Improving the Delivery of Evidence-Based HPV Patient Education

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Table of Contents

Abstract

Background: The human papillomavirus (HPV) is a common infection, spread by sexual contact that has many implications to several systems in the body. Though HPV has long been associated with the development of cervical cancer, the Centers for Disease Control (CDC) recently reported the cases of non-gynecological HPV-related cancer were greater than gynecological HPV-related cancers. Despite the potential implications of HPV on multiple systems, current patient education for HPV lacks complete, comprehensive information reflective of the current evidence. A review of literature for HPV patient education recommendations identified five themes across multiple specialties. These themes include transmission, screening, patient implications, partner implications, and prevention.

Objective: This project aims to improve the content of HPV patient education to reflect all healthcare specialties evidence-based education recommendations. This project seeks to answer: Do the HPV patient educational tools currently used in healthcare settings provide patients with information that reflects the current evidence-based recommendations provided by all healthcare areas, better than a multispecialty HPV education tool created based on the evidence?

Design: A comparative descriptive project will be utilized to answer the project question. The evaluation of current HPV tools was completed by the principle investigator and two additional expert panel members. Inter-rater reliability was determined using Fleiss' Kappa. An evidenced-based HPV educational tool was created using the Toolkit for Making Written Material. This content of the created tool was validated by an expert panel of healthcare providers. The created tool was then evaluated for understandable and actionable content using the Patient Education Material Assessment Tool (PEMAT). The results of the expert panel analysis were compared to

determine if the current or created tool provide information reflecting the evidence based recommendations.

Results: None of the current HPV tools evaluated contained all identified patient education recommendations. The Kappa ranged from *K* 0.22, to *K* 0.77, with an average of *K* 0.53. The created tool demonstrated and 97%-100% of the expert panel members strongly agreed or agreed each of the evidence-based recommendations were present. Of the thirty-three expert panel members that evaluated the created tool, a total of three questions regarding the presence of the patient education recommendations had neutral responses and there were no negative responses. The expert response to the presence of the recommendations was between 97-100%.

Conclusions: This project found the system specific HPV patient educational tools, fail to provide patients with comprehensive health information that patients need to be informed. The created HPV educational tool was found to provide information that reflects the current evidence-based recommendations provided by all healthcare areas better than the current HPV patient educational tools evaluated.

Chapter I: Introduction

The human papillomavirus (HPV) is the most common sexually transmitted disease, affecting millions of people worldwide (Emberger, 2014; Hutter & Decker, 2016). First identified in the 1950s, research has demonstrated the link between infection with HPV and the development of cancer (Hutter & Decker, 2016; Pytynia, Dahlstrom, & Sturgis, 2014; Zandberg, Bhargava, Badin, & Cullen, 2013). Infection with HPV has been identified to cause cervical, anal, oropharyngeal (OPC), vulvar, vaginal, and penile cancers; other ongoing research has suggested a linked between HPV and the development of esophageal, prostate, bladder, breast, and lung cancers (Jemal et al., 2013; Zandberg et al., 2013; zur Hausen, 2009).

There are more than 130 identified strains of HPV; these strains of HPV can be categorized into two groups: low risk and high risk (Zandberg et al., 2013). Strains of HPV that rarely cause cancer are identified as low risk, while strains of HPV known to have carcinogenic properties are identified as high risk (Montgomery & Bloch, 2010). The use of HPV throughout this paper should be understood as high-risk HPV, unless otherwise indicated.

The incidence of HPV-related disease in the United States (US) has continued to increase over the past decades and is projected to continue to increase in the coming decades. However, the cases of cervical cancer have steadily declined in the US, but non-gynecological HPV-related cancers are increasing significantly (Jemal et al., 2013). In 2016, the Center for Disease Control (CDC), reported non-gynecological HPV-related cancers outnumbered gynecological HPV-related cancers (CDC, 2016).

In 2012, multiple agencies, including the American Cancer Society (ACS), American Society for Colposcopy and Cervical Pathology (ASCCP), American Society for Clinical Pathology (ACP), and United States Preventative Service Task Force (USPSTF), revised cervical

cancer screening recommendations to include co-testing with HPV and pap in women over the age of 30; this change reflected the growing knowledge of the significant role that HPV plays in the development of cervical cancer (Priebe, 2013). Prior to the implementation of these recommendations, cervical HPV screening was used to triage abnormal cervical cytology (Katki, et al., 2013a). The transient, asymptomatic nature of HPV infections that will typically resolve spontaneously led to most infected individuals being unaware of the infection (Katki, et al., 2013a). As a consequence of these new guidelines, women, who have never had abnormal pap cytology, are now aware of an infection with HPV; it is estimated that 3.7% of women will have a normal pap with an HPV infection (Katki, H., Kinney, et al., 2011). Evidence suggest women may frequently be infected with HPV in multiple locations, such as the cervix and anus, simultaneously, and that partners of women with cervical HPV have a higher risk of developing HPV related OPC (D'Souza, Gross et al., 2014; Ortiz-Martinez et al., 2013).

Prior to these new guidelines patient were only aware of HPV infection when pre-cancerous cervical cytology was present or following the diagnosis of cancer. In non-gynecological HPV infection, the diagnosis of HPV infection is typically made following the diagnosis of cancer when pathology determines the cancer is caused by HPV (Mehanna, et al., 2013; Reyes-Ramos, Dukandar, & Borum, 2013).

The purpose of this project is to improve the content of HPV patient education in all clinical settings. This scholarly project will translate evidence into knowledge to improve healthcare by answering: Does the HPV patient educational tools currently used in healthcare settings provide patients with information that reflects the current evidence-based recommendations provided by all healthcare areas, better than a multispecialty HPV education tool created based on the evidence?

Background of Problem

A review of relevant HPV information including transmission, implications of infection, incidence and prevalence, prevention, and patient knowledge and awareness will be explored to establish a background of the problem.

HPV Transmission

Human papillomavirus is a contagious virus that infects the squamous epithelia where low levels of viral deoxyribonucleic acid (DNA) are maintained in the cells; the virus produces rapid replication and viral shedding that then infects surrounding cells (Hutter & Decker, 2016). Modes of transmission of HPV include vaginal, oral, and anal sex; non-penetrating genital contact; and autoinoculation (Hutter & Decker, 2016; D'Souza, G., Cullen, Bowie, Thorpe, & Fakhry, 2014; Martin-Hernan, Sanchez-Hernandez, Cano, Campo, & Romero, 2013). Direct contact with an infected person's genitals is the highest risk factor for acquiring HPV infection (Juckett & Hartman-Adams, 2010). Other identified risk factors for HPV infection include early sexual debut, multiple sexual partners, inconsistent use of barrier contraception, and tobacco use (Juckett & Hartman-Adams, 2010).

Implications

In the 1980s, Harald zur Hausen was the first researcher to explain the role of HPV infection has on the development of cancer (Pytynia, Dahlstrom, & Sturgis, 2014). In approximately 10% of HPV infections, the immune system fails to remove the infection and the infection becomes persistent; a persistent HPV infection can produce potentially life-threatening consequences (Zandberg et al., 2013). Persistent infection with HPV leads to integration of HPV DNA in the nuclear DNA of the human keratinocyte; integration of cells by HPV results in

degradation of tumor-suppressing proteins within the cell, while simultaneously accelerating viral proliferation within the cell that leads to malignancy (Pytynia, Dahlstrom, & Sturgis, 2014).

In the proceeding four decades since zur Hausen explained the link between HPV infection and cervical cancer, this relationship has been thoroughly studied and most emerging research related to cervical cancer support the conclusion that cervical cancer is almost exclusively caused by HPV infection (Clinical proceedings, 2009; Dunne, Friedman, Datta, Markowski, & Workpwski, 2011; Hernandez et al., 2008; Katki, et al., 2013a Zandberg et al., 2013). In addition to cervical cancer, HPV infection is also known to cause anal, oropharyngeal, vulvar, vaginal, and penile cancers (Jemal et al., 2013, Zandberg et al., 2013; zur Hausen, 2009). Other ongoing research suggests HPV may be a contributing factor in the development of esophagus, prostate, bladder, breast, and lung cancers (Zandberg et al., 2013; zur Hausen, 2009). Those patients with HPV infection who have a compromised immune system such as those with human immunodeficiency virus (HIV), transplant recipients, or patients taking immune-suppressing medication, have a higher risk for progression from HPV infection progressing to cancer (Frisch, et al., 2000; Meyer et al., 2003; Reyes-Ramos, Dukandar, & Borum, 2013).

Incidence & Prevalence

The human papillomavirus is the most common sexually-transmitted disease in the US, with an estimated 14 million new infections annually (Emberger, 2014; Hutter & Decker, 2016). It is estimated that 79% of sexually active women will be infected with HPV at some point during their life. Nyitray and colleagues (2010) estimate cervical HPV infection prevalence to be 42.7%, while the prevalence of anal HPV infection among heterosexual men is estimated to be 12% (Hutter & Decker, 2016; Nyitray, et al., 2010; Steinau et al., 2014). The estimated

prevalence of oral HPV infection is 7.3% in the US adult male population, and 3.8% in women (Sanders, Slade, & Patton, 2012; Steinau et al., 2014).

Cervical cancer rates continue to decline in the US, with approximately 11,771 new cervical cancer cases and 3,700 deaths every year. Cervical cancer remains the second most common cancer among women worldwide, with an estimated 500,000 new cases annually and more than 250,000 deaths still occur each year (Centers for Disease Control and Prevention [CDC], 2016b; Field & Caplan, 2008; Lewis, 2007). HPV-related OPC have increased by more than 70% in the last decade, now outnumbering cases of cervical cancer in the US (CDC, 2016b; Mehanna et al., 2013). Most recently, the CDC reported approximately 30,700 new cases of HPV-related cancers annually, with nearly two-thirds of these cancers being non-cervical (CDC, 2016b).

Prevention of HPV

On June 8, 2006, the US Food and Drug Administration approved the first HPV vaccine; the vaccine was indicated for use in the prevention of both cervical and anogenital cancers, as well as the prevention of genital warts (Nicol et al., 2015; Viscidi & Shah, 2007;). However, there is no indication for the use of HPV vaccine in the prevention of OPC, though research suggests that the HPV vaccine would likely prevent development of OPC (Herrero et al., 2013). The newest 9-vailent HPV vaccine protects against nine strains of HPV, including the original strains 6 and 11 (most common cause of genital wart), 16 and 18 (most common causes of cervical cancers), and five additional high-risk strains of HPV; the use of the 9-vailent vaccine has the potential to prevent more than 80% of all HPV-related cancers (Saraiya et al., 2015). In 2016, the CDC reported 92% of HPV related cancers in the US were caused by strains of HPV contained in the 9-valent HPV vaccine (CDC, 2016b).

The vaccination is recommended for females between the ages of 11 and 26, males between the ages of 13 and 21, and immunocompromised males and men having sex with men (MSM) between the ages of 21-26; the HPV vaccine is approved for all males and females starting as early as age nine and as late as age 26 (Petrosky et al., 2015).

Despite the US being the first country in the world to introduce a publicly funded HPV vaccination program, the HPV vaccine rates in the US have remained low (Bruni et al., 2016; Centers for Disease Control and Prevention [CDC], 2015). By comparison, Australia instituted a vaccination policy for HPV in 2007, a year after the US, and has the highest percentage of population to complete the HPV vaccination series in the world. Australia's rates of HPV vaccine course completion are: 41% ages 10-14, 69% ages 15-19, 65% ages 20-24, 49% ages 25-29, and 17% of the entire population, compared to completion rates for HPV vaccination in the US of: 28% ages 10-14, 41% ages 15-19, 34% ages 20-24, 6% in ages 25-29, and 7% of population (Bruni et al., 2016).

The Centers for Disease Control and Prevention (CDC) (2015), report a rise in initiation of HPV vaccine series among adolescents in the US, with 50% of males and 63% of females having received at least one vaccination of the series. Completion of the HPV series requires three immunizations; however, in the fall of 2016, the CDC changed recommendations to include using a two-series vaccination for adolescents younger than 15, as long as the vaccinations were six months apart (CDC, 2016a). However, HPV vaccination compliance rates are significantly less than the compliance for other age-related vaccinations such as Tdap with 86% and meningococcal with 81% (CDC, 2015). This suggests that patients are specifically avoiding HPV vaccination, rather than all vaccination.

It is essential that all healthcare providers discuss primary and secondary prevention for HPV with patients. The National Institute of Health (NIH) (2014) defines primary prevention as "the prevention of a new health condition" (p.12) or health-promoting education, and secondary prevention as "early detection and treatment of an asymptomatic or early stage health condition to prevent or slow the progression to a more serious condition or the prevention of the recurrence of a health condition" (p.12). In addition to vaccination, other methods of primary prevention could include abstaining from all sexual contact (Juckett & Hartman-Adams, 2010; NIH, 2014). Secondary prevention education should include delay of sexual debut, limiting sexual partners, use of condoms or another barrier contraceptive device, and never smoking or smoking cessation (Juckett & Hartman-Adams, 2010).

Patient Knowledge & Awareness of HPV

According to Blake et al. (2015), awareness of HPV by men and women in the US increased from 40% in 2005-2006 to 68% in 2013; however, HPV knowledge in specific populations remain below average. Asgary et al. (2015) found that less than half of the women living in New York homeless shelters were aware of HPV, and less than a third knew that HPV was transmitted sexually. Similarly, Latinas living along the Mexico-Texas border demonstrated below average knowledge of HPV (Sanderson et al., 2015). McCree et al. (2010) found that women recently participating in HPV screening as part of cervical cancer screening also had a low understanding of HPV.

Identified global barriers to HPV vaccination include concerns regarding vaccine safety, low perceived need for the vaccine, cost, and logistic barriers (Gerend, Shepherd, & Shepherd, 2013). Similarly, Brewer and Fazekas (2007) found that inadequate education and understanding of HPV were a potential causes for the low HPV vaccination rates. While Wilson et al., (2016)

identified lack of knowledge regarding transmission, potential disease implications of HPV infection, and benefits of vaccine, as well as not receiving an influential recommendation from a healthcare provider, as barriers to HPV vaccination. Among adolescent black females, barriers to starting HPV vaccination include a lack of perceived susceptibility (DiClemente, Murray, Graham, & Still, 2015).

Significance of Problem

Provider-guided patient education encounters create an environment of trust and empowerment for patients; while also establishing an atmosphere of participation for patients to make informed healthcare decisions (Patient education, 2000). Failure of healthcare providers to give significant information regarding the potential disease may have on overall health, diminishes the ability of patients to make informed decision regarding their health and can negatively affect outcomes (Kester, Shedd-Steele, Dotson-Roberts, Smith, & Zimet, 2014; Moons et al., 2001).

For a healthcare provider, it is often difficult to decide how much of any subject should be provided to the patient. It would simply be impossible to transfer everything known about any specific disease process in a way that would be meaningful to the patient. Provider-led HPV education is no different, however, providing all relevant evidence-based education is necessary for patients to adequately understand risks and potential prevention.

A review of patient education strategies found that verbal discussions, alone, were the least effective, and recommended that all verbal patient education should be used in combination with other patient education strategies (Friedman et al., 2011). In fact, the Centers for Medicare and Medicaid Services (CMS) created meaningful use standards that included providing patient-specific educational resources. Because meaningful use is now tied to reimbursement, failure to

provide patient educational resources results in loss of revenue for the provider (Shipman, Lake, Van Der Volgen, & Doman, 2016). Written patient education should not only be patient specific, but must also be created at an appropriate reading level and evaluated to assure the information is understandable (Friedman et al., 2011). Having an educational tool that encompasses current HPV education recommendations can help to guide patient-provider discussions, while ensuring the provider addresses all relevant information.

Limited time in the clinical setting creates challenges for healthcare providers to give all the recommended education; to overcome this barrier, the provider can use educational tools (NIH, 2014; Yarnell et al., 2003). Written educational material can enhance verbal education given by the healthcare provider and can be distributed and documented by a non-provider healthcare worker; this distribution can save providers time, and proper documentation can satisfy meaningful use requirements (Shipman, Lake, Van Der Volgen, & Doman, 2016). Use of a comprehensive educational tool during HPV-patient educational encounters can improve clinical practice by giving the provider an evidenced-based guide for discussion.

Multiple specialty groups have created HPV-patient education. However, there is a lack of inclusion criteria and consistency among available HPV-patient education tools. Most current HPV education tools remain focused on implications and risk of HPV to a specific body site rather than all potential risks of HPV infection (American College of Obstetrics and Gynecology, The [ACOG], 2014; CDC, 2014HPV and Mouth Cancer, (n.d.); HPV the facts, (n.d.); HPV, (n.d.); CDC, 2014; National Cervical Cancer Coalition [NCCC], 2015;). The use of these educational tools provide helpful insight to the site affected by HPV; however, these patient education tools fail to provide evidence-based comprehensive, multisystem risks of HPV infection.

Purpose of Project

The nurse practitioner has helped to relieve the shortage of healthcare providers in the US, while focusing on health promotion and disease prevention (Saverin, 2009). The purpose of this project is to advance the quality of healthcare provided to patients with HPV infection that includes comprehensive, evidence-based patient education recommendations. This project will establish recommendations in multiple specialty areas in medicine that should be provided to all with HPV infection. The change in practice guidelines to include HPV screening for cervical cancer, provides an opportunity for healthcare providers to focus on health promotion and early disease detection.

Setting for Use

The human papillomavirus can infect multiple sites that may be managed by differing medical specialties, with each specialty providing information for site-specific HPV infection. The creation of a patient education tool that comprises recommendations from all specialties including family medicine, gynecology, gastroenterology, otolaryngology, and pediatrics. The creation of this tool will involve creating an expert panel comprised of healthcare providers that currently practice in the specialty areas defined previously. This expert panel will review the clinician created HPV patient education tool and provide feedback. Once the tool's content has been validated and finalized each expert will be provided the tool to use within their practice specialty. The goal of the created written educational tool is to provide comprehensive evidence-based information to patients that enhances verbal patient education provided by the healthcare team and remains the same among all specialties.

Benefit to Practice

The best practice in healthcare is defined as "the 'best way' to identify, collect, evaluate, disseminate, and implement information about as well as to monitor the outcomes of health care interventions for patients/population groups and defined indications or conditions" (Perleth, Jakubowski, & Busse, 2001, p. 237). In 2001, The Institute of Medicine (IOM) released a plan to improve the quality of healthcare, by identifying six areas healthcare should improve; these areas include: safe, effective, patient-centered, timely, efficient, and equitable (Institute of Medicine [IOM], 2001). The identified aims of the IOM will be used to illustrate how providing consistent HPV patient education across the areas will enhance practice and improve the quality of healthcare.

The IOM's first aim for improving the quality of health care is safe; safe is defined as "avoiding injuries to patient from the care that was intended to help" (IOM, 2001, p.3). Providing HPV patient education based on recommendations from all areas will provide patients with comprehensive knowledge regarding HPV. This assures the patient is provided with all relevant information needed to understand behaviors that can be changed as well as recognize early symptoms of disease as significant and can seek care early.

The second aim identified by the IOM for improving the quality of healthcare is effective; described as "providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit" (IOM, 2001, p.3). By applying this description of effective the healthcare provider would first identify patients that would likely benefit from HPV education. The patients at risk for HPV and/or likely to benefit from HPV patient education would include: sexually active patients, patients with prior history of sexual activity, patients planning to become sexually active, patients diagnosed with HPV

infection, patients undergoing HPV screening as part of cervical cancer screening, and patients or parents considering HPV vaccination (Anhang, Goodman, & Goldie; 2004; Chaturvedi, et al., 2011; Dunne et al., 2011; Emberger, 2014; Lewis, 2007; McCree, et al., 2010). By this rational, nearly all people are likely to benefit from HPV education, and changing the content of HPV educational to be comprehensive and evidence based will assure the same recommended education will be given consistently to all patients' across the areas. The HPV patient education material would bring scientific knowledge from multiple areas into a tool that can be utilized easily in clinical settings and distributed to patients identified as likely to benefit from the education, and demonstrates how comprehensive HPV patient education would achieve the aim of effective.

Patient-centered is identified as the third aim to improve quality healthcare, and refers to "providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions" (IOM, 2001, p.3). To achieve patient-centered care the healthcare providers must allow patient to participate in the decision making which requires the provider to give patients the information they will need to make informed decisions regarding their care. The patient-provider relationship should be a continuous exchange of information with the provider serving as a resource for the patient. By providing the patient with comprehensive HPV patient education from all areas, the patient is able to use this information to aid in future and current healthcare decisions. This illustrates how this practice change project will provide patient-centered care.

The fourth aim described by IOM to improve the quality of healthcare is timely, and is defined as "reducing waits and sometimes harmful delays for both those who receive and those who give care" (IOM, 2001, p.3). The comprehensive HPV patient education will provide both

primary and secondary prevention measures, that can provide patients with measures to reduce risk of infection as well as information regarding risk of disease associated with HPV. The evidenced based comprehensive method of HPV patient education will reduce harmful delays in seeking healthcare for symptoms of HPV related disease. The use of an evidence based HPV patient educational tool can improve the quality of healthcare received by the patient.

The fifth aim of IOM to improve healthcare quality is efficient, and refers to "avoiding waste, including waste of equipment, supplies, ideas, and energy" (IOM, 2001, p.3). While each area is an expert in that field of medicine, failing to include known, existing recommendations and research because it was not completed within the area the healthcare provider practices, is not efficient, and it is wasteful of that knowledge. The creation of the multispecialty, comprehensive HPV patient education material, can aid in providing all patients with the same information. By changing the content of HPV patient education to include all areas will demonstrate efficiency.

The sixth aim identified by IOM to improve the quality of healthcare is equitable, or "providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status" (IOM, 2001, p.3). The IOM (2001) states, "Care should not vary illogically from clinician to clinician or from place to place" (p.4). However, the current HPV patient education varies widely, changing based on the area providing the information. Because HPV does not change from site to site, the information provided should remain the same, this project plans to change the delivery of patient education so that all HPV education will be equitable. The HPV patient education tool, will be created to be used across the area to provide equitable HPV patient education across all areas.

Conclusion

Infection with HPV is very common, can infect multiple sights, and may pose life threatening consequences (Jemal et al., 2013, Zandberg et al., 2013; zur Hausen, 2009; CDC, 2016). Patients continue to demonstrate a lack of understanding regarding HPV and the risks the infection poses (Kester, et al., 2014; Blake et al., 2015). The lack of patient knowledge regarding HPV may be caused by inconsistent patient education provided to patients by varying areas and directly contribute to the low vaccination rates in the US. Improving practice by changing the content of HPV patient education to include all recommendation is likely to increase understanding of HPV. An evidenced based HPV educational tool would improve the quality of healthcare by providing safe, effective, patient-centered, timely, efficient, and equitable patient education material that can be used in any healthcare setting more than HPV educational tools currently used in practice.

This evidence-based change of practice project will be divided into five chapters. Chapter one provides an overview of the project which includes an introduction, background of the problem, significance of the problem, purpose of the project, setting for use, and benefits of the project. Chapter two will examine existing literature focusing on HPV patient education within all applicable areas, review the concept of education, provide definitions, as well as provided a theoretical basis for the project. The third chapter will detail the methodology, project design, and data analysis procedures. Chapter four will provide analysis of project and the presentation of data. The final chapter will include a summary, conclusion, and recommendations.

Chapter II: Review of Literature

To improve the quality of healthcare provided to patients during HPV education encounters, it is essential to evaluate the literature for evidence based recommendations. To determine how to best provide adequate HPV patient I will explore the literature for patient education recommendations as well as provide a theoretical framework for this project.

Literature Search Strategies

A computer-based search was performed using the Discovery database, which conducts a search of all 128 databases available at Maryville University Library, and Google Scholar. The search was limited to journal articles available in English from 2007 to 2016. The following terms were searched "human papillomavirus" or "HPV" or "HPV patient education" AND "patient education recommendations" or "patient education guidelines" or "recommendations" or "guidelines" in multiple combinations. Each search produced more than 20,000 articles, so the articles were further limited by excluding research focusing on HPV vaccination, eliminating articles older that five years; however, this did not significantly reduce the number or research articles, so specialties such as "women's health" or "gynecology" or "otolaryngology" or "gastroenterology" or "family medicine" or "family practice" or "dermatology" or "pediatrics" were included in search combination with aforementioned keywords. I reviewed article abstracts to determine relevance and inclusion into the review. The limitation on publication date was expanded to include original research deemed essential and pertinent to the topic.

Finding of Search

The findings for HPV patient education recommendations are presented by area: Women's Health, Otolaryngology, Gastroenterology, and other areas. The review of literature

will present HPV patient education recommendations including: transmission, screening, patient implications, partner implications, and prevention.

Women's Health Recommendations

Transmission. Many patients have several misconceptions regarding HPV and it is recommended each provider give clear and direct information about HPV infections that clarifies transmission of HPV (Royer & Falk, 2012). When providing patient education regarding HPV, it is essential to be clear this is a sexual transmitted virus, and while transmission can occur from any genital contact, but is usually spread through vaginal or anal intercourse (Anhang, Goodman, & Goldie, 2004; Clinical proceedings, 2009; Dunne et al., 2011). A study of HPV transmission found the hands, scrotum, and female rectum to have high transmissivity of HPV but did not find oral sex or semen mode of transmission (Hernandez et al., 2008). However, Dunne et al. (2011) found both oral sex and non-penetrating genital contact modes of transmission.

Screening. The understating of the essential role HPV plays in the development cervical cancer has caused recommendations for cervical cancer screenings in the US have to be revised to include HPV screening and pap (co-testing), while European recommendations offer a stand-alone HPV screening infection (Guan et al., 2012; Katki, H. et al., 2013; von Karsa et al., 2015). Changes to the screening interval for cervical cancer using the co-testing are based on benchmarking cancer risk; the benchmarking provides evidence that a negative screening of both HPV and pap every five years have the same risk as negative pap alone every three years (Benard et al., 2014; Katki, H. A. et al., 2013;). This change to cervical cancer screening interval can cause worry and anxiety for patients, and should be discussed with the patient clearly (Benard et al., 2014; Dunne et al., 2011; Katki, H.A. et al., 2013). Patient education should include explanation that the pap is used to detect precancerous lesion caused by HPV infection

and the addition of HPV screening helps to identify patients who are at risk for cervical cancer (Anhang, Goodman, & Goldie, 2004). Patients should be provided with both oral and written education regarding the purpose of HPV screening at the time of such screening (Dunne et al., 2011). Patient should also be informed HPV screening only detects current HPV infection (Clinical proceeding, 2009; Dunne et al., 2011). Routine screening for HPV is not recommended under the age of thirty, and no screening is recommended for males (Clinical proceedings, 2009).

Patient Implications. Studies suggest many women believe HPV infection to be a permanent infection that will lead to cancer, and often perceive HPV infections to be a cancer diagnosis (Royer & Falk, 2012); for this reason, when presenting patients with diagnosis of HPV it is recommended for providers to stress the commonness and transient nature of HPV infections (Clinical proceedings, 2009; Dunne et al., 2011). The provider's ability to normalize the HPV infection for a patient should be balanced with providing education for patients with HPV infection and abnormal pap results about the importance of continued surveillance and treatment for precancerous lesions to prevent progression to cervical cancer (Clinical proceedings, 2009; Guan et al., 2012). Patients with HPV infection and abnormal pap should be provided detailed patient education regarding how HPV infection progresses to cervical cancer (Guan et al., 2012; Nobbenhuis et al., 2001). Patients who have received treatment for precancerous lesions or were treated for cervical cancer should be educated about the importance of continued screening for HPV infections, as this will help to predict reoccurrences or progression to cancer (Nobbenhuis et al., 2001).

Partner Implications. This review found very little research that included partner implications, however, patient education should be told there is no screening recommended for male partners (Clinical proceedings, 2009). The CDC also points out there is no mandatory

partner notification for HPV infection, and recommends providers counsel patients regarding voluntary reporting to partners (Dunne et al., 2011).

Prevention. Patient education should include techniques for preventing HPV infection including: use of condoms, limiting sexual partners or avoiding sexual contact, and vaccination (Dunne, et al., 2011). Patient education should include using condoms can reduce risk of HPV infection but do not eliminate the risk (Clinical proceedings, 2009). Research suggests many unvaccinated patients eligible for HPV vaccination have never received HPV education or recommendation for vaccination from a healthcare provider (Emberger, 2014; Hernandez et al., 2008; Kester et al., 2014). All patients eligible for HPV vaccine should be given a recommendation to receive HPV vaccine; the recommendation for vaccine should be provided despite the patients history of HPV infection, and should include limitations of the vaccine to prevent only HPV infection from the strains present in the vaccination, as well as vaccination is not treatment or cure for existing infections (Clinical proceedings, 2009; Dunne et al., 2011; Hernandez et al., 2008; Kester et al., 2014). The American College of Obstetrics and Gynecology (ACOG) recommends routine vaccination against HPV for all girls and boys starting as early as age nine (ACOG, 2015).

Otolaryngology Recommendations

Transmission. All patients diagnosed with oropharyngeal HPV infection or HPV positive OPC should be provided clear and direct patient education regarding the sexual transmission of HPV infection (Fakhry & D'Souza, 2013). Men are more likely to develop oral HPV infection, this is believed to be related to the woman's genitals holding and shedding more virus than a man's genitals (Pytynia, Dahlstrom, Sturgis, 2014). Martin-Hernan et al. (2013), D'Souza, G, Cullen, et al. (2014), and D'Souza, G., Agrawal, et al. (2009) found evidence that

oral HPV is transmitted through direct genital contact during oral sex. Beachler et al (2012) found anal-oral contact in 'rimming' to increase the risk of oral HPV infection in HIV positive individuals. Patients should be educated that oral HPV may be transmitted through deep oral kissing, though research is unclear if kissing is a mode of transmission for HPV. D'Souza, G, Agrawal et al. (2009) found evidence of transmission through deep open mouth kissing however, Edelstein et al. (2012) found no evidence of HPV transmission through kissing alone.

Screening. There are tests available to detect oral HPV infections, however, there are no recommendations to screen for oral HPV infections (Elrefaey, Massaro, Chiocca, Chiesa, & Ansarin, 2014). At this time, no precancerous lesions have been identified as a precursor to HPV positive OPC, and due to the high prevalence of oral HPV infection, screening would not yet be useful in the prevention of OPC cancer (Chu, Genden, Posner, & Sikora, 2013). It is important for patients to understand the diagnosis of HPV positive OPC is made only after pathology determines the HPV was the causative factor of the OPC and not an incidental finding (Deschler, Richmon, Khariwala, Ferris, & Wang, 2014).

Patient Implications. Patient's education for HPV positive OPC should include the relatively high cure rates compared to classical OPC cases (Deschler et al., 2014; D'Souza, G., Cullen et al., 2014; Elrefaey et al., 2014). Patients should be informed that successful treatment of HPV positive OPC may require less intensive treatments with high levels of achieving cancer free status (Elrefaey et al., 2014). Current research to fully explore the implications of HPV positive OPC is ongoing, it is important to discuss with patients that most educational information for HPV positive OPC comes from knowledge regarding HPV and cervical cancer and as gaps in knowledge are filled regarding HPV positive OPC, recommendations may change (Fakhry & D'Souza, 2013). Patients with HPV positive OPC should be educated about other

HPV related cancers they may be at risk for and encouraged to complete recommended screenings if available (Fakhry & D'Souza, 2013).

Partner Implications. Patient education for HPV positive OPC should include what, if any implications the diagnosis has on the patient's partner (Chu, Genden, Posner, & Sikora, 2013). Both the patient and partner should be assured partners of patients with HPV positive OPC do not be have an increased prevalence of oral HPV infections when compared to the general population (D'Souza, G., Gross, et al. 2014). Research has suggested the partners of women with cervical cancer or cervical dysplasia may be at an increased risk for developing HPV positive OPC, and female partners of HPV positive OPC should be encouraged to have routine gynecological exams that include cervical cancer screening (Fakhry & D'Souza, 2013; Pytynia, Dahlstrom, & Sturgis, 2014).

Prevention. Patients should be counseled that risk factors for HPV positive OPC include past or current cigarette smoking, early sexual debut, and multiple sexual partners (Sanders, Slade, & Patton, 2012). There are currently three vaccines for HPV on the market, however, none are indicated for use in the prevention of HPV related OPC (Pytynia, Dahlstrom, Sturgis, 2014). Initial studies suggest 90% of all HPV positive OPC are caused by strains of HPV contained in each vaccine; vaccination with HPV vaccine would likely be effective in the prevention of OPC (Herrero et al., 2013; Psyrri & DiMaio, 2008). Despite the lack of indication, several recommendations were given for HPV vaccination to all eligible patients (Deschler et al., 2014; D'Souza, G., Gross, et al., 2014; Elrefaey et al., 2014; Fakhry & D'Souza, 2013; Pytynia, Dahlstrom, Sturgis, 2014; Sanders, Slade, & Patton, 2012). The HPV positive OPC patient usually falls outside of the recommended vaccination age, and for this reason is not offered vaccination, however, when eligible the patient should be offered vaccination, and the provider

should consider discussing HPV vaccination for eligible children of patients (Deschler et al., 2014).

Gastroenterology Recommendations

Transmission. When providing patient education about rectal HPV infections, it is important to be clear that HPV is a sexually transmitted disease; while receptive anal intercourse is a risk factor in the development of anal HPV infection it is not mandatory (Frisch, M., Glimelius et al., 1997). The mode of transmission of HPV infection in the absence of anal sex is not well understood, however, Sonnex, Strauss, & Gray (1999) found evidence of HPV on the fingers of individuals with genital HPV infection and suggest autoinoculation could be a mode of transmission. Hernandez, et al. (2008) found possible modes of transmission between the male scrotum and the rectum. Esophageal cancers related to HPV are transmitted to the esophagus through oral sex (Rajendra et al., 2013).

Screening. There are screening tests available for anal cancer that include cytology and HPV, but there are no national guidelines to support routine screening for rectal cancer (Clinical proceeding, 2009). Healthcare providers can use the New York State Department of Health recommendations for anal pap and HPV screening for HIV positive individuals with history of: MSM, history or present anogenital warts, and women with abnormal cervical or vulvar cytology, as a guide for discussing screenings with patients (HIV articles, 2007; Welbeck, 2016).

Patient Implications. When discussing implications of anal HPV infection, it is important to educate patients regarding importance of early detection to decrease morbidity and mortality associated with anal cancer (Smyczek, Singh, & Romanowski, 2013). Women with anal HPV infection should be counseled regarding the high rates of dual infection of both the anus and cervix, and recommendations for annual gynecological exam provided (Ortiz-Martinez

et al., 2013). Patients with inflammatory bowel disease being treated with immunosuppressant medications should be counseled regarding the increased risks of developing HPV related cancers, and should receive recommended gynecological exams and screenings when applicable (Reyes-Ramos, Dukandar, & Borum, 2013)

Partner Implications. Recommendation for partners of patient with rectal HPV include, MSM partners should discuss benefits of screening for rectal cancer and HPV (Welbeck, 2016).

Prevention. Patients should receive education regarding risk factors for rectal HPV infection including multiple sexual partners, receptive anal intercourse, and tobacco use (Ortiz-Martinez et al. 2013). All patients meeting criteria for HPV vaccination should be counseled regarding vaccination and encouraged to complete the series (Reyes-Ramos, Dukandar, Borum, 2013; Ortiz-Martinez et al, 2013).

Other Areas

Transmission. The American Academy of Family Physicians (AAFP) acknowledge HPV infections occur through genital contact, anal intercourse, oral sex, and perinatal transmission (Juckett & Hartman-Adams, 2014).

Screening. The AAFP recommend discussing the addition of HPV screening in addition to pap for cervical cancer screenings in women thirty and older (Juckett & Hartman-Adams, 2014). The American Dental Association (ADA) recommends dentist preform a visual inspection of the oropharynx for abnormalities suggestive of HPV infection with each exam, and provide a referral for all abnormal findings (ADA, 2012).

Patient Implications. Both Shamanin et al. (1994) and Meyer et al. (2003) found higher rates of HPV known to cause non-melanoma skin cancer on post-transplant immunosuppressed

patients when compared to non-immunosuppressed patients; Meyer, et al. (2003) recommend increasing skin evaluations for those immunocompromised to as often as four times a year.

Partner Implications. No partner implication from other specialty groups were identified during this literature review.

Prevention. Patients should be educated regarding HPV prevention which includes delaying sexual debut, limiting sexual partners, smoking cession, and condom use (Juckett & Hartman-Adams, 2014). Both the AAFP, and American Academy of Pediatrics (AAP) recommend HPV vaccination for both boys and girls (AAFP, 2016; American Academy of Pediatrics, 2012); The ADA acknowledges widespread use of the HPV vaccine would likely decrease the incidence of OPC (ADA, 2012).

Summary of Literature

The recommendations from all areas, for patient education regarding the mode of transmission of HPV included discussion with the patient that HPV is a sexually transmitted disease (Anhang, Goodman, & Goldie, 2004; Fakhry & D'Souza, 2013; Frisch, M., Glimelius, et al., 1997; Juckett & Hartman-Adams, 2014). However, both gastroenterology and otolaryngology recommendations included discussion with patient regarding transmission of oral HPV infection through oral sex (Beachler et al., 2012; Martin-Herman et al., 2013; Rajendra et al., 2013); women's health recommendations had no consensus about oral sex as a mode of transmission, with Dunne et al. (2011) finding oral sex a mode of transmission, and Hernandez et al. (2008) not finding oral sex to be a mode of transmission of HPV. Both women's health and gastroenterology recommend discussing autoinoculation as a mode of transmission (Hernandez et al., 2008; Sonnex, Strauss, & Grey, 1999). While otolaryngology recommend discussing the possible transmission of HPV through open mouth kissing while clarifying the conflicting

findings about the viability of kissing as a mode of transmission (D'Souza, G., Agrawal et al., 2009; Edelstein et al., 2012). Family practice recommendations include discussing perinatal transmission from mother to child at time of delivery (Juckett, & Hartman-Adams, 2014).

The recommendations for HPV patient education regarding screening varied among the areas but each did recommend education about appropriate screening tests (Dunne et al., 2011; Steinau et al, 2014). Women's health recommendations include discussing HPV screening for women thirty and older or use of HPV screening to triage abnormal pap results (Katki, H. et al., 2013; Katki, H. A. et al., 2013). Gastroenterology has no national recommendations for HPV screening, though recommendations for discussing potential benefits of rectal pap and HPV screening for high risk individuals (Clinical proceeding, 2009; Welbeck, 2016). Otolaryngology does not recommend screening for oral HPV infections (Elrefaey et al., 2014). Both gastroenterology and otolaryngology specialties recommend discussing the importance of gynecological and cervical cancer screening for females with known HPV infection (Fakhry & D'Souza, 2013; Reyes-Ramos, Dukandar, & Borum, 2013), and otolaryngology recommends routine gynecological exams with cervical cancer screenings for all female partners of HPV positive OPC patients (Fakhry & D'Souza, 2013).

The recommendations for HPV patient education regarding patient implications varied among the areas. Women's health recommendations include patient education that stresses the high prevalence of HPV infection to normalize the diagnosis for the patient (Dunne et al., 2011; Royer & Falk, 2012), while simultaneously stressing the seriousness of infection and need for continued care (Guan et al., 2012; Nobbenhuis et al., 2001). Otolaryngology recommends discussing with patient about increased survival rate for HPV positive OPC compared to HPV negative OPC (Deschler et a., 2012; D'Souza, G., Cullen et al., 2014). Gastroenterology

recommends discussing the high prevalence of co-infection of the cervix for women with anal HPV infection, and increased survival with early detection (Ortiz-Martinez et al., 2013). Dermatology recommendations include increasing skin exams for immunocompromised patients (Meyer et al., 2003; Shamanin et al., 1994). Both otolaryngology and gastroenterology recommends discussing other HPV related cancers the patients may be at risk for (Fakhry & D'Souza, 2013; Reyes-Ramos, Dukandar, & Borum, 2013).

The patient education recommendations for discussing the implications of HPV infection on the patient's partner vary widely. Women's health recommendations discussing that no screening or treatment is needed for male partners (Clinical proceedings, 2009; Dunne et al., 2011). While some gastroenterology recommendations suggest providers should discuss screening for rectal cancer screening in some high-risk patients (Welbeck, 2016). Otolaryngology recommendations include providing patient education on HPV for both the patient with HPV positive OPC and the patient's regarding risk for transmission of HPV to partner and need for appropriate gynecological exams (Fakhry & D'Souza, 2013).

There is a consensus regarding recommendations prevention with use of HPV vaccination; across all areas, it is recommended all eligible patients be provided educations and recommendation for HPV vaccination (Elrefaey et al., 2014; Hernandez, et al., 2008; Juckett, Hartman-Adams, 2014; Reyes-Ramos, Dukandar, Borum, 2013). While otolaryngology recommend discussing HPV vaccination for eligible children and partners of HPV positive patients (Deschler et al., 2014). Other recommendations for HPV patient education include, discussing techniques to reduce risk of HPV transmission (delaying sexual debut and limiting sexual partners) was given from all specialty groups (Dunne et al., 2011; Juckett & Hartman-Adams, 2014; Ortiz-Martinez, et al., 2013; Sanders & Patton, 2012;). Gastroenterology,

otolaryngology, and family practice also advise patients to quit or never start smoking to reduce risks (Juckett & Hartman-Adams, 2014; Ortiz-Martinez et al., 2013; Sanders & Patton, 2012).

Synthesis of Evidence in Literature Review

Quality of Evidence

The literature matrix demonstrates a general high quality of the evidence (see Appendix A) for literature matrix. The levels of evidence varied widely among the research articles included in this literature review, and contained a high percentage of single qualitative studies. There are multiple studies from each area, and this increases the quality of the evidence. However, there was no limitation placed on quality, so this review also contains systematic reviews, control trials, quasi-experimental, cohort studies, evidenced based clinical practice guidelines, and expert opinion.

Identified Gaps

One gap in the literature identified is the lack of consistency in educational recommendations among the areas. With the exception of vaccination recommendations, all areas offer different HPV patient education recommendations. Recommendations of women's health fail to discuss HPV risks outside of the women's health spectrum, or inform patient about other HPV related cancer; however, other areas offer recommendations for HPV education that include discussion of risks of HPV infection outside their area. The otolaryngology research note that most HPV knowledge stems from research done within the gynecology area, and recognizes while HPV related OPC may be similar it is likely that emerging and future research will reveal HPV information that is much more specific to development of OPC (Fakhry & D'Souza, 2013).

A second gap identified is a lack of current guidelines for HPV education. Guidelines were often outdated. While all previously defined specialty groups provide some educational

recommendations, both otolaryngology and women's health had specific HPV educational recommendations. The surge in research and recommendations within otolaryngology, highlights the lack of recommendations or outdated recommendations within women's health. Because knowledge of HPV is constantly improving, all patient education recommendations should be examined frequently to assure patients are provided current information that reflects the existing research.

Strengths & Weakness

The strength of this literature review is the inclusion of multiple recommendations from all applicable areas. By reviewing literature for existing evidence based patient education recommendation from all applicable areas, the review was able to identify consistencies, discrepancies, and variations of recommendations.

The weakness of this review is it is not a complete review of existing literature, and this is a limitation. A systematic review of the literature for all HPV patient education recommendations, throughout all medical specialties would increase the validity of findings. Another identified limitation is the inclusion criteria of this review was limited to articles in English, as well as a lack of limitations on the level of quality of research for inclusion into the review and would likely improve validity if the studies were limited to only research that met higher quality standards.

Theoretical Framework

Health Belief Model

The Health Belief Model (HBM) was first described in the 1950s, by a group of psychologist attempting to explain why individuals did not utilize available preventative services (Strecher & Rosenstock, 1997). The psychologist identified four constructs to predict an

individual's health seeking behavior (Strecher & Rosenstock, 1997; Zareban et al., 2013). These constructs include: perceived susceptibility, perceived severity, perceived benefits, and perceived barriers; a fifth construct of self-efficacy was added to the model in 1988 (Zareban et al., 2013). Since that time, the HBM has become one of the most utilized conceptual frameworks for researching and understanding of health seeking behaviors of a patient while providing insight to the importance of health education for patients (Champion, & Skinner, 2008).

The use of the HBM as a theoretical basis for evaluating HPV patient education recommendations would include examining recommendations for discussion of the susceptibility and severity of HPV infections, benefits and barriers to HPV education, and identifying the impact the patient can have on HPV infections. Zareban et al. (2013) used the HBM as a guide to create patient education for diabetics and then evaluated the effectiveness of the patient education by monitoring hemoglobin A1C values.

Similarly, this project will utilize the constructs of the HBM to evaluate the patient education recommendations for HPV. Because the HBM constructs identify what induces health seeking behaviors in patients, the constructs are used to evaluate the recommendations from each medical specialty. To evaluate perceived susceptibility, perceived severity, perceived benefits, and self-efficacy the literature will be evaluated for educational recommendations regarding transmission, implications, screening, and prevention of HPV infection. The fifth construct of perceived barriers was not evaluated in this literature review.

Conclusion

This chapter provides a review of HPV patient education recommendations in the literature. The literature review found HPV patient education recommendations from multiple specialty areas including: gynecology, gastroenterology, otolaryngology, family medicine,

dermatology, and pediatrics. These educational recommendations included transmission, screening, implications for both patient and partner, and prevention. Many of the specialty areas provided similar recommendations, however, not all specialty areas provided the same recommendations.

This chapter demonstrates the narrow focus of the specialty areas when describing HPV, and a failure to see HPV infection as something that can infect multiple systems with varying consequences. The need for equitable, comprehensive HPV patient education across all specialty areas is highlighted by the lack of uniform recommendations. The methodology for evaluation of current HPV tools, the creation of an evidence- based multispecialty patient education tool, and comparison of the current and created tool will be further explored in Chapter III.

Chapter III

This chapter will discuss the methods that will be utilized for this practice improvement project to determine whether HPV patient educational tools currently used in the healthcare settings provide patients with information that reflects the current evidence based recommendations provided by all healthcare areas, better than a multispecialty HPV education tool created based on the evidence. The objectives and goals of the project will be clarified, as well as giving detailed description of the project. This chapter will provide methodology that includes a needs assessment, the project design, data collection tools, plans for analyzing data, resources needed, project budget, project timeline, and ethical consideration.

Methodology

A review of literature was done to identify current evidence-based recommendations for HPV patient education. A summary of the HPV patient education recommendations will be compiled for evaluation of current HPV patient educational tool, as well as develop a comprehensive HPV patient educational tool.

A random selection of two experts from the expert panel will be asked to review the current HPV educational tools used in practice (See Appendix B). The principle investigator will provide the experts with the current HPV educational tools, as well as a principle investigator-developed evaluation tool, the Current HPV Patient Educational Tool Evaluation Form (See Appendix C). The Current HPV Patient Educational Tool Evaluation Form is a Likert scale survey and was created by the principle investigator based on the recommendations identified in the literature review. The completed surveys will be converted (a=1, b=2, c=3) to a Microsoft Excel spreadsheet for evaluation. The frequency distribution will be utilized to summarize the data for each question and expert.

A patient education tool will be developed based on the recommendations identified in the review of literature using the Toolkit for Making Written Material (See Appendix D). The toolkit is accessible on-line and was developed to help healthcare providers create written patient education.

The created HPV patient educational tool will then be evaluated by members of the expert panel to determine appropriateness of content. The Expert Questionnaire (See Appendix E) is a Likert scale survey, created by the principle investigator to evaluate the developed HPV patient education tool. The Expert Questionnaire and developed HPV patient education tool will be distributed to all recruited members of the expert panel. The results of each expert questionnaire will be converted into a number (a=1, b=2, c=3, d=4, e=5), and the data will be saved in a Microsoft Excel document. The principle investigator will request that each expert provide written feedback for all questions answered c, d, or e ('c' represents a neutral response, while 'd' and 'e' represent negative responses). The written feedback will be saved in a Microsoft Word document titled "Expert Feedback- Round 1". Completing the Expert Questionnaire may take each expert one hour. Once all data has been collected, a frequency distribution will be completed to summarize the findings. The feedback and results from the analysis will be used to revise the developed HPV patient education tool. The revised HPV tool will then be re-evaluated by the expert panel using the Expert Questionnaire, with the data being stored and evaluated in the same fashion as described above. This process will be repeated until questions 3-15 and 18 (validity questions) provide a positive (a & b=positive) response in 90% of the expert panel.

The Expert Questionnaire (see Appendix E) will also be used to evaluate recommendations and willingness of the expert to use in their setting. The Expert Questionnaire contains questions that will determine if the identified recommendations are present. The Expert Questionnaire also

contains questions regarding use in practice; these questions will aid in determining the ability for the created tool to be utilized in multiple specialties.

The principle investigator-developed HPV patient educational tool will then be evaluated for actionable and understandable content using the Patient Educational Materials Assessment Tool (PEMAT) (See Appendix F). Permission for use of PEMAT in this project was obtained from the Agency for Healthcare Research and Quality (AHQR) (See Appendix G). The PEMAT is used to determine if the information contained within the patient education material is understandable and provides instructions to patients for ways the patient can eliminate or decrease risks of HPV. Three experts will be selected randomly to evaluate the created HPV patient education tool with the PEMAT. The individual expert scores will be calculated, and then the mode of the expert scores will be used to provide a combined expert rating. If the combined PEMAT score is less than 80%, the tool will be revised. After revision of the tool, three experts will evaluate the created HPV patient educational tool using the PEMAT. The data will be evaluated in the same fashion as described above. The principle investigator will request the same experts evaluate the tool for all rounds necessary; however, if an expert member chooses to withdraw during this process, another expert member will be randomly selected to replace the expert who withdrew. Revisions of the created HPV patient education tool will continue until the combined expert PEMAT score is 80% or higher.

The created HPV patient educational tool will be compared to current HPV patient educational tool. The frequency distribution of the combined Expert Questionnaire from the final round (questions 3-15 and 18), will be converted to a three point Likert scale (a & b=1, c=2, d & e=3). The converted Expert Questionnaire frequency distribution results will be compared to the combined Current HPV Patient Educational Tool Evaluation Form frequency distribution.

The last step of this project will be implementing the principle investigator-developed HPV patient education tool into practice. This will be accomplished by providing all members of the expert panel with the finalized tool. The Expert Questionnaire will be used to analyze the willingness of members of the expert panel to implement the tool into their practice and recommend the tool to other healthcare providers.

All surveys, questionnaires, current HPV educational tools, and created HPV educational tool will be provided to the expert panel for review on paper. The experts will be provided a self-addressed stamped envelope to return the surveys, as well as having the principle investigator's contact information, should the expert panel member prefer the principle investigator retrieve the survey. No names or identifying information is requested on any form or survey, to assure the experts can provide critical feedback. Handwritten explanations are requested on the expert questionnaire, this will be transcribed by the principle investigator and saved in a file on the principle investigator's password protected computer titled "Expert Questionnaire Feedback"; each round of questions will have a separate document titled "Round- #". The data saved in Microsoft Excel will be saved on the same password protected computer, each survey will be saved under the Title of the survey and each round will be given a number (for example: Expert Questionnaire, Round Two).

Each survey will be kept in a folder identifying the survey and the round for that survey (for instance, if an Expert Questionnaire requires four rounds of evaluations before achieving validation, then each round will be kept in an individual folder marked, for example, "Expert Questionnaire, Round 4"). The folders will be placed in a locked file cabinet, with the key remaining with only the principle investigator. All surveys will be destroyed after the data analysis is completed and finalized.

Project Design

The design of this project is a comparative descriptive project. This design allows the author to collect information to describe the content of current evidence based HPV patient educations recommendations being provided to patients and compare this to the HPV educational tool created based these recommendation. A descriptive project design is often, a necessary step before conducting experimental research, because a descriptive design helps to identify variables for manipulation.

Setting

The geographical setting for this project is Southeast Missouri, the experts recruited to evaluate the created HPV educational tool will all practice in Southeast Missouri. This intended setting for improving practice by providing comprehensive patient educational and utilizing the created educational tool will include all healthcare settings where HPV patient education occurs. Potential settings for implication of change in education will include: family practice, gynecology, gastroenterology, otolaryngology, pediatrics, and dermatology. An expert panel of healthcare providers will be assembled to assure representation from each of these specialty groups.

Participants

This project will require the formation of an expert panel. This panel will be comprised of healthcare providers from multiple specialty areas within healthcare, who will evaluate and validate the content of the created tool, as well as evaluate the content of current HPV patient education tools. For this project, an expert healthcare provider can be defined as a physician, advanced practice registered nurse, or physician assistant currently practicing in Southeast Missouri. There will be no specified number of experts required from each specialty area. There

should be enough participants from each discipline that all questionnaires will be remain confidential and without identifiers. There will be no gender, racial, or cultural restrictions. The sample size of experts will be no less than twenty-five. A convenient sample of expert panel member will be identified using a Google search of each area within Southeast Missouri. The project investigator will call the expert panel and ask the expert to participate.

All needed material, including current and created tools, evaluation tools, and informed consent (See Appendix H) will be provided to the expert panel members. A consent form will be provided to all participants; however, implied consent will be utilized, and by returning of the questionnaire the expert will understand they have agreed to participate in this project.

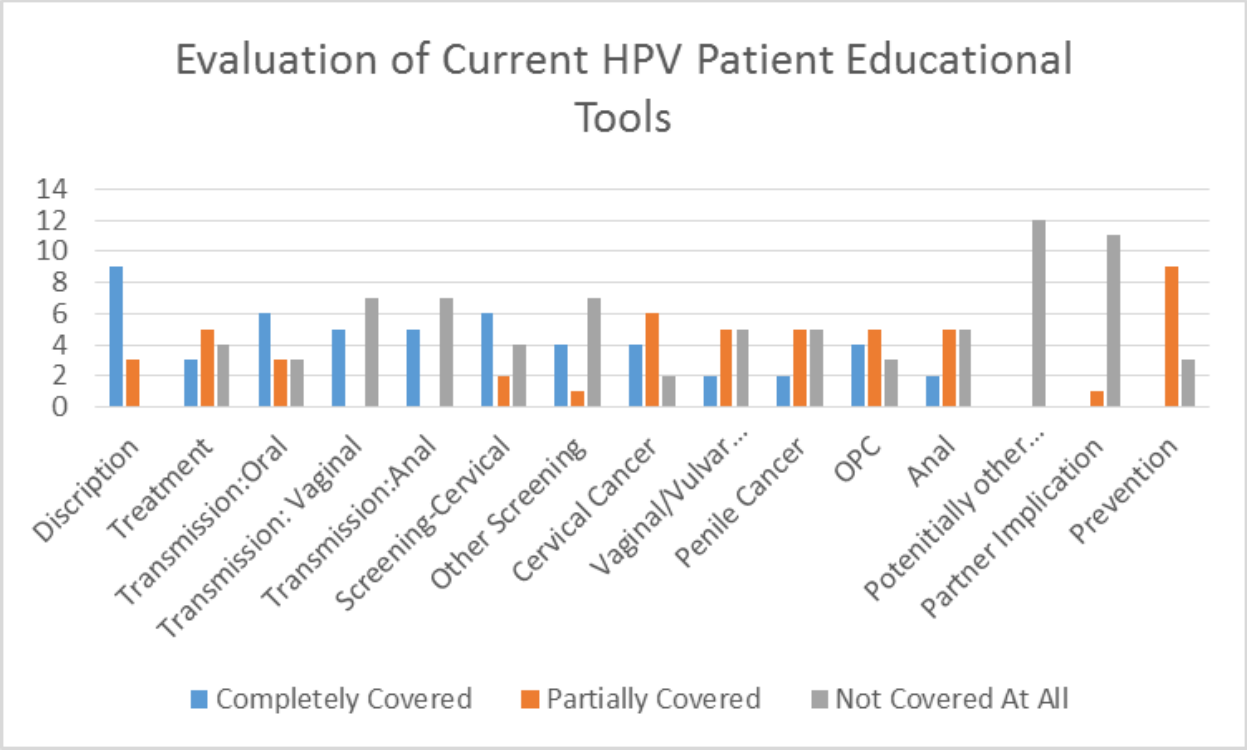
Needs Assessment

A needs assessment aids in determining gaps between what is, and what should be (Comprehensive Needs Assessment, 2001). The need assessment will help to lead improvement into practice. A needs assessment was completed to determine what is contained in current HPV patient education tools.

The first step in this needs assessment is establishing what is the evidenced based HPV patient educational recommendations. In the review of literature fifteen key recommendations for HPV patient education encounters were identified, these recommendations created the Evaluation Tool for HPV Educational Tools (see appendix C). The current HPV educational tools evaluated (appendix B) will be the same tools evaluated by the expert panel members. The results were transferred to a Microsoft Excel spread sheet and coded (1=completely, 2=partially, 3=not at all), the combined results for all tools for each question are illustrated in Chart 1.

Chart 1

Frequency of Content Covered by All HPV Patient Educational Tools Evaluated



The frequency distribution of each tool demonstrates the wide variation in content present in the current HPV patient educational tool. None of the tools had every key recommendation present. Of the current HPV patient educational tools evaluated CEC genital HPV tool had the most elements present, however, the title of the tool makes it unlikely to be used by all areas. The frequency distribution of answers (completely, partially, or not at all) is represented in Table 1.

The review of the current HPV educational tools also found an alarming amount of misinformation. Many of the tools used the phrase “cause” when discussing cervical cancer and “linked to” when discussing other cancers; this small difference is confusing and may

Table 1

Frequency Distribution of Covered Content in each HPV Patient Educational Tool

Name of Tool	Completely Covered	Partially Covered	Not Covered At All
FAQ073 (ACOG)	6	6	3
Ten Things To Know About HPV	7	6	2
Understanding HPV and Cervical Cancer.	4	3	8
CDC-OPC	4	2	9
CDC- Genital HPV	12	1	2
HPV: The Facts	3	6	6
Human Papillomavirus: A Parent' Guide	6	5	4
HPV and Mouth Cancer	0	8	7
HPV and Cervical Cancer Prevention	2	2	11
Oral Cancer and HPV	1	6	8
Common questions & answers about HPV-positive oropharyngeal squamous cell cancer (HPV-OSCC)	3	5	7
HPV (Unipath)	3	1	11
Total	81	45	78

indicate to the patient there is a difference between "cause" and "linked to" (ACOG, 2014; ASHA, 2015; HPV [Unipath], n.d.). Another example is two tools stated, "Two types (HPV-16 and HPV-18) affect the genital tract and cause the majority of cervical cancers…" (Mouth Cancer Foundation, n.d.; Oral Cancer and HPV, n.d.); of course there are more than forty strains of HPV that affect the genital tract with more than fifteen identified as high risk, it is essential the information healthcare providers give patients is factual. A final example would be, "Most of

the time, men don't develop health problems from HPV" (Association of Reproductive Health Professionals, 2015); this statement is just misleading, it is not false because most of the time, neither women or men develop significant problems from HPV infection, however, the wording suggest that only women develop health problems from HPV, which is just not factual.

This needs assessment illustrates the gap between the content of current HPV patient educational tools and evidence based patient education recommendations. The needs assessment demonstrates the inconsistent, and sometimes unreliable information present in current tools. The main opportunity for this practice change project is to improve the consistency and quality of information provided during HPV patient education encounters.

Project Tools

This project will use several data collection tools, including: Toolkit for Making Written Material Clear and Effective, Expert Questionnaire, Patient Educational Materials Assessment Tool (PEMAT), and Evaluation Tool for Current HPV Patient Education Tools. This section will discuss how the tools will be used during this project, as well as explore the validity and reliability of the tools.

Evaluation Tool for Current HPV Patient Education Tools

The Evaluation Tool for HPV Educational Tools (see appendix C) used in the needs assessment will be used to evaluate each current HPV patient educational tool for content by three expert reviewers (including myself). This is identified as the third step of the methodology of this project. The experts will review the same current HPV educational tools evaluated (appendix B) in the needs assessment. The results were transferred to a Microsoft Excel spread sheet and coded (1=completely, 2=partially, 3=not at all), the combined results for all tools for each question, and the mode of each question will be calculated.

Toolkit for Making Written Material Clear and Effective

The toolkit for making written material clear and effective was commissioned by the CMS to provide a set of tools healthcare professional could utilize to create written material that will increase the patient's health literacy (McGee & McGee, 2010). The toolkit contains eleven modules that provide comprehensive tools for the healthcare tear to create written material; the first two modules in the toolkit provide background information and instructions for using the toolkit. While modules three, four, and five provide comprehensive guides for writing and designing written material for patients. The sixth module provides a guide for testing the written materials, and the final five modules provide guidance for specialized areas (Centers for Medicare & Medicaid Services [CMS], 2012).

This toolkit will be utilized to create the evidence based HPV patient educational tool. This tool has been validated by expert concession (McGee & McGee, 2010). The use of this toolkit will help to format the content in a way that will increase the understanding of the content. Permission to use the Toolkit for Making Written Material Clear and Effective is available to use on-line (See Appendix D).

Expert Questionnaire

The questionnaire for the experts to evaluate the evidence based HPV patient educational tool will be used to validate the content, evaluate the presence of recommendations, and assess the willingness to use the tool in practice. The questionnaire combined all the key elements identified in the literature review and were also used in evaluation of current HPV patient educational tools in step two, as well as design, flow, and recommendations for use. The experts will evaluate the tool content of education as well as for format and design. The questionnaire is formatted in a Likert scale (Appendix E) to evaluate the content of the created tool, format of the

tool, and willingness to use and recommend the tools use into practice. Any neutral or negative score, requires the expert to provide written feedback as well.

The validity of a questionnaire can be ascertained by "asking experts whether the items are representative sample of the attitudes and traits you want to survey" (Fink, 2009, p. 43). To assure the questionnaire is reliable a pilot study is planned. This will require a small sample of questionnaires to be completed by experts, data collected and analyzed with Cronbach's Alpha to measure the reliability. Once it is determined the questionnaire is both valid and reliable, this questionnaire will be distributed to the experts for analysis of the created patient educational tool. The feedback from the questionnaire will be incorporated into the tool, and will repeat this step until most (all if possible) of the experts believe the tool to meet all of the goals.

Patient Educational Materials Assessment Tool (PEMAT)

The PEMAT will be used to assure the created HPV patient educational tool is both understandable and actionable. This is the ninth step in this project and will begin after expert consensus regarding content of the created tool. The PEMAT is comprised of two scales, one for understandability and one for actionality; both scales demonstrate a strong internal consistency, as well as all twenty-six items included on the scales were found to have a kappa < 0.40, which also indicates high reliability. The content of the tool was validated by experts and consumer testing further demonstrated a correlation between the PEMAT score and consumer testing results (Shoemaker, Wolf, & Brach, 2014).

The created evidence based HPV patient education will be analyzed with the PEMAT by three experts. The individual scores will be calculated as well as the mode of the all scores will be calculated. If the calculated PEMAT score is less than 80%, the tool will be revised and this tool will be reevaluated with PEMAT.

Plans for Data Analysis

This practice change project has multiple sets of data collection that will require analysis. Data analysis will include establishing reliability of the questionnaire, frequency distribution calculation, use of PEMAT, and comparison of current and created HPV patient educational tools. Plans for this data analysis will be explored here.

Current HPV Educational Tools

Each expert will evaluate the current HPV educational tools using the created assessment tool (appendix C). The results will be transferred to a Microsoft Excel spread sheet and coded (1=completely, 2=partially, 3=not at all). The expert evaluation will be scored individually, as well as the mode of the three experts score will be calculated. This frequency distribution will be used to describe the quality of the current tools inclusion of evidence based HPV patient education recommendations.

Expert Questionnaire

The created expert questionnaire will be tested using a pilot sampling for analysis with Cronbach's Alpha. According to Field (2009), the Cronbach's Alpha is a statistical measure of reliability which involves "splitting data in two in every possible way and computing the correlation coefficient for each split" (p. 674). If the scores on both halves of the data correlate with each other, the scale is considered reliable. This pilot will be used to demonstrate the reliability of the questionnaire prior to obtaining larger sample.

Once the reliability of the questionnaire is obtained, validated questionnaire samples will be entered into an excel program for analysis (1=strongly agree, 2=agree, 3=neither agree nor disagree, 4=disagree, 5=strongly disagree). The individual questionnaires will be evaluated for feedback and the frequency distribution of the entire sample will be calculated.

PEMAT

The created HPV educational tool will then be analyzed by PEMAT. To calculate understandability and readability of the created tool the questions will be answered (scored), the sum of the answers will be divided by the total score possible, and then multiplied by one hundred. The closer this score is to 100%, the more readable and understandable the content. If the created tool scores less than 80%, revisions to the tool will be made and repeat PEMAT testing will be performed (Shoemaker, Wolf, & Brach, 2014).

Compare Current HPV Education to Created HPV Education

The scores from the expert questionnaire will be converted to a positive, neutral, negative Likert scale for comparison to expert consensus on current HPV patient education. This comparison will demonstrate which educational tool provides patients with the most evidenced based patient education recommendations.

Needed Resources

This project will require the use of experts, tools, and analysis programs. While all of these resources are needed, this project cannot occur without expert willing participation. The tools used in this project are either created or open source and available on-line without restrictions (such as Toolkit for Making Written Material Clear and Efficient and PEMAT). The analysis systems will include Microsoft Excel and SPSS, both are accessible through my enrollment at Maryville University.

Project Budget

The largest cost for this proposed project will be expert participation. The author would also estimate an hourly rate of $50, and projection development time and analysis to be approximately 200 hours, for a total of $2,000. The expert hourly cost to be $50 and estimating

one hour per evaluation, would be approximately $800 per round of revision. The estimated cost of paper, printing supplies, and printing of the educational tool is estimated to be $200. Despite this estimate, the cost will be offset by having both the author and the experts volunteer their time. This brings the budget to a manageable $200, which the author will contribute to the project.

Project Timeline

The timeline for this project began in August of 2016 with completion of the concept analysis, and between October and December of 2016 the literature review was conducted. The project proposal started in January 2017 and will be completed March 2017. The Institutional Review Board process will be completed by May 2017. After approval from IRB, data collection will take place, this is project to take until September 2017, followed by analysis of data, to be complete no later than October 2017. Chapters four and five, will include the results and discussion and will be completed by November 2017, for a planned presentation in December 2017 (See Appendix I).

Ethical Consideration

The participants in this project will be providing expert opinion. To protect the anonymity and confidentiality of the expert panel no names or identifying information is requested on the questionnaire. For each neutral or negative response (b=neutral, c & d= negative response), the principle investigator will request that the expert provide a written explanation and suggestions for improvement. The written explanation and/or suggestions will be transcribed by the principle investigator into a Microsoft Word document and saved in a file on the principle investigator's password protected computer titled "Expert Questionnaire Feedback." Each round with the questionnaire will be saved in a specified document titled

"Round- #". The individual risk for the expert panel is minimal, with established protocols to decrease the risk of breach of confidentiality to any member of the expert panel in place, these individual risks are small. Each expert panel member will volunteer to share their knowledge and expertise.

This project requested exempt status from IRB at Maryville University. The principle investigator completed Collaborative Institutional Training Initiative (CITI) for Health Information Privacy and Security (HIPS) and CITI Biomedical Responsible Conduct of Research certifications to ensure understanding of human subject's rights (See Appendix J).

Conclusion

This chapter highlights the plans for this descriptive practice improvement project. Detailed descriptions were provided for each planned step of this project. The goal will be to adequately evaluate both current HPV patient educational tool, create an evidence based HPV educational tool, and compare the tools. By describing the content of current HPV patient educational tools, the needs assessment demonstrated a need for generalizable, comprehensive patient education that can be used across the areas.

The use of multiple tools for this project as well as how the data will be analyzed has been adequately discussed. The resources needed for the project have been discussed, as well as a budget. A projected timeline has been created, and will be used to keep the project moving on time. The next chapter will provide a description of the findings.

Chapter IV: Findings

Recruitment of Expert Panel

Expert panel members were identified in a Google search for healthcare providers working in the areas of gynecology, gastroenterology, otolaryngology, dermatology, pediatrics, and family medicine. The script for recruitment included purpose of the project and role in the project (see Appendix K). Thirty-five experts agreed to participate in this project. All experts were provided with needed resources and self-addressed stamped envelopes. After two week, only seven responses were collected. For this reason, an additional recruitment was completed in the same fashion and an additional forty-two expert agreed to participate. A total of thirty-four expert panel members responded.

Current HPV Tools

Two expert panel members were randomly asked to complete the review of current HPV tools. The evaluations by the expert panel members were compared to the finding in the needs assessment. Each tool evaluated utilized the Evaluation Tool for Current HPV Patient Education tools, which contains fifteen questions, and twelve current HPV tools were evaluated, for a total of 180 responses. The frequency distribution of each current HPV tool evaluated was completed (See Tables 2-13). None of the tools evaluated completely or partially contained all of the education recommendations. The fifteen-question survey completed by three evaluators, provided a possibility of forty-five responses; the individual tool evaluated with the most recommendations either completely are partially present was 39 out of 45 (See Table 6).

Table 2
Frequency Distribution of Current HPV Tool 1

Question	completely	partially	not at all
1	2	1	0
2	2	1	0
3	1	2	0
4	0	0	3
5	2	1	0
6	0	3	0
7	0	3	0
8	2	1	0
9	0	3	0
10	0	0	3
11	0	0	3
12	0	3	0
13	0	0	3
14	0	0	3
15	0	3	0
Total	9	21	15

Table 3
Frequency Distribution of Current HPV Tool 2

Question	completely	partially	not at all
1	0	3	0
2	2	1	0
3	1	2	0
4	2	1	0
5	2	1	0
6	1	2	0
7	0	1	2
8	2	1	0
9	1	2	0
10	1	2	0
11	0	3	0
12	0	3	0
13	0	0	3
14	0	1	2
15	0	3	0
Total	12	26	7

Table 4
Frequency Distribution of Current HPV Tool 3

Question	completely	partially	not at all
1	1	2	0
2	2	1	0
3	1	2	0
4	2	1	0
5	2	1	0
6	1	2	0
7	0	0	3
8	3	0	0
9	0	0	3
10	0	0	3
11	0	0	3
12	0	0	3
13	0	0	3
14	0	1	2
15	0	1	2
Total	12	11	22

Table 5
Frequency Distribution of Current HPV Tool 4

Questions	completely	partially	not at all
1	1	2	0
2	0	1	2
3	2	1	0
4	0	1	2
5	0	1	2
6	0	0	3
7	3	0	0
8	0	1	2
9	0	0	3
10	0	0	3
11	3	0	0
12	0	0	3
13	0	0	3
14	0	0	3
15	0	3	0
Total	9	10	26

Table 6
Frequency Distribution of Current HPV Tool 5

Question	completely	partially	not at all
1	3	0	0
2	3	0	0
3	3	0	0
4	3	0	0
5	3	0	0
6	2	1	0
7	3	0	0
8	3	0	0
9	3	0	0
10	3	0	0
11	3	0	0
12	3	0	0
13	0	0	3
14	0	0	3
15	1	2	0
Total	36	3	6

Table 7
Frequency Distribution of Current HPV Tool 6

Question	completely	partially	not at all
1	3	0	0
2	0	0	3
3	0	1	2
4	0	1	2
5	0	1	2
6	1	2	0
7	1	2	0
8	1	2	0
9	0	3	0
10	1	2	0
11	2	1	0
12	0	0	3
13	0	0	3
14	0	2	1
15	1	2	0
Total	10	19	16

Table 8
Frequency Distribution of Current HPV Tool 7

Question	completely	partially	not at all
1	2	1	0
2	3	0	0
3	3	0	0
4	3	0	0
5	2	1	0
6	0	0	3
7	0	1	2
8	2	1	0
9	1	2	0
10	1	2	0
11	1	2	0
12	1	2	0
13	0	0	3
14	0	2	1
15	1	2	0
Total	20	16	9

Table 9
Frequency Distribution of Current HPV Tool 8

Question	completely	partially	not at all
1	0	3	0
2	0	0	3
3	0	3	0
4	0	1	2
5	0	1	2
6	0	0	3
7	0	3	0
8	0	3	0
9	0	3	0
10	0	3	0
11	1	2	0
12	0	3	0
13	0	0	3
14	0	0	3
15	0	3	0
Total	1	28	16

Table 10
Frequency Distribution of Current HPV Tool 9

Question	completely	partially	not at all
1	1	2	0
2	0	0	3
3	0	0	3
4	0	0	3
5	0	0	3
6	3	0	0
7	0	0	3
8	2	1	0
9	0	0	3
10	0	0	3
11	0	0	3
12	0	0	3
13	0	0	3
14	0	0	3
15	1	2	0
Total	7	5	33

Table 11
Frequency Distribution of Current HPV Tool 10

Question	completely	partially	not at all
1	1	2	0
2	0	0	3
3	0	2	1
4	0	0	3
5	0	0	3
6	0	0	3
7	0	0	3
8	0	3	0
9	0	3	0
10	0	3	0
11	0	2	1
12	0	3	0
13	0	0	3
14	0	0	3
15	0	2	1
Total	1	20	24

Table 12
Frequency Distribution of Current HPV Tool 11

Question	completely	partially	not at all
1	1	2	0
2	0	1	2
3	3	0	0
4	0	1	2
5	0	0	3
6	0	1	2
7	0	1	2
8	0	1	2
9	0	1	2
10	0	0	3
11	2	1	0
12	0	1	2
13	0	0	3
14	0	3	0
15	0	3	0
Total	6	16	23

Table 13
Frequency Distribution of Current HPV Tool 12

Question	completely	partially	not at all
1	3	0	0
2	0	2	1
3	0	0	3
4	0	0	3
5	0	0	3
6	3	0	0
7	0	0	3
8	2	1	0
9	0	0	3
10	0	0	3
11	0	0	3
12	0	0	3
13	0	0	3
14	0	0	3
15	0	0	3
Total	8	3	34

The results of the individual tool's frequency distribution was compiled. The cumulative total for each category was calculated. Of the 540 questions, 131 recommendations were completely present, 178 recommendations were partially present, and 231 recommendations were not present at all. There is wide variation in individual tools that can be best demonstrated in Table 14.

Table 14

Frequency Distribution of Current HPV Tools

Tool	completely	partially	not at all	N
1	9	21	15	45
2	12	26	7	45
3	12	11	22	45
4	9	10	26	45
5	36	3	6	45
6	10	19	16	45
7	20	16	9	45
8	1	28	16	45
9	7	5	33	45
10	1	20	24	45
11	6	16	23	45
12	8	3	34	45
Total	131	178	231	540
Cumulative Percentage	24%	33%	43%	100%

The frequency distribution of each recommendations on the combined tools was calculated. The evaluation found a wide variation in information contained among the current tools (Table 15). All of the tools provided some description of HPV, however, none of the tools provided complete information regarding potential implications of HPV on partner or potential links to other cancers in the future. The evaluation of current HPV tools found the recommendation not

present on the tool 42% of the time, and the recommendations were completely present less than a quarter of the time.

Table 15

Frequent Distribution of Current HPV Tool by Question

Questions	*N*	Completely Present	Partially Present	Not Present
Describes HPV	36	16	20	0
Discuss no treatment for HPV, but some treatment for HPV related disease	36	9	6	21
Discuss transmission via oral sex	36	15	12	9
Discuss transmission via vaginal sex	36	12	7	17
Discuss transmission via anal sex	36	11	7	18
Discuss recommendations for cervical HPV screening	36	13	9	14
Discuss rational of no screening recommendations outside cervix	36	8	6	22
Discuss HPV can cause cervical cancer	36	15	16	5
Discuss HPV can cause vaginal cancer	36	6	16	14
Discuss HPV can cause penile cancer	36	6	15	15
Discuss HPV can cause OPC	36	13	13	10
Discuss HPV can cause anal cancer	36	7	15	14
Discuss HPV may be linked to additional cancers in the future	36	0	0	36
Discuss impact of HPV on partner	36	0	10	26
Discuss HPV prevention	36	5	25	6

The evaluation of current HPV tools completed in the needs assessment by this author was compared to each of the two evaluators. The first expert panel member scored a tool higher (the highest score indicated completely present recommendation), on 20 responses (11%), lower (the lowest score indicates recommendation not present), on 30 responses (16.6%), and the same as this author on 130 responses (72%). The second expert panel member scored a tool higher on 19 responses (10%), lower on 25 responses (13.9%), and the same on 136 responses (76%). See Table 2-13 for frequency distribution of each tool.

The inter-rater reliability between the three evaluators was calculated using the Fleiss' Kappa. The Kappa was evaluated for each of the twelve tools, and the findings ranged from the low of *K* 0.22 to the high of *K* 0.77, with and average *K* 0.53 (see Table 3).

Table 16
Fleiss' Kappa Inter-rater Reliability of all Current HPV Tools

Tool	p_bar	Pe	Kappa Value
1	0.78	0.37	0.65
2	0.56	0.43	0.22
3	0.64	0.37	0.44
4	0.73	0.42	0.54
5	0.91	0.66	0.74
6	0.56	0.35	0.31
7	0.56	0.36	0.30
8	0.87	0.51	0.73
9	0.87	0.57	0.69
10	0.82	0.48	0.66
11	0.60	0.41	0.33
12	0.91	0.61	0.77
Average	0.73	0.46	0.53

Expert Questionnaire.

A pilot study was completed, using four Expert Questionnaire to evaluate the created evidence-based HPV tool (see Appendix L) to assure the created questionnaire's reliability. A

small sample of three experts evaluated the created tool using the Expert Questionnaire. The results were analyzed in Microsoft Excel using an ANOVA: Two-Factor without replication to then calculate the Cronbach's Alpha. The results of the pilot study found the Cronbach's Alpha to be 0.847051 (Table 17).

Table 17

Expert Questionnaire Pilot Analysis using ANOVA: Two-Factor without Replication

Source of Variation	*SS*	*df*	*MS*	*F*	*P-value*	*F crit*
Rows	2.84	2.00	1.42	6.54	0.004	3.26
Columns	4.81	18.00	0.27	1.23	0.29	1.90
Error	7.82	36.00	0.22			
Total	15.47	56.00				
Cronbach's Alpha: 0.847051						

A frequency distribution for each question was completed using the data collected from the Expert Questionnaire. All 34 questionnaire were returned with all questions answered; the 18 non-demographic questions combined for 612 total responses; the distribution of these responses were as follows: 349 strongly agree, 257 agree, 6 neither agree nor disagree, 0 disagree, and 0 strongly disagree (see Table 18). Written feedback was provided by ten expert panel members (See Appendix M).

Table 18
Expert Questionnaire Frequency Distribution

Question	*N*	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
3. Content is valid and based on current evidence	34	19	15	0	0	0
4. Provides accurate description of HPV	34	18	16	0	0	0
5. Adequately explains the difference between treatment of HPV and treatment of HPV related disease	34	14	20	0	0	0
6. Adequately describes transmission of HPV including oral sex, vaginal sex, and anal sex	34	21	13	0	0	0
7. Adequately provides rational for recommendations for screening	34	16	17	1	0	0
8. Is clear that HPV can cause cervical cancer	34	21	13	0	0	0
9. Is clear that HPV can cause oropharyngeal cancer	34	25	9	0	0	0
10. Is clear that HPV can cause anal cancer	34	24	10	0	0	0
11. Is clear that HPV can cause penile cancer	34	23	11	0	0	0
12. Is clear that HPV can cause vulvar/vaginal cancer	34	21	13	0	0	0
13. Is clear HPV may be linked to other cancers in the future	34	19	15	0	0	0
14. The effects of HPV on patient's partner are adequately explained	34	18	15	1	0	0
15. Prevention of HPV is presented	34	20	13	1	0	0
16. The order of the tool is logical	34	16	17	1	0	0
17. The tool is easy to follow and read	34	20	14	0	0	0
18. Provides comprehensive HPV education	34	17	17	0	0	0
19. I would use this tool in practice	34	19	14	1	0	0
20. I would recommend this tool to other healthcare providers	34	18	15	1	0	0

The demographics for the expert panel members were obtained. The role of the expert panel member included 9 physicians and 25 advanced practice registered nurses (see Table 19). The 34 expert panel members provided healthcare in five main specialty practice areas, including 12 in gynecology, 11 in family medicine, 4 in gastroenterology, 2 in dermatology, and 2 in pediatrics. There were no expert responses received from otolaryngology area of practice. There were 3 expert members that practiced in other specialties; these specialties included (see Table 20).

Table 19
Expert Panel Role Demographic

Role	Frequency	Percentage
Physician	9	0.26
Advanced Practice Nurse	25	0.74
Physician Assistant	0	0.00
Total	34	1.00

Table 20
Expert Panel Practice Specialty Demographic

Practice Location	Frequency	Percentage
Gynecology	12	0.35
Otolaryngology	0	0.00
Gastroenterology	4	0.12
Family Medicine	11	0.32
Dermatology	2	0.06
Pediatrics	2	0.06
Other	3	0.09
Total	34	1.00

The inclusion criteria for this project, would exclude those expert in the ‘Other’ practice location. Analysis was complete eliminating these experts and found that one expert from the ‘Other’ practice provided neutral responses for the following questions: 7. adequately provides rationale for recommendation for screening and 14. the effect of HPV on patient’s partner are

adequately explained. Removal of the 'Other" providers from the analysis increased the satisfaction of the overall tool. The overall neutral responses with 'Other" was 6 of 612 questions, or 99.01% of responses were Strongly Agree or Agree compared to the overall neutral responses without inclusion of 'Other' was 4 of 558 questions, or a 99.34% of responses were Strongly Agree or Agree.

The expert questionnaire included questions regarding the willingness of the expert to utilize the created tool into their practice, as well as recommend the use of the tool to other healthcare providers. Of the 34 experts, 33 reported they would use the tool in their practice and recommend the use of the tool, with one expert neither agreeing nor disagreeing they would use the tool in their practice or recommend the tool to others (Table 21).

Table 21

Expert Questionnaire Frequency Distribution of Implications

Question	*N*	Strongly Agree	Agree	Neither Agree or Disagree	Disagree	Strongly Disagree
I would use this tool in my practice	34	19	14	1	0	0
I would recommend this tool to other healthcare providers	34	18	15	1	0	0

The frequency distribution of the 5-scale Expert Questionnaire was converted to a 3-response survey. The Strongly Agree and Agree responses were combined and the Disagree and Strongly Disagree were combined. Table 22 provides a frequency Distribution of the Expert Panel using the combined data (see Table 22).

Table 22

Expert Questionnaire Conversion to 3-Answer Scale Frequency Distribution

Questions	Strongly Agree & Agree	Neither Agree or Disagree	Disagree and Strongly Disagree
3. Content is valid and based on current evidence	34	0	0
4. Provides accurate description of HPV	34	0	0
5. Adequately explains the difference between treatment of HPV and treatment of HPV related disease	34	0	0
6. Adequately describes transmission of HPV including oral sex, vaginal sex, and anal sex	34	0	0
7. Adequately provides rational for recommendations for screening	33	1	0
8. Is clear that HPV can cause cervical cancer	34	0	0
9. Is clear that HPV can cause oropharyngeal cancer	34	0	0
10. Is clear that HPV can cause anal cancer	34	0	0
11. Is clear that HPV can cause penile cancer	34	0	0
12. Is clear that HPV can cause vulvar/vaginal cancer	34	0	0
13. Is clear HPV may be linked to other cancers in the future	34	0	0
14. The effects of HPV on patient's partner are adequately explained	33	1	0
15. Prevention of HPV is presented	33	1	0
18. Provides comprehensive HPV education	34	0	0

Patient Educational Materials Assessment Tool (PEMAT)

Three expert panel members evaluated the created tool using the PEMAT. The understandability PEMAT questions were totaled and scored per the PEMAT instructions, to determine a percentage of 95%, 100%, and 100%. The actionable PEMAT questions were

totaled and scored according to the instructions for PEMAT scoring, and all three experts' scores were 83% (See Table 23).

Table 23

Patient Educational Material Assessment Tool (PEMAT) Frequency Distribution

Expert	Understandability	Actionability
1	100%	83%
2	100%	83%
3	95%	83%

Comparing Current and Created Tool

The results of the frequency distribution of the Evaluation Tool for Current HPV Tools and the questions 4-15 on the Expert Questionnaire that was converted to 3-response scale (as these are the questions that evaluate presence of current recommendations). The comparison of the percentage of recommendations present for all the evaluated current HPV tools was compared to percentage of recommendations present on the created tool. The evaluation of all twelve current HPV tools found recommendations completely present 24% of the time, however, if the partially provided were included the percentage increased to 57% of the time.

The CDC's tool *Genital HPV Infection- CDC Fact Sheet*, was the individual tool with the most recommendations present, so this tool analyzed individually (CDC, 2014). The evaluation of this tool alone found that recommendations were completely present 80% of the time, and either completely or partially present 86.6% of the time.

The presence of recommendations were represented by the Strongly Agree and Agree responses on questions 4-13 of the Expert tool; experts found 98.6% of the recommendations were present on the created tool.

Conclusion

This project required multiple areas of data analysis including evaluation of current HPV tool content, inter-rater reliability analysis for evaluation of the current tools, evaluation of created tool for presence of recommendations, evaluation of created tool for use in practice, evaluation of created tool for understandable and actionable content, and comparing results of current and created tool. A frequency distribution of the data obtained from the Likert-scale tool, Evaluation Tool Current HPV Patient Educational Tools, was presented to describe the current HPV educational tool use of identified recommendations. The inter-rater reliability of the evaluators for the current tool was completed using Fleiss' Kappa. A pilot study for the Expert Evaluation tool was completed to demonstrate reliability of this tool. The frequency distribution of the data obtained from the Likert-scale tool, Expert Evaluation, was presented to describe the presence of identified recommendations, validity of content, and willingness to use in practice for the created tool. Finally, a description of the comparison of the current and created tool was presented. The next chapter will provide interpretation of these results.

Chapter V: Discussion

In this chapter, the findings will be interpreted into results for this project. A discussion of the strengths, limitation, implications for practice, and recommendations for further research will also be explored. The project question will also be answered.

Results

The finding of the data analysis will be fully explored. The results of evaluation of current HPV tools as well as the inter-rater reliability analysis will be discussed. The created tool had several components of analysis including pilot study of Expert Questionnaire, evaluation for presence of recommendations, demographics, use in practice, understandability, and actionable; each of these components will be discussed. Finally, the comparison of the current and created tool will be presented.

Current HPV Tools

The evaluation for presence of identified recommendations for the current tools found that all of the tools completely are partially described HPV, while no tool completely discussed HPV may be linked to additional cancers in the future or the impact of HPV on partners. Outside of these questions, there was wide variation between the recommendations being completely present, partially present or not present at all. This evaluation demonstrates that that many tools provide only part of the recommendations, and there many tools omit or do not completely provide information regarding the identified recommendations.

The frequency distribution for individual tools as well as cumulative total for all tools was calculated. Of the tools evaluated the identified recommendations were not present 43% of the time. The most complete tool completely or partially contained the recommendations 86.6% of the time. While one tool contained no part of the recommendation 75.5% of the time. This

suggest that the quality of HPV educational tools varies greatly, and many tools fail to provide many of the identified educational recommendations.

The evaluation for presence of identified recommendations for the current tools found that all of the tools completely are partially described HPV, while no tool completely discussed HPV may be linked to additional cancers in the future or the impact of HPV on partners. Outside of these questions, there was wide variation between the recommendations being completely present, partially present or not present at all. This evaluation demonstrates that that many tools provide only part of the recommendations, and there many tools omit or do not completely provide information regarding the identified recommendations.

The evaluation of the expert responses compared to this author, found a high percentage of agreement, 72% and 76%. The expert evaluators found the current tools to contain fewer recommendations than this author 16.6% and 13.9% of the time; the expert evaluator fount the current to contain more recommendations than this author 11% and 10% of the time. These findings suggest the finding of the needs assessment to be reflective of the tools, and this authors findings of the current HPV educational tools was free of bias.

The inter-rater reliability was assessed using Fleiss' Kappa. The Fleiss' Kappa for each individual tool ranged from *K* 0.22, to *K* 0.77. Fleiss Kappa above K0.3 is considered good, and over K0.7 is excellent (Field, 2009). The average Kappa of all the tools was *K* 0.53, which demonstrates overall good inter-rater reliability. The Fleiss' Kappa, demonstrate high agreement between the evaluators.

Created HPV Tool

A Likert-scale evaluation tool, Exert Questionnaire (see Appendix E), was created to evaluate the created HPV educational tool. A Likert scale convert quantitative data (expert opinion) into qualitative data for analysis. A pilot study of the created Expert Questionnaire

found the Cronbach's Alpha to be 0.847050754. According to Field (2009), a value "of .7 to .8 is an acceptable value for Cronbach's Alpha; values substantially lower indicate an unreliable scale" (p. 675). The Cronbach's Alpha for the Expert Questionnaire suggests high reliability for the created tool. As a result of this reliability analysis, no change or elimination of questions was necessary.

The expert panel was comprised of a mixture of 9 physicians and 25 advanced practice nurses that provide patient care in the areas of gynecology, gastroenterology, family medicine, dermatology, pediatrics, and other. Three of the expert panel members practice were advanced practice nurses providing care in the areas of breast care, orthopedics, and nurse educator. One of these experts provided two neutral responses with written feedback. These healthcare provider practice outside of the specified were excluded from validation, however, analysis was completed to include these experts as well because there was no negative responses and very limited neutral responses, removal of these experts only bolstered the created tool, and neutral feedback from an expert outside the mentioned field could provide meaningful feedback should the created tool have needed revision.

Thirty-four questionnaires were evaluated and the frequency distribution of data was completed, 31 of the experts met inclusion criteria and these results were analyzed for validity. This analysis found that only no negative response was received, and of the 558 questions, only 4 neutral responses were given. All 31 of the included expert panel members, strongly agree or agreed that the content of the created tool was valid and based on current evidence and provided comprehensive HPV education. Since expert opinion is often used to demonstrate the validity of tools, these responses provide validation for the content of the created HPV tool.

The frequency distribution for the two questions on the Expert Questionnaire regarding use in practice and recommendations for use was completed. This evaluation found 33 of the 34 experts would use the created HPV patient educational tool in their practice. Similarly, 33 of 34 experts would recommend the created HPV patient educational tool to other healthcare providers. One expert provided the written feedback, "I plan to start using this immediately, Great information" (see Appendix M). This findings suggest the created tool can be used in many specialty areas, and that healthcare providers believe the content of this tool would improve the quality of patient education provided. .

The evaluation of the created tool by the PEMAT was completed by a convenient sample of three expert panel members. Analysis of the evaluators assessment of the understandability of the created tool found two evaluators provided a perfect score of 100%, while the third evaluator scored understanding at 95%. The analysis for actionable content of the created tool was found to be 83% by all three evaluators. A PEMAT score of greater than 80% on each test can demonstrate understandability and actionable of the patient educational tool (Shoemaker, Wolf, & Brach, 2014). The PEMAT results for the created HPV tool indicate both understandability and actionable content.

Comparison of Tools

For the comparison of current tools to the created tools, the use of the converted 3-resonse Expert Questionnaire was use. The current HPV tools provided the identified recommendations 57% of the time compared to the created HPV tool that provided the identified recommendations 98.6% of the time. All twelve of the current HPV tools were found to omit at least one of the identified recommendations. The created HPV tool had no identified recommendations not present, but did have less than 1% neither agreed or disagreed the recommendations was present. The final evaluation aimed to answer the question does current HPV patient educational tools provided the evidence-based recommendations better than a

tool created based on these recommendations. This analysis demonstrate the created tool to provide the identified patient education recommendations better than the current HPV tools used in practice.

Strengths of Project

There are several strength of this practice improvement project. The first strength is the descriptive design that allows exploration of both the current and created HPV patient educational tools. The descriptive design allowed for use of Likert-scale to analyze opinion by qualitative means. The use of expert panel members to review the current educational tools and compare these results to the findings of the needs assessment helped remove bias and provide reliability of the findings.

Limitations of Project

Despite preparation and planning for this project, several limitations were identified by the principle investigator. These limitations include the review of literature was not exhaustive, lack of otolaryngology participation, expert members submitted survey in manner not specified in methodology, the setting, and participants of the project were all healthcare providers.

The review of literature for this project was focused; however, thousands of research articles regarding HPV over the past decade and only having one reviewer, prevented an exhaustive comprehensive review of literature. The review was focused on research and included all identified specialties, but limitations on the research reviewed could have resulted in recommendations for HPV patient education to not be identified. This would not negate the identified recommendations. To overcome this limitations, a complete and comprehensive search of all HPV research should be performed, to evaluate the comprehensiveness of the identified evidence-based recommendations.

The methodology specified feedback from all identified specialties, however, despite adequate recruitment for the project, no expert from the otolaryngology specialty provided a

response. This limitation does not allow the created tool to be validated among all desired specialties. I would recommend that the created tool be validated by this population. However, the lack of response by one specific specialty should not negate the findings of the combined specialties. The methodology for this project did not include any follow up or reminders for recruited participants and this could have contributed to the lack of response from experts that had agreed to participate. In the future, methodology should include a form of follow-up with all recruited participants to diminish the number of nonresponses.

On four occasions, healthcare providers submitted a completed expert questionnaire by email; this form of response differed from the collection method process specified. On these occasions, the submitted questionnaire was printed and placed in the receipt folder, and the email was deleted. The collection method was created to assure confidentiality and anonymity of the expert response, by taking the above measures would assure this was provided to the best of the principle investigators ability. These questionnaires were included in the analysis because the method of collection would not negate the information provided. In the future, to remove this limitation, I would recommend also including an electronic form submission procedure.

The expert participants were all from the same rural geographical location of Southeast Missouri. The setting could limit the application to urban practice locations. Though the expertise of the participants are not likely to change, it is possible that healthcare providers in Southeast Missouri approach HPV patient education tools differently than healthcare providers in a more urban setting. I would recommend inclusion of experts in the urban settings for additional evaluation of the educational tools.

The current and created HPV tools were analyzed by healthcare providers and there was no participation by potential patients. The validation of the content of the created tool required

expertise, however, the patient evaluation could provide valuable information regarding the effectiveness of the tools. For the purpose of this project, experts were needed, however, future evaluation of the tools ability to provide comprehensive HPV education should be evaluated with potential patients.

Implications for Practice

This practice improvement project has highlighted the rapidly growing body of evidence regarding HPV. It is this growth of knowledge and understanding regarding the implications of HPV infection that shape the recommendations for patient education. Providing adequate patient education for HPV will include utilization of research from multiple specialty groups. As the understanding of potential health implications for HPV infection grows, it will be essential to assure the educational tools utilized in practice reflect the current evidence.

The review of current HPV tools, demonstrated how quickly educational tools can become obsolete and lack needed information. Healthcare providers need to assure the quality of the educational tools being provided to patients. It is essential for all members of the healthcare team that provide patient education, continuously critically appraise the content of tools provided to patients.

This project found the system specific HPV patient educational tools, fail to provide patients with comprehensive health information that patients need to be informed. The CDC (2016), reported in 2016, the cases of non-gynecological HPV-related cancers has surpassed the gynecological HPV-related cancers; this alone demonstrates the need to educate patients about all potential risks of HPV infection, regardless of the specific specialty of practice.

The educational tool crated for this project, incorporated the recommendations from multiple specialties within healthcare. The inclusion of multiple specialty recommendations

resulted in a comprehensive HPV educational tool that is appropriate for use in all specialties. Of the 34 healthcare providers that evaluated the tool, 33 would use the tool in their practice and recommend other healthcare providers use the tool. The created HPV educational tool was found to provide more comprehensive health care information than the current tools it was compared to.

Recommendations for Future Research

This practice improvement was conducted within the limitations of a descriptive design. The findings of this project are not designed to determine the reason behind these results, but merely seeks to describe the findings. That being said, the result of this project bring up additional questions related to the created tool and patient education handouts. The following is a list of recommendation for future research related to this topic.

The first recommendations is that the effectiveness of the created HPV patient education tool in providing patient education should be examined. The tool was validated using experts, while this was necessary for initial development, evaluation among patients of different ages, race, culture, and gender should be conducted. This information could help further development of the tool.

The second recommendation for future research would be to explore how much knowledge and awareness healthcare providers have regarding the quality of patient educational materials they give to patients. This project examined readily patient educational material and found that the content was insufficient while occasionally containing inaccurate information. Future research should determine the healthcare provider's awareness of the tools provided during educational encounters.

This project demonstrated a poor response by recruited expert panel members for participation. Future research to explore barriers for healthcare providers participating in healthcare research.

The last recommendations for research would be to create a tool for making evidence-based, comprehensive patient educational material for healthcare conditions that affect multiple body systems. A single system approach for multisystem disease provides a gap in both care and education. Creating a toolkit to evaluate and create educational tools that affect multiple systems can aid in providing effective, efficient, and equitable care for all patients.

Conclusion

The IOM has identified a need to improve the quality of healthcare to provide patient's with safe, effective, patient-centered, timely, efficient, equitable care. This project describe the difficulty with provide this quality of care for patient's during HPV encounters that have arisen from the multiple areas within the body that can be effected by HPV. Chapter provided a background of HPV, the significance of the problems, as well as the how creating a solution for this problem would benefit practice.

A review of literature revealed multiple evidence-based HPV patient education recommendations. These recommendations were used to create a comprehensive HPV educational tool that could be used in all areas of healthcare, as well as evaluate current HPV educational tools.

The evaluation of the current HPV educational tools demonstrate inconsistency of content. This review found none of the evaluated tools contained all of the identified recommendations, and most provided inadequate information for patients to understand the potential implications of the infection.

The identified tools were used as a guide when creating the HPV educational tool. The evaluation of the created tool validated the content and found nearly all of the experts found the created tool to have all identified recommendations present. The created tool was found to be understandable with actionable content.

This practice improvement project sought out to improve the content of HPV patient education in all clinical settings. The expert panel members practice in multiple areas within healthcare, and nearly all stated they would use the created tool in their practice, as well as recommend the use of the created tool to others. The comparison of current HPV educational tools to the created HPV educational tools suggest the created tool would provide patients with information that reflects the current evidence-based recommendations better than the HPV educational tools currently used in clinical settings.

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Appendix A

Literature Review Matrix

Women's Health Research Matrix

Name of Study (citation)	Research Question	Method	Sample	Results	Recommendations
Guan et al. (2012)	Describe the distribution of HPV –positive women from normal cytology to ICC	Systematic literature review w/meta-analysis	115,789 women world-wide	HPV prevalence increased w/increasing severity of abnormal cervical cytology HPV 16 was the most frequently identified HR substyle across all groups	Manage HPV 16 & 18 more aggressively 2/2 high rates of ICC w/these strands globally HPV 45 was identified as the 3rd leading strain to cause ICC, cases w/45 should be monitored closely, especially in Africa where it has a high prevalence.
Katki, et al. (2013)	Does HPV negative/ASCUS pap have same cancer rates as negative pap	Longitudinal cohort study	1,100,741 women b/t ages 25-64	ASCUS/negative HPV has nearly same 5 year risk as negative pap alone	Screening for ASCUS/negative pap should occur in 3 years (same as pap- equal management for equal risk) *Study was used for to support new HPV screening guidelines (2012)
Katki, et al. (2013,2)	Using the CIN3+ risk for screening recommendations, what screening interval for pap and HPV contesting should be recommended to provide equivalent	Longitudinal cohort study	965,360 women b/t ages of 25-64	Based on CIN3+ risk, screening interval for negative pap alone is 3 years; negative pap/hpv interval is 5 years	Use of benchmarking will recommend ASCUS/+HPV RF tor colpo as this has higher risk of CIN3+ than LSIL pap Addition of HPV contesting will limit RF for ASCUS/HPV negative results as this can be treated the same as negative pap with screening interval of 3 years

	screening as pap alone testing				
Benard et al. (2014)	Identify barriers to appropriate use of the co-testing evidence based screening guidelines for cervical cancer	Controlled trial with two arms- one intervention arm and one control arm	2,246 women from FQHC in IL	Demonstrated the importance for providers to understand and buy-into the changes in screening and understand the evidence to support the change	Providing education about contesting and having providers understand the screening recommendations are essential for proper implementation of evidence based screening Providers must understand "the information on the harms of over-testing--- which may lead to over-diagnosis and overtreatment—is only useful to the extent that it is understood and accepted by providers" (p.7)
Nobbenhuis et al. (2000)	Can HPV screening w/cytology help predict treatment failure for cervical neoplasia	Observational study	184 women receiving treatment in Amste-Rdam b/t 90-96	The presence of HPV following treatment was the most significant risk factor for reoccurrence The duration of the HPV infection was even more predictive	Screening for HPV infection following cervical neoplasia treatment can offer guidance for future care of the patient
Royer & Falk (2012)	Describe young women's perceptions of HPV	Cross-sectional, survey data, Qualitative study	302 women b/t 18-24	Young women have many misconceptions about HPV including this is likely to cause cervical cancer	Providers should be aware that many young women may have incomplete or incorrect assumptions about HPV infection Providers should take each visit to discuss and clarify information
Clinical proceedings (2009)	Guidelines for patient education for HPV	Advisory Committee Opinion	n/a- multiple sources	Educational recommendations for: impact and	Education for: -high prevalence - different strains of HPV

			provided for rationale of rec.	epidemiology, HPV and external genital warts, screening for HPV-related cancers (cytology vs HPV), management of abnormal cervical cancer screening results, HPV and the adolescent, and HPV prevention	-screening for cervical cancer w/pap &/or HPV and rationale for decision -managing abnormal screening -prevention (vaccine, delay, and limit sexual partner) -specialized HPV education for adolescent population
Anhang, Goodman & Goldie (2004)	Provide an empiric basis for development of effective counseling messages about HPV and HPV testing	Literature Review	68 research articles reviewed	Themes identified were epidemiology and pathogenesis, clinical use of HPV testing, clinical guidelines. Awareness and knowledge of HPV, psychosocial responses to HPV testing and diagnosis, patients desired information, and sources of info	Patient centered education for HPV discussion w/patient is essential to expand knowledge for testing and implications Role of HPV testing vs Pap testing. Discussion of age r/t differences for HPV testing. Discussion of varying types HPV Increasing health literacy of each patient regarding HPV should be focus of each provider
Dunne, Friedman, Datta, Markowitz, & Worowski (2011)	HPV counseling recommendations	Systemic review of literature and with expert review by CDC panel	72 articles reviewed and included in justification for the recom-mendations	HPV epidemiology, prevention, testing, treatment of warts, implications for HIV population, and selected questions and answers	-guidance provided for counseling patients on HPV results -discussion of screening recommendations and rationale for use -implications of HPV on pregnancy, partner

					-HPV significance for women w/abnormal cervical cancer screening
Von Karsa, et al. (2015)	Supplements to European guidelines for quality assurance in cervical cancer screening	Expert opinion and explanation of guidelines w/evidence	49 references to help clarity and justify screening guidelines	HPV screening used as primary test for cervical cancer screening	-can use HPV stand alone -avoid use of co-testing at every age -stop HPV screening at 65 -start primary HPV screening at 35 -never start HPV screening under 30
Kester et al. (2014)	What effect does brief educational intervention for HPV have on HPHV knowledge and HPV vaccination intent?	Randomized quantitative study	131 female and male ages 18-26	Participants in intervention group had increased knowledge and intent to vaccination after education compared with the control group that did not receive education	Any educational intervention is likely to increase awareness of HPV Patient education will likely increase the HPV vaccination rates.
ACOG (2015)	HPV vaccination recommendation	Expert opinion	n/a	See recommendations	All eligible individuals should receive HPV vaccine

Otolaryngology Research Article Matrix

Name of Study (citation)	Research Question	Method	Sample	Results	Recommendations
Pytynia, Dahlstrom, & Sturgis (2014)	What is epidemiology of HPV associated cancers?	Systematic Review	133 articles included	HPV, HPV mode of transmission to oral cavity, HPV positive OPC, and prevention	-oral sex is mode of transmission for oral HPV infection -Vaccination of boys and girls would likely decreased future numbers of OPC
D'Souza, G., Agrawal, et al. (2009)	Does oral sexual behaviors increase	Cross-sectional Mixed Methods Study	332 control & 210 college aged men	Oral sex is a mode of transmission for oral HPV infection. Open	-oral HPV infections increase with increased numbers of oral

	risk of oral HPV infection			mouth kissing may also be a mode of transmission for HPV infections.	sexual partners and open mouthed kissing partners
D'Souza, G., Cullen, et al. (2014)	Do gender, age, and race difference in oral sexual behavior account for the distribution of oral HPV infection and HPV positive OPC?	Mixed Methods	2.116 men & 2.140 women	-Differences of oral sexual behavior were observed by gender, age, and race. Oral sexual behaviors are the primary predictor for HPV oral infection	-oral sexual behaviors differs by oral, age, and race. -White men have more oral partners -oral sexual behavior and gender are associated w/oral HPV infection -Age and race are not statistically significant.
D'Souza, G., Gross, et al. (2014)	What are the oral HPV infection and cancer risk among long-term sexual partners of patients with HPV positive OPC?	Quantitative study	164 participants	No increased risk of OPC cancer for partners of HPV positive OPC and oral HPV infection rates similar to general population	-Patients and partners should be educational that no increased risk for partners developing HPV positive OPC have been identified -Statistically significant amount of partners had hx of invasive cervical cancer or were tx for precancerous lesions r/t HPV, so having a sexual partner w/cervical HPV may increase risks of OPC
Martin-Hernan, et al (2013)	Is oral HPV infection transmitted through oral sex?	Literature Review	35 articles	Oral sex is a mode of transmission for oral HPV infection	-Risk factors oral sex, open mouth kissing, multiple sexual partners, and previous hx of STI -HPV positive OPC are increasing while HPV negative OPC are decreasing
Beachler, et al (2012)	What is the effect of HIV on oral HPV infection?	Co-hort quantitative study	379 HIV positive and 266 at risk patients	Prevalence of HPV oral infection in HIV positive patients was	-multiple recent oral sexual partners increases risk of HPV oral infection

				40% and 25% in at risk individuals	-reduction of CD4 has increased effect of HPV -smoking does not increase persistent infection but does increase risk for new infection -oral HPV infection is common among HIV positive patients
Deschler, et al. (2014)	What are the current recommendations for evaluation and treatment of patient suspected of having HPV positive OPC?	Literature review	26 peer reviewed literature and published practice guidelines	Discussion of presentation and history of OPC, primary sit identification, evaluation of the neck mass, imaging the HPV positive Head and Neck Cancer patient, implications for practice with questions and answers	-Providers should be aware HPV positive OPC are younger without traditional OPC risks -Discuss HPV positive OPC have significantly higher cure rates -recommendations for discussing HPV transmission and significance of this as STD -Q&A provided to help healthcare providers answer HPV question -HPV vaccine discussed and recommend vaccination for children
Fakhry & D'Souza (2013)	Guidelines for patient education	Systematic review	n/a	Provides healthcare providers multiple step to discussing oral HPV infection, transmission, implications for patient and partner, and prevention.	-large Q&A section w/references to studies for each -Discusses this information is important because this specially has not historically given patients STD dx and it is important to provide adequate guidance -Vaccine recommended
Edelstein, et al. (2012)	What is the prevalence of oral HPV infection in men?	Co-hort Quantitative Study	212 men	Most oral HPV infections were transient with very few persistent oral	-oral HPV infection often related to recent oral sex -Sexual contact and autoinoculation were identified

				HPV infections identified over 12m	as primary independent roles in transmission
Elrefaey, Massaro, Chiocca, Chiesa, & Anasarin (2014)	What are the basics to know in clinical practice in regards to HPV positive OPC?	Literature review	101 articles included in review	HPV risk factors, classifying HPV positive OPC, clinical difference of HPV positive OPC and HPV negative OPC, and vaccination	-HPV positive OPC have increased significantly in the past 20 years -Vaccination for HPV will likely decrease future rates -
Chu, Genden, Posner, & Sikora (2013)	How to provided patient centered care with emotional support for the patient receiving dx of HPV positive OPC	Review of literature (including counseling recommendations from other areas)	n/a	It is important to provide emotional support and be prepared to answer questions from the patient in a straight forward, matter of fact manner, leaving little up for interpretation by the patient.	-Specific answers for patients questions -It is important for the provider to be comfortable and knowledgeable discussing HPV transmission, prevention, and treatment -Implications for patient and partners discussed
Hererro et al., (2013)	Can HPV vaccine decrease incidence of HPV r/t oral cancers?	RCT	7.466 women in Costa Rica	HPV vaccine initiated in both males in females did demonstrate decrease in incidence of OPC among this populations	-study suggest HPV vaccine in males can decrease incidence of HPV positive OPC, recognizes need for long term study prior to indication given but recommends providers offer vaccine to males
Sanders & Patton (2012)	What are the risks factors and prevalence of oral HPV infection?	Qualitative Study w/detailed literature review	4846 people, 2 months and older	The prevalence of oral HPV infection in a representative sample of US general adult population is 7.3%. Risk factors include smoking, early sexual debut,	-No vaccine approved for prevention of OPC, it is likely that HPV vaccine would decrease the climbing prevalence of both HPV oral infection and HPV positive OPC -Patients should be educated about the transmission of oral

				and multiple sexual partners.	HPV infection during sexual contact and be advised ways to decrease risks of transmission.

Gastroenterology Recommendations Matrix

Name of Study (citation)	Research Question	Method	Sample	Results	Recommendations
Frisch, M., Biggar et al. (2000)	Manuscript for answers of common questions from patients with HPV positive OPC	Systematic Review and expert opinion	79 articles used to support answers to questions	The role HPV plays in OPC, discussing dx, patient education pamphlet for dx, tumors of HPV positive OPC, and Q&A	-How to discuss HPV with patients -Providing patient handout -Discussing transmission -Discussing risks to partners -Discussing risks of other cancers -Implications of HPV on OPC -vaccination
Frisch, M., Glimelius et al. (1997)	What are risk factors for anal cancer?	Population-based, case-controlled study	324 women & 93 men	-sexual promiscuity increases risk of anal cancer -Increase of sexual partners increases risk	-Patients should be counseled that HPV infection causes anal cancer -HPV infection can be transmitted into the rectum w/o receptive anal intercourse -
Sonnex, Strauss, & Gray (1999(	Do people who have genital warts carry HPV on their fingers?	Quantitative Study	22 men and women	People who have genital warts also have HPV on fingers	-Patients w/HPV infection in anogenital region may be able to transfer infection to partners by hand to genital contact
Hernandez et al (2008)	What is the modes of transmission for HPV among monogamous heterosexual couples	Quantitative Study	25 heterosexual couples	Multiple modes of HPV transmission exist between couples including: non-penetrating contact b/t scrotum	-women infect men more frequently than men to woman -patients should be explained all the modes of transmission

				and female rectum, and hands. But modes did not include semen and oral contact	-oral sex not found to be mode -contact w/hands and scrotum at the anus is likely a mode of transmission to rectal HPV infection
Clinical proceeding (2009)	See women's health -specific discussion of HPV r/t anal cancer discussion for those w/rectal cancer	See women's health	n/a	Anal cancer is highly associated w/HPV infection and screening is not recommended but can be considered for at risk groups	-discuss anal cancer screening w/at risk patients -HPV screening could be used to identify those at most risk in the high risk group.
Welbeck (2016)	Can increasing provider knowledge and improving clinical practice increase anal pap screening for at risk individuals?	Quasi-experimental quantitative study w/chart review	14 health care providers	Pre/post test showed that provider focused education did increase the provider knowledge of at risk individuals who would benefit from anal cancer screening	-despite a lack of national screening guidelines providers can use existing research to identify those at highest risk for anal cancer and consider screening for these individuals -providing healthcare providers with education about anal cancer screening can improve patient care
Smyczek, Singh, & Romanowski (2013)	Does evidence support screening for anal intraepithelial neoplasia?	Systematic review of evidence	72 articles reviewed	Epidemiology of anal cancer & AIN, HPV and anal cancer, screening for AIN, Controversies of anal pap	-Screening for anal cancer would be beneficial for high-risk groups in particular HIV positive MSM -High risks groups that may benefit from screening include: HIV positive heterosexual men & women, HIV negative MSM, women w/hx of genital cancer,

					patients on immunosuppressive meds
HIV articles (2007)	Anal cancer screening recommendations	New York State Department of Health screening recommendations	n/a	Anal cancer screening is recommended for at risk HIV patients	-Recommend discussion of importance of anal cancer screening for at risk HIV positive patients. -MSM, history or present anogenital warts, and women with abnormal cervical or vulvar cytology
Ortiz-Martinez et al (2013)	What is the concordance between cervical and anal HPV infection?	Population based cross sectional study	600 women b/t 16-64 living in San Juan Metropolitan area	Younger women (16-34) were more likely to have co-infection of HPV in rectum and cervix. And those w/10 or more partners were more likely to have co-infection -married women less likely than single to have co-infection	-education should include co-infection of cervix and rectum is common -limiting sexual partner and delaying sexual debut can decrease risk of HPV infection -All patients should be given recommendations for HPV vaccination.
Reyes-Ramos, Dukandar, & Borum (2013)	How frequently is HPV education and counselling provided to men and women with IBD who are on immunosuppressant's	Retrospective medical record review	341 medical records reviewed	HPV patient education for those on immunosuppressant medications is inconsistent	-women on immunosuppress-sant medications should receive counselling about increased risk of HPV-associated cervical dysplasia for women w/HPV infection -all IBD patients should receive education about increased risk of HPV associated anal and oral malignancies w/med use in those w/HPV infection

Other Area's HPV Research Article Matrix

Name of Study (citation)	Research Question	Method	Sample	Conclusions	Recommendations
Shamanin et al. (1999)	What strains of HPV are most often the cause of	Quantitative Study	291 patients	HPV 5 was the strain that was identified more when skin cancers though multiple	-Immunocompromised patients have increased risk of HPV related skin cancers from multiple strains of HPV and skin screening should be offered and hx of abnormal lesions should be performed.
Meyer et al. (2013)	What is the prevalence of HPV types in different benign, pre-malignant, and malignant skin tumors	Quantitative Study	110 patients	Immunosuppressed patients have increased incidence of non-melanoma skin cancer caused by HPV infection.	-Immunocompromised patients should receive frequent skin exams due to increased risk of persistent HPV infections that can lead to skin cancer.
Juckett & Hartman-Adams (2014)	HPV patient education recommendations	Literature review w/committee opinion	n/a	Patients should be provided with educations that includes transmission, manifestations, and prevention	-multiple modes of transmission -HPV is known cause of multiple cancers -Vaccine should be offered to all patients
ADA (2012)	Recommendations for dentist refer to ENT & discussion of HPV vaccine	Committee opinion and clinical guideline recommendations	n/a	-HPV r/t OPC are increasing and dentist are in unique position to evaluate for abnormal lesions and RF to ENT if observed	-OPC r/t HPV have younger patients not often associated to be at risk for OPC and dentists need to be aware of the change and ready to RF if lesions are observed -HPV vaccine would likely decrease HPV r/t OPC
AAFP (2016)	HPV vaccination recommendations	Committee Opinion	n/a	HPV vaccine is indicated for both boys and girls	-HPV vaccination should be recommended for all patients

Academy of pediatrics (2012)	HPV vaccination recommendations	Committee Opinion	n/a	HPV vaccine is indicated for both boys and girls	-All patients should receive recommendations for vaccination

Appendix B

Current HPV Patient Educational Tools Evaluated

Number corresponds to number provided for statistical evaluation:

1. American College of Obstetrics and Gynecologist, The [ACOG]. (2014). *Human Papillomavirus (HPV) Infection* [Pamplet, FAQ073]. (n.p): The American College of Obstetrics and Gynecologist. Retrieved from https://www.acog.org/-/media/For-Patients/faq073.pdf?dmc=1&ts=20170202T0019088914

2. American Sexual Helath Association [ASHA]. (2015). *Ten things to know about HPV.* [Pamplet]; The American Sexual Health Association. Retrieved from http://www.ashasexualhealth.org/pdfs/10ThingsHPV.pdf

3. Association of Reproductive Health Professionals. (2007). *Understanding HPV and cervical cancer.* [Pamphlet]. Association of Reproductive Health Professionals. Retrieved from http://www.healthyinfo.com/consumers/ho/arhp/UnderstandingHPV.pdf

4. Centers for Disease Control and Prevention. (2014). *Human papillomavirus (HPV) and oropharyngeal cancer* [Pamphlet]. (n.p.): CDC. Retried from https://www.cdc.gov/std/hpv/hpv-oropharyngeal-cancr-march-2014.pdf

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Appendix C

Evaluation Tool for Current HPV Patient Educational Tools

1. Describes what HPV is:
    a. Completely B. Partially C. Not at all

2. Discuss no treatment for HPV but some treatment for HPV r/t disease:
    a. Completely B. Partially C. Not at all

3. Provides Information on Transmission of HPV via:
    a. Oral Sex:
        A. Completely B. Partially C. Not at all
    b. Vaginal Sex:
        A. Completely B. Partially C. Not at all
    c. Anal Sex:
        A. Completely B. Partially C. Not at all

4. Discusses screening recommendations for
    a. Cervical HPV:
        A. Completely B. Partially C. Not at all
    b. Discuss no screening recommendations (outside cervical) and provide rationale:
        A. Completely B. Partially C. Not at all

5. Discusses potential for infection with HPV to cause cancer
    a. Cervical
        A. Completely B. Partially C. Not at all
    b. Vaginal/Vulvar
        A. Completely B. Partially C. Not at all
    c. Penile
        A. Completely B. Partially C. Not at all
    d. OPC
        A. Completely B. Partially C. Not at all
    e. Anal
        A. Completely B. Partially C. Not at all
    f. Discuss likely that HPV causes other cancers that have not been identified:
        A. Completely B. Partially C. Not at all

6. Discuss implications of HPV infection to patients partner:
    a. Completely b Partially c. Not at all

7. Discuss prevention:
    Completely b. Partially c. Not at all

Appendix D

Permission to use Toolkit for Making Written Material Clear and Effective

The following is a quote from Centers for Medicare & Medicaid Services states on the CMS.gov site regarding the use of the Toolkit for Making Written Material Clear and Effective ”You may save or print all or parts of this Toolkit from your personal computer. You are also allowed to make and distribute photocopies.” Retrieved from https://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit/index.html?redirect=/WrittenMaterialsToolkit/

Appendix E

Expert Questionnaire

Circle the letter of the answer for each of the following questions.

1. What is your title?

a. Physician
b. Advanced Practice Nurse
c. Physician Assistant

2. In what specialty do you currently practice?

a. Gynecology
b. Otolaryngology
c. Gastroenterology
d. Family Medicine
e. Dermatology
f. Pediatrics
g. Other: Please list_____

3. The content of this patient educational tool is valid and based on current evidence.

   a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

4. This patient educational tool provides an accurate description of HPV.

   a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

5. This patient educational tool adequately explains the difference between treatment of HPV and treatment of HPV related disease.

   a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

6. This patient educational tool adequately describes transmission of HPV including oral sex, vaginal sex, and anal sex.

   a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

7. This patient educational tool adequately provides rational for recommendations for screening.

   a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

8. In this patient educational tool it is clear that HPV can cause cervical cancer.

   a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

9. In this patient educational tool it is clear that HPV can cause oropharyngeal cancer.

   a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

10. In this patient educational tool it is clear that HPV can cause anal cancer.

    a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

11. In this patient educational tool it is clear that HPV can cause penile cancer.

    a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

12. In this patient educational tool it is clear that HPV can cause vulvar/vaginal cancer.

    a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

13. In this patient educational tool it is clear that HPV may be linked to other cancers in the future.

    a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

14. The order of this patient educational tool is logical.

    a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

15. The format of this patient educational tool is easy to follow and read.

    a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

16. The patient educational tool provides comprehensive HPV education.

    a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

17. I would utilize this patient educational tool in my practice.

    a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

18. I would recommend other healthcare providers use this patient educational tool.

    a. Strongly Agree b. Agree c. Neither Agree or Disagree d. Disagree e. Strongly disagree

Provide feedback on ways to improve any question rated c, d, or e:

Appendix F

The Patient Education Materials Assessment Tool (PEMAT)

Title of Material: _____

Understandability

Item #	Item	Response Options	Rating
Topic: **Content**			
1	The material makes its purpose completely evident.	Disagree=0, Agree=1	
2	The material does not include information or content that distracts from its purpose.	Disagree=0, Agree=1	
Topic: **Word Choice & Style**			
3	The material uses common, everyday language.	Disagree=0, Agree=1	
4	Medical terms are used only to familiarize audience with the terms. When used, medical terms are defined.	Disagree=0, Agree=1	
5	The material uses the active voice.	Disagree=0, Agree=1	
Topic: **Use of Numbers**			
6	Numbers appearing in the material are clear and easy to understand.	Disagree=0, Agree=1,	

		No numbers=N/A	
7	The material does not expect the user to perform calculations.	Disagree=0, Agree=1	
Topic: **Organization**			
8	The material breaks or "chunks" information into short sections.	Disagree=0, Agree=1, Very short material[i]=N/A	
9	The material's sections have informative headers.	Disagree=0, Agree=1, Very short material[i]=N/A	
10	The material presents information in a logical sequence.	Disagree=0, Agree=1	
11	The material provides a summary.	Disagree=0, Agree=1, Very short material[i]=N/A	
Topic: **Layout & Design**			

12	The material uses visual cues (e.g., arrows, boxes, bullets, bold, larger font, highlighting) to draw attention to key points.	Disagree=0, Agree=1, Video=N/A	
Topic: **Use of Visual Aids**			
15	The material uses visual aids whenever they could make content more easily understood (e.g., illustration of healthy portion size).	Disagree=0, Agree=1	
16	The material's visual aids reinforce rather than distract from the content.	Disagree=0, Agree=1, No visual aids=N/A	
17	The material's visual aids have clear titles or captions.	Disagree=0, Agree=1, No visual aids=N/A	
18	The material uses illustrations and photographs that are clear and uncluttered.	Disagree=0, Agree=1, No visual aids=N/A	
19	The material uses simple tables with short and clear row and column headings.	Disagree=0, Agree=1,	

		No tables=N/A	

***Total Points*: _____**

***Total Possible Points*: _____**

Understandability Score (%): _____

(Total Points / Total Possible Points x 100)

Actionability

Item #	Item	Response Options	Rating
20	The material clearly identifies at least one action the user can take.	Disagree=0, Agree=1	
21	The material addresses the user directly when describing actions.	Disagree=0, Agree=1	
22	The material breaks down any action into manageable, explicit steps.	Disagree=0, Agree=1	
23	The material provides a tangible tool (e.g., menu planners, checklists) whenever it could help the user take action.	Disagree=0, Agree=1	
24	The material provides simple instructions or examples of how to perform calculations.	Disagree=0, Agree=1, No calculations=NA	

25	The material explains how to use the charts, graphs, tables, or diagrams to take actions.	Disagree=0, Agree=1, No charts, graphs, tables, or diagrams=N/A	
26	The material uses visual aids whenever they could make it easier to act on the instructions.	Disagree=0, Agree=1	

***Total Points*: _____**

***Total Possible Points*: _____**

Actionability Score (%): _____

(Total Points / Total Possible Points x 100)

[i] A very short print material is defined as a material with two or fewer paragraphs and no more than 1 page in length.

Appendix G

Permission to Use PEMAT

Permission to Use PEMAT was obtained from AHQR. The email is attached in PDF form to this packet. The transcript of the email is:

Dear Ms. Dudley:
This email constitutes formal permission from the Agency for Healthcare Research and Quality (AHRQ) for you to use the *Patient Education Materials Assessment Tool (PEMAT) and User's Guide* (AHRQ Publication No. 14-0002-EF) in your doctoral research at Maryville University, St. Louis (MO). You can print out multiple copies of the print or audiovisual tools to evaluate different versions of the patient education materials you are developing, or if you plan to have more than one person evaluate the material. You also have permission to print a copy of the User's Guide for yourself, your doctoral committee members, and other persons involved in scoring the patient education materials you are developing. You do not have permission to print and sell copies of the PEMAT materials for profit.

Please give credit to AHRQ in your thesis or capstone paper. The suggested reference citation for the PEMAT and User's Guide is:

> Shoemaker SJ, Wolf MS, Brach C. The Patient Education Materials Assessment Tool (PEMAT) and User's Guide. (Prepared by Abt Associates, Inc. under Contract No. HHSA290200900012I, TO 4). Rockville, MD: Agency for Healthcare Research and Quality; November 2013. AHRQ Publication No. 14-0002-EF. (Accessible athttps://www.ahrq.gov/sites/default/files/publications/files/pemat_guide.pdf).

If you need suggested citations for print or audiovisual tools (PEMAT-p or PEMAT-av)—or for the auto-scoring form, I will be glad to help.

I wish you all the best in your doctoral program.

Sincerely,

David I. Lewin, M.Phil.
Health Communications Specialist/Manager of Copyrights & Permissions
Office of Communications
Agency for Healthcare Research and Quality
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Phone: +1 301-427-1895
Fax: +1 301-427-1783

Appendix H

Informed Consent

Improving the Delivery of Multispecialty Evidence Based HPV Patient Education

You are being asked to participate in a project conducted through Maryville University by Corrie Dudley, DNP student. I am working under the direction of my faculty advisor, Dr. Geralyn Frandsen, Professor of Nursing and Assistant Director of Nursing at Maryville. The University requires everyone who agrees to participate in this project to provide consent to do so.

The overall purpose of this research is to improve the quality of care provided to patient during human papillomavirus (HPV) patient education by developing a multispecialty evidence-based educational tool.

Your participation will involve being part of an expert panel. Members of the expert panel will be asked to evaluate created HPV patient educational tool with a survey to validate the content of information. Additionally, some participants will also be asked to: 1. Evaluate the created HPV patient educational tool with survey for usable and actionable information, and/or 2. Evaluate current HPV patient educational tools with survey for content.

The amount of time of your participation will be no more than one hour per evaluation of created tool content. Multiple revisions of the created tool may be required and with each revision, you will be asked to evaluate the created HPV tool. The evaluation for usable and actionable information of the created tool will take no more than one hour. The evaluation of current educational tools may take between 1-2 hours.
This research study may include the risks of inadvertent breach of confidentiality. Every survey will be provided anonymously, however, a breach of this anonymity could occur if a person on the expert panel writes their name on a form or if demographic information allows one expert to be identified. This breech in confidentiality may cause the participant embarrassment or other unwanted emotional reaction.

To minimize risks and maintain confidentiality, the researcher will employ the following safeguards: No expert panel member will be asked to provide their name on any evaluation form. To assure the expert panel anonymity all evaluation will be converted to excel, the surveys will be locked, and after data analysis is complete the surveys will be destroyed.

We do not promise you will receive benefits from this study. The possible benefits for you from this research include actively participating to improve healthcare delivery. There are no incentives, monetary or otherwise, provided for participation in this study.
An alternative to this project study would be not participating.
The results of this study will be printed in a doctoral project as well as shared with my research advisor.
If you have any questions regarding this study, or if any problems arise, you may call the researcher, Corrie Dudley at (573) 576-2742 or the researcher's faculty advisor, Dr. Geralyn Frandsen at (314) 529-9439. You may also ask questions, state concerns regarding your rights as a research subject, or express any feelings of pressure to participate by contacting: Dr. Robert Bertolino, Chair of the Institutional Review Board at Maryville University, (314) 529-9659.
Maryville University recognizes its federally mandated responsibility to ensure that research be conducted in an ethical and scholarly manner, respecting the rights and welfare of all the human participants. Any research misconduct including but not limited to fabrication, falsification, or plagiarism in proposing, performing and reviewing research, or in reporting research results, should be reported to Dr. Tammy Gocial, the Research Integrity Officer at Maryville University at (314) 529-6893.
Maryville University investigators, and their colleagues who are conducting research, recognize the importance of your contribution to the research studies which are designed to improve (therapeutic care; educational learning environments – insert whatever is appropriate given the purpose of your study). Maryville University investigators and their staffs will make every effort to minimize, control, and treat any complication that may arise as a result of this research. If you believe you are injured solely as a result of the research question being asked in this study, please contact the principle investigator or the Chair of the Institutional Review Board. Maryville reserves the right to make decisions concerning payment for medical treatments for injuries solely and directly related to your participation in the research.
By returning the survey(s) completed in whole or in part, you acknowledge that you are at least 18 years of age and have read and understand this form, and that you have had an opportunity to ask questions about the research project. You are voluntarily agreeing to participate in a study based on the information presented to you. You may choose to withdraw at any time without prejudice or penalty. You have been provided a printed copy of this form, which includes the name and phone number of the researcher and the IRB at Maryville University, should you have any questions.

_____ _____ _____

Researcher's signature Date Phone Number

Appendix I

Timeline for Project

	Concept Analysis	Comprehensive Literature Review	Proposal	Submission to IRB at MV and site	Data Collection	Data Analysis	Data Interputation	Discussion Section	Final Paper	Dissemenation
8/16	XXXX									
9/16										
10/16		XXXXXXXX								
11/16		XXXXXXXX								
12/16		XXXXXXXX								
1/17			XXX							
2/17			XXX							
3/17			XXX	XXXXXX						
4/17				XXXXXX						
5/17				XXXXXX						
6/17										
7/17										
8/17					XXXXX					
9/17					XXXXX	XXXX	XXXXXXX			
10/17						XXXX	XXXXXXX	XXXXX		
11/17								XXXXX	XXX	
12/17										XXXXXXX

Appendix J

Collaborative Institutional Training Initiative (CITI) Certification of Human Subject protection training/education

Corrie Dudley (researcher) has successfully completed the following training:

CITI Health Information Privacy and Security (HIPS)

Students conducting no more than minimal risk research

Biomedical Responsible Conduct of Research

Appendix K

Expert Panel Recruitment Script

You are being asked to participate in a project conducted through Maryville University by Corrie Dudley, DNP student. I am working under the direction of my faculty advisor, Dr. Geralyn Frandsen, Professor of Nursing and Assistant Director of Nursing at Maryville. The University requires everyone who agrees to participate in this project to provide consent to do so.

The overall purpose of this research is to improve the quality of care provided to patient during human papillomavirus (HPV) patient education.

Your participation will involve being part of an expert panel. Members of the expert panel will evaluate the researcher developed HPV patient educational tool with a survey to validate the content of information provided. Additionally, some participants will also be asked to: 1. Evaluate the created HPV patient educational tool with survey for usable and actionable information, and/or 2. Evaluate current HPV patient educational tools with survey for content.

The amount of time of your participation will be no more than one hour per evaluation of created tool content. Multiple revisions may be required and with each revision, you will be asked to evaluate the created HPV tool. The evaluation for usable and actionable information of the created tool will take no more than one hour. The evaluation of current educational tools will take between 1-2 hours.

This research study may include the risks of inadvertent breach of confidentiality and anonymity of the survey. To minimize risks, no participant name will be listed on any evaluation form, and forms will be destroyed after data analysis is complete.

I do not promise you will receive benefits from this study. An alternative to this project study would be not participating in the expert panel. You may choose to withdraw at any time without prejudice or penalty.

The results of this study will be printed in a doctoral project as well as shared with my research advisor. If you are willing to participate I will provide contact information for myself, my faculty advisor, Chair of Institutional Review Board at Maryville University, and the Research Integrity Officer at Maryville University.

Appendix L

Created HPV Patient Educational Tool- Page 1

Human Papillomavirus

Fact Sheet

What is HPV?

HPV stands for Human Papillomavirus (HPV). There are more than 150 identified strains of HPV. HPV has been divided into two groups: high-risk and low-risk. High-risk strains of HPV are known to cause cancer, and low-risk strains not likely to cause cancer, such as strains that cause non-genital and genital warts.

How did I get HPV?

HPV is spread by direct skin contact with an infected person. HPV is easily spread through oral, vaginal, and anal sex, but can also be spread through intimate contact. HPV is the most commons sexually transmitted disease, and most sexually active people will be infected with HPV during their lifetime. It is possible to be infected with HPV in multiple areas of the body at the same time, such as the cervix and the rectum, or be infected with multiple strains of HPV at the same time. Rectal infection with HPV is common for both men and women wo do not have anal sex.

How is HPV be treated?

There is no treatment for HPV infection; there are treatments available for the problems caused by HPV, such as genital warts, cervical changes, and cancer. However, most infections are removed or suppressed by the immune system in 1 or 2 years.

What types of cancer does HPV infection cause?

HPV is a known cause of cervical, oropharyngeal (mouth/throat), anal, penile, and vulvar/vaginal cancers. Ongoing research suggests HPV may contribute to other forms of cancer. The development of a HPV-caused cancer can take decades from the initial HPV infection.

How do I know if I am at risk for developing cancer?

Most immune systems remove or suppress HPV infections within 2 years; however, there is no reliable way to predict when your body will clear the infection or if you will develop a persistent infection that leads to cancer. A persist infection with a high-risk HPV strain, smoking, and a weak or compromised immune system increase your risks for developing a HPV-caused cancer, A weak immune system can be caused by many things, including medical conditions (such as HIV) or medications (such as chemotherapy or steroids).

Do I need to be tested for HPV?

Women over the age of 30 years, can have cervical HPV screening done with Pap testing. For younger women and men, there are no recommendations for HPV screening. Because HPV infection in the mouth/throat and anus are common with no predictable test to detect or treatment for precancerous lesions, routine testing in these locations is not recommended.

September 2017

Appendix L

Created HPV Patient Educational Tool- Page 2

Talking to Your Partner

About HPV

- It can take years after exposure to HPV for the infection to be detected. This means it is usually impossible to determine when or from whom HPV may have been contracted.
- A recent diagnosis with HPV does not necessarily mean someone has been unfaithful.
- Most infections with HPV go undiagnosed, and these infections do not result in visible symptoms or health complications.
- Some strains of HPV cause warts and some strains cause cancer, but rarely will one strain of HPV cause both warts and cancer.
- It is possible to be infected with multiple strains of HPV at the same time.
- It may be possible to have a "subclinical" case of HPV, where the virus is suppressed to the point that the viral load is not detected by the test but may remain in the body. In these cases, spreading HPV to sexual partners will become less likely over time.
- The medical risks of HPV do exist for both men and women. Both partners need to be aware of signs and symptoms of genital, anal, and oral cancers.
- When the diagnosis of high-risk HPV infection is made in one partner, it can be assumed both have been or are infected. For this reason, both partners should inform all your healthcare providers, and discuss your personal risk.

Can I prevent HPV infection?

Yes, Vaccination can prevent infection. The HPV vaccine, Gardasil-9, protects against the 7 most common high-risk strains and 2 strains that cause genital warts, and has been shown to be very safe and effective. HPV vaccine is recommended for boys and girls at age 11 or 12, however, if you did not get the vaccine at that time, you can be given the vaccine through age 26. Vaccination is not recommended past the age of 26. Ways to decrease your risks for HPV are limiting sexual partners and consistent us of a barrier, such as condoms. Condoms do not prevent HPV, but correct and consistent condom use, can decrease your risk.

What can I do about a current HPV infection?

A healthy diet and exercise are important for creating a strong immune system, which will remove the HPV infection. Tobacco use increase the risk of persistent infection, so if you use tobacco products, quitting can help. If you are under the age of 27, and have not started or completed the HPV vaccine series, you should start of finish vaccination. Finally, if you are infected with a high-risk strain of HPV, you need to know signs and symptoms of all the HPV caused cancers, share any concerns you may have with your healthcare provider, and keep recommended follow-up appointments.

Where Can I Find More Information?

National Cancer Institute
www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-fact-sheet

National Cervical Cancer Coalition
www.nccc-online.org/hpvcervical-cancer/cervical-cancer-overview/

The Oral Cancer Foundation
oralcancerfoundation.org/understanding/hpv/hpv-oral-cancer-facts/

American Cancer Society
www.cancer.org/cancer/anal-cancer/causes-risks-prevention/risk-factors.html

MD Anderson Cancer Center
www.mdanderson.org/publications/oncolog/august-2016/screening-for-hpv-related-cancers.html

The CDC
https://www.cdc.gov/hpv/index.html

National Cancer Institute
https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-vaccine-fact-sheet

9/2017

Appendix M

Expert's Written Response

1. "'Page 2' & 'Fact Sheet' may be better as page 1 and 'Talking to Your Partner'-page 2"*
2. "Overall- Excellent Work"
3. "Just a suggestion: you might not want to name the product Gardasil since trade names may change, e.g. Just say there is one available which covers those types"
4. "I might like to have the immunization schedule for the series of injection requirement for immunity"
5. "The discussion of anal lesions may be more fully explained by gravity or touching"
6. "A description of the raised rough painless lesions may be helpful for the lay person to distinguish from herpes or other infections."
7. "I like the colors on the information and the layout is easy to read"
8. "The rational for HPV screening could have been better explored"
9. "I plan to start using this immediately, Great information"