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***Psychosocial Factors Related to Parental  
Acceptance of Human Papillomavirus (HPV)  
Vaccines for Adolescent Daughters***

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**A thesis submitted in fulfillment of the requirements  
for the degree of Doctor of Philosophy.  
The University of Auckland, 2012.**

## ABSTRACT

### Purpose

This research had two main objectives. First, to assess at baseline the psychosocial factors related to: a) initiation of HPV vaccination by adolescent girls; and b) parents' intentions to vaccinate their daughters within 12 months. Secondly, to assess at follow-up if HPV vaccine uptake among adolescent girls who were unvaccinated at baseline differs by whether their parents are recipients of the *gain-framed* message (benefits of vaccinating daughters against HPV) or *loss-framed* message (potential consequences of *not* having daughters vaccinated against HPV).

### Methods

Parents and caregivers of 11-15 year old girls were the target for recruitment through 18 schools in the Auckland Region in New Zealand. This was a prospective study with one experimental component whereby parents were provided with one of two framed messages at baseline. Participants chose to complete the baseline research questionnaire online, or request a hard-copy by mail. A follow-up was undertaken to obtain HPV vaccine uptake data 6-9 months post-baseline.

The outcome variable at baseline was the girls' HPV vaccination status, which was a three-level nominal variable comparing parents who did *not* intend to vaccinate daughters within 12 months (n=72) to parents who intended to do so (n=87), and to parents whose daughters had initiated HPV vaccination (n=63). Bivariate analyses were done to assess whether girls' HPV vaccination status at baseline was related to a broad range of independent variables. Adjusting for covariates that were found to be important in the bivariate analysis, multinomial logistic regression analyses were done with girls' HPV vaccination status as the dependent variable, and anticipated regret measures, worry measures and Health Belief Model variables as the main independent variables. HPV vaccine uptake at follow-up was defined in two ways: initiation of HPV vaccination by girls; and the level of completion of the HPV vaccination series by girls. Among parents whose daughters were unvaccinated at baseline, the effect of message framing on initiation of HPV vaccination by follow-up was assessed using logistic regression.

## Results

Two hundred and twenty-nine parents completed the baseline research questionnaire; of these, 121 (53%) participated online and 176 (77%) provided consent for the follow-up phase of the study. Compared to parents who did *not* intend to vaccinate daughters within 12 months, parents whose daughters had initiated HPV vaccination and who intended to do so within 12 months were significantly more likely to: have greater levels of anticipated regret in the event that daughters were unvaccinated and developed cervical cancer or contracted genital warts (*inaction* regret); place more value on recommendations by their general practitioner and family/friends to vaccinate daughters against HPV; perceive HPV-related illness as more likely to occur in girls without vaccination; perceive the vaccine as more effective in preventing HPV-related illnesses; and be unaware that Gardasil® also prevents genital warts. Additionally, parents whose daughters had initiated HPV vaccination had reduced levels of worry regarding HPV and genital warts, and were less concerned about potential HPV vaccine side-effects. Parents who intended to vaccinate daughters within 12 months perceived HPV and cervical cancer as having more severe consequences to their daughters' health than parents who did *not* intend to do so. However, a number of factors were unrelated to girls' HPV vaccination status, notably: anticipated regret in the event that daughters were vaccinated against HPV and initiated sexual activity at an early age (*action* regret); and worry regarding cervical cancer. Anticipated *inaction* regret measures partially mediated the relationship between perceived likelihood of HPV-related illnesses and girls' HPV vaccination status at baseline.

At the end of the study, the HPV vaccination status of 181 girls (79% of the sample) had been determined; 50% had completed the series of three injections and 25% had initiated but not completed vaccination series. Message framing was unrelated to HPV vaccine uptake by girls at follow-up, and risk likelihood did not moderate this relationship.

## Conclusions, implications and recommendations

Parents who have vaccinated daughters against HPV and who report their intention to do so in the near future are motivated greatly by *inaction* regret. However, *action* regret is not a deterrent of HPV vaccination as generally, parents did not believe that having daughters vaccinated against HPV would lead to early sexual activity. Vaccinating daughters against HPV appears to

reduce parental worry regarding HPV and genital warts. HPV vaccination is more acceptable when parents believe that the vaccines are effective, do not cause side-effects, and would be supported by their physicians and family/friends. Parents are also more willing to vaccinate daughters if they believe that HPV-related illnesses are likely to occur without vaccination or would have serious consequences to their daughters' health.

Future research could prospectively investigate whether HPV vaccine uptake can be enhanced by: informing parents that vaccinating daughters would alleviate some worries regarding HPV infections and genital warts; using framed messages that incorporate triggers of inaction regret while minimizing psychological distress and ethical concerns; and comparing framed messages directed at both parents and their daughters versus parents alone. Additionally, qualitative studies could provide better insight on whether stigma or other factors discourage vaccine acceptability among parents who are aware that Gardasil® also prevents genital warts. The present study should also be replicated in a larger sample that is more ethnically and socio-economically diverse to increase external validity. Findings from such research could be beneficial when preparing HPV vaccination information for target populations and in determining the most effective ways of delivery.

## **DEDICATION**

This work is dedicated to the loving memory of my dear friend, *Victoria (Vicki) Latella*, who lost her battle with colon cancer on 21 July, 2010. To someone of exceptional humanity, and admirable bravery and courage, this is for you. For her unwavering friendship, kindness, encouragement and wisdom, I am eternally grateful.

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## TABLE OF CONTENTS

<b>Abstract.....</b>	<b>ii</b>
<b>Dedication.....</b>	<b>v</b>
<b>Acknowledgements .....</b>	<b>vi</b>
<b>Table of Contents.....</b>	<b>vii</b>
<b>List of Appendices.....</b>	<b>xiv</b>
<b>List of Figures.....</b>	<b>xv</b>
<b>List of Tables .....</b>	<b>xvi</b>
<b>List of Abbreviations .....</b>	<b>xix</b>
<b>CHAPTER 1: INTRODUCTION .....</b>	<b>1</b>
1.1 Overview .....	1
1.2 Context and aims of the thesis.....	3
1.3 Roles of the candidate .....	4
1.4 Structure of the thesis .....	5
<b>CHAPTER 2: HUMAN PAPILLOMAVIRUSES (HPV), CERVICAL CANCER, GENITAL                   WARTS, AND HPV VACCINES .....</b>	<b>6</b>
2.1 Human Papillomaviruses (HPV) .....	6
2.1.1 <i>HPV infection</i> .....	6
2.1.2 <i>Burden of HPV</i> .....	8
2.1.3 <i>Risk factors for HPV infection</i> .....	9
2.2 Genital Warts.....	12
2.2.1 <i>Development and burden of genital warts</i> .....	12
2.2.2 <i>Risk factors for genital warts</i> .....	13
2.3 Cervical Cancer .....	14
2.3.1 <i>Development and burden of cervical cancer</i> .....	14
2.3.2 <i>Risk factors for cervical cancer</i> .....	14



2.4	Prevention of HPV, cervical cancer and genital warts .....	17
2.4.1	<i>HPV vaccines</i> .....	17
2.4.2	<i>Other preventive measures</i> .....	20
2.5	Summary .....	21
<b>CHAPTER 3: PSYCHOLOGICAL FACTORS AND HEALTH BEHAVIORS TO BENEFIT CHILD HEALTH.....</b>		<b>22</b>
3.1	Anticipated regret .....	22
3.1.1	<i>Introduction</i> .....	22
3.1.2	<i>Anticipated regret and parental actions/intentions to benefit child health</i> .....	23
3.1.2.1	Vaccination.....	27
3.1.2.2	Other parental actions/intentions to benefit child health .....	29
3.2	Worry.....	30
3.2.1	<i>Introduction</i> .....	30
3.2.2	<i>Worry and parental actions/intentions to benefit child health</i> .....	31
3.2.2.1	Vaccination.....	35
3.2.2.2	Other parental actions/intentions to benefit child health .....	36
3.3	The Health Belief Model (HBM) .....	38
3.3.1	<i>Introduction</i> .....	38
3.3.2	<i>Studies on the HBM and parental acceptability of HPV vaccination for daughters</i> .....	39
3.3.2.1	Study characteristics and limitations .....	39
3.3.2.2	HBM dimensions.....	40
3.4	Message framing .....	45
3.4.1	<i>Introduction</i> .....	45
3.4.2	<i>Message framing and parental actions/intentions to benefit child health</i> .....	47
3.5	Summary .....	53
<b>CHAPTER 4: RATIONALE, OBJECTIVES, AND HYPOTHESES.....</b>		<b>54</b>

4.1	Rationale.....	54
4.2	Objectives .....	54
4.3	Hypotheses .....	55
<b>CHAPTER 5: RESEARCH METHODOLOGY.....</b>		<b>56</b>
5.1	Study population and design .....	56
5.1.1	<i>Participants</i> .....	56
5.1.2	<i>Sample size estimation</i> .....	56
5.1.3	<i>Study design</i> .....	57
5.1.3.1	The cross-sectional baseline survey .....	57
5.1.3.2	The follow-up phase .....	58
5.1.4	<i>Ethical approval</i> .....	58
5.2	Recruitment .....	58
5.2.1	<i>Selection of participating schools</i> .....	58
5.2.1.1	Phase one .....	59
5.2.1.2	Phase two.....	59
5.2.2	<i>Recruitment of participants</i> .....	60
5.3	Data collection and tools .....	61
5.3.1	<i>The research questionnaire</i> .....	61
5.3.1.1	Design of research questionnaire.....	61
5.3.1.2	Pilot of research questionnaire .....	66
5.3.2	<i>Questionnaire administration</i> .....	67
5.3.3	<i>Follow-up of study participants</i> .....	67
5.3.4	<i>Prize draw</i> .....	67
5.3.5	<i>Feedback to participating schools and parents</i> .....	68
5.4	Measures.....	69
5.4.1	<i>Parents' sociodemographic information</i> .....	70
5.4.2	<i>Girls' sociodemographic information and vaccination history</i> .....	70

5.4.3	<i>Girls' HPV vaccination status at baseline</i> .....	70
5.4.4	<i>Message framing content</i> .....	71
5.4.5	<i>Parents' HPV-related knowledge, attitudes and beliefs</i> .....	73
5.4.6	<i>Parents' vaccination and health experiences</i> .....	73
5.4.7	<i>Anticipated regret</i> .....	73
5.4.8	<i>Worry</i> .....	74
5.4.9	<i>Health Belief Model (HBM) variables</i> .....	75
5.5	<b>Statistical analyses of baseline data</b> .....	79
5.5.1	<i>Outcome variable at baseline</i> .....	79
5.5.2	<i>Primary independent variables</i> .....	79
5.5.3	<i>Secondary independent variables (covariates)</i> .....	80
5.5.4	<i>Bivariate analyses</i> .....	81
5.5.5	<i>Multivariate analyses</i> .....	81
5.5.5.1	<i>Anticipated regret with girls' baseline HPV vaccination status</i> .....	83
5.5.5.2	<i>Worry with girls' baseline HPV vaccination status</i> .....	83
5.5.5.3	<i>HBM variables with girls' baseline HPV vaccination status</i> .....	84
5.5.6	<i>Mediation analysis</i> .....	84
5.6	<b>Statistical analyses of follow-up data</b> .....	86
5.6.1	<i>Outcome variables at follow-up</i> .....	86
5.6.2	<i>Bivariate analyses</i> .....	87
5.6.3	<i>Multivariate analysis</i> .....	88
5.7	<b>Summary</b> .....	89
<b>CHAPTER 6: BASELINE RESULTS</b> .....		<b>90</b>
6.1	<i>School response rate</i> .....	90
6.2	<i>Participant response rate</i> .....	92
6.3	<i>Mode of questionnaire completion</i> .....	93
6.4	<i>Descriptive statistics</i> .....	95

6.4.1	<i>Parents sociodemographic baseline characteristics</i> .....	95
6.4.2	<i>Baseline characteristics of adolescent girls</i> .....	95
6.4.3	<i>Girls' HPV vaccination status at baseline</i> .....	98
6.4.4	<i>Parents' HPV-related knowledge, attitudes and beliefs</i> .....	100
6.4.5	<i>Parents' vaccination and health experiences</i> .....	102
6.5	<b>Bivariate analyses results</b> .....	103
6.5.1	<i>Sociodemographic factors associated with girls' HPV vaccination status</i> .....	103
6.5.2	<i>HPV-related knowledge and attitudes associated with girls' HPV vaccination status</i> .....	105
6.5.3	<i>Parents' health experiences associated with girls' HPV vaccination status</i> .....	107
6.5.4	<i>Parents' vaccination experiences associated with girls' HPV vaccination status</i> .....	107
6.5.5	<i>Relationship between anticipated regret and girls' HPV vaccination status</i> .....	110
6.5.6	<i>Relationship between parental worry and girls' HPV vaccination status</i> .....	112
6.5.7	<i>Relationship between HBM variables and girls' HPV vaccination status</i> .....	114
6.5.8	<i>Correlations between psychological measures</i> .....	119
6.6	<b>Multivariate analyses results</b> .....	123
6.6.1	<i>Anticipated regret</i> .....	123
6.6.2	<i>Worry</i> .....	130
6.6.3	<i>Health Belief Model (HBM) variables</i> .....	136
6.7	<b>Mediation analysis results</b> .....	138
6.7.1	<i>Perceived likelihood of HPV-related illnesses and HPV vaccination status at baseline</i> ....	138
6.7.2	<i>Potential mediators and perceived likelihood of HPV-related illnesses</i> .....	138
6.7.3	<i>Anticipated regret as a potential mediator</i> .....	138
6.7.4	<i>Worry as a potential mediator</i> .....	139
6.8	<b>Summary</b> .....	144
<b>CHAPTER 7: FOLLOW-UP RESULTS</b> .....		<b>146</b>
7.1	<b>Participation rate at follow-up</b> .....	146
7.2	<b>Uptake of HPV vaccination by girls at follow-up</b> .....	146

7.3	HPV vaccine uptake at follow-up by HPV vaccination status at baseline .....	147
7.4	HPV vaccine uptake at follow-up by sources of uptake data .....	149
7.5	Message framing results .....	150
7.5.1	<i>Bivariate analyses results</i> .....	150
7.5.1.1	Selected baseline characteristics with type of message framing content.....	150
7.5.1.2	Anticipated regret and worry with type of message framing content.....	152
7.5.1.3	Health Belief Model (HBM) variables with type of message framing content .....	152
7.5.1.4	HPV vaccine uptake at follow-up with type of message framing content.....	155
7.5.2	<i>Multivariate analysis results</i> .....	155
7.6	Summary .....	157
<b>CHAPTER 8: DISCUSSION.....</b>		<b>158</b>
8.1	Baseline .....	158
8.1.1	<i>Anticipated regret and HPV vaccine acceptance by parents</i> .....	158
8.1.2	<i>Worry and HPV vaccine acceptance by parents</i> .....	161
8.1.3	<i>The Health Belief Model (HBM) and HPV vaccine acceptance by parents</i> .....	162
8.1.4	<i>Sociodemographic factors and HPV vaccine acceptance by parents</i> .....	166
8.2	Follow-up .....	169
8.2.1	<i>HPV vaccine uptake at follow-up by adolescent girls</i> .....	169
8.2.2	<i>Message framing and HPV vaccine uptake at follow-up</i> .....	171
8.3	Strengths .....	173
8.3.1	<i>What this study adds</i> .....	173
8.3.2	<i>Methodology</i> .....	173
8.4	Limitations.....	174
8.4.1	<i>Study design</i> .....	174
8.4.2	<i>Recruitment and data collection</i> .....	175
8.4.3	<i>Potential biases</i> .....	176
8.4.4	<i>External validity/ generalizability of findings</i> .....	176

8.5 Summary ..... 177

**CHAPTER 9: CONCLUSIONS, IMPLICATIONS AND RECOMMENDATIONS ..... 178**

9.1 Psychosocial factors and HPV vaccine acceptability ..... 178

9.2 Methodology considerations ..... 179

9.3 Recommendations for future research..... 180

**References..... 182**

**Appendices..... 199**

## **LIST OF APPENDICES**

Appendix A: Participant information sheet for school principals.....	199
Appendix B: Consent form for school principals .....	205
Appendix C: Pre-questionnaire research invitation letter for parents .....	207
Appendix D: Pre-questionnaire participant information sheet for parents .....	209
Appendix E: Questionnaire request form.....	215
Appendix F: Research invitation letter (with questionnaire) for parents .....	217
Appendix G: Participant information sheet (with questionnaire) for parents .....	219
Appendix H: Consent form for parents.....	225
Appendix I: Parental questionnaire .....	228
Appendix J: Message framing content.....	248

## LIST OF FIGURES

Figure 1: Average rating of web-survey attributes during the pilot study (n=11) .....	66
Figure 2: Hypothesized mediation models of the indirect effect of perceived risk of HPV-related illnesses on HPV vaccination status through anticipated emotions .....	85
Figure 3: Summary of recruitment of and participation by schools and parents .....	92
Figure 4: Parent participation via online versus paper questionnaires, stratified by school decile (n=226) .....	94
Figure 5: Parental report of HPV vaccine uptake at baseline and intention to vaccinate daughters in the next 12 months (n=222).....	98
Figure 6: Parental intention to vaccinate and/or discuss HPV vaccination with daughters, and intention to obtain more information about the HPV vaccine.....	99
Figure 7: HPV vaccine uptake at follow-up in the entire study population (n=228).....	147
Figure 8: HPV vaccine uptake at follow-up stratified by HPV vaccination status at baseline (n=228) .....	148
Figure 9: HPV vaccine uptake at follow-up by sources of HPV vaccine uptake data among parents who provided follow-up consent and whose daughters had not initiated HPV vaccination at baseline (n=175) .....	149



## LIST OF TABLES

Table 1: Summary of studies on anticipated regret and parental behaviors/intentions to benefit child health .....	24
Table 2: Summary of studies on worry and parental behaviors/intentions to benefit child health .....	32
Table 3: Summary of selected studies on the Health Belief Model and parental acceptability of HPV vaccines .....	41
Table 4: Summary of selected studies on the Health Belief Model and HPV vaccine uptake by adolescent girls .....	42
Table 5: Summary of studies on message framing and parental behaviors/intentions to benefit child health .....	48
Table 6: Estimation of sample size .....	57
Table 7: Number of schools approached in phase two by school type .....	60
Table 8: Survey questions and content adapted from previous research .....	62
Table 9: Summary of information collected in the parental questionnaire .....	69
Table 10: Gain-framed HPV vaccination message .....	72
Table 11: Loss-framed HPV vaccination message .....	72
Table 12: Spearman Correlation Coefficients ( $r$ ) for items created using the Health Belief Model ...	77
Table 13: Number and participation rate of schools in phases one and two of recruitment .....	91
Table 14: Decile distribution of participating schools compared to eligible schools in the Auckland North.....	91
Table 15: Parents' baseline sociodemographic characteristics .....	96
Table 16: Baseline characteristics of adolescent daughters of participating parents .....	97
Table 17: Parents' HPV-related knowledge, attitudes and beliefs.....	101
Table 18: Parents' vaccination and health experiences .....	102
Table 19: Bivariate analysis of sociodemographic factors with girls' baseline HPV vaccination status .....	104
Table 20: Bivariate analysis of parents' HPV-related knowledge and attitudes with girls' baseline HPV vaccination status.....	106

Table 21: Bivariate analysis of parents' health experiences with girls' baseline HPV vaccination status.....	108
Table 22: Bivariate analysis of parents' vaccination experiences with girls' baseline HPV vaccination status.....	109
Table 23: Bivariate analysis of anticipated regret measures with girls' baseline HPV vaccination status.....	111
Table 24: Bivariate analysis of parental worry measures with girls' baseline HPV vaccination status.....	113
Table 25: Bivariate analysis of cues to action, perceived likelihood and severity of HPV-related illnesses, and perceived HPV vaccine effectiveness with girls' baseline HPV vaccination status.....	117
Table 26: Bivariate analysis of parents' perceived barriers of HPV vaccination with girls' baseline HPV vaccination status.....	118
Table 27: Spearman Correlation Coefficients ( $r$ ) for psychological measures.....	121
Table 28: Multinomial logistic regression analysis for parents' anticipated regret in the event that daughters were unvaccinated and contracted an HPV infection that led to cervical cancer (n=199).....	125
Table 29: Multinomial logistic regression analysis for parents' anticipated regret in the event that daughters were unvaccinated and contracted genital warts (n=199).....	127
Table 30: Multinomial logistic regression analysis for parents' anticipated regret in the event that daughters were vaccinated and initiated sexual activity at an early age (n=196).....	129
Table 31: Multinomial logistic regression analysis for parental worry regarding HPV (n=202).....	131
Table 32: Multinomial logistic regression analysis for parental worry regarding genital warts (n=201).....	133
Table 33: Multinomial logistic regression analysis for parental worry regarding cervical cancer (n=202).....	135
Table 34: Multinomial logistic regression analysis for Health Belief Model variables (n=188).....	137
Table 35: Logistic regression analysis of the relationship between perceived likelihood of HPV-related illnesses and HPV vaccination status at baseline.....	140

Table 36: Spearman Correlation Coefficients ( <i>r</i> ) between potential mediators and perceived likelihood of HPV-related illnesses without HPV vaccination .....	141
Table 37: Logistic regression analysis of whether potential mediators are related to HPV vaccination status at baseline while adjusting for perceived likelihood of HPV-related illnesses without HPV vaccination .....	142
Table 38: Summary of factors associated with HPV vaccine acceptability at baseline.....	145
Table 39: Selected baseline characteristics with type of HPV vaccination message-framing content received by parents whose daughters had not initiated HPV vaccination at baseline (n=159) .....	151
Table 40: Anticipated regret and worry measures with type of HPV vaccination message-framing content received by parents whose daughters had not initiated HPV vaccination at baseline (n=159) .....	153
Table 41: HBM variables with type of HPV vaccination message-framing content received by parents whose daughters had not initiated HPV vaccination at baseline (n=159).....	154
Table 42: HPV vaccine uptake at follow-up with type of HPV vaccination message-framing content received by parents who provided follow-up consent and whose daughters had not initiated HPV vaccination at baseline (n=112).....	156
Table 43: Multivariate analysis of type of HPV vaccination message-framing content with HPV vaccine uptake at follow-up, among parents who provided follow-up consent and whose daughters had not initiated HPV vaccination at baseline (n=111) .....	157

## LIST OF ABBREVIATIONS

ADC	Adenocarcinomas
ADSC	Adenosquamous Carcinomas
CI	Confidence Interval
CIN	Cervical Intraepithelial Neoplasia
CIN1	Cervical Intraepithelial Neoplasia grade 1
CIN2	Cervical Intraepithelial Neoplasia grade 2
CIN3	Cervical Intraepithelial Neoplasia grade 3
DNA	Deoxyribonucleic Acid
HBM	Health Belief Model
HPV	Human Papillomavirus
IARC	International Agency for Research on Cancer
ICC	Invasive Cervical Cancer
ICESCC	International Collaboration of Epidemiological Studies of Cervical Cancer
NMSC	Non-Melanoma Skin Cancer
NZ	New Zealand
OR	Odds Ratio
<i>r</i>	Correlation Coefficient
SAS	Statistical Analysis Software®
SCC	Squamous Cell Carcinomas
SD	Standard Deviation
STI	Sexually Transmitted Infection
VAIN	Vaginal Intraepithelial Neoplasia
VAIN1	Vaginal Intraepithelial Neoplasia grade 1
VAIN2	Vaginal Intraepithelial Neoplasia grade 2
VAIN3	Vaginal Intraepithelial Neoplasia grade 3
VIN	Vulval Intraepithelial Neoplasia
VIN1	Vulval Intraepithelial Neoplasia grade 1
VIN2	Vulval Intraepithelial Neoplasia grade 2
VIN3	Vulval Intraepithelial Neoplasia grade 3
vs.	Versus
WDHB	Waitemata District Health Board

## **CHAPTER 1: INTRODUCTION**

### **1.1 Overview**

Human Papillomavirus (HPV) infections, the most common sexually transmitted infections globally, are often asymptomatic and clear within 2 years. However, genital HPV infection is associated with development of cervical cancer, cervical neoplasia, anogenital warts, and other anogenital cancers.[1] Worldwide, cervical cancer is the second most common cancer affecting women, with about half a million incident cases and over a quarter of deaths annually.[2] In New Zealand (NZ), genital warts is the second most commonly diagnosed sexually transmitted infection (STI),[3] whereas cervical cancer ranks third among 15-44 year old females.[2]

Two vaccines against HPV types that are responsible for most cervical cancer cases have been developed and tested in clinical trials. The quadrivalent vaccine, Gardasil® (Merck, New Jersey, United States), protects against HPV types 16, 18, 6 and 11.[4-7] On the other hand, the bivalent vaccine, Cervarix® (GlaxoSmithKline, Middlesex, United Kingdom), protects against HPV types 16 and 18.[8, 9] These vaccines are expected reduce the incidence of anogenital cancers and precancerous lesions, with the quadrivalent vaccine providing additional protective benefits against genital warts.[10] In June 2006, the American Cancer Society recommended routine HPV vaccination of 11-12 year old girls and ‘catch-up’ vaccinations for 13-18 year old girls.[10] In NZ, free HPV vaccination (Gardasil®) of females aged 17-18 years old and 12-16 years old commenced in September 2008 and January 2009, respectively, through schools and healthcare providers. At present, the vaccine is free for females born on or after January 1st, 1990.[11]

Most medical interventions, including vaccination, for children under the age of 16 years require parental consent in NZ.[12] The scope of this thesis is to get a better understanding of parental actions and intentions regarding HPV vaccination for their adolescent daughters in relation to: parental anticipated affective reactions; and parental perceptions of their children’s risk for and the severity of HPV-related illnesses, the effectiveness of HPV vaccines, barriers towards obtaining the vaccine (such as, concerns about side-effects), and the influence of subjective norms.

The importance of affective reactions in decision making regarding preventive health behaviors has been described by a number of theories. For instance, the *common-sense model* by Leventhal et al [13] posits that there are two parallel independent systems that create psychologically objective representations of health threats and emotional states (such as, fear), which influence adaptation and evaluation of coping mechanisms (self-regulative system). In addition, the *risk-as-feelings* hypothesis by Loewenstein et al [14] proposed that responses to decision making and other risky situations partly result from direct emotions. It also supports the notion that cognitive evaluation of risky alternatives has affective consequences, as well as the existence of a reciprocal influence of emotions on cognitive evaluations. Hence, the risk-as-feelings hypothesis focuses on the complementary role between the two components.

Anticipated emotions are feelings that “are typically not experienced in the immediate present but are expected to be experienced in the future” (p. 268), meaning that the emotions are an element of expected consequences of decision making.[14] Anticipation of negative consequences for failing to undertake a beneficial behavior or performing an unsafe behavior is thought to increase the likelihood of preventive actions.[15-17] Regret and worry are some of the anticipated affective reactions that have been assessed in relation to health behavior. Regret can affect decision making when options that could produce it are avoided by decision makers.[18] Motivations to act to reduce the chance of a disease occurring may also be enhanced by disease-related worry.[19] In addition, emotions are thought to mediate the effect of cognitive evaluations on behavior.[14]

It is hypothesized in the Health Belief Model (HBM) that health-related actions are influenced by: subjective perception of vulnerability to an illness (perceived susceptibility); feelings regarding the seriousness of an illness (perceived severity); the belief in the effectiveness of preventive measures to reduce health threats (perceived benefits); factors thought to impede health actions (perceived barriers); and stimuli that trigger the decision-making process (cues to action).[20-22] The HBM is widely used to explain and predict why people choose to engage in health behaviors or not to do so, and is therefore an important aspect of the research presented in this thesis.

Messages that have negative appeals (disease prevention) are thought to enhance one's beliefs about the severity of a health threat than messages that have positive appeals (improved health).[23] In this thesis, goal frames, which focus on how action (or inaction) is associated with achieving (or not achieving) a desired outcome,[24] are used to investigate whether two framed HPV vaccination messages have a differential effect in enhancing HPV vaccine uptake (behavior).

## **1.2 Context and aims of the thesis**

The primary aim of this thesis is to assess whether parental anticipated regret, parental worry, and Health Belief Model constructs are related to: initiation of HPV vaccination by adolescent girls; and parental intentions to vaccinate adolescent daughters within 12 months of baseline. The secondary aim is to assess at follow-up if HPV vaccine uptake among adolescent girls who were unvaccinated at baseline differs by whether parents are recipients of the *gain-framed* message (benefits of vaccinating daughters against HPV) or *loss-framed* message (potential consequences of not having daughters vaccinated against HPV). The goal of this research is to better understand what factors encourage parents to vaccinate or deter them from obtaining the HPV vaccine for daughters, especially where parental consent is required. A better understanding of such factors may be beneficial in finding ways to encourage HPV vaccine uptake in order to reduce the incidence of HPV-related illnesses and their associated burden.

To address the study aims, a prospective study was undertaken that included an experimental component in which participants were provided with one of the two framed HPV vaccination messages. Parents/caregivers of adolescent girls (approximately 11-15 years old) were recruited through 18 schools in the Auckland Region. From February 2010, participants were invited to complete a baseline research questionnaire to obtain data on the girls' HPV vaccination status and various parental psychological and sociodemographic factors. In the follow-up phase of the study that took place 6-9 months post-baseline, data on HPV vaccine uptake by girls was collected via health records or parental report, depending on parental consent.

### 1.3 Roles of the candidate

As the principal investigator, the candidate was involved in all of the major aspects of this study including:

- Conceptualizing the study, including its aims and methodology
- Designing the research questionnaire (online and paper versions), participation information sheets, consent forms and other research materials.
- Piloting the research questionnaire
- Obtaining ethical approval for the study
- Recruiting schools to participate in the study
- Data collection and data entry (for paper questionnaires)
- Day-to-day running of the study
- Data management and cleaning
- Performing statistical analyses of the data collected and summarizing results in tables and figures, which are presented in this thesis
- Obtaining funding for conference travel and presenting some preliminary study findings in April 2010 at a Behavioral Medicine conference in the USA.

Research assistants were hired to help with assembling research packets (n=3,995) containing invitations to parents and information about this study, which were then sent to the 18 participating schools. For HPV vaccine uptake data obtained via parental report during the follow-up phase, a research assistant was hired to contact parents via phone or email for this information. In cases where parents consented that their daughters' HPV vaccine uptake data be extracted from health records, this data were obtained through Ms. Selena Griffith and Ms. Bronwen Jackson during their roles in 2010 as HPV Project Manager and HPV Team Coordinator, respectively, at the Waitemata District Health Board (WDHB), North Shore City, New Zealand.

After completion of this thesis, participating schools and parents will be debriefed and provided with a summary of the study's findings.



## 1.4 Structure of the thesis

This chapter has briefly described why HPV and HPV-related conditions affecting women are an important public health issue and the availability of HPV vaccines as a preventive measure. It also highlights why undertaking research to assess psychosocial factors related to parental acceptability of HPV vaccination for adolescent daughters is important, and then briefly describes the approach used in this thesis to address this issue.

*Chapter 2* provides more detailed information of what HPV is and its burden, especially in causing cervical cancer and genital warts. It also describes the relatively recent availability of HPV vaccines, which are expected to reduce the incidence of HPV-related illnesses.

*Chapter 3* reviews the available literature on anticipated regret, worry and message framing in relation to parental actions/intentions to benefit child health. Literature on the Health Belief Model and vaccination decisions by parents on their children's behalf is also presented.

*Chapter 4* presents the rationale of the study, as well as the study objectives and hypotheses.

*Chapter 5* describes the study population and design, and provides information on recruitment of schools and parents, the questionnaire design, data collection processes, measures, and the statistical techniques used to analyze the data collected.

*Chapter 6 and 7* present findings from analysis of baseline and follow-up data, respectively, primarily the relationship between girls' HPV vaccination status and a number of parental psychological and sociodemographic factors.

*Chapter 8* summarizes and highlights the study's findings and describes how these compare to published literature that is relevant to this topic. The strengths and limitations of this study are also detailed. Finally, *Chapter 9* presents the conclusions drawn from this study, their implications, and recommendations for future research.

## **CHAPTER 2: HUMAN PAPILOMAVIRUSES (HPV), CERVICAL CANCER, GENITAL WARTS, AND HPV VACCINES**

This chapter describes human papillomaviruses (HPV), HPV infections, and the burden of and risk factors for HPV infection. Information is also provided on the development and burden of cervical cancer and genital warts, and the risk factors for these HPV-related conditions. Finally, preventive measures against HPV, cervical cancer and genital warts are described, including the role of HPV vaccines, which have the potential of reducing the burden of HPV-related illnesses in the future. The information presented here provides an understanding of why acceptability of HPV vaccines by parents of adolescent girls – who are the primary target for vaccination in order to maximize effectiveness prior to occurrence of HPV infection – is imperative.

### **2.1 Human Papillomaviruses (HPV)**

#### **2.1.1 HPV infection**

Papillomaviruses are double-stranded deoxyribonucleic acid (DNA) viruses that are small, non-enveloped and icosahedral with a diameter of 52–55 nanometers.[25, 26] They are also epitheliotropic, which means that they generate productive infections merely within the stratified epithelia of the skin, oral cavity and anogenital tract. Infection of basal epithelial cells initiates the viral life cycle, which is linked to differentiation of the infected epithelial cells.[1]

Of more than 100 HPV types that have been differentiated molecularly, approximately 40 types are known to infect the genital tract.[27] HPV infections are the most common sexually transmitted infections globally. Genital HPV infection is associated with development of cervical cancer, cervical neoplasia, anogenital warts, and other anogenital cancers.[1] However, cervical infections with HPV are often asymptomatic and clear within one to two years of infection through the hosts' cell-mediated immunity.[28] Worldwide, the prevalence of HPV infections among women with normal cytology is about 10%.[2, 29, 30] However, in all world regions, there are age disparities in HPV prevalence whereby women under the age of 35 years have the highest HPV prevalence.[30] For instance, among college women participating in a longitudinal study in the United States (U.S.), HPV prevalence among females with normal cytology was 24.4%.[31]

HPV-16 and HPV-18 were classified as human carcinogens in 1995 by the International Agency for Research on Cancer (IARC).[32] Data pooled from 11 case-control studies resulted in the classification of 15 HPV types as *high-risk* (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, and 82), three HPV types as *probable high-risk* types (26, 53, and 66), and 12 HPV types as *low-risk* (6, 11, 40, 42, 43, 44, 54, 61, 70, 72, 81, and CP6108).[33] High-risk HPV types are considered to be carcinogenic and are often associated with invasive cervical cancer (ICC). On the other hand, low-risk HPV types are mainly associated with genital warts.[34] In women with normal cytology who are infected with high risk HPV types, HPV-16 infections have a significantly lower 18-month clearance rate than other high-risk HPV types. Furthermore, women with HPV-16 infections that persist are more likely to develop cervical intraepithelial neoplasia (CIN) grade 3 (CIN3) or cervical cancer than women who have persistence infections with other high-risk HPVs.[35]

Prevalence of HPV DNA in ICC cases - regardless of HPV type - is homogenous across geographic regions, ranging from 75% to 100%.[36] A meta-analysis of HPV prevalence in over 10,000 ICC cases from 85 studies found no significant geographical differences. Adjusting for histological type, geographic region, type of HPV DNA specimen, and polymerase chain reaction (PCR) primers used in HPV detection, HPV prevalence was reported as follows: 87.7% in South and Central America; 88.1% in North America and Australia; 86.7% in Europe; 79.3% in Asia; and 86.5% in Africa.[37]

Conversely, the prevalence of HPV among women with normal cytology is lower in developed countries (10.0%) compared to less developed regions (15.5%). Worldwide, HPV-16 followed by HPV-18 are the most prevalent HPV types in women with normal cytology. By geographic region however, HPV-18 is the second most common HPV type in Europe, Central America and South America, but ranks third in Africa and fourth in Asia and North America. HPV-52 is the second most prevalent HPV type in Africa and Asia, while HPV-53 ranks second in North America.[30]

### 2.1.2 *Burden of HPV*

Harald zur Hausen, a German virologist, won the 2008 Nobel Prize in Physiology or Medicine for establishing the link between oncogenic genital HPV and cervical cancer in the late 1970s to early 1980s.[38-40] HPV is a necessary cause of cervical cancer. In a multi-national study using data from 22 countries, HPV DNA was detected in 93% of biopsy specimens from over 900 sequential ICC cases.[36] Further analysis of 7% of the specimens that initially tested negative for HPV DNA increased the prevalence of HPV in ICC cases to 99.7%, leading to the conclusion that HPV-negative cervical cancers are very uncommon.[41]

An estimated 70.1% of invasive cervical cancers have been attributed to HPV-16 (54.4%) and HPV-18 (15.9%) globally. However, in Australia and New Zealand, 77.6% of cervical cancers are attributed to HPV-16 (56.4%) and HPV-18 (21.1%).[2] The two HPV types are also responsible for approximately 50% of CIN3.[42] In young women with incident HPV-16 or HPV-18 infections, 20% and 6.7% develop CIN grade 2 (CIN2) and CIN3, respectively, within 36 months of infection.[43]

Of more than 35 HPV types, five types (HPVs 16, 18, 45, 31 and 33) account for 80% and 94% of the distribution in squamous cell carcinomas (SCC) and adenocarcinomas (ADC) of the cervix, respectively.[44] Moreover, in a pooled analysis of 11 case-control studies, 95% of SCCs positive for HPV DNA were due to HPV types 16, 18, 45, 31, 33, 52, 58, and 35.[33] The overall HPV prevalence does not vary between SCC, ADC, and adenosquamous carcinomas (ADSC) of the cervix.[37] In an IARC multi-center case-control study, 94.6% of SCC cases and 90.9% of ADC/ADSC cases were positive for HPV DNA.[45] However, there is variation in HPV prevalence by HPV type in these carcinomas. The relationship between HPV type and tumor histology has shown that 68% of viral types found in SCC are accounted for by HPV-16 and related viruses (HPV types 31, 33, 35, 52, and 58). For both ADC and ADSC, 71% of viral types found in these tumors are accounted for by HPV-18 and related viruses (HPV types 39, 45, 59, and 68).[36] A meta-analysis of over 10,000 ICC cases from all continents found HPV-16 prevalence to be significantly higher in SCC (55.2%) than ADC and ADSC combined (31.3%). In contrast, HPV-18 prevalence was significantly lower in SCC (12.3%) than ADC and ADSC combined (37.7%).[37]

HPV is also associated with vaginal and other anogenital cancers. It has been found in a large proportion of vaginal cancers (64%-91%), severe vaginal intraepithelial neoplasia (VAIN-3) lesions (82%-100%), and anal cancers (88%-94%). In addition, in young individuals, 60%-90% of cancers of the vulva and penis are associated with HPV. However, less than 10% of these cancers are related to HPV in older individuals. The disparity between younger and older individuals in the burden of HPV in cancers of the vulva and penis is due to differences in histological types normally affecting these groups.[27] Although penile cancer is rare, accounting for no more than 0.5% of cancers in males globally, approximately 40%-50% of these cancers are HPV DNA positive.[1]

Non-anogenital cancers have also been linked to HPV. HPV DNA has been detected in head and neck SCCs. Most HPV-positive oropharyngeal (86.7%), oral (68.2%) and laryngeal (69.2%) SCCs are due to HPV-16.[46] Epidermodysplasia verruciformis HPV types, especially HPV-5 and HPV-8, are thought to be co-carcinogens in the development of non-melanoma skin cancer (NMSC), in addition to ultraviolet radiation and immunosuppression.[27] NMSC is the most common form of malignancy among people with fair skin.[47] For instance, in 2010 in the United States (U.S.), it is estimated that over one million incident cases of NMSC occurred.[48] HPV DNA has been found in about 90% of NMSCs among immunosuppressed organ transplant recipients, but only in 30%-50% of NMSCs among immunocompetent individuals.[49]

### **2.1.3 Risk factors for HPV infection**

#### *Sexual transmission*

The major risk factors for HPV infection are behaviors related to sexual activity.[1] A cohort study in Denmark found that among women who had not initiated sexual activity at recruitment, 35.4% of those who became sexually active by the two-year follow-up were HPV DNA positive. However, none of the women who had not initiated sexual activity at follow-up tested positive for HPV DNA.[50] In another cohort sub-sample of over 400 HPV-negative college women in the U.S., the 24-month cumulative incidence of HPV infection did not vary between women who were sexually active at recruitment (38.8%) and those who initiated sexual activity during

follow-up (38.9%). In contrast, among women who did not initiate sexual activity, the 24-month cumulative incidence of HPV infection was only 2.4%. [51]

Other studies have also found that females who have not initiated sexual activity are uninfected with HPV or have a very low HPV prevalence. In a clinical cohort of 60 females aged 14-17 years old in the U.S., participants who had never been sexually active (five percent) all tested negative for HPV. [52] A longitudinal study of university women in the U.S. found that three percent of those who reported never being sexually active tested positive for HPV. [31] In addition, a population-based study of young Swedish women found that HPV prevalence was four percent among those who had not initiated sexual activity; however, none of these women had an abnormal cervical smear. [53]

HPV incidence appears to vary by the length of time since acquisition of new male partners by females. In a cohort study of university women in the U.S. who were HPV DNA negative at recruitment, women with new sexual partners in the previous 5-8 months had the greatest risk for incident HPV infections, followed by women with new sexual partners in the previous 8-12 months and 0-4 months. Furthermore, women with new partners in the previous 5-8 months had the highest risk for infection with HPV-16. [51] Another U.S. study found that compared to women who had been in a relationship for 12 months or less with their regular partner, women in relationships for more than 12 months with a regular partner were less likely to be HPV-positive. [31]

#### *Number of lifetime sexual partners among females*

The number of sexual partners has been shown to be one of the most important risk factors for HPV transmission. [31, 50, 53-56] Detection of HPV DNA in both males and females increases significantly with an increasing number of lifetime sexual partners. [57, 58] Additionally, the risk for HPV infection in women has been shown to increase with the number of male sexual partners both in the last six months and in the women's lifetime. [31]

In a study of 467 women in the U.S., the number of lifetime sexual partners was a significant predictor of HPV infection. Furthermore, a significant trend indicated an increase in the odds of

HPV infection with an increasing number of lifetime sexual partners. For instance, compared to women who had one sexual lifetime partner, women who had 6-9 and 10 or more lifetime partners had five times the odds and eleven times the odds of HPV infection, respectively.[54] Another study in Denmark found that compared to women who had one sexual partner during follow-up, those who had three or more partners had almost ten times the odds of being HPV DNA positive.[50] Among young Swedish women participating in a population-based study, the number of lifetime male sexual partners was the only independent risk factor for HPV infection. Women with six or more lifetime sexual partners had more than seven times the odds of being HPV-positive, compared to women with one lifetime partner.[53]

In Denmark, Kjaer et al [55] investigated whether the association between HPV infection and the number of lifetime sexual partners among females differs by the HPV type. Their results showed that as the number of lifetime sexual partners increased, women were more likely to test positive for oncogenic (high-risk) HPV types, but not non-oncogenic (low-risk) HPV types.

#### *Male characteristics*

In the U.S., Winer et al [51] found that compared to women who reported having monogamous male sexual partners, women whose male sexual partners had other partners and women who were unaware if their male sexual partners had other partners had five times and eight times the risk for incident HPV infection, respectively. Another U.S. study found that women had three times the odds of being HPV-positive if their male sexual partners had 4-10 lifetime partners compared to women whose male partners had one lifetime partner.[31] A pooled analysis of IARC HPV prevalence surveys showed an association of a lesser magnitude; women whose husbands had extramarital relationships had approximately one-and-a-half times the odds of being HPV-positive.[56] An increase in the age differences between women and their first sexual partner has also been shown to be a risk factor for HPV infection, as older male partners would have a greater likelihood of being HPV carriers.[50]

#### *Other risk factors*

Other factors not directly related to sexual behavior have been identified as the risk factors for HPV infection. An increased risk for HPV infection has also been associated with long-term oral

contraceptive use,[51, 54] Black or Hispanic ethnicity,[31, 54] and a history of Chlamydia infections.[55]

## 2.2 Genital Warts

### 2.2.1 *Development and burden of genital warts*

Approximately 90% of genital warts – also known as *condylomata acuminata* – are caused by infection with HPV-6 and HPV-11.[52, 59-62] Genital warts are highly contagious with the majority of warts developing within 2-3 months of infection.[43, 63] Winer et al [43] found the median duration between incident infection with HPV-6 or HPV-11 and development of genital warts to be 2.9 months among 18-20 year old females in the U.S. Furthermore, among females newly infected with HPV-6 and HPV-11, about two-thirds developed clinically-diagnosed genital warts within three years of infection.

Although genital warts do not result in major morbidity or mortality, they are associated with psychological distress,[63] and significant medical costs.[64-66] For instance, in the United Kingdom (UK), it costs an estimated £216 for one successful treatment episode,[66] resulting in approximately £31 million per year in total medical costs.[67] An international study (Canada, France, Germany, the UK, and the U.S.) of 80 male and 84 female patients with genital warts found that those affected by the disease experience a high level of anxiety during diagnosis and treatment, as well as discomfort, pain and embarrassment.[68] With treatment, the median duration of clearance of genital warts is about six months.[43]

The highest rates of genital warts occur among 15-24 year old females and 20-29 year old males.[69] There is also an increase in the age-specific prevalence of genital warts in younger birth cohorts.[70] In 2003 in NZ, people aged 15-24 year olds had the highest rates of genital warts among those visiting sexual health and family planning clinics; this was the second most common STI diagnosed. In addition, males had higher rates of genital warts than females among attendees at sexual health clinics (5.2% vs. 3.8%) and family planning clinics (1.3% vs. 0.2%). Among people visiting sexual health clinics, rates of genital warts were highest among 20-24



year olds (5.7%) closely followed by 15-19 year olds (5.2%). These two age groups also had the highest rates of genital warts among attendees at family planning clinics.[3]

Studies in some countries have shown genital warts to be more prevalent in females than males. In a 2000 national survey of 16-44 year olds in the UK, the proportion of respondents who had ever been diagnosed with genital warts was 3.6% and 4.1% among males and females, respectively.[71] Similarly, the Australian Study of Health and Relationships found that 4.0% of males and 4.4% females aged 16-59 years old had a history of genital warts.[72] Over five percent of 18-59 year old participants of the National Health and Nutrition Examination Survey (NHANES) from 1999-2004 reported a history of genital warts; a greater proportion of females than males (7.2% vs. 4%) had previously been diagnosed with genital warts.[73] In a population-based cross-sectional study of over 69,000 women aged 18-45 years old residing in Denmark, Iceland, Norway and Sweden, 10.6% of respondents had a history of genital warts with 1.3% having genital warts in the past year.[70]

### **2.2.2 Risk factors for genital warts**

Changes in sexual behavior are probably the key factor behind the increasing rates of genital warts over time.[67] Development of genital warts in young women has been associated with an increasing number of sexual partners,[70, 74] and acquisition of new partners 12 months prior to development of genital warts.[74] For instance, Kjaer et al [70] found that compared to women who had one lifetime partner, women with 15 or more lifetime partners had over nine times the odds of having a history of genital warts.

A study of young Swedish women found that 65% of those with genital warts were HPV-positive.[53] About 91% of genital wart lesions found in over 8,000 women who were participants in the placebo-arms of HPV vaccine trials in multiple countries were positive for HPV DNA; of these, 95% were positive for HPV-6 and HPV-11.[74]

Other factors that have been associated with women having a history of genital warts include ever use of hormonal contraceptives, and previous history of genital chlamydial infection, gonorrhea, genital herpes or trichomoniasis.[70]

## **2.3 Cervical Cancer**

### ***2.3.1 Development and burden of cervical cancer***

For cervical cancer to develop, the following occur: infection with HPV; persistence of HPV infections; development of precancerous lesions in cervical cells that have been persistently infected with HPV; and invasion of cervical cells (cancer). It is common for HPV infections to clear, but less common for precancerous lesions to regress to normal cells.[75]

Cervical cancer ranks as the second most common cancer among both women of all ages and those 15-44 years old worldwide. It was estimated in 2007 that every year, nearly half a million women are diagnosed with cervical cancer and over a quarter of a million die from it.[2] In 2008, the IARC cervical cancer global estimates for incidence and mortality were 530,232 cases and 275,008 cases, respectively. About 88% of the incident cases occurred in developing countries.[76]

In 2007, cervical cancer was the eighth most frequent cancer among women of all ages in NZ and ranked third among 15-44 year old females. The World Health Organization (WHO) estimates that every year in NZ, there are 228 incident cases and 82 deaths associated with cervical cancer.[2]

### ***2.3.2 Risk factors for cervical cancer***

The fundamental determinant of risk for cervical cancer to women is male sexual behavior.[57] In countries with a low and intermediate risk for cervical cancer (e.g. UK and Spain), males' lifetime number of sexual partners and having sex workers as sexual partners have been found to be key determinants of cervical cancer risk in their wives.[57, 77, 78] In addition, penile HPV prevalence shows a positive trend with an increase in these two factors.[57] In countries with a high risk for cervical cancer (e.g. Columbia), no association is observed between penile HPV DNA or other indicators of male sexual behavior and cervical cancer risk in female partners.[58] The absence of such associations in high-risk countries has been attributed to a reduced ability of case-control studies to distinguish those at higher risk in populations where the HPV prevalence is already high.[44]

Bosch et al [57] found that women had five times the odds of developing cervical cancer if their husbands or regular sexual partners were HPV DNA positive. Furthermore, prevalence of HPV DNA was higher among husbands or regular sexual partners of women with cervical cancer than partners of women without cervical cancer (17.5% vs. 3.5%). Even among monogamous women, a positive significant trend exists between cervical cancer risk and the number of extra-marital female sexual partners their husbands have had (accounting for the duration of marriage); a similar trend also exists when the husbands' extra-marital partners are restricted to sex workers.[57]

Cigarette smoking, long-term oral contraceptive use, high parity and co-infection with human immunodeficiency virus (HIV) have been established as cofactors in cervical carcinogenesis. Immunosuppression and co-infection with herpes simplex virus type-2 or Chlamydia Trachomatis are probable cofactors that increase the risk for cervical cancer, while diets with high fruit and vegetable contents have a probable protective effect.[27] In a review by Bosch and de Sanjosé,[44] co-factors that increase cervical cancer risk among HPV DNA positive women were identified as follows: long-term oral contraceptive use (five or more years); high parity (five or more full-term pregnancies); cigarette smoking; co-infection with HIV; and co-infection with other STIs, such as, Chlamydia Trachomatis and herpes simplex virus type-2. It has been hypothesized that hormonal changes during pregnancy and long-term oral contraceptive use could encourage and hasten carcinogenesis in the cervix.[79, 80] Seropositivity to Chlamydia trachomatis in males as a measure of their lifetime sexual promiscuity (or male sexual behavior) has been shown to be more consistent in discriminating women at high risk for cervical cancer.[81]

The International Collaboration of Epidemiological Studies of Cervical Cancer (ICESCC) was established mainly to investigate whether hormonal contraceptive use and other factors increased the risk of cervical cancer. The ICESCC combined 25 epidemiological studies and found an increase in parity and a decrease in age at first full-time pregnancy to be independent risk factors for ICC. When the analysis was restricted to HPV-positive women, these findings did not change.[82] In addition, a pooled analysis of ten case-control studies among women positive for

HPV DNA found a significant trend in the odds of SCC of the cervix with an increase in the number of full-term pregnancies. However, no relationship was observed between parity and ADC or ADSC.[83]

The ICESCC also found that compared to women who had never smoked, current smokers had an increased risk for SCC of the cervix, but not for ADC of the cervix. The risk for SCC of the cervix increased with the number of cigarettes smoked per day, but not with the duration of smoking.[82] In a sample of over 1,800 women in the U.S. who were positive for oncogenic HPV DNA at baseline, smoking intensity among current smokers was associated with an increased risk for development of CIN3 or cervical cancer.[84] Another cohort study among 18-35 year old women in the U.S. found that compared to those who had never smoked, women who had ever smoked maintained HPV infections for a significantly longer duration of time.[85]

An increasing duration of combined estrogen-progestogen oral contraceptive use has been associated with an increased risk of developing ICC.[86, 87] Among women positive for HPV DNA who participated in 10 case-control studies, users of oral contraceptives for five years or longer were more likely to have cervical cancer than never users. This association was stronger for ICC than carcinoma in situ; users of oral contraceptive for five or more years had four times the odds and more than three times the odds of having ICC and carcinoma in situ, respectively.[88]

An IARC multi-center case-control study using data from seven countries found that HPV-positive women who were also seropositive for Chlamydia Trachomatis antibodies were more likely to have invasive SCC, but not invasive ADC or ADSC of the cervix.[45] Data from the same study showed that HPV-positive women with a herpes simplex virus type-2 co-infection had more than two times the odds of having SCC and over three times the odds of having ADC or ADSC of the cervix.[89]

A review by Garcia-Closas et al [90] described the role of diet and nutrition on the risk for cervical cancer and persistent HPV infections and also classified the evidence found as either “convincing”, “probable”, “possible” or “insufficient”. *Probable* dietary protective factors

against cervical carcinogenesis that were identified included: diets rich in folate, retinol, Vitamins E, C and B12; alpha- and beta-carotene; lycopene; lutein/zeaxanthin; and cryptoxanthin. In addition, diets rich in fruits, vegetables, vitamins C and E, beta- and alpha-carotene, lutein/zeaxanthin, lycopene, and cryptoxanthin may have a *possible* protective effect against persistence of HPV infections.

## **2.4 Prevention of HPV, cervical cancer and genital warts**

### **2.4.1 HPV vaccines**

There are two vaccines currently available to prevent infection with HPV types responsible for most cervical cancer cases. The aim of prophylactic vaccination is to reduce incidence of anogenital cancers and precancerous lesions, with additional protective benefits against genital warts for those receiving the quadrivalent vaccine.[10]

In June 2006, the U.S. Food and Drug Administration (FDA) approved the prophylactic quadrivalent vaccine, Gardasil® (Merck, New Jersey, United States), for females aged 9-26 years old.[10] This vaccine prevents cervical cancer precursors and external genital lesions caused by HPV-6, HPV-11, HPV-16 and HPV-18.[4-7] Gardasil® is an HPV-6/11/16/18 virus-like-particle (VLP) vaccine with an amorphous aluminum hydroxyphosphate sulfate adjuvant. It is produced in yeast (*Saccharomyces cerevisiae*) and consists of purified L1 major capsid proteins of HPV-16, HPV-18, HPV-6 and HPV-11. Gardasil® is administered via intra-muscular injection at 0, 2 and 6 months in 0.5-mL doses.[91-93] Phase 3 trial results from the Females United to Unilaterally Reduce Endo/Ectocervical Disease (FUTURE) I study showed that in 16-24 year old females with an average of three years of follow-up, recipients of the quadrivalent HPV vaccine who were HPV-negative at baseline had 100% protection against: 1) CIN grades 1 to 3 or adenocarcinoma in situ; and 2) external anogenital and vaginal lesions. In the intention-to-treat analysis that included participants who tested positive for vaccine-type HPVs at baseline, vaccine efficacy was 55% for cervical lesions of all grades and 73% for external anogenital and vaginal lesions combined.[4]

With regard to high-grade cervical lesions (CIN2, CIN3, or adenocarcinoma in situ) associated with HPV-16 and HPV-18, the FUTURE II study showed that after an average of three years of follow-up of over 12,000 females aged 15-26 years old, efficacy of the quadrivalent vaccine was 98% among women who were HPV-negative at baseline and 44% in the intention-to-treat analysis.[6]

In over 18,000 females aged 16-26 years old who have been in follow-up for an average of three years in the FUTURE studies, efficacy of the quadrivalent vaccine against vulval intraepithelial neoplasia grades 2 to 3 (VIN2–3) and vaginal intraepithelial neoplasia grades 2 to 3 (VAIN2–3) was assessed. Efficacy of the vaccine in preventing VIN2-3 and VAIN2–3 associated with HPV-16 and HPV-18 was 100% among women who were HPV-negative at baseline and 71% in the intention-to-treat analysis.[5]

The 42-month follow-up of 17,622 participants in the FUTURE I and II demonstrated that in women who were HPV-negative at baseline and received all three HPV vaccinations, the quadrivalent vaccine was effective in preventing 96% of CIN grade 1 (CIN1), 100% of VIN grade 1 (VIN1) and VAIN grade 1 (VAIN1), and 99% of anogenital warts disease associated with the four HPV types the vaccine protects against. In the intention-to-treat analysis however, vaccine efficacy was of 69% for CIN1 and VIN1, 83% for VAIN1, and 79.5% anogenital warts.[7] Therefore, findings from these clinical trials illustrating that HPV vaccination is most effective in uninfected females have been used to support why vaccination is target at adolescent girls, as they are more likely to be HPV negative.

The bivalent vaccine, Cervarix® (GlaxoSmithKline, Middlesex, United Kingdom), is an HPV-16/18 VLP vaccine that protects against HPV types 16 and 18. Intra-muscular injections of the vaccine are administered in 0.5-mL doses at 0, 1 and 6 months.[8, 9] Cervarix® was approved by the U.S. FDA in October 2009.[94] After a four-and-a-half year follow-up of 15-25 year old females, Cervarix® was reported to be 97% effective against incident HPV-16 and HPV-18 infections among participants who completed three doses of the vaccine. The combined efficacy of the vaccine against the two HPV types was reduced to 94% in the intention-to-treat analysis.[8] Furthermore, in 15-25 year old females from 14 countries, Cervarix® was found to

be 90% effective in preventing CIN2, CIN3, adenocarcinoma in situ and invasive carcinoma associated with HPV-16 and HPV-18 after an average follow-up time of 14.8 months.[9]

Due to the lower prevalence of cervical cancer in developed countries compared to developing countries, the primary goal of HPV vaccination for developed countries is to reduce the number of females with abnormal cervical cytology results and CIN2 or CIN3 diagnoses. On the other hand, cervical cancer prevention is the main objective of HPV vaccination in developing countries.[95] Challenges posed by HPV vaccination are mainly due to the fact that its effectiveness is maximized among uninfected females and hence, prior to onset of sexual activity. As a result, some parents are concerned about vaccinating adolescent girls against a STI and have difficulties reconciling HPV vaccination for their adolescent daughters and the possibility of cancer development further in the future.[95] Furthermore, it is unclear what the duration of protection provided by HPV vaccines is and whether booster vaccinations will be required.[96]

Guidelines for use of prophylactic HPV vaccines for prevention of CIN and cervical cancer were provided by the American Cancer Society in June 2006. Their recommendations included routine HPV vaccination of 11-12 year old girls, 'catch-up' vaccinations for 13-18 year old girls, and continued cervical screening for both vaccinated and unvaccinated females.[10] In NZ, vaccination with the quadrivalent HPV vaccine, Gardasil®, of females aged 17-18 years and 12-16 years commenced in September 2008 and January 2009, respectively; currently, the vaccine is still free for females born on or after January 1<sup>st</sup>, 1990.[11] From 2009, HPV vaccination for 12 year old girls became a part of the NZ immunization schedule.[97] The UK and Australia have also implemented HPV vaccination programs for adolescent and young adult females. In the UK, a school-based vaccination commenced in September 2008 for 12-13 year old females with the bivalent HPV vaccine, Cervarix®. Additionally, a three-year 'catch-up' HPV vaccination program for 14-18 year old females was introduced at the same time.[98] On the other hand, Australia's HPV vaccination program started earlier and has targeted a wider age-group of females. From April 2007, ongoing HPV vaccination using Gardasil® was introduced for 12-13 year old females via a school-based program. Furthermore, 'catch-up' HPV vaccinations were

provided to females aged 13-18 years old and females under 27 years old through a school-based program and a community-based program, respectively.[99]

#### **2.4.2 Other preventive measures**

Schiffman et al [75] state that the “risk of cervical cancer is mainly a function of HPV infection and lack of effective screening” (p. 894). Cervical cancer screening programs are designed to identify and offer treatment to females with precancerous cervical lesions and early invasive cancers in order to reduce incidence and mortality rates of ICC.[100] Therefore, cervical cancer progression can be prevented through early detection of HPV and treatment of precancerous lesions.[101]

In 2004, an IARC Working Group on the Evaluation of Cancer Preventive Strategies concluded there was sufficient evidence that high-quality cervical cancer screening for 35-64 year old females every three to five years could reduce ICC incidence by 80%.[100] Garnett et al [102] estimated that in screened populations where one group continues with cervical screening and another does not, HPV vaccines assumed to be effective for 10 years would result in some benefits for women who continue screening; however, the incidence of cervical cancer deaths in women who cease to attend cervical screening would possibly increase over time as the protective effects of HPV vaccination subside.

There are mixed findings on whether condom use decreases the risk for HPV infection and HPV-related illnesses. It has been reported that regular condom use reduces the risk for genital warts by about 60-70%, as well as ICC, CIN2 and CIN3.[103] In a prospective study in the Netherlands of women with CIN lesions and their male partners, condom users had a significantly higher two-year cumulative regression rate for CIN lesions and HPV clearance.[104] Data from the same study also showed that regression of male genital lesions among those who were positive for HPV DNA was accelerated by regular condom use.[105]

However, HPV infection can still occur through contact with body parts that are not protected by condoms.[106] Among HPV DNA negative women in the U.S. who reported always using condoms with new partners, no protective effect against HPV infection was observed when



compared to women who did not always use condoms with new partners.[51] On the other hand, a prospective study of 1000 Danish women found that compared to women who had never used condoms, women who were current condoms users were more likely to test positive for non-oncogenic HPV types, but not oncogenic HPV types.[55] This finding may be because data collected on condom use (never/former/current use) did not measure consistent versus inconsistent condom use, which could more likely influence HPV status. Another cross-sectional study assessing ever/never condom use found that women who had ever used condoms had an increased odds of having a history of genital warts than women who had never used condoms.[70] Due to the cross-sectional design of this study, it is possible that the association observed was due to women using condoms as a protective measure after contracting genital warts.

Finally, findings by Castellsagué et al [107] suggest that compared to uncircumcised males, circumcised males are less likely to harbor HPV, which results in a reduced risk for both HPV DNA genital prevalence and cervical cancer in their female partners.

## **2.5 Summary**

This chapter has provided an overview of what HPV is and its burden especially with regard to causing genital warts and cervical cancer in women. In addition, it describes the relatively recent availability of HPV vaccines to prevent HPV types contributing to most of these illnesses. It also presents findings from research showing that HPV vaccines are most effective when females have not initiated sexual activity, as they are more likely to be free of HPV infections. This information provides a better understanding of why HPV vaccines are targeted at females before initiation of sexual activity. Given that parental consent is required for most medical interventions among adolescents (before the age of 16 years in NZ) and increasing HPV vaccine uptake is expected to reduce the incidence of HPV-related illnesses, it is important to investigate factors that could influence parental acceptability of HPV vaccines for adolescent daughters. Next is a description of some psychological constructs that have been used to better understand health behaviors, with a focus on parents' actions and intentions with respect to child health.

## **CHAPTER 3: PSYCHOLOGICAL FACTORS AND HEALTH BEHAVIORS TO BENEFIT CHILD HEALTH**

This chapter describes the psychological constructs applied in the research presented in this thesis and reviews the literature on their application in understanding parental actions/intentions to benefit child health, including vaccination. Specifically, it presents relevant applications of anticipated regret, worry, the HBM and message framing.

### **3.1 Anticipated regret**

#### **3.1.1 Introduction**

Regret can affect decision making when options that could produce it are avoided by decision makers.[18] It includes feelings of blame and responsibility, and a subjective evaluation comparing the outcome of the chosen option to another that might have occurred. In addition, occurrence of regret depends on availability of information about the outcome to decision makers as this affects evaluation of outcomes and the subsequent choices made.[108] Connolly and Reb [109] identified three types of decision-related regret differentiated by their targets as follows: where the outcome of a decision is the target of regret (outcome regret); where the decision alternative chosen is the target of regret (option regret); and where the decision process that precedes a choice is the target of regret (process regret).

Regret theory is based on the assumption that alternatives are simultaneously rejected when deciding to choose a course of action, while attempting to avoid decisions that could potentially lead to regret.[110, 111] Anticipated regret refers to “the main psychological effects of the various regrets and worries that beset the individual before any negative consequences actually materialize” (p. 191).[16] Therefore, it is expected that people who anticipated negative consequences for failing to undertake a beneficial behavior or after undertaking an unsafe behavior would be more likely to take preventive actions.[15-17] A choice resulting in higher levels of anticipated regret compared to available alternatives motivates individuals to find options that minimize regret.[112]

Research on anticipated regret in relation to health behavior has been done on various topics including, exercise among adults,[113, 114] expectations about future condom use among young adults,[115, 116] intentions to comply during orthodontic treatment,[117] and tick inspection of children to prevent Lyme disease.[118] With regard to vaccination, there are studies investigating the role of anticipated regret on influenza vaccination among adults [119, 120] and vaccination of infants by mothers.[121] However, there are only a few published studies on parental anticipated regret in relation to HPV vaccine uptake by daughters [122, 123] and parents' intentions to vaccinate daughters against HPV.[122, 124] Moreover, a systematic literature review published in 2007 on HPV vaccine acceptability among adolescents, young adults and parents of adolescents found that no studies had investigated anticipated regret.[125]

The research presented in this thesis investigated whether parents would regret if daughters were unvaccinated against HPV and later: contracted an HPV infection that led to cervical cancer (adapted from Ziarnowski et al [122]), or contracted genital warts (*inaction regret*). The present study adds to previous reports on this topic by assessing parental regret regarding genital warts. Since there are reports that some parents against HPV vaccination believe that obtaining the vaccine would negatively influence girls' sexual behavior,[126-128] *action regret* focused on whether parents would regret if their daughters were vaccinated and initiated sexual activity at an earlier age (adapted from Ziarnowski et al [122]). The relationship between these regret measures and girls' HPV vaccination status (initiation of HPV vaccination and parents' intentions to vaccinate daughters) was assessed in the present study.

### ***3.1.2 Anticipated regret and parental actions/intentions to benefit child health***

There is limited literature on parental regret and childhood vaccination in general. Hence, a review of the literature was expanded to include research on the relationship between anticipated regret and parental behaviors/intentions to promote health or prevent illness in children. A summary of these studies is presented in Table 1.

**Table 1: Summary of studies on anticipated regret and parental behaviors/intentions to benefit child health**

Source	Relevant outcomes	Study design and population	Effect of regret	Comments
Ziarnowski et al (2009), USA.[122]	Initiation of HPV vaccination and caregivers' intentions to vaccinate daughters in the next year	Cross-sectional telephone survey with 889 caregivers of 10-18 year old girls	<ul style="list-style-type: none"> <li>– Caregivers reporting higher vaccination (<i>action</i>) regret were less likely to have vaccinated daughters.</li> <li>– Caregivers with greater intentions to vaccinate daughters reported higher <i>inaction</i> regret and lower vaccination (<i>action</i>) regret.</li> </ul>	<ul style="list-style-type: none"> <li>– Sample of households with telephone lines.</li> <li>– Caregivers of girls who had initiated HPV vaccination were compared to a combination of caregivers with and without the intention to have girls vaccinated.</li> </ul>
Brewer et al (2011), USA.[123]	HPV vaccine uptake at follow-up among girls who were unvaccinated at baseline	Longitudinal study with 567 caregivers of 10-18 year old females who had not initiated HPV vaccination at baseline.	Caregivers who at baseline anticipated greater regret if daughters were unvaccinated ( <i>inaction</i> ) and got an HPV infection that could lead to cervical cancer were more likely to initiate HPV vaccination for daughters	<ul style="list-style-type: none"> <li>– Sample of households with telephone lines.</li> <li>–27% of girls initiated vaccination between baseline and follow-up.</li> </ul>

Source	Relevant outcomes	Study design and population	Effect of regret	Comments
Morison et al (2010), United Kingdom.[124]	Parental intention to agree to obtain the HPV vaccine for daughters if it is offered to them in the next year	Cross-sectional survey with 245 parents/guardians of 11-12 year old girls	Parental intention to vaccinate daughters against HPV was greater among parents reporting higher <i>inaction</i> regret and lower <i>action</i> regret	<ul style="list-style-type: none"> <li>– Sample includes 45 households completing two questionnaires each (and one questionnaire each from 155 homes).</li> <li>– Household response rate of 24.5%.</li> </ul>
Wroe et al (2004), NZ.[121]	Vaccination of infants (at 8-10 weeks of age)	Prospective study with 195 women recruited in their third trimester of pregnancy	Mothers were more likely to have vaccinated their infants if they reported higher levels of <i>inaction</i> regret and lower levels of <i>action</i> regret	<ul style="list-style-type: none"> <li>– Women were recruited through antenatal care providers.</li> <li>– Of women approached to participate 55% expressed interest, 83% of whom participated.</li> </ul>

Source	Relevant outcomes	Study design and population	Effect of regret	Comments
Bos et al (2005), Netherlands.[117]	Parents' intentions to stimulate their child to comply with orthodontic treatment/advice	Cross-sectional study with 157 patients (aged 9-17 years old) and their parents/caretakers	Parents who reported greater intention to stimulate children to comply with treatment anticipated higher levels of regret from inaction	<ul style="list-style-type: none"> <li>– Authors do not specify all their measures of anticipated regret.</li> <li>– Female parents had higher rating of anticipated regret.</li> </ul>
de Vries and van Dillen (2002), Netherlands.[118]	Whether or not parents regularly inspect children for ticks (to prevent Lyme disease) and their intention to do so during the coming year.	Cross-sectional study with 230 parents of 4-12 year old children	Parents who regularly inspected their children for ticks anticipated more regret should children be infected with Lyme disease than parents who infrequently inspected their children for ticks	<ul style="list-style-type: none"> <li>– Participants were recruited though healthcare providers in high endemic regions.</li> <li>– Participation rate of 58% (based on usable questionnaires)</li> <li>– Results not provided on anticipated regret in relation to intention to perform tick inspection in the coming year.</li> </ul>

### 3.1.2.1 Vaccination

In two reports using the same study sample of caregivers of 10-18 year old females in the United States, parental regret was associated with initiation of HPV vaccination and parental intentions to vaccinate daughters in the baseline analysis,[122] as well as HPV vaccine uptake in the longitudinal analysis after follow-up.[123] Inaction regret was assessed by asking caregivers to rate how much regret they would experience if girls were unvaccinated against HPV and contracted an HPV infection that could lead to cervical cancer. For action regret, caregivers were asked to rate how much regret they would experience if girls became more sexually active earlier than they would have otherwise been because they had received the HPV vaccine. Findings showed that caregivers reported greater regret from inaction than action.[122] Caregivers with greater action (vaccination) regret were less likely to have obtained the vaccine for daughters and had lower intentions of having daughters vaccinated against HPV, whereas those with higher anticipated inaction regret had higher intentions to have daughters vaccinated.[122] With regard to HPV vaccine uptake at follow-up, caregivers who reported greater inaction regret at baseline were more likely to vaccinate daughters against HPV, whereas action regret was unrelated to vaccination behavior.[123]

One of the limitations of the studies from this sample is potential selection bias that could have resulted from use of telephone surveys and random-digit dialing to recruit participants. It is possible to selectively exclude people without telephones lines at home, who are not registered in phonebooks, or who are not at home to answer the telephone call. In addition, the cross-sectional findings on parental regret in relation to initiation of HPV vaccination by girls was in comparison to a combination of caregivers with and without the intention to obtain the vaccine for daughters,[122] but these two groups are probably heterogeneous. Despite this limitation, studies of this ethnically diverse sample were the first to investigate and illustrate that parental anticipated regret is associated with HPV vaccine uptake among daughters and parents' intentions to obtain the vaccine for them. Furthermore, the follow-up study confirmed the cross-sectional findings and established causality regarding the relationship between parental anticipated regret and HPV vaccine uptake by daughters.

In a cross-sectional study in the UK with 245 parents of 11-12 year old girls recruited through 10 schools, action regret focused on unpleasant experiences by girls during vaccination, whereas inaction regret focused on the occurrence of abnormal Papanicolaou's (Pap) smears in the future.[124] For anticipated action regret, parents were asked whether they would regret if daughters were vaccinated against HPV in the next year and experienced some pain or distress during vaccination. Inaction regret assessed how parents would feel if daughters were *not* vaccinated in the next year and had abnormal cervical smears in the future. HPV vaccination intention was assessed by asking parents whether they would agree to have daughters vaccinated if the vaccine was offered to them in the next year. Results showed that intention to vaccinate daughters against HPV was greater among parents reporting higher *inaction* regret and lower *action* regret. As indicated by the authors, one limitation of this study is that it was impossible to determine how many parents received research materials that were distributed to their daughters at school. In addition, the study sample comprised of 45 households that returned two questionnaire each (90 participants) and 155 participants from different households. Therefore, it is likely that responses from the same household are correlated as these individuals would share some similar attitudes and beliefs about HPV vaccination for the child. There is also a possibility of response bias because the household response rate of 24.5% in this study was relatively low. Nonetheless, this study adds to previous research on HPV vaccination and anticipated regret by assessing parental regret regarding discomfort to daughters during vaccination and the possibility of side-effects.

With regard to non-HPV vaccines, a NZ study of 195 mothers investigated whether anticipated regret among mothers (assessed antenatally) was related to immunization of infants at approximately 8-10 weeks of age.[121] Immunizations of interest were for diphtheria, tetanus, whooping cough, hepatitis B, influenza type B and polio. Mothers were asked to rate how much they would regret if infants were not vaccinated for each of these six diseases and then developed the disease(s) later (inaction regret). In addition, after being informed about some adverse effects that can result from vaccination (e.g. soreness and fever) and then reassured that scientific evidence was lacking on more serious side-effects (e.g. brain damage), mothers were asked to rate how much they would regret vaccinating infants if the adverse effects occurred (action regret). The authors found that mothers were more likely to have vaccinated their infants if they



reported higher levels of inaction regret and lower levels of action regret. The longitudinal design of this study allowed for causal inference to be made between parental anticipated regret and vaccination of infants. A potential limitation of this study is the use of a clinical sample which may have resulted in selection bias as these women may be more involved with health matters than parents in the general population.

### **3.1.2.2 Other parental actions/intentions to benefit child health**

A cross-sectional study in the Netherlands investigated the relationship between anticipated regret and intentions of orthodontic patients (aged 9-17 years old) to comply with treatment/advice and parental intention to stimulate this compliance.[117] Patients and their parents/guardians were recruited after discussing their treatment plan during orthodontic care visits. Parental inaction regret focused on whether parents' expected to later experience regret if negative outcomes occurred as a result of their failure to stimulate children to comply. Anticipated regret was a significant predictor of parents' intentions to stimulate compliance. Hence, parents who reported greater intention to stimulate compliance anticipated higher levels of regret from inaction. Although the authors state that they used five items to assess anticipated regret among both patients and their parents, specific information on how all of these items were operationalized is not provided. Furthermore, specific details on variables included in the regression analysis are lacking. For instance, given that female parents reported greater levels of anticipated regret than males, it is unknown whether gender was accounted (adjusted) for in the analysis.

Another cross-sectional Dutch study investigated whether parental tick inspection among their children (aged 4-12 years old), as a Lyme disease preventive measure, was related to anticipated regret.[118] Parents were recruited through participating healthcare providers in high endemic regions; they were randomly selected from a combined file of all eligible parents. The authors assessed parents' anticipated regret should their children be infected with Lyme disease. Findings showed that parents who regularly inspected their children for ticks anticipated more regret should their children contract Lyme disease than parents who infrequently inspected their children for ticks. Therefore, parents who performed the preventive measure would regret non-inspection (inaction) if Lyme disease was to occur later. Although the authors assessed parental

intention to perform inspection in the coming year, they did not report the relationship between intention and anticipated regret. The authors acknowledge that since participants were recruited from high endemic regions, their findings may not be generalizable to other regions and that the cross-sectional design limits inferences on causality. In addition, it was impossible for the authors to determine whether parents who responded to the participation invitation differed from those who did not. Social desirability bias is also likely to have occurred as tick inspection would be likely perceived as the right thing to do by parents, hence causing them to overstate how often this was done.

## **3.2 Worry**

### **3.2.1 Introduction**

The *risk-as-feelings* hypothesis proposes that responses to decision making and other risky situations partly result from direct emotions, such as, feelings of worry.[14] Motivations to act to reduce the chance of a disease occurring may be enhanced by disease-related worry.[19] Worry has also been shown to mediate the effect of risk probability on actions, and is thought to influence judgments about risk probability.[129]

The relationship between worry and health behaviors has been researched in various areas including, influenza vaccination among adults,[119, 120] sexual risk-taking behavior among adults,[130] women's interest in genetic testing for breast cancer susceptibility,[19, 131] mammography use,[132, 133] and the value of participating in cervical screening.[134]

Parental worry in relation to actions or intentions to act to benefit child health has been addressed in a number of topics, including vaccination against influenza A/H1N1,[135] and continuous glucose monitoring for type 1 diabetes.[136] In addition, parental worry about asthma has been assessed in relation to their children's repeat attendance at hospital emergency departments for asthma attacks,[137] and compliance with influenza vaccination for children.[138] However, in some cases, parental worry is associated with actions that inadvertently promote symptoms of illness. For instance, in a retrospective study of adolescents with chronic musculoskeletal pain and their parents, Guite et al [139] found that parental worry about their children's physical

health was significantly related to pain promoting behavior, such as, giving children extra attention, special privileges and permission not to attend school.

With regard to HPV vaccination, de Visser and McDonnell [140] assessed whether parental worry about children being infected with HPV was associated with HPV vaccine acceptability. However, no published studies have specifically investigated if parental worry regarding genital warts or cervical cancer is associated with HPV vaccine acceptability for daughters. Therefore, the research presented in this thesis addressed this issue by investigating whether the level of parental worry regarding HPV, genital warts and cervical cancer is related to girls' HPV vaccination status (initiation of HPV vaccination and parents' intentions to vaccinate daughters).

### ***3.2.2 Worry and parental actions/intentions to benefit child health***

There is also limited literature on parental worry and childhood vaccination in general. Hence, a review of the literature was broadened to include research on the relationship between worry and parental behaviors/intentions to promote health or prevent illness in children. A summary of these studies is presented in Table 2.

**Table 2: Summary of studies on worry and parental behaviors/intentions to benefit child health**

Source	Relevant outcomes	Study design and population	Effect of worry	Comments
de Visser and McDonnell (2008), England.[140]	Whether parents would have their child vaccinated against HPV	Cross-sectional study with 390 parents of school-aged children (male and female) aged 4-16 years old	Greater parental worry about the possibility of children contracting HPV infections was related to higher HPV vaccine acceptability	<ul style="list-style-type: none"> <li>– HPV vaccine acceptance similar for girls and boys (75% and 73%, respectively)</li> <li>– Response rate not reported.</li> <li>– Participants were from areas with higher educated and more Caucasian residents.</li> </ul>
Setbon and Raude (2010), France.[135]	Intention to vaccinate children against pandemic influenza A/H1N1 ('swine flu')	Cross-sectional survey with 1001 residents aged 15 years and older, some of whom were parents	Parents with higher levels of worry were more likely to report that they intended to obtain the influenza A/H1N1 vaccine for their child	<ul style="list-style-type: none"> <li>– Telephone survey using random digit dialing.</li> <li>– 65% of parents intended to vaccinate children under the age of 16 years.</li> <li>– Number of parents in the sample is unspecified.</li> </ul>

Source	Relevant outcomes	Study design and population	Effect of worry	Comments
Szilagyi et al (1992), USA.[138]	Vaccination of asthmatic children against influenza	Within an experimental study, a cross-sectional study was done with 48 parents of children with moderate to severe asthma.	Parental worry about asthma was greater among parents whose asthmatic children had been vaccinated against influenza	– Relatively small sample – Interviewer contacting parents for the survey was ‘blinded’ on the children’s vaccination status. – 68% of the 63 parents invited to participate completed the survey.
Wakefield et al (1997), Australia.[137]	Children’s repeat attendance at hospital emergency departments for asthma attacks (more than one visit in the previous year)	Cross-sectional survey that included 272 asthmatic children under the age of 15 years and their parents/ guardians	Parental asthma worry was positively associated with repeat attendance at hospital emergency departments for asthma in the previous year	– 62% of asthmatic children were repeat attendees at emergency departments. – Recall bias possible if the parents’ recollection of the number of emergency department visits differs by whether or not they worry.

<b>Source</b>	<b>Relevant outcomes</b>	<b>Study design and population</b>	<b>Effect of worry</b>	<b>Comments</b>
Kashmer et al (2009), USA.[136]	Parents' interest in continuous glucose monitoring for children with type 1 diabetes	Cross-sectional survey with 457 parents of children with type 1 diabetes	Greater interest in continuous glucose monitoring for diabetic children among parents who were worried about: effects of high blood glucose; and possibility of hypoglycemia.	– The children's mean age was 10 years. – More than 90% of parents had a high level of interest in continuous glucose monitoring for children.

### 3.2.2.1 Vaccination

In England, a cross-sectional study with parents of 4-16 year old children assessed whether parental acceptance of HPV vaccination was related to their level of worry regarding the possibility that children might be infected with HPV.[140] Parental worry about HPV was assessed using a single item on a four-point ordinal scale (not worried, a little worried, moderately worried, very worried). The authors found that greater parental worry about the possibility that their children might be infected with HPV was related to higher HPV vaccine acceptability for both female and male children. This is the only published study reporting on parental worry about HPV in relation to acceptability of HPV vaccines for their children. A limitation of this study is the recruitment of parents with daughters as young as four years old, some of whom would not be eligible for vaccination for several years. Participants also came from areas that are more likely to have people who are younger, non-religious, Caucasian, and have higher education qualifications compared to other regions in the UK; this likely limits generalizability of the study's findings.

Research on parental worry in relation to influenza vaccination for children has been addressed in a number of studies. A cross-sectional study of people aged 15 year and older residing in France investigated whether vaccination intention against pandemic influenza A/H1N1 ('swine flu') was related to worry.[135] Participants who were parents were asked about their intentions to vaccinate children under the age of 16 years, if the vaccine was made available. Worry was operationalized as extent to which participants were worried about the influenza pandemic. With regard to parental worry and vaccination of their children, results showed that parents with higher levels of worry were more likely to report that they intended to obtain the influenza A/H1N1 vaccine for their child. Although the authors state that they used proportional random digit dialing to obtain a representative study sample, there is a possibility of selection bias due to selective exclusion of people without telephone lines or who are not available to answer calls to participate in the survey. In addition, the number of parents who took part in the study is unspecified.

Another study performed a cross-sectional analysis on the intervention group of an experimental study assessing the effectiveness of a reminder system on vaccine uptake by children with moderate to severe asthma.[138] Parental worry in relation to influenza vaccination for children was assessed among participants in the intervention group, who were attendees at a clinic serving impoverished children. Parents were asked about the amount they were worried about asthma, which was rated on a four-point Likert scale. Interviewers were blinded to the children's influenza vaccination status as the survey occurred within an experimental study. Findings showed that parental worry about asthma was greater among parents whose asthmatic children had been vaccinated against influenza. It is plausible that asthma worry levels were not lower among parents with vaccinated children compared to those with unvaccinated children because worry levels are in reference to an ongoing condition (asthma) and not the illness the vaccine protects against (influenza). It could also be due to the high-risk nature of the study population. Limitations of this study include the relatively small sample and inability to reach some participants due to absence of phones. In addition, because the sample was comprised of parents of children with moderate to severe asthma, these findings may not be generalizable to parents whose children have asthma with varying degrees of severity. Although the authors found no significant difference in vaccine uptake between participants who could be reached for an interview and those who could not (33% vs. 25%), this may be due to the relatively small sample size for this aspect of the study (type II error).

### **3.2.2.2 Other parental actions/intentions to benefit child health**

Wakefield et al [137] assessed whether asthma worry among parents was associated with their children's repeat attendance at hospital emergency departments for asthma attacks (more than one visit in the previous year). In this cross-sectional study, parents of asthmatic children under the age of 15 years were asked whether or not they worry about their child getting an asthma attack even when the child is feeling well. The authors found that compared to parents without asthma worry, parents experiencing asthma worry even when children were feeling well were more likely to have children who had repeatedly attended emergency departments for asthma in the past year (two times the odds). The main limitation of this study is that causality cannot be established as information on parental worry was collected in a survey while emergency department attendance was about past asthma attacks (and not prospective data). Recall bias may



be another limitation of this study as the parents' ability to recall their children's emergency department visits due to asthma attacks may vary by whether parents worry or not. The use of a clinical sample also limits generalizability of finding to parents of asthmatic children in the general population. The authors acknowledge that because recruitment was dependent on the initiative by hospital staff to invite attendees to participate, not all people meeting the study criteria were approached, which may have resulted in selection bias. Furthermore, parents who agreed during hospital visits to be contacted for the survey may have differed from those who did not in their asthma worry. For instance, worried parents may have been more eager to participate than those who did not worry as much, especially given that asthma worry was specifically about instances when the child feels well.

A U.S. study investigated whether parental worry about high or low glucose levels in children with type 1 diabetes was related to parents' interest in continuous glucose monitoring if insurance covered the device.[136] Parents of children attending diabetic clinics and visiting a childhood diabetes website were invited to complete an anonymous online survey. The parents were asked to rate the degree of worry about various aspects of their child's diabetes, which were later dichotomized. Findings indicated that parents who were worried about the effects of high blood glucose in diabetic children had greater interest in continuous glucose monitoring devices. A similar association was observed for parental worry regarding the possibility that a diabetic child might have a low blood sugar reaction (hypoglycemia). A possible limitation of this study is selection bias because the methods used to recruit participants may have selectively included parents who are more active in seeking health information on the internet or who visit health providers more often. In addition, the online survey would have required participants to have access to the internet and the ability to use it, which could have resulted in some selection bias. These issues would limit the generalizability of findings to parents of children with type 1 diabetes in the general population.

### 3.3 The Health Belief Model (HBM)

#### 3.3.1 Introduction

The Health Belief Model (HBM) has been widely used to better explain or predict why people engage or do not engage in a variety of health behaviors. The HBM consist of the following dimensions, which are hypothesized to influence health-related actions: perceived susceptibility; perceived severity; perceived benefits; perceived barriers; and cues to action.[20-22] *Perceived susceptibility* refers to the subjective perception of vulnerability to an illness/condition. *Perceived severity* refers to feelings regarding the seriousness of an illness, including its clinical and social consequences. *Perceived benefits* imply that choices made depend on one's beliefs in the effectiveness of the options available to reduce a health threat. *Perceived barriers* refer to factors that could impede someone from undertaking a recommended health behavior.[20, 22] Cues to action are stimulus – internal or external – that trigger the decision-making process, such as, recommendations by health professionals to take specific actions.[20]

According to Rosenstock [22], a combination of levels of perceived susceptibility and severity provide the motivation to act, whereas a cost-benefit analysis of the effectiveness of a behavior over its barriers offers a preferred path of action. With regard to preventive health actions, a review by Janz and Becker [21] found that “susceptibility”, “barriers” and “benefits” were consistently associated with outcomes, but “severity” was less likely to be related to outcomes. The authors postulated that findings on perceived severity of illnesses were because this dimension was more difficult for study respondents to conceptualize when they were symptom-free, had limited experience with the illness, or thought the health threats were long-term. Furthermore, for conditions, such as cancer, that most respondents view as serious, limited variability in this measure reduced its ability to differentiate between people who comply from those who do not.[21]

Other than its use in research on HPV vaccine acceptability, the HBM has been applied in research on factors influencing parents decisions regarding vaccination for hepatitis B,[141] influenza,[142, 143], measles,[144] varicella,[145] as well as vaccination for infants in

general.[146] Next is a review of the literature on the HBM and parental acceptability of HPV vaccination for adolescent girls, especially HPV vaccine uptake and parental intentions to vaccinate daughters against HPV.

### **3.3.2 *Studies on the HBM and parental acceptability of HPV vaccination for daughters***

#### **3.3.2.1 Study characteristics and limitations**

Previous studies on the relationship between the HBM and parental acceptability of HPV vaccination for adolescent daughters have been mostly cross-sectional or qualitative in design, and typically recruited parents/caregivers of females in the 8-18 year age-range. Most studies have used population-based samples, recruited parents through their daughters' schools, used convenience samples usually from clinical settings, or obtained information from secondary data sources (e.g. health records from health insurance companies).

Limitations in the generalizability of findings from some studies have been due to how study participants are sourced, which indicates possible selection bias. Recruiting participants through clinical settings or secondary data from health insurance records in countries where universal healthcare is inadequate, such as the U.S.,[147-154] is likely to result in selection bias as it excludes people who cannot afford health insurance. It is therefore possible that an underestimation of parental acceptability of HPV vaccination for daughters has occurred in such studies due to the inversely relationship with income.[155, 156] Furthermore, even when people have health insurance, initiation of HPV vaccination is less likely to occur among girls whose parents are unsure if the vaccine is covered by their daughters' health insurance.[150] In the U.S. HPV vaccine uptake has been shown to be more likely to occur among females whose health insurance coverage includes HPV vaccination.[157]

Selection bias could also result from use of telephone surveys or random-digit dialing to recruit participants as has been done in some previous studies.[123, 126, 127, 155, 156] This is likely to selectively exclude people without telephones lines at home, who are not registered in phonebooks, or who are not at home to answer the telephone call. With telephone surveys, there

is also the potential that participants disconnect calls before some vital questions are asked. For instance, in a statewide Behavioral Risk Factor Surveillance System (BRFSS) survey, 486 eligible participants disconnected calls before the HPV questions that were towards the end of the survey were asked.[155]

Another limitation of some previous studies is the use of samples that do not exclusively consist of parents whose daughters are eligible for HPV vaccination or parents in general, which means that the issue under investigation may not be equally relevant to all participants. For instance, Christian et al [155] recruited participants who were all not parents but instead the sample comprised of adult females aged 18 years and older without hysterectomies. In addition, Hausdorf et al [158] surveyed 20-60 year olds about acceptability of HPV vaccination for children. A study in England recruited parents with daughters as young as four years old,[140] some of whom would not be eligible for vaccination for several years. Another issue is where published reports do not distinguish between HPV vaccine acceptability for male and female children, or group these two together.[154, 158]

Although most studies focus on whether or not parents would accept HPV vaccination for daughters, intend to vaccinate, or have initiated vaccination for daughters, there are cases where acceptability is measured as a continuous/ordinal variable. In a study by Dempsey et al [147], HPV vaccine acceptability was measured on a continuous scale. This makes interpretation problematic as for example, it is difficult to know what a one-point difference on such a scale means in real life circumstances or clinical practice. Furthermore, when parents who respond that they are neutral or unsure about whether they will vaccinate daughters against HPV are categorized as non-accepters,[127, 159] an overestimation of the proportion of parents against HPV vaccination is likely to occur.

### **3.3.2.2 HBM dimensions**

Studies investigating the relationship between multiple dimensions of the HBM and parental acceptance of HPV vaccines or HPV vaccine uptake by girls are summarized in Table 3 and Table 4, respectively.

**Table 3: Summary of selected studies on the Health Belief Model and parental acceptability of HPV vaccines**

Source	Design and population	Significant relationship with HPV vaccine acceptability				Comments
		Susceptibility	Severity	Benefits	Barriers	
Dempsey et al (2006), USA.[147]	Randomized intervention within a cross-sectional survey with 840 parents/ caregivers of 8-12 year old children	Yes (positive relationship)	No	Yes (positive relationship)	Yes (inverse relationship)	– Response rate of 53% – Use of health insurance records. – Items on perceived barriers were about vaccination in general.
Marlow et al (2007), England.[128]	Cross-sectional (school-based) survey with 684 mothers of 8-14 year old girls	Yes (positive relationship)	Yes (positive relationship)	NA	Yes (inverse relationship)	– Fifty-seven percent participation rate. – 93% of participants were Caucasians.
de Visser and McDonnell (2008), England.[140]	Cross-sectional study with 390 parents of school-aged children aged 4-16 years old	NA	Yes (positive relationship)	Yes (positive relationship)	Yes (inverse relationship)	– Response rate not reported. – Participants from areas with higher educated and more Caucasian residents.

NA, Not Applicable

**Table 4: Summary of selected studies on the Health Belief Model and HPV vaccine uptake by adolescent girls**

Source	Design and population	Significant relationship with HPV vaccine uptake				Comments
		Susceptibility	Severity	Benefits	Barriers	
Reiter et al (2009), USA.[150]	Cross-sectional telephone survey with 889 caregivers of 10-18 year old girls	Yes ( <i>inverse</i> relationship)	No	Yes (positive relationship)	Yes (inverse relationship)	– Twelve percent of girls had initiated HPV vaccination. – Sample of households with telephone lines.
Brewer et al (2011), USA.[123]	Longitudinal study with 567 caregivers of 10-18 year old females who had not initiated HPV vaccination at baseline.	No	No	No	Yes (inverse relationship)	–27% of girls initiated vaccination between baseline and follow-up. – Possible that parents who rate higher on perceived susceptibility and benefits vaccinated daughters at baseline. – Sample of households with telephone lines.

NA, Not Applicable

### *Perceived susceptibility*

Acceptability of HPV vaccination for daughters has been found to be greater among parents with higher perceived susceptibility of daughters/children to HPV infections [128, 147, 148] and STIs,[147] and among those who believe that their children will be exposed to HPV eventually.[153] Moreover, parents whose daughters have not initiated HPV vaccination report significantly higher perceived likelihood of daughters getting cervical cancer.[150] On the other hand, lower HPV vaccine acceptability by parents is related to parents' denial of need,[126] and believing that daughters are not at risk for infection.[153]

### *Perceived severity*

Studies have shown parental acceptability of HPV vaccination for daughters to be associated with higher perceived severity of HPV [128] and higher perceived physical severity of STIs.[140] However, a lack of association between parental acceptance of HPV vaccines and perceived severity of cervical cancer has also been reported.[150] Additionally, Dempsey et al [147] found no relationship between HPV vaccine acceptance and the belief that HPV infections could result in serious consequences.

### *Perceived benefits and perceived barriers*

Higher HPV vaccine acceptability by parents has been shown to be related to greater perceived benefits or effectiveness of HPV vaccines [140, 147, 150] and believing in protection offered by childhood vaccines.[140]

Concerns about HPV vaccine side-effects are a major deterrent of vaccine acceptability. Parents are less likely to find HPV vaccines acceptable for adolescent girls with increasing concerns about potential side-effects of the vaccine.[126, 150, 152, 160] In addition, concerns about the long-term safety of the vaccine are a deterrent even among parents who have been offered HPV vaccines for daughters.[148] Lenselick et al [161] found that opposition to HPV vaccination was mainly due to concerns about side-effects that may occur in the long-term since vaccine is

relatively new. Believing that children will experience discomfort or danger during vaccination is also associated with decreased HPV vaccine acceptability.[147]

General concerns about any vaccines have been reported as a reason parents choose not to vaccinate daughters against HPV.[126, 128, 162] On the other hand, parents who believe in safety of vaccines in general are more likely to find HPV vaccines acceptable for their daughters.[140]

Some studies have shown that parents who believe HPV vaccines could negatively affect their daughters' sexual behavior are less willing to accept it. Concern regarding the effect the vaccine might have on moral sexual behavior has been reported as a reason why parents are against HPV vaccination.[126] In addition, some studies in the UK found acceptability of HPV vaccines to be greater among parents who do not believe that unsafe sex would be encouraged by STI vaccines,[140] and lower among parents who believe that HPV vaccines would make girls more likely to have unprotected sex.[128] In a qualitative study in the UK, some parents of 8-14 year old girls were concerned that STI vaccines would encourage risky sexual behavior leading to exposure to other STIs.[163] In a Canadian study, parents who believed HPV vaccines had a "limited influence" on sexual behavior (compared to a "negative influence") were more likely to report that they intended to obtain the vaccine for their daughters.[127]

The cost of HPV vaccines has been shown to reduce its acceptability. In an Australian study, factoring in HPV vaccine costs resulted in decreased vaccine acceptability for: 30% of adults initially likely/extremely likely to vaccinate a child; 55% of those initially extremely unlikely/unlikely to vaccinate a child; and 43.7% of those initially unsure about HPV vaccination for children.[158] This suggests that when cost has to be considered, it makes it more difficult for parents to obtain HPV vaccines for daughters, possibly even after modifiable beliefs among those against HPV vaccination are addressed.

### *Cues to action*

Parents have been shown to be more likely to accept HPV vaccination if they believe HPV vaccination is supported by family members or friends [127, 140] and if it is recommended to



them by a physician or health professional.[127, 147, 148, 150, 154] HPV vaccine uptake has also been shown to be related to parents hearing about the vaccine through healthcare providers and family members or friends.[149] Additionally, parents who believe that HPV vaccines are supported by their peer are more likely to accept the vaccine for their daughters.[140, 147]

### 3.4 Message framing

#### 3.4.1 Introduction

According to the World Health Organization, immunization is one of the most cost-effective health tools in eliminating and preventing infectious diseases.[164] It is therefore important to undertake research to assess whether information frames could be used to encourage HPV vaccine uptake in order to reduce the incidence of HPV-related illnesses.

During the decision making process to undertake specific actions or make particular choices, people consider the possible outcomes or consequences, and their associated contingencies. This is influenced by personal norms, habits and characteristics, as well as how people frame the particular problem.[165] Factors that have been suggested to be determinants of the influence of framed information on behavior include: the need for information presented to be processed sufficiently by the individual; acceptance of the framed information by the individual it is presented to; and perception of the appropriateness of the behavior being promoted.[166, 167]

With regard to message framing for health-related outcomes, two frames characterized by Levin et al [24] are often used: *attribute frames* and *goal frames*. When the focus of framing is on a characteristic of an event or item (e.g. a beverage is 95% alcohol-free, or has five percent alcohol content), this is referred to as attribute framing. Goal frames on the other hand focus on how action (or inaction) is associated with achieving (or not achieving) a desired outcome. When framing is based on attributes, messages that inform on the benefits of action (positive frame) are judged more favorably. For framing based on goals, messages that inform on the consequences of inaction (negative frame) seem to have an advantage because people are motivated to act to avoid the costs of inaction.[24] In addition, negative information is thought to have a

systematically greater impact on one's judgment (negativity bias) over objectively equivalent positive information.[168]

The research presented in this thesis applies goal frames to present two comparable HPV vaccination messages to parents in order to investigate their impact on HPV vaccine uptake by adolescent daughters. One message focuses on the benefits of vaccinating daughters against HPV (gain-framed message) and the other focuses on the potential consequences of not having daughters vaccinated against HPV (loss-framed message). The effects of goal frames are assessed by comparing the rate at which a behavior is adopted; that is, which message has a greater effect in enhancing the behavior being promoted.[24] The attractiveness of options offered to a decision-maker varies when an issue is framed in different ways, which can lead to reconsideration of original positions.[165]

Other classifications of framing effects have been published. Rothman et al [169] described *same consequences* framing as presenting of information in a manner where a behavior results in similar consequences, but in one situation the outcomes/consequences are obtained as a result of action (positive frames), while in the other situation they are not obtained due to inaction (negative frames). They also defined *different consequences* framing as presenting information on the positive or negative consequences (e.g. likelihood of survival vs. death) of the same behavior.[169] Same consequences framing is thought to be a subset of goal framing, and different consequences framing to be comparable to attribute framing.[24]

Rothman and Salovey [167] argued that gain-framed messages and loss-framed messages are advantageous in promoting prevention behaviors (e.g. dental flossing) and detection behaviors (e.g. mammography), respectively. This conclusion is on the basis of prospect theory which states that gains are more motivating than losses for low-risk behavior, but the inverse is apparent when people are contemplating risky actions (e.g. mammography could result in detection of cancer).[170] However, when a meta-analysis of 93 studies on message framing and disease prevention behaviors was undertaken by O'Keefe and Jensen,[171] this previously proposed advantage of gain-framed messages was apparent for dental hygiene behaviors, but not for prevention behaviors unrelated to dental hygiene.

Messages that have negative appeals (disease prevention) are thought to enhance one's beliefs about the severity of a health threat than messages that have positive appeals (improved health).[23] The impact of a framed message on behavior depends on how the behavior itself is perceived. Hence, people have to perceive the issue they are considering in terms of gains or losses. In addition, for an alternative behavior to be adopted, it has to be perceived as either a risky or safe option.[167]

### **3.4.2 *Message framing and parental actions/intentions to benefit child health***

Few studies have investigated whether message framing has an impact on parental behaviors/intentions to promote health or prevent illness in children. Even rarer are studies on whether message framing influences parental actions/intentions to vaccinate children against any childhood illness. Although a few studies have been published on message framing and HPV vaccination intent among young adult females,[172-174] and one study has focused on parental intentions to vaccinate daughters against HPV,[175] no published studies addressing actual HPV vaccine uptake (behavior) could be identified. Hence, one of the aims of this thesis is to address this information-gap by investigating whether providing parents with framed HPV vaccination messages results in differential HPV vaccine uptake rates among adolescent daughters.

Due to limited literature on framing and childhood vaccination in general, a review of the literature was broadened to research on the effect of message framing on parental behaviors/intentions to promote health or prevent illness in children. Four published studies were identified, which addressed the following outcomes: parental intentions to vaccinate daughters against HPV,[175] intentions to vaccinate children against measles, mumps and rubella (MMR),[176] hypothetical parental decisions to initiate resuscitation for extremely premature newborns,[177] and intentions to vaccinate infants with a hypothetical new vaccine for respiratory illnesses.[178] These studies are summarized in Table 5.

**Table 5: Summary of studies on message framing and parental behaviors/intentions to benefit child health**

<b>Source</b>	<b>Relevant outcomes</b>	<b>Study design and population</b>	<b>Framing effects</b>	<b>Comments</b>
Leader et al (2009), USA.[175]	Intention to vaccinate daughters (ages 0-26 years) against HPV with and without cost involved	Online survey of a representative sample of 635 adults (male and female) randomly provided with one of three framed paragraphs addressing different aspects of the HPV vaccine	No differences in effect of frames on parental vaccination intentions for females aged 0-9 years, 9-17 years or 18-26 years, regardless of cost conditions	– The study had limited power (25%) to detect small framing effects that may have existed. – It is unlikely that parents would make vaccination decisions for 18-26 year old daughters.
Abhyankar et al (2008), United Kingdom.[176]	Intention to obtain the measles, mumps and rubella (MMR) vaccine for children	Cross-sectional study of 140 women (mean age of 35 years) with and without children randomly assigned to receive gain-framed or loss-framed messages	Loss-framed message showed an advantage for vaccination intentions. Stronger loss-frame effect among parents who had previously vaccinated a child against MMR.	– A mixed sample of women with and without children (asked to “imagine” they had a child), but issue likely to be more relevant to women with children. – Use of a convenience sample and insufficient sociodemographic data limits inferences on generalizability of results.

Source	Relevant outcomes	Study design and population	Framing effects	Comments
Haward et al (2008), USA.[177]	Hypothetical parental decisions to initiate resuscitation of extremely premature infants (delivered at 23 weeks of gestation)	Online survey of male and non-pregnant female volunteers (n=292) randomly assigned to a prognostic positive frame (infant survival with no disability) or a negative frame (infant death, or survival with possible disability).	Survival (positive) frame and mortality (negative) frame recipients were more likely to choose resuscitation and comfort care, respectively.	– Survival frame group was younger and hence possibly have more women of child- bearing age than the mortality frame group. – Data on education level, age and gender available for only 66% of respondents.
Donovan and Jalleh (2000), Australia.[178]	Intentions to vaccinate infants with a hypothetical new vaccine for respiratory illnesses	Sub-group of a convenience sample of 50 females (18-45 years old) who had infants, were pregnant, or intending to get pregnant in the next 12 months. Information framed as the likelihood of absence (positive) or occurrence (negative) of side-effects.	No significant differences in vaccination intentions between the two frame groups	– Distinguished subjects for whom the issue was more relevant (women with or about to have children) from other groups of women combined (low involved). – Relatively small sample size. – Hypothetical vaccination

Leader et al [175] investigated the effect of three randomly assigned framed paragraphs on parental intention to vaccinate female children (ages 0-26 years) or recommend vaccination to them, under both cost and no cost conditions. Other than providing general information on the HPV vaccine and HPV-related illnesses, the authors chose to frame three paragraphs (averaging 160 words) to highlight different aspects of the HPV vaccine that could be raised in the media or during public discussion. The first frame focused on cervical cancer prevention, the second frame highlighted both cervical cancer and STI prevention, and the third frame included information in the second frame as well as mentioning that HPV vaccination may or may not result in increased promiscuity. The study found no significant differences between the three frame groups on intentions to vaccinate daughters in various age groups (under 9 years old, 9-17 years old, and 18-26 year old daughters), with cost and no cost conditions. The authors stated they were unable to detect any small effects due to insufficient power. Despite the null findings, the authors concluded that the message with STI information (second frame) reduced vaccination intentions, because of lower intention scores in this group than among recipients of the frame focusing only on cervical cancer prevention.[175] Although this is a possibility, it may not be a valid conclusion to deduce from the study's null findings. With regard to parental intentions to vaccinate 18-26 years old daughters, it's unlikely that parents would make decisions for this age-group. It would be more beneficial to make conclusions on framing effects and HPV vaccination in young women who do not need parental consent from studies that directly present the framed information to this population. Although this study was unable to investigate actual HPV vaccine uptake as it was conducted at the same time the FDA approved Gardasil®, it was the first published study to assess whether framed information had a differential effect on parental intentions to vaccinate daughters against HPV.

A study in the UK of 140 women (with and without children) hypothesized that compared to recipients of the gain-framed message, parents assigned to the loss-framed message would have higher intentions to obtain the MMR vaccine for a child.[176] The authors stated that despite the suggestion that gain-framed messages are more advantageous in promoting prevention behaviors,[167] they viewed MMR vaccination as a risky choice to parents given the media controversy regarding the vaccine and autism. Findings showed that recipients of the loss-framed

message had higher intentions to obtain the MMR vaccine for children. Although the authors did not find a difference by offspring status or an interaction between frame and offspring status, women with children had higher vaccination intentions than women without children (asked to “imagine” they had a child).[176] Therefore, the lack of differences in vaccination intentions by offspring status may be due to limited power to detect one, and not necessarily because the two groups of women reacted to the frames in a comparable manner. It is reasonable to expect that women with children would react differently to a health issue regarding a child they have due to its relevance, compared to women without children who in this case would be responding to a hypothetical situation. The limitations of this study include the use of a convenience sample consisting of women with and without children and the insufficient sociodemographic data (e.g. education level), which make it difficult to determine the generalizability of findings. Additionally, a response rate was unavailable because the authors were unable to determine how many women had been invited to participate in the study. Despite these limitations and the focus on intentions over actual vaccination behavior, this was the only identified study to assess goal framing effects on intentions to vaccinate children against any childhood illness.

Haward et al [177] undertook a study to assess whether parental decisions to initiate resuscitation of premature infants (or opt for comfort care) would differ when the outcomes for an infant at 23 weeks of gestation were presented positively and negatively (attribute frames). The authors recruited male and non-pregnant female volunteers (n=292) who were asked about a hypothetical situation in which they (or someone close) were threatened with delivery at 23 weeks of gestation. The prognosis of premature delivery was framed positively by presenting survival and non-disability rates, while the negative frame presented mortality rates and disability rates in surviving infants; these frames were randomly assigned to participants. The authors acknowledge that since this was the first study to address this issue, they were ethically required to first undertake the study using non-pregnant females due to the unknown consequences the framed information could cause to pregnant women (e.g. anxiety). Accounting for participants’ religiousness, parental status and beliefs about preservation of life, the survival frame and mortality frame recipients were more likely to choose resuscitation and comfort care, respectively.[177] The limitations of this study include the possibility of selection bias as 20% of recruited subjects who did not complete the survey may differ from the 80% who did. In

addition, although information on education level, age and gender were available for only 66% of respondents and the authors state that the frame groups were comparable, the survival frame group had a higher proportion of 18-39 year old participants than the mortality frame group (66% vs. 49%). Hence, the survival frame group would possibly have more women of child-bearing age. Additionally, age was not adjusted for in the multivariate analysis. As a result, there may be an overestimation and underestimation of the effects observed in the survival frame group and mortality frame group, respectively, as the issue may elicit more emotion in women of child bearing age. Nevertheless, the study was able to recruit a large number of subjects, exceeding the estimated sample size. Although hypothetical, the study was also able to apply message framing to an area where limited information is available, while accounting for participants' religiousness, parental status, and beliefs about preservation of life.

In a sub-group of 50 Australian females who had infants, were pregnant, or intending to get pregnant in the next 12 months, the impact of gain- and loss-frames on intention to vaccinate infants against a hypothetical new vaccine for respiratory illnesses was investigated.[178] Participants were presented with information on a hypothetical vaccine protecting infants up to the age of one year against bronchitis and pneumonia. The positive frame related to participants that 90% of children do not develop side-effects, while the negative frame stated that 10% of children do develop side-effects (attribute framing). For ethical reasons, possible side-effects were not described as very serious or untreatable. The authors did not find significant differences in vaccination intentions between the two frames in this sub-group of participants. Study limitations included investigation of a hypothetical vaccine and the relatively small convenience sample with each framing group having only 25 women. Nevertheless, the study was able to delineate subjects for whom the issue was more relevant by separately assessing the effect of positive and negative frames on vaccination intent among 50 women with or about to have children (high involved), and also for all other women (n=52) not in these categories (low involved). In doing so, the authors illustrated a positive framing effect in the low involved group, but no effect in the high involved group.

The above framing studies were cross-sectional in design, and investigated intention or hypothetical actions/behavior, but not actual behavior including HPV vaccination. In addition,



some studies combined groups of participants with some for whom the issues being investigated had more relevance. Varying results in the framing studies described could be due to differences in operationalization of framing of information,[24, 169] the decision makers' characteristics, the uniqueness of health behaviors being investigated,[169] and insufficient power to detect small framing effects. The present study adds to previous research by collecting actual behavioral data prospectively on a non-hypothetical health issue (HPV vaccination uptake by adolescent girls) after random assignment of framed messages to parents, which is a group for whom this issue is highly relevant.

### **3.5 Summary**

Anticipated regret, worry and message framing have not been widely applied in pediatric health research. The published literature on anticipated regret and HPV vaccination (three studies) consistently shows that anticipated *inaction* regret is a predictor of parental acceptability of HPV vaccines for daughters. In addition, only one published study has investigated and found HPV vaccine acceptance to be related to parental worry regarding the possibility of HPV infections in children; none have addressed parental worry about genital warts and cervical cancer in relation to vaccine acceptability for adolescent girls. Literature on whether providing parents with framed HPV vaccination information has an effect on HPV vaccine uptake by adolescent girls is limited, with the only published study showing no relationship with vaccination intentions. In contrast, the HBM is commonly used to explain or predict parents' decisions regarding vaccination for their children. Generally, the perceived susceptibility (likelihood), perceived benefits and perceived barriers dimensions are more commonly related to parental acceptance of HPV vaccines, than the perceived severity dimension. Previous studies on parental acceptability of HPV vaccines for adolescent daughters are mostly cross-sectional or qualitative in design. Furthermore, most studies have not collected actual HPV vaccine uptake data and have based their estimates of vaccine acceptability on whether or not parents report that they will obtain the vaccine for their daughters.

## **CHAPTER 4: RATIONALE, OBJECTIVES, AND HYPOTHESES**

### **4.1 Rationale**

The principal focus of this doctoral thesis is to investigate psychosocial predictors of HPV vaccine acceptability by parents with adolescent daughters (approximately 11-15 years old). This age-group was chosen primarily for two reasons. Firstly, the study was undertaken when free HPV vaccination was available in NZ to females aged 12-18 years old. Secondly, in NZ, most medical interventions, including vaccination, for children under the age of 16 years require parental consent.[12]

In addition, the availability of free HPV vaccination in NZ to 12-18 year old females at the time this study was undertaken provided a timely opportunity to assess parental acceptability of HPV vaccination with limited biases associated with affordability of HPV vaccines. When this study commenced, there was a lack of published literature specific to NZ on this topic, and hardly any international studies that had collected HPV vaccine uptake data prospectively. Finally, information obtained from this study would likely provide a better understanding about factors influencing HPV vaccine acceptability and uptake, which could be beneficial to cervical cancer prevention programs.

### **4.2 Objectives**

The objectives of this study are:

1. To determine psychosocial predictors of:
  - a) Parental acceptability of HPV vaccines as indicated by initiation of HPV vaccination by their adolescent daughters.
  - b) Parents' intentions to vaccinate adolescent daughters against HPV in the next 12 months.
2. To determine at follow-up if HPV vaccine uptake among adolescent girls who were unvaccinated at baseline differs by whether parents received the gain-framed or loss-framed message at baseline.

### 4.3 Hypotheses

The hypotheses of this study are:

1. Compared to parents who do not intend to vaccinate daughters against HPV in the next twelve months, parents who intend to do so or whose daughters have initiated vaccination will have:
  - a) Higher levels of anticipated regret in the event that daughters are unvaccinated and contract an HPV infection that could lead to cervical cancer;
  - b) Higher levels of anticipated regret in the event that daughters are unvaccinated and contract genital warts; and
  - c) Lower levels of anticipated regret in the event that daughters are vaccinated and become sexually active at an early age.
2. Compared to parents whose daughters have initiated HPV vaccination, parents with and without the intention to vaccinate daughters in the next twelve months will have higher levels of worry regarding HPV, genital warts and cervical cancer.
3. Compared to parents whose daughters have initiated HPV vaccination and who intend to do so in the next twelve months, parents without the intention to vaccinate daughters in the next twelve months will:
  - a) Rate higher on perceived barriers of HPV vaccination, such as, concerns about potential vaccine side effects;
  - b) Rate lower on cues to action to vaccinate daughter against HPV (subjective norms);
  - c) Rate lower on perceived likelihood of HPV-related illnesses if daughters are not vaccinated against HPV;
  - d) Rate lower on perceived severity of HPV and cervical cancer; and
  - e) Rate lower on perceived effectiveness of the HPV vaccine.
4. In the sub-group of parents whose daughters are unvaccinated at baseline and who consent to participate in the follow-up, recipients of the loss-framed HPV vaccination message will be more likely to have daughters who initiate HPV vaccination than recipients of the gain-framed message.

## **CHAPTER 5: RESEARCH METHODOLOGY**

This section provides a detailed description of the target population, study design, and steps undertaken when selecting study participants. In addition, the design of the research questionnaire, data collection procedures, and measures derived from the questionnaire data are described. Procedures and techniques used to perform statistical analyses of baseline and follow-up data are also detailed.

### **5.1 Study population and design**

#### **5.1.1 Participants**

Parents and caregivers of 11-15 year old girls were the target population for recruitment in this study. Participants were recruited through 18 schools in the Auckland Region in NZ that serve girls in this age range. In NZ, girls in the 11-15 year old age-group are mostly likely to be between their seventh and tenth year of schooling (Years 7-10). For the purpose of this thesis, any subsequent reference to “parents” will include both parents and caregivers.

#### **5.1.2 Sample size estimation**

The aim of this sample size estimation is to allow for recruitment of a sufficient number of participants which would enable a comparison of parents who would accept HPV vaccination for daughters (initiate vaccination or intend to obtain the vaccine) to those who do not find the HPV vaccine acceptable at baseline. A post-hoc power analysis for analysis of the effect of framed messages on HPV vaccine uptake at follow-up is available in Section 5.6.

An estimation of the number of participants targeted for recruitment into this study is shown in Table 6. The number of Years 7 to 10 female students - who would be expected to be between 11 and 15 years old – attending school in the Auckland Region in July 2009 (n=40,688), [179] was the base population used to estimate the sample size for this study. It was hypothesized that at baseline, the combined proportion of adolescent girls who would have initiated HPV vaccination and whose parents intended to have them vaccinated against HPV within 12 months would be 80% (+/-5%). This estimate was based on the uptake rate of three doses of a meningococcal B vaccination campaign in NZ (known as, MeNZB™) in people under the age of 20 years, which

was undertaken from mid-2004 to mid-2006.[180] For an alpha level of 5%, the target sample size estimate for this study was 245 parents with daughters approximately 11-15 years old. Sample size estimation was done using the web-based tool, Open Source Epidemiologic Statistics for Public Health.[181]

**Table 6: Estimation of sample size**

Source of the base population	Years 7 to 10 female students attending school in the Auckland Region in July 2009
Size of base population	40,688
Hypothesized combined % frequency of initiation of HPV vaccination by girls and of parents intentions to vaccinate daughters within 12 months	80% (+/-5%)
Confidence level (100% - alpha)	95%
<b>Estimated sample size</b>	<b>245</b>

### **5.1.3 Study design**

This was a prospective study, with one experimental manipulation (message frame). It consisted of a cross-sectional survey (baseline) and a follow-up to collect information on HPV vaccine uptake and completion of the vaccination series by the participants' daughters.

#### **5.1.3.1 The cross-sectional baseline survey**

The aim of the baseline cross-sectional survey was to administer a research questionnaire to parents to collect information on their daughters' HPV vaccination status, sociodemographic factors, and psychological measures. Information on a broad range of factors, such as past history with HPV-related illnesses, which could potentially influence parents decisions regarding HPV vaccination for daughters were also obtained.

The research questionnaire was completed by parents recruited through their daughters' schools. Two questionnaires were used in the survey. These questionnaires differed only on the message framing content, which was the experimental component of this study. Hence, the two questionnaires had different health messages targeted at parents whose daughters had *not* been vaccinated against HPV at the time of the survey. To avoid biasing the message framing findings, parents were blinded to the study's use of two different questionnaires; parents were not informed of this aspect of the study in the information sheet. Parents had a choice between completing an online questionnaire or a paper questionnaire.

### **5.1.3.2 The follow-up phase**

The aim of the follow-up was to obtain information on HPV vaccine uptake and completion of the vaccination series by the participants' daughters. This information was obtained (approximately 6-9 months post-baseline) through one of two ways depending on parental consent. One option allowed for parents to be contacted directly via phone or email for information on their daughters' progress with HPV vaccinations; that is, the number of HPV vaccine injections received thus far. The other option involved obtaining HPV vaccination dates from staff at the Waitemata District Health Board (WDHB) HPV vaccination school-based program, which were then used to determine the number of injections received. These two options were included in the parents' consent form for those completing paper questionnaires, and were also a part of the online questionnaire.

### **5.1.4 Ethical approval**

In December 2009, the Māori Research Review Committee at the WDHB approved the research proposal. Ethical approval to undertake this study was received in January 2010 from the *Northern X* Regional Ethics Committee (reference number: NTX/10/EXP/004).[182]

## **5.2 Recruitment**

### **5.2.1 Selection of participating schools**

Invitations to schools to participate in this study were made in two phases. After the first phase, a collaborative partnership with staff at the WDHB HPV vaccination school-based program was

established. The information sheet and consent form provided to school principals during the recruitment process are available in Appendix A and Appendix B, respectively.

#### **5.2.1.1 Phase one**

The schools invited to participate met all of the following criteria: located in the Auckland region; intermediate or secondary schools (*school type*); and co-educational or girls' schools. Thirty schools from diverse decile rankings were selected at random from the NZ school directory, which is compiled by the Ministry of Education.[179] School decile rankings are indicators of the proportion of students from low socio-economic communities, whereby schools ranked decile one and ten represents 10% of schools with the highest and lowest proportion of students from low socio-economic communities, respectively.[183] Of the thirty schools selected, fourteen were intermediate schools (Years 7–8 students) and the remaining sixteen were secondary schools. The latter school type consisted of either Years 7–15 students or Years 9–15 students.

In November 2009, a brief email was sent to school principals explaining the purpose of the study, the target population, and who the investigators were. In addition, information was provided on how the schools could assist by allowing the investigators to send non-personalized research invitations to parents through girls in Years 7–10 (approximately 11–15 year old girls) at these schools.

#### **5.2.1.2 Phase two**

Schools in the jurisdiction of the WDHB HPV vaccination school-based program (hereafter, *WDHB schools*) were approached in this phase of school selection. Seventy-four of eighty-two WDHB schools were invited to participate in the study in January 2010 (Table 7). Of the eight WDHB schools excluded, two schools had already expressed their participation interest in the previous phase, and six schools had either declined participation or not responded to the invitation.

**Table 7: Number of schools approached in phase two by school type**

School Type	Schools Approached	
	n	%
Composite (Years 1–15)	7	9.46
Full Primary (Years 1–8)	36	48.65
Intermediate (Years 7–8)	10	13.51
Secondary (Years 7–15)	7	9.46
Secondary (Years 9–15)	14	18.92
<b>Total</b>	<b>74</b>	<b>100.00</b>

### 5.2.2 *Recruitment of participants*

Between mid-March 2010 and mid-May 2010, non-personalized research invitations addressed to “*parents/caregivers*” were distributed by the schools’ administration systems to female students in Years 7–10 attending the participating primary (Years 1–8), intermediate (Years 7–8), composite (Years 1–15) and secondary (Years 7–15 or Years 9–15) schools. The girls were asked to take the study research invitation packet home to their parents, which consisted of: a research invitation letter (see Appendix C); an information sheet (see Appendix D); a questionnaire request form (see Appendix E); and a prepaid envelope for reply. The information sheet communicated to parents that participants would be entered into a prize-draw.

Due to cost constraints, it was not possible to initially provide questionnaires to all parents invited to participate in the study. Therefore, the invitation letter provided parents with information on the two options through which they could participate. One option was to complete the baseline survey online through [www.surveymonkey.com](http://www.surveymonkey.com) on encrypted survey pages. The other option involved parents completing and mailing the *questionnaire request form* to ask that a hard copy of the questionnaire be mailed to them.



## 5.3 Data collection and tools

### 5.3.1 *The research questionnaire*

#### 5.3.1.1 Design of research questionnaire

The research questionnaire was developed by the candidate and was guided by published literature on parental acceptability of HPV vaccination for adolescent girls. Several questions from previous research were used directly or modified for use in the baseline survey. The adapted content and sources, as well as specific modifications made to the adapted content are presented in Table 8. A detailed description of the measures in the research questionnaire can be found under *Measures*.

Two questionnaires were created, but these only differed on one experimental component that comprised of either a gain-framed or a loss-framed HPV vaccination message (see Appendix J). The messages were in a sub-section of the questionnaire answered by parents whose daughters had not been vaccinated against HPV during the baseline survey. HPV vaccination messages used in this study were adapted from published work done by Gerend and Shepherd.[172] Using goal frames, two comparable HPV vaccination messages were presented to parents in order to investigate their impact on HPV vaccine uptake by adolescent daughters. One message focused on the benefits of vaccinating daughters against HPV (gain-framed message) and the other focused on the potential consequences of not having daughters vaccinated against HPV (loss-framed message). The effects of goal frames are assessed by comparing the rate at which a behavior is adopted (e.g. vaccination); that is, which message has a greater effect in enhancing the behavior being promoted.[24]

**Table 8: Survey questions and content adapted from previous research**

<b>Content description</b>	<b>Adapted questions /content</b>	<b>Source of content</b>	<b>Modifications made for this study</b>
Information on the questionnaire cover-page	“An HPV vaccine is now available that protects against most genital warts and cervical cancer. Sometimes it’s called the cervical cancer vaccine, HPV shot, or Gardasil. I’ll call it the HPV vaccine.”	Hughes et al (2009), USA.[149]	“An HPV vaccine is now available to protect against cervical cancer and most genital warts. It is sometimes called the cervical cancer vaccine or Gardasil. In this questionnaire, I will call it the HPV vaccine.”
Girls’ HPV vaccination status at baseline	“Has [daughter’s name] had any shots of the HPV vaccine?”	Hughes et al (2009), USA.[149]	“Has your <i>daughter</i> had the HPV vaccine?”; and “How many shots of the HPV vaccine has your <i>daughter</i> had so far?” (response options: <i>one shot; two shots; three shots</i> )
Parental HPV vaccine awareness	“Have you ever heard of the HPV vaccine before today?”	Hughes et al (2009), USA.[149]	“Before today, had you heard of the HPV vaccine?”
Sources of information on the HPV vaccine	“Have you ever heard about the HPV vaccine from any of these sources?” (response options: <i>health care provider; family or friend; brochure; advertisement from drug company; television; radio; internet; and newspaper</i> )	Hughes et al (2009), USA.[149]	Question not modified. Response options modified to: <i>your daughter’s school; family or friend; general practitioner (GP) or other health professional; TV; radio; internet; newspaper; billboard; and other specified sources.</i>

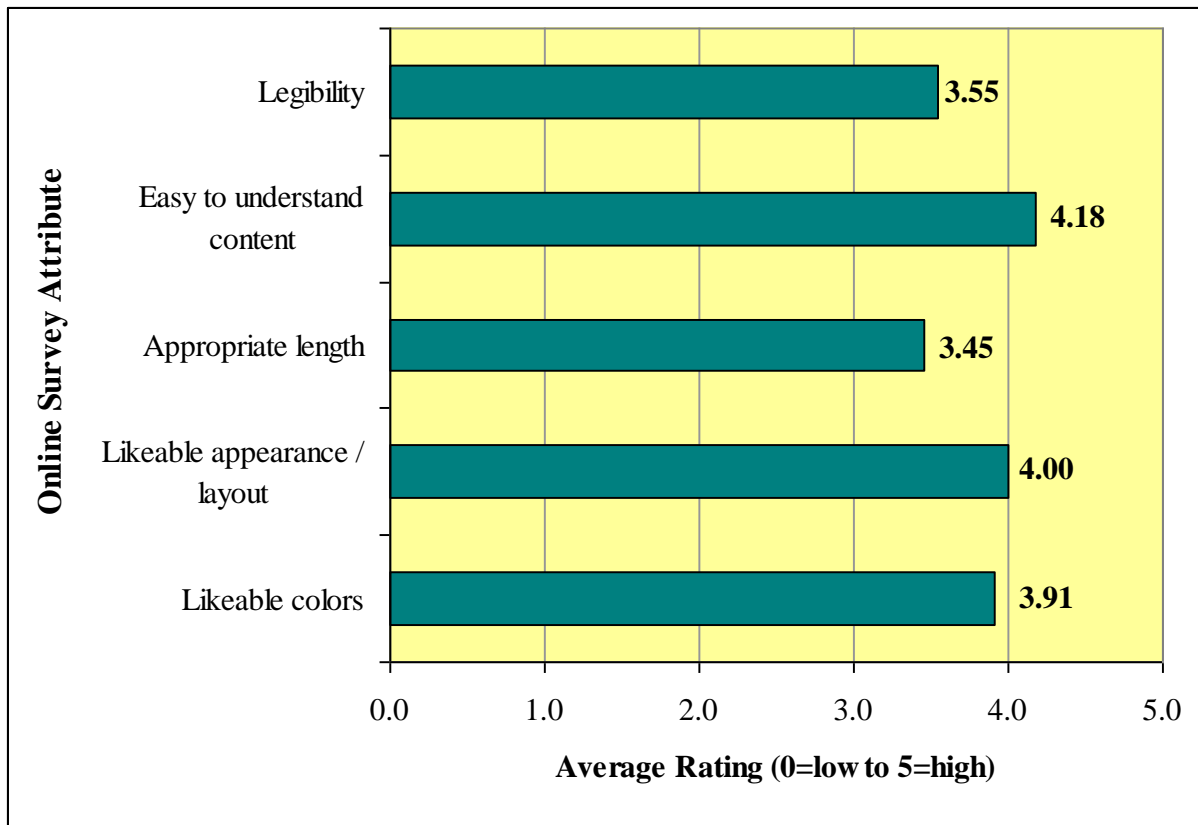
<b>Content description</b>	<b>Adapted questions /content</b>	<b>Source of content</b>	<b>Modifications made for this study</b>
History of delaying vaccination for children	“Have you ever chosen to delay one of the recommended vaccinations for any of your children?”	Marlow et al (2007), United Kingdom.[162]	None
History of choosing not to vaccinate children	“Have you ever chosen not to have one of the recommended vaccinations for any of your children?”	Marlow et al (2007), United Kingdom.[162]	None
History of adverse reactions to vaccines by children	“Have any of your children ever had a bad reaction to a vaccination?”	Marlow et al (2007), United Kingdom.[162]	None
Parent regrets a prior decision to vaccinate a child	“Have you ever regretted a decision to have one of your children vaccinated?”	Marlow et al (2007), United Kingdom.[162]	None
Parental/familial history of abnormal Pap smears, cervical cancer, genital warts, or STI	Information on parental history of HPV-related illnesses and sexually transmitted infections was obtained using 4 questions by asking whether “you or anyone close to you” had experienced abnormal Pap smears, cervical cancer, genital warts, or STI	Dempsey et al (2006), USA.[147]	None

Content description	Adapted questions /content	Source of content	Modifications made for this study
Message framing	HPV vaccination health gain-framed and loss-framed messages were addressed to undergraduate female students.	Gerend et al (2007), USA.[172]	The gain-framed and loss-framed messages were paraphrased to give parents information on benefits of or risks of not vaccinating daughters against HPV. A statement on the availability of free HPV vaccination through schools and primary care was also included.
Anticipated <i>inaction</i> regret	“Imagine that [daughter's name] got an HPV infection that could lead to cervical cancer, but the HPV vaccine might have prevented it. How much would you regret that she did not get the HPV vaccine?” (response options: <i>not at all; a little; a moderate amount; a great deal</i> )	Ziarnowski et al (2009), USA.[122]	1) “Imagine that your <i>daughter</i> did NOT get the HPV vaccine and got an HPV infection that could lead to <i>cervical cancer</i> , but the HPV vaccine might have prevented it. How much would you regret that she did NOT get the HPV vaccine?” 2) “Imagine that your <i>daughter</i> did NOT get the HPV vaccine and got <i>genital warts</i> , but the HPV vaccine might have prevented it. How much would you regret that she did NOT get the HPV vaccine?” (response options: <i>not at all; a little; a moderate amount; a great deal</i> )

<b>Content description</b>	<b>Adapted questions /content</b>	<b>Source of content</b>	<b>Modifications made for this study</b>
Anticipated <i>action</i> regret	“Imagine that your daughter became more sexually active earlier than she would have otherwise because she got the HPV vaccine. How much would you regret that she did get the vaccine?” (response options: <i>not at all; a little; a moderate amount; a great deal</i> )	Ziarnowski et al (2009), USA.[122]	“Imagine that your <i>daughter</i> got the HPV vaccine and became sexually active earlier than she would have otherwise been. How much would you regret that she did get the vaccine?” (response options: <i>not at all; a little; a moderate amount; a great deal</i> )
Worry	1) “To what extent are you worried about getting breast cancer?” 2) “To what extent are you concerned about getting breast cancer?” (response options ranging from 1 ( <i>not at all</i> ) to 7 ( <i>extremely</i> ))	Cameron and Diefenbach (2001), USA.[131]	1) To what extent are you worried about: HPV; genital warts; and cervical cancer. 2) To what extent are you concerned about your daughter getting: HPV; genital warts; and cervical cancer. (response options: <i>not at all; a little; somewhat; a lot</i> )

**5.3.1.2 Pilot of research questionnaire**

The questionnaire was piloted online with a convenience sample of eleven parents with 11–15 year old daughters. Feedback was sought from the volunteers at the end of the pilot survey. Using a five-point Likert scale (strongly agree, agree, neutral, disagree, strongly disagree), the volunteers were asked to provide feedback on the following statements: “wording/text is too small”; “survey is easy to understand”; “survey is too long”; “survey has a good appearance”; and “I like the colors used”. Figure 1 presents parents’ ratings of these statements with regard to the research questionnaire during the pilot study. No major issues were identified during the pilot study. The substantial change made to the online survey was an increase in the font size used.



**Figure 1: Average rating of web-survey attributes during the pilot study (n=11)**

### **5.3.2 Questionnaire administration**

Parents who requested a hard copy of the questionnaire were asked to specify the school from which they had received the research invitation. This allowed for the two questionnaire versions (with a gain-framed or a loss-framed message) to be provided systematically to parents by alternating one questionnaire or the other for requests received through the same school.

Therefore, the questionnaire version mailed to a particular parent was different from the version that had been mailed during the preceding request by a parent sourced from the same school. The goal was to maintain a balance in the number of parents receiving gain-framed and loss-framed HPV vaccination messages within each participating school. On the other hand, the online survey allowed for random ordering of the message framing content to avoid order bias.

Parents who requested a hard copy of the questionnaire were mailed the following: a cover letter containing participation instructions (see Appendix F); an information sheet (see Appendix G); a consent form (see Appendix H); a research questionnaire (see Appendix I); and prepaid envelope to return the completed questionnaire. Parents were asked to complete the consent form and questionnaire, and return these by mail in the prepaid envelope provided to them. To attempt to increase participation, reminder cards were provided once to girls to deliver to their parents 1-2 months after initial contact (May and June 2010), through participating schools.

### **5.3.3 Follow-up of study participants**

Information was obtained on the number of HPV vaccinations received by daughters of parents who gave consent to a follow-up during the baseline survey (approximately 6-9 months post-baseline). With the parents' consent, their daughters' HPV vaccination dates were obtained from staff at the WDHB HPV vaccination school-based program in November 2010, in order to determine how many injections the girls had received. Other parents gave consent to be contacted by phone and/or email for information on the number of HPV vaccine injections their daughters had received thus far; this was done between November 2010 and January 2011.

### **5.3.4 Prize draw**

In January 2011, five participating parents were selected to receive gift vouchers worth 40.00 NZ dollars each. Selection of prize winners was accomplished by simple random sampling with no

replacement using SAS/STAT<sup>®</sup> software, Version 9.2 of the SAS System for Windows (Copyright © 2010, SAS Institute Inc., Cary, NC, USA).

### **5.3.5     *Feedback to participating schools and parents***

A summary of research findings will be provided to participating schools and parents who gave consent to receive this information. They will also be debriefed on the experimental component of the study. This will be done via email or postal mail in October/November 2011 (after submission of this thesis).



## 5.4 Measures

A summary of information collected using the research questionnaire is presented Table 9. The complete questionnaire can be found in Appendix I.

**Table 9: Summary of information collected in the parental questionnaire**

<b>Questionnaire section</b>	<b>Information collected</b>
Section A (1 to 8)	Parent/caregiver demographics
Section B (1 to 6)	Girls' demographics and vaccination history
Section B (7 to 14)	HPV vaccinated girls' data
Section B (15 to 20)	Non-HPV vaccinated girls' data
	<i>B.20</i> : Message framing content used to produce two versions of the questionnaire that differ only on this experimental component.
Section C (1 to 10)	Parental knowledge and attitudes about the HPV vaccine and HPV
Section C (11a to 11b)	Cues to action to vaccinate daughters against HPV (subjective norms)
Section C (11c to 11f)	Perceived risk (perceived likelihood and perceived severity) of HPV-related illnesses
Section C (11g to 11h)	Perceived effectiveness of the HPV vaccine
Section C (11i to 11n)	Perceived barriers to HPV vaccination
Section C (11o)	Parent-daughter communication about sexual health and puberty
Section C (11p)	Parents' need for more information on HPV, HPV vaccines, genital warts, and cervical cancer
Section C (12)	Worry
Section C (13 to 15)	Anticipated regret
Section D (1 to 8)	General health and vaccination experiences
Section E (1 to 5)	Parent/caregiver contact details

#### **5.4.1 Parents' sociodemographic information**

The questionnaire collected the following demographic information from participating parents: month and year of birth; gender; marital status; self-identified ethnicity; highest level of education completed; religious affiliation; and suburb and city of residence. In addition, respondents who were married or living with a partner were asked about their partners' self-identified ethnicity.

#### **5.4.2 Girls' sociodemographic information and vaccination history**

Parents were asked to identify the participating schools attended by daughters from whom they had received invitations to participate in the study. This information made it possible to assign school decile rankings, which would likely be an important sociodemographic variable when analyzing HPV vaccination outcomes.

Information was also collected on the girls' month and year of birth, and history of vaccination for childhood illnesses (such as, measles) and meningitis (meningococcal B). Parents were asked for an explanation if they reported that their daughters had not been vaccinated for childhood illnesses and/or meningitis.

#### **5.4.3 Girls' HPV vaccination status at baseline**

Information on the girls' HPV vaccination status at baseline was obtained by asking parents, "Has your daughter had the HPV vaccine?" (Response options: *yes; no; don't know*). For parents whose daughters had initiated HPV vaccination, further information was collected on the following: month and year the first injection was administered; the location of HPV vaccination (school, doctor's office or primary care, or other specified location); whether parents had paid for the vaccine; and whether parents whose daughters had received a free HPV vaccine would pay for it if they were required to do so. Moreover, specific information on HPV vaccine uptake was obtained by asking these parents, "How many shots of the HPV vaccine has your daughter had so far?" (Response options: *one shot; two shots; three shots*). Parents who responded that daughters had received one or two injections were then asked, "The HPV vaccine requires 3 shots. Do you think your daughter will receive all 3 shots of the HPV vaccine?" (Response options: *definitely won't; probably won't; probably will; definitely will*).

For parents who stated that their daughters had not received the HPV vaccine or who were unsure whether or not their daughters had been vaccinated, data was collected on their vaccination intentions and reasons for daughters being unvaccinated at baseline. Specifically, using a four-point ordinal scale, parents were asked whether they intended to “get your *daughter* the HPV vaccine in the next 12 months”, “have a discussion with your *daughter* about the option of getting the HPV vaccine”, and “get more information about the HPV vaccine” (response options: *definitely won't*; *probably won't*; *probably will*; *definitely will*).

#### **5.4.4 Message framing content**

A message framing experimental component was targeted at parents whose daughters had not received the HPV vaccine or who were unsure whether or not their daughters had been vaccinated. Two differently-worded messages on HPV vaccination – a *gain-framed* message and a *loss-framed* message – were used to produce two questionnaires that were assigned at random to potential participants. These frames were obtained from previous research and modified for this study.[172] The gain-framed (Table 10) and loss-framed (Table 11) messages presented the *benefits of vaccinating* and *risks of not vaccinating* daughters against HPV, respectively.

If the questionnaire was completed online, parents were asked the following question before proceeding to the page that contained the HPV vaccination message: “Please select one of the following health messages” (response options: *health message X*; *health message Y*). The order in which the message selection options were presented to participants appeared at random to avoid order bias; that is to say, each option could appear as the first or second option in the list of response options presented to participants (i.e. message “X” then “Y”, or “Y” then “X”). It was not possible to preselect and present just one message to a participant, as the web survey tool used did not allow for this level of manipulation. The online questionnaire was designed to prevent parents from going back to previous pages of the survey to avoid the possibility of changing their selection and as a result, reading both framed messages. Next, parents were asked whether after reading the HPV vaccination message they intended to vaccinate daughters against HPV (response options: *yes*; *no*; *not sure*).

**Table 10: Gain-framed HPV vaccination message**

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**There are benefits your daughter may experience if she gets the HPV vaccine**

- If you decide to get the HPV vaccine for your daughter, this may decrease her chances of getting an HPV infection.
- By choosing to get the HPV vaccine for your daughter, she may be less likely to develop cervical cancer.
- By choosing to get the HPV vaccine for your daughter, she may be less likely to get genital warts.
- Getting the HPV vaccine may help your daughter feel the peace of mind that comes with taking charge of her body and health.

If in the future your daughter may be sexually active, it is important that you consider getting the HPV vaccine.

The vaccine is currently available at no cost to 12-18 year old girls through schools and primary care.

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**Table 11: Loss-framed HPV vaccination message**

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**There are risks your daughter may experience if she doesn't get the HPV vaccine**

- If you decide NOT to get the HPV vaccine for your daughter, this may increase her chances of getting an HPV infection.
- By choosing NOT to get the HPV vaccine for your daughter, she may be more likely to develop cervical cancer.
- By choosing NOT to get the HPV vaccine for your daughter, she may be more likely to get genital warts.
- NOT getting the HPV vaccine may keep your daughter from feeling the peace of mind that comes with taking charge of her body and health.

If in the future your daughter may be sexually active, it is important that you do NOT fail to consider getting the HPV vaccine.

The vaccine is currently available at no cost to 12-18 year old girls through schools and primary care.

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#### **5.4.5 Parents' HPV-related knowledge, attitudes and beliefs**

Parents were asked whether they had heard of the HPV vaccine before the day of survey completion, and if they had, to select sources of this information from a checklist. In addition, information was obtained on whether before the day of the survey, parents knew that: HPV is a sexually transmitted virus; the HPV vaccine, Gardasil®, also prevents genital warts; and vaccinating girls against HPV at a younger age could provide better protection. Information was collected on whether parents found most acceptable a vaccine that prevented against cervical cancer and genital warts, cervical cancer only, or neither of the two vaccines. Parents were asked at what age they thought females should receive the HPV vaccine and when girls were old enough to make responsible decisions about sexual relationships. After informing parents that HPV is sexually transmitted, they were asked if they believed that boys should also be vaccinated against HPV. Although HPV vaccination was free for 12-18 year old females in NZ when this study was undertaken, parents were asked to report the highest dollar amount they would be willing to pay for the vaccine if they had to.

#### **5.4.6 Parents' vaccination and health experiences**

To assess parents' past general vaccination experiences with any of their children, they were asked: whether they had ever delayed or chosen not to have a recommended vaccination; whether they had ever regretted to have or not to have a recommended vaccination; and if any child had ever had a bad reaction to a vaccine. Information was collected on parents' personal or familial history of abnormal cervical/Pap smears, cervical cancer, or a sexually transmitted infection.

#### **5.4.7 Anticipated regret**

Three separate questions were used to measure anticipated regret (questions C.13 to C.15; Appendix I) – two measuring *inaction* regret and one measuring *action* regret – on a four-point ordinal scale (response options: *not at all*; *a little*; *a moderate amount*; *a great deal*). *Inaction* regret was assessed by asking parents to imagine their daughters were not vaccinated against HPV and developed cervical cancer or genital warts that would have been prevented by the HPV vaccine, and then rate how much they would regret these situations. On the other hand, *action* regret was assessed by asking parents to imagine that daughters received the HPV vaccine and

became sexually active at an earlier age than they would have otherwise been, and then rate how much regret this circumstance would cause them.

The two *inaction* regret variables and one *action* regret variable were scored on an ordinal scale ranging from one to four, with higher scores representing greater levels of regret to match the corresponding response scale on the questionnaire. The *inaction* regret variables were highly correlated ( $r = .824$ ), but both were uncorrelated with the *action* regret variable.

#### 5.4.8 Worry

Using a four-point ordinal scale (response options: *not at all; a little; somewhat; a lot*), parents were asked to rate: 1) the extent to which they were *worried* about HPV, genital warts or cervical cancer; 2) the extent to which they were *concerned* about daughters' getting an HPV infection, genital warts or cervical cancer; and 3) how much *thinking* about HPV, genital warts or cervical cancer bothered them (question C.12; Appendix I).

*Cronbach's Coefficient Alpha* was used to assess the degree to which the three worry questions (per condition) were measuring the same underlying concept; that is, tests for reliability.[184] For each health condition (HPV, genital warts and cervical cancer) the three items (worry item, concern item and thinking item) were highly correlated, indicating high internal consistencies as follows:  $r=.81$  for HPV worry;  $r=.85$  for genital warts worry; and  $r=.84$  for cervical cancer worry.

The proportion of participants missing all three items assessing worry about HPV, genital warts and cervical cancer were respectively, 4.4%, 4.8% and 3.9%. In addition, 1.3% ( $n=3$ ) of the 229 respondents completed at least one item, but not all three items required to create worry scores; this was the case for the three worry measures. For each of the three health conditions (HPV, genital warts and cervical cancer), the *worry* item, *concern* item and *thinking* item were strongly correlated. Hence, imputations were performed in instances where participants completed only one or two items out of the three items assessing parental worry for a particular health condition. If participants rated two out of three items for a specific health condition, the missing item was rated as the average of the two items with non-missing values. On the other hand, if participants

rated one out of three items for a specific health condition, the ratings for the two missing items were assigned the value of the rated (non-missing) item.

After imputations for parental worry items were done, *worry total scores* for each health condition (HPV, genital warts and cervical cancer) were calculated separately by summing parents' ratings on the *worry* item, *concern* item and *thinking* item. Since each of these items were assessed on a four-point ordinal scale ranging from one to four - with four being the highest level of worry reported - the total score for each health condition ranged from three to twelve (three variables, one for each health conditions).

#### **5.4.9 Health Belief Model (HBM) variables**

These consisted of items assessed on a four-point Likert scale, which were created based on the HBM (response options: *strongly agree*; *agree*; *disagree*; *strongly disagree*). Where items were summed together to create scores, participants were only included if they had complete data for the items needed to calculate specific scores.

*Cues to action* to vaccinate daughters against HPV (subjective norms) were assessed using two items that were summed together to create one variable (Table 12). The two items, which had a strong positive correlation ( $r = .72$ ) assessed the extent to which recommendations by doctors and recommendations by family/friends to vaccinate daughters against HPV would influence the parents' decision to do so (questions C.13a and C.13b; Appendix I).

Three items were summed together ( $r = .64$  to  $.77$ ) to create a score for *perceived likelihood* of HPV-related illnesses. These items assessed parents' beliefs regarding the likelihood of their daughters getting an HPV infection, contracting genital warts, or developing cervical cancer without HPV vaccination (questions C.13c to C.13e; Appendix I).

*Perceived severity* was assessed by asking parents to rate the extent to which an HPV infection or cervical cancer would have serious consequences on their daughters' health (question C.13f; Appendix I).

*Perceived effectiveness* of the HPV vaccine was measured using two items that were summed together to create a single variable. These items had a very strong positive correlation ( $r = .94$ ) and provided information on parents' belief that the HPV vaccine would reduce the likelihood of their daughters: 1) contracting HPV; and 2) getting cervical cancer or genital warts (questions C.13g and C.13h; Appendix D).

*Perceived barriers* of HPV vaccination that were assessed included: daughters' fear of needles; concern about potential vaccine side-effects; whether knowing that HPV is sexually transmitted influences vaccine acceptability; concerns that girls vaccinated against HPV will initiate sexual activity at an early age; and whether parents are generally against vaccines (questions C.13i, C.13j, C.13l, C.13m and C.13n; Appendix D). Perceived barriers were also enumerated (ranging from no barriers to five barriers) and categorized as: none or one barrier; two barriers; and three to five barriers. Items assessing perceived barriers of HPV vaccination had very weak or weak correlations with each other. To address whether parents would find HPV vaccines affordable if they had to pay for it, they were asked to rate how affordable HPV vaccination costing 450–500 NZ dollars would be to them.



**Table 12: Spearman Correlation Coefficients (*r*) for items created using the Health Belief Model**

	Cues to action		Perceived likelihood			Perceived severity	Perceived effectiveness		Perceived barriers				
	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11	Item 12	Item 13
<b>Item 1</b>	1.00	.72*	.46*	.36*	.41*	.37*	.55*	.56*	.20*	-.27*	-.04	-.16*	-.40*
<b>Item 2</b>	.72*	1.00	.42*	.42*	.40*	.25*	.46*	.48*	.14*	-.26*	.08	-.04	-.26*
<b>Item 3</b>	.46*	.42*	1.00	.64*	.77*	.10	.42*	.41*	.18*	-.26*	.06	-.05	-.16*
<b>Item 4</b>	.36*	.42*	.64*	1.00	.76*	.15*	.38*	.38*	.10	-.23*	.10	.07	-.10
<b>Item 5</b>	.41*	.40*	.77*	.76*	1.00	.17*	.39*	.38*	.06	-.25*	.08	.0004	-.15*
<b>Item 6</b>	.37*	.25*	.10	.15*	.17*	1.00	.41*	.41*	.05	-.04	-.02	-.19*	-.36*
<b>Item 7</b>	.55*	.46*	.42*	.38*	.39*	.41*	1.00	.94*	.15*	-.36*	-.03	-.18*	-.47*
<b>Item 8</b>	.56*	.48*	.41*	.38*	.38*	.41*	.94*	1.00	.15*	-.34*	-.01	-.11	-.46*
<b>Item 9</b>	.20*	.14*	.18*	.10	.06	.05	.15*	.15*	1.00	.08	.03	-.02	-.03
<b>Item 10</b>	-.27*	-.26*	-.26*	-.23*	-.25*	-.04	-.36*	-.34*	.08	1.00	.01	.02	.17*
<b>Item 11</b>	-.04	.08	.06	.10	.08	-.02	-.03	-.01	.03	.01	1.00	.35*	.11
<b>Item 12</b>	-.16*	-.04	-.05	.07	.00	-.19*	-.18*	-.11	-.02	.02	.35*	1.00	.24*
<b>Item 13</b>	-.40*	-.26*	-.16*	-.10	-.15*	-.36*	-.47*	-.46*	-.03	.17*	.11	.24*	1.00

\* Statistically significant (p-value &lt;0.05)

**Item**      **Description**

Item 1:      If my general practitioner (GP) recommended that I get my daughter the HPV vaccine, I would do it

Item 2:      If my family or friends recommended that I get my daughter the HPV vaccine, I would do it

- Item 3: With no HPV vaccine, it is likely that my daughter would get an HPV infection
- Item 4: With no HPV vaccine, it is likely that my daughter would get cervical cancer
- Item 5: With no HPV vaccine, it is likely that my daughter would get genital warts
- Item 6: If my daughter got an HPV infection or cervical cancer, it would have serious consequences on her health
- Item 7: The HPV vaccine will reduce the chance that my daughter will get an HPV infection
- Item 8: The HPV vaccine will reduce the chance that my daughter will get cervical cancer or genital warts
- Item 9: My daughter is afraid of needles
- Item 10: I am concerned that the HPV vaccine may have side-effects
- Item 11: Knowing that HPV is sexually transmitted affects my decision about having my daughter vaccinated
- Item 12: I am concerned that girls who get the HPV vaccine will become sexually active at an earlier age
- Item 13: I am against vaccines in general

## 5.5 Statistical analyses of baseline data

All statistical analyses, data cleaning, and variable coding and scoring were done using SAS/STAT<sup>®</sup> software, Version 9.2 of the SAS System for Windows (Copyright © 2010, SAS Institute Inc., Cary, NC, USA). The p-values presented are all two-sided and statistical significance refers to p-values below 0.05.

### 5.5.1 Outcome variable at baseline

The following measures were used to define the baseline outcome: 1) whether or not parents had vaccinated daughters against HPV (one or more injections); and 2) whether parents whose daughters had not initiated HPV vaccination or who did not know if daughter had been vaccinated intended to vaccinate them in the next 12 months. Participants categorized as intending to vaccinate daughters against HPV were those who reported that they “definitely will” or “probably will” do so in the next 12 months. On the other hand, parents categorized as not intending to vaccinate daughters against HPV were those who reported that they “definitely won’t” or “probably won’t” do so in the next 12 months.

This resulted in a three-level nominal variable that grouped participants as follows: parents whose daughters had initiated HPV vaccination; parents who intended to have daughters vaccinated within 12 months; and parents who had no intention of vaccinating daughters in the next 12 months.

### 5.5.2 Primary independent variables

Psychological measures were the main independent variables in this study and included: anticipated regret, worry, and HBM variables.

There were three anticipated regret variables: anticipated regret regarding cervical cancer and genital warts if girls did not get the HPV vaccine (*inaction* regret); and anticipated regret regarding the possibility of earlier initiation of sexual activity if girls were vaccinated against HPV (*action* regret). Although the two inaction regret measures were correlated, they were *not* combined as it was expected that parental anticipated regret regarding cervical cancer would be

greater than regret about genital warts, given that the former has more serious health consequences.

Parental worry about HPV, genital warts and cervical cancer were the three variables used in the analyses. These were also *not* combined into one variable. It was expected that given the seriousness of cervical cancer over HPV infections and genital warts, the levels of parental worry regarding these conditions would likely differ.

The HBM variables were: cues to action to vaccinate daughters against HPV (subjective norms); perceived likelihood of HPV-related illnesses; perceived effectiveness of the HPV vaccine; perceived severity of HPV and cervical cancer; daughters' fear of needles; concern about potential HPV vaccine side-effects; whether knowing that HPV is sexually transmitted influences vaccine acceptability; concerns that girls vaccinated against HPV will initiate sexual activity at an early age; and whether parents are generally opposed to vaccines.

### **5.5.3     *Secondary independent variables (covariates)***

Covariates comprised of quantitative data collected in the questionnaire, excluding the outcome variable and primary independent variables. These included: parents' sociodemographic data; girls' demographic data and vaccination history; parents' HPV-related knowledge, attitudes and beliefs; and parents' past vaccination and relevant health experiences. Most covariates were analyzed as collected in the questionnaire. However, depending on responses by participants, some variables were regrouped to allow for adequate numbers within variable categories and more meaningful interpretation.

For parents' highest level of education completed, a five-level categorical variable was created as follows: less than a high school qualification; a high school qualification (or equivalent); one to three years of university education; a bachelor's degree; and more than a bachelor's degree. Parents' religious affiliation was categorized as: Catholic; Protestant; unspecified Christian denominations; no religious affiliation; and other specified religious affiliations. Using the month and year of birth, the parents' age and girls' age were calculated as of 1st March 2010; data collection commenced in March 2010.

Ethnicity was categorized using the New Zealand Ministry of Health guidelines published in February 2004, which described “procedures for the standardized collection, recording and output of ethnicity data for the New Zealand health and disability sector”.[185] Therefore, if participants in this study self-identified as belonging to multiple ethnic groups, the following hierarchy was used to group each participant into only one ethnic group: Māori; Pacific Peoples; Asian; and European and other ethnicities.

#### **5.5.4 Bivariate analyses**

Tests for normality were done to determine whether for parents’ age and girls’ age had parametric (normal) distributions. This was assessed using the *Shapiro-Wilk W* test in the *UNIVARIATE* procedure in SAS, Version 9.2. Parents’ age had a parametric distribution and was therefore summarized using mean and standard deviation. However, girls’ age had a nonparametric distribution and was presented using median and range (minimum and maximum values). Categorical data were summarized using counts and percents. Data on psychological measures were presented using means and standard deviations.

Bivariate analyses were performed to test for associations between the outcome variable (girls’ baseline HPV vaccination status) and both the primary independent variables (psychological measures) and the secondary independent variables (covariates). Associations between baseline HPV vaccination status and categorical independent variables were assessed using the *Chi-Square test*. However, if one or more of the expected cell count values were less than five, the *Fisher’s Exact test* was used.[186] For ordinal and nonparametric independent variables, associations with baseline HPV vaccination status were assessed using the *Kruskal-Wallis test*, and for parametric variables analysis of variance (ANOVA) for unbalanced designs was used. The p-value estimates for Chi-Square and Fisher’s Exact tests, Kruskal-Wallis test, and ANOVA for unbalanced designs were obtained in SAS, Version 9.2, via the *FREQ* procedure, *NPARIWAY* procedure, and *GLM* procedure, respectively.

#### **5.5.5 Multivariate analyses**

The *LOGISTIC* procedure in SAS/STAT<sup>®</sup> software, Version 9.2, was used to perform multinomial logistic regression analysis. This analysis uses a generalized logits model to

estimate multiple sets of parameters [equivalent to the number of levels in the outcome variable minus one (the reference group)] for both the independent variables in the model and the intercept terms.[187] Hence, for this analysis, two sets of parameter estimates for the intercept terms and independent variables were produced; one set of parameters corresponded to *initiation of HPV vaccination* and the other set to *parental intention to vaccinate daughters within 12 months*. These parameter estimates were modeled in comparison to the sub-sample of parents *without* the intention to vaccinate daughters within 12 months (reference group). The results were summarized using adjusted odds ratios and their 95% confidence intervals.

Analyses were done separately for each anticipated regret measure (three models), each parental worry score (three models), and the HBM variables (one model), with these measures as primary independent variables. The multivariate models also included (i.e. adjusted for) covariates that met *both* of the following criteria in the bivariate analyses: covariates were related to HPV vaccination status at baseline at a p-value of 0.10 or less; and covariates, if categorical, had at least 15 observations per cell when cross-tabulated with girls' HPV vaccination status at baseline.

Sociodemographic variables that met these criteria in the bivariate analysis (girls' age; school decile ranking; and parents' age and education) were included in all the multivariate models regardless of whether they were statistically significant in the multivariate analysis. For the remaining covariates meeting these criteria, *forward selection* was used to determine if the covariates were statistically significant ( $p < 0.05$ ) before inclusion in the multivariate model. This was further confirmed by examining the p-value of the *residual score statistic* (Residual Chi-Square test). It tests the null hypothesis that a model produced during forward selection is adequate and addition into the multivariate model of other covariates is unnecessary.[187]

Observations included in a multivariate model consisted only of subjects without missing data for all the variables in a particular model. The overall fit of each multinomial logistic model was assessed using the *likelihood ratio statistic*, which tests the *global null hypothesis* that the parameters in the model are jointly equal to zero; that is, beta is equal to zero.[187] Therefore, a non-significant p-value for the *likelihood ratio statistic* indicates a good model fit.

Guided by published work done by Chapman and Coups,[119] an exception was made to also include the two risk likelihood measures (perceived likelihood of HPV-related illnesses and perceived severity of HPV and cervical cancer) in the multivariate models of the three worry and anticipated regret measures, regardless of whether they were statistically significant or not.

#### **5.5.5.1 Anticipated regret with girls' baseline HPV vaccination status**

Multinomial logistic regression models for the three anticipated regret measures (which were analyzed separately) with girls' baseline HPV vaccination status (outcome) started with these seven independent variables in the initial model: the anticipated regret measure; girls' age; parents' age; parents' education; school decile ranking; perceived likelihood of HPV-related illnesses without HPV vaccination; and perceived severity of HPV and cervical cancer.

Forward selection was then used to determine whether it was necessary to add to the initial model the variable assessing parents' awareness that Gardasil® prevents warts. In all the three initial multivariate models for the three anticipated regret measures, the *residual score statistic* p-values were less than 0.05 if parents' awareness that Gardasil® prevents warts was excluded from the models. Therefore, the *residual score statistic* null hypotheses – that including the measure on parents' awareness that Gardasil® prevents warts to all three initial multivariate models was unnecessary – were rejected and this variable remained in the final multivariate models.

#### **5.5.5.2 Worry with girls' baseline HPV vaccination status**

Similar to the multinomial logistic regression modeling done for anticipated regret measures, multivariate models for the three parental worry measures (which were analyzed separately) with girls' baseline HPV vaccination status initially included the following seven independent variables: the parental worry measure; girls' age; parents' age; parents' education; school decile ranking; perceived likelihood of HPV-related illnesses without HPV vaccination; and perceived severity of HPV and cervical cancer.

Next, a determination was made by forward selection as to whether it was necessary to include the variable assessing parents' awareness that Gardasil® prevents warts in the multivariate

models. In all three multivariate models for the three worry measures, the analyses showed that inclusion of the parents' awareness that Gardasil® prevents warts was necessary; this was indicated by residual score statistic p-values of less than 0.05 if this variable was excluded from the models. Thus, the each of the three final multivariate models included eight independent variables.

### **5.5.5.3 HBM variables with girls' baseline HPV vaccination status**

In the multivariate analysis of HBM variables, the initial model commenced with the following eight variables: cues to action to vaccinate daughters against HPV; perceived likelihood of HPV-related illnesses without HPV vaccination; perceived severity of HPV and cervical cancer; perceived effectiveness of the HPV vaccine; girls' age; parents' age; parents' education; and school decile ranking.

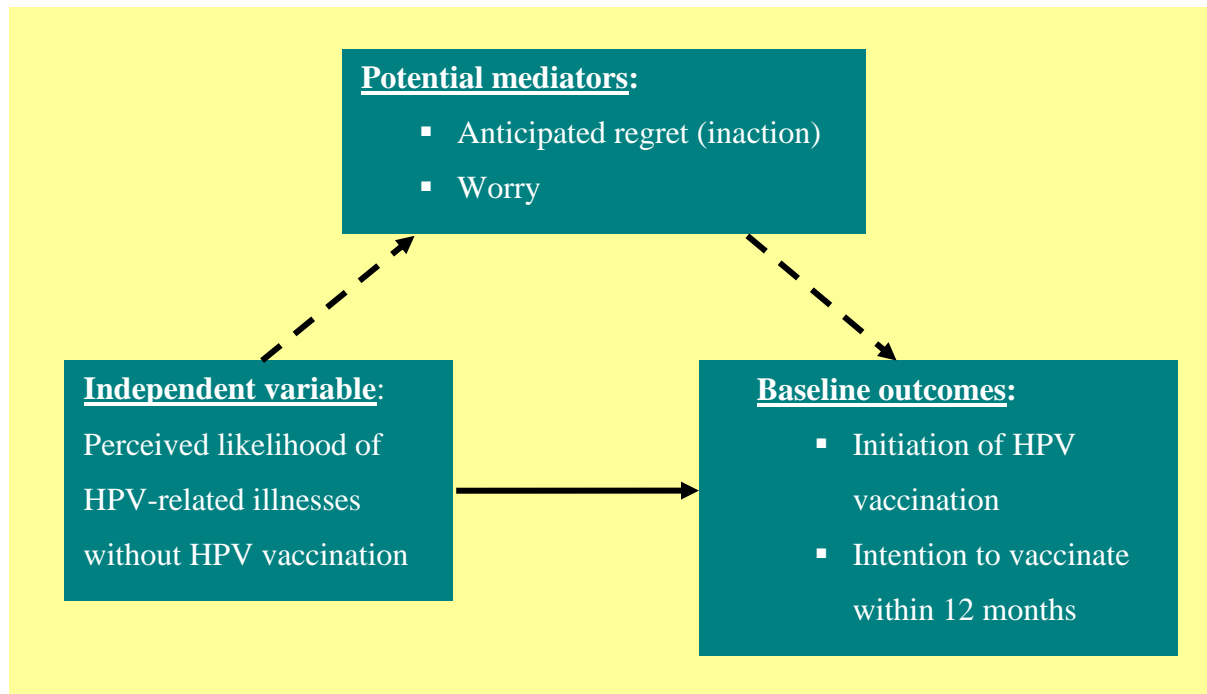
Using forward selection, analysis was done to determine whether it was necessary to add to the initial multinomial logistic regression model three perceived barriers of HPV vaccination (concern about HPV vaccine side-effects, daughters' fear of needles, and general opposition to vaccines) and parents' awareness that Gardasil® also prevents warts. Of these four variables, two variables – parents' concerns about HPV vaccine side-effects and daughters' fear of needles – were found to add meaningful information to the multivariate model as indicated by *residual score statistic* p-values of less than 0.05 if these variables were excluded. However, parents' general opposition to vaccines and their awareness that Gardasil® prevents warts did not meet the criteria to enter the multivariate model. Hence, the final multivariate model in this analysis consisted of ten independent variables.

### **5.5.6 Mediation analysis**

Analysis was done to test whether anticipated *inaction* regret and worry mediate the relationship between perceived likelihood of HPV-related illnesses and girls' HPV vaccination status at baseline. The question was, other than a direct effect between perceived likelihood of HPV-related illnesses and girls' HPV vaccination status, does perceived likelihood of HPV-related illnesses (risk likelihood) also indirectly affects girls' HPV vaccination status (behavior) through anticipated regret and worry (emotions). The hypothesized mediation pathways investigated are summarized in Figure 2. Since the outcome was a three-level nominal variable, statistical tests



done consisted of two sets of analyses: 1) parents whose daughters had initiated HPV vaccination compared to parents without the intention to vaccinate daughters within 12 months; and 2) parents who intended to vaccinate daughters within 12 months compared to those who did not intend to do so.



**Figure 2: Hypothesized mediation models of the indirect effect of perceived risk of HPV-related illnesses on HPV vaccination status through anticipated emotions**

Mediation analysis was done using the processes described by Baron and Kenny, MacKinnon et al, and MacKinnon and Dwyer.[188-190] Firstly, two binary logistic regression models were used to assess whether perceived likelihood of HPV-related illnesses was significantly related to HPV vaccination status at baseline (**Step 1**). This was done separately for initiation of HPV vaccination and for parents' intentions to vaccinate daughters against HPV within 12 months, with parents without intentions to vaccinate daughters in the next 12 months as the comparison group.

Secondly, Spearman correlations were used to assess whether the potential mediators were related to perceived likelihood of HPV-related illnesses without HPV vaccination (**Step 2**).

Thirdly, with HPV vaccination status at baseline as the dependent variable and perceived likelihood of HPV-related illnesses as the main independent variable, separate binary logistic regression models were created to assess whether each of the potential mediation variables were statistically significant when added to this model (**Step 3**).

There is evidence of mediation when a potential mediator shows a statistically significant association in both Step 2 and Step 3 above,[190] and a reduction in the regression coefficient relating the main independent variable to the outcome variable also occurs in Step 3 compared to Step 1 above.[188] Finally, to test whether the apparent mediation was statistically significant, a SAS macro program developed by Jasti et al [191] was applied to calculate the Sobel and Goodman tests using logistic regression.

## **5.6 Statistical analyses of follow-up data**

### **5.6.1 Outcome variables at follow-up**

There were two outcome variables for HPV vaccine uptake follow-up. Firstly, a dichotomous variable categorized daughters as having initiated HPV vaccination or not. For parents who provided consent for HPV vaccine uptake data to be obtained via health record checks (n=94), daughters were categorized as having initiated HPV vaccination if they had at least one HPV vaccination date on record. Girls were categorized as unvaccinated if: 1) their personal identifiers were available in health records but there were no HPV vaccination dates associated with these; or 2) their parents had on record declined HPV vaccination via the school vaccination program or primary care. For parents who preferred to be contacted for their daughters' HPV vaccination uptake information (n=82), they were asked via phone and/or email to provide information on the number of HPV vaccine injections their daughters had received thus far using the following response options: *one shot; two shots; three shots; not vaccinated against HPV; don't know*. None of the parents reported that they did not know the number of injections their daughters had received. Therefore, initiation of HPV vaccination was defined as daughters having received one or more injections of the HPV vaccine. If parents did not provide consent for a follow-up but their daughters were already known to have initiated HPV vaccination at baseline (n=11), they were also included in this outcome variable.

Secondly, HPV vaccine uptake at follow-up was defined based on the level of completion of the vaccination series. This grouped girls as follows: completed the HPV vaccination series (three shots); initiated HPV vaccination, but series incomplete (one or two shots); not vaccinated against HPV; and information unavailable at follow-up. Among parents who consented to a follow-up via health record checks, one girl's HPV vaccination status could not be determined due to lack of a match to the health records. Among parents who consented to be contacted for their daughters' HPV vaccination data at follow-up, four parents could not be reached after three attempts.

### **5.6.2 Bivariate analyses**

Although HPV vaccine uptake was determined for the entire study population where possible, further analysis of follow-up data focused on the subsets of parents: 1) whose daughters were unvaccinated at baseline (n=159); and 2) who had consented to a follow-up and had unvaccinated daughters at baseline (n=112).

It was important to determine whether parents randomly assigned to loss-framed and gain-framed HPV vaccination messages were comparable on baseline psychological measures and sociodemographic factors related to HPV vaccination at baseline. Therefore, among parents whose daughters were unvaccinated at baseline (n=159), those who received a gain-framed message (n=97) were compared to those who received the loss-framed message (n=62) on the following factors: anticipated regret; worry; HBM variables; parents' age and education; girls' age; school decile ranking; and parents' awareness that Gardasil® also protects against genital warts. In addition, the message framing groups were compared on parental intentions to vaccinate daughters within 12 months and the source of HPV vaccination follow-up data (parental report or health records).

Among parents who provided follow-up consent and whose daughters had not initiated HPV vaccination at baseline (n=112), the Cochran-Mantel-Haenszel statistic was used to assess whether the message framing groups differed by the following: 1) initiation of HPV vaccination by daughters; and 2) the level of completion of the HPV vaccination series by daughters.

### 5.6.3 *Multivariate analysis*

The level of completion of the vaccination series was not analyzed as an outcome in the multivariate analysis due to the relatively small number of parents with daughters who had initiated HPV vaccination, but had not completed the series of three injections.

Logistic regression analysis was used to determine whether initiation of HPV vaccination at follow-up differed based on whether parents received the gain-framed or loss-framed message at baseline. This was done among parents who provided follow-up consent and whose daughters had not initiated HPV vaccination at baseline (n=112). The logistic model commenced with message framing assignment as the main independent variable and as covariates, variables that had p-values of 0.10 or less when the message framing groups were compared in the bivariate analyses among parents with unvaccinated daughters. These covariates were: girls' age; anticipated regret in the event that daughters were unvaccinated and got genital warts; and anticipated regret in the event that daughters were vaccinated and initiated sexual activity at an early age. Forward selection was used to determine if the covariates were statistically significant ( $p < 0.05$ ) for inclusion in the multivariate model. The *residual score statistic* (Residual Chi-Square test) was also examined to determine if each model produced during forward selection was adequate and whether addition into the multivariate model of other covariates was necessary. Girls' age was the only covariate that entered the model. Results were summarized using adjusted odds ratios and 95% confidence intervals. Also assessed was whether the relationship between initiation of HPV vaccination at follow-up and message framing assignment was moderated by perceived likelihood of HPV-related illnesses without HPV vaccination (interaction effect).

#### *Post-hoc power analysis*

For a two-sided confidence interval of 95%, the analysis comparing HPV vaccine uptake between loss-framed message recipients (n=46) to gain-framed message recipients (n=66) for whom HPV vaccine uptake was 69% and 56%, respectively, had 28.3% statistical power. Therefore, this aspect of the study did not have sufficient statistical power to detect framing effects.

## **5.7 Summary**

This chapter has described the study design and the procedures used to recruit participants. It has also detailed how the questionnaire was developed and the measures derived from it. Statistical procedures used to analyze baseline and follow-up data have been described and the rationales for selecting specific techniques have been stated briefly. The next chapter presents and describes findings from the baseline phase of the study.

## **CHAPTER 6: BASELINE RESULTS**

This chapter provides information on response rates for participating schools and parents, and the mode of questionnaire completion. It also presents findings from analyses done to assess the relationship between girls' HPV vaccination status and the following: anticipated regret; worry; HBM variables; sociodemographic factors; parental HPV-related attitudes and beliefs; and parents' relevant health and general vaccination experiences. Descriptive statistics on these variables are also presented.

### **6.1 School response rate**

Of the 30 schools approached in phase one, four schools expressed interest in participating in the study. This consisted of two intermediate schools of decile rankings two and three, and two secondary schools of decile rankings three and four. Non-participating schools that responded either simply stated that they did not wish to participate or gave reasons for their decline. Reasons given by three schools for declining participation were: refusal by their board of trustees; being too busy; and feeling that they had received several requests for other surveys and had therefore “done their share” at the time. In this phase, over 12% of schools invited agreed to participate, 19% declined and the remaining schools did not respond.

About 19% of the 74 schools approached in phase two agreed to participate, seven percent declined, and the remainder did not respond. Reasons given by two non-participating schools for declining to participate were shortage of school management staff at the time and having already received a request on HPV vaccination research from a former student. Other non-participating schools that responded simply stated that they did not wish to participate.

By the time recruitment of schools was terminated, a total of 104 schools had been approached to participate in this study (Table 13). Of these, approximately 17% (n=18) agreed to participate.

**Table 13: Number and participation rate of schools in phases one and two of recruitment**

Phase	School response				School Participation
	Will participate	Will NOT participate	No Response	Total	Rate %
Phase One	4	6	20	30	13.33
Phase Two	14	5	55	74	18.92
<b>Total</b>	<b>18</b>	<b>11</b>	<b>75</b>	<b>104</b>	<b>17.31</b>

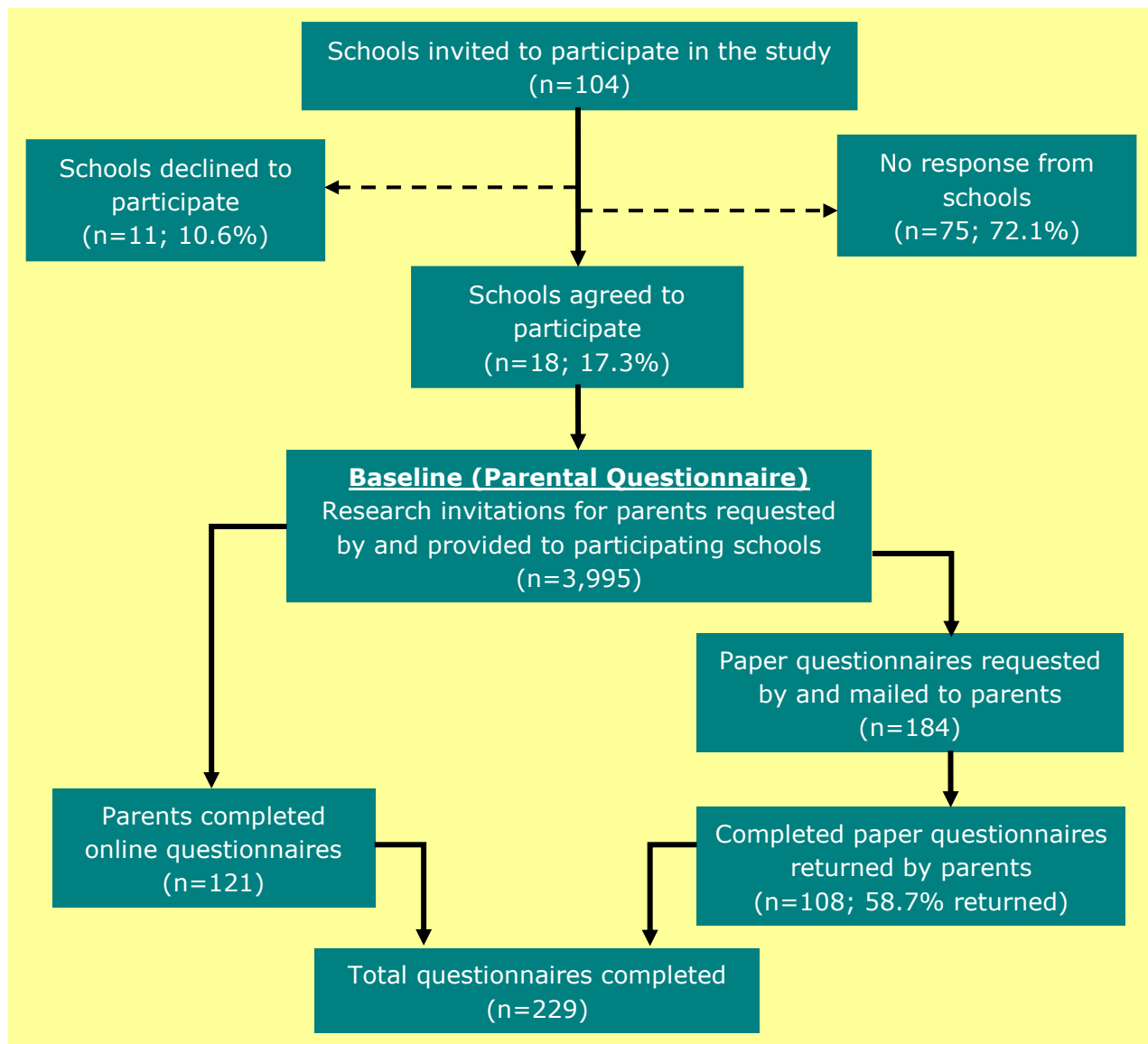
Table 14 compares the decile rankings of schools participating in this study to decile rankings of schools located in Auckland North that are similar in type (primary, composite, intermediate and secondary schools) to those invited to participate in this study. It shows that the present study had similar proportions of schools ranked deciles 8–10 and deciles 1–3 to schools of similar types located in Auckland North, but had a slightly lower proportion (five percent difference) of schools ranked deciles 4–7. Nevertheless, the differences in the proportion of schools belonging to various decile ranking categories that participated in this study to those located in Auckland North were not statistically significant ( $p=0.216$ , Chi-Square test).

**Table 14: Decile distribution of participating schools compared to eligible schools in the Auckland North**

Decile (July 2009)	Schools Participating in the Study	Primary, Composite, Intermediate and Secondary Schools in Auckland North
	(n=18) n (%)	(n=145) n (%)
1 to 3	5 (27.78)	36 (24.83)
4 to 7	5 (27.78)	48 (33.10)
8 to 10	8 (44.44)	61 (42.07)

## 6.2 Participant response rate

The 18 participating schools requested a total of 3,995 research invitations to be provided to parents through their daughters who were attending these schools (Figure 3). Of the 184 parents who on request were provided with a hard-copy of the questionnaire, 108 (58.7%) returned a completed questionnaire. In addition, 121 parents completed the questionnaire online. This resulted in a total of 229 parents participating at baseline.

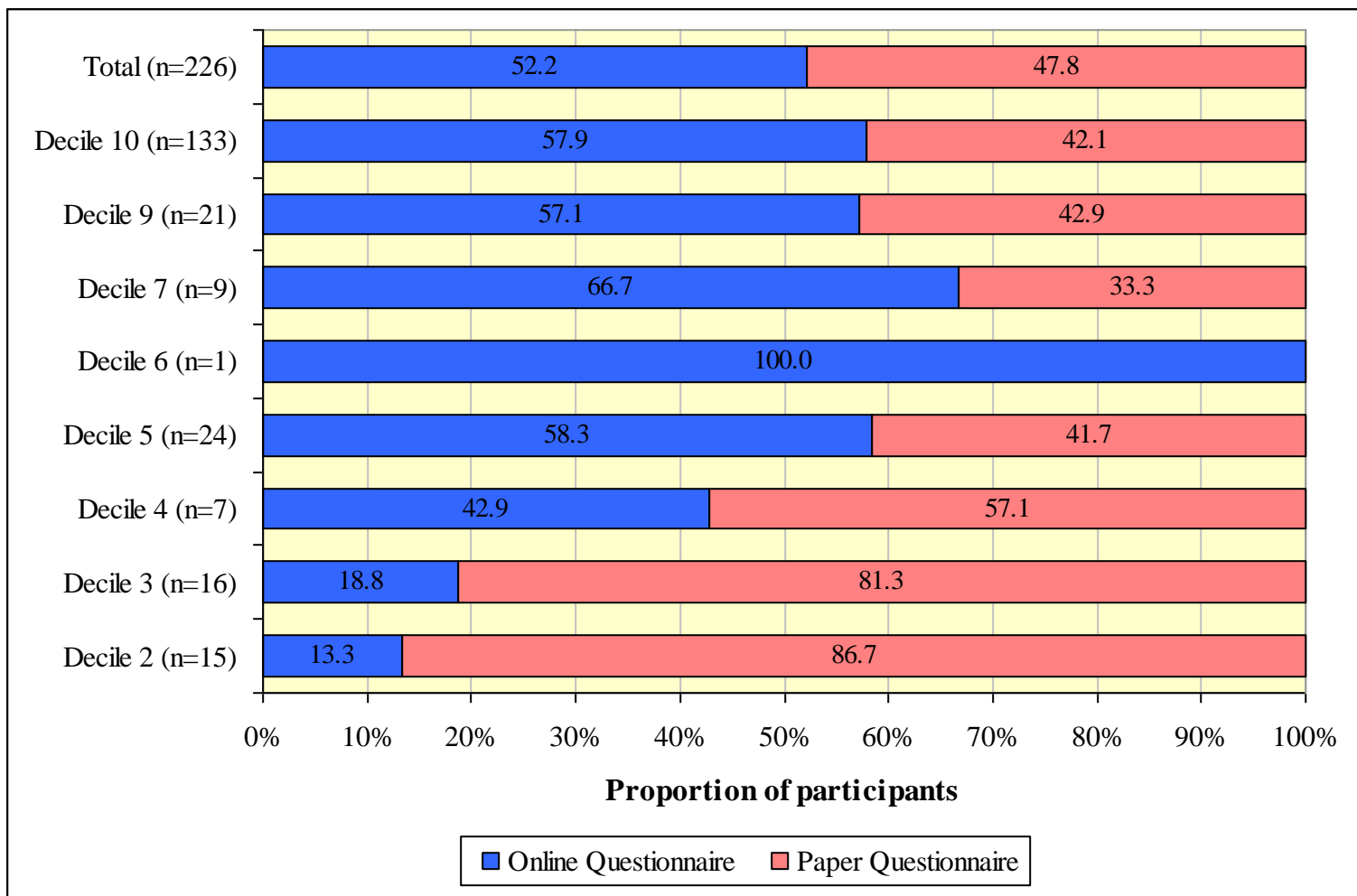


**Figure 3: Summary of recruitment of and participation by schools and parents**



### **6.3 Mode of questionnaire completion**

Of the 229 questionnaires completed, 53% were completed online and the remaining 47% were paper questionnaires. Information of the decile rankings of schools attended by daughters of participating parents was available for 98.7% (n=226) of participants; three parents did not specify which schools their daughters attended (Figure 4). Parents whose daughters attended schools with higher proportions of students from low socio-economic communities (lower deciles) were significantly more likely to complete paper questionnaires than online questionnaires (p=0.003, Wilcoxon Rank Sums test).



**Figure 4: Parent participation via online versus paper questionnaires, stratified by school decile (n=226)**

## 6.4 Descriptive statistics

### 6.4.1 *Parents sociodemographic baseline characteristics*

Participating parents had a mean age of 44.2 years (Table 15). The majority of parents were female, married, and of European and other ethnicities. About one-third each had either a high school qualification or completed one to three years of university education. Parents with no religious affiliation constituted the largest proportion of the sample (40%), and a similar proportion of parents were either Catholics or Protestants.

### 6.4.2 *Baseline characteristics of adolescent girls*

Daughters of participating parents had a median age of 12.5 years with age ranging from 10.8 to 16.2 years (Table 16). Over two-thirds (68%) of the girls attended schools ranked decile eight or higher and the remaining 32% attended schools ranked decile seven or lower; this reflects the socioeconomic status (SES) of residents in the area where most participating schools are located (Auckland North).

Twenty eight percent of girls (n=63) had initiated HPV vaccination, and of these 96.8% (n=61) of parents provided information at baseline about the number of injections their daughters had received. Among girls who had initiated HPV vaccination, more than half had received one injection of the vaccine and one-third had completed the HPV vaccination series (three injections). None of the parents reported having to pay for the HPV vaccine.

Almost 90% of parents reported that daughters had received all recommended childhood vaccinations. With regard to vaccination against meningococcal B, 84% of parents reported that daughters had been vaccinated.

**Table 15: Parents' baseline sociodemographic characteristics**

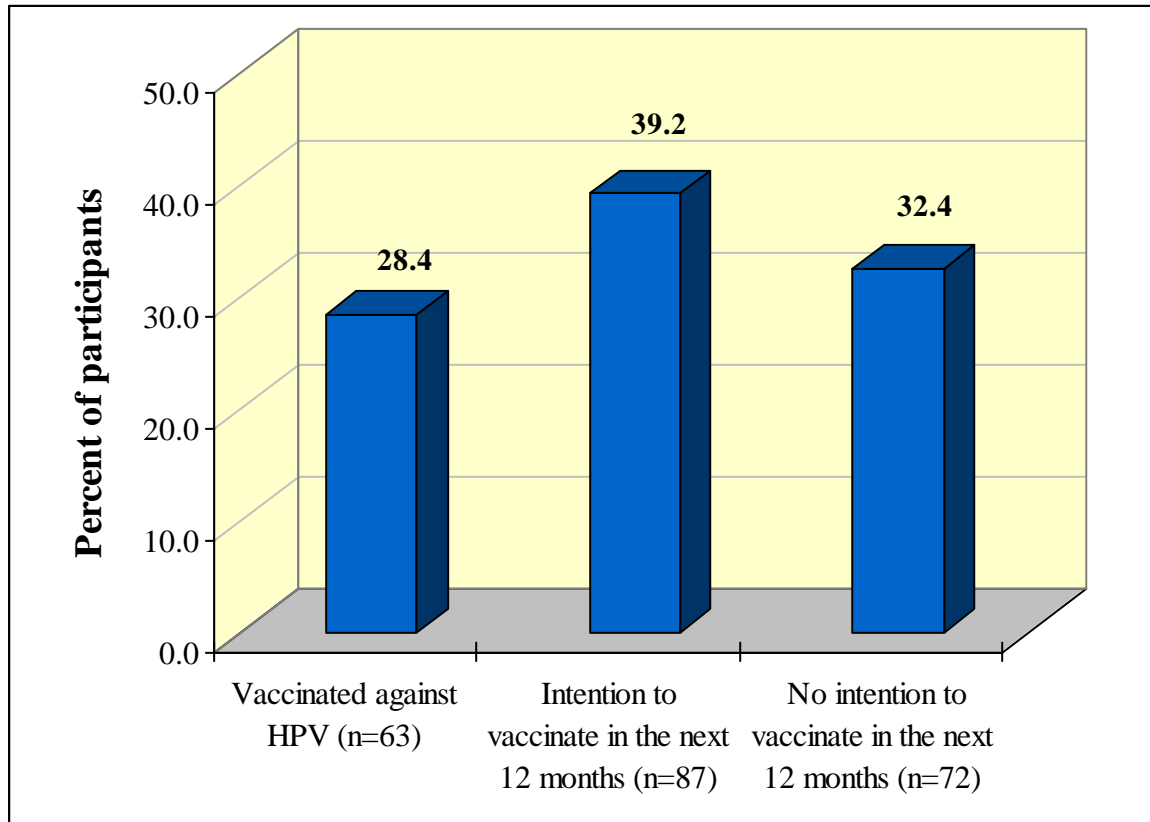
<b>Variable</b>	<b>n (%)</b>
Parents' age (years) (mean $\pm$ SD) (n=225)	44.21 $\pm$ 5.61
Gender (n=225)	
Female	209 (92.89)
Male	16 (7.11)
Ethnicity (n=229)	
Maori	18 (7.86)
Pacific Island	15 (6.55)
Asian	14 (6.11)
European and other	182 (79.48)
Highest level of education completed (n=228)	
Less than high school	8 (3.51)
High school qualification	79 (34.65)
1 to 3 years university	66 (28.95)
Bachelors degree	49 (21.49)
More than Bachelors degree	26 (11.40)
Marital status (n=224)	
Married	158 (70.54)
De facto (living with partner)	24 (10.71)
Divorced	19 (8.48)
Separated	13 (5.80)
Widowed	1 (0.45)
Never married	9 (4.02)
Religious affiliation (n=222)	
Christian - Roman Catholic	55 (24.77)
Christian - Protestant	60 (27.03)
Christian, unspecified	8 (3.60)
None	89 (40.09)
Other	10 (4.50)

**Table 16: Baseline characteristics of adolescent daughters of participating parents**

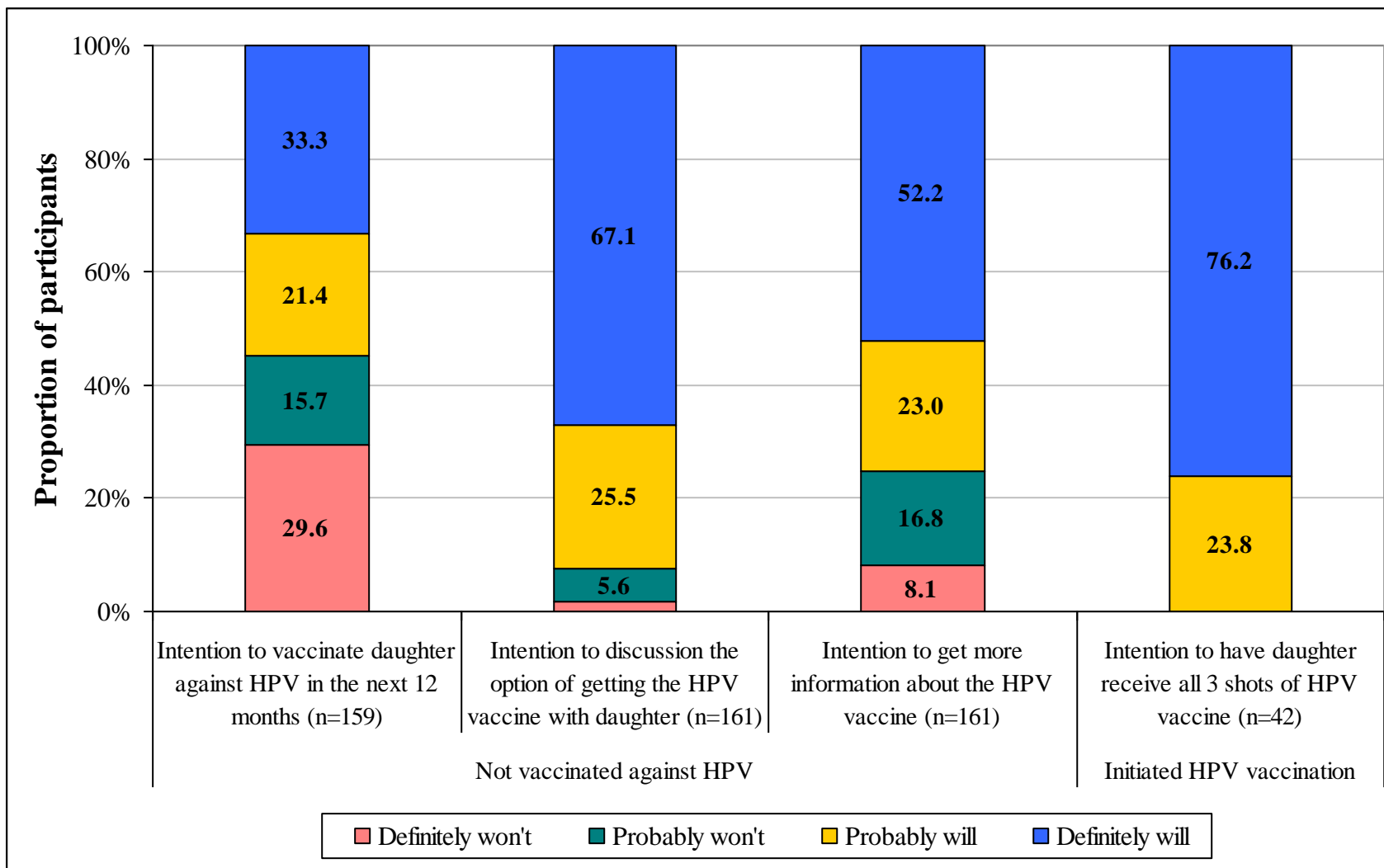
<b>Variable</b>	<b>n (%)</b>
Girls' age (years) (median; range) (n=225)	12.50 (10.83 – 16.16)
School decile ranking (socioeconomic indicator) (n=226)	
≤ Decile 7 (lower SES)	72 (31.86)
> Decile 7 (higher SES)	154 (68.14)
Vaccinated against HPV (n=227)	
Yes	63 (27.75)
No	157 (69.16)
Don't know	7 (3.08)
Vaccinated for childhood illnesses (n=227)	
Vaccinated for ALL childhood illnesses	201 (88.55)
Vaccinated for SOME childhood illnesses	16 (7.05)
Not vaccinated for childhood illnesses	5 (2.20)
Don't know	5 (2.20)
Vaccinated for meningitis / meningococcal B (n=224)	
Yes	189 (84.38)
No	22 (9.82)
Don't know	13 (5.80)
<b><i><u>Only girls vaccinated against HPV by baseline (n=63)</u></i></b>	
Number of HPV vaccine shots received by baseline (n=61)	
One shot	33 (54.10)
Two shots	8 (13.11)
Three shots	20 (32.79)
Parent paid for HPV vaccine (n=62)	
Yes	0 (0.0)
No	62 (100.0)

### 6.4.3 *Girls' HPV vaccination status at baseline*

The HPV vaccination status of girls at baseline (n=222) was categorized as: initiation of HPV vaccination; parental intention to vaccinate daughters within 12 months; and no intention by parents to vaccinate daughters within 12 months. At baseline, almost three-quarters of girls had *not* initiated HPV vaccination (Figure 5).



**Figure 5: Parental report of HPV vaccine uptake at baseline and intention to vaccinate daughters in the next 12 months (n=222)**



**Figure 6: Parental intention to vaccinate and/or discuss HPV vaccination with daughters, and intention to obtain more information about the HPV vaccine**

Parents whose daughters had initiated HPV vaccination were mostly confident in their intention to ensure that daughters received all three injections of the HPV vaccine (Figure 6). Other than reporting on vaccination intentions, the majority of parents whose daughters were unvaccinated (n=161) intended to discuss the option of getting the HPV vaccine with their daughters. In addition, three-quarters of parents with unvaccinated daughters reported that they intended to obtain more information about the HPV vaccine.

#### **6.4.4 Parents' HPV-related knowledge, attitudes and beliefs**

Before completing the questionnaire, the majority (96.4%) of parents had heard of the HPV vaccine and 83% were aware that HPV is a sexually transmitted virus (Table 17). In addition, about two-thirds of parents knew that the HPV vaccine, Gardasil®, also prevents genital warts, and were aware that vaccinating girls against HPV at a younger age would likely result in a better protective effect. Over four-fifths of parents agreed that boys should also be vaccinated against HPV given that it is a sexually transmitted virus.

Majority (86%) of parents supported an HPV vaccine that prevents both cervical cancer and genital warts. The median ages at which parents felt that females should be vaccinated against HPV and thought females would be responsible enough to make decisions about sexual relationships were ages 13 years and 17 years, respectively. The median of the highest amount that parents would be willing to pay for HPV vaccination was about 9-10 times less than the actual cost of the vaccination series.



**Table 17: Parents' HPV-related knowledge, attitudes and beliefs**

<b>Variable</b>	<b>n (%)</b>
Had heard of the HPV vaccine (n=225)	217 (96.44)
Knew that HPV is a sexually transmitted virus (n=223)	185 (82.96)
Knew that the HPV vaccine, Gardasil®, also protects against genital warts (n=223)	144 (64.57)
Knew that vaccinating girls against HPV at a younger age increases chances for better protection (n=221)	148 (66.97)
Whether boys should also be vaccinated against HPV, given that it is a sexually transmitted virus (n=217)	186 (85.71)
HPV vaccine most acceptable to parents (n=219)	
An HPV vaccine preventing cervical cancer ONLY	5 (2.28)
An HPV vaccine preventing cervical cancer and genital warts	189 (86.30)
None of the above	25 (11.42)
Preferred age (years) for girls/women to be vaccinated against HPV (median; range) (n=186)	13.00 (9.00 – 50.00)
Age at which young women are responsible enough to make decisions about sexual relationships (median; range) (n=209)	17.00 (11.00 – 30.00)
The highest amount (NZD) parents would be willing to pay for the HPV vaccine (median; range) (n=161)	\$50.00 (\$1.00 – \$500.00)

### 6.4.5 *Parents' vaccination and health experiences*

About one-third of participants reported that they or someone close to them had experienced cervical cancer, and almost twice as many reported that they or someone close to them had experienced an abnormal cervical/Pap smear (Table 18).

With regard to past vaccination experiences with any child, 21% of parents had previously chosen to *delay* a recommended vaccination. A slightly lower proportion had chosen *not to have* a recommended vaccination, reported that a child had previously had a bad reaction to a vaccination, or had regretted a decision to vaccinate a child. Among parents who had previously chosen *not to have* a child vaccinated (n=38), none reported regretting these decisions.

**Table 18: Parents' vaccination and health experiences**

Variable	n (%)
Parent/someone close to parent has experienced an abnormal Pap smear (n=221)	138 (62.44)
Parent/someone close to parent has experienced cervical cancer (n=219)	70 (31.96)
Parent/someone close to parent has experienced a STI (n=221)	107 (48.42)
Ever chosen to <u>delay</u> a recommended vaccine for any child (n=219)	45 (20.55)
Ever chosen <u>not to have</u> a recommended vaccine for any child (n=221)	38 (17.19)
Whether any child has ever had a bad reaction to a vaccination (n=219)	34 (15.53)
Ever regretted the decision to have any child vaccinated (n=218)	34 (15.60)
STI, Sexually Transmitted Infection	

## **6.5 Bivariate analyses results**

### **6.5.1 *Sociodemographic factors associated with girls' HPV vaccination status***

There were significant differences in girls' baseline HPV vaccination status by parents' age, girls' age and school decile ranking, but not by parents' education level or their religious affiliation (Table 19).

Parents who intended to vaccinate daughters against HPV were significantly younger than both parents who did not intend to do so and whose daughters had initiated HPV vaccination. Girls who had initiated HPV vaccination were significantly older than those who had not.

The proportion of parents who intended to vaccinate daughters against HPV in the next 12 months was significantly greater among those whose daughters attended schools ranked decile seven or less (lower SES), than among parents whose daughters attended schools ranked above decile seven (higher SES). However, the proportion of girls who had initiated HPV vaccination was relatively comparable among those attending schools ranked above decile seven and schools ranked decile seven or less.

**Table 19: Bivariate analysis of sociodemographic factors with girls' baseline HPV vaccination status**

Variable	Vaccinated against HPV (n=63)	Intention to vaccinate daughters in the next 12 months		p-value
		Yes (n=87)	No (n=72)	
Parents' age (years) (mean ± SD)	45.1 ± 5.5	42.4 ± 5.6	45.5 ± 5.5	0.001 <sup>a</sup>
Girls' age (years) (median; range)	13.5 (11.3 – 16.0)	12.1 (10.8 – 15.7)	12.5 (10.8 – 16.2)	<0.001 <sup>b</sup>
School decile ranking (n, %)				
≤ Decile 7	17 (24.29)	38 (54.29)	15 (21.43)	0.007 <sup>c</sup>
> Decile 7	46 (30.46)	49 (32.45)	56 (37.09)	
Parents' highest level of education completed (n, %)				
Less than high school/ High school qualification	24 (28.57)	40 (47.62)	20 (23.81)	0.086 <sup>c</sup>
1 to 3 years university	15 (23.81)	20 (31.75)	28 (44.44)	
Bachelors degree/ More than Bachelors degree	24 (32.00)	27 (36.00)	24 (32.00)	
Parents' religious affiliation (n, %)				
Christian - Roman Catholic	17 (32.08)	16 (30.19)	20 (37.74)	0.220 <sup>c</sup>
Christian - Protestant	19 (32.20)	19 (32.20)	21 (35.59)	
None	21 (23.86)	42 (47.73)	25 (28.41)	

<sup>a</sup> Analysis of variance for unbalanced designs<sup>b</sup> Kruskal-Wallis test<sup>c</sup> Chi-Square test

### **6.5.2 *HPV-related knowledge and attitudes associated with girls' HPV vaccination status***

Girls' baseline HPV vaccination status was significantly related to: parents' awareness that HPV is a sexually transmitted virus; parents' awareness that Gardasil® also protects against genital warts; and the belief that boys should be vaccinated against HPV (Table 20). However, whether or not parents knew that vaccinating girls against HPV at a younger age increases the chances for better protection was unrelated to girls' HPV vaccination status.

Awareness that HPV is a sexually transmitted virus or that Gardasil® also protects against genital warts appeared to be deterrents of parental intentions to vaccinate daughters against HPV. Among parents who aware HPV is a sexually transmitted virus, one-third intended to vaccinate their daughters against HPV within 12 months, whereas two-thirds intend to do so among parents not aware that the virus was sexually transmitted. In addition, the proportion of parents who intended to vaccinate daughters against HPV was lower among parents who knew that Gardasil® also protects against genital warts than among those who did not know this before the survey (32% vs. 52%).

Parents' intentions to vaccinate daughters against HPV and initiation of HPV vaccination by daughters was greater among parents who believed that boys should be vaccinated against HPV given that it is a sexually transmitted virus. The inverse was observed whereby the proportion of parents without the intention to vaccinate daughters was much lower among those who believed that boys should be vaccinated against HPV than those who did not (25% vs. 73%).

**Table 20: Bivariate analysis of parents' HPV-related knowledge and attitudes with girls' baseline HPV vaccination status**

Variable	Vaccinated against HPV (n=63)	Intention to vaccinate daughters in the next 12 months		p-value
		Yes (n=87)	No (n=72)	
Knew that HPV is a sexually transmitted virus (n, %)				
Yes	52 (28.57)	63 (34.62)	67 (36.81)	0.002 <sup>a</sup>
No	10 (27.03)	23 (62.16)	4 (10.81)	
Knew that the HPV vaccine, <i>Gardasil</i> <sup>®</sup> , also protects against genital warts (n, %)				
Yes	41 (28.87)	46 (32.39)	55 (38.73)	0.007 <sup>b</sup>
No	21 (27.27)	40 (51.95)	16 (20.78)	
Knew that vaccinating girls against HPV at a younger age increases chances for better protection (n, %)				
Yes	48 (32.65)	53 (36.05)	46 (31.29)	0.125 <sup>b</sup>
No	14 (20.00)	33 (47.14)	23 (32.86)	
Whether boys should also be vaccinated against HPV, given that it is a sexually transmitted virus (n, %)				
Yes	58 (31.69)	79 (43.17)	46 (25.14)	<0.001 <sup>a</sup>
No	4 (13.33)	4 (13.33)	22 (73.33)	

<sup>a</sup> Fisher's Exact test<sup>b</sup> Chi-Square test

### **6.5.3 *Parents' health experiences associated with girls' HPV vaccination status***

Parents' personal or familial history with abnormal cervical smears, cervical cancer and STIs were not significantly related to girls' HPV vaccination status (Table 21). Therefore, among parents who had experienced these health conditions, the proportion who intended to vaccinate their daughters against HPV or whose daughters who had initiated HPV vaccination did not differ significantly from the proportion among parents without such experiences.

### **6.5.4 *Parents' vaccination experiences associated with girls' HPV vaccination status***

Girls' HPV vaccination status was significantly related to whether parents had ever chosen to delay or not to have a recommended vaccine, regretted the decision to vaccinate a child, and had a child experience an adverse reaction to a vaccine (Table 22). Parents who had ever chosen to delay or not to have a recommended vaccine, regretted the decision to vaccinate a child, or had a child experience an adverse reaction to a vaccine were less likely to have daughters who had initiated HPV vaccination or to report that they intended to do so in the next 12 months.

**Table 21: Bivariate analysis of parents' health experiences with girls' baseline HPV vaccination status**

Variable	Vaccinated	Intention to vaccinate daughters		p-value *
	against HPV	in the next 12 months		
	(n=63)	Yes (n=87)	No (n=72)	
	n (%)	n (%)	n (%)	
Parent (or someone close) experienced an abnormal Pap smear				
No	23 (27.71)	27 (35.53)	33 (39.76)	0.131
Yes	38 (28.36)	59 (44.03)	37 (27.61)	
Parent (or someone close) has experienced cervical cancer				
No	44 (29.93)	58 (39.46)	45 (30.61)	0.542
Yes	16 (23.53)	27 (39.71)	25 (36.76)	
Parent (or someone close) has experienced a STI				
No	37 (32.74)	38 (33.63)	38 (33.63)	0.130
Yes	24 (23.08)	48 (46.15)	32 (30.77)	

\* Chi-Square test



**Table 22: Bivariate analysis of parents' vaccination experiences with girls' baseline HPV vaccination status**

Variable	Vaccinated	Intention to vaccinate daughters		p-value *
	against HPV	in the next 12 months		
	(n=63)	Yes (n=87)	No (n=72)	
	n (%)	n (%)	n (%)	
Ever chosen to <u>delay</u> a recommended vaccine for any child				
No	55 (32.16)	75 (43.86)	41 (23.98)	<0.001
Yes	5 (11.36)	11 (25.00)	28 (63.64)	
Ever chosen <u>not to have</u> a recommended vaccine for any child				
No	57 (31.84)	82 (45.81)	40 (22.35)	<0.001
Yes	4 (10.53)	4 (10.53)	30 (78.95)	
Whether any child has ever had a bad reaction to a vaccination				
No	55 (30.39)	76 (41.99)	50 (27.62)	0.003
Yes	6 (17.65)	8 (23.53)	20 (58.82)	
Ever regretted the decision to have any child vaccinated				
No	55 (30.56)	79 (43.89)	46 (25.56)	<0.001
Yes	5 (14.71)	6 (17.65)	23 (67.65)	

\* Fisher's Exact test

### 6.5.5 *Relationship between anticipated regret and girls' HPV vaccination status*

**Hypothesis:** Compared to parents who do not intend to vaccinate daughters against HPV in the next twelve months, parents who intend to do so or whose daughters have initiated vaccination will have: *higher* levels of anticipated regret in the event that *daughters are unvaccinated and contract an HPV infection that could lead to cervical cancer*; *higher* levels of anticipated regret in the event that *daughters are unvaccinated and contract genital warts*; and *lower* levels of anticipated regret in the event that *daughters are vaccinated and become sexually active at an early age*.

There were significant differences by girls' HPV vaccination status in parental *inaction* regret measures, but not in the *action* regret measure (Table 23).

As hypothesized, parents' anticipated regret in the event that daughters were unvaccinated and contracted an HPV infection that could lead to *cervical cancer* was significantly lower among parents who did not intend to vaccinate daughters against HPV, than both among parents who intended to do so and those whose daughters had initiated HPV vaccination. A similar pattern was observed for parents' anticipated regret in the event that daughters were unvaccinated and contracted *genital warts*. There was no significant difference between parents whose daughters had initiated HPV vaccination and those who intended to do so within 12 months in levels of anticipated regret in the event that daughters were unvaccinated and contracted an HPV infection that could lead to *cervical cancer* ( $p=0.208$ , Wilcoxon Rank Sums test) or contracted *genital warts* ( $p=0.209$ , Wilcoxon Rank Sums test). In addition, regardless of their daughters' HPV vaccination status, parents had higher levels of anticipated regret regarding cervical cancer than genital warts, possibly due to the greater seriousness of the former.

Contrary to the hypothesis, parents' anticipated regret in the event that daughters were vaccinated and initiated sexual activity at an early age was unrelated to their daughters' HPV vaccination status at baseline.

**Table 23: Bivariate analysis of anticipated regret measures with girls' baseline HPV vaccination status**

Measure	Vaccinated against HPV (n=63)		Intention to vaccinate daughters in the next 12 months				p-value *
			Yes (n=87)		No (n=72)		
	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD	
Parental regret if daughter did NOT get the HPV vaccine and got an HPV infection that led to cervical cancer	60	3.88 ± 0.37	86	3.79 ± 0.49	67	2.81 ± 1.14	<0.001
Parental regret if daughter did NOT get HPV vaccine and got genital warts	60	3.80 ± 0.44	86	3.67 ± 0.58	67	2.67 ± 1.13	<0.001
Parental regret if daughter was vaccinated for HPV and initiated sexual activity at an early age	59	2.75 ± 1.21	84	2.73 ± 1.20	67	2.97 ± 1.19	0.353

\* Kruskal-Wallis test

SD, standard deviation

### 6.5.6 *Relationship between parental worry and girls' HPV vaccination status*

**Hypotheses:** Compared to parents whose daughters have initiated HPV vaccination, parents with and without the intention to vaccinate daughters in the next twelve months will have *higher* levels of worry regarding *HPV*, *genital warts*, and *cervical cancer*.

Bivariate associations of parental worry measures with girls' HPV vaccination status at baseline did not vary regardless of whether the analysis was restricted to respondents with non-missing data for the three items used to calculate a total score (the *worry* item, *concern* item and *thinking* item), or if the analysis included imputed data for participants missing one or two of the three items (Table 24). Therefore, further analyses were done using the worry variables that included participants with imputed data (refer to statistical analysis section for details).

Levels of parental worry about HPV, genital warts and cervical cancer all differed significantly by girls' baseline HPV vaccination status. As hypothesized, compared to parents who intended to vaccinate daughters within 12 months, parents whose daughters had initiated HPV vaccination had significantly lower mean levels of worry regarding *HPV*, *genital warts* and *cervical cancer*. Therefore, vaccinating daughters against HPV appears to have reduced parental worry about these health conditions, relative to parents intending to vaccinate daughters within 12 months. However, parents whose daughters had initiated HPV vaccination and those who did not intend to vaccinate daughters within 12 months had comparable levels of worry regarding HPV, genital warts and cervical cancer (respectively,  $p=0.722$ ,  $p=0.698$  and  $p=0.389$ ; Wilcoxon Rank Sums test). Regardless of their daughters HPV vaccination status, parents had higher levels of worry about cervical cancer than genital warts or HPV, possibly because cervical cancer is more serious.

**Table 24: Bivariate analysis of parental worry measures with girls' baseline HPV vaccination status**

Variable	Vaccinated against HPV (n=63)		Intention to vaccinate daughters in the next 12 months				p-value *
			Yes (n=87)		No (n=72)		
	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD	
<b><i>Complete (non-missing) data only</i></b>							
Parental worry regarding <u>HPV</u>	59	6.64 ± 2.38	86	7.92 ± 2.57	68	6.81 ± 2.53	0.007
Parental worry regarding <u>genital warts</u>	58	6.40 ± 2.61	86	7.84 ± 2.60	68	6.59 ± 2.56	0.002
Parental worry regarding <u>cervical cancer</u>	59	7.97 ± 2.98	86	9.10 ± 2.57	68	7.59 ± 2.72	0.003
<b><i>Including imputed data for missing items</i></b>							
Parental worry regarding <u>HPV</u>	60	6.68 ± 2.38	86	7.92 ± 2.57	70	6.85 ± 2.58	0.009
Parental worry regarding <u>genital warts</u>	59	6.49 ± 2.69	86	7.84 ± 2.60	70	6.64 ± 2.62	0.003
Parental worry regarding <u>cervical cancer</u>	60	8.03 ± 3.00	86	9.10 ± 2.57	70	7.63 ± 2.74	0.004

\* Kruskal-Wallis test

SD, standard deviation

### 6.5.7 *Relationship between HBM variables and girls' HPV vaccination status*

**Hypotheses:** Compared to parents whose daughters have initiated HPV vaccination and parents who intend to vaccinate daughters in the next twelve months, parents without the intention to vaccinate daughters in the next twelve months will: rate *higher* on *perceived barriers* of HPV vaccination; rate *lower* on *cues to action* to vaccinate daughter against HPV; rate *lower* on *perceived likelihood* of HPV-related illnesses if daughters are not vaccinated against HPV; rate *lower* on *perceived severity* of HPV and cervical cancer; and rate *lower* on *perceived effectiveness* of the HPV vaccine.

There were significant bivariate associations between girls' HPV vaccination status at baseline and parental report on the following: cues to action to vaccinate daughters against HPV; perceived likelihood of HPV-related illnesses without the HPV vaccine; perceived severity of HPV and cervical cancer; and perceived effectiveness of the HPV vaccine (Table 25). The observed associations were as hypothesized.

The positive influence to parents of recommendations by their general practitioner and family or friends to vaccinate their daughters against HPV (cues to action) were rated significantly *higher* by parents whose daughters had initiated HPV vaccination and those who intended to do so within 12 months, than by parents who did not intend to vaccinate daughters within 12 months. On this measure, however, there was no significant difference between parents whose daughters had initiated HPV vaccination and those who intended to do so within 12 months ( $p=0.699$ , Wilcoxon Rank Sums test).

The perceived likelihood of girls getting HPV infections, cervical cancer and genital warts without the HPV vaccine was rated significantly *lower* by parents who did not intend to vaccinate daughters against HPV within 12 months, than by both parents whose daughters had initiated HPV vaccination and those who intended to do so within 12 months. In contrast, perceived likelihood of HPV-related illnesses without the vaccine did not differ between parents whose daughters had initiated HPV vaccination and those who intended to do so within 12 months ( $p=0.632$ , Wilcoxon Rank Sums test).

Parents whose daughters had initiated HPV vaccination and those who intended to do so within 12 months perceived HPV and cervical cancer as having *more severe consequences* to their daughters' health, than parents who did not intend to vaccinate daughters against HPV within 12 months. However, perceived severity of HPV and cervical cancer was comparable among parents whose daughters had initiated HPV vaccination and parents who intended to vaccinate daughters within 12 months ( $p=0.318$ , Wilcoxon Rank Sums test).

The HPV vaccine was perceived as *more effective* in reducing the likelihood of HPV infections, cervical cancer and genital warts in girls by parents whose daughters had initiated HPV vaccination and those who intended to do so within 12 months, compared to parents who did not intend to vaccinate daughters within 12 months. Parents who intended to vaccinate daughters within 12 months and parents whose daughters had initiated HPV vaccination had comparable ratings on the perceived effectiveness of the HPV vaccine ( $p=0.417$ , Wilcoxon Rank Sums test).

Parents' ratings on their concerns about potential HPV vaccine side-effects, objection to vaccines in general, and daughters' fear of needles were all related to their daughters' HPV vaccination status (Table 26). However, contrary to the hypotheses, girls' HPV vaccination status was unrelated to: parents' level of concern that girls vaccinated against HPV would initiate sexual activity at an earlier age; and whether parents' awareness that HPV is sexually transmitted affected their support for or opposition to HPV vaccination.

As hypothesized, potential side-effects of the HPV vaccine side-effects were of *most concern* to parents who did not intend to vaccinate daughters against HPV and of least concern to parents whose daughters had initiated HPV vaccination. Compared to parents whose daughters had initiated HPV vaccination, concern about HPV vaccine side-effects was rated significantly higher both by parents who intended to vaccinate daughters within 12 months and those who did not intend to do so. In addition, concern about HPV vaccine side effects was rated significantly higher by parents who did not intend to vaccinate daughters against HPV within 12 months than by parents intended to do so ( $p<0.001$ , Wilcoxon Rank Sums test).

Fear of needles by daughters was rated significantly *higher* by parents who intended to vaccinate daughters within 12 months, than both by parents whose daughters had initiated HPV vaccination and parents who did not intend to vaccinate daughters within 12 months. The two latter groups of parents did not differ in their views of the extent to which their daughters were afraid of needles ( $p=0.111$ , Wilcoxon Rank Sums test). This observed association was in the inverse direction of the hypothesis whereby fear on needles was expected to be a vaccination barrier among girls whose parents who did not intend to have them vaccinated within 12 months.

General opposition to vaccines was comparable between parents whose daughters had initiated HPV vaccination and parents who intended to do so within 12 months. In contrast and as hypothesized, compared to parents who did not intend to vaccinate daughters within 12 months, general opposition to vaccines was rated significantly *lower* by parents whose daughters had initiated HPV vaccination and those who intended to vaccinate daughters within 12 months.

Further analysis was done to assess whether the number of perceived barriers of HPV vaccination identified by parents was related to girls HPV vaccination status. The analysis showed that as the number of HPV vaccination barriers increased, the proportion of parents who did not intend to vaccinate daughters against HPV also increased significantly. Among parents with none or one barrier of HPV vaccination, one-fifths did not intend to vaccinate daughters within 12 months, whereas about one-half of those who identified three to five barriers of HPV vaccination had no intention of vaccinating daughters within 12 months.



**Table 25: Bivariate analysis of cues to action, perceived likelihood and severity of HPV-related illnesses, and perceived HPV vaccine effectiveness with girls' baseline HPV vaccination status**

Variable	Vaccinated against HPV (n=63)		Intention to vaccinate daughters in the next 12 months				p-value *
			Yes (n=87)		No (n=72)		
	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD	
Cues to action to vaccinate daughter against HPV	61	6.30 ± 1.22	84	6.36 ± 1.30	71	3.85 ± 1.37	<0.001
Perceived likelihood of HPV-related illnesses without HPV vaccination	57	6.89 ± 1.67	83	7.12 ± 2.04	68	5.25 ± 1.75	<0.001
Perceived severity of HPV and cervical cancer	60	3.52 ± 0.60	84	3.58 ± 0.66	71	3.30 ± 0.60	0.002
Perceived effectiveness of the HPV vaccine	60	6.85 ± 1.12	83	7.01 ± 1.04	66	5.05 ± 1.71	<0.001

\* Kruskal-Wallis test

SD, standard deviation

**Table 26: Bivariate analysis of parents' perceived barriers of HPV vaccination with girls' baseline HPV vaccination status**

Variable	Vaccinated against HPV (n=63)		Intention to vaccinate daughters in the next 12 months				p-value
			Yes (n=87)		No (n=72)		
	n	Mean ± SD	n	Mean ± SD	n	Mean ± SD	
Daughter is afraid of needles	59	2.25 ± 0.86	86	2.63 ± 0.92	69	2.04 ± 1.02	<0.001 <sup>a</sup>
Concern about HPV vaccine side-effects	59	2.59 ± 0.65	84	3.00 ± 0.74	71	3.41 ± 0.79	<0.001 <sup>a</sup>
Knowing that HPV is sexually transmitted affects parent's decision to vaccinate daughter	58	2.38 ± 0.95	85	2.38 ± 0.94	70	2.44 ± 1.02	0.906 <sup>a</sup>
Concern that girls vaccinated against HPV will become sexually active at an earlier age	61	1.79 ± 0.61	85	1.80 ± 0.81	70	2.06 ± 0.90	0.110 <sup>a</sup>
Against vaccines in general	61	1.44 ± 0.65	85	1.41 ± 0.66	71	2.18 ± 1.03	<0.001 <sup>a</sup>
	<b>n (%)</b>		<b>n (%)</b>		<b>n (%)</b>		<b>p-value</b>
Number of perceived barriers of HPV vaccination							
None or 1 barrier	33	(40.24)	32	(39.02)	17	(20.73)	0.002 <sup>b</sup>
2 barriers	21	(25.30)	34	(40.96)	28	(33.73)	
3 to 5 barriers	7	(13.21)	20	(37.74)	26	(49.06)	

<sup>a</sup> Kruskal-Wallis test<sup>b</sup> Fisher's Exact test

SD, standard deviation

### 6.5.8 *Correlations between psychological measures*

Spearman correlations between psychological measures that were significantly related to girls' baseline HPV vaccination status in the bivariate analysis are displayed in Table 27.

Parental regret in the event that daughters were vaccinated and initiated sexual activity at an early age was only significantly correlated with one psychological measure, showing a very weak positive correlation with parental worry regarding cervical cancer ( $r=.15$ ). On the other hand, the two action regret measures were significantly correlated with each other and with several of the other psychological measures. Parents' anticipated regret in the event that daughters were unvaccinated and contracted an HPV infection that could lead to cervical cancer had a strong positive correlation with parents' anticipated regret in the event that daughters were unvaccinated and contracted genital warts ( $r=.82$ ). In addition, these two inaction regret measures had significant moderate positive correlations with cues to action to vaccinate daughters against HPV ( $r=.51$ ) and perceived HPV vaccine effectiveness ( $r=.4$ ). However, both inaction regret measures had significant but very weak to weak positive correlations with the three worry measures, perceived likelihood of HPV-related illnesses without the vaccine, and perceived severity of HPV and cervical cancer. Parents' concerns about HPV vaccine side-effects and parents' general opposition to vaccines also had significant weak negative correlations with both action regret variables.

The three worry measures were significantly correlated with each other. Parental worry about HPV had a very strong positive correlation with parental worry about genital warts ( $r=.91$ ) and a strong positive correlation with parental worry regarding cervical cancer ( $r=.76$ ). There was also a strong positive correlation between the measures of parental worry regarding genital warts and cervical cancer ( $r=.79$ ). All three worry measures had significant: weak positive correlations with cues to action to vaccinate daughter against HPV; moderate positive correlations with perceived likelihood of HPV-related illnesses without the vaccine; and very weak to weak positive correlations with perceived HPV vaccine effectiveness and daughters' fear of needles. However, parents' concerns about HPV side-effects and their opposition to vaccines in general were both not correlated with any of the worry measures. Although perceived severity of HPV and cervical

cancer had a significant but very weak correlation with parental worry regarding cervical cancer ( $r=.19$ ), it was not correlated with the other two worry measures.

Cues to action to vaccinate daughters against HPV, perceived likelihood of HPV-related illnesses without the vaccine, perceived severity of HPV and cervical cancer, and perceived HPV vaccine effectiveness had weak to moderate significant correlations with each other. Perceived HPV vaccine effectiveness was moderately correlated with cues to action to vaccinate daughters against HPV ( $r=.56$ ), but weakly correlated with perceived likelihood of HPV-related illnesses without the vaccine ( $r=.42$ ) and perceived severity of HPV and cervical cancer ( $r=.41$ ). In addition, cues to action to vaccinate daughters against HPV had a moderate correlation with perceived likelihood of HPV-related illnesses without the vaccine ( $r=.46$ ) and a weak correlation with perceived severity of HPV and cervical cancer ( $r=.33$ ). Only a very weak borderline association ( $p=0.05$ ) was observed between perceived likelihood of HPV-related illnesses without the vaccine and perceived severity of HPV and cervical cancer ( $r=.13$ ).

Fear of needles by adolescent girls had very weak significant correlations with cues to action to vaccinate daughters against HPV ( $r=.17$ ), perceived likelihood of HPV-related illnesses without the vaccine ( $r=.15$ ) and perceived HPV vaccine effectiveness ( $r=.15$ ). On the other hand, it was not significantly correlated with perceived severity of HPV and cervical cancer, parents' concerns about HPV side-effects, and parents' general opposition to vaccines. Parents' concerns about potential HPV vaccine side-effects had a very weak significant positive correlation with parents' general opposition to vaccines ( $r=.17$ ), but weak significant negative correlations with cues to action to vaccinate daughters against HPV ( $r=-.28$ ), perceived likelihood of HPV-related illnesses without the vaccine ( $r=-.24$ ) and perceived HPV vaccine effectiveness ( $r=-.36$ ). Furthermore, parents' general opposition to vaccines had significant negative correlations with cues to action to vaccinate daughters against HPV ( $r=-.36$ ), perceived severity of HPV and cervical cancer ( $r=-.36$ ) and perceived HPV vaccine effectiveness ( $r=-.47$ ). However, it had a very weak negative correlation with perceived likelihood of HPV-related illnesses in girls without the vaccine ( $r=-.15$ ).

**Table 27: Spearman Correlation Coefficients (*r*) for psychological measures**

Measure	Var 1	Var 2	Var 3	Var 4	Var 5	Var 6	Var 7	Var 8	Var 9	Var 10	Var 11	Var 12	Var 13
	<i>r</i>	<i>r</i>	<i>r</i>	<i>r</i>	<i>r</i>	<i>r</i>	<i>r</i>	<i>r</i>	<i>r</i>	<i>r</i>	<i>r</i>	<i>r</i>	<i>r</i>
<b>Var 1</b>	1.00	.82*	.11	.29*	.31*	.34*	.51*	.38*	.26*	.43*	.13 <sup>†</sup>	-.23*	-.38*
<b>Var 2</b>	.82*	1.00	.07	.30*	.37*	.28*	.51*	.37*	.25*	.39*	.18*	-.25*	-.32*
<b>Var 3</b>	.11	.07	1.00	.11	.09	.15*	-.04	.02	-.01	-.01	-.06	.07	.06
<b>Var 4</b>	.29*	.30*	.11	1.00	.91*	.76*	.27*	.40*	.12	.19*	.18*	.04	.01
<b>Var 5</b>	.31*	.37*	.09	.91*	1.00	.79*	.32*	.44*	.10	.17*	.19*	-.01	-.01
<b>Var 6</b>	.34*	.28*	.15*	.76*	.79*	1.00	.34*	.37*	.19*	.18*	.20*	.04	-.07
<b>Var 7</b>	.51*	.51*	-.04	.27*	.32*	.34*	1.00	.46*	.33*	.56*	.17*	-.28*	-.36*
<b>Var 8</b>	.38*	.37*	.02	.40*	.44*	.37*	.46*	1.00	.13 <sup>†</sup>	.42*	.15*	-.24*	-.15*
<b>Var 9</b>	.26*	.25*	-.01	.12	.10	.19*	.33*	.13 <sup>†</sup>	1.00	.41*	.05	-.04	-.36*
<b>Var 10</b>	.43*	.39*	-.01	.19*	.17*	.18*	.56*	.42*	.41*	1.00	.15*	-.36*	-.47*
<b>Var 11</b>	.13 <sup>†</sup>	.18*	-.06	.18*	.19*	.20*	.17*	.15*	.05	.15*	1.00	.08	-.03
<b>Var 12</b>	-.23*	-.25*	.07	.04	-.01	.04	-.28*	-.24*	-.04	-.36*	.08	1.00	.17*
<b>Var 13</b>	-.38*	-.32*	.06	.01	-.01	-.07	-.36*	-.15*	-.36*	-.47*	-.03	.17*	1.00

\* Statistically significant (p-value &lt;0.05)

<sup>†</sup> Borderline association (p-value = 0.05)**Measure**   **Description**

Var 1: Parental regret if daughter did NOT get the HPV vaccine and got an HPV infection that led to cervical cancer

Var 2: Parental regret if daughter did NOT get HPV vaccine and got genital warts

Var 3: Parental regret if daughter was vaccinated for HPV and initiated sexual activity at an early age

Var 4: Parental worry regarding HPV

- Var 5: Parental worry regarding genital warts
- Var 6: Parental worry regarding cervical cancer
- Var 7: Cues to action to vaccinate daughter against HPV
- Var 8: Perceived likelihood of HPV-related illnesses in unvaccinated girls
- Var 9: Perceived severity of HPV and cervical cancer
- Var 10: Perceived effectiveness of the HPV vaccine
- Var 11: My daughter is afraid of needles
- Var 12: I am concerned that the HPV vaccine may have side-effects
- Var 13: I am against vaccines in general

## 6.6 Multivariate analyses results

The results presented here are from analyses of the relationship between psychological measures and HPV vaccination status, while adjusting (controlling) for factors that were significant or approaching significance ( $p < 0.10$ ) in the bivariate analyses.

### 6.6.1 *Anticipated regret*

#### *Parents' anticipated regret in the event that daughters were unvaccinated and contracted an HPV infection that led to cervical cancer*

Findings from the multivariate logistic regression analysis showed that after adjusting for demographics and other factors, parents' anticipated regret in the event that *daughters are unvaccinated and contract an HPV infection that could lead to cervical cancer* was an independent predictor of: 1) initiation of HPV vaccination by adolescent girls; and 2) parents' intentions to vaccinate daughters within 12 months (Table 28).

With increasing anticipated regret in the event that daughters are unvaccinated and contract an HPV infection that could lead to cervical cancer, parents were more likely to have daughters who had initiated HPV vaccination (OR=4.99; 95% CI=2.23–11.16). A similar association of lesser magnitude was observed for parents who intended to vaccinate daughters within 12 months (OR=2.78; 95% CI=1.50–5.13).

For both initiation of HPV vaccination and parental intention to vaccinate within 12 months, other independent predictors were perceived likelihood of HPV-related illnesses without HPV vaccination and parents' lack of awareness that Gardasil® also prevents genital warts. With increasing levels of their perceived likelihood of HPV-related illnesses in daughters if they were not vaccinated, parents were more likely to have daughters who had initiated HPV vaccination or report their intention to do so within 12 months. In addition, parents who were unaware that Gardasil® also prevents genital warts were more likely to have daughters who had initiated HPV vaccination or intended to do so within 12 months.

On the other hand, girls' age was an independent predictor of initiation of HPV vaccination, but not of parents' intentions to vaccinate daughters against HPV within 12 months. The probability of initiation of HPV vaccination by adolescent girls increased significantly as girls' age increased; the odds of parents having daughters who had initiated HPV vaccination over parents not intending to vaccinate daughters against HPV within 12 months increased by a factor of 2.12 every year.

Parents' age and education, perceived severity of HPV and cervical cancer, and school decile ranking were not independent predictors of initiation of HPV vaccination by adolescent daughters in this multivariate model.



**Table 28: Multinomial logistic regression analysis for parents' anticipated regret in the event that daughters were unvaccinated and contracted an HPV infection that led to cervical cancer (n=199)**

Variable	‡ Adjusted OR (95% CI)	
	† Vaccinated against HPV (n=56)	† Parents intend to vaccinate in the next 12 months (n=81)
Regret about cervical cancer in girls	4.99 (2.23 – 11.16)*	2.78 (1.50 – 5.13)*
Girls' age (years)	2.12 (1.36 – 3.32)*	0.75 (0.48 – 1.18)
Parents' age (years)	0.93 (0.85 – 1.02)	0.92 (0.84 – 1.01)
Parents' education		
High school qualification or less	Reference	Reference
1 to 3 years university	0.81 (0.25 – 2.59)	0.89 (0.30 – 2.64)
Bachelors degree or more	1.24 (0.39 – 3.92)	1.46 (0.50 – 4.27)
School decile ranking	0.98 (0.79 – 1.22)	0.95 (0.79 – 1.14)
Perceived likelihood of HPV illnesses	1.52 (1.08 – 2.14)*	1.76 (1.28 – 2.43)*
Perceived severity of HPV illnesses	1.16 (0.55 – 2.47)	1.51 (0.75 – 3.03)
Not aware that Gardasil® prevents warts	3.59 (1.19 – 10.82)*	3.50 (1.29 – 9.49)*

† Compared to parents with no intention to vaccinate daughters in the next 12 months

‡ Adjusted for all variables shown in the table (i.e. variables are adjusted for each other)

\* Statistically significant (p<0.05)

OR, odds ratio

CI, confidence interval

*Parents' anticipated regret in the event that daughters were unvaccinated and contracted genital warts*

Parents' anticipated regret in the event that *daughters are unvaccinated and contract genital warts* was an independent predictor of both initiation of HPV vaccination by adolescent girls and parents' intentions to vaccinate daughters within 12 months (Table 29). With increasing parental anticipated regret in the event that daughters are unvaccinated and contract genital warts, parents were more likely to have daughters who had initiated HPV vaccination (OR=3.99; 95% CI=2.06–7.73). In addition, parents were more likely to report their intention to vaccinate daughters within 12 months with increasing levels of anticipated inaction regret regarding genital warts.

As with the multivariate model of parents' anticipated regret regarding cervical cancer, the multivariate model of anticipated regret in the event that daughters are unvaccinated and contract genital warts showed similar adjusted associations of covariates with HPV vaccination status. Greater perceived likelihood of HPV-related illnesses without HPV vaccination was associated with greater likelihood of parents having daughters who had been vaccinated or reporting their intention to do so within 12 months. Similarly, parents who were unaware that Gardasil® also prevents genital warts were more likely to have daughters who had initiated HPV vaccination or intended to do so within 12 months.

The probability of parents having daughters who had initiated HPV vaccination increased significantly as girls' age increased (OR=1.91; 95% CI=1.23–2.98). However, girls' age was not an independent predictor of parents' intentions to vaccinate daughters against HPV within 12 months. Other covariates in the multivariate model that were unrelated to initiation of HPV vaccination by adolescent daughters included: parents' age and education; perceived severity of HPV and cervical cancer; and school decile ranking. In addition, these covariates were not independent predictors of parents' intentions to vaccinate daughters within 12 months.

**Table 29: Multinomial logistic regression analysis for parents' anticipated regret in the event that daughters were unvaccinated and contracted genital warts (n=199)**

Variable	‡ Adjusted OR (95% CI)	
	† Vaccinated against	† Parents intend to
	HPV (n=56)	vaccinate in the next 12 months (n=81)
Regret regarding genital warts in girls	3.99 (2.06 – 7.73)*	2.82 (1.57 – 5.04)*
Girls' age (years)	1.91 (1.23 – 2.98)*	0.69 (0.44 – 1.07)
Parents' age (years)	0.93 (0.84 – 1.02)	0.92 (0.84 – 1.00)
Parents' education		
High school qualification or less	Reference	Reference
1 to 3 years university	0.70 (0.22 – 2.24)	0.79 (0.27 – 2.37)
Bachelors degree or more	1.16 (0.37 – 3.65)	1.33 (0.45 – 3.91)
School decile ranking	0.99 (0.88 – 1.22)	0.95 (0.79 – 1.15)
Perceived likelihood of HPV illnesses	1.54 (1.09 – 2.16)*	1.77 (1.28 – 2.45)*
Perceived severity of HPV illnesses	1.26 (0.60 – 2.63)	1.67 (0.84 – 3.33)
Not aware that Gardasil® prevents warts	3.28 (1.09 – 9.82)*	3.23 (1.19 – 8.79)*

† Compared to parents with no intention to vaccinate daughters in the next 12 months

‡ Adjusted for all variables shown in the table (i.e. variables are adjusted for each other)

\* Statistically significant (p<0.05)

OR, odds ratio

CI, confidence interval

*Parents' anticipated regret in the event that daughters were vaccinated and initiated sexual activity at an early age*

Unlike the action regret measures, parents' anticipated regret in the event that *daughters are vaccinated and become sexually active at an early age* was unrelated to girls' HPV vaccination status at baseline (Table 30). With increasing anticipated regret in the event that daughters are vaccinated and become sexually active at an early age, parents were no more likely to have daughters who had initiated HPV vaccination (OR=0.83; 95% CI=0.57–1.20) or to report their intention to do so within 12 months (OR=0.77; 95% CI=0.54–1.09), over intending *not* to do so.

Similar to the action regret multivariate models, perceived likelihood of HPV-related illnesses without HPV vaccination and parents' lack of awareness that Gardasil® also prevents genital warts were independent predictors of both initiation of HPV vaccination and parental intention to vaccinate within 12 months. However, the magnitude of this relationship between parents' unawareness that Gardasil® also prevents genital warts and girls' HPV vaccination status was less than observed in the action regret multivariate models.

Girls' age was an independent predictor of both initiation of HPV vaccination by adolescent girls and parents' intentions to vaccinate daughters within 12 months. With every unit increase in girls' age, the odds were 1.81 times higher of parents having daughters who had initiated HPV vaccination over parents intending *not* to vaccinate daughters against HPV within 12 months. In contrast, the odds of parents intending to vaccinate within 12 months over intending *not* to do so decreased significantly with girls' age (OR=0.65; 95% CI=0.43–0.98).

Perceived severity of HPV and cervical cancer was also an independent predictor of parents' intentions to vaccinate daughters within 12 months (OR=1.89; 95% CI=1.02–3.52), but not of initiation of HPV vaccination by adolescent girls (OR=1.38; 95% CI=0.71–2.68). On the other hand, parents' age, parents' education, and school decile ranking were not significant predictors of both initiation of HPV vaccination by adolescent girls and parents' intentions to vaccinate daughters within 12 months.

**Table 30: Multinomial logistic regression analysis for parents' anticipated regret in the event that daughters were vaccinated and initiated sexual activity at an early age (n=196)**

Variable	‡ Adjusted OR (95% CI)	
	† Vaccinated against HPV (n=55)	† Parents intend to vaccinate in the next 12 months (n=79)
Regret about early sexual activity by girls	0.83 (0.57 – 1.20)	0.77 (0.54 – 1.09)
Girls' age (years)	1.81 (1.22 – 2.68)*	0.65 (0.43 – 0.98)*
Parents' age (years)	0.95 (0.87 – 1.04)	0.93 (0.86 – 1.01)
Parents' education		
High school qualification or less	Reference	Reference
1 to 3 years university	0.67 (0.23 – 1.94)	0.78 (0.28 – 2.16)
Bachelors degree or more	1.07 (0.38 – 3.03)	1.27 (0.46 – 3.47)
School decile ranking	1.01 (0.83 – 1.22)	0.97 (0.81 – 1.15)
Perceived likelihood of HPV illnesses	1.88 (1.38 – 2.57)*	2.13 (1.57 – 2.89)*
Perceived severity of HPV illnesses	1.38 (0.71 – 2.68)	1.89 (1.02 – 3.52)*
Not aware that Gardasil® prevents warts	2.83 (1.07 – 7.48)*	2.84 (1.14 – 7.08)*

† Compared to parents with no intention to vaccinate daughters in the next 12 months

‡ Adjusted for all variables shown in the table (i.e. variables are adjusted for each other)

\* Statistically significant (p<0.05)

OR, odds ratio

CI, confidence interval

## 6.6.2 Worry

### Parental worry regarding HPV

Parental worry regarding HPV was an independent predictor of initiation of HPV vaccination by adolescent girls, but not of parents' intentions to vaccinate daughters within 12 months (Table 31). With increasing parental worry regarding HPV, parents were less likely to have daughters who had initiated HPV vaccination (OR=0.73; 95% CI=0.60–0.89), but were no more likely to report their intention to vaccinate daughters within 12 months (OR=0.99; 95% CI=0.83–1.18).

In this multivariate model, other independent predictors of both initiation of HPV vaccination and intention to vaccinate within 12 months were: perceived likelihood of HPV-related illnesses without the vaccine; parents' lack of awareness that Gardasil® also prevents genital wart; and girls' age. Higher levels of perceived likelihood of HPV-related illnesses without HPV vaccination and unaware that Gardasil® also prevents genital warts were associated with both HPV vaccination behavior and intentions. With every unit increase in girls' age, the odds were nearly two times higher of parents having daughters who had initiated HPV vaccination (OR=1.98; 95% CI=1.31–3.00) over parents intending *not* to vaccinate daughters against HPV within 12 months. Conversely, the odds of parents intending to vaccinate daughters against HPV within 12 months over intending *not* to do so decreased with an increase in girls' age (OR=0.63; 95% CI=0.42–0.92). Although perceived severity of HPV and cervical cancer was not significantly related to initiation of HPV vaccination by adolescent girls (OR=1.52; 95% CI=0.76–3.03), it was an independent predictor of parents' intentions to vaccinate daughters within 12 months (OR=1.86; 95% CI=1.01–3.41).

Parents' age and education and school decile ranking were not independent predictors of initiation of HPV vaccination by adolescent daughters in this multivariate model. For parents' intentions to vaccinate their daughters within 12 months, parents' age and education and school decile ranking were also not independent predictors.

**Table 31: Multinomial logistic regression analysis for parental worry regarding HPV (n=202)**

Variable	‡ Adjusted OR (95% CI)	
	† Vaccinated against HPV (n=56)	† Parents intend to vaccinate in the next 12 months (n=81)
Parental worry about HPV	0.73 (0.60 – 0.89)*	0.99 (0.83 – 1.18)
Girls' age (years)	1.98 (1.31 – 3.00)*	0.63 (0.42 – 0.92)*
Parents' age (years)	0.96 (0.89 – 1.05)	0.94 (0.86 – 1.02)
Parents' education		
High school qualification or less	Reference	Reference
1 to 3 years university	0.78 (0.26 – 2.29)	0.78 (0.29 – 2.16)
Bachelors degree or more	0.86 (0.30 – 2.48)	1.23 (0.45 – 3.33)
School decile ranking	0.98 (0.80 – 1.20)	0.97 (0.82 – 1.15)
Perceived likelihood of HPV illnesses	2.26 (1.61 – 3.17)*	2.18 (1.58 – 3.01)*
Perceived severity of HPV illnesses	1.52 (0.76 – 3.03)	1.86 (1.01 – 3.41)*
Not aware that Gardasil® prevents warts	3.72 (1.36 – 10.12)*	3.18 (1.27 – 7.97)*

† Compared to parents with no intention to vaccinate daughters in the next 12 months

‡ Adjusted for all variables shown in the table (i.e. variables are adjusted for each other)

\* Statistically significant (p<0.05)

OR, odds ratio

CI, confidence interval

*Parental worry regarding genital warts*

Initiation of HPV vaccination by adolescent girls was significantly related to parental worry regarding genital warts (Table 32). With increasing parental worry regarding genital warts, parents were less likely to have daughters who had initiated HPV vaccination (OR=0.74; 95% CI=0.61– 0.89), but were no more likely to report their intention to vaccinate daughters within 12 months (OR=1.00; 95% CI=0.84–1.19).

Perceived likelihood of HPV-related illnesses without the vaccine, parents' lack of awareness that Gardasil® also prevents genital wart, and girls' age were also independent predictors of both initiation of HPV vaccination and intention to vaccinate within 12 months. As with the HPV worry multivariate model, perceived likelihood of HPV-related illnesses without HPV vaccination and unaware that Gardasil® also prevents genital warts were positively associated with both HPV vaccination behavior and intentions. With every unit increase in girls' age, the odds were 1.90 times higher of parents having daughters who had initiated HPV vaccination over parents intending *not* to vaccinate daughters against HPV within 12 months. However, the odds of parents intending to vaccinate daughters against HPV within 12 months over intending not to do so decreased with an increase in girls' age (OR=0.62; 95% CI=0.41–0.94).

Parents' age and education, school decile ranking, and perceived severity of HPV and cervical cancer were unrelated to initiation of HPV vaccination by adolescent daughters and parents' intentions to vaccinate daughters within 12 months.



**Table 32: Multinomial logistic regression analysis for parental worry regarding genital warts (n=201)**

Variable	‡ Adjusted OR (95% CI)	
	† Vaccinated against HPV (n=55)	† Parents intend to vaccinate in the next 12 months (n=81)
	Parental worry about genital warts	0.74 (0.61 – 0.89)*
Girls' age (years)	1.90 (1.25 – 2.87)*	0.62 (0.41 – 0.94)*
Parents' age (years)	0.97 (0.89 – 1.05)	0.94 (0.86 – 1.02)
Parents' education		
High school qualification or less	Reference	Reference
1 to 3 years university	0.78 (0.26 – 2.28)	0.80 (0.20 – 2.18)
Bachelors degree or more	0.90 (0.31 – 2.59)	1.25 (0.46 – 3.39)
School decile ranking	0.98 (0.80 – 1.20)	0.97 (0.82 – 1.15)
Perceived likelihood of HPV illnesses	2.30 (1.63 – 3.24)*	2.18 (1.58 – 3.02)*
Perceived severity of HPV illnesses	1.46 (0.73 – 2.91)	1.83 (1.00 – 3.36)
Not aware that Gardasil® prevents warts	3.20 (1.17 – 8.73)*	3.15 (1.25 – 7.92)*

† Compared to parents with no intention to vaccinate daughters in the next 12 months

‡ Adjusted for all variables shown in the table (i.e. variables are adjusted for each other)

\* Statistically significant (p<0.05)

OR, odds ratio

CI, confidence interval

*Parental worry regarding cervical cancer*

Unlike measures of parental worry regarding HPV and genital warts which were independent predictors of initiation of HPV vaccination by adolescent girls, parental worry regarding cervical cancer was not associated with girls' HPV vaccination status at baseline in the multivariate analysis (Table 33). With increasing parental worry regarding cervical cancer, parents were no more likely to have daughters who had initiated HPV vaccination (OR=0.91; 95% CI=0.78–1.06), or to report their intention to vaccinate daughters within 12 months (OR=1.05; 95% CI=0.90–1.22).

Additionally, parents' age and education, school decile ranking, and perceived severity of HPV and cervical cancer were unrelated to HPV vaccination status in this multivariate model. Covariates that were significant predictors of both initiation of HPV vaccination and parents' intentions to vaccinate within 12 months were: perceived likelihood of HPV-related illnesses without the vaccine; parents' lack of awareness that Gardasil® also prevents genital wart; and girls' age. These associations were comparable in magnitude to those observed in the other parental worry multivariable models.

**Table 33: Multinomial logistic regression analysis for parental worry regarding cervical cancer (n=202)**

Variable	‡ Adjusted OR (95% CI)	
	† Vaccinated against HPV (n=56)	† Parents intend to vaccinate in the next 12 months (n=81)
	Parental worry about cervical cancer	0.91 (0.78 – 1.06)
Girls' age (years)	1.78 (1.20 – 2.63)*	0.63 (0.41 – 0.95)*
Parents' age (years)	0.96 (0.88 – 1.04)	0.94 (0.86 – 1.02)
Parents' education		
High school qualification or less	Reference	Reference
1 to 3 years university	0.72 (0.25 – 2.07)	0.78 (0.29 – 2.15)
Bachelors degree or more	1.05 (0.38 – 2.91)	1.27 (0.47 – 3.44)
School decile ranking	0.99 (0.81 – 1.20)	0.96 (0.81 – 1.15)
Perceived likelihood of HPV illnesses	1.99 (1.44 – 2.74)*	2.11 (1.54 – 2.90)*
Perceived severity of HPV illnesses	1.45 (0.75 – 2.79)	1.82 (0.99 – 3.34)
Not aware that Gardasil® prevents warts	3.02 (1.15 – 7.97)*	3.21 (1.29 – 7.98)*

† Compared to parents with no intention to vaccinate daughters in the next 12 months

‡ Adjusted for all variables shown in the table (i.e. variables are adjusted for each other)

\* Statistically significant (p<0.05)

OR, odds ratio

CI, confidence interval

### 6.6.3 *Health Belief Model (HBM) variables*

In this multivariate logistic model, cues to action to vaccinate daughters against HPV and perceived HPV vaccine effectiveness were the strongest predictors of initiation of HPV vaccination and intention to vaccinate daughters within 12 months (Table 34). With increasing levels in cues to vaccinate daughters against HPV, the odds of parents having daughters who had initiated HPV vaccination and of parents intending to do so within 12 months were 3.81 and 3.73, respectively. With increasing perceived HPV vaccine effectiveness, parents were more likely to have daughters who had initiated HPV vaccination (OR=2.20; 95% CI=1.19– 4.07) or to report their intention to do so within 12 months (OR=3.18; 95% CI=1.66–6.11).

Parents' ratings of their daughters' fear of needles was unrelated to initiation of HPV vaccination, but was significantly associated with intention to vaccinate daughters within 12 months. Parental concerns about potential side-effects of HPV vaccination were unrelated to their vaccination intentions. However, with increasing parental concerns regarding vaccine side-effects, parents were less likely to have daughters who had initiated HPV vaccination (OR=0.21; 95% CI=0.08–0.52).

Girls' age was an independent predictor of initiation of HPV vaccination, but not of parents' intentions to vaccinate daughters against HPV within 12 months. The probability of initiation of HPV vaccination by adolescent girls increased significantly as girls' age increased. With every unit increase in girls' age, the odds were 2.65 times higher of parents having daughters who had initiated HPV vaccination over parents intending *not* to vaccinate daughters against HPV within 12 months.

Perceived likelihood of HPV-related illnesses without HPV vaccination, perceived severity of HPV and cervical cancer, parents' age and education, and school decile ranking were unrelated to girls' HPV vaccination status in this multivariate model.

**Table 34: Multinomial logistic regression analysis for Health Belief Model variables (n=188)**

Variable	‡ Adjusted OR (95% CI)	
	† Vaccinated against HPV (n=52)	† Parents intend to vaccinate in the next 12 months (n=76)
	Cues to action to vaccinate daughters	3.81 (2.16 – 6.73)*
Perceived likelihood of HPV illnesses	0.99 (0.65 – 1.52)	1.30 (0.87 – 1.95)
Perceived severity of HPV illnesses	0.58 (0.21 – 1.62)	0.65 (0.24 – 1.76)
Perceive HPV vaccine effectiveness	2.20 (1.19 – 4.07)*	3.18 (1.66 – 6.11)*
Daughter is afraid of needles	1.95 (0.96 – 3.96)	2.31 (1.17 – 4.54)*
Concern about HPV vaccine side-effects	0.21 (0.08 – 0.52)*	0.61 (0.26 – 1.48)
Girls' age (years)	2.65 (1.44 – 4.89)*	0.80 (0.43 – 1.47)
Parents' age (years)	0.90 (0.79 – 1.03)	0.88 (0.77 – 1.00)
Parents' education		
High school qualification or less	Reference	Reference
1 to 3 years university	0.30 (0.06 – 1.54)	0.42 (0.09 – 2.05)
Bachelors degree or more	0.58 (0.12 – 2.69)	0.72 (0.16 – 3.16)
School decile ranking	1.02 (0.77 – 1.33)	1.05 (0.82 – 1.35)

† Compared to parents with no intention to vaccinate daughters in the next 12 months

‡ Adjusted for all variables shown in the table (i.e. variables are adjusted for each other)

\* Statistically significant (p<0.05)

OR, odds ratio

CI, confidence interval

## 6.7 Mediation analysis results

**Hypotheses:** Firstly, anticipated *inaction* regret is a potential mediator of the relationship between perceived likelihood of HPV-related illnesses without HPV vaccination and girls' HPV vaccination status at baseline. Secondly, among parents whose daughters are unvaccinated, worry is a potential mediator of the relationship between perceived likelihood of HPV-related illnesses without HPV vaccination and parental intention to vaccinate daughters within 12 months. Because initiation of HPV vaccination led to a decrease in parental worry which was *not* assessed as conditional on vaccination occurring, mediation analysis results for worry measures are reported in relation to whether or not parents intended to vaccinate daughters within 12 months.

### 6.7.1 *Perceived likelihood of HPV-related illnesses and HPV vaccination status at baseline*

Logistic regression analysis showed that perceived likelihood of HPV-related illnesses without HPV vaccination was significantly related ( $p < 0.001$ ) to both initiation of HPV vaccination (beta = 0.633) and parental intentions to vaccinate daughters against HPV within 12 months (beta = 0.616) (Table 35).

### 6.7.2 *Potential mediators and perceived likelihood of HPV-related illnesses*

Parental worry and anticipated *inaction* regret measures had significant ( $p < 0.001$ ) positive correlations with perceived likelihood of HPV-related illnesses without HPV vaccination (Table 36).

### 6.7.3 *Anticipated regret as a potential mediator*

For the relationship between initiation of HPV vaccination by girls at baseline and perceived likelihood of HPV-related illnesses without HPV vaccination, there was evidence of partial mediation by parental anticipated regret in the event that daughters were unvaccinated and got an HPV infection that could lead to cervical cancer (Model 1a; Table 37). Similarly, parental regret regarding cervical cancer partially mediated the relationship between parental intentions to vaccinate daughters against HPV within 12 months and perceived likelihood of HPV-related illnesses without HPV vaccination (Model 1b; Table 37). These findings are consistent with the

hypothesis. In both cases, parental regret regarding cervical cancer was statistically significant in the logistic regression model ( $p < 0.001$ ). In addition, the coefficients for perceived likelihood of HPV-related illnesses *decreased* from 0.633 to 0.379 for initiation of HPV vaccination by girls and from 0.616 to 0.459 for parental intentions to vaccinate daughters within 12 months when compared to models in Table 35. The Sobel and Goodman II tests confirmed that these mediation effects were statistically significant. Parental anticipated regret regarding cervical cancer accounted 39.95% and 22.71% of the effect of risk likelihood on initiation of HPV vaccination ( $p = 0.004$ , Sobel test) and parental intention to vaccinate daughters in the next year ( $p = 0.006$ , Sobel test), respectively.

Parental regret in the event that daughters were not vaccinated against HPV and contracted genital warts also showed evidence of partially mediating the relationship between girls' HPV vaccination status at baseline and perceived likelihood of HPV-related illnesses without HPV vaccination. For both initiation of HPV vaccination by girls and parental intentions to vaccinate daughters against HPV within 12 months, parental regret regarding genital warts was statistically significant ( $p < 0.001$ ) in the logistic regression models (Models 2a and 2b; Table 37). Compared to the models in Table 35, the coefficients for perceived likelihood of HPV-related illnesses in these models also *decreased* from 0.633 to 0.371 for initiation of HPV vaccination by girls and from 0.616 to 0.461 for parental intentions to vaccinate daughters within 12 months. These mediation effects were statistically significant as indicated by the Sobel and Goodman II tests. Parental anticipated regret regarding genital warts accounted 33.12% and 18.79% of the effect of risk likelihood on initiation of HPV vaccination ( $p = 0.006$ , Sobel test) and parental intention to vaccinate daughters in the next year ( $p = 0.010$ , Sobel test), respectively.

#### **6.7.4 Worry as a potential mediator**

Parental worry regarding HPV, genital warts and cervical cancer were all unrelated to parental intentions to vaccinate daughters within 12 months when perceived likelihood of HPV-related illnesses was adjusted for in the analysis (Models 3b, 4b and 5b; Table 37). Therefore, mediation could not be inferred here as hypothesized.

**Table 35: Logistic regression analysis of the relationship between perceived likelihood of HPV-related illnesses and HPV vaccination status at baseline**

<b>Model</b>	<b>Dependent Variable</b>	<b>Independent Variable</b>	<b>Coefficient (Beta)</b>	<b>Standard Error</b>	<b>p-value</b>
<b><i>Step 1</i></b>					
Model 1:	Initiation of HPV vaccination	Perceived likelihood of HPV-related illnesses without HPV vaccination	0.633	0.152	<0.001
Model 2:	Intention to vaccinate daughters within 12 months	Perceived likelihood of HPV-related illnesses without HPV vaccination	0.616	0.132	<0.001



**Table 36: Spearman Correlation Coefficients (*r*) between potential mediators and perceived likelihood of HPV-related illnesses without HPV vaccination**

Potential mediators	Perceived likelihood of HPV-related illnesses			
	† Step 2a		‡ Step 2b	
	n	<i>r</i> (p-value)	n	<i>r</i> (p-value)
Parental regret if daughter did NOT get the HPV vaccine and got an HPV infection that led to <i>cervical cancer</i>	120	.500 (<0.001)	147	.398 (<0.001)
Parental regret if daughter did NOT get HPV vaccine and got <i>genital warts</i>	120	.477 (<0.001)	147	.392 (<0.001)
Parental worry regarding <i>HPV</i>	NA	NA	150	.424 (<0.001)
Parental worry regarding <i>genital warts</i>	NA	NA	150	.469 (<0.001)
Parental worry regarding <i>cervical cancer</i>	NA	NA	150	.417 (<0.001)

† Subgroup of parent whose daughters have initiated HPV vaccination and parents who do not intend to do so within 12 months

‡ Subgroup of parent who intend to vaccinate daughters within 12 months and those who do not intend to do so

NA, Not applicable

**Table 37: Logistic regression analysis of whether potential mediators are related to HPV vaccination status at baseline while adjusting for perceived likelihood of HPV-related illnesses without HPV vaccination**

Model	Dependent Variable	Independent Variables	Coefficient (Beta)	Standard Error	p-value
<b><u>Step 3a: Initiation of HPV vaccination</u></b>					
Model 1a:	Initiation of HPV vaccination	Anticipated <i>regret</i> regarding <i>cervical cancer</i>	1.441	0.402	<0.001
		Perceived likelihood of HPV-related illnesses without HPV vaccination	0.379	0.167	0.023
Model 2a:	Initiation of HPV vaccination	Anticipated <i>regret</i> regarding <i>genital warts</i>	1.333	0.348	<0.001
		Perceived likelihood of HPV-related illnesses without HPV vaccination	0.371	0.167	0.026
<b><u>Step 3b: Parents' intentions to vaccinate daughters within 12 months</u></b>					
Model 1b:	Parental intention to vaccinate	Anticipated <i>regret</i> regarding <i>cervical cancer</i>	1.138	0.285	<0.001
		Perceived likelihood of HPV-related illnesses without HPV vaccination	0.459	0.139	0.001
Model 2b:	Parental intention to vaccinate	Anticipated <i>regret</i> regarding <i>genital warts</i>	1.006	0.254	<0.001
		Perceived likelihood of HPV-related illnesses without HPV vaccination	0.461	0.139	0.001

Model	Dependent Variable	Independent Variables	Coefficient (Beta)	Standard Error	p-value
Model 3b:	Parental intention to vaccinate	Parental <i>worry</i> about <i>HPV</i>	-0.032	0.080	0.687
		Perceived likelihood of HPV-related illnesses without HPV vaccination	0.628	0.140	<0.001
Model 4b:	Parental intention to vaccinate	Parental <i>worry</i> about <i>genital warts</i>	-0.029	0.080	0.716
		Perceived likelihood of HPV-related illnesses without HPV vaccination	0.628	0.142	<0.001
Model 5b:	Parental intention to vaccinate	Parental <i>worry</i> about <i>cervical cancer</i>	0.055	0.072	0.442
		Perceived likelihood of HPV-related illnesses without HPV vaccination	0.578	0.137	<0.001

## 6.8 Summary

Highlighted in Table 38 is a summary of factors found to be associated with parental acceptability of HPV vaccination for daughters. Anticipation of greater regret in the event that daughters are unvaccinated and developed cervical cancer or contracted genital warts (*inaction* regret) was strongly associated with initiation of HPV vaccination and parents' intentions to vaccinate daughters within 12 months. In addition, anticipated *inaction* regret measures partially mediated the relationship between perceived likelihood of HPV-related illnesses and girls' HPV vaccination status at baseline. However, parental anticipated regret in the event that daughters were vaccinated against HPV and initiated sexual activity at an early age (*action* regret) was unrelated to HPV vaccination status of girls.

This study also showed that compared to parents who did *not* intend to vaccinate daughters within 12 months, parents whose daughters had initiated HPV vaccination and who intended to do so within 12 months were significantly more likely to: report greater positive influence of recommendations by their general practitioner and family/friends to vaccinate daughters against HPV; perceive HPV-related illness as more likely to occur among daughters without vaccination; and perceive the HPV vaccine as more effective in preventing HPV-related illnesses. Parents who intended to vaccinate daughters within 12 months perceived HPV and cervical cancer as having more severe consequences to their daughters' health than parents who did *not* intend to do so. Initiation of HPV vaccination by daughters appeared to reduce parental worry regarding HPV and genital warts, but parental cervical cancer worry remained comparable to that of parents with unvaccinated daughters. The main deterrents of acceptability of HPV vaccines for daughters were concerns about potential side-effects and awareness that Gardasil® also prevents genital warts.

Next, information regarding the composition of parents who participated in the follow-up phase of the study is presented. Answers are also provided on whether the framed messages had a differential and significant effect on HPV vaccine uptake at follow-up.

**Table 38: Summary of factors associated with HPV vaccine acceptability at baseline**

<b>Parental factors related HPV vaccine acceptability (multivariate analyses)</b>	<b>Significantly associated with:</b>	
	<b>Initiation of vaccination by girls</b>	<b>Parental intention to vaccinate within 12 months</b>
Higher anticipated regret regarding cervical cancer	Yes <sup>†</sup>	Yes <sup>†</sup>
Higher anticipated regret regarding genital warts	Yes <sup>†</sup>	Yes <sup>†</sup>
Reduced levels of parental worry about HPV	Yes <sup>†</sup>	<i>No</i>
Reduced levels of parental worry about genital warts	Yes <sup>†</sup>	<i>No</i>
Greater influence of subjective norms (cues to action to vaccinate)	Yes <sup>†</sup>	Yes <sup>†</sup>
Higher perceived likelihood of HPV-related illnesses without the vaccine	Yes <sup>†</sup>	Yes <sup>†</sup>
Higher perceived severity of HPV-related illnesses	<i>No</i>	Yes <sup>†</sup>
Higher perceive HPV vaccine effectiveness	Yes <sup>†</sup>	Yes <sup>†</sup>
Less concerned about potential side-effects of HPV vaccines	Yes <sup>†</sup>	<i>No</i>
Having daughters who are more afraid of needles	<i>No</i>	Yes
Unawareness that the HPV vaccine, Gardasil®, also prevents warts	Yes	Yes
Having daughters who are older (increasing age)	Yes	–
Having daughters who are younger (decreasing age)	–	Yes

<sup>†</sup>In agreement with the study's hypotheses

## CHAPTER 7: FOLLOW-UP RESULTS

This chapter provides information on the participation rate at follow-up, as well as the HPV vaccine uptake rate among girls in this population. It also presents findings from analyses assessing whether providing parents with two framed HPV vaccination messages has a differential effect on HPV vaccine uptake by adolescent girls who were unvaccinated at baseline.

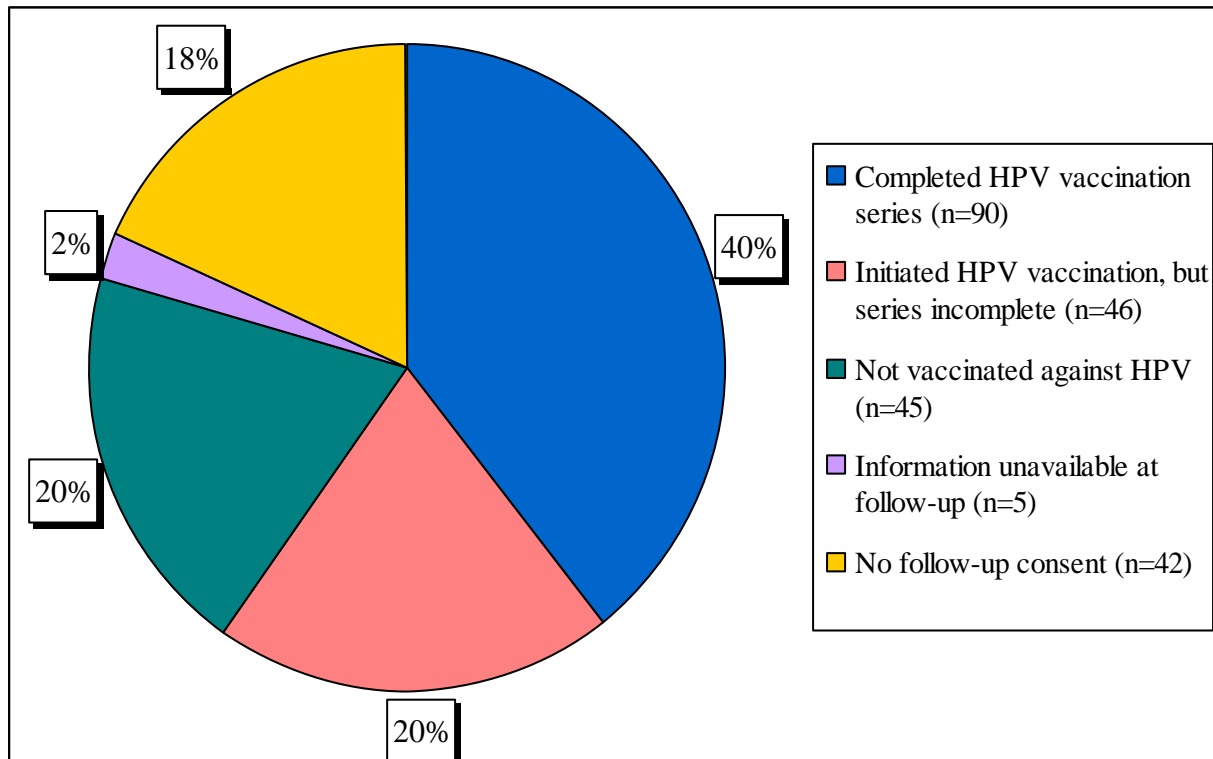
### 7.1 Participation rate at follow-up

Of the 229 parents who completed the research questionnaire at baseline, 176 parents (76.9%) provided consent for information on their daughters HPV vaccine uptake to be obtained via health records or direct contact with the parent (parental report). HPV vaccine uptake data were obtained for 96.6% of daughters of the 176 parents participating in the follow-up phase of the study. Follow-up consent/dissent by parents was unrelated to their daughters' HPV vaccination status or the type of message framing content received.

### 7.2 Uptake of HPV vaccination by girls at follow-up

It was possible to determine whether 79% (n=181) of the 229 participants' daughters had initiated HPV vaccination by the end of the study. This comprised of: 170 girls whose parents who consented to a follow-up; and 11 girls whose parents did not consent to a follow-up, but were already known to have initiated HPV vaccination at baseline (as reported in the questionnaires). Of the 181 girls with HPV vaccination status data available at the end of the study, 75% had initiated HPV vaccination or completed the HPV vaccination series of three injections, and 25% of girls had not been vaccinated against HPV.

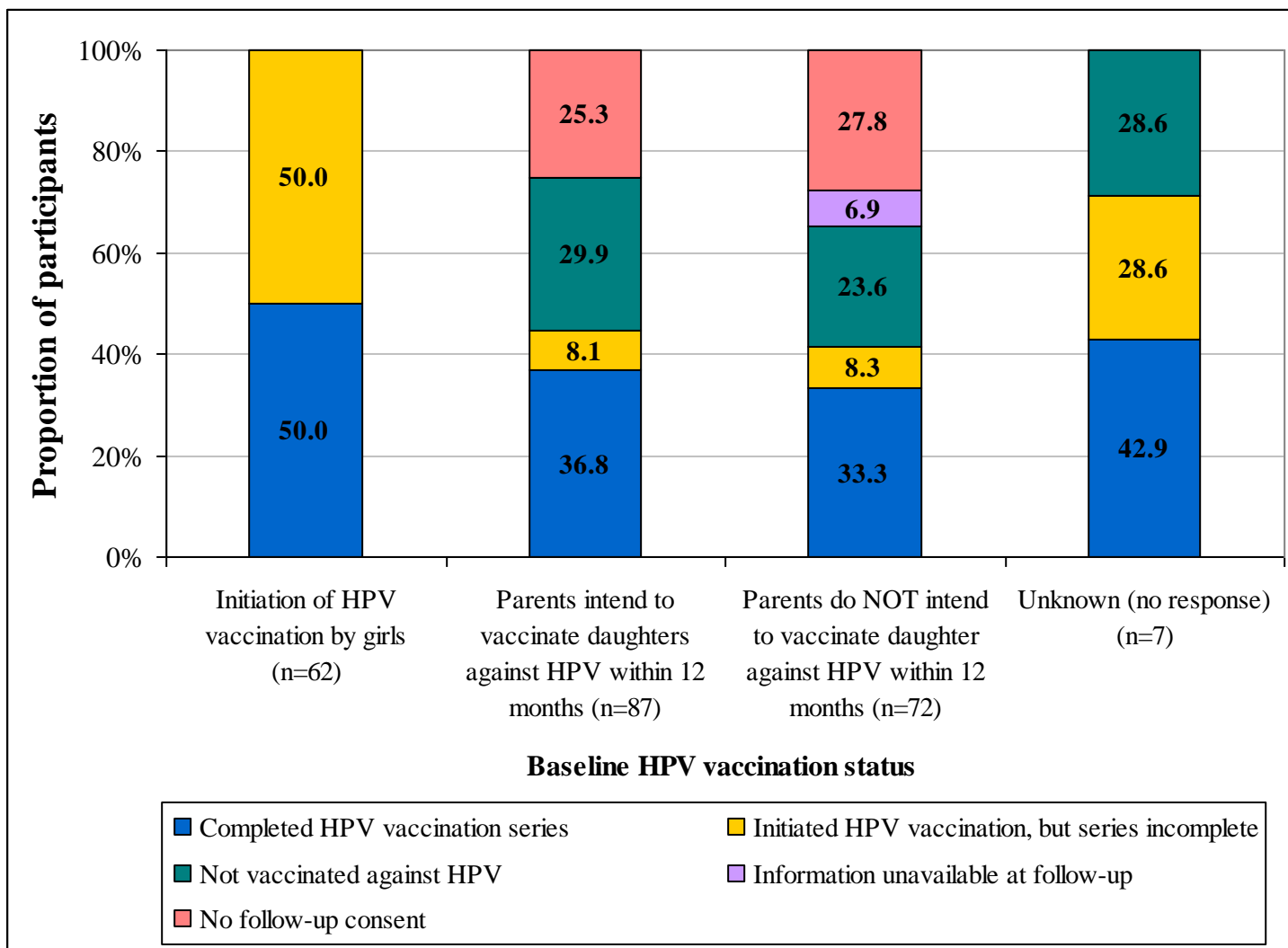
With regard to HPV vaccine uptake in the entire sample, 40% of girls had completed the HPV vaccination series (three injections) and 20% of girls had initiated HPV vaccination, but not completed the series of three injections (Figure 7). Twenty percent of girls had *not* been vaccinated against HPV, 18% of parents did *not* provide follow-up consent, and information on HPV vaccine uptake at follow-up was unavailable for 2% (n=5) of the girls. HPV vaccination status could not be categorized for one girl due to insufficient information provide by their parent; hence, the denominator for HPV vaccine uptake at follow-up in the entire sample was 228 participants.



**Figure 7: HPV vaccine uptake at follow-up in the entire study population (n=228)**

### 7.3 HPV vaccine uptake at follow-up by HPV vaccination status at baseline

Half of the girls who had initiated HPV vaccination at baseline had completed the series of three injections by follow-up (Figure 8). Among girls who were unvaccinated at baseline and whose parents intended to have them vaccinated within the next 12 months, 37% had completed HPV vaccination at follow-up, 8% had initiated HPV vaccination and 30% were still unvaccinated. For parents who did not intend to vaccinate their daughters within 12 months, one-third had completed HPV vaccination at follow-up, 8% had initiated HPV vaccination and 24% were still unvaccinated. The proportion of parents who did not consent to follow-up was comparable between parents who intended to vaccinate daughters within 12 months and those who did not intend to do so. Girls for whom HPV vaccine uptake data was unavailable after attempted follow-ups (n=5) were all daughters of parents who had no intention of vaccinating them against HPV within 12 months.

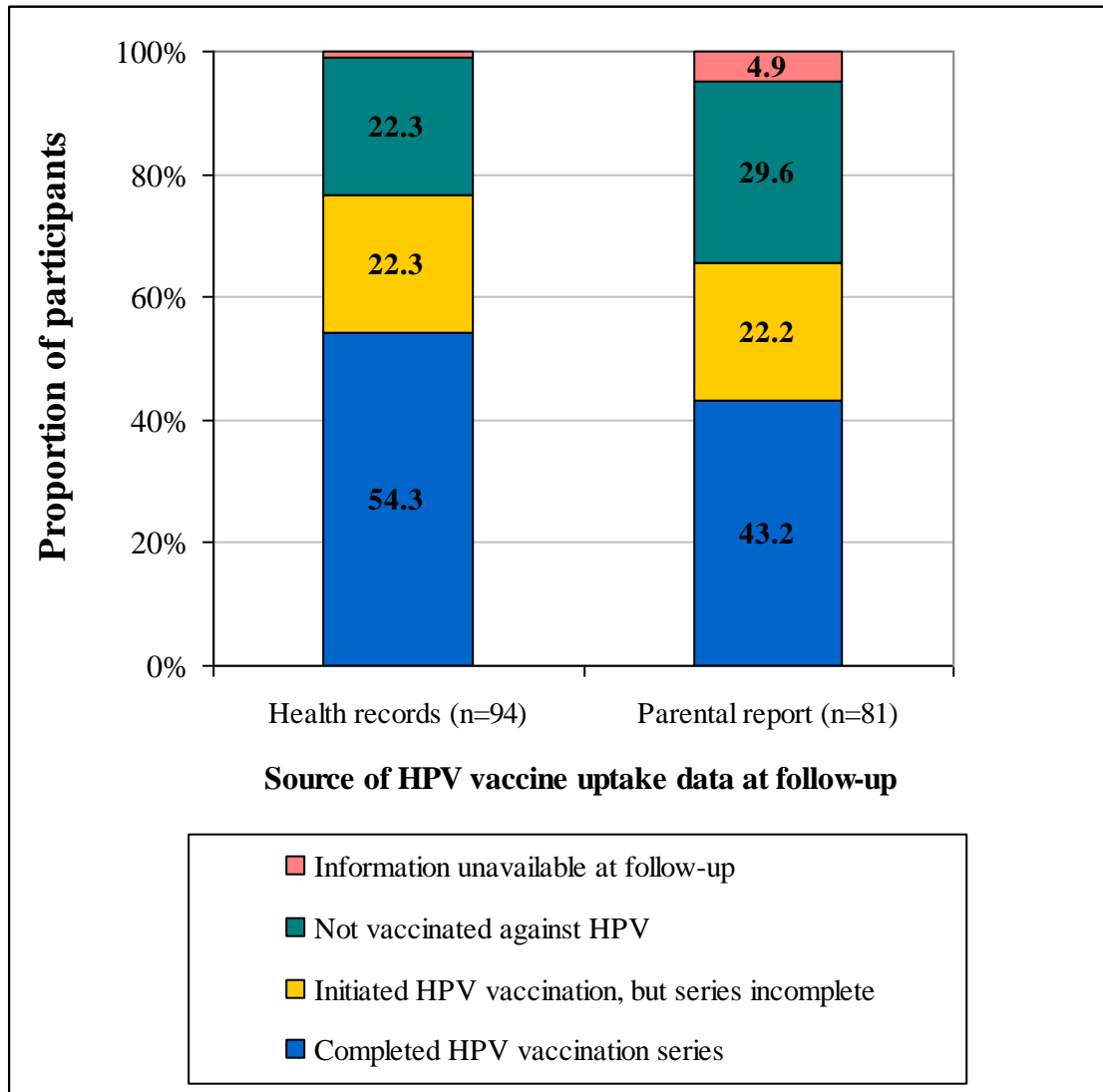


**Figure 8: HPV vaccine uptake at follow-up stratified by HPV vaccination status at baseline (n=228)**



### 7.4 HPV vaccine uptake at follow-up by sources of uptake data

About 54% and 46% of HPV vaccination data at follow-up was obtained via health records (n=94) and parental report (n=81), respectively (Figure 9). Data on the level of completion of the three injections of the HPV vaccination series by girls at follow-up did *not* vary significantly by the source of HPV vaccine uptake data (p=0.168, Cochran-Mantel-Haenszel statistic).



**Figure 9: HPV vaccine uptake at follow-up by sources of HPV vaccine uptake data among parents who provided follow-up consent and whose daughters had not initiated HPV vaccination at baseline (n=175)**

## 7.5 Message framing results

### 7.5.1 *Bivariate analyses results*

Bivariate analyses were done to determine whether parents who received the loss-framed and gain-framed HPV vaccination messages were comparable on baseline psychological measures and socioeconomic and demographic factors related to HPV vaccination at baseline. Of the 159 parents whose daughters were unvaccinated at baseline, 61% (n=97) had received the gain-framed message and 39% (n=62) the loss-framed message. Also worth noting is that ‘loss-framed’ and ‘gain-framed’ message recipients did not differ in their intentions to vaccinate daughters within 12 months ( $p=0.498$ ; Chi-Square test), or in the source of their daughters’ HPV vaccine uptake data at follow-up ( $p=0.212$ ; Chi-Square test).

#### 7.5.1.1 **Selected baseline characteristics with type of message framing content**

Parents who received gain-framed and loss-framed HPV vaccination messages did not differ from each other on characteristics significantly associated with HPV vaccination status at baseline. These included: parents’ age and education, girls’ age, school decile ranking, and parental awareness that Gardasil® also prevents genital warts (Table 39).

**Table 39: Selected baseline characteristics with type of HPV vaccination message-framing content received by parents whose daughters had not initiated HPV vaccination at baseline (n=159)**

Baseline characteristic	Type of HPV vaccination message		p-value
	Gain-framed message (n=97)	Loss-framed message (n=62)	
Parents' age (years) (mean ± SD)	43.73 ± 5.50	43.98 ± 6.10	0.788 <sup>a</sup>
Girls' age (years) (median; range)	12.50 (10.83 – 16.16)	12.08 (10.83 – 15.75)	0.080 <sup>b</sup>
Parents' highest level of education completed (n, % row)			
Less than high school/ High school qualification	31 (51.67)	29 (48.33)	0.157 <sup>c</sup>
1 to 3 years university	33 (68.75)	15 (31.25)	
Bachelors degree/ More than Bachelors degree	33 (64.71)	18 (35.29)	
School decile ranking (n, % row)			
≤ Decile 7	30 (56.60)	23 (43.40)	0.447 <sup>c</sup>
> Decile 7	66 (62.86)	39 (37.14)	
Awareness that Gardasil® also protects against genital warts (n, % row)			
No	35 (62.50)	21 (37.50)	0.891 <sup>c</sup>
Yes	62 (61.39)	39 (38.61)	

SD, standard deviation

<sup>a</sup> Analysis of variance for unbalanced designs

<sup>b</sup> Kruskal-Wallis test

<sup>c</sup> Chi-Square test

### **7.5.1.2 Anticipated regret and worry with type of message framing content**

Parent who received the loss-framed message had significantly higher levels of anticipated regret regarding genital warts in the event that daughters were unvaccinated against HPV (mean = 3.50) compared to parents who received the gain-framed message (mean = 3.07) (Table 40). In addition, they also had significantly higher levels of anticipated regret in the event that daughters were vaccinated against HPV and initiated sexual activity at an early age (mean = 3.12) than the gain-framed message recipients (mean = 2.66). However, gain-framed and loss-framed message recipients did not differ in their levels of anticipated regret in the event that daughters were unvaccinated and contracted an HPV infection that could lead to cervical cancer.

There were no significant difference in the levels of parental worry about HPV, genital warts and cervical cancer between parents who received the loss-framed and gain-framed HPV vaccination messages (Table 40).

### **7.5.1.3 Health Belief Model (HBM) variables with type of message framing content**

Gain-framed and loss-framed message recipients did not differ significantly in their ratings of the positive influence of recommendations by their general practitioner and family or friends to vaccinate their daughters against HPV (cues to action) (Table 41). Moreover, the two message framing groups were comparable in their ratings of the perceived effectiveness of the HPV vaccine, perceived likelihood of HPV-related illnesses without HPV vaccination, and perceived severity of HPV and cervical cancer. Also not significantly different between the two groups were: parents' ratings of their daughters' fear of needles; parental concerns about potential HPV vaccine side-effects; parental concerns that vaccinated girls would initiate sexual activity at an early age; and whether parents' awareness that HPV is a sexually transmitted virus affects their decision to vaccinate daughters.

**Table 40: Anticipated regret and worry measures with type of HPV vaccination message-framing content received by parents whose daughters had not initiated HPV vaccination at baseline (n=159)**

Measure	Type of HPV vaccination message				p-value *
	Gain-framed message		Loss-framed message		
	n	Mean ± SD	n	Mean ± SD	
<b><u>Anticipated regret measures</u></b>					
Parental regret if daughter did NOT get the HPV vaccine and got an HPV infection that led to <i>cervical cancer</i>	95	3.25 ± 1.06	58	3.53 ± 0.78	0.154
Parental regret if daughter did NOT get HPV vaccine and got <i>genital warts</i>	95	3.07 ± 1.06	58	3.50 ± 0.82	0.011
Parental regret if daughter was vaccinated for HPV and initiated sexual activity at an early age	94	2.66 ± 1.24	57	3.12 ± 1.07	0.029
<b><u>Worry measures</u></b>					
Parental worry regarding <i>HPV</i>	97	7.19 ± 2.53	59	7.85 ± 2.74	0.129
Parental worry regarding <i>genital warts</i>	97	7.04 ± 2.61	59	7.73 ± 2.72	0.119
Parental worry regarding <i>cervical cancer</i>	97	8.32 ± 2.80	59	8.64 ± 2.65	0.488

\* Kruskal-Wallis test

SD, standard deviation

**Table 41: HBM variables with type of HPV vaccination message-framing content received by parents whose daughters had not initiated HPV vaccination at baseline (n=159)**

Variable	Type of HPV vaccination message				p-value *
	Gain-framed message		Loss-framed message		
	n	Mean ± SD	n	Mean ± SD	
Cues to action to vaccinate daughter against HPV	95	5.09 ± 1.97	60	5.38 ± 1.56	0.410
Perceived likelihood of HPV-related illnesses without vaccine	93	6.18 ± 2.09	58	6.52 ± 2.17	0.312
Perceived severity of HPV and cervical cancer	95	3.41 ± 0.69	60	3.48 ± 0.57	0.668
Perceived effectiveness of the HPV vaccine	91	6.11 ± 1.84	58	6.18 ± 1.42	0.992
Daughter is afraid of needles	96	2.31 ± 0.95	59	2.46 ± 1.09	0.426
Concern about HPV vaccine side-effects	96	3.22 ± 0.77	59	3.14 ± 0.82	0.601
Knowing that HPV is sexually transmitted affects parent's decision to vaccinate daughter	96	2.35 ± 0.97	59	2.49 ± 0.97	0.359
Concern that girls vaccinated against HPV will become sexually active at an earlier age	97	1.92 ± 0.87	58	1.91 ± 0.84	0.940
Against vaccines in general	97	1.84 ± 1.05	59	1.64 ± 0.69	0.727

\* Kruskal-Wallis test

SD, standard deviation

#### 7.5.1.4 HPV vaccine uptake at follow-up with type of message framing content

Although not statistically significant, a greater proportion of parents who received the loss-framed message at baseline had daughters who initiated HPV vaccination at follow-up than gain-framed message recipients (70% vs. 56%) (Table 42). Furthermore, a similar pattern was observed when the level of completion of the HPV vaccination series was assessed among parents with daughters who had initiated HPV vaccination. Compared to parents who received the gain-framed message, a greater proportion of recipients of the loss-framed had daughters who had completed the HPV vaccination series of three injections at follow-up (44% vs. 59%;  $p=0.116$ ). However, a similar proportion of loss-framed and gain-framed message recipients had daughters who had initiated but not completed the HPV vaccination series.

#### 7.5.2 *Multivariate analysis results*

**Hypothesis:** In the sub-group of parents whose daughters were unvaccinated at baseline and who consented to participate in the follow-up, recipients of the loss-framed HPV vaccination message will be more likely to have daughters who initiate HPV vaccination than recipients of the gain-framed message.

In the multivariate analysis, the relationship between message framing and initiation of HPV vaccination at follow-up was not statistically significant (OR=1.95; 95% CI=0.85–4.45) (Table 43). Girls' age was the only significant predictor of HPV vaccine uptake at follow-up among girls who were unvaccinated at baseline and had HPV vaccination data available at follow-up. The probability of initiation of HPV vaccination by adolescent girls increased significantly as their age increased. With every unit increase in girls' age, the odds were over one-and-a-half times higher of parents having daughters who had initiated HPV vaccination (OR=1.63; 95% CI=1.08–2.48) over parents having unvaccinated daughters. There was no interaction effect ( $p=0.06$ ) between message framing assignment and perceived likelihood of HPV-related illnesses without HPV vaccination.

**Table 42: HPV vaccine uptake at follow-up with type of HPV vaccination message-framing content received by parents who provided follow-up consent and whose daughters had not initiated HPV vaccination at baseline (n=112)**

HPV vaccine uptake at follow-up	Type of HPV vaccination message		p-value *
	Gain-framed message (n=66)	Loss-framed message (n=46)	
	n (%)	n (%)	
Initiation of HPV vaccination by girls at follow-up (one or more shots)			
Yes	37 (56.06)	32 (69.57)	0.148
No	29 (43.94)	14 (30.43)	
Level of completion of HPV vaccination series by girls at follow-up			
Completed HPV vaccination series (3 shots)	29 (43.94)	27 (58.70)	0.116
Initiated HPV vaccination, but series incomplete (1 or 2 shots)	8 (12.12)	5 (10.87)	
Not vaccinated against HPV	29 (43.94)	14 (30.43)	

\* Cochran-Mantel-Haenszel Statistic



**Table 43: Multivariate analysis of type of HPV vaccination message-framing content with HPV vaccine uptake at follow-up, among parents who provided follow-up consent and whose daughters had not initiated HPV vaccination at baseline (n=111)**

Variable	Initiated HPV vaccination at follow-up		Adjusted OR (95% CI)	p-value
	Yes (n=69)	No (n=42)*		
Type of HPV vaccination message (n, % row)				
Gain-framed message	37 (56.92)	28 (43.08)	Reference	Reference
Loss-framed message	32 (69.57)	14 (30.43)	1.95 (0.85 – 4.45)	0.114
Girls' age (years) (median; range)	12.41 (10.83 – 16.16)	12.04 (10.83 – 14.92)	1.63 (1.08 – 2.48)	0.021

\* One participant has missing information on daughters' age

OR, odds ratio

CI, confidence interval

## 7.6 Summary

As illustrated in this chapter, 77% of the 229 participants agreed to participate in the follow-up, which was highly successful with HPV vaccination status determined for 97% of the follow-up participants' daughters. The HPV vaccine uptake rate was 75%, which includes parents with daughters who have completed (50%) or initiated but not completed (25%) the series of three injections.

However, vaccine uptake was unrelated to message framing assignment. The next chapter discusses findings presented in this chapter and the previous chapter and how these compare with the published literature. It also describes the study's strengths and limitations.

## CHAPTER 8: DISCUSSION

Presented in this chapter is a synopsis of the findings for each psychological construct applied, as well as the main sociodemographic factors assessed in relation to parental acceptability of HPV vaccination for adolescent daughters. These findings are compared to relevant published literature and some possible explanations for conflicting findings are provided. In addition, the HPV vaccine uptake rate in the present study is compared to the few studies that have collected such data and also more broadly, to reports on the proportion of parents willing to vaccinate daughters against HPV. The chapter ends with a description on the study's strengths, including its contributions to the literature, and the potential limitations.

### 8.1 Baseline

#### 8.1.1 *Anticipated regret and HPV vaccine acceptance by parents*

In the present study, anticipated *inaction* regret measures were strong predictors of initiation of HPV vaccination by girls and of parental intention to vaccinate daughters within 12 months. These measures specifically assessed parents' anticipated regret in the event that daughters were unvaccinated against HPV and contracted genital warts or an HPV infection that could lead to cervical cancer. With increasing levels of *inaction* regret, parents were more likely to have daughters who had initiated HPV vaccination or to report their intention to do so within 12 months. In addition, *inaction* regret measures partially mediated the relationship between perceived likelihood of HPV-related illnesses and girls' HPV vaccination status. The greater the perceived risk likelihood, the greater the parental regret from inaction, which in turn was related to parents being more likely to have daughters who are vaccinated against HPV or to report their intention to do so within 12 month. However, parental regret in the event that daughters were vaccinated against HPV and initiated sexual activity at an early age (*action* regret) was unrelated to the girls' HPV vaccination status at baseline.

The findings in the present study are consistent with the theoretical notion that people who anticipate negative consequences for failing to undertake a beneficial behavior are more likely to take preventive actions.[15, 16] Since regret can influence the decision making process when people choose to avoid options that could produce it,[18] parents who presently support HPV

vaccination for daughters choose to do so partly to avoid regret that could occur from the potential consequences of their inaction. Furthermore, in agreement with the *risk-as-feelings* hypothesis which posits that cognitive evaluation of risky alternatives have affective consequences,[14] this study showed that anticipated inaction regret partially mediates the relationship between judgments of risk likelihood and vaccination behavior and intentions.

The present study is the first to investigate the relationship between HPV vaccine acceptability and parental anticipated regret regarding genital warts. The finding that anticipated regret regarding cervical cancer motivates parents who presently support HPV vaccination for adolescent daughters is comparable to two reports from a U.S. sample of caregivers of 10-18 year old girls.[122, 123] Caregivers with greater intentions to vaccinate daughters reported higher inaction regret regarding the potential occurrence of cervical cancer as a result of HPV infections in unvaccinated girls.[122] Furthermore, in a follow-up study of caregivers whose daughters were unvaccinated at baseline, caregivers who anticipated greater regret if daughters were not vaccinated and got an HPV infection that led to cervical cancer (inaction regret) were more likely to initiate HPV vaccination for daughters.[123]

Unlike the present study, findings from the U.S. sample showed that parents with higher levels of anticipated regret if vaccination resulted in daughters being more sexually active at an earlier age (action regret) were less likely to have initiated HPV vaccination for daughters,[122, 150] or to intend to have them vaccinated.[122] However, in the follow-up analysis this association was absent,[123] possibly due to an increase in the proportion of parents who had vaccinated daughters against HPV. Although action regret was operationalized in a manner similar to the present study, the U.S. study [122] had a lower proportion of girls who had initiated HPV vaccination at the time of data collection than the present study (12% vs. 28%). Therefore, it appears that action regret is a deterrent of HPV vaccination when the rate of vaccine uptake is low, but is less influential as HPV vaccine uptake rates increase. Another possible reason could be a greater influence of religion on beliefs in the U.S. sample. Although information on the participants' religion (or lack thereof) is not reported for the U.S. sample, 40% of participants in the present study had no religious affiliation.

Other forms of parental anticipated inaction regret regarding the negative consequences of HPV infections or childhood illnesses have been shown to influence preventive actions and intentions by parents. Comparable to the findings in the present study that inaction regret is associated with vaccination intentions, Morison et al [124] found that parents with higher intentions to vaccinate 11-12 year old daughters against HPV if the vaccine was offered to them anticipated greater regret if daughters were *not* vaccinated in the next year and had abnormal cervical smears in the future. In addition, mothers have been shown to be more likely to vaccinate infants if they anticipated greater regret if infants were to become ill because they were *not* vaccinated against diphtheria, tetanus, whooping cough, hepatitis B, influenza type B and polio.[121]

A similar influence of anticipated regret on vaccine acceptability observed in the present study has been reported in a number of vaccination studies among adults, primarily, the role of anticipated regret on influenza vaccination behavior and intentions.[119, 120] Chapman and Coups [119] found that anticipated regret was associated with influenza vaccine uptake and intentions to obtain the vaccine in the future. Adults who expected that a larger reduction in regret would occur after influenza vaccination were more likely to report their intention to obtain the vaccine, or to have been vaccinated by follow-up. In addition, a study by Weinstein et al, [120] showed that adults were more likely to have obtained the influenza vaccine if they anticipated they would regret *not* obtaining the vaccine and becoming ill with influenza later.

The present study's findings that inaction regret mediates the relationship between risk likelihood and vaccine acceptability is comparable to findings Chapman and Coups [119] on influenza vaccination among adults. They found that anticipated regret partially mediated the relationship between perceived risk likelihood and influenza vaccination behavior and intentions. The authors acknowledge that although it appears that perceived risk likelihood triggers emotions, which in turn trigger vaccination behavior and intentions, it was impossible to determine whether perceptions of risk precede feelings of regret, or whether these occur vice-versa or in parallel. This is also a consideration for the present study.

### **8.1.2 Worry and HPV vaccine acceptance by parents**

In the present study, girls' baseline HPV vaccination status was related to parental worry regarding HPV and genital warts, but not cervical cancer. Compared to parents who at baseline intended not to vaccinate daughters within 12 months, parents with daughters who had initiated HPV vaccination had reduced levels of worry regarding HPV and genital warts. On the contrary, there were no significant differences in parental worry about HPV and genital warts between parents who intended to vaccinate daughters within 12 months and those who did not intend to do so. These findings suggest that once girls are vaccinated against HPV, parental worry regarding HPV infections and genital warts is likely to decrease because preventive measures against these health conditions have been taken. Furthermore, the absence of a significant finding for parental worry regarding cervical cancer may be explained by the high levels of worry it elicits for all groups of parents being compared. This is not surprising as cancer is the more serious of the three health conditions and hence would elicit comparable levels of worry among parents regardless of whether daughters are vaccinated against HPV or not. There was also no evidence of mediation by parental worry measures of the relationship between perceived likelihood of HPV-related illnesses and girls' HPV vaccination status in the present study. To some extent, this study's findings on parental worry are in agreement with Loewenstein et al [14] *risk-as-feelings* hypothesis that decision making partly results from direct emotions, but the absence of mediation effects by parental worry are not in agreement with notion that cognitive evaluation of alternatives has affective consequences.

The relationship between parental HPV worry and HPV vaccine acceptability observed in the present study is consistent with findings in the only study in the published literature that addresses this issue.[140] Greater parental worry about the possibility that their children might be infected with HPV, assessed on a four-point ordinal scale (not worried, a little worried, moderately worried, or very worried), was related to higher HPV vaccine acceptability among parents of 4-16 year old children in the UK.[140] An investigation into why some parents worry about their adolescent children's risk of contracting STIs while others do not was undertaken by Strum et al.[192] The authors found that parental worry regarding adolescent STI risk was predicted by the parents' view that children were sexually active or their unawareness of whether

they were, as well as parents' prior experience with STIs. On the other hand non-worry was related to parents' confidence that their actions to communicate with and teach their children about STIs would reduce susceptibility.

Other areas of research have illustrated a reduction in parental worry after undertaking actions on their children's behalf. For instance, in a U.S. prospective study of children with recurrent acute and/or chronic otitis media referred for surgical interventions, parental worry regarding their child's ear problems reduced significantly by one and six months post-surgery.[193]

Unlike the null findings in the present study of the relationship between parental worry and HPV vaccination *intentions*, Setbon and Raude [135] found that parents with higher levels of worry were more likely to report that they intended to obtain the influenza A/H1N1 vaccine for their child. This difference in findings between HPV vaccination and influenza vaccination for children could be partly due to the high media coverage on the pandemic 'swine flu' and the greater urgency to act to prevent it. Moreover, parents may feel that there is less control over whether children will be infected with an airborne disease compared to HPV-related illnesses.

Reports from research on influenza vaccination for adults also show conflicting results on the relationship between worry and vaccination behavior and intentions. Chapman and Coups,[119] found that adults who expected a greater reduction in worry to occur after influenza vaccination were more likely to report their intention to be vaccinated and to later obtain the vaccine. However, in a prospective study by Weinstein et al,[120] the extent to which adults were worried about getting influenza was unrelated to subsequent vaccination against the disease.

### **8.1.3 The Health Belief Model (HBM) and HPV vaccine acceptance by parents**

Findings in the present study on the relationship between HPV vaccine acceptability and HBM dimensions are largely consistent with the theoretical framework that perceived susceptibility, perceived severity, perceived benefits, perceived barriers and cues to action can be used to explain health behavioral actions and intentions.[20, 22] Perceived likelihood and perceived benefits were associated with both initiation of HPV vaccination and parental intention to vaccinate daughters within 12 months, but perceived severity was only related to intentions. A

review by Janz and Becker [21] which found that “severity” was less likely to be related to outcomes, whereas “susceptibility”, “barriers” and “benefits” were consistently associated with outcomes. In addition, the view that cancer is serious is thought to limit variability in the severity measure thus reducing its ability to differentiate between people who comply from those who choose not to.[21]

*Cues to action to vaccinate against HPV (subjective norms)*

In the present study, the positive influence to parents of recommendations by general practitioners and family/friends to vaccinate daughters against HPV was significantly greater among parents with vaccinated daughters and those who intended to do so within 12 months, than among parents who had no intention of vaccinating daughters within 12 months.

In support of these findings, initiation of HPV vaccination was more likely have occurred among 10-18 year old girls in the U.S. whose caregivers had received a doctor’s recommendation to do so.[150] Using data from the same study, Hughes et al [149] found that caregivers who had heard of HPV vaccines from healthcare providers or family/friends were also more likely to have obtained one or more injections of the vaccine for their daughters. In Canada, intention to vaccinate 8-18 year old girls against HPV was greater among parents who were influenced by subjective norms, such as, recommendations by physicians and family/friends.[127]

Other studies have shown that parents are more likely to report that HPV vaccination would be acceptable for their daughters if they believe that their physicians, family/friends and peers would recommend this to them or have a favorable view of it. In a study of parents in the UK, greater vaccine acceptability for 4-16 year old girls was related to stronger subjective norms, which were assessed as whether vaccination was supported by family/friends and peers (parents at participants’ children’s schools), and if the participants’ support for the vaccine was influenced by these groups.[140] Dempsey et al [147] also found that physician recommendations and peer-group influence increased HPV vaccine acceptance among parents and caregivers of 8-12 year olds girls in the U.S. A qualitative study in the U.S. with mothers of 11-17 year old girls who accepted HPV vaccination for daughters during preventive care visits reported strong physician recommendations as a reason for their decision.[148]

### *Perceived likelihood of HPV-related illnesses*

In this study, parents who perceived HPV-related illnesses (HPV infections, cervical cancer and genital warts) as likely to affect their daughters without HPV vaccination were more likely to have daughters who were vaccinated or report their intention to do so in the next 12 months.

Similar findings have been reported in other studies. In a study in the U.S., caregivers of 10-18 year old girls who had not initiated HPV vaccination reported a significantly greater likelihood of daughters getting cervical cancer.[150] Parental acceptability of HPV vaccination for daughters has also been shown to be positively related to parents' perceptions of their daughters' susceptibility to HPV infections,[128, 147, 148] and to parents' belief that their children will be exposed to HPV eventually.[153]

### *Perceived severity of HPV and cervical cancer*

This study found parents' appraisals of the severity of HPV and cervical cancer to be positively associated with their intentions to vaccinate daughters within 12 months. However, there were no differences in perceived severity of HPV and cervical cancer between parents whose daughters had initiated HPV vaccination and those who did not intend to do so within 12 months.

As with the present study, higher perceived seriousness of HPV was positively associated with parental intentions to vaccinate their 8-14 year old daughters in a study in the UK.[128] However, some studies have shown no relationship between parental acceptability of HPV vaccination for daughters and their belief that HPV infections could result in serious consequences,[147] or their perception of the severity of cervical cancer.[150] As suggested in a review by Janz and Becker [21], when most participants view an illness as serious (e.g. cancer), it limits the variability in severity measures hence increasing the likelihood of having non-significant results.

### *Perceived effectiveness of the HPV vaccine*

Findings from this study showed that parents who perceived the HPV vaccine as more effective in preventing HPV, cervical cancer and genital warts were more likely to have daughters who



had initiated HPV vaccination or to report that they intended to have daughters vaccinated within 12 months. This association was stronger for the latter group of parents than the former.

In agreement with findings in the present study, Reiter et al [150] found initiation of HPV vaccination among 10-18 year old girls in the U.S. to be related to higher perceived effectiveness of the HPV vaccine by their parents. In addition, parental acceptability of HPV vaccines was related to higher perceived effectiveness among parents of school-aged children aged (4-16 years old) in the UK,[140] and also among parents/caregivers of 8-12 year old children in the U.S.[147]

### *Perceived barriers to HPV vaccination*

In the present study, parents whose daughters had initiated HPV vaccination were significantly less concerned about potential side-effects of the HPV vaccine than parents who did not intend to vaccinate daughters within 12 months. In contrast, parents who intended to vaccinate daughters within 12 months and those who did not intend to do so had comparable levels of concern about potential side-effects of the vaccine. Several studies, both cross-sectional and qualitative, have reported parental concerns about potential HPV vaccine side-effects as one of the main deterrents of vaccine acceptability and of initiation of HPV vaccination by daughters. This has been reported in studies in the U.S.,[126, 148, 150] Netherlands,[161], and Australia.[160] Decreased HPV vaccine acceptability has also be shown to be related to parental concerns about discomfort or danger to children during vaccination.[147] Furthermore, parents' concerns about vaccines in general decreases the likelihood of HPV vaccine acceptability for daughters.[126, 128, 162]

Awareness that Gardasil® also prevents against genital warts by parents in the present study appeared to be a deterrent of HPV vaccine acceptability. Parents who were unaware that Gardasil® prevents genital warts were more likely to have daughters who had initiated HPV vaccination or report their intention to have daughters vaccinated within 12 months. This finding may be explained in part by the social stigma associated with genital warts as it causes sufferers psychological distress,[63] as well as anxiety, discomfort and embarrassment,[68] possibly due to the visible physical symptoms. Although parents' personal/familial history of STIs was

unrelated to girls' HPV vaccination status at baseline, the present study did not ask parents specifically about their past experiences with genital warts.

Parents' ratings of their daughters' fear of needles was not a barrier of parental intentions to vaccinate daughters within 12 months and was unrelated to initiation of HPV vaccination by girls. In fact, compared to parents who did not intend to vaccinate daughters within 12 months, parents who intended to do so were more likely to report that their daughters' feared needles. Although this finding is quite unique, it may be that vaccinations requiring several injections may cause parents to delay obtaining such vaccines for children who are afraid of needles. Some findings that may support this view are from a cross-sectional study in the U.S. which reported that HPV vaccine uptake and intention to vaccinate 11-17 year old daughters was more likely among parents whose daughters would not object to three injections.[151]

#### **8.1.4 Sociodemographic factors and HPV vaccine acceptance by parents**

##### *Girl's age*

In the present study, an increase in girls' age was an independent predictor of initiation of HPV vaccination, while a decrease in girls' age was a predictor of parents' intentions to vaccinate daughters within 12 months. Since the HPV vaccination intent and initiation groups were compared to parents who did not intend to vaccinate daughters within 12 months, it is probable that parents who intended to obtain the vaccine for daughters within 12 months were waiting for daughters to be older and/or to be eligible for free HPV vaccination in NZ. In addition, these results suggest that parents who did not intend to vaccinate daughters against HPV within 12 months are likely more influenced by factors other than the age of their daughters (who were generally older than daughters of parents with vaccination intent).

As with the present study, 10-18 year old girls who had initiated HPV vaccination were more likely to be older than unvaccinated girls in a U.S. study.[150] In a study of mother-daughter pairs in the U.S., initiation of HPV vaccination among 9-17 years old girls was also positively related to girls' age.[194] Six percent of parents participating in a cross-sectional study in the U.S. reported they were likely to vaccinate girls before the age of 16 years, but not before the age

of 13 years, suggesting that some parents who may not support HPV vaccination in early teens will do so when daughters are older.[126] Another U.S. study with parents and caregivers of 8-12 year old girls found that respondents were more willing to accept HPV vaccination for daughters when they were older than at their present age.[147] Although a U.S. qualitative study among mothers of 11-17 year old girls who were offered the vaccine found no significant difference in HPV vaccine acceptance by girls' age, some parents who declined to vaccinate daughters believed they were too young.[148] However, there was no relationship between parental acceptability of HPV vaccination and their daughters' age in a U.S. study among mothers of 11-17 year old daughters.[151]

A qualitative study by Waller et al [163] also found that parents of 8-14 year old girls in the UK who were hesitant about vaccinating them against HPV preferred to wait until daughters were older. In another study in the UK, parents' intentions to vaccinate 8-14 year old daughters were greater among those with older daughters.[128] A different study by the same authors found that compared to parents whose youngest daughters were eight years old or younger, HPV vaccine acceptability was greater among parents whose youngest daughters were 13-16 years old. However, there was no significant difference in HPV vaccine acceptability between parents whose youngest daughters were 9-12 years old and those whose youngest daughters were 13-16 years old.[195]

#### *Parents' age and religious affiliation*

Parents' age and religious affiliation were not independent predictors of initiation of HPV vaccination and HPV vaccination intent at baseline in the present study. There are mixed findings on the relationship between parents' age and their willingness to vaccinate daughters against HPV. No association was found between parents' age and HPV vaccine acceptance for daughters in studies in the U.S.,[148, 150, 151] Netherlands,[161] and UK.[128, 195] In contrast, in a Canadian study of parents with daughters aged 8-18 years old, parents aged 40 years and older were less likely report that they intended to vaccinate daughters against HPV compared to younger parents.[127]

Similar to the present study, no association was observed between parents' religious affiliation and acceptability of HPV vaccination for 10-12 year old girls in the Netherlands,[161] and for 8-18 year old girls in Canada.[127] Furthermore, reporting that religious beliefs guide daily decisions was unrelated to HPV vaccination intentions.[127] However, although Marlow et al [128] found no difference in HPV vaccine acceptability between Christian parents of 8-14 year old girls in the UK and those without a religious affiliation, parents of 'other' religions were less likely to accept HPV vaccination than non-religious parents.

*Parental education and school decile ranking (socioeconomic measures)*

In the present study, school decile ranking and parental education were not independently related to girls HPV vaccination status. There have been mixed findings on the relationship between HPV vaccine acceptability for daughters and a range of socioeconomic measures. For instance, parental acceptance of HPV vaccines has been shown to be lower among those with health insurance coverage,[155] higher income,[155, 156] and higher education level.[151, 155] However, a number of studies have found no relationship between parents' education level and HPV vaccine acceptability for adolescent daughters.[127, 128, 148, 150, 161, 195]

*Parents' relevant health experiences*

In the present study, parents' personal/familial history of an abnormal Pap smear, cervical cancer or STIs were all unrelated to girls' HPV vaccination status at baseline. In agreement with these findings and using similar survey questions, Dempsey et al [147] found HPV vaccine acceptability to be unrelated to personal experiences with cervical cancer and abnormal Pap smears among parents of 8-12 year old girls in the U.S. In addition, Reiter et al [150] did not find a relationship between initiation of HPV vaccination by 10-18 year old girls in the U.S. and their parents' personal/familial history with cervical cancer and genital warts. Another cross-sectional study in the U.S. found no association between mothers' history of HPV-related disease and HPV vaccination uptake/intentions for 11-17 year old daughters.[151] However, a U.S. study found initiation of HPV vaccination among 9-17 year old girls to be more likely to occur if their mothers' had a history of an abnormal Pap smear.[194]

There are mixed findings for the relationship between parents' personal/familial history with any cancer and HPV acceptance for adolescent daughters. For instance, in the UK, a study with parents of 8-14 year old girls found that those who had experienced cancer in their family were more likely to report that they intended to vaccinate their daughters against HPV.[128] In contrast, a study of parents with 8-18 year old daughters in Canada found no relationship between parental intentions to vaccinate daughters against HPV and whether parents had even been diagnosed with any cancer, or knew someone who had a cancer diagnosis.[127]

In a sample of female parents with 11-17 year old daughters recruited from pediatric primary care clinics in the U.S., Rosenthal et al [151] found that parents with a history of STIs were more likely to have daughters who had initiated HPV vaccination or intended to have daughters vaccinated. In another study in the U.S. of 9-17 year old girls and their mothers, initiation of HPV vaccination was more likely to occur among girls whose mothers had a history of anogenital warts or other STIs, whereas completion of the vaccination series was related to mothers' history of anogenital warts but not other STIs.[194]

## **8.2 Follow-up**

### **8.2.1 *HPV vaccine uptake at follow-up by adolescent girls***

Among the 181 participants' daughters for whom HPV vaccine uptake information was available by follow-up (79% of total sample), 50% of girls had completed the series of three HPV vaccine injections and 25% had initiated but not completed the vaccination series. Therefore, by the end of the study, 75% of girls had been vaccinated against HPV and 25% of girls were still unvaccinated. Irrespective of parental vaccination intentions, a comparable proportion of parents whose daughters has *not* initiated HPV vaccination at baseline obtained the vaccine by follow-up. Ajzen et al [196] explained that discrepancies between intentions and actions (hypothetical bias) are likely to occur when one's beliefs at the time a behavior is performed differ from the beliefs they had when reporting their behavioral intentions. For the present study, it is probable that the participating parents later sought additional information and advice about HPV vaccination contributing to changes in vaccination intentions, or decisions to delay vaccination.

Additionally, the framed messages provided to participants at baseline may have played a role to some extent, albeit statistically non-significant.

Most studies on parental acceptability of HPV vaccination for daughters have been cross-sectional or qualitative in design. The majority have examined whether parents find the HPV vaccine acceptable or intend to have their daughters vaccinated, with few reporting on actual vaccine uptake. Nevertheless, in these studies, the proportion of parents reported to support HPV vaccination for their daughters is fairly comparable to the proportion of parents in the present study whose daughters were vaccinated against HPV.

In a prospective study of 12 and 13 year old girls attending 36 schools in the UK, HPV vaccine uptake for the first and second doses were 71% and 69%, respectively,[197] which is relatively comparable the proportion of girls who had initiated HPV vaccination in the present study. Studies in the U.S. reporting HPV vaccine uptake data have found lower rates of initiation of HPV vaccination among girls of similar age-groups, possibly due to the lack of free HPV vaccination which eliminates cost as a barrier of uptake of this relatively expensive vaccine. In a nationally representative U.S. sample, Caskey et al [198] found that 30% of 13-17 year old females had initiated HPV vaccination a year and a half after Gardasil® was approved by the U.S. FDA. In another U.S. study using health insurance record data, 27% of females aged 9-17 years old had initiated HPV vaccination; of these, 42.5% completed the HPV vaccination series within a year.[194] In a sample of 13-26 year old females recruited in a clinical setting in the U.S., 36% initiated HPV vaccination six months post-baseline.[157] Although Reiter et al [150] reported that 12% of 10-18 year old girls had initiated HPV vaccination at baseline, Brewer et al [123] found that 27% of those who were unvaccinated at baseline initiated HPV vaccination after a follow-up 12-17 months later.

With regard to HPV vaccine acceptance by parents in the U.S., a cross-sectional survey of over 500 parents found that 75% of respondents with daughters aged 18 years or younger would likely obtain the vaccine for their daughters before 13 years of age.[126] A study of women with 8-14 year old children reported that 67% of those with daughters would accept the HPV vaccine for their child.[152] Similarly, in another cross-sectional study, 68% of respondents thought HPV

vaccination would be acceptable for 10-15 year old girls. However, the respondents in this study were people aged 18 years and older and not an exclusive sample of parents.[156] This may partly explain the lower rate of vaccine acceptance as the issue would be less relevant to respondents without children, as well as those without daughters who are eligible for HPV vaccination and require parental consent to obtain it.

Among Canadian parents with at least one female child aged 8-18 years old, 74% reported that they intended to vaccinate daughters against HPV.[127] In a cross-sectional study of parents with 8-14 year old daughters in the UK, the HPV vaccine was found to be acceptable to 75% of respondents.[128] Although a study of parents with school-aged children (4-16 years old) in the UK found that 75% of parents would accept HPV vaccination for female children, it included a broader age-group with children not eligible for HPV vaccination than the present study.[140] In an Australian cross-sectional survey of over 2,000 households, HPV vaccine acceptance for daughters in a subgroup of 601 parents was 75.5% (68.9% for both daughters and sons, and 6.6% for daughters only). However, the authors neither mention the age group of the children for whom parental acceptability of HPV vaccination was assessed, nor do they report their findings by the children's age.[160] There were much higher rates of HPV vaccine acceptance in a study in the Netherlands which reported that 88% of parents would be willing to vaccinate 10-12 year old daughters against HPV.[161]

### **8.2.2 *Message framing and HPV vaccine uptake at follow-up***

The present study found no significant difference in HPV vaccine uptake by girls at follow-up irrespective of whether parents were recipients of loss-framed or gain-framed HPV vaccination messages. Hence, the hypothesis that the recipients of the loss-framed message would be more likely to have daughters who initiate HPV vaccination than recipients of the gain-framed message could not be accepted. These findings do not support the notion that for goal frames, messages which inform on the consequences of inaction have an advantage over those that inform on the benefits of action.[24] The null framing findings are likely due to an inadequate sample size to detect any small effects; this is evident in the relatively wide 95% confidence interval in the odds ratio for the relationship between message framing and HPV vaccine uptake (OR=1.95; 95% CI=0.85–4.45). Small framing effects are not necessarily unimportant.[171] This

especially applies to situations where a cumulative process could potentially occur in the real world, for example, the persuasive effects of advertising.[199] In addition, the effects of goal frames may disappear or reverse when it is relatively easy for people to discount negative frames (loss-framed messages) in order to avoid the undesirable possibilities.[24] However, because all participants in the present study had adolescent daughters and hence HPV vaccination was a relevant issue to them, it is unlikely that the null findings are due to parents discounting the loss-framed message.

Levin et al [24] suggested that the comparison of findings from different studies be based on the type of framing used; for instance, studies applying goal frames should be compared to studies using this framing technique. This is because varying framing effects in published literature have been partially attributed to differences in operationalization of framing of information.[24, 169] Studies that have applied goal frames to HPV vaccination intentions/behavior have been done in young adult women, primarily among undergraduate students. Gerend et al [173] found a loss-frame message advantage in HPV vaccination intentions by undergraduate female students in the U.S., but only among participants informed that a single injection was required and not those informed that six injections were required. The authors concluded that behavioral frequency moderates the effect of framing. A separate study in a similar population in the U.S. found an advantage in the loss-framed message over the gain-framed message to be apparent only among participants with risky behavior, which was measured as having multiple sexual partners and infrequently using condoms.[172] Therefore, it appears that goal framing effects on HPV vaccination intentions are moderated by other factors.

Other applications of goal frames include a study in the UK of a mixed sample of women with and without children (asked to “imagine” they had a child), which found the loss-framed message to have an advantage over the gain-framed message in the participants’ intentions to obtain the MMR vaccine for children.[176] However, due to this study’s use of groups of women for whom relevance of MMR vaccination differed, there is uncertainty in the degree to which these findings can be compared to the present study. Given the advantage of loss-frames for low-frequency behavior as reported by Gerend et al,[173] which MMR vaccination is, HPV vaccination intentions/behavior may be less likely to show framing effects due to the higher



behavioral frequency (three injections required over six months), especially where sample size is not large enough to detect small difference.

### **8.3 Strengths**

#### **8.3.1 *What this study adds***

This study makes a number of contributions. Of most importance is the collection of actual prospective data on HPV vaccine uptake, which provides estimates of the proportion of parents for whom HPV vaccines are acceptable for their adolescent daughters.

There are findings in this study that have not been previously reported in the published literature. First, the present study showed an apparent decrease in parental worry regarding genital warts among parents whose daughters have initiated HPV vaccination. Secondly, the study illustrated that parental anticipated regret regarding cervical cancer and genital warts partially mediated the effect of risk likelihood on parental acceptability of HPV vaccination for adolescent daughters. Third, the finding that awareness of the protective benefits of Gardasil® against genital warts hinders vaccine acceptability has not been reported.

This study applied message framing to an area where little has been done by assessing its impact on actual HPV vaccine uptake by adolescent girls. It is the first study to apply goal frames to assess whether providing framed HPV vaccination information to parents has an effect on HPV vaccine uptake among their adolescent daughters.

Finally, there are no published findings specific to New Zealand on the topic addressed by this thesis. As illustrated in the literature review, most of the previous published studies in this area were undertaken in the United States or United Kingdom.

#### **8.3.2 *Methodology***

The study design was unique in that it included an experimental component within a prospective study. In addition, the study population comprised of parents for whom HPV vaccination was a relevant issue and who would need to provide consent for daughters to obtain the HPV vaccine.

The participating parents all had daughters who were eligible for free HPV vaccination or would be within approximately one year.

The approach used to recruit study participants minimized the possibility of selection bias. This is evident by the lack of significant differences between the decile rankings of schools participating in this study and the decile rankings of schools in Auckland North that serve 11-15 year old females.

This study was also able to recruit a reasonably-sized sample of 229 parents. Of these, 77% agreed to participate in the follow-up, which is a relatively high participation rate. Among the 176 parents who provided consent for their daughters' HPV vaccination data to be obtained at follow-up, this was successfully done for 97% of the participants' daughters.

## **8.4 Limitations**

### **8.4.1 Study design**

Baseline questionnaire data on psychosocial factors and girls HPV vaccination status was collected at the same time. Hence, there is a possibility that some attitudes and beliefs among parents whose daughters had initiated HPV vaccination at baseline do not precede vaccination behavior. Therefore, a causal relationship cannot be established in this case.

The framing analysis could have benefited from a larger sample size to increase statistical power to detect any small framing effects that may exist. It is also impossible to control or know what other information may have influenced the parents' and/or their daughters' decisions regarding HPV vaccination after the framed messages were provided. It is likely that parents and daughters sought additional information on HPV vaccines, especially since its use is relatively recent.

Strathman et al [200] described *Consideration of Future Consequences* (CFC) as “the extent to which individuals consider the potential distant outcomes of their current behavior and the extent to which they are influenced by these potential outcomes” (p. 743). Therefore, people who are low and high in CFC are expected to be more likely to act in order to address needs/concerns

with immediate and distant consequences, respectively. One of the possible limitations of the framing aspect of the present study is a lack of measures on CFC. Since parents low in CFC in the present study may view cervical cancer as a distant (long-term) consequence of choosing not to vaccinate daughters and hence decide not to act immediately, CFC may be a potential moderator that was not addressed by this study.

#### **8.4.2 Recruitment and data collection**

The process of recruiting parents into this study was dependent on girls attending participating schools delivering research invitations to their parents. Hence, it is difficult to know how many of the 3,995 research invitations requested by schools to provide to adolescent girls were actually delivered to their parents.

Twenty-three percent (n=53) of the 229 parents who participated in this study did not provide follow-up consent to obtain their daughters HPV vaccine uptake data. Therefore, it was impossible to determine whether these parents' daughters – most of whom were unvaccinated at baseline (n=42) – later initiated HPV vaccination at follow-up. Moreover, if these parents declined to participate in the follow-up because they are against HPV vaccination, this may have resulted in an overestimation of the HPV vaccine uptake rate at follow-up because such participants would mostly be excluded from the denominator and hardly contribute to the numerator.

Among the 159 parents whose daughters were unvaccinated at baseline, a significantly higher proportion of parents with daughters attending schools ranked decile seven or lower provided follow-up consent, compared to parents whose daughters attended schools ranked above decile seven (90.6% vs. 64.8%). In addition, a significantly greater proportion of parents who were unaware Gardasil® prevents genital warts consented to a follow-up than parents who were aware of this (83.9% vs. 67.3%). However, in this sub-sample, there were no differences between parents who consented to participate in the follow-up and those who declined on parents' age and education level, girls' age, and whether parents were recipients of gain-framed or loss-framed messages. Therefore, the significant difference observed between follow-up consenters and dissenters may have resulted in an overestimation of HPV vaccine uptake rate among parents

who participated in the follow-up. This is because at baseline, the results showed that parents who were unaware of the protective benefits of Gardasil® against genital warts were more likely to initiate HPV vaccination for daughters or report their intention to do so. Furthermore, some studies have reported that parents of lower socioeconomic status are more willing to vaccinate daughters against HPV.[155, 156]

Follow-up data were obtained via parental report and health records, depending on parental consent. It may be argued that data obtained via parental report data is less accurate. However, there are no known biases that may have occurred as a result on obtaining this information in two ways. Moreover, there were no significant differences in the level of completion of the three injections of the HPV vaccination series by sources of uptake data.

#### **8.4.3 *Potential biases***

Response bias may have occurred if parents who were more interested in the research topic responded to the invitation to participate in the study. Although unknown, if parents declining to participate in the follow-up would be disproportionately less likely to vaccinate daughters against HPV, this would inflate the HPV vaccine uptake rates at follow-up especially given that vaccine uptake at follow-up was comparable among those with and without the intention to vaccinate daughters in the next year.

Social desirability bias may have affected the assessment of issues such as, parents' personal and familial history with STIs. Because the questionnaire was not anonymous, some questions may have caused participants to provide responses they perceived as socially desirable. However, the research questionnaire included only a small number of personal questions, which suggests that that this bias is a minor issue in this study.

#### **8.4.4 *External validity/ generalizability of findings***

The study primarily recruited schools in Auckland North so that HPV vaccine uptake data could be obtained via the staff at the WDHB school-based program in 2010. Compared to other parts of the Auckland Region, people residing in this part of Auckland have higher SES and are more

likely to be of European ethnicity. This is evident in the ethnic composition of the study participants and the decile rankings of schools attended by their daughters.

## **8.5 Summary**

The findings on anticipated regret are consistent with the theoretical notion that people who anticipate negative consequences for failing to undertake a beneficial behavior are more likely to take preventive actions. The findings on parental worry and the mediation effect of anticipated inaction regret to some extent agree with the *risk-as-feelings* hypothesis. The findings based on HBM dimensions are largely consistent with the theoretical framework that perceived susceptibility, perceived severity, perceived benefits, perceived barriers and cues to action explain health behavioral actions and intentions. However, the message framing results do not support the notion that for goal frames, messages which inform on the consequences of inaction have an advantage over those that inform on the benefits of action; this could be due to limited power in this study to detect small differences. This chapter has also described the contributions this study makes to the literature and the potential limitations that should be considered when interpreting the study findings. The final chapter is next and presents the study's conclusions, their implications, and recommendations for future research.

## **CHAPTER 9: CONCLUSIONS, IMPLICATIONS AND RECOMMENDATIONS**

This chapter highlights the conclusions drawn from this study and describes the meaning of the study's findings from a public health and policy perspective, as well as a theoretical perspective. In addition, recommendations for future research and methodology considerations are described.

### **9.1 Psychosocial factors and HPV vaccine acceptability**

The present study had shown that affective reactions, specifically, regret and worry, are significantly related to parental acceptability of HPV vaccines. This is in agreement with the *risk-as-feelings* hypothesis that emotions play a prominent role in decision making.[14] Parents who have vaccinated daughters against HPV and who report their intention to do so in the near future are motivated greatly by *inaction* regret. However, after adjusting for other factors, cervical cancer worry is comparable among parents regardless of their daughters' HPV vaccination status, probably due to its greater perceived seriousness. In addition, parents whose daughters have been vaccinated experience significant reductions in worry regarding HPV and genital warts. Anticipated *inaction* regret also accounts for a proportion of the effect that risk likelihood has on parental acceptability of HPV vaccination for adolescent daughters. It appears that perceptions of greater risk of HPV-related illnesses without vaccination cause parents to anticipate feelings of regret from inaction, which leads to greater HPV vaccine acceptability. Health behaviors can be enhanced by encouraging people to focus on affective reactions that could result from a specific action/inaction.[16] With respect to findings from the present study, parents who have not vaccinated daughters against HPV can be informed that vaccinating daughters would alleviate some worries and concerns about HPV infections and genital warts.

Regarding the findings on the positive influence of subjective norms, encouraging patient-provider communication is important as parents who place greater value on recommendations by health professionals to vaccinate their daughter against HPV are more likely to have daughters who have been vaccinated, or to intend to do so. Furthermore, since parents who greatly value recommendations by family/friends are also more likely to vaccinate daughters against HPV,

public education could enhance acceptability since more of the parents' family members and peers will be informed.

Manufacturing safe vaccines is a vital issue as parental concerns about HPV vaccine safety do not seem to necessarily emanate from experiences with HPV vaccines, but are likely due to general views about vaccines. In addition, media reports linking MMR vaccination and autism is thought to enhance concerns about vaccine safety.[201] From a policy perspective, it is important to keep in mind that negative opinions parents may have about past vaccination experiences may be transferred to new vaccines. Therefore, ensuring that vaccines are safe for the public would benefit the general perception about vaccines and encourage parents to vaccinate children against various preventable illnesses.

The cost of HPV vaccines appears to be a major barrier to HPV vaccine uptake in countries where the free HPV vaccination programs have not been implemented. This view is supported by the disparity in the proportion of parents in U.S. studies who state they would accept HPV vaccination for daughter versus the actual uptake rates. Furthermore, in the present study, the median of the highest dollar amount parents would be willing to pay for the HPV vaccination series was 9-10 times less than the actual cost of the vaccine. Therefore, having affordable HPV vaccines would reduce some vaccination barriers, which would increase uptake rates and aid in reducing incidence of cervical cancer and genital warts (for those receiving Gardasil®).

## **9.2 Methodology considerations**

Collinearity occurs when several variables are involved in some mutual dependence or have a high degree of interrelationship. For instance, if two such variables are included in the same regression model, “the effect of one might not be apparent because when one is high, the other would also be high and their combined effect would tend to cancel each other out” (p. 336).[202] Hence, the correlation between two such independent variables would mask true effects and result in imprecise parameter estimates due to high standard errors.[187] In this regard, the inclusion of potential predictors that are moderately or highly correlated into a single multivariate model would lead to loss of meaningful information regarding factors that could be addressed to enhance HPV vaccine acceptability. For instance, in the present study an attempt

was made to perform multivariate analyses that combined all HBM dimensions and measures of anticipated emotions. Individually, subjective norms (cues to action) and anticipated inaction regret measures were the strongest predictors of HPV vaccine acceptability, but they were also moderately correlated. Hence, when placed together into one multivariate model, the effect of inaction regret ‘disappeared’ and that of subjective norms was inflated. This is because people who scored high on inaction regret also scored high on subjective norms. Although these factors are providing different pieces of information, the role of one factor on behavior is ‘lost’ and that of the other factor is overestimated. From a disease prevention perspective, it may be more beneficial to determine how various factors influence health behavior, instead of focusing on which of a broad range of factors would stand-out the most when these are combined in one model. This is because underestimating the importance of some factors would result in missed opportunities to utilize information that could enhance preventive health actions, or to address barriers that deter people from undertaking beneficial health behaviors.

Another methodological issue that requires caution is where scores are created from multiple correlated variables that are not part of a standardized scale. An illustration of such a scenario can be drawn from the present study. Although measures of parental worry regarding HPV, genital warts and cervical cancer were highly correlated ( $r=.76$  to  $.91$ ), cervical cancer worry was not an independent predictor of girls’ HPV vaccination status in the multivariate analysis. In a scenario where these three variables are summed together and the scored variable is found to be related with the outcome, the conclusion drawn regarding cervical cancer worry (in combination with worry about HPV and genital warts) would be incorrect.

### **9.3 Recommendations for future research**

Triggering inaction regret in a manner that minimizes in psychological distress or ethical concerns is an area that has understandably received little attention. One way in which this could be tested in future research is by incorporating triggers of inaction regret into framed messages and assessing their impact on HPV vaccination decisions prospectively.

Future research could also investigate whether framed messages directed at both parents and their daughters versus parents alone would be more persuasive in accelerating HPV vaccine



uptake, and whether CFC mediates such relationships. Another area of future work in this area would be to assess factors that potentially moderate the effect of framing on parental acceptability of HPV vaccines.

Qualitative studies could provide better insight as to why parental awareness that Gardasil® also prevents genital warts is a deterrent of vaccine acceptability. Stigma associated with genital warts is a potential reason, but there could be other factors that if better understood could be incorporated into health information provided to parents.

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## **APPENDICES**

### **Appendix A: Participant information sheet for school principals**

## **PARTICIPANT INFORMATION SHEET – SCHOOL PRINCIPALS**

This document contains important information. Please take your time to read it.

**Title of Project:** Parental acceptance of the Human Papillomavirus (HPV) vaccine for 11–15 years old girls

**Invited Participants:** Parents and primary caregivers of 11–15 year old girls

**Primary Researcher:** Carol Chelimo, PhD Student, Department of Psychological Medicine

**Other Researchers:**

1. Trecia Wouldes, PhD, Senior Lecturer, Department of Psychological Medicine
2. Linda Cameron, PhD, Professor, Department of Psychology

### **Project Description and Invitation**

We are inviting your school to participate in a research project that is being done to learn more about factors related to parental acceptance/non-acceptance of the cervical cancer vaccine (also known as, the HPV vaccine or *Gardasil*). We hope that your school will allow us to provide information about this project to parents/caregivers of 11–15 year old girls (Years 7 to 10).

Similar research has been done in other countries, but information on factors related to parental acceptance/non-acceptance of HPV vaccination for adolescent girls is currently unavailable for New Zealand. This research is important because what we learn from it could benefit cervical cancer prevention in New Zealand. The HPV vaccine is currently available to 12–18 year old girls at no cost through schools and primary care.

This project will consist of:

1. A research questionnaire to be completed by parents/caregivers.
2. A follow-up after questionnaire completion to enable the researchers to collect information on the girls' progress with HPV vaccinations.

This project is being done by researchers in the Department of Psychological Medicine (Carol Chelimo and Dr. Trecia Wouldes) and Department of Psychology (Prof. Linda Cameron) at the University of Auckland.

### **General Information about Cervical Cancer and HPV (Human Papillomavirus)**

In New Zealand, cervical cancer is the 8<sup>th</sup> most common cancer among women. In addition, every year, about 230 women are diagnosed with cervical cancer and about 80 die from it.

HPV are types of viruses that cause certain types of cancer and warts. Different types of HPV affect different parts of the body, including the cervix. It is spread by direct, skin-to-skin contact with a person who has the virus. HPV infection of the cervix occurs through sexual contact. About 80 percent of women who have ever been sexually active will have an HPV infection at some point. Most women who develop HPV infections clear the virus naturally and do not develop cervical cancer.

### **General Information about the HPV vaccine**

*Gardasil* is the name of the free HPV vaccine that is available to New Zealand girls. It has been licensed for use in more than 100 countries, including New Zealand. *Gardasil* targets HPV types that are responsible for most cases of cervical cancer and genital warts. Research has shown that *Gardasil* is able to prevent these HPV types in women who have not been infected. Research has also shown that protection against HPV infection lasts for at least five years after vaccination, and suggests that protection will last much longer. More research is being done to find out how long protection will last. *Gardasil* does not protect against all HPV types that can cause cervical cancer, and as with any vaccine, it may not provide protection for everyone who is vaccinated. It is therefore important that women continue to have regular cervical smear tests even if they have been vaccinated. The HPV vaccine is given by injection in the upper arm. Three injections are given over 6 months.

### **Study Procedure**

Your school's participation in this research is completely voluntary.

#### ***I. Selection of Participants***

Parents/caregivers of 11–15 year old girls will be provided with an invitation to participate in this project. We propose that girls be given the research packet to take home to their parent or caregiver.

Each research packet consists of the following:

- A research invitation letter for the parent/caregiver
- An information sheet for the parent/caregiver
- A consent form for the parent/caregiver
- A research questionnaire
- A freepost envelope: this will be used by parents to mail the completed questionnaire and signed consent form to the researchers.

## ***II. Data Collection***

- a) **The questionnaire:** Parents will receive information with the option to complete either the paper-version of the questionnaire in the research packet or an online-version of the same questionnaire. Parents who choose to complete the paper-version of the questionnaire will be able to send it to the researchers (along with the signed consent form). Parents who choose to complete the online-version of the questionnaire will give their consent to participate on an online consent form before starting the survey.
- b) **The follow-up:** Vaccination against HPV consists of a series of 3 injections over 6 months. The aim of the follow-up is to get information on the girls' progress with HPV vaccinations.

## ***III. Data Storage***

All information obtained during this research will be stored securely in locked cabinets and password-protected computer files at the University of Auckland. Data access will be limited to the researchers. To ensure data security, questionnaires will be coded and stored separately from participants' identifying information. After 6 years, the researchers will ensure that questionnaires are shredded and computer files are deleted.

## ***IV. Analysis of Data***

Our aim is to learn more about factors related to parental acceptance/non-acceptance of the cervical cancer vaccine for 11–15 year old girls. Data collected from the questionnaires will be analyzed to try to determine why some parents are more likely to agree to have their daughters vaccinated against HPV, and why some parents prefer not to. We hope that information obtained from this research will benefit cervical cancer prevention in New Zealand.

## ***V. Presentation of Results***

A summary of research findings will be offered to all participating parents and schools. We also hope to publish the findings in an international journal. If the information obtained from this project is reported or published, this will be done in a way that does not identify the participants as its source.

### **Advantages of Participation**

1. Participating parents will have the chance to win gift cards during a prize draw.
2. Information obtained from this research could benefit cervical cancer prevention in New Zealand.

### **Disadvantages of Participation**

1. We will take some of your school's time when research packets are provided to girls to take home to their parents/caregivers.
2. The questionnaire will take 10–15 minutes of a parent's time to complete.
3. Since we will collect parents' contact details and identifying information to be able to follow-up on their daughters' progress with HPV vaccinations, the information provided to the researchers is not anonymous.

### **Study Contact Details**

#### Primary Researcher

Carol Chelimo, PhD Student, Department of Psychological Medicine

Tel: (09) 373-7599, Ext. 86562

#### Other Researchers

1. Trecia Wouldes, Senior Lecturer, Department of Psychological Medicine

Tel: (09) 373-7599, Ext. 86221

2. Linda Cameron, Professor, Department of Psychology

Tel: (09) 373-7599, Ext. 86869

#### Head of Department

Rob Kydd, Professor, Department of Psychological Medicine

Tel: (09) 373-7599, Ext. 83774

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050

Free fax: 0800 2 SUPPORT (0800 2787 7678)

Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

**Approved by the Northern X Regional Ethics Committee on 26 January 2010 until 30 August 2011, Reference NTX/10/EXP/004**



**Appendix B: Consent form for school principals**

## CONSENT FORM – SCHOOL PRINCIPALS

This form will be held for six years

**Primary Researcher:** Carol Chelimo

**Title of Project:** Parental acceptance of the Human Papillomavirus (HPV) vaccine for 11–15 years old girls

I have read the information sheet about the research that is being done to learn more about factors related to parental acceptance/non-acceptance of the cervical cancer vaccine. I have had the chance to ask questions about this project and I know who to contact if I want to know more. I have had the chance to discuss this project with my school's Board of Trustees.

- I understand that my school's participation in this project is voluntary.
- I understand that the researchers wish to give information about this project to 11–15 year old girls to take home to their parents/primary caregivers.
- I understand that the researchers will inform parents/caregivers that their participation in this project is voluntary.
- I understand that no material that could identify the participating parents will be used in any reports on this research project.

I agree to my school's participation in this research

Our school is interested in receiving a summary of the research findings

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

Principal's Full Name (PRINT): \_\_\_\_\_

**Approved by the Northern X Regional Ethics Committee on 26 January 2010 until 30 August 2011, Reference NTX/10/EXP/004**

**Appendix C: Pre-questionnaire research invitation letter for parents**

**RESEARCH INVITATION LETTER (*PRE-QUESTIONNAIRE*) - PARENTS**

Dear Parent (Caregiver),

**SUBJECT: Invitation to complete a parental questionnaire on the cervical cancer vaccine  
(HPV vaccine)**

We are pleased to invite you to participate in a survey to learn more about factors related to parental acceptance/non-acceptance of the cervical cancer vaccine (also known as, the HPV vaccine or *Gardasil*). You are welcome to participate in this project whether or not your daughter has had the HPV vaccine.

Enclosed please find:

- 1) An information sheet with more details about this project
- 2) A questionnaire request form
- 3) A freepost envelope for reply

You may participate in this project by:

- 1) Completing the survey online at:

**<https://www.surveymonkey.com/s/hpvproject>**

**(NOTE:** There is an “s” after “http”)

**OR**

- 2) Completing the enclosed *questionnaire request form*. Return the form to the researchers in the freepost envelope and a questionnaire will be mailed to you.

We look forward to hearing from you.

Thank you.

Sincerely,

Carol Chelimo.

**Phone:** (09) 373 7599, Ext. 86562; **Email:** [c.chelimo@auckland.ac.nz](mailto:c.chelimo@auckland.ac.nz)

**Appendix D: Pre-questionnaire participant information sheet for parents**

## **PARTICIPANT INFORMATION SHEET (*PRE-QUESTIONNAIRE*) – PARENTS**

This document contains important information. Please take your time to read it.

**Title of Project:** Parental acceptance of the Human Papillomavirus (HPV) vaccine for 11–15 year old girls

**Invited Participants:** Parents and primary caregivers of 11–15 year old girls

**Primary Researcher:** Carol Chelimo, PhD Student, Department of Psychological Medicine

**Other Researchers:**

1. Trecia Wouldes, PhD, Senior Lecturer, Department of Psychological Medicine
2. Linda Cameron, PhD, Professor, Department of Psychology

### **Project Description and Invitation**

You are invited to participate in a research project that is being done to learn more about factors related to parental acceptance/non-acceptance of the cervical cancer vaccine (also known as, the HPV vaccine or *Gardasil*).

Similar research has been done in other countries, but information on factors related to parental acceptance/non-acceptance of HPV vaccination for adolescent girls is currently unavailable for New Zealand. This research is important because what we learn from it could benefit cervical cancer prevention in New Zealand. The HPV vaccine is currently available to 12–18 year old girls at no cost through schools and primary care.

This project will consist of:

1. A research questionnaire to be completed by parents/caregivers.
2. A follow-up after questionnaire completion to enable the researchers to get information on your daughter's progress with HPV vaccinations.

This project is being done by researchers in the Department of Psychological Medicine (Carol Chelimo and Dr. Trecia Wouldes) and Department of Psychology (Prof. Linda Cameron) at the University of Auckland.

### **General Information about Cervical Cancer and HPV (Human Papillomavirus)**

In New Zealand, cervical cancer is the 8<sup>th</sup> most common cancer among women. In addition, every year, about 230 women are diagnosed with cervical cancer and about 80 die from it.

HPV are types of viruses that cause certain types of cancer and warts. Different types of HPV affect different parts of the body, including the cervix. It is spread by direct, skin-to-skin contact with a person who has the virus. HPV infection of the cervix occurs through sexual contact. About 80 percent of women who have ever been sexually active will have an HPV infection at some point. Most women who develop HPV infections clear the virus naturally and do not develop cervical cancer.

### **General Information about the HPV vaccine**

*Gardasil* is the name of the free HPV vaccine that is available to New Zealand girls. It has been licensed for use in more than 100 countries, including New Zealand. *Gardasil* targets HPV types that are responsible for most cases of cervical cancer and genital warts. Research has shown that *Gardasil* is able to prevent these HPV types in women who have not been infected. Research has also shown that protection against HPV infection lasts for at least five years after vaccination, and suggests that protection will last much longer. More research is being done to find out how long protection will last. *Gardasil* does not protect against all HPV types that can cause cervical cancer, and as with any vaccine, it may not provide protection for everyone who is vaccinated. It is therefore important that women continue to have regular cervical smear tests even if they have been vaccinated. The HPV vaccine is given by injection in the upper arm. Three injections are given over 6 months.

### **Study Procedure**

Your participation in this research is completely voluntary.

#### ***I. Selection of Participants***

Parents/caregivers of 11–15 year old girls will receive an invitation to participate in this project through intermediate schools, high schools and colleges.

The research packet consists of the following:

- A research invitation letter

- An information sheet
- A questionnaire request form
- A freepost envelope

## **II. Data Collection**

- a) **The questionnaire:** You have the option to complete the questionnaire online, or you may use the *questionnaire request form* to have a questionnaire mailed to you. You have the right to decline to answer all or any questions in this survey.

If you choose to complete the survey online, you may do so at:

<https://www.surveymonkey.com/s/hpvproject>

(**NOTE:** There is an “s” after “http”)

This website provides data security by encrypting links and survey pages using what is known as, Secure Sockets Layer (SSL). It will also ensure that data transmitted from the survey website to the researchers is in an encrypted format. You will be able to give your consent to participate on an online consent form before starting the survey.

If you prefer to complete the paper-version of the questionnaire, please complete the *questionnaire request form* and send it to the researchers in the freepost envelope provided.

- b) **The follow-up:** Vaccination against HPV consists of a series of 3 injections over 6 months. The aim of the follow-up is to get information on your daughter’s progress with HPV vaccinations. When you complete the questionnaire, you will be able to give your consent for the researchers to obtain this information in one of the following ways:

- **Option 1:** The researchers will contact you directly for information on your daughter’s progress with HPV vaccinations.

**OR**

- **Option 2:** The researchers will obtain your daughter’s HPV vaccination dates from the staff at the Waitemata District Health Board (WDHB) HPV vaccination school-based program.



### ***III. Data Storage***

All information obtained during this research will be stored securely in locked cabinets and password-protected computer files at the University of Auckland. Data access will be limited to the researchers. To ensure data security, questionnaires will be coded and stored separately from participants' identifying information. After 6 years, the researchers will ensure that questionnaires are shredded and computer files are deleted.

### ***IV. Analysis of Data***

Our aim is to learn more about factors related to parental acceptance/non-acceptance of the cervical cancer vaccine for 11–15 year old girls. Data collected from the questionnaires will be analyzed to try to determine why some parents are more likely to agree to have their daughters vaccinated against HPV, and why some parents prefer not to. We hope that information obtained from this research will benefit cervical cancer prevention in New Zealand.

### ***V. Presentation of Results***

A summary of research findings will be offered to all participants. We also hope to publish the findings in an international journal. If the information obtained from this project is reported or published, this will be done in a way that does not identify you as its source.

### **Advantages of Participation**

1. Participating parents will have the chance to win gift cards during a prize draw.
2. Information obtained from this research could benefit cervical cancer prevention in New Zealand.

### **Disadvantages of Participation**

1. The questionnaire will take 10–15 minutes of a parent's time to complete.
2. Since we will collect parents' contact details and identifying information to be able to follow-up on their daughters' progress with HPV vaccinations, the information provided to the researchers is not anonymous.

## **Study Contact Details**

### Primary Researcher

Carol Chelimo, PhD Student, Department of Psychological Medicine

Tel: (09) 373-7599, Ext. 86562

### Other Researchers

1. Trecia Wouldes, Senior Lecturer, Department of Psychological Medicine

Tel: (09) 373-7599, Ext. 86221

2. Linda Cameron, Professor, Department of Psychology

Tel: (09) 373-7599, Ext. 86869

### Head of Department

Rob Kydd, Professor, Department of Psychological Medicine

Tel: (09) 373-7599, Ext. 83774

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050

Free fax: 0800 2 SUPPORT (0800 2787 7678)

Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

**Approved by the Northern X Regional Ethics Committee on 26 January 2010 until 30 August 2011, Reference NTX/10/EXP/004**

**Appendix E: Questionnaire request form**

**QUESTIONNAIRE REQUEST FORM**

If you would like a questionnaire sent to you, please complete this form and mail it to the researchers in the freepost envelope provided.

N	A	M	E	:																																																		
A	D	D	R	E	S	S	:																																															
S	U	B	U	R	B	:																																																
C	I	T	Y	:																																																		
P	O	S	T	A	L		C	O	D	E	:																																											

**From which school did you receive this form?**


Thank you!

**Appendix F: Research invitation letter (with questionnaire) for parents**

**RESEARCH INVITATION LETTER (WITH QUESTIONNAIRE) - PARENTS**

Dear Parent (Caregiver),

**SUBJECT: Invitation to complete a parental questionnaire on the cervical cancer vaccine  
(HPV vaccine)**

We are pleased to invite you to participate in a survey to learn more about factors related to parental acceptance/non-acceptance of the cervical cancer vaccine (also known as, the HPV vaccine or *Gardasil*). You are welcome to participate in this project whether or not your daughter has had the HPV vaccine.

Enclosed please find:

- 1) An information sheet with more details about this project
- 2) A consent form
- 3) A questionnaire
- 4) A freepost envelope for reply

You may participate in this project by:

- 1) Completing the enclosed questionnaire and consent form. Please return these to the researchers in the freepost envelope provided.

**OR**

- 2) Completing the survey online at:

**<https://www.surveymonkey.com/s/hpvproject>**

**(NOTE:** There is an “s” after “http”)

We look forward to hearing from you.

Thank you.

Sincerely,

Carol Chelimo.

**Phone:** (09) 373 7599, Ext. 86562; **Email:** [c.chelimo@auckland.ac.nz](mailto:c.chelimo@auckland.ac.nz)

**Appendix G: Participant information sheet (with questionnaire) for parents**

## **PARTICIPANT INFORMATION SHEET (WITH QUESTIONNAIRE) – PARENTS**

This document contains important information. Please take your time to read it.

**Title of Project:** Parental acceptance of the Human Papillomavirus (HPV) vaccine for 11–15 year old girls

**Invited Participants:** Parents and primary caregivers of 11–15 year old girls

**Primary Researcher:** Carol Chelimo, PhD Student, Department of Psychological Medicine

**Other Researchers:**

1. Trecia Wouldes, PhD, Senior Lecturer, Department of Psychological Medicine
2. Linda Cameron, PhD, Professor, Department of Psychology

### **Project Description and Invitation**

You are invited to participate in a research project that is being done to learn more about factors related to parental acceptance/non-acceptance of the cervical cancer vaccine (also known as, the HPV vaccine or *Gardasil*).

Similar research has been done in other countries, but information on factors related to parental acceptance/non-acceptance of HPV vaccination for adolescent girls is currently unavailable for New Zealand. This research is important because what we learn from it could benefit cervical cancer prevention in New Zealand. The HPV vaccine is currently available to 12–18 year old girls at no cost through schools and primary care.

This project will consist of:

1. A research questionnaire to be completed by parents/caregivers.
2. A follow-up after questionnaire completion to enable the researchers to get information on your daughter's progress with HPV vaccinations.

This project is being done by researchers in the Department of Psychological Medicine (Carol Chelimo and Dr. Trecia Wouldes) and Department of Psychology (Prof. Linda Cameron) at the University of Auckland.



## **General Information about Cervical Cancer and HPV (Human Papillomavirus)**

In New Zealand, cervical cancer is the 8<sup>th</sup> most common cancer among women. In addition, every year, about 230 women are diagnosed with cervical cancer and about 80 die from it.

HPV are types of viruses that cause certain types of cancer and warts. Different types of HPV affect different parts of the body, including the cervix. It is spread by direct, skin-to-skin contact with a person who has the virus. HPV infection of the cervix occurs through sexual contact. About 80 percent of women who have ever been sexually active will have an HPV infection at some point. Most women who develop HPV infections clear the virus naturally and do not develop cervical cancer.

## **General Information about the HPV vaccine**

*Gardasil* is the name of the free HPV vaccine that is available to New Zealand girls. It has been licensed for use in more than 100 countries, including New Zealand. *Gardasil* targets HPV types that are responsible for most cases of cervical cancer and genital warts. Research has shown that *Gardasil* is able to prevent these HPV types in women who have not been infected. Research has also shown that protection against HPV infection lasts for at least five years after vaccination, and suggests that protection will last much longer. More research is being done to find out how long protection will last. *Gardasil* does not protect against all HPV types that can cause cervical cancer, and as with any vaccine, it may not provide protection for everyone who is vaccinated. It is therefore important that women continue to have regular cervical smear tests even if they have been vaccinated. The HPV vaccine is given by injection in the upper arm. Three injections are given over 6 months.

## **Study Procedure**

Your participation in this research is completely voluntary.

### ***Selection of Participants***

Parents/caregivers of 11–15 year old girls will receive an invitation to participate in this project through intermediate schools, high schools and colleges.

The research packet consists of the following:

- A research invitation letter
- An information sheet
- A consent form
- A research questionnaire
- A freepost envelope: this will be used by parents to mail the completed questionnaire and signed consent form to the researchers.

### ***Data Collection***

**The questionnaire:** You have the option to complete either the paper-version of the questionnaire in this research packet or an online-version of the same questionnaire. You have the right to decline to answer all or any questions in this survey.

If you choose to complete the paper-version of the questionnaire, please send it to the researchers (along with the signed consent form) in the freepost envelope provided.

If you choose to complete the survey online, you may do so at:

**<https://www.surveymonkey.com/s/hpvproject>**

**(NOTE:** There is an “s” after “http”)

This website provides data security by encrypting links and survey pages using what is known as, Secure Sockets Layer (SSL). It will also ensure that data transmitted from the survey website to the researchers is in an encrypted format. You will be able to give your consent to participate on an online consent form before starting the survey.

**The follow-up:** Vaccination against HPV consists of a series of 3 injections over 6 months. The aim of the follow-up is to get information on your daughter’s progress with HPV vaccinations. You may give your consent for the researchers to obtain this information in one of the following ways:

- **Option 1:** The researchers will contact you directly for information on your daughter’s progress with HPV vaccinations.

**OR**

- **Option 2:** The researchers will obtain your daughter's HPV vaccination dates from the staff at the Waitemata District Health Board (WDHB) HPV vaccination school-based program.

These options are included in your consent form.

### ***Data Storage***

All information obtained during this research will be stored securely in locked cabinets and password-protected computer files at the University of Auckland. Data access will be limited to the researchers. To ensure data security, questionnaires will be coded and stored separately from participants' identifying information. After 6 years, the researchers will ensure that questionnaires are shredded and computer files are deleted.

### ***Analysis of Data***

Our aim is to learn more about factors related to parental acceptance/non-acceptance of the cervical cancer vaccine for 11–15 year old girls. Data collected from the questionnaires will be analyzed to try to determine why some parents are more likely to agree to have their daughters vaccinated against HPV, and why some parents prefer not to. We hope that information obtained from this research will benefit cervical cancer prevention in New Zealand.

### ***Presentation of Results***

A summary of research findings will be offered to all participants. We also hope to publish the findings in an international journal. If the information obtained from this project is reported or published, this will be done in a way that does not identify you as its source.

## **Advantages of Participation**

1. Participating parents will have the chance to win gift cards during a prize draw.
2. Information obtained from this research could benefit cervical cancer prevention in New Zealand.

## **Disadvantages of Participation**

1. The questionnaire will take 10–15 minutes of a parent's time to complete.
2. Since we will collect parents' contact details and identifying information to be able to follow-up on their daughters' progress with HPV vaccinations, the information provided to the researchers is not anonymous.

## **Study Contact Details**

### Primary Researcher

Carol Chelimo, PhD Student, Department of Psychological Medicine

Tel: (09) 373-7599, Ext. 86562

### Other Researchers

1. Trecia Wouldes, Senior Lecturer, Department of Psychological Medicine  
Tel: (09) 373-7599, Ext. 86221
2. Linda Cameron, Professor, Department of Psychology  
Tel: (09) 373-7599, Ext. 86869

### Head of Department

Rob Kydd, Professor, Department of Psychological Medicine

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If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050

Free fax: 0800 2 SUPPORT (0800 2787 7678)

Email: [advocacy@hdc.org.nz](mailto:advocacy@hdc.org.nz)

**Approved by the Northern X Regional Ethics Committee on 26 January 2010 until 30 August 2011, Reference NTX/10/EXP/004**

**Appendix H: Consent form for parents**

## CONSENT FORM – PARENTS

This form will be held for six years

**Primary Researcher:** Carol Chelimo

**Title of Project:** Parental acceptance of the Human Papillomavirus (HPV) vaccine for 11–15 year old girls

I have read the information sheet about the research that is being done to learn more about factors related to parental acceptance/non-acceptance of the cervical cancer vaccine. I have had the chance to ask questions about this project and I know who to contact if I want to know more.

I have had the chance to discuss this project with a friend or family (whānau).

- I understand that my participation in this project is voluntary (my choice).
- I understand that I am free to choose which questions to answer when completing the questionnaire.
- I understand that the survey is not anonymous as my contact details will be requested.
- I understand that no material that could identify me will be used in any reports on this research project.

I agree to take part in this research

I am interested in receiving a summary of the research findings

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

Parent's Full Name (PRINT): \_\_\_\_\_

*(Please turn over)*

The researchers would like to follow-up on your daughter's progress with HPV vaccinations. Please **choose one** of the following options to help us get this information.

**OPTION 1:**

- I agree to be contacted by the researchers for information on my daughter's progress with HPV vaccinations.

My contact information is provided below:

Phone: \_\_\_\_\_

Mobile: \_\_\_\_\_

Email: \_\_\_\_\_

**OPTION 2:**

- I agree that the researchers may obtain my daughter's HPV vaccination dates from the staff at the Waitemata District Health Board (WDHB) HPV vaccination school-based program.

My daughter's name, school and date of birth are provided below:

*(NOTE: If you received more than 1 invitation to participate in this project, please tell us about your youngest daughter in the 11-15 year age-group)*

Your daughter's name: \_\_\_\_\_

Name of your daughter's school: \_\_\_\_\_

Your daughter's date of birth:

		/			/		
D	D	/	M	M	/	Y	Y

**Approved by the Northern X Regional Ethics Committee on 26 January 2010 until 30 August 2011, Reference NTX/10/EXP/004**

## **Appendix I: Parental questionnaire**



# Parental Questionnaire on the Cervical Cancer Vaccine

[Human Papillomavirus (HPV) Vaccine]

An HPV vaccine is now available to protect against cervical cancer and most genital warts. It is sometimes called the cervical cancer vaccine or Gardasil.

In this questionnaire, I will call it the HPV vaccine.

**For office use only:**

CODE NUMBER

--	--	--	--	--

DATE

		-				-		
D	D	-	M	M	M	-	Y	Y

**SECTION A: ABOUT YOU (PARENT/CAREGIVER)***Please tell us about yourself*

A.1 Month and year you were born:

		/				
M	M	/	Y	Y	Y	Y

A.2 Your gender:

Female	1
Male	2

A.3 Your current marital status:

Never married	1
Married	2
De Facto (living with partner, but NOT married)	3
Separated	4
Divorced	5
Widowed	6
Civil union	7

A.4 Your self-identified ethnicity: **(Please circle all options that apply)**

NZ European	1
NZ Māori	2
Samoan	3
Cook Island Māori	4
Tongan	5
Asian	6
Other (please specify):	7

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A.5 If you are currently married or are living with a partner, what is his/her self-identified ethnicity? **(Please circle all options that apply)**

NZ European	1
NZ Māori	2
Samoan	3
Cook Island Māori	4
Tongan	5
Asian	6
Other (please specify):	7

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A.6 Your highest level of education completed:

1 <sup>st</sup> to 6 <sup>th</sup> Year	1
Form 1	2
Form 2	3
Form 3	4
Form 4	5
Form 5	6
Form 6	7
Form 7	8
1 Year University	9
2 Years University	10
3 Years University	11
BA/BSc/BCom/LLB	12
MA/MSc/MBChB/MD	13
PhD	14
Other (please specify):	15

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A.7 Your religious affiliation:

Christian - Roman Catholic	1
Christian - Protestant	2
Muslim	3
Hindu	4
Buddhist	5
Jewish	6
None	7
Other (please specify):	8

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A.8 In which suburb and city do you live?

Suburb: \_\_\_\_\_

City: \_\_\_\_\_

**SECTION B: ABOUT YOUR 11-15 YEAR OLD DAUGHTER**

*Please tell us about your 11-15 year old daughter*

*(NOTE: If you have received more than 1 invitation to participate in this project, please tell us about your youngest daughter in this age-group)*

B.1 Month and year your daughter was born:

		/				
M	M	/	Y	Y	Y	Y

B.2 Name of your daughter's school:

---

B.3 In which suburb and city is your daughter's school located?

Suburb:

\_\_\_\_\_

City:

\_\_\_\_\_

B.4 Did your daughter get vaccinated for *childhood illnesses*, such as, measles?

Vaccinated for ALL childhood illnesses	1
Vaccinated for SOME childhood illnesses	2
Not vaccinated for childhood illnesses	3
Don't know	4

*a. If you did NOT vaccinate your daughter in childhood, please explain why?*

\_\_\_\_\_

\_\_\_\_\_

B.5 Was your daughter vaccinated for meningitis (meningococcal B)?

Yes	1
No	2
Don't know	3

*a. If your daughter was NOT vaccinated for meningitis, please explain why?*

\_\_\_\_\_

\_\_\_\_\_

B.6 Has your daughter had the HPV vaccine?

Yes <b>(go to B.7)</b>	1
No <b>(go to B.15)</b>	2
Don't know <b>(go to B.15)</b>	3

***If your daughter has the HPV vaccine, please answer the following:  
(otherwise, go to B.15)***

B.7 When did your daughter have her **1st** shot of the HPV vaccine?

		/				
M	M	/	Y	Y	Y	Y

B.8 Where did your daughter get her HPV vaccination?

Her school	1
GP's office or primary care	2
Other (please specify):	3

B.9 Did you have to pay for your daughter's HPV vaccine?

Yes <b>(go to B.11)</b>	1
No	2

B.10 If you had to pay for the HPV vaccine, would you vaccinate your daughter against HPV?

Yes	1
No	2

B.11 How many shots of the HPV vaccine has your daughter had so far?

One shot	1
Two shots	2
Three shots <b>(go to B.13)</b>	3

B.12 The HPV vaccine requires 3 shots. Do you think your daughter will receive all 3 shots of the HPV vaccine?

Definitely won't	1
Probably won't	2
Probably will	3
Definitely will	4

B.13 Was the decision to vaccinate your daughter against HPV influenced by any of the following? **(Please circle all options that apply)**

	Yes	No
Family members (Whānau)	1	2
Your partner	1	2
Your daughter for whom the HPV vaccine is recommended	1	2
GP (or other health professional)	1	2
HPV vaccine TV advertisements	1	2
Other (please specify):	1	2

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B.14 Here are some reasons that have been given by parents for deciding to vaccinate girls against HPV. Which of the following were reasons for your decision to vaccinate your daughter against HPV?

**(Please circle all options that apply)**

	Yes	No
Believing the vaccine will protect against HPV and cervical cancer	1	2
The HPV vaccine was recommended by a GP	1	2
The HPV vaccine is available at no cost (free)	1	2
Having the HPV vaccine in schools saves parents some time	1	2
Believing that children should get all recommended vaccines	1	2
Other (please specify):	1	2

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***If your daughter has NOT had the HPV vaccine or you don't know if she has, please answer the following (otherwise, go to SECTION C):***

B.15 Do you intend to get your daughter the HPV vaccine in the next 12 months?

Definitely won't	1
Probably won't	2
Probably will	3
Definitely will	4

B.16 Do you intend to have a discussion with your daughter about the option of getting the HPV vaccine?

Definitely won't	1
Probably won't	2
Probably will	3
Definitely will	4



B.17 Do you intend to get more information about the HPV vaccine?

Definitely won't	1
Probably won't	2
Probably will	3
Definitely will	4

B.18 Have any of the following influenced why your daughter has NOT had the HPV vaccine before today?

**(Please circle all options that apply)**

	Yes	No
Family members (Whānau)	1	2
Your partner	1	2
Your daughter for whom the HPV vaccine is recommended	1	2
GP (or other health professional)	1	2
HPV vaccine TV advertisements	1	2
Other (please specify):	1	2

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B.19 Here are some reasons that have been given by parents as to why their daughters have NOT had the HPV vaccine. Which of the following are reasons why your daughter has NOT had the HPV vaccine before today?

**(Please circle all options that apply)**

	Yes	No
You are waiting for your daughter's school-based HPV vaccination program to begin	1	2
NOT having enough information about the HPV vaccine	1	2
Having concerns about side-effects of the HPV vaccine	1	2
Feeling your daughter is too young to get the HPV vaccine	1	2
Feeling your daughter is NOT at risk of getting an HPV infection	1	2
Feeling that the HPV vaccine will affect the sexual behavior of girls	1	2
Having concerns about vaccines in general	1	2
Other (please specify):	1	2

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B.20 Please read the following health message and answer the question that follows:

**MESSAGE FRAMING CONTENT INSERTED HERE TO CREATE TWO DIFFERENT QUESTIONNAIRES** (see Appendix J)

After reading the health message above, do you intend to vaccinate your daughter against HPV?

Yes	1
No	2
Not sure	3

## SECTION C: THE HPV VACCINE AND HPV

C.1 Before today, had you heard of the HPV vaccine?

Yes	1
No (go to C.3)	2

C.2 Have you ever heard about the HPV vaccine from any of these sources?

**(Please circle all options that apply)**

	Yes	No
Your daughter's school	1	2
Family (Whānau) or friend	1	2
GP (or other health professional)	1	2
TV	1	2
Radio	1	2
Internet	1	2
Newspaper	1	2
Billboard	1	2
Other (please specify):	1	2

C.3 Before today, did you know that HPV is a sexually transmitted virus?

Yes	1
No	2

C.4 Before today, did you know that the HPV vaccine, Gardasil, also protects against genital warts?

Yes	1
No	2

C.5 Before today, did you know that vaccinating girls against HPV at a younger age increases the chances for better protection?

Yes	1
No	2

C.6 There are two HPV vaccines currently used overseas. One vaccine protects against cervical cancer ONLY, while the other vaccine protects against BOTH cervical cancer and most genital warts. If you were to choose one of the two HPV vaccines, which one would you find most acceptable for your daughter?

An HPV vaccine that protects against cervical cancer ONLY	1
An HPV vaccine that protects against cervical cancer & genital warts	2
None of the above	3

C.7 At what age do you think girls/young women should be vaccinated against HPV?

--	--

C.8 At what age do you think young women are responsible enough to make decisions about sexual relationships?

--	--

C.9 Since HPV is a sexually transmitted virus, do you think boys should also be vaccinated against HPV?

Yes <b>(go to C.10)</b>	1
No	2

*a. If not, why not?*

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C.10 If you had to pay for your daughter's HPV vaccine, what is the highest amount you would be willing to pay for it?

NZ \$ 

--	--	--	--

C.11 How do you feel about following statements:

<b>(Please circle one answer for each statement)</b>		Strongly Agree	Agree	Disagree	Strongly Disagree
a.	If my general practitioner (GP) recommended that I get my <u>daughter</u> the HPV vaccine, I would do it	1	2	3	4
b.	If my family (Whānau) or friends recommended that I get my <u>daughter</u> the HPV vaccine, I would do it	1	2	3	4
c.	With no HPV vaccine, it is likely that my <u>daughter</u> would get an HPV infection	1	2	3	4
d.	With no HPV vaccine, it is likely that my <u>daughter</u> would get cervical cancer	1	2	3	4
e.	With no HPV vaccine, it is likely that my <u>daughter</u> would get genital warts	1	2	3	4
f.	If my <u>daughter</u> got an HPV infection or cervical cancer, it would have serious consequences on her health	1	2	3	4
g.	The HPV vaccine will reduce the chance that my <u>daughter</u> will get an HPV infection	1	2	3	4
h.	The HPV vaccine will reduce the chance that my <u>daughter</u> will get cervical cancer or genital warts	1	2	3	4
i.	My <u>daughter</u> is afraid of needles	1	2	3	4
j.	I am concerned that the HPV vaccine may have side-effects	1	2	3	4

k.	If I had to pay NZ \$450-\$500 for my <u>daughter's</u> HPV vaccine, I would be able afford it	1	2	3	4
l.	Knowing that HPV is sexually transmitted affects my decision about having my <u>daughter</u> vaccinated	1	2	3	4
m.	I am concerned that girls who get the HPV vaccine will become sexually active at an earlier age	1	2	3	4
n.	I am against vaccines in general	1	2	3	4
o.	I have regular discussions with my <u>daughter</u> about puberty and sexual health issues	1	2	3	4
p.	I need more information about HPV, HPV vaccine, genital warts, and cervical cancer	1	2	3	4

C.12 Please answer the following:

**(Please circle one answer for each question)**

Not at all  
A little  
Somewhat  
A lot

a. To what extent are you worried about:

i. HPV	1	2	3	4
ii. Genital warts	1	2	3	4
iii. Cervical cancer	1	2	3	4

b. To what extent are you concerned about your daughter getting:

i. An HPV infection	1	2	3	4
ii. Genital warts	1	2	3	4
iii. Cervical cancer	1	2	3	4

c. How much does thinking about the following bother you:

i. HPV	1	2	3	4
ii. Genital warts	1	2	3	4
iii. Cervical cancer	1	2	3	4

C.13 Imagine that your daughter did NOT get the HPV vaccine and got an HPV infection that could lead to **cervical cancer**, but the HPV vaccine might have prevented it. How much would you regret that she did NOT get the HPV vaccine?

Not at all	1
A little	2
A moderate amount	3
A great deal	4

C.14 Imagine that your daughter did NOT get the HPV vaccine and got **genital warts**, but the HPV vaccine might have prevented it. How much would you regret that she did NOT get the HPV vaccine?

Not at all	1
A little	2
A moderate amount	3
A great deal	4

C.15 Imagine that your daughter got the HPV vaccine and became sexually active earlier than she would have otherwise been. How much would you regret that she did get the vaccine?

Not at all	1
A little	2
A moderate amount	3
A great deal	4



**SECTION D: GENERAL HEALTH AND VACCINATION EXPERIENCES**

D.1 Have you ever chosen to DELAY one of the recommended vaccinations for any of your children?

Yes	1
No	2

D.2 Have you ever chosen NOT TO HAVE one of the recommended vaccinations for any of your children?

Yes	1
No	2

D.3 Have any of your children ever had a bad reaction to a vaccination?

Yes	1
No	2

D.4 Have you ever regretted a decision to have one of your children vaccinated?

Yes	1
No	2

D.5 Have you ever regretted a decision NOT TO HAVE one of your children vaccinated?

Yes	1
No	2

D.6 Have you or anyone close to you ever experienced an abnormal pap/cervical smear?

Yes	1
No	2

D.7 Have you or anyone close to you ever experienced cervical cancer?

Yes	1
No	2

D.8 Have you or anyone close to you ever experienced a sexually transmitted infection?

Yes	1
No	2

### SECTION E: CONTACT DETAILS (PARENT/CAREGIVER)

E.1 May we contact you if we need more information about what you have told us this survey?

Yes	1
No <b>(go to E.5)</b>	2

E.2 Please provide your contact details:

Name:

\_\_\_\_\_

Home Phone:

\_\_\_\_\_

Mobile:

\_\_\_\_\_

Email:

\_\_\_\_\_

E.3 How would you prefer that we contact you?

**(Please circle all options that apply)**

Home Phone	1
Mobile	2
Email	3

E.4 What is the best time to call you?

**(Please circle all options that apply)**

Morning (9:00am to 12 noon)	1
Afternoon (12 noon to 5:00pm)	2
Evening (5:00pm to 8:00pm)	3

E.5 If on the consent form you have agreed to receive a summary of findings from this project, please provide your mailing address:

Name:

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Mailing address:

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***Thank you for participating in this survey!***

## **Appendix J: Message framing content**

### GAIN-FRAMED MESSAGE

**There are benefits your daughter may experience if she gets the HPV vaccine**

- If you decide to get the HPV vaccine for your daughter, this may decrease her chances of getting an HPV infection.
- By choosing to get the HPV vaccine for your daughter, she may be less likely to develop cervical cancer.
- By choosing to get the HPV vaccine for your daughter, she may be less likely to get genital warts.
- Getting the HPV vaccine may help your daughter feel the peace of mind that comes with taking charge of her body and health.

If in the future your daughter may be sexually active, it is important that you consider getting the HPV vaccine.

The vaccine is currently available at no cost to 12-18 year old girls through schools and primary care.

### LOSS-FRAMED MESSAGE

**There are risks your daughter may experience if she doesn't get the HPV vaccine**

- If you decide NOT to get the HPV vaccine for your daughter, this may increase her chances of getting an HPV infection.
- By choosing NOT to get the HPV vaccine for your daughter, she may be more likely to develop cervical cancer.
- By choosing NOT to get the HPV vaccine for your daughter, she may be more likely to get genital warts.
- NOT getting the HPV vaccine may keep your daughter from feeling the peace of mind that comes with taking charge of her body and health.

If in the future your daughter may be sexually active, it is important that you do NOT fail to consider getting the HPV vaccine.

The vaccine is currently available at no cost to 12-18 year old girls through schools and primary care.