

UGSM-Monarch Business School Doctoral Dissertation Proposal

The Role of Communication & Education in the Sustainability of
HPV Vaccination in India: A Framework For Fostering Collaboration

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Doctor of Philosophy in Business Research Dissertation Proposal
UGSM-Monarch Business School Switzerland

TABLE OF CONTENTS

1.0 INTRODUCTION	3
1.1 THE HPV VACCINES	4
1.2 IMMUNIZATION POLICY IN INDIA	5
1.3 WOMEN AND EDUCATION IN INDIAN SOCIETY	5
1.4 FAMILY INFLUENCE IN INDIA	6
1.5 CERVICAL CANCER AWARENESS	7
1.6 THE INFLUENCE OF MEDIA	8
2.0 THE MAIN RESEARCH QUESTION	9
3.0 THE RESEARCH RELEVANCE	10
4.0 CONTRIBUTION TO EXISTING KNOWLEDGE	11
5.0 THE RESEARCH METHODOLOGY	13
5.1 PHENOMENOLOGICAL RESEARCH	14
5.2 DATA ANALYSIS	17
5.3 ETHICAL CONSIDERATIONS	17
6.0 THE LITERATURE REVIEW	17
6.1 INDUSTRY KNOWLEDGE	19
6.2 THEORIES OF COMMUNICATION	20
6.2.1 The Social Cognitive Theory	20
6.2.2 Problematic Integration Theory	21
6.2.3 Cross-Cultural Psychology Theory	21
6.3 THEORIES OF EDUCATION	22
6.3.2 Behaviorism Theory	22
6.3.3 Cognitivism Theory	23
6.3.4. Constructivist Theory	23
7.0 RESEARCH PLAN	24
8.0 RESEARCH TIMELINES	24
9.0 RESEARCH BUDGET	25
10.0 RESEARCH PROPOSAL APPROVAL	27
BIBLIOGRAPHY	28

1.0 INTRODUCTION

Despite being a preventable disease, cervical cancer claims the lives of almost half a million women worldwide each year (Dabash, Vajpayee , & Jacob , 2005). Genital human papillomavirus, also called HPV, is the most common sexually transmitted infection (C.D.C., 2012). It is passed on through genital contact and almost all cervical cancer is caused by HPV (C.D.C., 2012). India bears one fifth of the global burden of the disease with approximately 130,000 new cases a year (Dabash, Vajpayee , & Jacob , 2005) and about 73,000 women die of the cervical cancer annually, the first cause of death of women (W.H.O., 2010). In Europe, the introduction of HPV vaccination has illustrated the importance of new stakeholders such as scientific societies as well as Civil Society Organisations (CSOs) such as cancer leagues, women's associations and patient groups (Laurent-Ledru, Thomson, & Monsenegro, 2010).

It appears that the public's main source of acquiring information about the disease and its vaccinations has been mainly through online medical website access. Hence, there has been an evolution in healthcare away from a "disease-centered" approach towards a "patient-centered" approach (Laurent-Ledru, Thomson, & Monsenegro, 2010). Also, the newer avenues for information dissemination provided by social media like Youtube, Blogger, Facebook and Twitter have a tremendous potential for delivering information and in some cases have led to the increased empowerment of the public

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

(Laurent-Ledru, Thomson, & Monsenegro, 2010; Gupta & Udupa, 2011). In addition, social media tools also enable users to generate, broadcast, and share information and health experiences online in a way that is not available with conventional websites; hence both pro-vaccine and anti-vaccine groups are able to effectively spread their message (Kim & Chung, 2007).

In reviewing the seminal literature it appears that there is a lack of study on the “patient-centered” approach in India. In order to address this apparent lack of study the contemplated research will review the following important areas that have a bearing on the transformation of Indian society and medical information from that of a “disease-centered” approach toward that of a “patient-centered” approach, these include:

1. The HPV Vaccines
2. Immunization Policy
3. Women and Education
4. Family Influence In India
5. Cervical Cancer Awareness
6. The Influence of Media

1.1 THE HPV VACCINES

Two vaccines, Cervarix™ from GlaxoSmithKline and Gardasil® from Merck & Co., are presently on the market. Gardasil® also protects against genital warts and has been shown to protect against cancers of the anus, vagina and vulva. More than 85 types of papillomaviruses have been identified (Zur Hausen , 1999). Both vaccines are available for females; Gardasil® is also available for males (C.D.C., 2012). Gardasil® was launched in India on October 14th, 2008

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

(Jha , 2012). The sales of Gardasil® increased 72% over 2009 in India.

Cervarix™ launched in 2009 in India and has increased in volume by 60% in 2010 (Madhumati & Jyothi Datta, 2010).

1.2 IMMUNIZATION POLICY IN INDIA

Presently, under the Universal Immunization Programme (UIP), vaccines for six-preventable diseases, i.e.: tuberculosis, diphtheria, pertussis, tetanus, poliomyelitis and measles are available free of cost to all. The UIP was launched in 1985-86 and the target is to achieve 100% immunization coverage (Nilanjan, 2006). Several National Immunization Programs are already in place, such as the *Pulse Polio immunization Programme*. It began in December 1995 as part of a major national effort to eradicate polio (Nilanjan, 2006). Madhavi (2003) noted that strong indications of immunization policy are pushed by the pharmaceutical industry and mediated by international organisations (Madhavi , 2003). The Government of India currently spends 28.6 million euros annually on the procurement of the six UIP vaccines alone (Parliament of India, 2009). The private sector, an out of pocket market, provides another way to access the HPV vaccination and accounts for more than 80% of total healthcare spending in India (PriceWaterhouseCoopers, 2007).

1.3 WOMEN AND EDUCATION IN INDIAN SOCIETY

With a population of more than 1.2 billion people, India is the world's largest democracy and its economic growth has brought significant economic and

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

social benefits to the country (The World Bank, 2012). However, social, cultural and economic factors continue to inhibit women from gaining adequate access even to the existing public health facilities (Nilanjan, 2006). Women's lives are governed by multifaceted and nuanced realities where class, caste and religion intersect with each other in complex ways to reinforce women's subordination (Sarojini, Anjali, & Ashalata, 2010). The importance of the role of education, literacy and more specifically female literacy in making people more health conscious is also agreed upon by many researchers (Dreze, 1993; George & Nandraj, 1993). Also, a survey carried out by the International Agency for Research on Cancer, IARC, in Asia shows that there is a direct association between education level and HPV prevalence (Anh, Hieu, & Herrero, 2003).

1.4 FAMILY INFLUENCE IN INDIA

The decision-making around vaccination takes place within the family and the mother has the primary responsibility for seeing that it is carried forth (Bingham, Drake, & Lamontagne, 2009). Hence, parents are the decisions makers for childhood vaccines and will be an important primary audience for communication about the HPV vaccine (Sherris et al., 2006). Moreover, parents are also an important secondary audience as their attitudes towards vaccination are a major predictor of adolescent attitudes towards vaccines (Zimet, 2005).

1.5 CERVICAL CANCER AWARENESS

The awareness of human papillomavirus (HPV) was found to be 48.9% in India (Joy et al., 2011). Furthermore, Civil Society Organisations (CSOs) have been voicing their concerns regarding the safety and efficacy of the two HPV vaccines, the unethical promotion of the vaccines, the public health implications and the consequence if the vaccines were introduced into the country's Universal Immunisation Programme (Sarojini, Anjali, & Ashalata, 2010). A group composed of physicians, community health groups, human rights and women's associations and patient groups submitted two memoranda to the Union Minister of Health enumerating these concerns (Dabade , 2010; Abhiyan , 2010). In fact, the National AIDS Research Institute, NARI, based in Pune and the Program for Appropriate Technology in Health, PATH, jointly conducted a formative study of HPV vaccine introduction in the Indian States of Andhra Pradesh and Gujarat. This study was part of the five year global project known as: *HPV Vaccines: Evidence for Impact* (Jacob, 2010).

In July 2009, the Indian unit of PATH, a US based healthcare organisation, launched a demonstration project for vaccination against cervical cancer (Dabade , 2010). The project was a collaboration between The Indian Council of Medical Research, ICMR, and the state Government with support from the Bill and Melinda Gate Foundation (Sarojini, Anjali, & Ashalata, 2010; Dhar A., 2010). The three doses of the Human Papilloma Virus, HPV, vaccine Cervarix™ were administered to 16,000 girls between 10 and 14 years of age in Andhra

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

Pradesh (Sarojini, Anjali, & Ashalata, 2010). Similarly, in August 2009, the Gujarat government launched a two year “Demonstration Project for Cancer of the Cervix Vaccine” to immunise 16,000 girls between 10 and 14 years with three doses of Gardasil® with the vaccines being provided free of cost by the two pharmaceutical companies (Sarojini, Anjali, & Ashalata, 2010). In April 2010, the Government called a halt to trials of HPV vaccines after seven girls died. This was widely reported in the media (Sarojini, Anjali, & Ashalata, 2010).

1.6 THE INFLUENCE OF MEDIA

Advertising is a powerful force that shapes the attitudes and behavior of people (Khosla , 2011). The reseach of Gregory A. Poland argues that “sadly, we have moved from an evidence-based medicine to media and celebrity based one”, (Poland, 2010, p. 2361). An unbranded disease awareness campaign named “Guard yourself”, www.guardyourself.in, was launched at the end of November 2011 in Bangalore by MSD India, the Indian subsidiary of Merck & Co, which included the Bollywood superstar Sonali Bendre as the concept ambassador. Advertising of prescription drugs is not presently allowed in India because of the potential for harm from inappropriate use (Khosla , 2011). However, with the trends of an open society and fast increasing access to world class information through the internet the Indian consumer has easier on-demand access to the Gardasil website: www.gardasil.com. India had 52 million active Internet users in 2009 and this population is being increasingly exposed to advertising for prescription drugs (Gupta & Udupa, 2011).

2.0 THE MAIN RESEARCH QUESTION

With the aforementioned discourse in mind, the following main research question has been developed:

The Main Research Question

“How does communication and education influence the perception of Indian women in relation to the adoption of HPV vaccines?”

Sub-Research Questions

In order to more fully address the Main Research Question, a series of Sub-Research Questions has been developed focussing on the “why” and the “how” inclinations of the phenomenon as it pertains to the society in India. The Sub-Research Questions will in-turn inform the nature of the analysis with regards to the Main Research Question. They are:

- SRQ-1. Have CSOs begun to mobilize themselves in matters of health and women’s rights protection?
- SRQ-2. Are women relying on communication from print media, newspapers and online information in their choice for HPV vaccination?
- SRQ-3. Have the CSOs begun to create partnerships with other stakeholders, e.g.: the pharmaceutical industry, government and Society of Paediatricians / Gynaecologists for the HPV vaccination awareness?
- SRQ-4. Do women trust the vaccine and the related marketing efforts of the pharmaceutical industry?

3.0 THE RESEARCH RELEVANCE

The main objective of the research is to develop a framework for efficient collaboration, education & communication between the main stakeholders of the vaccination program. The successful introduction of any new vaccine depends on many factors, including the need for broad-based support from policy decision-makers, healthcare professionals, and the general public (Waisbord & Larson, 2005; Wittet, 2001). Consumers are increasingly turning to online sources for healthcare education and the pharmaceutical industry needs to be aware of this new trend and be better prepared.

Presently, communication and education about HPV vaccines come from various sources and may appear to be confusing at times. In addition, there appears to be a lack of specific data from India concerning the HPV vaccination. Keeping this in mind, the contemplated research focuses on five main objectives:

1. To identify the role of CSOs in the HPV vaccination;
2. To gain a better understanding of the habits of Indian women in matters of medicine-specific information, their reliance and trust on CSO communication and social marketing from the pharmaceutical industry;
3. To provide a comparative analysis of lessons learned from previous launches in North America and Europe;
4. To compare and contrast the findings to the existing academic literature related to communication and education theories, and;
5. To develop an ethical framework of communication strategies for women.

4.0 CONTRIBUTION TO EXISTING KNOWLEDGE

The process of business and more precisely the introduction of a new vaccine requires interactions with a number of entities who through their activities become stakeholders. James E. Post, Lee E. Preston & Sybille Sachs (2002) define the stakeholders of a corporation as:

“the individuals and constituencies that contribute, either voluntary or involuntarily, to its wealth-creating capacity and activities, and they are therefore, its potential beneficiaries and/or risk bearers” (Post, Preston, & Sachs, 2002).

Table 4.0 below illustrates some of the main categories of stakeholders found within the academic literature as delineated across primary and secondary as well as social and non-social categories.

TABLE 4.0 Classification of Stakeholders			
Primary Social Stakeholders	Secondary Social Stakeholders	Primary Non-Social Stakeholders	Secondary Non-Social Stakeholders
Investors	Government and Regulators	Nature Environment	Environmental pressure groups
Employees Including Managers	Civic Institutions	Future Generations	Animal Welfare Organisations
Local Communities	Social Pressure Groups	Non-Human Species	
Suppliers	Media and Academic Commentators		
Other Business Partner	Trade Bodies		
	Competitors		
Source: (Wheeler & Sillanpaa, 1997)			

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

With respect to the contemplated research the stakeholders of primary importance are indentified as: pharmaceutical companies, medical practitioners, individual women, Civil Society Organizations, NGOs and Government.

Throughout the contemplated research a level of analysis methodology will be maintained that seeks to focus on the critical considerations facing the above groups as compartementalized within the following schema:

TABLE 4.0 B Levels of Analysis & Stakeholders Schema		
Level	Organizational Level	Unit Level
MACRO	Societal	Government, Media
MESO	Social	Corportions, NGOs, CSOs, IGOs, Trade Bodies, Knowledge Workers, Physicians, Scientific Community, Patient Groups
MICRO	Individual	Indian women, Relatives
Source: UGSM-Monarch Business School Switzerland		

As indicated by the color application in Table 4.0 B and due to limited resources available, the contemplated research will focus solely on the Micro and Meso levels of analysis and will therefore ignore aspects pertaining to or specific to the Macro level. This focus is intentional so as to provide the necessary attention and importance on the individuals within the stakeholder community that are believed to be key players, decision makers and gatekeepers of vaccine adoption practices.

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

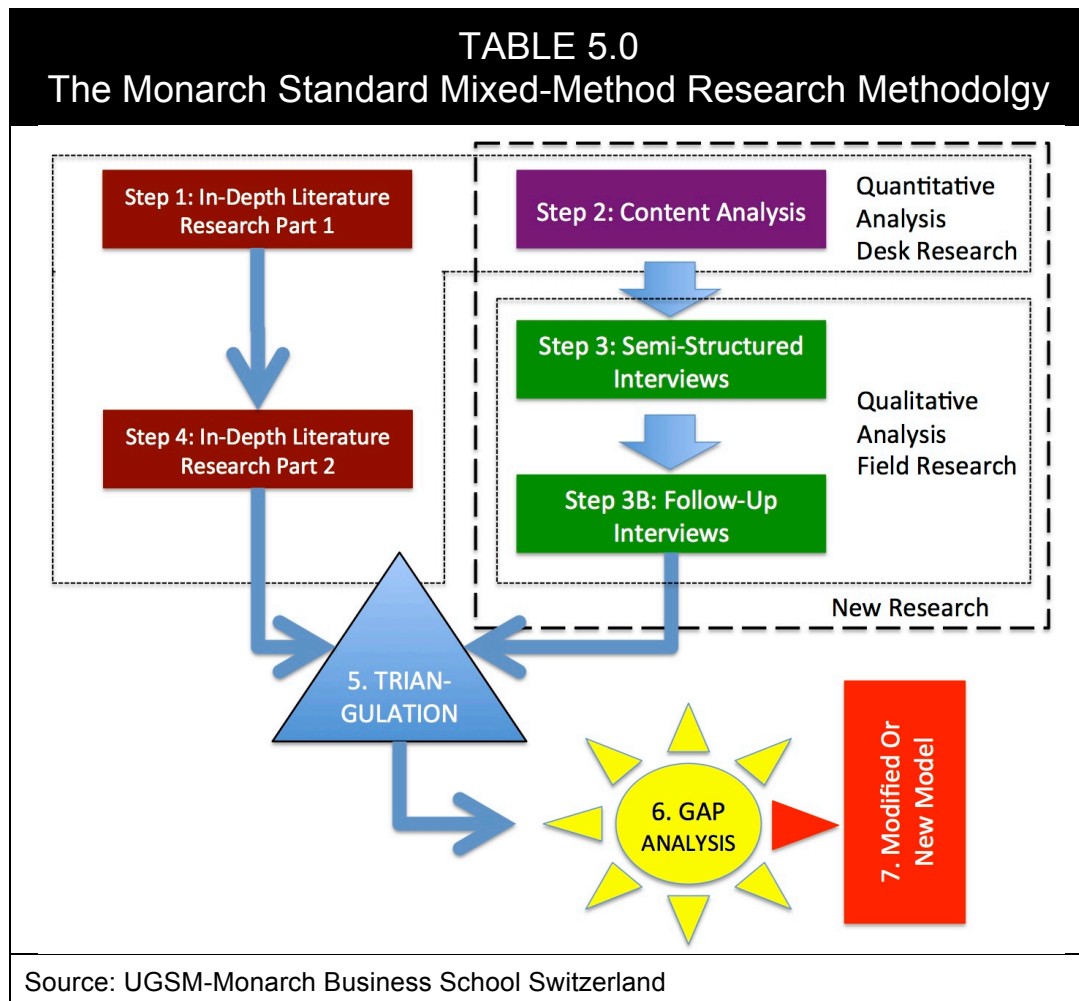
It is further believed that a focus on the imperatives of the individual whether they be categorized within the Micro or Messo level of analysis will provide an unique view and understanding of the critical nature of the adoption process for vaccinations and will therefore provide a unique perspective to the domain of knowledge. It is believed that there presently lacks sufficient study of the phenomenon of vaccine adoption through an analysis by way of a triangulation of data between the three primary groups within the contemplated research, being: individual women, civil society knowledge workers and industry decision makers. It is believed that this lack of focus and integration represents a gap in knowledge within the domain and within the geography studied and therefore provides the possibility for the uncovering and identification of unique and new understandings.

5.0 THE RESEARCH METHODOLOGY

Authors William Emory and Donald Cooper understand research as “a systematic inquiry aimed at providing information to solve problems” (Emory & Cooper, 1991, p. 14). A systematic enquiry is a work that rigorously follows commonly accepted scientific methods (Glaser Barney & Strauss Anselm, 1967). The contemplated research will employ a mixed-method research methodology based on both quantitative and qualitative research methods to data collection which is often the most useful approach for exploring audiences’

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

knowledge, attitudes, beliefs, behaviors, and communications needs and preferences (Sherris, et al., 2006).



5.1 PHENOMENOLOGICAL RESEARCH

The quantitative research method will be based on an extensive literature review of the salient and resilient theories within the domains of communication and education complemented by a content analysis of critical industry specific research. The quantitative analysis will be compared and contrasted with a

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

qualitative research method based on two-step, semi-structured and follow-up interview sampling.

The qualitative research process will be focussed on three distinct sample groups, being: Indian women (consumers), Industry (suppliers) and Civil Society Organizations (knowledge workers). The purpose of the phenomenological approach is to identify phenomena and how they are perceived by the actors in a situation (Lester, 1999). It seeks essentially to describe rather than explain and to start from a perspective free from hypotheses or preconceptions (Husserl, 1970). With this in mind, group interviews will be conducted in a two stage process designed to uncover personally held beliefs and subtle understandings of the phenomenon unique to each group:

Group 1: Indian Women: (Micro Level of Analysis)

1. Step-One: Interviews: Interviews based on semi-structured open-ended questions will be employed. The target audience will be comprised of approximately 25 women aged between 20 and 70 years from upper and upper-middle classes in Bangalore, Hyderabad and Mumbai. They will be English speakers and thus no translation in local languages will be required.
2. Step-Two: In-depth Interviews: In-depth interviews informed from the data obtained in Step-One will be concluded with a sub-set sample population from Group 1 of approximately 10 women.

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

Group 2: Industry: (Meso Level of Analysis)

1. Step-One: Interviews: Interviews based on semi-structured open-ended questions will be employed. The target audience will be comprised of approximately 25 executives, C-suite or VP level managers from industry. They will be English speakers and thus no translation in local languages will be required.
2. Step-Two: In-depth Interviews: In-depth interviews informed from the data obtained in Step-One will be concluded with a sub-set sample population from Group 2 of approximately 10 participants.

Group 3: Knowledge Workers-CSOs: (Meso Level of Analysis)

1. Step-One: Interviews: Interviews based on semi-structured open-ended questions will be employed. The target audience will be comprised of approximately 25 knowledge workers holding key positions within their respective civil society organizations, being NGOs, IGO or GOs. They will be English speakers and thus no translation in local languages will be required.
2. Step-Two: In-depth Interviews: In-depth interviews informed from the data obtained in Step-One will be concluded with a sub-set sample population from Group 3 of approximately 10 knowledge workers evenly balanced between industry and NGO/IGO/GOs.

5.2 DATA ANALYSIS

Quantitative research data will be analysed using SPSS or MiniTab. The qualitative research data will be analysed using the NVIVO or MaxQDA software. Questionnaires will be pre-tested to ensure the accuracy of the questions. Interviews will be face-to-face, audio recorded and are expected to be 30 minutes in length. The objective is to have an in-depth understanding of the roles, missions, perception of HPV vaccines and working habits of the different groups. Telephone interviews will be used in the case that physical interviewing is impossible due to time constraint.

5.3 ETHICAL CONSIDERATIONS

Informed consent and the continuing voluntary nature of participation will be required for the research. Anonymity will be granted to participants and responses will be kept confidential. No vulnerable population will be involved in the study, i.e.: minors, illiterate individuals or individuals with a disability.

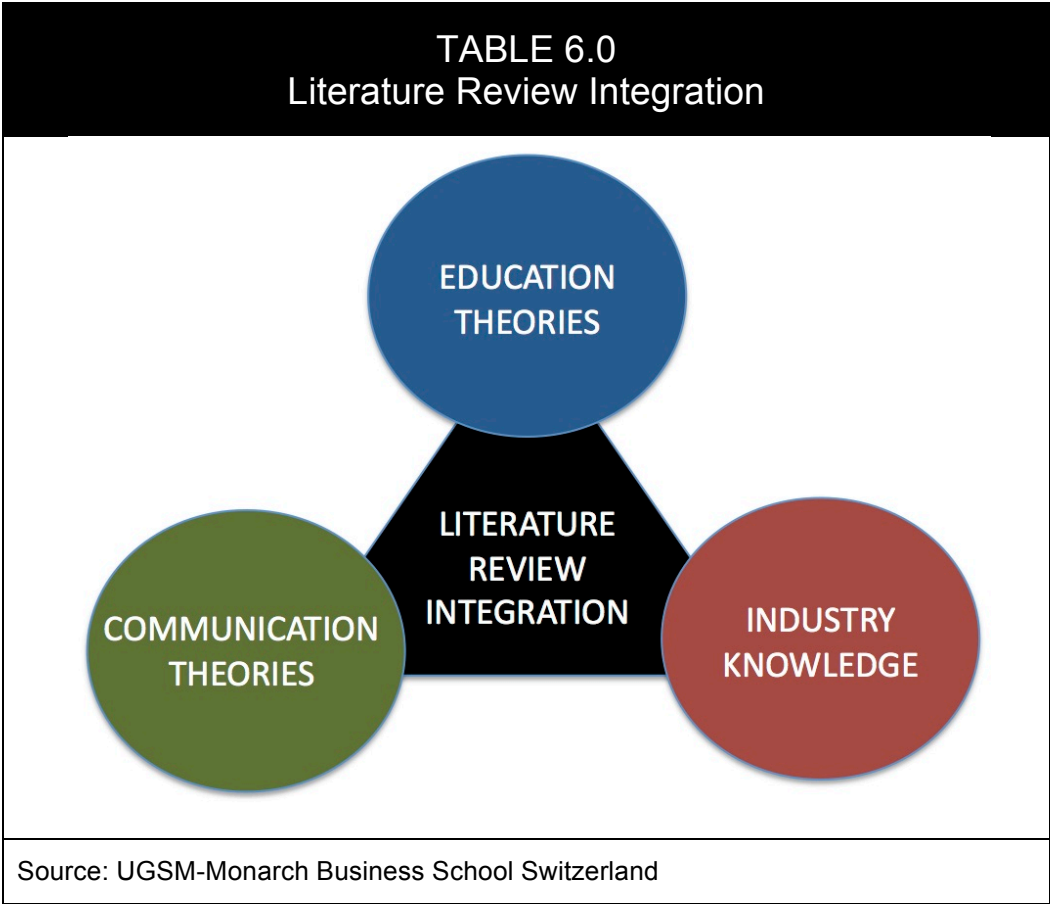
6.0 THE LITERATURE REVIEW

The literature review will extensively investigate the following three themes or approaches:

1. Industry Knowledge
2. Education Theories
3. Communication Theories

The Role Of Communication And Education In The Sustainability Of HPV
Vaccination In India: A Framework For Fostering Collaboration

An analysis of the intersection of the above three areas or domains of knowledge is believed to be of critical importance to the better understanding of the phenomenon behind the adoption of HPV programs and therefore constitute the main focus of the literature review. The integration of the separate knowledge pillars will enable a merging of both academic theory and industry praxis. The academic literature will constitute a review of the salient and resilient communication and education theories while content analysis will provide a practical and applied orientation through the review of industry knowledge and documentation.



The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

Both the review of theory-based approaches and praxis-based approaches should provide a much more rich and well rounded grounding of the literature for the purpose of thoroughly responding to the main research question.

6.1 INDUSTRY KNOWLEDGE

Content analysis refers to information obtain from industry specific sources or non-academic sources. In the context of the present research this refers to documentation such as: annual reports, CSR reports, white papers, medical studies, position papers, etc., produced by or for government, the NGO sector or private enterprise.

In a study conducted by PATH in India, “participants at all levels emphasized that education and outreach regarding the HPV vaccine would facilitate its acceptance” (PATH, 2009, p. 17). Findings from medico-marketing articles and stakeholders handbooks or/and CSR reporting from pharmaceutical groups published in their website will therefore be analysed. It is expected that these sources will provide an overview of facts and figures of organizations as well as information about their relationships with primary, secondary and tertiary stakeholders who participate in constructive dialogue, form partnerships, support patients associations; provide humanitarian assistance and answer many others needs (Sanofi, 2013).

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

The importance of the role of Civil Society Organisations in Europe has already been acknowledged by the research community (Marlow, Waller, & Wardle, 2007; McMelland & Liamputtong, 2009). These studies recognise the importance of public perception in the process of getting vaccinated and promoting participation through community development projects (Mansuri & Rao, 2012). HPV message-testing research remains limited in most parts of the world. Moreover, studies in the U.S. have revealed that information about HPV may be confusing, anxiety-provoking, and stigmatizing (CDC, 2005; Friedman & Shepeard, 2005). The contemplated research will review evidence from industry on existing HPV message-testing campaigns in an attempt to distill important information concerning the key success factors promoting education and information dissemination.

6.2 THEORIES OF COMMUNICATION

Various theories of communication will have a direct impact on the analysis and elucidation of the main research question. The more salient and resilient theories are reviewed below.

6.2.1 The Social Cognitive Theory

Social cognitive theory provides an explanation of how behaviour can be shaped through the observation of models in mass media presentations. It is a model that proposes very specific conditions under which social learning will occur. Social cognitive theory has been very attractive to agents who are trying

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

to institute social change (Miller K. , 2005). Seminal authors that will be reviewed are Albert Bandura, Neal Elgar Miller and John Dollard.

6.2.2 Problematic Integration Theory

The theory of message reception and processing provides insight into not only how “receivers” of communication make sense of messages but also how “senders” of communication might strategically design messages to have the desired impact. Austin Babrow proposed this theory in 1992 as a way to integrate ideas from communication and related disciplines about how individuals receive, process and make sense of specific messages and situations in their lives. It is a very general theory of message reception and processing, one that considers how aspects of the mind are interdependent with larger concepts of relationships, society, and culture (Babrow, 1992).

6.2.3 Cross-Cultural Psychology Theory

Cross-cultural psychology is concerned with the understanding of the behaviour of people across cultures:

“Cross-cultural psychology is the empirical study of members of various culture groups who have had different experiences that lead to predictable and significant differences in behaviour. In the majority of such studies, the group under study speak different languages and are

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

governed by different political units (Brislin, Lonner, & Thorndike, 1973, p. 5)".

Values are the currently held normative expectations that underlie individual and social conduct (Laungani, 1997). Seminal authors specialised of cross-cultural psychology of India and Europe are Laungani Pittu, Marshall H. Segall, Pierre R. Dasen and John W. Berry.

6.3 THEORIES OF EDUCATION

There is no greater tool for economic consciousness, employment, and development than knowledge through education. Knowledge in India is linked to European epistemology and therefore several prominent theories will be reviewed and critiqued in an attempt to further illuminate the research question.

6.3.2 *Behaviorism Theory*

Donald H. Bullok (1982) identifies the basic assumptions of the behaviourist:

"objectivism, where the key to analysing human behaviour lies in the observation of external events; environmentalist, in which the environment is the significant factor in determining human behaviour; and reinforcement, where the consequences of our actions affect subsequent behaviour." (Bullock, 1982)

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

Seminal authors within the domain include: Ivan Pavlov, John Watson, Burrhus Frederic Skinner.

6.3.3 Cognitivism Theory

Cognitivism, the belief that much of human behaviour can be understood if we understand first how people think presently represents the mainstream of thinking in both psychology and education (Bower & Hilgard, 1981). Current cognitive approaches to learning stress that learning is an active, constructive, cumulative, and self-directed process that is dependent on the mental activities of the learner (Schuell, 1986) (Sternberg, 1996). Learning is cumulative in nature: nothing has meaning or is learned in isolation. Seminal authors are John Anderson, Jean Piaget.

6.3.4. Constructivist Theory

Constructivism has been described as “a theory of knowledge with roots in philosophy, psychology and cybernetics” (Von Glaserfeld E., 1995). It asserts two main principles:

1. Knowledge is not passively received but actively built up by the cognizing subject;
2. The function of cognition is adaptive and serves the organisation of the experiential world not the discovery of ontological reality.

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

In modern psychology, the notion of cognitive construction was first forged into a major component of developmental theory by James Mark Baldwin, Jean Piaget, and Ernst Von Glasersfeld.

7.0 RESEARCH PLAN

The research is to be complete over 36 months. Interviews for each group will take place over a 5 month period from September 2013 to January 2014 after which the data will be analysed and the manuscript will be perfected. Each face to face or telephone interview should last a maximum of 30 minutes at a location and time that is amenable to participants. Interviews will be conducted throughout the Indian provinces or towns of Kerala, Mumbai, Bangalore, Hyderabad.

8.0 RESEARCH TIMELINES

The contemplated research is expected to conclude over a 36 month period between March 2012 and March 2015. The Gantt chart provided in Table 8.0 illustrates the duration of each task anticipated within the research process. Although every effort has been made to anticipate the steps within the research variation in the plan may be encountered due to variables beyond the control of researcher. Variables that may have a significant effect on the research timeline which lay beyond the control of the researcher are accessibility and available time periods for sample participants which may result in a modification of travel schedules and prolongation of the field research stages.

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

TABLE 8.0 Project Timeline												
	2012			2013				2014				'15
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Preliminary Literature Review												
Chapter 1: Introduction												
Chapter 2: Lit Research												
Chapter 3: Research Method												
Field Research:												
Stage 1 Interviews												
Stage 1 Analysis												
Stage 2 Interviews												
Stage 2 Analysis												
Chapter 4: Data Analysis												
Chapter 5: Synthesis												
Chapter 6: Conclusions												
Manuscript Submission												
Source: Aurelia Ravet												

9.0 RESEARCH BUDGET

The research will be funded privately. Therefore, no requests for supplementary grants, assistantships, or scholarships will be made. Moreover, no funds will be received from any public body or pharmaceutical company in the carrying out of the contemplated research. The budget of the research is presented below as approximately 8,200 Euros. No additional resources or funding will be asked of UGSM-Monarch Business School Switzerland. The budget is presently fully funded and research may begin immediately.

Ms. Aurelia Ravet, M.Sc.
Doctor of Philosophy in Business Research Dissertation Proposal
UGSM-Monarch Business School Switzerland

The Role Of Communication And Education In The Sustainability Of HPV
Vaccination In India: A Framework For Fostering Collaboration

TABLE 9.0 Research Budget	
Item	Euros
Hotel accommodations	1,000
Books and Articles Purchases	2,500
Travel Expenses	1,500
Conferences	1,000
Software and Digital Recording	1,500
Reproduction Expenses- Manuscript	200
Miscellaneous Supplies & Charges	500
Total Approximate Costs	8,200

10.0 RESEARCH PROPOSAL APPROVAL

The contemplated research proposed herein has been approved by the University and the student may commence the research immediately. The student is not to deviate from the proposed research unless expressly confirmed by both the Supervisor and the University in written form.

Approved by the University

On 22-April-2013 in Zug-Switzerland

By: Dr. Jeffrey Henderson, D.Phil.

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

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Ms. Aurelia Ravet, M.Sc.
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 UGSM-Monarch Business School Switzerland

The Role Of Communication And Education In The Sustainability Of HPV Vaccination In India: A Framework For Fostering Collaboration

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