Program Development of Human Papillomavirus Education Program for Health Officials in the Achham District of Nepal

by

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Abstract

Human Papillomavirus (HPV) is one of the most common sexually transmitted infections in the world. Cervical cancer, caused almost exclusively by HPV infection, is the most common cancer among women in Nepal, despite being only the fourth most common female cancer globally and the tenth most common female cancer in more developed regions. Nepal intends to address this by initiating a national HPV vaccination program. However, there are low levels of awareness and understanding of HPV, its vaccine, and cervical cancer are present among the general population, medical and nursing students, and likely among local government healthcare officials. Medical professionals are among the most trusted sources for parents when deciding upon vaccination, so capacity building for HPV in the healthcare system is a matter of public health importance. The education program proposed in this paper, to be managed by the Nepal Fertility Care Center, will provide of cervical cancer and HPV training to the healthcare staff in the district of Achham. Through this program, the district healthcare system will be prepared for the increased screenings, vaccinations, and community engagement that will be required for the HPV vaccination campaign. This would facilitate a reduction of rates of HPV and ultimately cervical cancer in the district.

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Preface

I would like to thank Dr. Mary Hawk for her reviews and comments on an earlier version of this document written for the course BCHS 2523 at the University of Pittsburgh Graduate School of Public Health, as well as her assistance as my advisor. I would also like express my deepest gratitude to Dr. Martha Ann Terry, for her incredible advice for this thesis and in all her classes over the years. I would like to thank Joanne Russell both for the opportunity to study in Nepal and her advice on this thesis, as well as Dr. Candace Kammerer for graciously agreeing to join the thesis committee. I am grateful to the Nepal Fertility Care Center for hosting my practicum experience and providing the inspiration for this program proposal.

1.0 Introduction

Human Papillomavirus, also known as HPV, is one of the most common sexually transmitted infections in the world. An estimated 70 million people are infected with HPV with 14 million new transmissions occurring every year. It is the only identified causative agent of cervical cancer, and has been found to dramatically increase the risk of developing at least five other kinds of cancer (Harden and Munger 2017). Cervical cancer is the most closely associated with HPV, and the prevalence of cervical cancer can be used as an approximation of HPV infection prevalence. Fortunately, vaccines can prevent transmission of the high-risk strains of HPV that account for approximately 90% of cervical cancer cases, and cervical cancer is treatable with early detection during screening.

Low-income countries such as Nepal bear a disproportionately high share of the burden of cervical cancer, despite significant progress on the development of its healthcare system. Cervical cancer is the fourth most common cancer globally, but it is the most common cancer among women in Nepal (Bruni, Barrionuevo-Rosas et al. 2017), and less than 20% of women between the ages of 25 and 64 have ever been screened for cervical cancer (de Sanjosé, Serrano et al. 2012). Nepal faces considerable barriers to the implementation of an HPV vaccination program, including a geographic terrain considered among the most remote and formidable in the world and a cultural terrain that is nearly as complex and diverse as the landscape. In addition, levels of awareness and understanding of HPV, its vaccine, and cervical cancer are low among the general population (Singh, Shah et al. 2010), health students (Joy, Sathian et al. 2011), and likely among medical and

government healthcare officials. Medical professionals and officials are among the most trusted sources for parents when deciding upon vaccination, so it is imperative that these professionals are willing to recommend and provide the HPV vaccine. This is particularly important considering the Government of Nepal has plans to scale up HPV vaccine provisions across the country in the coming years (Government of Nepal 2017).

To address the gap in awareness and knowledge, this paper proposes an HPV education program for all of the government healthcare officials, doctors, and medical staff and assistants in the far-western district of Achham. The program will be carried out primarily by the staff of the Nepal Fertility Care Center (NFCC), which has extensive experience in both HPV and large capacity-building initiatives that work within the government structure. Since 1988, it has been contracted by the government to provide training sessions for doctors and health staff across Nepal on giving birth control injections and prescribing other forms of birth control. It is also currently involved in a menstrual health program that relies on a "train-the-trainer" model to coach local health officials and teachers on how to teach reproductive and menstrual health topics within the context of government-run schools and local women's groups. Finally, it is involved in several epidemiological studies examining HPV risk and prevalence and has an interest in getting more involved with HPV.

With this context in mind, the proposed program was developed utilizing the "train-the-trainer" model, and is supported by both the Diffusion of Innovations Theory and the Theory of Organizational Change. The program will encourage the dissemination of information about HPV, its vaccine, and cervical cancer to all the active healthcare employees, as well as the uptake of the program into the level of the institution. The program will involve the training of the first set of "primary trainers": the staff of the district health office of Achham and lead physicians at the

district's hospitals. These primary trainers will then conduct sessions with the "secondary trainers," which include the directors of health posts, sub-health posts, and primary health centers, as well as hospital physicians. These secondary trainers will then complete the final sessions, which will train the local staff of health posts, nurses and medical assistants, and female community health volunteers. These trainings are expected to reach 1300 participants. Outcomes and evaluations will be measured through pre- and post-tests for the participants and ongoing process evaluations of the training sessions. Surveys will be completed at clinics to also measure how well the information gained during the sessions has been implemented with patients. After ten years, the program aims to reduce mortality due to cervical cancer by 20%.

The second chapter of this paper will discuss the background and context for the program. This includes information on HPV microbiology and epidemiology, the country of Nepal and its healthcare system, and the current state of HPV prevalence and awareness in Nepal. It will also introduce the Nepal Fertility Care Center and its existing programs and research. The third chapter will describe the program design, the theories it is based on, as well as data collection and evaluation. Finally, this proposal will address the implications of the program, potential opportunities, and limitations.

2.0 Background

2.1 Human Papillomavirus

Human Papillomavirus is one of the most common sexually transmitted infections globally, and it has been identified as the cause of nearly 100% of all cervical cancers. Fortunately, vaccines are available to target the high-risk types of HPV known to cause cervical cancer. The HPV vaccine is not yet available in Nepal; however, the government has expressed interest in offering the vaccine more widely across the country. However, awareness and understanding of HPV and its vaccine are low across both the general population and medical professionals.

HPV is a small, DNA-based virus that targets squamous epithelial cells and replicates in the deep basal layer of cells. This cell layer is not easily accessible on most regions of the skin, and for an infection to occur it requires microscopic wounds that allow access to this layer. Certain mucosal regions of the skin lining the cervix and anus have been found to be particularly vulnerable to HPV infection (Harden and Munger 2017). Over 200 types of papillomavirus in humans have been identified and classified, the majority of which cause varieties of warts, however, several strains have been linked to cancer (Steinbach and Riemer 2018).

2.1.1 HPV Proliferation and Cancer

Of the 205 identified strains of HPV, several are classified as "high-risk" for their association with a variety of cancers. Most of the high-risk strains belong to the alpha genus, and the two most common high-risk strains, HPV16 and HPV18, account for 60% and 15% of cervical cancers,

respectively (Steinbach and Riemer 2018). During virus-amplified proliferation of the infected basal cells, the papillomavirus protein E6 deactivates the cellular p53 tumor suppressor and blocks the immune system's response to the newly cancerous cells (Harden and Munger 2017). Although the majority of HPV infections are cleared by the immune system within one to two years after infection, several high-risk strains of HPV can remain indefinitely and result in cancerous lesions. While the most common cancer caused by HPV is cervical cancer, it can also cause vaginal, anal, penile, and oropharyngeal cancer (Steinbach and Riemer 2018). However, since DNA from HPV has been identified in virtually all cases of cervical cancer, cervical cancer is most closely associated with HPV incidence and prevention efforts.

2.1.2 Screening, Treatment, and Prevention

Complete primary prevention of HPV and HPV-mediated cancers can currently be achieved only with the HPV vaccine. Vaccination against HPV has been available since the Gardasil® vaccine was released in 2006. Initially providing protection only against the two most common low-risk strains (HPV6 and HPV11) and the two most common high-risk strains (HPV16 and HPV18), the most recently released HPV vaccines protect against nine strains of high- and low-risk HPV (Harden and Munger 2017). This coverage protects against the strains of HPV that account for approximately 90% of all HPV cases, and has also been shown to confer limited cross protection against HPV strains not explicitly targeted by the vaccine. The Advisory Committee on Immunization Practices recommends the HPV vaccine be routinely provided for males and females between 11-12 years of age. It also recommends that previously unvaccinated females between the ages of 13-26 and males between the ages of 13-21 receive the vaccination (Harden and Munger 2017). In its 13 years of use, the HPV vaccine has received excellent safety ratings,

and is increasingly adopted into national vaccination programs of countries across the world (Vorsters, Arbyn et al. 2017).

Secondary prevention of HPV-mediated cancers, particularly of cervical cancer, occurs through clinical screening. For over 60 years, the clinical standard for cervical cancer screening has been the Papanicolaou smear, or Pap test, which tests a sample of cervical cells for abnormalities. With the introduction of DNA sequencing technology, HPV DNA testing has been increasingly utilized as an alternative to the Pap smear. This test screens for the presence of the DNA of high-risk HPV strains, however it is primarily available in high-income countries (Harden and Munger 2017). Visual Inspection with Acetic Acid (VIA) is commonly used in low-income countries for cervical cancer screening due to its affordability and ease of use. Acetic acid (found in vinegar) is swabbed onto the surface of the cervix. When cervical cancer lesions come into contact with the acid they become white and are visible to the naked eye. This method has been found to have similar accuracy to the Pap smear, and is an efficient and low-cost alternative for low income regions (Sauvaget, Fayette et al. 2011).

In the case of lesions presenting on the surface of the cervix, several treatments can be done in the same session as the screening to quickly remove the affected tissue of the cervix. These include cryotherapy, loop electrosurgical excision procedure (LEEP), or the surgical cold knife conization. Most of the single-visit methods are available in low resource settings such as Nepal. However, if the lesions present over a significant portion of the surface of the cervix, the patient is instead referred to radiation and/or chemotherapy (World Health Organization 2013).

2.2 Nepal

Nepal, officially called the Federal Democratic Republic of Nepal, is a developing nation of nearly 30 million people in a region that is highly geographically and culturally diverse. Recently, the country has faced serious economic and health setbacks from an earthquake in 2015 that killed approximately 9000 people and caused US\$7 billion in damages, triggering a financial crisis. In addition, Nepal faced political turmoil and severe flooding in 2016 and 2017, respectively. However, economic data from the 2018 fiscal year suggest a strong acceleration of growth, with the economy growing by 6.3% in one year (World Bank 2018). Nepal's healthcare spending has also been increasing rapidly in recent years, from 3.57% of the GDP in 2010 to 6.15% in 2015 (World Health Organization 2015). Despite this progress, Nepal faces significant obstacles to economic development and the improvement of health outcomes.

2.2.1 Geography

Nepal is a small, landlocked nation wedged between the Tibetan region of China and the fertile rainforests of India. Two Indian panhandles separate Nepal from Pakistan to the west and Bhutan to the east. It spans a significant portion of the large Himalayan range and includes Mount Everest, the world's highest point. As a result, large portions of the nation remain difficult to access without significant effort, as demonstrated by Figure 1 below. Its geography is divided into three primary regions, the mountains, the hills, and the fertile plains (referred to as the "terai"). As a result of its topography, 83.2% of the nation's 28.5 million citizens live in rural areas (World Health Organization 2015), and 93.3% of the population resides in the hill and terai regions. The

mountainous region, though inhospitable, is still home to over 1.9 million Nepalis (Government of Nepal 2011).

2.2.2 Culture, Ethnicity, and Religion

Nepal is a highly diverse country, home to people of over 100 different ethnicities. Though officially illegal, the remnants of the caste system still impact the culture of Nepal, and caste, ethnicity, and geographic location often overlap and intersect to create a wide variety of identities. The largest ethnic group, the Chhettri, comprise 16.6% of the population, while the Brahman-Hill, the Magar, and the Tharu comprise 12.2%, 7.1%, and 6.6% of the population, respectively. Approximately 5.8% of the population are Tamang, and 5% are Newar. The remaining ethnic groups each account for less than 5% of the population (Government of Nepal 2011). Many of these groups speak unique languages or dialects, and this high degree of diversity creates complex challenges to creating health system interventions.

Conversely, Nepal is dominated by just one religion, Hinduism. Approximately 81.3% of the population identifies as Hindu, with a significant minority identifying as Buddhists, at 9% (Government of Nepal 2011). The former Kingdom of Nepal was officially a Hindu nation until its collapse in 2008; as a result, Hinduism plays a significant role in daily life in Nepal and informs much of its social norms. Sexual activity and health, particularly of youth, is rarely discussed in the home setting since sexual activity outside of marriage is viewed as unacceptable (Regmi, Van Teijlingen et al. 2010). Marriage of child or teenaged girls is still practiced in many regions of Nepal. These beliefs may limit the willingness of parents or medical professionals to discuss or permit HPV vaccination.

2.2.3 Government and Political Factors

Until recent decades Nepal was a reclusive state that had little contact or trade with the rest of the world. Its government was a monarchy until 2008, when a civil war resulted in the overthrow of the monarchy and the implementation of a democratic state. Since then, Nepal has faced the slow development of a democratic, multi-party system, and is seen as a state in transition (World Bank 2018). The final stage, the first democratic elections under its new constitution, was completed in December 2017, with the communist party winning the majority of the seats. Prior to these elections, Nepal had undergone decades of unstable political transitions, in which no single party was ever able to control a majority of the seats in Parliament. Approximately one year ago, in February 2018, the new government was seated for the first time. The new government is tasked with implementing an entirely new structure of governance, in a shift from a unitary state to a federalist state (World Bank 2018).

With this switch to federalism comes a dramatic change in the way that both the government and the healthcare system are administered. The new federal government is tasked with "amending over 400 existing acts, restructuring the civil service at all levels, devolving fiscal management, and determining the division of funds, functions, and functionaries between various levels of government" (World Bank 2018, page 1), which will likely be a time-consuming and risky undertaking. As control over local affairs and funding begin to be parceled out at the district and Village Development Community (VDC) levels, healthcare administration will be directly affected. Local representatives and civil service workers will be able to tailor budget decisions and programming to their local health needs, and this will increase opportunities for community participation in the process (Thapa, Bam et al. 2018).

However, interruptions in the delivery of medical supplies and services may occur as responsibility is shifted between stakeholders. There may also be a human resources crisis, as many localized sub-health posts at the VDC level lack the administrative personnel to carry out management activities that were formerly the responsibility of the federal government or subcontracted non-governmental organizations (Thapa, Bam et al. 2018), of which Nepal has many (Malla, Giri et al. 2011). In 2018, Nepal passed the Health Insurance Act, which follows through on the new constitution's guarantee of health as a human right through the implementation of a nationalized health insurance provision. In the coming years the details of this act must be finalized and implemented, and it may take some time before national insurance is fully functional (Thapa, Bam et al. 2018). Technical support for district and local governments will be required for a smooth transition under the new constitution, and the healthcare situation is likely to experience periods of instability.

2.2.4 Nepal Healthcare System

Nepal formally adopted a national healthcare policy in 1991, and since then has committed itself to the expansion of the healthcare system. Despite interruptions and setbacks due to political instability and the earthquake of 2015, rural access to healthcare has expanded dramatically. In the mid-1990s there was a rapid burst of growth, in which the number of health facilities expanded twelve-fold (World Health Organization 2007). Healthcare is distributed at the most local level through several types of primary care facilities, including health posts, sub-health posts, and primary care centers. These are located at the municipal and electoral constituency levels, with each of the 205 electoral constituencies containing at least one primary healthcare center. Each of the 75 districts contains a District Health or Public Health Office, and 65 contain district hospitals.

Local facilities may refer more complex cases to the zonal hospitals located in each of the 14 zones, to the five regional hospitals, or to a handful of specialized hospitals located in urban areas. (Government of Nepal 2018)

Many private hospitals and practices exist; however, 47% of these are concentrated in or near the capital of Kathmandu. The majority of practicing doctors in the country are employed at public facilities; however, 90% of doctors employed in the public sector are also involved in private practice or services (World Health Organization 2007).

2.2.5 HPV Epidemiology in Nepal

Cervical cancer, caused almost exclusively by HPV infection, is the most common cancer among women in Nepal, despite being only the fourth most common female cancer globally (Bruni, Barrionuevo-Rosas et al. 2017) and the tenth most common female cancer in more developed regions (de Sanjosé, Serrano et al. 2012). Rates of cervical cancer in Nepal are similar to those of neighboring Southeast Asian countries such as India and Bangladesh. The age-standardized incidence rate of cervical cancer in Nepal is 19 cases per 100,000 women per year, compared to 19.3 in Southern Asia generally, 14 worldwide, and 3.7 in high-income countries (Organization for Economic Cooperation and Development 2018; World Health Organization 2018). Several local and regional studies have been conducted in attempts to estimate HPV and cervical cancer prevalence, as well as to assess potential risk factors. The risk factors that have been identified include smoking, which has been associated with an increased risk of developing cervical cancer from an HPV infection. The female smoking rate in Nepal is one of the highest in in the world,

with 29% of the adult population of women identified as regular smokers (de Sanjosé, Serrano et al. 2012).

In Nepal, a high percentage of men migrate for work opportunities, and sexual contact with with a man who migrates for work has been identified as a risk factor for contracting HPV (Bhatta, Johnson et al. 2017). Only about 55% of men and 19% of women are engaged in wage-earning activities in Nepal, and 32% of households report receiving remittances from family members working elsewhere. In 2004, nearly one million Nepalis sent remittances from abroad, and this number is likely higher today (Lokshin and Glinskaya 2009). Of these remittances, nearly 89% are from men (Seddon, Adhikari et al. 2002). Men who spend many months separated from their families for financial incentives may be returning with sexually transmitted infections, resulting in the higher risk for HPV contraction among female partners.

In one study, a geospatial analysis was conducted to examine reproductive tract infections (RTIs) among women whose husbands migrate for work. Of the 9607 married women included in the study, 31.9% had a husband who migrated for work. Those whose husbands had been gone for more than one year were between 1.93 and 2.89 times more likely to present with an RTI than the rest of the study population (Johnson, Lhaki et al. 2017). In a study of 647 women who attended a health camp, women whose husbands migrated for work were between 2.9 and 3.3 times more likely to be HPV positive (Bhatta, Johnson et al. 2017). A final study of 1289 women found HPV infection to be associated with having a husband who had been previously married, education level, and smoking (Shakya, Syversen et al. 2017). These three studies reported high-risk HPV incidence rates of between 7.5% and 8.9% (Johnson, Lhaki et al. 2016; Bhatta, Johnson et al. 2017; Shakya, Syversen et al. 2017). This is compared to an approximate 5.5% global high-risk HPV incidence rate (Bruni, Diaz et al. 2010).

All of these studies targeted HPV and cervical cancer through the use of isolated testing camps, in which researchers set up a tent with HPV testing and screening and offer these services to the local population for a limited period of time. None of these testing camp studies addressed the issue at the system or behavioral levels. Only the pilot HPV vaccination campaign, supported by the Global Alliance for Vaccines and Immunisation (GAVI), has approached the issue from a population prevention standpoint. This campaign reported that despite low initial awareness of HPV and cervical cancer, parents was remarkably willing to allow their children to receive the vaccine once the preventative benefits had been explained, and 99.3% of the 1,096 participants in the pilot study received all three doses of the vaccine (Singh, Shah et al. 2010).

2.2.6 HPV Knowledge

Despite the prevalence and risk, knowledge and awareness of HPV is low among people in Nepal (Singh, Shah et al. 2010); this lack of awareness likely extends to those in the medical professions. A cross-sectional study of 528 female undergraduate students in India and 480 students in Nepal indicated that only 58.6% of educated female youth in Nepal were aware of cervical cancer at all, compared to 65.9% of Indians (Joy, Sathian et al. 2011). Similar studies have been completed in India that specifically examine HPV perception and awareness among medical and paramedical professionals and students. One study discovered that among 957 students of the medical professions, only 44.9% demonstrated "good" knowledge of HPV and its vaccine, and of the 892 who had not previously been vaccinated for HPV, 48.5% would not be willing to take the vaccine

themselves. Most of these respondents questioned the vaccine's efficacy (Swarnapriya, Kavitha et al. 2015). Among 590 actively practicing healthcare professionals in India, only 47% would recommend that young women be vaccinated for HPV, and only 27% of the paramedical staff were aware of the HPV vaccines on the market (Chawla, Chawla et al. 2016). The curriculum for Tribhuvan University's medical program, regarded as one of the largest and most premier programs in Nepal, references detection and treatment of other STIs, but does not include HPV (Tribhuvan University 2008).

It is estimated that less than 20% of women between the ages of 25 and 64 in Nepal have ever been screened for cervical cancer (de Sanjosé, Serrano et al. 2012), and approximately 1,367 women die of cervical cancer in Nepal every year (Bruni, Barrionuevo-Rosas et al. 2017). The recommended screening in Nepal is the Visual Inspection with Ascetic Acid (VIA), which is relatively simple and inexpensive to perform. Therefore, the lack of knowledge and initiative of healthcare professionals likely plays a role in low levels of screening as Nepal gradually extends its healthcare access to all individuals.

2.2.7 Current Policies and Intended Vaccination Program

According to the national Cervical Cancer Screening and Prevention Plan (CCSP), set forth by the Nepal government in 2010, the primary method for cervical cancer prevention in Nepal is screening through the Visual Inspection with Acetic Acid (VIA), as noted above. Subsequent treatment for observed lesions will be handled through the Single Visit Approach (SVA), in which treatment occurs in the same session. Cryotherapy is the recommended treatment method during the visit for lesions that cover less than 75% of the surface of the cervix, or cold coagulation if available. In cases where the lesions cover more than 75% of the surface, the patient is referred to

zonal, regional, tertiary, or national hospitals for Loop Electrosurgical Excision Procedure (LEEP) or surgery and further treatments. Where facilities are available, Pap smear is recommended in place of VIA and biopsies may be used (Government of Nepal 2010).

The target population for cervical cancer screening is women between the ages of 30 and 60, and they should receive screening once every five years. According to the plan, screenings must be provided at Mobile VIA/SVA clinics and Mobile Screening Health Camps, primary health care centers (PHCC), district hospitals, zonal and regional hospitals, and tertiary care or specialized cancer hospitals. CCSP services are also integrated into the existing family planning clinics, gynecology clinics, HIV/AIDS and STI clinics wherever women of the target group already seek services. The goal of the plan is to screen 50% of the eligible population within five years; currently less than 20% of eligible women in Nepal have ever received a cervical cancer screening (de Sanjosé, Serrano et al. 2012). The plan references HPV vaccination as a potential future prevention method but not as a screening replacement. HPV DNA testing is recommended in the plan as a primary screening method wherever available; however, the cost prevents it from being included in Nepal's current strategy. The plan concludes by suggesting that simple oral and breast cancer screenings also be phased into the cervical cancer screening visits (Government of Nepal 2010).

Currently, the HPV vaccine has been provided free by the government in only two districts of Nepal through a pilot program funded by GAVI, the Global Alliance for Vaccines and Immunization (Singh, Shah et al. 2010). The program found that the vaccine was readily accepted by the recipients and their parents, and that the primary barriers to scaling up the vaccination campaign are cost and general awareness. In funding request documents submitted to GAVI, Nepal

has expressed interest in initiating an HPV vaccination program in 2019 (Government of Nepal 2017). However, it has not published any public plans for the program to date.

2.2.8 Achham District

Achham distict is located in the seventh province of Nepal, in the highly remote Far-Western region of the country. The town of Mangalsen acts as the headquarters for the district. There are 12 health posts, 60 sub-health posts, 227 primary health care/outreach clinics, and 225 EPI vaccination clinics spread throughout the district. There are two hospitals, one run by a non-profit and one run by the government. These serve approximately 263,000 people in the district, including 75,062 women between 15-44 years of age (Government of Nepal 2017).

The target population for the proposed HPV education program is all government healthcare employees in the district of Achham. As of 1998, the most recent available data for all of Nepal, the Department of Health Services employed 922 doctors, 1160 nurses, 1084 health assistants, 4659 auxiliary health workers (AHWs), 1601 assistant nurse midwives (ANMs), 3176 maternal child health workers (MCHWs), 12,682 traditional birth attendants, and 42,427 female community health volunteers (FCHVs), as well as 1075 workers in other positions (Rai, Rai et al. 2001). This accounts for 68,786 staff members across the country, although this number has likely increased significantly in the past 20 years. There are 943 FCHVs working in Achham; however, no specific data exist on the numbers of the rest of the staff members. Assuming the relative ratios of staff members to FCHVs across the country holds for Achham, there should be approximately 500-600 other staff members. Out of about 1500 total healthcare workers, the program aims to reach 90%, or about 1350.

The healthcare staff in Nepal have several strengths that create a strong foundation for the program. They are primarily locally-based, meaning that they live and work among the people they serve on a daily basis. Many staff, particularly the FCHVs and other health workers, were recruited directly from the local population, thus they have natural relationships with the local women's and mothers' groups, who act as a strong village force. However, the majority of these women do not have advanced degrees or strong health education backgrounds outside of what is provided by the district level education teams. Fortunately, Achham District already has and maintains a Health Training Program, which is dedicated to conducting trainings for all staff across the district, as well as a robust vaccination program. It is also representative of the rural western districts and has existing ties to the Nepal Fertility Care Center, which could assist in the implementation of a pilot program.

2.3 Nepal Fertility Care Center

The Nepal Fertility Care Center (NFCC) is a locally-based non-governmental organization in Kathmandu, Nepal. It was founded in 1988 to address a deficit in the access to and provision of birth control methods across Nepal. It has a stated mission of "Available, Accessible, and Affordable Reproductive Health for All," and initially focused on the provision of training programs in various birth control methods, as well as certification to provide Depo-Provera injections. It has since expanded into development and management of other programs and research focused on the areas of menstrual health and rights, prevention of gender-based violence (GBV) child marriage, and HPV. Within these topic areas, NFCC focuses on advocacy, research, capacity building, and implementation. It has worked in extensive collaboration with the

government of Nepal, international NGOs, the University of Alabama-Birmingham and the University of Pittsburgh.

2.3.1 Structure and Current Programs

NFCC consists of three working departments, Programming, Monitoring and Evaluation, and Finances. It primarily partners with larger international organizations and funders on specific programs and topics areas; for example, it collaborates with and receives funding from WaterAID on its menstruation program, and with UNICEF on its program focused on prevention of child marriage. The majority of the programs are structured as capacity-building or in a cascade "train the trainer" model. It has three large, primary programs: Ghar Ghar Ma Swasthya, Rupantaran, and Menstrual Hygiene Management.

Ghar Ghar Ma Swasthya (GGMS), which means "Healthy Homes," is a large national program comprised of many arms, one of which is the coordination of injection trainings for Depo-Provera and birth control implants in 49 districts. It is USAID funded from 2010-2020, and is one of many projects addressing contraception, infant and maternal mortality, and HIV/AIDS. NFCC conducts provider trainings for this program on a contract basis. Three types of trainings are provided: sangini ("injection") basic training (three days), sangini refresher training (two days), and contraceptive update training (one day).

Rupantaran, which means "transformation," has been implemented in three districts and has the goal of ending child marriage by empowering adolescents to confront social norms. The program focuses on education for adolescents, parents and local government officials. The adolescent training sessions consist of life skills training, which aims to increase adolescents' practical and social knowledge. The adult training sessions are intended to increase parents'

knowledge about the topics the adolescents are learning and to orient local government officials to the Rupantaran program. The trainings cover a wide variety of topics, including information on menstrual hygiene, reproductive health, microfinance and savings practices, as well as holding facilitated discussions on the community norms and expectations surrounding child marriage. Government officials are oriented to the Rupantaran package in order to bring the program to the local level for sustainability.

Menstrual Hygiene Management (MHM) is a training package developed by NFCC that consists of eight sessions to provide education on the biological basis of menstruation, how to manage menstruation hygienically, and how to use menstrual products, particularly reusable cloths. It is a large program which NFCC was subcontracted by USAID to develop. The program has been integrated into the School Health Program, where it is taught during a standardized free period on Friday afternoons. The program also involves community education sessions for adult women in the community or others not reached by the school sessions. It is currently in two districts, Sindhupalchowk and Dolakha, in 34 VDCs (Village Development Centers), 22 resource centers, and 91 schools. The objectives of the program are to increase knowledge of MHM, develop human resources at the local level and monitor the outcomes of the program.

The cascade "train the trainer" model was used for the MHM trainings, so that the facilitators were local, typically the heads of health clinics and Female Community Health Volunteers (FCHVs). In terms of impact, 64 people have been reached with the facilitator trainings, 119 with the resource center trainings, and 471 FCHVs have been trained. In addition, 2454 adolescent girls were reached in school sessions, and 6441 people were reached through community sessions. Pre- and post-tests have been used to measure change in knowledge. The

primary focus of the program for the future is sustainability and advocacy, so that the program can continue in these two districts and be expanded to others.

2.3.2 Capacity

NFCC is a relatively small organization, with approximately 20 staff members in its headquarters in Kathmandu, and another 10-15 staff members placed in local district offices to oversee program implementation. However, they are well connected with both the Nepali government and a wide variety of large international NGOs, and have extensive experience in implementing programs with a wide reach. They often achieve this by training local community members to implement their training sessions. They also aim for sustainability by leveraging their connections within the Nepali government to persuade the government to uptake the program, and to slowly transfer program funding and management to the government. The training package they developed for MHM is currently under the final stages of approval by the various government bodies required to allow it to be scaled up in all the other districts by the government

2.3.3 HPV Research and Interest

Over the past several years, NFCC has collaborated with the University of Alabama-Birmingham to conduct several studies examining HPV awareness and infection rates in Nepal as well as the feasibility of HPV DNA testing as a screening strategy. In total, seven papers were published from this collaboration. One study (Johnson, Bhatta et al. 2014) examined HPV awareness and vaccine acceptability in a traditional Newari ethnic community in Lalitpur, in the Kathmandu Valley, as well as in a village in Accham District in far-western Nepal. In both places, knowledge of HPV

was low, but vaccine acceptance was high, indicating that there could be good uptake rates. Two health camps were conducted in these same two communities to determine rates of HPV and other STIs. In Lalitpur, the women underwent a pelvic screening for cervicitis and vaginosis. Cervicitis was found at a rate of 23.5% of women, indicating possibly high rates of STIs (Johnson, Chamot et al. 2013). In Accham District, data at the health camp were procured through self-collected and clinician-collected cervico-vaginal specimens to test for HPV. The HPV prevalence was 9.6%, with high agreement between the self-collected and the clinician-collected samples (Johnson, Bhatta et al. 2014). Those samples positive for HPV were later DNA-sequenced to examine the prevalence of high-risk forms of HPV (Makowsky, Lhaki et al. 2016).

Another study (Bhatta, Johnson et al. 2017) conducted among Nepali and Bhutanese refugees in Eastern Nepal used the same dual sample technique and found an HPV prevalence rate of 8.9%. Significantly, this study also found that women whose husbands migrated for work were much more likely to be HPV positive. Two further studies were conducted to examine this relationship between migration and HPV. One used cross-sectional data from the Nepal Demographic and Health Survey to examine the relationship between partner migration and reproductive tract infections (RTIs) among women (Johnson, Lhaki et al. 2017). The second (Johnson, Lhaki et al. 2016) was a study conducted in rural western Nepal. The cross-sectional study (Johnson, Lhaki et al. 2017) found an association of husband's migration with RTIs only in the western districts, while the second study (Johnson, Lhaki et al. 2016) did not show a significant relationship.

In addition to these studies, NFCC has collaborated with both the Nepal Cancer Hospital and the Kathmandu Maternity Hospital to help bring expensive HPV DNA testing machines to the hospitals, as well as to establish cervical cancer screening and treatment clinics in hospitals over

the next few years. It is also interested in addressing the lack of HPV education in medical and nursing schools' standardized curriculums. With its history of capacity building, use of cascade education models, and interest in HPV, NFCC is well equipped to implement this program.

3.0 Program Design

With the Nepali government considering major expansions to both its cervical cancer screenings and HPV vaccination programs, capacity building is critical. The educational program proposed in this paper will support the coordination of cervical cancer and HPV training across the entire chain of the healthcare staff in the district of Achham. Through this, the healthcare system will be prepared for the increased screenings, vaccinations, and community engagement that will be required as the government extends its focus to HPV and cervical cancer. This would facilitate a successful campaign to reduce rates of HPV and ultimately cervical cancer in the district.

3.1 Theory and Choice of Approach

The proposed education program is intended to address low awareness and knowledge of HPV, cervical cancer screenings and treatment among medical professionals in Nepal. With future vaccination campaigns planned by the government, this program will address a critical gap in knowledge, will encourage medical professionals to increase their rates of screening and appropriate treatment for cervical cancer cases, and will increase comprehension and recommendation of the HPV vaccine. The critical theories utilized in the design of this program are the Diffusion of Innovations Theory and the Theory of Organizational Change, which can be used to target both the adoption of an innovation (in this case, HPV vaccination) by individuals and the structural changes required to maintain this adoption. The program will utilize the "train-the-trainer" approach to deliver the HPV education with this theoretical basis in mind. Through

this approach, the program aims to reduce HPV incidence and cervical cancer incidence and mortality through increased screening and vaccination rates.

3.1.1 Healthcare Professionals as Target Population

No intervention to improve HPV education among medical professionals has yet to be implemented in Southeast Asia, although it has been a successful approach in the United States (Reiter et al., 2011). Medical professionals are a key population to target for HPV education, since they carry out the vaccination, screening, and treatment activities that affect prevention, morbidity, and mortality.

While some experts have recommended that education campaigns on HPV should focus on parents, children, and teachers (Garland, Park et al. 2008), studies have shown that knowledge of HPV has a significant effect on the likelihood of physicians to recommend the use of the HPV vaccine in the first place (Krupp, Marlow et al. 2010). Low provider recommendation rates may nullify the positive effects of patient and parent knowledge. Studies in a wide variety of settings have shown that physicians and healthcare providers are often seen as the most trustworthy deliverers of HPV and other health information, and therefore may act as gatekeepers for new medicines and treatments in their communities (Sherris, Friedman et al. 2006). Additionally, initial evaluations of HPV knowledge and awareness have shown willingness among parents to accept the vaccine for their children, particularly if it is recommended by the medical authorities (Johnson, Bhatta et al. 2014). For these reasons, the proposed program has been designed to target the providers, using a model that has proven to be effective with other populations and public health issues.

3.1.2 Diffusion of Innovation Theory

Diffusion of Innovation Theory examines how new technologies are adopted in the healthcare setting, with particular attention to the length of time that it takes for research to be put into practice. Kerner, Rimer et al. (2005) observed that "efforts to move effective preventive strategies into widespread use too often have been unsystematic, uncoordinated, and insufficiently capitalized, and little is known about the best strategies to facilitate active dissemination and rapid implementation of evidence-based practices" (page 314). The Diffusion of Innovation Theory seeks to systematically organize this disorganized process.

The theory is comprised of five key concepts: diffusion, dissemination, innovation, communication channels, and social system (Rogers 2002). Diffusion is the overall spread of the innovation in a passive manner. Dissemination is the more controlled and systematic method of diffusing an innovation, and is the basis for this program design. The innovation can be any idea, practice, or piece of technology, and in this case comprises the HPV vaccine and standardized cervical screening practices. The communication channels of this program are through the hierarchical structure of the district's healthcare system, with the majority of the participants being trained by those they report to. The final key element is the social system, which is the employment structure of the district healthcare system. This system provides several advantages, including the benefit of the existing trust and loyalty to work superiors. The rigidity of the structure may present challenges, due to reduction in community participation and input in the development and implementation of program.

The theory also identifies five consecutive stages of adoption: innovation development, adoption, implementation, maintenance, sustainability, and institutionalization (Oldenburg and Glanz 2008). This program is designed to assist the movement of innovation of HPV vaccination

uptake through these stages. The theory also delineates three types of knowledge that are required for the decision to adopt to occur. These include "awareness knowledge," or knowing about the existence of the innovation. "Procedural knowledge" consists of the understanding of how to use the innovation, and "principles knowledge" consists of a comprehension of how the innovation works (Oldenburg and Glanz 2008). These three aspects of knowledge will be measured in the pre- and post-tests the participants take as a part of the HPV training.

Everett Rogers, in his descriptions of the Diffusion of Innovation Theory (2002), explained the ways in which an innovation that is designed to be preventative might be adopted differently than a standard technological innovation, as well as five steps that can be taken to facilitate the process. First, the relative advantage of the innovation must be emphasized. Second, "champions" of the innovation may influence others to follow them (Rogers 2002). In the case of the program proposed in this paper, these would be the district health officials and local doctors enlisted to receive the first training. Third, the norms of the system must be changed, in this case through official government endorsement of the program. Fourth, entertainment must be used, and finally, peer networks should be activated to assist in the diffusion of the innovation (Rogers 2002). These suggested methods encourage active guidance of the innovation diffusion.

3.1.3 Theory of Organizational Change

Theories of organizational change are those that focus on the characteristics, change, and interventions that impact the organizational or institutional levels of the socioecological model. According to Butterfoss, Kegler et al. (2008), interventions and strategies for change within an organization are "most effective and likely to be sustained when they are directed at multiple levels of organization, while simultaneously taking the external environment into account" (page 337).

Four primary dimensions of organizational change impact public health interventions: organization-wide change versus sub-system change, transformational versus incremental change, remedial versus developmental change, and reactive versus proactive change. Organizational change is likely to be defined by these dimensions.

The Stage Theory of organizational change operates in a way similar to the Stages of Change behavioral theory, and to the Diffusion of Innovation Theory. It comprises four major consecutive stages: the awareness stage, the adoption stage, implementation of change, and the institutionalization of change stage (Butterfoss, Kegler et al. 2008). These aspects of organizational change will be supported by the trainings and engagement and measured by the evaluation of the program's ability to change the behavior of the organization at the level of the clinics.

3.1.4 Existing Research and Interventions

Currently, no interventions to address either HPV or cervical cancer are being implemented in Nepal. The bulk of the programs aimed at sexually transmitted infections have been targeted towards the control of HIV/AIDS, despite the fact that Nepal has relatively low prevalence of HIV; approximately 2000 new infections are diagnosed yearly (Paudel, Singh et al. 2016). Several programs designed for HIV/AIDS prevention have been implemented, including some aimed at behavior change, condom distribution, testing, and needle exchanges. These were shown to have a low overall coverage of the at-risk populations, and awareness of HIV prevention among youth actually decreased between 2006 and 2011 (Paudel, Singh et al. 2016).

Meanwhile, 1,367 women die each year of cervical cancer in Nepal, and these deaths represent only a small fraction of HPV infections (Bruni, Barrionuevo-Rosas et al. 2017). In addition, programs targeting sexually transmitted infections and HIV in Nepal have primarily

targeted specific groups that are at a high-risk for HIV, such as injection drug users, female sex workers, and men who have sex with men (Paudel, Singh et al. 2016). For HPV, on the other hand, anyone having sexual intercourse is at significant risk, due to the high prevalence of the virus in the population. Women who have sex with men, generally considered a "low-risk" group for HIV, are at much greater risk of complications of HPV due to its strong association with cervical cancer.

3.1.5 Train-the-Trainer Approach

"Train the trainer" is a common model for many education interventions, including several currently run by the Nepal Fertility Care Center. It involves initial stages of training, in which the organization implementing the program trains a core group of key figures, who gain the knowledge and skills to teach the material to others in later training stages. It may contain two or more "levels" of training, and the proposed program contains three: trainings of "primary trainers," who will then implement trainings of "secondary trainers," who will ultimately deliver the material to local service providers.

The model has been shown to be effective with medical providers in the past; one study found "train the trainer" to be a more effective method for training physicians on the management of geriatric conditions than the traditional use of continuing education (Levine, Brett et al. 2007). Other studies in medical provider settings in the United States support this conclusion (Green 2005; Stratos, Katz et al. 2006; Allen, Connelly et al. 2011), including at the state-level governmental setting (Gabel and Pearsol 1993). No evaluation of a "train the trainer" program has been completed in Nepal; however, a similar program in India designed to increase knowledge about HIV among nurses proved to be effective (Nyamathi, Vatsa et al. 2008). Given the similarities in HIV and HPV as topics (both sexually transmitted viruses with similar methods of

prevention) these data support the "train the trainer" approach as potentially effective for HPV education in Nepal.

3.2 Program Activities

The program's key activities will be carried out largely by key staff from NFCC and the district health office of Achham, and training will be disseminated in a cascade model, as demonstrated in Figure 1 below. The HPV education package will be developed in conjunction with NFCC, then all relevant NFCC staff will be trained in its contents and use. The next step in the training will involve training district health officers, so that they will also be able to train others. They will then proceed to train key staff members at every health post and clinic. Finally, these local point persons will train their local staff. Separate trainings for key hospital doctors will be led by an NFCC medical doctor, and these doctors will then train the staff members who report to them. All trainings will utilize the same education package except the final ones, which will not include instructions on how to further train lower staff, and may be tailored for those with lower education.

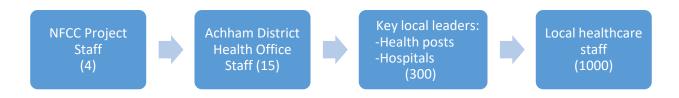


Figure 1 Program Training Cascade

Ongoing process evaluation will be conducted by NFCC staff in conjunction with the head of the NFCC department of Monitoring and Evaluation. Evaluation activities will include pre- and

post-tests at every level of training, feedback forms, and random monitoring of sessions. This monitoring will assess how the program is being implemented and determine if any changes need to be implemented as more trainings are delivered. Several NFCC staff (approximately three) will be expected to dedicate 33% of their efforts to this program, with more required for the initial rounds of trainings. Two ten-hour training sessions will be conducted with the district health office staff and the doctors of the district hospital. Approximately 15-20 ten-hour training sessions will then be conducted by the district staff with about 300 key staff members for every health post and clinic. These 300 key staff will then each conduct at least one training in their district with their dependent staff. This final eight-hour training is expected to reach approximately 1000 participants, for an overall total of over 1300 participants trained in the important elements of HPV and cervical cancer prevention.

3.2.1 Participant Engagement

HPV and cervical cancer have become topics of interest among members of the Nepal government and other agencies, due to the increasing awareness of the burden of cervical cancer, and trial HPV vaccination campaigns (Koirala 2016). Both members of government and medical associations can be contacted by NFCC to assess interest and garner support. Additionally, the staff of the district health office as well as the primary officers of all district health posts in Achham and head doctors of the district hospital will be recruited and involved before the onset of the program, so that they understand the program and are more invested. They will be contacted and recruited by doctors from the NFCC staff and district office to confer status and persuade more effectively.

The activities of the program will be carried out during regular employment hours with the permission and reimbursement of the government, allowing for the district staff to be fairly

compensated for their time, and to reinforce the idea that the program is part of their regular employment duties. Several major stakeholders will be involved closely in the implementation of the program. These include the Nepal government (particularly the health department), the district-level health office staff of Achham, and the doctors and health officers of the district. NFCC will assist with the design of the material and implementation of the program, since it has significant previous experience running similar programs to educate medical professionals on the methods of birth control and their use. Both the Nepal government and NFCC have a stake in HPV prevention, having previously collaborated on the GAVI-funded HPV vaccine pilot program in two districts. NFCC also maintains active connections to medical professional associations that it can draw upon.

3.2.2 Training Session Curriculum

The curriculum for the training sessions will be adapted from existing medical education literature, such as medical curricula currently in use in Nepal and Southeast Asia, as well as Continuing Medical Education (CME) programs. The program will cover the topics relevant to HPV and cervical cancer in general as well as including Nepal-specific information. There has been no analysis of existing HPV education curricula in either Nepal or the region in general. One study of web-based CME programs in the United States that covered HPV identified 45 commonly delivered messages in five general topic areas (Kornides, Garrell et al. 2017). These topic areas were as follows:

- 1. Delivering recommendations for HPV vaccination;
- 2. Addressing parental concerns;
- 3. Strategies to increase vaccine coverage;

- 4. HPV epidemiology and vaccine coverage; and
- 5. HPV vaccine guidelines.

Some of the most common messages noted in the programs were specifying the recommended age ranges for vaccination for both boys and girls, noting how influential provider recommendations are in patient and parent decisions, and identifying the clinical implications of HPV infection. The authors recommended that more CME programs educate on how to address parental concerns as well as vaccine coverage in the medical professionals' clinics on both the interpersonal and structural levels (Kornides, Garrell et al. 2017).

These topic areas will be supplemented with Nepal-specific information, such as the Nepal government's recommended age ranges for vaccination. Additionally, this program will address cervical cancer screening standards, as well as the importance of recommending cervical cancer screening to patients. It will also contain a refresher section on how to perform the VIA screening method for the medical professionals qualified to perform the procedure. Finally, the first two levels of the program will include "train-the-trainer" modules on how to present this information to others. This module will include a session in which each participant will practice presenting a module to their fellow trainees and receive feedback on their presentation. There is no standardized method for implementing a "train-the-trainer" program, so the managing organization must remain flexible and willing to revise the program as needed (Orfaly, Frances et al. 2005). As noted above, the final level of the program will not include the "train-the-trainer" modules.

3.3 Measurement Tools

The pre- and post-tests implemented with the staff and medical professionals will be adapted from a survey instrument created at Florida International University utilizing the Health Belief Model (Thomas, Dalmida et al. 2016). The items in this tool will be adjusted to be country-specific and to measure diffusion of the innovation; several questions may be removed or added as needed. An advisory team comprising NFCC and Achham health office staff, in addition to at least one doctor and at one assistive health staff (such as an Associate Nurse), will approve the final survey instrument. Some example questions taken from the Florida International University instrument include the following:

- 1. Using condoms can prevent HPV (yes/no);
- 2. Men are at risk for contracting HPV (yes/no); and
- 3. A vaccine against HPV could prevent [cervical cancer] (yes/no)

(Thomas, Dalmida et al. 2016).

Finally, a process evaluation monitoring tool will be developed using the training manual as a guide. For instance, the evaluator will select which sections of the training were completed by the trainer and assign a subjective score to the training facilitation. Additionally, the evaluator will identify potential areas for ongoing change in the curriculum. The baseline and six-month survey instrument will contain basic yes or no questions directly assessing the progress toward the listed outcomes, such as "Did your healthcare worker discuss HPV with you today/offer screening?" and "Do you know one way to prevent HPV?" These will be used to inform the assessment of the short-term outcomes.

3.3.1 Internal and External Validity

Internal validity for the tools is high, because the pre-test will be administered immediately before the training, and the post-test will be administered immediately after, negating the effects of other factors on changes that may be observed between the two tests. Some threats to internal validity include the "baseline effect," in which participants learn how to better take the test, not necessarily the material, and those who may cheat on the test by sharing answers. Cheating will be minimized with reminders not to share responses.

The primary threat to external validity will be the ways in which the health professionals in Nepal's Achham District may be different from health professionals in the rest of the country. Nepal is a highly diverse country, with dozens of ethnic groups, languages, and differences in culture. This may affect the extent to which the results from the evaluation of the program can be generalized to the rest of the country.

3.4 Deliverables

The first deliverable will be the completed training packets, both for the "train the trainer" programs and the general education program. The first round of trainings will involve the staff members of the Achham District Health Office, who will be trained in the delivery of the program to key local point-persons, such as the heads of the health posts. This initial training session will be ten total hours, and will be evaluated using a sign-in sheet for attendance and a pre- and post-test to measure the improvement in knowledge both related to HPV and cervical cancer, and to how to implement the trainings for the key local staff. The sessions will include practice activities

where the staff will demonstrate their ability to present the training materials, evaluated by the lead trainer with a form.

These district health officers will then implement the trainings with key stakeholders from each of the local health posts and clinics. Each session will contain 15-25 participants, measured by attendance sheets. These sessions will also total ten hours, and will contain the same pre- and post-test measures and practice training activities to evaluate change in knowledge. After the key stakeholders have received this training, they will then return to their post or clinic and provide an eight hour training to their local health employees and volunteers, to be divided among one or more days at their discretion. This will also be monitored with attendance sheets, as well as a pre- and post-test that is slightly different from the "train the trainer" version, focusing only on HPV/cervical cancer and best practices.

Six months after the initial rounds of trainings, the outcomes will begin to be measured. The program expects that within six months, cervical cancer screenings and HPV counseling will be offered to 75% of eligible women who are coming to the clinics for any kind of treatment. The Nepal guidelines for cervical cancer screening include all women between the ages of 30-60, at least once every five years (Thapa, Maharjan et al. 2018). As a result, within six months, cervical cancer screenings will increase by 60%, and of those with positively diagnosed cases, 95% will be referred to appropriate treatment. Finally, ability to identify the modes of transmission and one method of prevention for HPV will increase in women attending the clinics by 50%. These outcomes will be determined by conducting brief baseline surveys in person at a representative sample of clinics prior to trainings, and again at approximately the six-month mark. After ten years, the program expects to achieve a 20% reduction in mortality rates due to cervical cancer. This will be measured through the national morbidity and mortality surveillance systems.

3.5 Data Collection

The data collection at the initial training session with the Achham health office staff will be completed by the Nepal Fertility Care Center staff members who are implementing the train-the-trainer program. Further data collection for the train-the-trainer program will be completed by the Achham staff members, and the data will be forwarded immediately to NFCC staff for compilation and monitoring of the process measures. For the general education program, the local trainers will implement the pre- and post-tests and forward them to the district health office, who will forward them to NFCC. The pre- and post-tests will be completed by a majority of participants, due to the program being implemented in the regular course of their employment, and the evaluations being an expected portion of the training session. NFCC and district health office staff will perform spot monitoring of at least 10% of the approximately 300 general education training programs. At these sessions, they may assist with collection of attendance sheets and pre-/post-tests, and they will also complete an evaluation form to determine whether there are any issues or complications in either the curriculum or to the manner in which it is delivered. These forms will determine if changes need to be made mid-program, or if more support or additional trainings are required.

The baseline and six-month clinic comparison surveys will be completed by NFCC staff in conjunction with the staff from the Achham District Health office. Approximately 60 clinics and health posts, representing 20% of the total, will be chosen through a process of stratified sampling to ensure that rural and urban locations are equally represented. For the baseline surveys, the heads of the clinics will first be contacted by NFCC staff so that they are aware of the purpose and process of the survey implementation, and they will be assured that the information cannot reflect negatively on their clinic's individual performance.

3.6 Timeline

As shown below in Table 1, the program contains five key activities occurring over the course of one year, beginning with the development of training materials and of meetings with key stakeholders, which is set to take approximately three months to complete. Next, all of the Achham District Health Office staff will receive the complete training, which should occur over a period of two to four months. After enough of the district level staff are trained, they can begin their training sessions with the 300 key staff members at the local level, such as the heads of local health outposts and clinics, which should take place over a period of five months. Once those key staff members are trained, they will be encouraged to provide the last training level within one month to the staff members who report directly to them, including the nursing assistants, midwives, and Female Community Health Volunteers (FCHVs). Monitoring and evaluation will occur throughout.

Table 1 Gantt Chart Timeline

	Months											
ACTIVITY	1	2	3	4	5	6	7	8	9	10	11	12
Pre-Activity: Develop Materials												
A. Draft training session materials												
B. Review of all materials by expert committee												
C. Print and construct training packets												
D. Make contacts with doctors and district staff												
I. Train district level staff												
A. Conduct training session, pre- and post-test												
II. Train key staff at health posts/clinics												
A. Conduct training session, pre- and post-test												
III. Key staff train auxiliary staff of health posts												
A. Conduct training session, pre- and post-test												
IV. Monitoring and Evaluation												
A. Ongoing monitoring and evaluation												
B. Data collection, entry, and cleaning												
C. Final evaluation												

3.7 Evaluation

The evaluation of the program will utilize the RE-AIM framework, and will draw data from the participant pre- and post-tests at all levels of trainings, the evaluation forms completed by the Monitoring and Evaluation team at NFCC for at least 10% of the sessions, feedback forms from the participants, and the final evaluation comparing awareness and practice at the clinics between baseline and six-months.

3.7.1 **RE-AIM Framework**

RE-AIM is an acronym for Reach, Effectiveness, Adoption, Implementation, and Maintenance. Reach and Effectiveness are measured at the individual participant level, while Adoption and Implementation are measured at the organizational level. Maintenance may be measured at both levels (Glasgow and Linnan 2008).

The Reach portion of the evaluation measures the proportion of eligible participants who took part in the program and how representative they are of the target population. This will be measured using attendance sheets and information provided by the district health office on the total numbers of employees of the various positions. Effectiveness examines the consequences of the program on the primary outcomes. This can be measured through both the pre- and post-tests and the feedback forms submitted by participants during the training.

Adoption concerns the percentage of intervention staff that participate in the implementation of the program. This will be measured by examining how many of the staff trained in each of the "trainer" sessions proceed to implement and document training sessions for the staff in their local area or hospital. For each training, they will have to submit documentation, including the pre- and post-tests and feedback forms. Similarly, the Intervention portion examines the degree to which the intervention was delivered as intended, and how much delivery may have changed over time or from facilitator to facilitator. For this program, this will be measured primarily through evaluation forms, completed by program staff, that will determine whether changes need to be made to the curriculum or its delivery. Finally, Maintenance measures will record how well the entire program was implemented and adopted over time (Glasgow and Linnan 2008). The long-term effects will be examined through the clinic surveys, and institutionalization will be determined by the potential adoption of the program by the government of Nepal.

3.7.2 Reporting Out

The process evaluation data, including those from attendance records, the pre- and post-test measurement, and the evaluation forms will be summarized and shared by NFCC staff in conjunction with the University of Pittsburgh with all the key and primary stakeholders. These stakeholders include the major funder(s), Achham District Health Office staff, and key point persons within the Government of Nepal's Department of Health. This information will be shared through formal summary emails that are distributed on a bi-monthly basis.

Within one month of completion of the six-month clinic evaluations, a formal final report giving both a summary and detailed analysis of the outcomes will be produced for dissemination. This report will be given to the key stakeholders mentioned above, as well as additional recipients. These may include members of the Nepali media, such as the Himalayan Times, and will be more widely distributed among the members of the Nepal government, to all departments that may have some part in determining the expansion of the program. It will also be sent to the leaders of the district health offices in the other 76 districts in the country, as well as to all the local health offices that participated in the original program, so that they can be aware of their own impact and the results of the program they participated in. After ten years, the mortality data from Achham District will be reviewed to see if any significant change has occurred in cervical cancer mortality. The results from this examination will again be sent to all the major stakeholders, as well as the Nepali media and government if HPV education programs have not already been implemented.

3.8 Sustainability

For sustainability, the package and the outcome evaluation of the program will be presented to members of the Nepal government's health department, including the costs and benefits of adopting the program in the other 76 districts of Nepal. Since the program is relatively low-cost and is extremely pertinent to the government's other objectives, they are likely to choose to uptake the program package before or in conjunction with the rollout of the HPV vaccine across the country. In addition, other funders may be sought to assist in rolling out the program in further districts. Nepal has a high concentration of international non-governmental organizations (INGOs), many of whom are also addressing similar issues.

4.0 Discussion

This program was designed to address a gap between the limited working knowledge of HPV and its related cancers among government medical professionals in Nepal and the anticipated future expansion of access to the HPV vaccine innovation. The standard time lag in between the publication of research findings and the implementation of these findings into practice is 17 years (Morris, Wooding et al. 2011). The HPV vaccination innovation is spreading to Nepal faster than an understanding of how to engage medical professionals in medical education about HPV. This program seeks to reduce this time lag and address HPV awareness and knowledge by introducing capacity building prior to the widespread release of the vaccine. Focusing on capacity building early has the potential to increase vaccination rates and efficiency, and to reduce waste and unintended consequences of introducing the HPV vaccine in Nepal.

The literature suggests that medical professionals are highly influential in the decision of parents and patients on vaccination. However, in the region, less half of medical students would accept the HPV vaccine themselves or recommend it to patients. Low-income countries like Nepal bear a significant proportion of the global burden of cervical cancer, and the HPV vaccine is is predicted to widen this gap in the next decades by reducing cervical cancer rates to below 6 per 100,000 in some high-income countries, based on their current vaccination rates (Simms, Steinberg et al. 2019).

NFCC has extensive experience with capacity building and HPV research in Nepal, the natural outcome of which is a program on capacity building for HPV. Since the organization already has a history of "train-the-trainer" interventions within the district government structure, this was the most practical route of intervention. Behavioral and organizational theories such as

the Diffusion of Innovation and Organizational Change theories also support this mode of program implementation. The program will entail three levels of training, as described in Chapter 3, in order to reach exponentially more participants with each descending level. Ultimately, the program will reach approximately 1350 government medical professionals in the District of Achham.

This program model could potentially be adapted for use for other healthcare topics in Nepal or countries with similar healthcare system structures. It could be useful as a method of capacity building that is relatively low-cost and efficient. This program aims to translate research into practice in a rapid and efficient manner by utilizaing existing government and non-profit structures, in order to facilitate the adoption of the HPV vaccine innovation to reduce the burden of preventable cancers in Nepal.

5.0 Conclusion

This program will use a "train-the-trainer" educational model in one initial training provided by

NFCC to the Achham district health office staff, and in 10-20 secondary trainings provided by the Achham district staff to approximately 300 key government health staff members and hospital physicians across the district. These trainings will cover the key curriculum elements about HPV, the HPV vaccine, cervical cancer, and screening and prevention methods. They will also cover the basics of providing the training to others. Those 300 key staff members and physicians will then provide the final educational training to approximately 1000 local healthcare staff members. In this way, the "train-the-trainer" model, informed by the Diffusion of Innovation and Organizational Change theories, will facilitate a "cascading" of important information down the healthcare system structure in one district prior to the implementation of the HPV vaccine. With this capacity building, staff will have the knowledge and understanding to inform their vaccination recommendations to patients and parents. They will be knowledgeable about the risks of HPV, methods of prevention, the benefits of vaccination, and the appropriate screening recommendations of the Nepal government. Qualified professionals will be refreshed on how to complete the VIA cervical cancer screening. Within sixth months, the program aims to see 75% of eligible women who come to local clinics being offered information on HPV prevention and cervical cancer screenings, and a resulting increase in screenings, cervical cancer diagnoses and treatment, and an increase in clinic attendees' awareness of HPV. Through this mechanism, the program intends to prepare local government healthcare professionals and clinics for the HPV vaccination access expansion, increase vaccination coverage, and ultimately reduce mortality due to cervical cancer in the district.

Some limitations presented in the development of this program were that it is not feasible to access all of the studies that have been done on HPV, HPV in Nepal, and the use of "train-thetrainer" programs in Nepal and elsewhere. Additionally, this paper has added no knowledge to the literature. However, further research is needed on the precise situation of knowledge and awareness of HPV in Nepal. Only a handful of limited studies have been used to assess understanding of HPV among the general population and medical professionals. Studies that have been done have not separated private and governmental medical professionals in their HPV and cervical cancer knowledge. In addition, many other basic things are not understood about healthcare and program implementation in Nepal. No formal evaluations have been completed of any "train-the-trainer" program in the country nor on any program focused on the government medical professionals as a population. HPV epidemiology is only recently beginning to be understood in the country, with the majority of publications occurring in the last five years. As a result, there is little understanding of the overlapping impacts of demographics, culture, and geography. Finally, Nepal is in a state of transition. Its healthcare system is in the process of being overhauled in the switch to a federal system, and little can be known about the potential positive and negative consequences of this transition.

Additional program planning may be required to address other gaps and needs in Nepal that overlap with HPV prevalence. For example, efficient supply chain management will be required to transport the HPV vaccine to the remote regions of Nepal, and on a larger political scale, road and transportation improvements are necessary to facilitate all healthcare initiatives in the country. In addition, health issues such as sexual education and contraceptive access impact the transmission of HPV, and more programs are recommended for these issues. Finally, rigorous

evaluation of existing programs in Nepal, such as NFCC's Menstrual Hygiene Management program, are recommended to inform the development of further similar programs.

The program will result in a complete training package, complete with curriculum, budget, and thorough evaluation. This training package would be made available for NFCC or the government of Nepal to implement in more districts of the country. It would also provide a rigorously tested model for capacity building for other healthcare issues in Nepal. The burden of cervical cancer in Nepal and other low-income countries is entirely preventable. The HPV vaccination is an innovation that is predicted to exceed initial expectations in its reduction of cervical cancer in high-income countries. With charitable organizations such as GAVI willing to fund vaccine provision and distribution, the final barrier in bringing Nepal to the same anticipated minimal cervical cancer burden as high-income countries is the capacity of its healthcare staff.

Appendix Logic Model

INPUTS		OUTPUTS			OUTCOMES				
		Activities	Participants		Short	Medium	Long		
Training materials and supplies Funding source Local expertise, connections of the Nepal Fertility Care Center (NFCC) NFCC staff knowledgeable in HPV and capable of training the trainer in the local language, and administering surveys Approval of the Nepal Department of Health, permission to use clinic spaces Pitt Public Health expertise for data collection, analysis, and evaluation Previous NFCC and other research indicating low medical professional awareness		Creation of train-the-trainer and training materials Staff from NFCC train district-level health officers in the training program -10 hours of training District health officers train one key stakeholder from each health post, sub-health post, and primary care clinic, as well as the district hospital -10 hours of training -10-20 training sessions Key stakeholder from each location provides training to other staff, promotes awareness -8 hours -1-2 training sessions per location Data collection and evaluation activities Distribution of evaluation results	Approximately 10 Achham district health office employees 12 heath post officers 60 sub- health post officers 227 PHC officers 1 (minimum) from hospital = 300 participants (15-30 per session) Approximately 1000 health staff members, including Female Community Health Volunteers Nepal government and relevant stakeholders	4	Formal training package established within 3 months 90% of district health employees score 95% or higher on HPV/cervical cancer knowledge exam, demonstrate readiness to implement program 300 stakeholders score 95% or higher in knowledge, demonstrate readiness to implement trainings 1000 staff members score 90% or higher in knowledge, demonstrate increased willingness to discuss and screen for HPV and cervical cancer in patients Nepal government formally expresses willingness to expand program	Within 6 months: Cervical cancer screenings and HPV counseling are being offered to 75% of eligible women coming to clinics for treatment Screenings increase by 60% Among all women visiting the clinic, ability to identify transmission modes of HPV increase by 50% Increase in cervical cancer diagnoses, referral to treatment in 95% of cases	Reduction in mortality rates due to cervical cancer Lower prevalence of HPV Increased knowledge and awareness of HPV, cervical cancer, prevention, vaccine, and treatment among both medical professionals and the general public Adoption by Nepal government of training program in all districts, to run concurrently with planned expansion of HPV vaccination program		

Assumptions/Theoretical Constructs

- Diffusion of Innovation Theory knowledge will be disseminated from key members of the healthcare system
- Theory of Organizational Change Education of health professionals will result in adoption of new clinical behaviors

External Factors

- Geographic barriers in Nepal are significant, participants may be difficult to reach
- Sustainability of program may be affected by government willingness to sustain the training program over time

Figure 2 Logic Model

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