcards in this study may have been due to the timing of receiving the cards (after the decision to vaccinate had been made, not before) and the limited intensity of the intervention. Optimizing the timing and the intensity of exposure to Vaxcards could improve the outcome

Strengths and Limitations of this study

- This trial was conducted in a real world, pragmatic setting. Behavior change interventions are complex in their nature due to the ways in which behaviors develop in different contexts for different individuals.

– reward of Vaxcards for returning a consent card regardless of response may mean the incentive to return a form consenting 'yes' was diluted, impacting the main outcome measured.

-It may not have been able to effectively control for bias in this sample.

-There may have been an unrecorded data-reporting lag by the council if they were still waiting for consent cards to come in retrospectively after following up students within schools.

Background

Vaccines are a safe and efficacious preventive measure for many illnesses. Despite a long history and evidence of safety and effectiveness, vaccination rates are variable depending on geography, socioeconomic status, and confidence in vaccination [1-4]. Education, incentives for vaccination, and engagement with those who are hesitant to vaccinate are critical areas to investigate in order to increase vaccination rates [4].

Vaccination rates vary globally but dip below targeted goals for vaccine coverage in many advanced economies including Australia, where vaccination coverage is around 90–94% [5]. Within Australia, there is variation in vaccine coverage between states. Meanwhile, within states there can be substantial regional variation [5]. Growing understanding from social network analysis shows clustering of vaccine refusal and lowering herd immunity, potentially providing focal points for outbreaks.[6-8]

Incentivizing vaccination is a common practice in population health programs.[9-12] It has been shown that monetary and non-monetary incentives improve vaccination uptake by up to three times[13]. A Cochrane review of strategies to improve vaccine uptake in adolescents showed health education, class-based school vaccine strategy, multi-component provider interventions and targeting parents and financial incentives may all improve uptake [14].

Recent government programs within Australia implemented in 2001 such as 'no jab, no play' and 'no jab, no pay', involve withholding childcare or welfare payments from parents of unvaccinated children. The aim with these programs is to deter vaccination avoidance by withholding financial support to families eligible for these schemes [15]. This strict approach appears to increase catch-up vaccine status, especially in lower socioeconomic groups [16], but the full implication on longer term

vaccine trust and confidence is not understood. Other research has suggested it is unclear whether this punitive approach is effective [15,17]. Three percent of children aged 1-6 years are affected by registered or presumptive (unregistered) vaccination objection, which suggests that the overall impact of vaccination objection on vaccination rates has remained largely unchanged [17].

Large vaccination programs, such as in schools, rely on simple systems to provide informed consent to participate in the programs. Ethically, individuals must understand the risks and benefits of vaccination and organisations must gain consent before invasive procedures like intramuscular injections [18]. The informed consent process can be a barrier to participation in these programs and result in missed opportunities for vaccination [19]. Students in the state of Victoria, Australia, are provided a consent card prior to vaccination that their parents must sign and return in order to receive the HPV and DtPa vaccines around age 12, at their school. This occurs in the first year of their secondary schooling. Depending on the local region, students are provided this form from one to six months in advance, determined by their school. This means sometimes they can transition from primary to secondary school during the time period in which they are required to return the consent form. Many forms are lost, forgotten or deprioritised during this transition period and there is little incentive for the student or parent to return the form other than the benefit of receiving the vaccination [19]. Some vaccine programs monetarily incentivize schools or parents to attain minimum rates of consent form return; however, this school level incentivization has limited impact on target vaccination levels [20].

The school vaccination program is a target area for interventions that can help increase vaccination rates. However, there is no consensus as to what interventions are most effective to incentivize and educate about vaccination in adolescents. The

Cochrane review called for more understanding of adolescent specific hesitancy and targeted interventions that are class-based, multimodal, use appropriate incentives and involve health-education delivery [14]. There is other evidence game-based interventions can be a successful modality for behaviour change, when they are carefully designed for the right context and consider the right mechanism of action[21]. All of these are a potentially modifiable by Vaxcards - a collectable, educational table-top card game.

Collectables and gamification are educational tools that can help children engage with learning, generate discussion, and provide incentive to engage with the content being delivered[21 22]. This medium of education increases motivation and engagement [22]. The collectable card game 'Vaxcards', has cards with characters based on diseases that children are vaccinated against. Vaxcards was launched after a successful crowdfunding campaign in 2016, and its viability as a stand-alone game with educational quality is shown by being listed as a staff pick new games award on Kickstarter and by being selected in the National Serious games working group[23]. Within the health community it has attracted significant interest, being the topic of a top shared and read article on the Bill & Melinda Gates Foundation supported GAVI website and the focus of a feature article in *The Lancet* [24]. The authors write, "Vaxcards appear to be an innovative card game for children, but beneath that they may have the potential to overcome some of the behavioral barriers when incorporated with existing vaccination programs".

The objective of the present trial is to test the use of Vaxcards as an ethical, non-monetary incentive, to support school vaccination programs for secondary school students. It will determine if the return of the consent form for vaccination improves when the card game is offered as an incentive. We hypothesize that students in schools that were incentivised to return the vaccination consent form will show improved vaccination consent form return rates.

Methods

The study will be reported using Consort guidelines and extensions for cluster and pragmatic trials[25].

a) Trial design

A pragmatic, cluster randomised controlled trial [26] involving secondary schools within a large local government area in the outer south east of Melbourne, Australia. Block randomisation was used to allocate participating schools to one of two groups forming experimental and control groups.

b) Participants and setting

The participating local government area is in southeast Victoria, Australia, on the fringes of the state capital city of Melbourne. It encompasses a diverse cultural population of high and low socioeconomic status families as well as being one of the highest growth areas in the state. The vaccination consent rate within the catchment schools in 2018 varied from 64.6% to 91.3%, which is below the WHO and Australian government target of 95% coverage. At this age (12-13 years), children in this area are receiving the Australian Schedule vaccination for HPV and Diphtheria, tetanus and pertussis booster. It is also a target age for collectable card games. We were not able to collect specific individual level data on exact breakdown of age/gender/socioeconomic status of the individual students due to our ethics agreement with data collection from the council and governmental department of Education, we relied on council reported immunization rates at the school level only.

c) Control arm.

The control arm took part in the normal processes of the school-based vaccination program. In this arm, parents of children received information about the

vaccination program during term 4 of the preceding school year as usual. They were asked to sign and return a consent form to the school before the vaccination program occurs early in term 1 of the next school year. The local government council records return rates of consent to vaccination forms.

Experimental arm.

Students underwent the normal government vaccination process as above. At the time of consent form distribution, children and their parent/caregiver were provided a handout advising them that children who return the consent form will be given a "basic pack" of the card game Vaxcards. This form contained an explanatory statement about the study and offered the chance for parent or carer to decline participation of their child in the study or to contact the research team for further information.

The school staff member responsible for coordinating the government vaccination program provided one basic pack of Vaxcards to children who returned a vaccination consent form in the intervention schools in February 2019. Consistent with the pragmatic nature of the trial, the school determined which staff member was responsible for this. The card pack was handed to each student who returned his or her vaccination consent form, regardless of response or consent to vaccination. This was done to not exclude non-consenting students from the intervention because they could change their consent status any time prior to vaccination.

Proposed intervention,

Vaxcards packs contain 13 disease character cards that represent the diseases vaccinated against during the routine childhood immunisation schedule in Australia (measles, mumps, rubella, diphtheria, tetanus, pertussis, HPV, rotavirus, haemophilus B, hepatitis B, meningococcal, pneumococcal, varicella). Each character is designed to anthropomorphise the disease, with traits of symptoms of the disease

and information or 'powers' that reflect the microbiology of the disease, the vector or mode of transmission and information on global incidence and mortality that reflect how powerful the character is within the game. Each player collects their own set of disease characters and exchanges addition, subtraction and multiplier game mechanics to influence a sliding scale of 'hit points'. The game is designed so disease characters maintain their scientific names and encourage the use of terminology and symptomatology amongst players. The game play is light-hearted in nature and nonviolent or threatening.

d) Outcomes

The primary outcome was consent to vaccination based on returned council consent forms, routinely collected by local government councils.

e) Procedure for randomisation and blinding

A statistician, blinded to the school characteristics, conducted the randomisation and allocation sequence performed, by assigning clusters to interventions. It was not possible to blind participants to the intervention; however, they were blinded to information about the existence of a control/experimental group until after vaccination. Block randomisation determined allocation of participating schools to one of two groups forming experimental and control groups. To ensure balanced proportions of these school characteristics in each cluster in the test and control groups we stratified the randomisation by school based upon number of year 7 student enrolments ('less than 100' and 'more than 100') and consent return (<90% and ≥90%). After randomisation and allocation to groups, the lead investigator, who was not blinded, consented and recruited schools to participate. The statistician remained blinded.

Initially, two schools included in the randomisation process were not identified as specialised schools for children with intellectual disability (ID 25 and

12). Once identified, these two schools were removed from the original randomisation allocation (as both were randomly allocated to the control group) because a likely confounder was student type. Instead of excluding these two schools, reallocation occurred after creation of another stratification factor (special needs) of one school to the test group and other to control. For pragmatic reasons, the school scheduled to begin the vaccination program later in the year than the other school was assigned to the test group, as this gave the researchers more time to introduce the intervention. The control school was the other school.

f) Sample size and pre-trial power calculation

Within the 31 schools in the local government council, 25 were participating in the 2019 local government vaccination program. Of these, in 2018, there were 12 schools in this council area with enrolments of less than n=100 year 7 students aged 12-13 and n=11 schools with 100 or more. There were eight schools with ahistorical consent return rate of less than 90%.

Of the 31 eligible schools, six schools were not participating in the council vaccination program and were excluded (Figure 1). One school had already returned the council consent forms and was excluded. This school (from the experimental group) was replaced by another school from the same strata, randomly selected from the control group. Of the remaining 24 schools, 19 agreed to participate in the trial and seven were randomised to the experimental arm (n=965 students) and 12 to the control arm (n=2122 students).

A pre-study power calculation was conducted assuming 23 clusters of school involvement. The study had ample power (>95%) to detect a change in proportion of 5%. The power calculation was done using Stata statistical software for a stepped-wedge trial with 23 clusters defined at the level of the school. The primary outcome measure was the return of the consent form from 120 students per school, significance level set at 0.05, intraclass correlation coefficient (ICC) within schools of

0.3, approximately half the schools receiving the intervention (ie steps=1) , and data examined at two time points (baseline (returns in 2018), year 1 (returns in 2019).

g) Data collection methods, instruments used:

The primary outcome data was de-identified, routinely reported local government council data on consent form returns which was provided to the researchers by the local government council. Return of consent cards and number consenting to vaccination was reported to the researchers for analysis.

h) Patient and Public Involvement

No patients were involved in the study. Stakeholders of teachers and council vaccination services were involved in the design of the trial to best fit in the existing vaccine schedule without disrupting workflow of the current consent card collection and vaccination process.

Data analysis

The main outcomes were the consent rate change (HPV, DaPa, both) for each school, which was calculated by the comparison between the council collected vaccine consent rates from the baseline in 2018 compared to the trial year of 2019.

We used linear regression to investigate each of these three outcomes with three bivariate independent variables of 2018 school students in year 7 (>100; <100), previous 2018 consent form return rates (<90%; >90%), and intervention group allocation (test; control).

We used Stata 16 (Stata Corp, College Station, TX) for the regression analyses.

h) Participant flow

Several schools declined the invitation to be involved in the trial. The most common reasons included they did not participate in the council vaccine program (six) were too busy or had other commitments (two), the research topic was 'too sensitive'(three) and one school requested the investigators seek an additional approval from a Catholic schools research ethics committee which was unable to be attained within the timeframe of the study (one).

Figure 1 PRISMA chart showing the flow of participant's through the RCT

Results

The trial involved a total of 3087 secondary school students in 19 school clusters. Consent forms were returned from n=2754 students. Of those returned n=2081 were marked 'yes' comprising 75.6% of all returned HPV forms (range between schools= 50.3% - 90.6%) and n=2113 (76.7%) of all returned DaPa forms (range between schools= 54.6% – 92.2%) in 2019. There were 327 outstanding consent cards that were not returned according to council data.

In regards to primary outcome, there was so significant difference between control and experimental groups in vaccine consent rates.

Subgroup analysis demonstrated a significant improvement in consent to vaccination between 2018-2019 for students from small schools (<100 students in the year level). The combined increase in returned 'yes' forms for both vaccines in these schools was 4.49% (10.99% better than larger schools, with a coefficient -0.11 for

school size on vaccination rate change, p. 0.04 CI(-0.22 - -0.01)). There was no significant difference on sub-group analysis of prior vaccination rates in schools. (see table 1)

Compared to the historical comparison, there was a mean global reduction in 'yes' responses in returned consent forms across all schools of -4.21% for HPV and -4.69% for DaPa. The average 'yes' response (ie. a positive response consenting to participation in vaccination) across all schools for the previous year (2018) was 79.77% for HPV (range of 56.6% - 90.72%) and 81.42% for DaPa (range of 61.54% – 95.88%). There was no statistically significant difference between the change in proportion of returned consent forms between experimental and control groups with a consent to vaccination. (see table 2)

There was considerable intra-school variation in the proportion responding 'yes' between 2018 and 2019. 'Yes' consent for HPV forms ranged from -21.5% to +34.02%, and yes consent for DaPa ranged from -17.27% to +29.92%.

Table 1: Analysis vaccination consent rate changes between Intervention and sub-strata.

HPV^					
	% change	**Difference**	**Coef.**	**p.**	**95% CI**
	control	**intervention**			
Intervention	-2.05%	-2.74%	0.69%	0.37	-0.05 (-0.16 - 0.07)
	<100 students	100+ students			
Size of school	3.98%	-6.33%	10.31%	0.06	-0.11 (-0.22 - 0.01)
	Low consent school	High consent school			

Previous consent rate	0.44%	-6.65%	7.10%	0.28	-0.06 (-0.17 - 0.05)
DtPa*					
	% change	**Difference**	**Coef.**	**p.**	**95% CI**
	control	**intervention**			
Intervention group	-2.35%	-1.79%	-0.57%	0.43	-0.04 (-0.15 - 0.07)
	<100 students	100+ students			
Size of school	5.00%	-6.67%	11.68%	0.03	-0.12 (-0.23 - -0.01)
	Low consent school	High consent school			
previous consent rate	0.89%	-6.89%	7.78%	0.2	-0.06 (-0.17 - 0.04)
Combined DtPa* + HPV^					
	% change	**Difference**	**Coef.**	**p.**	**95% CI**
	control	**intervention**			
Intervention group	-2.20%	-2.26%	0.06%	0.39	-0.05 (-0.15 - 0.06)
	<100 students	100+ students			
Size of school	4.49%	-6.50%	10.99%	0.04	-0.11 (-0.22 - -0.01)
	Low consent school	High consent school			
previous consent rate	0.67%	-6.77%	7.44%	0.22	-0.1 (-0.17 - 0.04)

^HPV = Human Papilloma Virus vaccine

*DtPa = Diphtheria, Tetanus and Pertussis vaccine

Table 2: Combined intervention and control school consent rate changes

HPV	2018 average consent	2019 average consent	Difference
consent all schools	79.7%	75.6%	-4.2%
range	56.6 - 90.7%	50.3 - 90.6%	-21.5 - 34.0%
DtPa			
consent all schools	81.4%	76.7%	-4.7%
range	61.5 - 95.9%	54.5 - 92.2%	-17.3 - 29.9 %
Combined HPV +DtPa			
consent all schools	80.6%	75.9%	-4.75%
Range	59.4 - 93.3%	52.4 - 91.4%	-19.4 - 32.0%

Discussion

There was no significant difference in the consent rates between experimental and control groups and this likely reflects the complexity of vaccine confidence interventions and the challenges of behavior change that requires multimodal interventions. One major finding from this data is the low consent rates and the global reduction in consent rates between 2018 and 2019 for both the control and experimental groups. Consent for vaccination is far below target range specified by the local government council area in which this trial was undertaken of 95%. This highlights the need for interventions to increase these rates and prevent further vaccine hesitancy in the setting of public-school vaccination programs.

In order to improve vaccination rates towards target levels of >95%, we must improve the low consent rates of these students. Consent is required by these school

vaccination programs in order to vaccinate the children, so without targeting the barriers to consenting, we will not improve actual rates of vaccinated individuals in the student population.

Vaxcards can be considered a desirable and 'ethical', non-monetary incentive to influence behavior change that is directed toward the adolescents being vaccinated. Collectables and gamification are important educational tools that can help children engage with learning, generate discussion, and provide an incentive to engage with the content being delivered [22]. The theoretical underpinnings of Vaxcards as an intervention is multifaceted. This is represented in our logic model of the theory of change (Figure 2). Initially, the use of receiving Vaxcards as an incentive to return consent forms acts, from a behavioral standpoint, as a reward. As we previously mentioned, rewards have shown good effect in increasing vaccine uptake, but there have been no tangible take-home interventions directly designed for this age group. Secondly, Vaxcards acts as a social tool for students, parents, peers and teachers to interact and lower the barrier to discussing topics around vaccination and diseases. Thirdly, it utilizes these educational points throughout the gameplay to increase knowledge of the infectious diseases in the content of the game, increasing salience of their risks and the benefit of preventative vaccination against them. This requires the buy in of government or organisations to distribute Vaxcards alongside vaccination programs, and school stakeholders to also deliver and engage with the tool. The timely delivery and playing of the game should theoretically result in increased vaccine consent and uptake, conversations around vaccines, knowledge of the diseases and increase vaccine confidence. The intervention drew on principles of use of incentive, and took a pragmatic approach adding to existing council and school strategies to improve consent return rates, but was unable to impact return rates in this trial.

Figure 2: Logic Model (or theory of change) for Vaxcards.

The first limitation to improving consent is reducing the logistical barriers to returning the consent card. The card is provided in some schools the year before the vaccination occurs. This means that some students receive the cards in their last year of primary school, to bring home and have their parent's sign, only to attempt returning the card to the child's school when the new school year begins. Many students change schools during these two years and there is a risk of lost to follow-up when changing school systems.

Smaller schools did show a significant improvement in consent for vaccination, irrespective of previous vaccination consent levels. One explanation may be that smaller schools are better placed to communicate health promotion activities to students and parents given the individual concerns vaccination can generate. It could explain why larger schools are having trouble improving vaccine consent given the large difference between the one-year time difference and the concurrent emergence of hesitancy in the community.

There is also an element of timing in the provision of the incentive and the intensity of the intervention. Perhaps exposure to the intervention earlier will lead to more of an impact. For example, receiving the Vaxcards with the educational packet from the council instead of as a reward for returning consent forms will enable a chance of impacting vaccine hesitancy to those who are most likely to require it, who never returned consent cards and were therefore not exposed to the intervention. It is also likely that the intensity was not enough. In this study we do not know how the participants used the cards, whether they engaged with the information in the cards, or had an opportunity to clarify their understanding to learn more about them. Introduction or integration of the game in science or health classes could reinforce

the educational aspects and impact on vaccine uptake, as evidenced in the Cochrane review of adolescent vaccine interventions [14].

In a pragmatic sense it is unlikely a single intervention alone will largely change complex paradigm like vaccine hesitancy. In future trials, we would like to investigate the intervention in combination with other incentives and educational material to determine if a multifaceted approach can shift consent rates.

Strengths and Limitations

The outcomes of this trial were impacted by the unexpectedly large deviation in vaccination consent between the clusters of schools. The sample size was based in part on an estimated effect size, which may have been too optimistic. A larger study considering all these things is needed to more definitively determine efficacy of Vaxcards as a standalone intervention when delivered as an ethical incentive for vaccination. We also do not know the vaccine outcome of children who did not return a consent form, declined school vaccine or ticked 'had elsewhere'. It is possible these students did indeed get vaccinated outside the school program and the 'consent' rates do not infer true vaccine status of the group. Lastly, all students who returned consent cards were given a pack of Vaxcards, regardless of response. This decision was made pragmatically by the schools to not discriminate based on responses and to include all students. It also aligned with incentives of the school, which are measured in total consent card return rate, not consent 'yes' return rates. This is an interesting point to possible consider as a target to increase consent 'yes' rates, to change school performance indicators to align with public health outcomes rather than the return of forms regardless of outcome. Nevertheless, reward of Vaxcards for returning a consent card regardless of response may mean the incentive to return a form consenting 'yes' was diluted, impacting the main outcome measured.

A further limitation of this study includes the insufficient cluster sizes required for statistical assessment. Also, it may not have been able to effectively control for bias in this study and so there are lessons for future studies of Vaxcards and of vaccine hesitancy in schools for a larger trial. There may have been an unrecorded data-reporting lag by the council if they were still waiting for consent cards to come in retrospectively after following up students within schools.

This trial was also conducted in a real world, pragmatic setting. Behavior change interventions are complex in their nature due to the ways in which behaviors develop in different contexts for different individuals. [27 28]. The design of this trial may also have dilution the effect if the intervention efficacy that may impact the results. For this reason, a much larger trial involving more clusters to account for this dilution effect would be suitable to further assess the intervention.

Conclusions

Vaxcards is a novel intervention that addresses many recommendations made in the recent Cochrane review of effective interventions to improve vaccine uptake in adolescents [14]. These elements include being an ethical incentive that can be incorporated into other health education and health promotion initiatives as part of multi-component approaches to support vaccine uptake amongst school-aged children. This potential requires further investigation to assess impact on vaccine uptake and vaccine confidence. A combination of optimizing the timing and the intensity of the intervention as part of a multimodal approach will be required to significantly shift hesitancy and improve consent rates and ultimately uptake of vaccination.

Conflicts of interest

The lead author is the creator of Vaxcards that supplied the card games for evaluation in this study and this was disclosed to the participating schools and

councils involved in the vaccination project. This interest will be disclosed in all subsequent research output.

Contribution statement:

DE, JE, HL and CB contributed to the conception or design of the study, data collection analysis, interpretation of data drafting the work or revising it critically, final approval of the version to be published and agreement to be accountable for all aspects of the work. JE contributed to the conception or design of the study, data collection analysis, interpretation of data drafting the work or revising it critically, final approval of the version to be published and agreement to be accountable for all aspects of the work

Data sharing: Data from the trial is accessible with email correspondence to the authors.

Competing interests: The lead author is the creator of Vaxcards that supplied the card games for evaluation in this study and this was disclosed to the participating schools and councils involved in the vaccination project. This interest will be disclosed in all subsequent research output.

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Figure legend:

Figure 1 PRISMA chart showing the flow of participant's through the RCT

Figure 2 Logic Model (or theory of change) for Vaxcards.

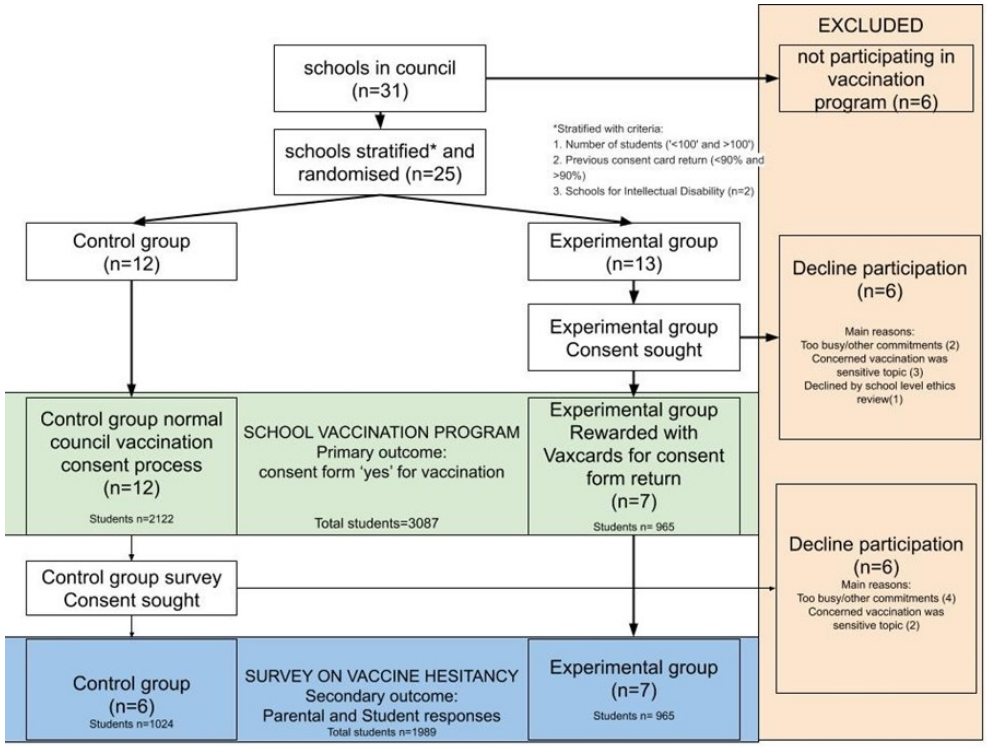

Figure 1 PRISMA chart showing the flow of participant's through the RCT

159x119mm (146 x 146 DPI)

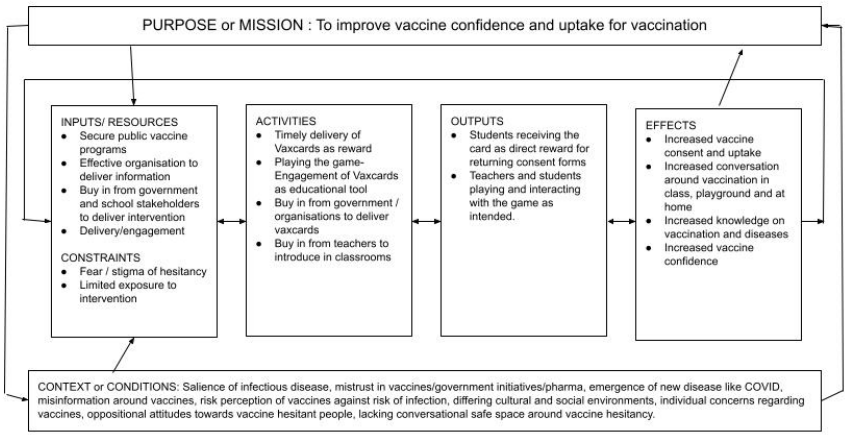

Figure 2 logic model

338x254mm (72 x 72 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7
Participants	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	10
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	na
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	9

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	12
	13b	For each group, losses and exclusions after randomisation, together with reasons	13
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	12
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	13
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	13
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	13
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	12
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	18
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	18
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.