Ogilvy Public Relations Worldwide

HUMAN PAPILLOMAVIRUS HEALTH CARE PROVIDER MATERIALS TESTING REPORT

Final Report

Prepared by Ogilvy Public Relations Worldwide and the Centers for Disease Control and Prevention

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I. Introduction

A. Background

Genital HPV is the most common sexually transmitted viral infection in the United States (U.S.), with approximately 20 million Americans currently infected (CDC, 2005). It is spread through genital contact during sex. It is so prevalent that most sexually active adults will have it at some point in their lives, though most will never know it because the majority of infections are asymptomatic and resolve on their own without clinical consequence. The types of HPV that affect the genital area are characterized by the sequelae they can produce. Types known as "low risk" can cause genital warts, while other types, known as "high-risk," are associated with anogential cancers, the most common of which is cervical cancer in women. Yet cervical cancer is a rare outcome of HPV infection, particularly in women who receive routine cervical cancer screening and appropriate follow-up. In the U.S., cervical cancer most often occurs among women who are never or rarely screened. (Gerberding, 2004)

The Pap test, using either conventional or liquid-based cytology methods, remains the gold standard for cervical cancer screening in the U.S. (Sawaya, 2005). However, the recent introduction of HPV DNA testing has resulted in new options for cervical cancer screening and management (*see Appendix A for more information on cervical cancer screening technologies and guidelines for use*). Moreover, promising research now offers hope of a vaccine to prevent certain types of genital HPV infection and their sequelae in the next few years. While there remain many unanswered questions about the transmission, prevention, progression, and clearance of HPV, research from basic, clinical, and behavioral sciences are quickly moving this field forward.

As the science and technologies evolve, it is important that health care providers keep current with information about HPV and related conditions, since they play a critical role in the prevention, diagnosis, treatment, and management of anogenital warts, cervical dysplasia and cervical cancer. Yet in 1999, a Centers for Disease Control and Prevention (CDC) report of an external consultant's meeting indicated that some providers may be unaware of the latest information about genital HPV infection and HPV-related conditions. The report concluded that many clinicians were unclear "about the relationship of genital warts to cancer, the indication for use of various management strategies [for anogenital warts and abnormal Pap test results], transmission-related issues, and the indications for partner evaluation [for patients with HPV-related conditions]" (CDC, 1999). This may come as little surprise, in light of a recent review of available print and online provider education materials, which revealed that information in these materials may be outdated, inaccurate, or incomplete (ACOG, 2004).

It is also imperative that providers possess current knowledge of HPV because they play an essential role in educating patients about HPV and its associated conditions. Providers have been cited as the primary and most trusted sources of HPV-related information by members of the general public (ORC Macro, 2003; Ogilvy PR & CDC, 2005) and by patients with genital warts (Maw et al., 1998) or an HPV-positive test result (McCree & McFarlane, 2005; Sharpe et al., 2004). Clinicians can provide psychosocial support and counseling to these patients and help them make informed decisions about treatment options and the future prevention of HPV transmission to sex partners (Harper, 2004; Maw et al., 1998; Reitano, 1997). This is important, since several studies suggest that newly diagnosed patients, particularly women with HPV-positive or abnormal Pap test results, have many questions about sex partners and may experience considerable psychological distress, anxiety, fear, and confusion (Beresford & Gervaize, 1986; Brandt et al., 2004; Doherty et al., 1991; Filiberti et al 1993; Fylan et al., 1998; Gath et al., 1995; Lerman et al., 1991; Linnehan & Groce, 2000; Marteau et al., 1990; McCaffery et al., 2003; McCree & McFarlane, 2004; Quilliam, 1988; Rogstag, 2002; Ramirez et al., 1997; Reitano, 1997; Sheppard et al., 1995; Spigener & Mayeaux, 1998; Stone, 1995; Waller et al., 2004; Waller et al., 2005; Wilkinson et al., 1990; Wyatt et al., 2003a; 2003b). Women who do not understand the meaning or implications of their positive HPV or abnormal Pap test results may experience high levels of anxiety, distress, and concern, which can serve as barriers to follow-up (Beresford & Gervaize, 1986; Fylan et al., 1998; Lerman et al., 1991; Lerman et al., 1992; Maissi et al., 2004; Marteau et al., 1990).

Studies have shown that patient counseling and education about an abnormal Pap test result can reduce patients' psychological distress and fears of cancer, and enhance their ability to cope and comply with medical follow-up (Lerman et al., 1992; Linnehan & Groce, 2000). Other studies suggest that accurate information about HPV, its link to cervical cancer, and appropriate follow-up care, can alleviate women's fears and concerns about an HPV-positive test result (McCaffery et al., 2003; Waller et al., 2004).

Until recently, only limited information has been available about clinicians' HPV-related knowledge. Some studies have suggested that a misinformed provider may mismanage, mistreat, and misinform patients diagnosed with genital warts or HPV-positive or abnormal Pap test results, which can result in unnecessary medical procedures and undue anxiety for patients (Chandler, 1996; Clarke et al., 1996; Filiberti et al 1993; Maw et al., 1998; Reitano, 1997; Sheppard et al., 1995). Moreover, there is little data on the extent to which scientifically accurate and updated information is shared with patients diagnosed with HPV and associated conditions, or to which non-judgmental, supportive counseling is provided.

B. Purpose of the Research

In early 2001, Congress mandated that the Secretary of Health and Human Services prepare and distribute educational materials for healthcare providers and the public that include information on HPV. Such materials were to address the following: a) modes of transmission; b) consequences of infection, including the link between HPV infection and cervical cancer; c) the available scientific evidence on the effectiveness or lack of effectiveness of condoms in preventing infection with HPV; and d) the importance of regular Pap smears and other diagnostics for early intervention and prevention of cervical cancer. This report addresses CDC's efforts to develop and test effective and appropriate educational materials to reach health care providers.

To inform its health education efforts, CDC's Division of Sexually Transmitted Disease Prevention (DSTDP) has engaged in literature research and qualitative and quantitative research activities including interviews, focus groups, national surveys to explore health care providers' a) knowledge, attitudes, and practices regarding the prevention, screening, diagnosis, and management of genital HPV and associated conditions; b) attitudes and perceptions about female patients who received positive HPV test results in the context of cervical cancer screening; c) HPV-related patient communication and counseling practices; and d) HPV-related information needs. This research was funded through external contracts and extramural research programs. It included:

- Key-informant interviews with primary care clinicians and health care professionals who diagnose and manage patients with anogenital warts, provide cervical cancer screening, and manage abnormal Pap tests; HPV researchers, developers of HPV educational materials, laboratory representatives, health maintenance organization representatives, and developers and marketers of HPV-specific products and services. This research was conducted by ORC Macro (ORC Macro, 2002);
- Focus groups with primary care clinicians (working in family practice, general practice, adolescent medicine, college health, and internal medicine) and health care professionals (working as physician's assistants, nurse practitioners, and nurse midwives) in the U.S. This research was conducted by ORC Macro (ORC Macro, 2002);
- In-depth discussion groups with 35 health care providers in a rural region of South Carolina, across a range of specialties, including obstetrics and gynecology (OB/GYN); general, internal, preventive, and family medicine; and social work. This research was conducted by the University of South Carolina (Sharpe et al., 2002);
- In-depth interviews of 34 primary care and specialty clinicians who diagnose and manage patients with anogenital warts, provide cervical cancer screening, and manage abnormal Pap tests. This research was conducted by CDC under contract with Battelle Centers for Public Health Research and Evaluation (Battelle, 2005); and
- A national survey of over 4,000 physicians and mid-level clinicians from nine specialty areas, including family and general practice, general internal medicine, adolescent medicine, OB/GYN, dermatology, and urology physicians; and nurse practitioners, certified nurse midwives, and physicians' assistants. This research was conducted by CDC under contract with Battelle Centers for Public Health Research and Evaluation (Battelle, 2005).
- Literature reviews on patient and provider knowledge, attitudes, behaviors (KABs) and communication practices and preferences related to HPV infection, genital warts, cervical cancer, and cervical cancer screening and prevention; as well as reviews of available HPV-related educational resources and materials for patients and providers. This research was conducted by CDC (Friedman, 2003).

This research on providers, along with formative research conducted with the general public and patients, was used to inform the development of CDC's National HPV Health Communication Plan and to refine communication goals and strategies for reaching providers. Key findings from this provider research are reviewed below.

C. Key Research Findings

1. Provider Knowledge

According to CDC qualitative research conducted in 2002, the HPV-related knowledge of some providers was not completely up-to-date, particularly among primary care clinicians, compared to other health care professionals (ORC Macro, 2002). Focus groups revealed that some clinicians were not well informed about the natural history, management, treatment, or prevention of genital HPV infection and associated conditions. Some were unaware of appropriate guidelines for partner notification, prevention, and management of HPV, and did not understand the science supporting the effectiveness or lack of effectiveness of condom use for reducing the risk of HPV infection, cervical cancer, or anogenital warts. Even some providers who treated HPV-associated conditions in their practice held misconceptions about the link between genital warts and cervical cancer. Both providers and key-informants in this exploratory research voiced the need to establish definitive and accessible sources of HPV information, either based on a consensus or endorsed by national clinical organizations. Respondents stressed that such sources should acknowledge both the known facts about HPV, as well as information about HPV that is currently unknown or evolving (ORC Macro, 2002).

In-depth individual interviews with 34 primary care and specialty clinicians supplemented this research, supporting earlier research findings that many clinicians were not clear that different HPV types are related to warts and cancer. Moreover, clinicians did not conceptualize or manage patients in terms of genital HPV infection per se. Rather, they conceptualized genital HPV infection in terms of the HPV-related diseases that generate symptoms or signs (such as anogenital warts, abnormal Pap tests, etc.), and treated genital warts and cervical abnormalities as two different clinical entities. For some, this may be due to the fact that, unlike other STDs for which screening for infection status is commonplace (e.g., chlamydia, gonorrhea, syphilis), tests to screen male patients for any indication and to screen female patients for HPV infection outside the context of cervical cancer screening, are not approved by FDA or recommended by national guidelines. (Barnes, Hsu, Freeman, 2003; ORC Macro, 2002)

This research was expanded upon in 2004 with a national survey, which showed that the vast majority of respondents knew that HPV infection is common (89%), often asymptomatic (95%), a risk factor for cervical dysplasia and cancer (98%), and the cause of anogenital warts (87%). However, less than half of respondents knew that most genital HPV infections clear without medical intervention (35%), that the HPV types usually associated with genital warts differ from those usually associated with cervical cancer (47%), and that genital warts do not increase cancer risk at the same anatomic site where the warts are located (38%). More than one-third did not know that genital HPV infection increases the risk of anogenital cancer in men. (Battelle, 2005; Freeman et al., 2005)

These findings highlight the need to reach providers with accurate and current information about the natural history, epidemiology, prevention, and treatment of genital HPV infection and associated conditions. These materials should cover information about (a) the transient nature of HPV; (b) the links between HPV, cervical cancer, and genital warts, including the distinction between cancer-causing and wart-causing types of HPV; and (c) guidelines for patient screening, management, and treatment.

2. HPV-related Screening, Management, and Treatment Practices

i. Genital Warts. Results from the qualitative and quantitative research revealed that men and women with genital warts are generally treated by the clinician and monitored through follow-up. Many (including 70% of nationally surveyed clinicians) also reported testing these patients for other sexually transmitted infections (STIs). However, patients were managed differently depending on gender, with female patients typically being referred for Pap testing, a practice that is not recommended by CDC (Battelle, 2005; ORC Macro, 2002). In fact, about 80% of national survey respondents reported recommending prompt Pap testing to female patients and almost 50% reported recommending that these patients receive more frequent Pap testing in the future (Battelle, 2005).

The majority of national survey respondents (70%) expressed a desire for clinical training materials or support tools addressing the diagnosis and treatment, biologic causes, modes of transmission, and methods of prevention of genital warts (Battelle, 2005). They also wanted to know how to counsel patients about informing their sex partners, and about any upcoming vaccines to prevent acquisition of genital HPV or genital warts.

ii. Cervical Cancer. *Screening Guidelines.* According to results from CDC's national provider survey, the most commonly reported screening and management guidelines used by Pap test providers were those of the provider's own clinical specialty organization, followed by the American College of Obstetrics and Gynecology (ACOG), CDC, and the American Cancer Society (ACS). Most (78%) of these providers reported using liquid-based cytology, which facilitates HPV test specimen collection. (Battelle, 2005; Irwin et al., 2005)

In 2002, qualitative research had indicated that many providers were confused about the appropriate screening and management practices for cervical cancer. They took a relatively aggressive, "better safe than sorry" approach toward monitoring and managing patients with borderline or *atypical squamous cells of undetermined significance*[1] (ASCUS) and more severe Pap test abnormalities. These providers had expressed the need for a definitive set of guidelines on cervical cancer and HPV screening, detection, and management of abnormal results, which would address the impact of these recommendations on resources, cost, time, and quality of life. At the time, they had identified the prevention and detection of HPV infection as the most critical areas of need for further education and training. (ORC Macro, 2002)

Pap Test. National survey results revealed that among the 2,980 primary care clinicians who reported providing Pap tests at their primary practice site, over 75% provide liquid-based cervical cytology. This technology was reportedly used by fewer adolescent medicine physicians (58%) than other clinical specialties. Almost half (46%) of Pap test providers in this survey indicated that patients with abnormal Pap tests can receive cervical colposcopy at their practice.

More than 90% of surveyed clinicians reported that clinical training materials, clinical decision support tools, or patient materials should address information about abnormal Pap tests, including the biologic causes, appropriate follow-up and treatment, influence of treatment on persistent HPV infection and infectiousness to partners, and whether they are related to external anogenital warts, fertility, pregnancy outcomes, or newborn health.

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[1] A result is classified as 'ASCUS' when the cell sample does not clearly fit within the 'normal' or 'precancerous/cancerous' categories.

HPV Test. At the time of CDC's exploratory research in 2002, most providers were not aware of the HPV DNA test (ORC Macro, 2002), which had recently been approved by the U.S. Food and Drug Administration (FDA) as a follow-up test for women who had abnormal or inconclusive Pap test results[2] (US FDA, March 2000).

Later that same year, discussion groups were conducted in South Carolina with providers from four federally funded clinics who were using the HPV DNA test with Paps for cervical cancer screening. At that time, providers were unaware of whether their particular clinic had a standard or written protocol for HPV DNA testing. Some providers reported that the test was automatically performed by the labs on Pap results of ASCUS or higher. Others reported that it was performed "when indicated," which was vaguely defined by a woman's level of risk, determined by a combination of characteristics, including history of HPV infection, other STDs, or vaginal infections; being 19-50 years of age; having multiple sex partners; and being single. Management of HPV varied across clinic sites. Generally, women with high-risk HPV were referred for colposcopy or treated with cryotherapy, whereas women with low-risk HPV were recommended for a repeat Pap test in three-to-six months. (Sharpe et al., 2002)

CDC's national provider survey revealed that while some respondents were unaware of the HPV test, about half (54%) reported ever using the test. Use of the HPV DNA test differed by provider specialty, with adolescent and internal medicine physicians reporting the lowest rates of use, and OB/GYNs, nurse midwives, and those with on-site colposcopy capability reporting the highest rates of use. Among the subset of providers who reported using the HPV test for patients with borderline or abnormal Pap test results, the majority reported using the test for patients with borderline ASCUS Pap tests, an indication approved by FDA and endorsed by national guidelines. However, many also reported using the test for patients with higher-grade abnormalities, for which HPV testing is not approved or recommended. Roughly one-fifth of surveyed providers also reported using the HPV test as an adjunct to Pap, although it was more commonly used for patients under 30, for whom the test is not recommended, than for those over 30, for whom the test is recommended. Other non-approved uses of the HPV test were also reported. For example, between one-quarter and one-third of providers reported using the test to check HPV infection status of patients diagnosed with other STDs (34%) or genital warts (33%), and to check the sex partners of patients with other STDs (21%). Also, 30% reported using the test to check infection status of asymptomatic patients and those who requested the test. Additionally, between 16% and 32% of providers reported using the test in men, for whom the test is not FDA-approved or recommended by national guidelines. (Battelle, 2005; Jain et al., 2005; Irwin et al., 2005)

More than 90% of surveyed clinicians said they felt the following topics would be important to include in clinical training materials, clinical decision support tools, or materials for educating or counseling patients: (a) the role of the HPV test in cervical cancer screening; (b) modes of genital HPV transmission and methods of future prevention; (c) the value of informing sex partners and

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[2] It should be noted that it was not until March 2003 that the FDA approved expanded use of the HPV DNA test, to include simultaneous use with the Pap test to screen for cervical cancer in women age 30 and older. Interim guidelines issued by the National Cancer Institute, the ASCCP, and the American Cancer Society recommended that if this combination is used, women who receive negative results on both tests should be re-screened no more frequently than every 3 years (Wright et al., 2004).

how to counsel patients on this; and (d) information on future preventive vaccines. (Battelle, 2005)

3. HPV-related Education and Counseling Practices

Focus groups and in-depth interviews with primary care and specialty clinicians revealed that clinician-patient conversations are driven by the particular HPV-related diagnosis. Wart manifestations generate discussions about treatment and the sexually transmitted nature of HPV, whereas cervical abnormalities generate discussions about more frequent Pap testing, but seldom about HPV as an STD (Barnes, Hsu, Freeman, 2003; ORC Macro, 2002).

i. HPV-related Education and Counseling Practices in the Context of an External Genital Warts Diagnosis. Results from focus groups with health care professionals and clinicians revealed that the topic of HPV arises naturally when a patient presents with genital warts. These providers indicated that such conversations typically consist of three main components: education about HPV, available treatment options, and the importance of follow-up. According to providers, discussions of treatment options typically involve a dialogue about the cost and pain associated with each treatment, as well as an explanation that successful treatment does not mean the virus has been cured. Effectively conveying the concept that the virus can still be present and infectious even once the lesions have cleared was perceived to be a major challenge to these discussions. (ORC Macro, 2002)

National survey research further indicated that the vast majority of surveyed providers reported discussing sexual risk, STI prevention, and prevention of future HPV transmission with genital wart patients. They reported telling patients that not much is known about the duration of infection or the likelihood of future transmission. (Battelle, 2005)

Many providers in both the qualitative and quantitative studies also reported counseling female patients with genital warts about their increased risk of developing cervical cancer and the need for more frequent Pap tests (ORC Macro, 2002; Battelle, 2005). Providers in the focus groups expressed that a major challenge to these discussions was trying to strike a balance between patient concern and reassurance, so that the patient was not too afraid to return for follow-up (ORC Macro, 2002).

ii. HPV-related Education and Counseling Practices in the Context of Cervical Cancer Screening. Qualitative and quantitative research has suggested that providers do not consistently address HPV with their patients in the context of cervical cancer screening, and that when they do they may not be conveying accurate information to their patients (Sharpe et al., 2002; ORC Macro, 2002). Results from provider focus groups and from the national provider survey revealed that most providers do not address HPV with women in the context of cervical cancer screening, unless a patient receives an abnormal Pap test result (ORC Macro, 2002; Sharpe et al., 2002; Battelle, 2005; Jain et al., 2005).

Several major barriers to discussing HPV were commonly identified by providers in both research studies, including (a) provider discomfort addressing sexual topics and patients' emotional reactions to a diagnosis; (b) the lack of answers to common patient questions related to acquisition and future transmission; (c) the difficulty explaining the scientific uncertainties and complexities of HPV infection in meaningful terms; (d) uncertainty about recommendations for partner notification and testing; and (e) the time constraints placed on the patient-provider encounter (ORC Macro, 2002; Sharpe et al., 2002). Many of these findings also emerged in the national survey, as challenges to HPV-related discussions with patients (Battelle, 2005).

In both qualitative research studies, providers identified the need for materials to facilitate patient counseling and tools to promote effective communication about future prevention of HPV transmission, as well as recommendations for partner disclosure and management. For example, they wanted tools to help answer difficult but common patient questions about HPV in meaningful, simple terms, and to effectively communicate the role of the Pap and HPV tests; the importance of follow-up; and screening guidelines based on age, cost, and quality of life. Further, they identified the need for culturally and literacy appropriate patient materials in English and non-English languages, which can be accessed for free or at low-cost. (ORC Macro, 2002; Sharpe et al., 2002)

4. Research Implications

Together, this research suggests that sub-optimal prevention and clinical practices may be common, highlighting the need for interventions to promote HPV-related prevention, testing, management, and treatment practices that are evidence-based and consistent with national guidelines. Moreover, some providers may share inaccurate, outdated, or incomplete information with patients who have HPV-related diagnoses (Battelle, 2005; ORC Macro, 2002; Sharpe et al., 2002), which may be adding to the anxiety these patients already experience. It suggests the need to educate health care providers about the rapidly evolving science of HPV to promote appropriate clinical practices and the dissemination of accurate information from providers to their patients, and from patients to their partners.

D. Development of an Evidence-Based HPV Health Communication Plan

The research findings support the need to develop scientifically accurate and up-to-date clinical training materials, clinical decision support tools, and patient education and counseling materials to help guide clinicians in the prevention, screening, management, treatment, education, and counseling related to HPV infection and associated diseases. Findings were used to inform the development of evidence-based materials to support optimal clinical practice and patient education and counseling.

In response to this research, CDC identified the need for an approach that focuses first on increasing provider knowledge about the science of HPV and cervical cancer screening guidelines, and second on improving patient-provider communication. CDC outlined two main objectives for provider education in its HPV Health Communication Plan (CDC, 2004):

1. To increase provider knowledge and use of cervical cancer and Pap screening guidelines.

2. To enhance health care providers' abilities to communicate more effectively about HPV with their patients.

This plan was further refined and expanded in fall 2004, as follows:

1. Develop and test messages/materials to educate providers about HPV with the goal of improving provider knowledge and clinical and management practices related to HPV infection and HPV-related conditions.

2. Develop and test messages/materials to assist health care providers in their HPV-related communications and counseling with patients[3], with the goal of facilitating and improving patient-provider interactions regarding HPV, particularly with low-literacy, non-English-speaking patients. These messages will also be tested with patients.

The following report outlines the educational materials development and testing process, addressing the first objective in this plan. Activities to accomplish the second objective of developing and testing counseling materials and support tools will begin in summer/fall of 2005. A report on that process will be published upon completion of that task.

II. Methodology

Ogilvy PR contracted with J. Reckner Associates, Inc. (JRA), a marketing research firm, to conduct a minimum of 36 and maximum of 45 telephone interviews in May 2005 with three main types of health care providers (physicians, nurse practitioners, and registered nurses), working predominantly with one of five identified racial/ethnic segments of patients (African American, Asian American, Caucasian, Hispanic, and Native American), across a mix of primary care specialties and practice settings, all of which served primarily lower income patients.

Ogilvy PR aimed to recruit primary care providers working with the identified target audiences. Upon the guidance of an external HPV expert consultant, CDC identified physicians, nurse practitioners, and registered nurses as priority segments, based on the greatest need for, and potential to benefit from educational materials about HPV. The project's recruitment criteria excluded OB-GYNs because it is believed that these providers generally have a greater knowledge of HPV and already have been targeted by HPV information initiatives sponsored by other organizations.

A. Research Approach

A two-pronged research approach was used to collect reactions to draft materials. First, a one-hour telephone interview was conducted with primary care providers to gather feedback on the pamphlet content and design, as well as preferences and needs for HPV educational materials. Second, eight CDC subject matter experts (SMEs) reviewed the draft brochure and provided input on the scientific accuracy and appropriateness of scope and content. They also provided feedback on the pamphlet designs. The recommendations at the end of this report reflect the final analysis of the two sets of data.

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[3] Patients were defined as women with a diagnosis of high-risk HPV (from HPV DNA test), ASCUS, or abnormal Pap test result

B. Participant Segmentation

To allow for possible differences by provider type and population served, the research design segmented providers by the following variables:

1. Patient Population

The providers primarily served one of five specific patient population segments, including African Americans, Asian Americans, Caucasians, Hispanics, and Native Americans. Providers were segmented this way to account for cultural differences they may encounter related to norms, attitudes, and behaviors regarding health care seeking, cancer prevention, and sexual health within that patient population. Providers working with African-Americans, Caucasians, and Hispanics were selected because these populations represent the largest racial and ethnic population segments in the U.S. Providers working with Asian Americans and Native Americans also were included due to the high rates of cervical cancer incidence within these groups. A total of six to nine providers were interviewed from each patient racial and ethnic group.

For the Asian American population segment, only providers who worked with Korean, Filipino, or Vietnamese populations were considered due to the higher rate of cervical cancer incidence in these sub-segments. Providers working with Native Americans were recruited if they worked in the following identified Indian Health Service Areas, which have higher cervical cancer incidence and mortality rates: Bemidji, Phoenix, Navajo, and Oklahoma. In addition, providers working with Hispanic and Asian American patients were not selected for participation if English was the primary language spoken by their patients.

In addition to the required population segments, providers were required to work with female patients between the ages of 18 and 65. An emphasis was placed on recruiting providers who worked primarily with lower income patients.

2. Provider Type

Within each patient racial or ethnic group, participants were further segmented by provider type (physicians, nurse practitioners, and registered nurses) to account for possible differences in the types of information and/or resources needed. The recruiters aimed to include one registered nurse per group, and three to four physicians and nurse practitioners per group.

3. Specialty Area, Practices, and Location

Participants were recruited to obtain a mix of specialties (family practice, general practice, and general internist) and primary practice settings (ranging from solo practice, to community health clinic, and to a government health facility). *A complete list of practice settings is provided in the Recruitment Screener in Appendix B.* The recruitment process was designed to ensure that at least half of providers performed Pap tests and provided health maintenance exams/routine checkups. In addition, the participants were required to spend more than 20 hours a week in direct patient care; see more than 20 percent female patients; and be in practice for more than one year. All of the providers were required to see HPV positive patients each quarter, with a diagnosis of HPV defined as detection of genital warts, a positive HPV test result, abnormal Pap test, or a combination of these factors.

In addition, providers were recruited across geographic locations to achieve a mix, with a special effort not to over-recruit in New York and Los Angeles, where several focus groups were held during previous phases of this research. For providers working with Native American populations, recruitment focused on providers in the Indian Health Service Areas of Bemidji, Phoenix, Navajo, and Oklahoma.

C. Participant Recruitment

Participants were recruited by JRA's professional fieldwork firms based on the following specifications:

- Potential participants only were considered if they met the following inclusion criteria:
    - ➢ Currently a practicing physician, nurse practitioner, or registered nurse
    - ➢ Spend 50 percent or more time in a family practice, general practice, or general internist specialty
    - ➢ Spend more than 20 hours a week in direct patient care[4]
    - ➢ Have more than 20 percent female patients between the ages 18 and 65
    - ➢ Have been in practice for more than a year
    - ➢ Have a patient population of which 60 percent or more is from one of the five designated racial/ethnic groups[5]

- Potential participants were not selected for participation if they met the following exclusion criteria:
    - ➢ Had ever been employed in a OB-GYN or specialty outside of primary care
    - ➢ Had ever been employed in a hospital or other inpatient setting
    - ➢ Do not see any patients with a diagnosis of HPV each quarter
    - ➢ Had ever participated in a focus group about HPV or cervical cancer during the prior six months

The recruiters were provided with a recruitment screener that outlined the inclusion and exclusion criteria to guide the identification of appropriate participants. *A copy of the screener can be found in Appendix B.* Per instruction from CDC and Ogilvy PR, the recruiters aimed to recruit a minimum of six and a maximum of nine participants for each population segment.

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[4] *In some groups where recruiting was difficult, the hours working in direct patient care requirement was relaxed slightly to include participants who worked only 16 hours a week.*

[5] *In groups where recruiting was difficult, the patient population requirement was slightly relaxed to include participants for whom 50 percent of their patient population was from the designated population.*

Participants were identified through various methods, including utilizing JRA's national provider databases, snowball sampling (asking those recruited to refer colleagues who meet the criteria), and referrals from CDC's partner organizations, as needed. Also, participants were recruited from geographic locations across the country based on a high concentration of the identified racial/ethnic patient populations in those areas.

Participation in the focus groups was confirmed by a letter and telephone call. Potential participants were told they would receive a monetary incentive for participating in the focus groups. The incentives matched the competitive market price of $150.00 for physicians and $125.00 for nurse practitioners and registered nurses. *Copies of the informed consent forms are provided in Appendices C1-C2.*

D. Screener and Interview Guide Development

Ogilvy PR developed a screener instrument and an interview guide in consultation with CDC and JRA. CDC approved the final versions of these elements prior to the interviews. Following the first interview, slight revisions were made to the guide to ensure there was sufficient time to cover all of the topics and questions and to probe for participant questions and concerns. The revised interview guide was used in all of the subsequent interviews. *A copy of the final interview guide is provided in Appendix D.*

E. Materials Tested

1. Pamphlet Content

One version of the text for the Clinicians' Educational Pamphlet on Genital Human Papillomavirus was tested with the participants. The content was provided in a Word document with limited design. The pamphlet content was developed with direction from an external HPV expert in consultation with CDC. CDC provided input into and approval of the final content that was tested. Topics covered in the pamphlet include HPV transmission, prevention, testing, and clinical management, and are outlined further in the *Discussion Topics* section below. *A copy of the pamphlet content is provided in Appendix E.*

2. Pamphlet Designs

Two sets of pamphlet designs, which were randomly labeled A and B, were tested with the participants. The designs contained minimal copy – primarily key headings and tables. The designs only were incorporated into the first four pages of each pamphlet, with blank pages filling the rest of the pamphlet to indicate the approximate length of the piece. *Copies of the pamphlets can be found in Appendices F1-F2.*

Design A compliments the CDC HPV general population materials, with a brighter and more informal look and feel. The primary color was orange-brown, and the shape was slightly wider and shorter than a typical pamphlet. The cover included four photographs, two representing health care providers and two depicting medical images. The inside pages contained two clinical images.

Design B had a more traditional look. Its primary color was blue, and it was sized as a standard pamphlet that fits into a #10 business envelope. The cover contained a list of the key topics addressed by the content, and a larger version of the program identity image and CDC logo. Design B's inside pages contained five clinical images – several more than Design A.

F. Conduct of Interviews

Each interview was conducted by a professional moderator with audiotaping and transcription services. Observers from Ogilvy PR and CDC listened to the interviews in a listen-only mode (preventing them from speaking directly with participants) in order to take notes. Each participant was asked to complete and return a consent form via fax two days prior to the interview. The consent form confirmed the information each participant had provided during the recruitment process; provided information about the focus group topic; disclosed that the interview would be audio-taped and monitored; stated the participants' rights; and provided an assurance that participant responses would remain confidential and accessible only to the study team. Participants also received a packet of materials in advance of the call, which included the pamphlet content in a Word document and color mock-ups of Designs A and B.

After providing a brief overview of the interview process, and confirming that the participants had received the package of testing materials and reviewed them prior to the call, the moderators presented the discussion topics by posing questions from the interview guide. As the participants responded to the various pre-determined questions, the moderators posed additional questions to explore participants' responses and reactions in order to obtain as much detail as time allowed. At the end of each interview, the moderator thanked the participants for their time, instructed them to return the testing materials in a provided FedEx envelope, and advised them on when they would receive their incentive payment.

G. Discussion Topics

The interview guide was designed to explore participants' responses to the materials described above, their needs for additional materials and their communication preferences, after briefly assessing their current HPV-related clinical practices and information sources.

1. Current Practices

The participants were asked about their current practices for cervical cancer screening, HPV testing, and patient counseling regarding HPV-associated conditions, as well as whether they perform colposcopy in their practice.

2. Information Sources

The participants were asked about the primary influences that have shaped the practices described above, and about the genital HPV educational tools and materials they find useful for themselves and for their patients. They also were asked the best way for CDC to reach them with information about the materials being tested.

3. Pamphlet Content

For purposes of discussion, the pamphlet content was broken into four key sections that addressed a series of different topics. The sections were structured as follows:

Section 1

- Why is HPV Important?
- What is HPV?
- Types of HPV
- How Common is HPV?
- What Are the Risk Factors for Acquiring a Genital HPV Infection?
- How is HPV Transmitted?
- Natural History of Genital HPV Infections

Section 2

- What is the Risk Associated with Genital HPV Infection?
- Prevention of Genital HPV Infection

Section 3

- Counseling People Infected with Genital HPV
- HPV Vaccines
- Prevention of Cervical Cancer

Section 4

- HPV DNA Testing
- Clinical Management Issues

Participants were asked to review each section with the moderator and answer a series of questions. The questions covered participants' initial reactions to the information along with probes about what was confusing or useful. Following discussion of the fourth section, the participants were asked questions about the content overall, such as what they would do with the information; whether it would be useful to them; and how it could be improved upon.

4. Pamphlet Design

Participants were asked whether they preferred Design A or Design B. Once they had made their selection, they were asked specific questions about the preferred design, including reactions to the overall look, colors, organization, and clinical images. Participants also were asked questions about the format, such as whether they would like the pamphlet to contain tabs and whether they would prefer the algorithms to be provided on a heavy-stock paper or as a tear-off. At the end, participants were asked to briefly discuss why the other design did not appeal to them.

In addition, participants were asked about the types of HPV materials that they would prefer for their practice in terms of size and format, and whether they would use the designs being tested. They also were asked about which elements would be most useful to them in a toolkit, what additional tools they might find useful, and what would make them least likely to disregard or throw away the materials.

H. Supplemental Scientific Review by CDC Experts

Eight CDC subject matter experts were sent the draft pamphlet content and asked to provide feedback on the scientific accuracy, scope, and appropriateness of the material. The experts provided feedback by sending written comments. Seven experts also provided comments on the two pamphlet designs, either through email or verbal communication with the CDC Project Officers.

I. Analysis Approach

As an observational method, interviews yield qualitative findings that cannot be statistically analyzed. Similarly, the written comments provided by the CDC experts are difficult to quantify. However, experienced researchers use a variety of documentation and assessment methods to summarize findings. For this effort, the interviews were audio taped and transcribed. The findings presented within this report represent the outcome of several steps, including:

- Systematic review of each transcript to identify common themes, perceptions, and comments relevant to each topic;

- Separate compilation of CDC subject matter expert feedback into a spreadsheet and review and comparison of data within each section for themes and consistency; and

- Subsequent discussion about areas of agreement and conflict with respect to the themes and perceptions, as well as the interview findings compared to the CDC expert results. This "notes-based" analysis is a commonly accepted and literature-supported process for qualitative research assessment. A team of six researchers participated in this process.

- The final recommendations presented within this report also were examined in light of the available literature and CDC qualitative and quantitative research on providers’ HPV-related knowledge, attitudes, clinical and counseling practices, and information needs.

III. Key Findings

A. Participants

A total of 37 primary care providers, including 17 physicians, 14 nurse practitioners, and six registered nurses, participated in interviews in May 2005. Each of the participants predominantly served patients who were from one of five designated racial/ethnic groups. Within each patient population group, one registered nurse and approximately three or four physicians and nurse practitioners were recruited. Due to strict recruitment criteria, there were some challenges in recruitment, particularly for providers working with Asian American and Native American populations. Certain recruitment criteria were slightly relaxed to meet minimum sample sizes for these segments.

Table 1 details the number of providers interviewed by racial/ethnic patient population served and provider type.

Table 1. Provider Segmentation

Patient Population Served	Number and Type of Provider
African-American	3 Physicians 4 Nurse Practitioners 1 Registered Nurses **8 Total**
Asian American	3 Physicians 2 Nurse Practitioners 1 Registered Nurses **6 Total**
Caucasian	4 Physicians 4 Nurse Practitioners 1 Registered Nurses **9 Total**
Hispanic	4 Physicians 3 Nurse Practitioners 1 Registered Nurses **8 Total**
Native American	3 Physicians 1 Nurse Practitioners 2 Registered Nurses **6 Total**
Total	**37 Providers**

A large number of participants worked in community or public health settings, and primarily served lower-income patients. The participants were from geographically dispersed locations around the country, including the Northeast, South, Southwest, West, and Midwest. Although an attempt was made not to recruit heavily from California, 12 providers were located there because of the challenges mentioned above with finding providers serving specific populations. Table 2 provides additional detail about the participants by provider type. *A grid listing information about each participant is provided in Appendix G.*

Table 2. Provider Characteristics

Provider Type	Population Served	Specialty Area	Practice Setting	Patient Base
Physicians (17)	Caucasian (4) Hispanic (4) African American (3) Asian American (3) Native American (3)	Family practice (11) General internist (6)	Community/public health (5) Multi-specialty (3) Single-specialty (3) Solo practice (3) University clinic (1) Ambulatory care (1) VA hospital (1)	Lower SES (13) Middle SES (4)
Nurse Practitioners (14)	African American (4) Caucasian (4) Hispanic (3) Asian American (2) Native American (1)	Family practice (12) General internist (1) General practice (1)	Community/public health (6) Multi-specialty (2) Single-specialty (2) Ambulatory care (2) Solo practice (1) University clinic (1)	Lower SES (9) Middle SES (3) Higher SES (1)
Registered Nurses (6)	Native American (2) African American (1) Asian American (1) Caucasian (1) Hispanic (1)	Family practice (3) General internist (3)	Community/public health (2) Multi-specialty (1) Single-specialty (1) Solo practice (1) Private practice (1)	Lower SES (4) Middle SES (1) Higher SES (1)

Information about the participants' clinical practices and experience is provided in Table 3.

Table 3. Provider Clinical Practices

Provider Type	Practice Obstetrics*	Hours spent in direct patient care	Number of HPV patients seen per quarter	Use HPV DNA as follow up or with Pap testing in women >30
Physicians	Practice obstetrics (3) Provide prenatal care (1)	40 or more (15) 20 to 39 (2)	10 or more (13) 5 to 10 (3) Fewer than 5 (1)	Use test (10) Do not use test (7)
Nurse Practitioners**	Practice obstetrics (5) Provide prenatal care (3)	40 or more (8) 20 to 39 (6)	10 or more (7) 5 to 10 (5) Fewer than 5 (1)	Use test (9) Do not use test (5)
Registered Nurses	Practice obstetrics (2)	40 or more (3) 20 to 39 (2) Fewer than 20 (1)	10 or more (4) 5 to 10 (2)	Use test (3) Do not use test (3)

**Some participants were asked if they deliver prenatal care and deliver babies in the initial recruiting stages. The question later was changed to ask whether participants practice obstetrics. All of the results are reported here.*

*** One nurse practitioner reported that 10 percent of her patients per quarter have HPV, which could not be quantified into the existing categories.*

B. Current Cervical Cancer Screening and Genital HPV Testing Practices

1. Talking About HPV and Cervical Cancer

Among the health care providers interviewed, the frequency with which they had the opportunity or need to speak with patients about topics related to HPV or cervical cancer varied. However, more than half of the respondents cited that they had "frequent" or "daily" need to do so. The reason that the need was high was usually due to a higher-risk patient population that frequently had abnormal Pap test results or an existing STI. Overall, most health care providers mentioned that they discuss HPV with their patients during a Pap test and following abnormal Pap test results, as well as with patients who have multiple sex partners.

- *"Very often. I'm a women's health care nurse practitioner. I see women all the time who I have to talk to about HPV." (Nurse Practitioner, Caucasian patient population)*

- *"Daily. Multiple times in a day." (Physician, Caucasian patient population)*

- *"I talk to patients fairly frequently, particularly when they come in for their annual physical exam. I speak to young women about HPV and cervical cancer, but also to young men about HPV." (Physician, African-American patient population)*

2. Cervical Cancer Screening/Pap Tests

When asked about their current approach to cervical cancer screening for female patients with no risk factors, almost all of the health care providers stated that they perform annual Pap tests on patients who are sexually active or over the age of 21. Just over 25 percent of the providers mentioned that they reduce the frequency of Pap tests to every two to three years when a patient has had two or three normal tests.

- *"We tend to do the yearly Pap smear. We don't have a cut line for age – not above 30 or 35. I think it's basically individualized. When we see that the patient has absolutely no risk factors then we can advise them to get a Pap smear every two to three years." (Physician, African-American patient population)*

Sixty percent of the respondents who use the test said they use liquid-based Pap tests because they are more accurate and easier to use. The remaining 40 percent of respondents using the test said they use conventional Pap tests. Several of these providers cited the cost of switching to liquid-based tests as the primary reason that they have not yet switched. Only one respondent (registered nurse, serving African-American patient population) replied that she does not conduct Pap tests for any of her patients.

3. Testing Procedures

About 50 percent of the health care providers responded that HPV DNA testing is performed within their practices. Additionally, nearly 60 percent of the participants said they are able to perform coloposcopies on site. The participants from clinics that are unable to perform this procedure on site said they refer patients to another clinic or schedule exams when a visiting provider can perform one.

4. Organizational Guidelines

Responses to the question about organizational guidelines for cervical cancer screening varied widely across all types of providers. The American Cancer Society (ACS) guidelines were cited most frequently as the source for cervical cancer screening information, followed by the ACOG and the U.S. Preventive Services Task Force (USPSTF). Several respondents said that they did not follow any specific guidelines or could not remember which one, if they did. Some individuals mentioned additional guidelines, including those corresponding to the American College of Pathologists, the American Society of Cervical Pathology, and the California Public Health Guidelines.

C. Current Sources of Genital HPV Information, Tools, and Materials

1. Primary Influences

The providers were asked to describe the primary influences that have helped shape their cervical screening practices. The majority of physician respondents cited professional literature and continuing medical education programs and conferences as their primary sources of influence. They often referred to journals, such as the *Journal of American Family Practice*, *American Society for Colposcopy and Cervical Pathology (ASCCP)*, *Journal of the American Medical Association* (*JAMA*), and *Women's Health and Primary Care Journal.* To a lesser extent, the physicians also mentioned fellow colleagues and clinical experience as influencers.

- ➢ *"Just basic research from different entities, like the CDC, different drug companies…I do tend to read a lot of journals. I tend to go to a lot of symposia and different conferences from time to time." (Physician, African-American patient population)*

Among nurse practitioners and registered nurses, primary influences included fellow colleagues, mentors, and clinical experience. Some nurses mentioned journals or professional literature, but did not specify any in particular.

- ➢ *"I had a wonderful mentor physician when I came to work. I still do. It's not the same one, but I still do have physicians who are very helpful and very good for me to work with." (Nurse Practitioner, Native American patient population)*

2. Materials and Tools

Health care providers were asked about their resource preferences in order to learn more about where they go for information about HPV and what tools or materials they have found useful for HPV patient education.

In response to the question about reliable resources for obtaining current information about HPV, the majority of respondents across all provider types could not identify any one resource that they consistently rely upon for HPV information, although several people mentioned that they search the Internet or professional literature for information when needed. Furthermore, many respondents replied that there are no adequate tools or resources that they use on a regular basis. Only a few providers mentioned a specific resource.

- ➢ *"I don't have any materials. We really don't have any materials to read up on and there's nothing to give to patients." (Registered Nurse, Hispanic patient population)*

- ➢ *"I have three other colleagues that I work with and we've all talked about the need for a real solid HPV pamphlet because we've all felt that the one we have is okay, but I think we need a better one." (Nurse Practitioner, Caucasian patient population)*

- ➢ *"I really haven't seen anything specific to primary care physicians. It's really what medical textbooks I've read in medical school and then I've recently used something called www.uptodate.com. Up-to-date is an online sort of encyclopedia for physicians…What they do is review the current literature and update it every few months." (Physician, Asian American patient population)*

The availability of HPV patient education materials also is limited, according to most health care providers who were surveyed. Many providers revealed that they often create their own materials or drawings for patients due to the lack of adequate materials. They also stressed that having one-on-one conversations with patients is more valuable than any existing resources. Among the providers who cited specific resources, materials from the CDC Web site, the American Academy of Family Physicians, www.uptodate.com, and www.familydoctor.org were believed to be useful. Additionally, several providers mentioned that they only were allowed to disseminate patient brochures developed by their state or county health departments.

- ➢ *"Over the years, I've kind of developed my own little tool from the information I've gotten…I have some diagrams that I use that I've kind of developed on my own." (Nurse Practitioner, Caucasian patient population)*

- ➢ *"I've really not used any tools. So, no. Basically, it's the counseling that I do and I do extensive counseling with patients. But as for us using any booklets and tools of any kind, I've not used any." (Physician, Caucasian patient population)*

- ➢ *"I usually go to the CDC Web site to see if I can find anything…I print it out and hand it to my patients. It's usually after the fact – when the diagnosis comes back – when I hand this information out." (Nurse Practitioner, African-American patient population)*

D. Reactions to Pamphlet Content

Following the discussion of sources of information, tools, and materials, the participants were asked to discuss and provide reaction to the pamphlet content. For purposes of organizing the discussion, the content was broken into four sections. See page 21 of the Methodology section for a list of the topics that were discussed within each section.

1. Section one: Definition & Natural History of HPV

i. Overall Reactions. Virtually all of the health care providers responded favorably to the first section of the pamphlet content. The physicians, registered nurses, and nurse practitioners generally felt that the content was very informative, comprehensive, clear, concise, easy-to-understand, interesting, and important to know.

A few individuals expressed some surprise and confusion regarding the statistics on HPV prevalence and the high-risk HPV types. However, most respondents felt these data were useful – particularly for validating that the HPV information presented is well studied and for addressing patient questions in a way that emphasizes HPV's extremely common occurrence.

Several participants were unfamiliar with the various risk factors for genital HPV, particularly cigarette smoking, oral contraceptive use, and nutritional deficiencies.

One nurse practitioner responded that the content provides a "much more accurate and hopeful picture of HPV" than older literature she has used, which fails to explain that most HPV infections are asymptomatic, transient, and resolve without treatment – leaving one to assume that, "If you've got a wart, you've got HPV, you're going to get cervical cancer."

ii. Key Messages and Topics. The participants were asked to identify the key messages within each section. However, in *section one* – as well as the other three sections – they usually provided responses addressing the broad topics that they felt each section covers or that interested them, instead of providing detailed responses to specific messages presented within the content.

Most of the physicians and some of the registered nurses and nurse practitioners felt that the main message or topic presented within the first section focuses on the fact that HPV is highly prevalent and has many different types – some of which can lead to cancer in men and women.

Others – primarily registered nurses and nurse practitioners – felt that the key points centered on what HPV is; how it is transmitted; and why it is important for clinicians to screen their patients for HPV and to educate them about the virus so they can take adequate precautions to prevent infection.

A few participants cited the risk factors and asymptomatic and transient nature of HPV to be the prominent points of discussion within the section.

- *"The transient nature of HPV infections and the fact that there are several serotypes that commonly cause cancer and you have to have a persistent infection to potentially develop cancer. But most of these are self-limited and resolve." (Physician, Caucasian patient population)*

- *"The main message was about how prevalent HPV is and how common it is, what the types are, and I'm not so familiar with the types but I know that there's low risk and high risk. The other part is how is it transmitted. And kind of even thinking about the risk factors there. So,* *how common it is, how it's transmitted." (Registered Nurse, Native American patient population)*

- ➢ *"Just basically telling me what it is, how it's transmitted, who should I screen, who's got the highest risk of acquiring this infection, and what the interpretation of the common types is—what is the difference between a cervical dysplasia versus the venereal wart presentation. I think it's good to see that. And what's the natural history of it too. (Nurse Practitioner, African-American patient population)*

iii. Areas of Confusion. While the statistics presented within the first section of content generally were well received, some participants were confused by the discussion of the different types of HPV. Specifically, respondents requested clarification of all of the types of HPV that account for cervical cancer and data supporting the discussion of the high- and low-risk types. Several health care providers also commented that references to too many complex statistics made the content difficult to digest. To simplify the data listed under "How Common is HPV?" a few physicians suggested combining two of the key statements to read, "About half of the 20 million people who have HPV are sexually active adolescents and young adults."

- ➢ *"I had a question under high risk HPV types. The two bullets say 16 is the most commonly found in half of all cervical cancers. HPV 18 accounts for 10 to 12 percent of cervical cancers. That took me put to 62 percent of all cervical cancers, I think. I think that meant you could total those two. But I don't know that for sure. I was confused by that because if 16 and 18 are the most frequent, where are the other cervical cancers? We developed a vaccine for 16 and 18 and we're preventing all cancers. How do we only get 60 here? So, the total percentages didn't make sense to me. That wasn't clear." (Physician, Native American patient population)*

Participants also expressed a significant degree of confusion concerning the discussion of HPV risk factors – particularly cigarette smoking, oral contraceptive use, lack of circumcision of male partners, and nutritional deficiencies. They generally wanted more detailed information about how each of these risk factors plays a role in the acquisition of HPV and requested supporting scientific citations. They also sought specific guidance on how patients can effectively be counseled to address these concerns.

- ➢ *"Just a couple of things I would like supported like the less commonly identified risk factors. Some of it I would have liked to have seen the resources where that came from. And the one that's standing out in my mind is the circumcision of male partners. We are quite mixed in our practice about that. So, if those things can be cited where we can go and look those up, it would be great." (Nurse Practitioner, African-American patient population)*

With respect to HPV transmission, a few providers were confused by the statement that HPV can be transmitted by "inanimate objects." They requested clarification on the types of "environmental surfaces" that can spread HPV. They also felt that CDC should specify whether HPV can be transmitted through sex toys.

- *"I don't know what you mean by environmental surfaces. And one thing that should be included explicitly is whether sex toys can do it also. Environmental surfaces, does that mean a toilet seat? I think that needs to be spelled out." (Physician, African-American patient population)*

Many respondents were confused by the statement that "as many as 91 percent" of new HPV infections clear within two years, when they later read, "it is unclear whether women who become HPV DNA negative actually clear the virus from their bodies. It is possible that in some women the virus remains in a nondetectable dormant state for a considerable period of time and then reactivates many years later." As such, the respondents requested CDC's clarification on whether or not HPV actually clears or stays within the body.

- *"One thing that wasn't clear and maybe I'm not reading right is about the natural history of genital HPV on the bottom of page three. It says the body can naturally clear within one year and most people can clear within two years, 91 percent. But it's a virus, so maybe it's not true, but most times viruses don't completely leave the body and I don't think it says that here. It's unclear whether women actually clear the virus from their bodies. It becomes dormant. So, I guess that says it stays in the body then." (Nurse Practitioner, African-American patient population)*

iv. Missing Information. The majority of participants responded that they felt *section one* was complete and they did not require any additional information about the natural history of HPV after reading it. However, within the discussion of HPV transmission, one physician noted that there is no discussion of whether gay men or women can transmit and/or are at higher risk of contracting HPV. Since the current content appears only to apply to heterosexuals, this clarification was deemed particularly important.

- *"You don't say anything about whether women who have sex with women can transmit this virus and I believe they can because many lesbian women think they're safe from sexually transmitted diseases. Most people assume gay men might be at higher risk or whatever. But that absolutely to me has to be a point in here and that's absolutely omitted." (Physician, African-American patient population)*

The same physician responded that CDC should specify the percentage of women who actually develop cervical cancer, among the 10 percent who develop persistent infection. To simplify the complexity of such content, she suggested incorporating a flow chart or other diagram that reflects this breakdown.

v. Tone/Volume. Overall, the health care providers found the tone of the content presented within the first section to be very comfortable, clear, consistent, and "to-the-point." In particular, several physicians commented that they perceived the tone to be very neutral and objective, with one practitioner likening it to NIH research that he had read in the past.

- *"The tone is clear. It's clear and crisp. It's not badgering. It's not offensive. It's not bothersome. It's comfortable reading. I don't have any problems with the tone." (Physician, Caucasian patient population)*

- *"I think it's at the level where it's not scientific, scientific, but on the other side of the coin, it's not down to the level of the lay person. So, I think it's at a level to me that was very acceptable. I liked it. It read easily. It wasn't verbose. It was more concise and readable. It was readable as opposed to trying to not study it. It made reading it easier associated also with intake." (Physician, Asian American patient population)*

- *"I think it's very good. It's simple enough to understand." (Registered Nurse, Asian American patient population)*

With respect to the volume of content that was presented, many individuals responded that they felt the level of information was adequate and appropriate for health care providers.

vi. Format/Organization. All of the physicians, registered nurses, and nurse practitioners responded favorably to the format and organization of *section one*. The majority of respondents were very enthusiastic, stating the content was very concise, well organized, and easy to understand. Numerous participants – particularly physicians and nurse practitioners – felt that the use of bullet points and bold subheads made the extensive content easy to navigate and helped them focus on the topics of greatest importance to their practice.

- *"I think it was easy reading. I think separating out each item and having a nice bold title to each area makes it easy because if you already know why is HPV important, for example, and you want to skip that, well, you can go onto the next one, or whatever else—types of HPV. So, I think in that regard, it was pretty easy reading." (Physician, Caucasian patient population)*

- *"I thought it was nicely laid out. This is why HPV is important, what is it, the types, how common. That's like standard when you're dealing with any disease. I think the format is fine." (Registered Nurse, African-American patient population)*

- *"It was very good. It was very well presented. This is definitely very readable, very concise, very specific. I like the way you've got the little boxes listing the high-risk types, the low-risk types, the types that are not yet established. I like that because sometimes when we're so busy in our practices, we tend to skim more than we tend to get into reading. So, this is very, very nice the way you've got it presented." (Nurse Practitioner, African-American patient population)*

A few respondents commented that the "risk factors for acquiring HPV" table was an especially useful and well-structured presentation of key information. One physician suggested adding another table or diagram to depict the natural history of genital HPV, because she felt that the current bullet-point format makes the concept difficult to comprehend. Specifically, she recommended incorporating a graphic that depicts how many people can expect to acquire HPV over a lifetime; how many people can anticipate high-risk versus low-risk infection; how many people will receive abnormal Pap tests; and how many people ultimately will have cervical cancer.

- *"I like your tables. That's what people like to see. They want to get the information and keep going." (Nurse Practitioner, African-American patient population)*

- *"[With respect to the natural history section] it's just hard to…on one hand, most infections are transient and asymptomatic and you're not going to have a clinical problem and they will be undetectable after a certain time. But then you're talking about abnormalities. So, it's just a complicated topic. I'm not sure how to simplify it. I'm just not sure that the bullets work. Again, I think flowcharts and diagrams would be useful here." (Physician, African-American patient population)*

vii. Usefulness/Appropriateness of Information. Overall, the health care providers were very enthusiastic about the usefulness of the information provided in *section one*. The respondents consistently reported that the upfront content provided them with a better understanding of HPV and would serve as a good resource for explaining to patients what the virus is; how it is transmitted; and the percentage of people who are affected by it. Many physicians and some registered nurses and nurse practitioners commented that the information served as a good "refresher" of important HPV facts for them, personally, and that it would help ensure that their colleagues have the appropriate education and training for effective HPV screening, diagnosis, and treatment.

- *"I think it's very useful as a reminder for me. That's number one. Number two, the clinic is a residency training clinic with also a lot of students. It's very good to have this material in hand to show the residents and students. And also it may help in discussion with the patients." (Physician, African-American patient population)*

- *"It's useful to me in that I learned something. So that in and of itself, it was information basically that I knew, but seeing it again in this kind of format kind of organized it for me. Again, it made me think twice about how important it is to do this screening and to talk to the clients. Like I said, I already do that, but I'll make sure I won't miss it." (Registered Nurse, African-American patient population)*

- *"This would be useful for me on a daily basis when I'm interfacing with patients. I do Paps not every day, but two to three times a week. So, like I said, it's not uncommon that in those interactions HPV is going to be mentioned or asked about. So, I think the information would be useful regularly in my clinical practice." (Nurse Practitioner, Caucasian patient population)*

None of the participants reported finding any of the content within this section to be inappropriate. Everyone commented that they would be receptive to using the information.

2. Section two: Risks and Prevention of HPV

i. Overall Reactions. The second section of content also garnered a positive response, with many participants commenting that it provides a good overview of strategies for HPV prevention and contains a lot of useful information that is not widely known.

While a few physicians commented that they felt this section is somewhat verbose, others felt the content is concise, well organized, and utilized a reasonable amount of space given the complexity of the topic.

ii. Key Messages and Topics. By and large, the participants perceived the second section of content to emphasize the current science on, and strategies for HPV prevention and risk reduction. Along these lines, numerous physicians and several nurse practitioners commented that, although it is important to advise patients—particularly college students—about reducing their number of sex partners, it is a very "tough sell"—even impractical—to counsel them about abstaining from sex.

Some providers felt the most important points focus on the risk to infants born to mothers who are infected with HPV. One nurse practitioner commented that it would be especially beneficial for health care providers to have this discussion with patients who are young and just getting ready to begin families when they learn they have HPV, as it will help prevent or alleviate unnecessary panic. One registered nurse and one nurse practitioner believed that the overall message within the second section is that HPV is transmitted through skin-to-skin contact. Another nurse practitioner responded that the section primarily focuses on how health care providers can identify patients who tend to develop a chronic presentation of HPV and therefore are at greatest risk for cervical cancer.

- *"I think awareness of who is at risk and how you can prevent it, what to say to people to prevent this thing from happening in the first place." (Physician, Hispanic patient population)*

- *"Again, counseling. Counseling patients. That's the most important thing here. You've got to counsel your patients and tell them how to prevent HPV." (Nurse Practitioner, African-American patient population)*

- *"The transmission. The fact that it can be transmitted through skin-to-skin contact, which like I said, it's good that we really get that point across to patients. I think that's good." (Registered Nurse, Hispanic patient population)*

iii. Areas of Confusion. Within *section two*, several respondents mistakenly believed that the discussion under, "What is the Risk Associated with Genital HPV Infection?" provided the same content as the prior section, which focused specifically on the risk factors for acquiring a genital HPV infection. However, this section was drafted to address the risks that are associated with the persistence of genital HPV infection and progression to cervical cancer, once HPV is contracted.

Further, several physicians did not understand the statement, "one large case-control study reported relative risks of over 100 for cervical cancer for all of the high-risk types of HPV." One asked if the point is in reference to high grade SIL. Another physician felt that the reference to relative risk distorts the information by making the cervical cancer risk sound much more serious than it actually is.

- ➢ *" I hate that information. I hate getting information like that. This is what happens. If you have something that only occurs in a tenth of one percent within a population and you have something that occurs in two-tenths of one percent, that's a 100 percent relative risk increase. I just think that it distorts information hugely. If you have a very small amount and you double it, you still have a very small amount. And somehow that just tends to scare people and make it seem huge and it doesn't give good information." (Physician, African-American patient population)*

A few providers also requested clarification of the "lack of adequate Pap test screening" risk factor that is listed within a table. One nurse practitioner did not understand its meaning, while one physician stated that the point should clarify that inadequate Pap test screening has to do with poorly performed Pap smears as well as infrequent screening.

Numerous respondents were confused by the statement that "evidence indicates that currently available therapies for HPV-related cervical cell abnormalities and genital warts may reduce infectiousness, but probably do not eliminate it." They asked CDC to clarify whether the virus really clears the body or lies dormant. One physician stressed that a subsequent point seems to contradict this statement, by saying, "70 percent of HPV DNA positive women with cervical cancer precursors who undergo surgical excision subsequently become HPV DNA negative." One nurse practitioner emphasized that CDC needs to more clearly explain that some cases of HPV may be lifelong.

- ➢ *"Because it talked about that treating the genital warts could reduce the infection, but probably do not eliminate it...But then it talks about the studies that demonstrate that approximately 70 percent of HPV DNA positive women with cervical cancer precursors to undergo surgical excision become HPV DNA negative. So, I think I kind of muddled through that to see if I was getting a conflict there." (Nurse Practitioner, Native American patient population)*

iv. Missing Information. A few providers acknowledged that the discussion of risks within the second section did not detail the risks concerning men, which they felt is necessary since women and infants are listed. Even if the only considerable risk for men entails spreading HPV to their partner(s), these providers felt that it warrants some discussion.

- ➢ *"Maybe have a section on the risks to men. Maybe they could add a tiny little section on that—there's really not any real risk of penile cancer or whatever that we have found with this infection. The only risk would be to spread it to a partner. So, maybe that little insert could be added there." (Physician, Caucasian patient population)*

Quite a few respondents expressed significant interest in learning more about the perinatal transmission of HPV infection, specifically with respect to how it is treated and the baby's prognosis. One physician asked how it can be prevented if C-sections are not protective. Another provider requested clarification on whether C-section babies have the same rate of HPV infection during delivery as non-C-section babies.

- *"The only thing I would like to know a little bit more is about this perinatal transmission of the HPV infection. That's very interesting. Sometimes it's nice to put a Web site in there. That's a very unusual presentation. I've never heard of this or seen it. But it's interesting to read about. And I think you might find more midwives and obstetrical people who would be more interested in reading more about that. So, a Web site is always nice to go to." (Nurse Practitioner, African-American patient population)*

Others requested an explanation of the types of treatments that are available for HPV-associated diseases, in the absence of a vaccine. Specifically, one physician wanted to know what the pharmacologic agents are and questioned whether *Aldara* is among them. One nurse practitioner wanted to know if CDC is referring to colposcopy, "cryo," or something else.

One physician felt strongly that CDC needs to add a section explaining what patients should do to prevent transmission after learning that they have HPV. Specifically, he felt that guidance is needed on the measures HPV-positive patients should take to prevent further transmission.

v. Tone/Volume. As with the first section, the majority of health care providers reported that the tone of the second section was very balanced, straightforward, and appropriate. However, several physicians and a few registered nurses and nurse practitioners responded that the volume of content within the second section was a bit excessive. Several individuals provided specific examples of information that could be shortened or eliminated to avoid repetition, including the introductory section addressing the three key strategies for reducing sexually transmitted infections. However, others acknowledged that although there was a considerable amount of content to digest within the second section, it is too important to limit or exclude from the document.

- *"I think it's great. It tells you the things that are important, but it doesn't weigh you down with a lot of…it gives you a few statistics, but not enough to really weight you down." (Nurse Practitioner, Caucasian patient population)*

- *"I like section one better than section two. In section one, there were brief little sections with a few bullets. There's a little bit more reading in section two that you have to go through and there's fewer bullets. It would be better if whatever you had to say were in brief little bullets rather than having to read the paragraphs." (Physician, Asian American patient population)*

- *"It may be a little bit too much, but then again…it's a little bit too much because in some of these it repeats how it's transmitted. Some of the same information is repeated in other* *sections. So, maybe just cutting down on repeating things." (Registered Nurse, African-American patient population)*

vi. Format/Organization. As with the first section, all of the respondents provided a favorable reaction to the format and organization of *section two*. However, some individuals noted that the content is denser in the second section and could benefit from additional bullet points as opposed to paragraphs. A few participants suggested replacing some of the words with charts or graphs to make the content easier to digest.

- *"I felt that everything was a little bit more wordy compared to earlier. I think it would have been a little bit more effective if they just sort of instead of having so much prose here that they should just put bullet points. So, more bullet points than these mini-paragraphs here for each thing." (Physician, Asian American patient population)*

- *"I think it was a little difficult to digest all of that information. And I think if I saw more charts or graphs with the information sort of laid out in there, it would have been a little easier to take in because I would have been looking at different methods of the information being delivered." (Physician, African-American patient population)*

vii. Usefulness/Appropriateness of Information. As with *section one*, the respondents felt that the content provided within *section two* would be extremely useful in their daily clinical practices – particularly as a reference tool for detecting and treating HPV and for counseling patients about screening and prevention.

- *"It would be information to give patients when you talk about risk factors and why you're doing a pap smear and what decreases the risk of cancer or any type of STD and then the other situation is when you find somebody who has been tested and has a known exposure or has tested positive. Then you would bring those things up." (Physician, Hispanic patient population)*

- *"[I would use the information] probably during the education period where I'm sitting down and talking to…especially young women, teenagers who are sexually active. They really need all of this information more than anyone because they're the ones who seem to think nothing can happen to them until they show up with an STD or they show up pregnant." (Registered Nurse, African-American patient population)*

- *"Just knowing who to screen, how we can decrease the efficiency of the transmission, what things can I tell my patients as far as how they may or may not develop a more severe presentation of this problem. Also, it's very interesting about the condom use, that it's still transmitted even with using condoms, although not that I would want my patients to stop using condoms. But the fact that if they are even 100 percent using condoms, it doesn't protect them. So, the most important thing I think they can do here is to have dialogue with their partners before having intercourse as to what their risk factors are." (Nurse Practitioner, African-American patient population)*

None of the respondents found any of the content within *section two* to be inappropriate. Everyone commented that they would be receptive to using the information.

3. Section three: Counseling People Infected with Genital HPV, HPV Vaccines, and Prevention of Cervical Cancer

i. Overall Reactions. Overall, the participants expressed positive reactions to *section three*, saying it contains good information that is easy to understand and read or skim. However, the specific content areas that were cited as most striking varied by provider type.

Most physicians and registered nurses, but only a few nurse practitioners, reported that the "HPV Vaccines" section, in particular, provides very interesting and new information. Some providers had heard that a vaccine is under development, but knew little about it. For others, the information was completely new.

Almost all of the registered nurses cited the screening guidelines table as an important, useful, and easy-to-use resource. However, neither the physicians nor the nurse practitioners mentioned this element frequently.

The counseling section elicited the widest variety of responses. Participants agreed that patient counseling is an important aspect of their work, and over half said they liked the length and detail in this section, including the key educational messages for patients and the discussion of patient anxiety and lack of knowledge. One physician, for example, described this as "one of the most important parts in the whole pamphlet," and said, "I think it addresses a lot of issues that are very important to know." Several physicians and nurse practitioners disagreed, however, stating that while the key educational messages are very useful, the remainder of the section provides too much detail and contains information that they already knew.

In discussing both *sections three* and *four*, numerous providers took issue with the cervical cancer screening guidelines themselves, specifically the three-year interval for cytologic screening. Several commented that they believed more frequent screening is warranted for women at greater risk of acquiring an HPV infection. Some respondents simply disagreed with the guidelines and said they performed more frequent screening on these female patients, while others believed that more frequent screening was part of the guidelines, although this was missing from the guidelines table.

ii. Key Messages and Topics. In *section three*, participants identified messages about the future availability of HPV vaccines, the importance of patient counseling, and the box of key educational messages for patients as key topics:

- ➢ *"The hope of an HPV vaccine, I think that's exciting." (Nurse Practitioner, Caucasian patient population)*

- ➢ *"I think the key educational messages that patients should get, that was kind of a nice thing." (Physician, Caucasian patient population)*

To a lesser extent, some participants – particularly nurse practitioners and registered nurses – cited the screening guidelines table as a key area:

- ➢ *"How important screening for cervical cancer is and the age guidelines. That to me was the most important." (Registered Nurse, Caucasian patient population)*

iii. Areas of Confusion. The majority of participants reported that they did not find anything in *section three* confusing.

However, a small number of participants described the "HPV Vaccines" section as somewhat difficult to understand, with one nurse practitioner explaining that it contains some unfamiliar terms.

- ➢ *"I didn't find anything to be confusing or unclear. The term that was new to me was these VLPs on page eight. They have the terminology 'VLPs' and then they use the terminology 'recombinant HPV capsid proteins' and a term like 'coassemble' …I can grasp what those mean, but if you asked me do I speak in that language, no. I don't." (Nurse Practitioner, Caucasian patient population)*

A few providers also asked for clarification about whether the vaccines are intended for both men and women or women only. Based on the difficulties of testing men and on the fourth paragraph, which lists the results of a study conducted with adolescent girls, these providers assumed the vaccine is designed only for women.

Within the "Prevention of Cervical Cancer" section, there were a number of minor areas where participants requested clarification. Two physicians indicated that the Bethesda classification term, "ASCUS," would be more familiar and immediately meaningful to providers than "high-grade cervical cancer precursors." One physician also requested clarification as to whether the text in this section separates ASCUS from HGSIL and LGSIL. One nurse practitioner requested clarification as to whether the post-hysterectomy screening recommendations vary depending on the type of hysterectomy a woman has. Additionally, two nurse practitioners commented that the word "only" is confusing because it implies that the number of cases and deaths in 2005 will be lower in comparison to 2004, but the 2004 numbers are not provided as a comparison.

- ➢ *"On page nine at the top…it says according to the American Cancer Society in 2005 there will be only 10,370 cases of cervical cancer and 3,700 deaths. You said 'only.' What were the previous statistics? How much reduction was there? That was a question of mine when I read that statement." (Nurse Practitioner, African-American patient population)*

iv. Missing Information. The majority of participants reported that they felt *section four* was complete and thorough and that they did not require any additional information about HPV DNA testing or clinical management after reading it.

As described above, many participants were very interested in the HPV vaccine information. Some physicians, nurse practitioners, and registered nurses said they were interested in getting updates about the status of the vaccine as well as notification of when it will become available, preferably by visiting a Web site.

A few providers mentioned that they would like Web resources for more information on topics throughout the pamphlet, and one nurse practitioner specifically requested a Web site providing detailed information about the screening guidelines.

- ➢ *"[After reading this, I might want] a newly available brochure or a Web site [that] is available for the patients to get easy information. Something of that nature may be a good thing to add here." (Physician, Caucasian patient population)*

- ➢ *"The vaccine stuff is going to have to be continually updated… So, you could actually put something down next to the bottom of that saying, 'in preliminary stages, for further developments…' and then put a Web site down." (Nurse Practitioner, African-American patient population)*

v. Tone/Volume. None of the participants expressed any reservations about the tone of *section three*, which they generally described as "good," "fine," and "neutral." Questions about the tone did not generate significant discussion in sections three or four.

Several providers reported that the length and amount of information in *section three* was "about right." They felt that all the information needed to be included and that it was presented in a concise format that they could easily skim and absorb. On the other hand, almost half of the physicians – but only a few nurse practitioners and registered nurses – disagreed, commenting that the section, "Counseling People Infected with Genital HPV," could be reduced significantly in length and/or moved to a less prominent location in the pamphlet. Of these participants, several believed that the discussions of patient anxiety and limited knowledge are unnecessary because providers already know this information, or they suggested that the whole section could be shortened down to just the box of key educational messages for patients. The two paragraphs preceding the box were perceived to be especially unnecessary, particularly by a small number of providers who seemed insulted by the suggestion that they need to be told to counsel patients and how.

- ➢ *"Nothing to be de-emphasized. I think all are important points and all are concise. The information is very important. It's true that there is limited knowledge and there is a need for more information and definitely there is an anxiety component when the patient knows about the HPV." (Physician, African-American patient population)*

- ➢ *"It's a little bit lengthy here. It's a little too long. [Moderator: Which areas are too long?] The anxiety and concern and the need for more information – Again, I think some of this stuff is pretty well known." (Physician, Caucasian patient population)*

Whereas the physicians were particularly interested in the "HPV Vaccines" section, some nurse practitioners and registered nurses suggested that this section could be shortened and made more concise by using more bullet points, which also would highlight key points and make the section easier to read. They felt it was not necessary to include detailed information about the vaccines because they are not currently available and the information is likely to change.

- *"The HPV Vaccines, I thought that was important, but it's too much information because it's not approved yet." (Registered Nurse, Hispanic patient population)*

vi. Format/Organization. In *section three*, providers greatly appreciated the use of a checkbox for presenting the key educational messages for patients, which they felt was a useful tool that would help them make sure they delivered all the essential information to their patients. Several also commented that the table is an effective means of presenting the cervical cancer screening guidelines because it was easy to skim and absorb and made it easy to see what the differences and similarities are between the various screening guidelines. One physician requested that the last two rows on the table be combined into a single row with subheads or bullets to separate the recommendations before and after age 30.

- *"What I really liked was …the key educational messages that patients should get. It's kind of a wrap-up. Did I give them the message that it's transient, harmless, they need pap smears early to detect them? It's kind of a wrap-up for me. Did I make them go away with the message they should have instead of just flat scaring them to death and then they'll never come back to see me again?" (Nurse Practitioner, Caucasian patient population)*

- *"On page nine, the format is excellent. The way it's formatted with age to initiate and screening frequency, I like that. On the box at the top of page eight, the key educational message that patients should get, to me with the little check marks that's telling me that the doctor or I should tell the patient those are the most important with the check marks." (Registered Nurse, Hispanic patient population)*

As mentioned above, two nurse practitioners suggested moving all of *section three* to the end of the pamphlet or pulling it out and presenting it as an addendum. While they regarded this information as important, they felt it was more appropriate at the end of the pamphlet. They also explained that this shift would place the "HPV DNA Testing" and "Clinical Management" sections earlier, which was preferable because they perceived these to be the most useful sections.

- *"It's information that clinicians need to know, but I think it could be further back in your pamphlet. [Moderator: Why?] Because I really wanted information on the outcome and that's like the last section." (Nurse Practitioner, African-American patient population)*

vii. Usefulness/Appropriateness of Information. Most participants also described *section three* as being useful in their clinical practices, especially when counseling patients or answering patient questions about HPV and cervical cancer screening. Several mentioned the box of key educational messages for patients as a particularly useful part of this section.

A few participants – mostly physicians – cited the vaccine information as useful. In addition, a few nurse practitioners and registered nurses said the screening guidelines table would be useful for determining the age to initiate screening or for counseling patients about screening.

- *"[I'd use this] when I was counseling a patient or when I wanted to check on the latest." (Physician, Native American patient population)*

- *"For patients who had questions about this kind of information. Probably the people most at risk for HPV. Also on page nine the box on age to initiate screening. I will use that as a guide." (Nurse Practitioner, Caucasian patient population)*

- *"What I thought was most useful? There was so much. Probably the counseling and maybe the screening guidelines were a little bit more useful." (Registered Nurse, Hispanic patient population)*

None of the participants reported finding anything in this section inappropriate.

4. Section four: HPV DNA Testing, Clinical Management Issues

i. Overall Reactions. Participants had very positive reactions to *section four*, which they felt contains a great deal of useful information. Many, especially among the physicians and nurse practitioners, were enthusiastic in their praise, saying it is very clear, straightforward, easy-to-understand, and "this was the information I really needed." One physician responded by saying, "It's complete and it answers everybody's questions. The clinician can't make a mistake because it's all right there. It tells you what to do." Some physicians who said they do not regularly perform colposcopy or handle the follow-up on abnormal Pap results said this section contains a lot of unfamiliar information requiring them to read more slowly or read it more than once. However, even these physicians commented that they liked this section and did not think any content should be cut from it.

The registered nurses, on the other hand, had more mixed reactions to the content. While half described this section as very clear and interesting and said it greatly enhanced their knowledge, the other half tended to feel it is too detailed and contained "too much" information. Two registered nurses commented that they had difficulty understanding some parts of it.

Participants liked the algorithms, and cited them as an effective means of communicating a lot of information quickly and concisely.

ii. Key Messages and Topics. Physicians, nurse practitioners, and registered nurses identified two key messages or topics for *section four*. The first involved clinical management of patients based on their Pap results and/or the results of an HPV DNA test. To a lesser extent, some participants also mentioned the HPV DNA test and details about what it is; how it is designed; and its specificity. A few who do not conduct HPV DNA testing commented that the test seems like a useful tool and said they wished their offices used it.

- *"It's clinical management. I think that's what they're trying to address." (Nurse Practitioner, Caucasian patient population)*

- *"It kind of gives us a guideline of what's your next step. It kind of helps us to know what the next step is as far as positive results or what's the next thing, how it is managed." (Registered Nurse, Hispanic patient population)*

- *"The main message was basically how to manage a patient based on their cytology and their DNA test." (Physician, Asian American patient population)*

iii. Areas of Confusion. Most of the nurse practitioners and half of the physicians reported that they did not find anything confusing in *section four*. Each of the registered nurses who were interviewed, however, expressed confusion about some part of this section. Some registered nurses said it was not the type of information they use in clinical settings and one said, "truthfully, this is a little bit over my head."

A few providers expressed some difficulty understanding the technical language and terminology in the "HPV DNA Testing" section. A few individuals found the information in the second and fourth bullet points about the sensitivity of the HPV DNA test contradictory. One of these bullets explains that, using this test, 90 to 95 percent of women with CIN 2,3 are classified as high-risk HPV DNA positive, whereas the fourth bullet explains that the test determines not whether or not someone is infected with HPV, but rather whether they are at risk of having or developing a CIN 2,3 lesion in the next three years. Some physicians also requested information about how the HPV DNA test actually is conducted, such as whether the test is conducted using the Pap smear sample or whether separate samples are required.

- *"We could have done a little bit better in explaining the best technique of obtaining the HPV DNA testing." (Physician, Caucasian patient population)*

- *"We want to know how we should do the test." (Physician, Hispanic patient population)*

Under "Clinical Management Issues," in the section discussing routine screening in women 30 and older, two nurse practitioners had difficulty understanding what is meant by the phrase "routine adjunctive screening." In addition, one physician felt that this recommendation is confusing within the context of earlier content stating that younger women are at greater risk of acquiring a genital HPV infection.

iv. Missing Information. After reading *section four*, most of the participants felt that they did not need any additional information about the topics covered in the "HPV DNA Testing" or "Clinical Management Issues" sections. The majority of participant requests for more information were isolated comments that were not echoed by others.

A few participants made comments suggesting that they wanted to receive updates on any changes to the pamphlet content. Two others felt that Web resources would be helpful for getting updates on the vaccine's availability; new guidelines; and general clinical management issues. Web resources also were requested by two other providers who wanted to locate more detailed information on particular topics.

A small number of providers felt they needed additional information about why USPSTF feels there is insufficient evidence to recommend for or against the routine use of HPV DNA testing as a primary screening test for cervical cancer. Without this information, they felt they did not know how to interpret the fact that USPSTF could not support the recommendation. For example, these providers felt it would be helpful to know whether USPSTF deemed that not enough studies had been conducted or whether the studies that had been conducted showed too many false positives or other troublesome findings.

A few respondents asked for clarification on whether there is an upper age limit for cervical cancer screening and HPV DNA testing.

One nurse practitioner suggested that if the algorithms reflect a particular organization's recommendations, such as ACS or USPSTF, then the algorithms should be labeled to indicate this.

➢ *"[I'd like more information on] a place to go to in order to find out what the latest is. In other words, if this is going to be on a handout to me, then date it and tell me a place to go to find out how to update any of this. A lot of this is changing as we speak." (Physician, Native American patient population)*

➢ *"It just adds to the confusion. There's one organization that says something different and now you have this U.S. Preventive Services Task Force…Why can't they agree?" (Nurse Practitioner, Asian American patient population)*

v. Tone/Volume. All of the participants felt that the tone of *section four* was fine.

➢ *"The tone is neutral. It's not one way or the other. It's just right." (Physician, Asian American patient population)*

The majority of providers reported that the volume of information in *section four* was good, although registered nurses and nurse practitioners were more likely to feel this way than physicians. Several participants acknowledged that this section contains a great deal of detailed information, and some said it took them longer to read this section as a result. But overall, even these participants reported that they appreciated the level of detail and felt that they needed to know everything presented within the section. Participants praised the section's algorithms and use of bullet points, which made it easy to navigate and digest, despite the significant amount of information presented.

Roughly one-third of the physicians, but only a few of the registered nurses and nurse practitioners, felt that this section was too long and could be shortened. These tended to be the same providers who favored shortening the entire pamphlet. One physician, for example, commented that the length of the pamphlet as a whole led her to believe that the piece was designed as a reference piece rather than a pocket guide. However, the providers who felt that the section needed to be shortened could not identify any information that they felt should be reduced or eliminated.

- *"I think it's the right amount of information. I think we need to know all of this stuff. I think it's very good for us to see the different presentations and where to go with it and how to routinely screen for it. I think you're doing quite well. And I especially like your algorithm on page 12." (Nurse Practitioner, African-American patient population)*

- *"There was a lot here. It wasn't that it wasn't that clear. There was just a lot." (Physician, Asian American patient population)*

- *"I think it should be shortened somewhat." (Registered Nurse, Hispanic patient population)*

vi. Format/Organization. Overall, participants found the format and organization of *section four* effective and concise. As mentioned above, the algorithms, in particular, were considered highly effective at clearly and quickly conveying large amounts of detailed information without overwhelming the reader. Even those who commented on the large amount of information within this section frequently stated that format makes it easy to navigate. Only two participants – a physician and a nurse practitioner – commented that they would prefer to read a series of bullet points rather than the more visual algorithms.

A small number of providers felt that the content in the "HPV DNA Testing" section could be reorganized to make it easier to read. Two physicians and a registered nurse felt the section jumps back and forth between discussing different types of HPV tests, making these sections difficult to understand. Another registered nurse thought that the list of HPV types detected by the HPV DNA test is redundant with the list of HPV types provided in *section one*, suggesting that this information may not stand out sufficiently from the rest of the text for providers to read and understand it.

In addition, one physician requested that the reference numbers be presented as superscript numbers rather than in parentheses because he felt this format is more familiar to providers.

- *"I think the format is fine. There's nothing I would change with that. The information is all there and it's fairly concise. Even though there are little paragraphs and bullets, they were all informative." (Physician, Asian American patient population)*

- *"The whole format is really concise and…[good use of] bullets. It's easy reading and it's quick and to the point and concise." (Nurse Practitioner, Hispanic patient population)*

vii. Usefulness/Appropriateness of Information. The majority of providers – especially the physicians and nurse practitioners – felt *section four* would be extremely useful to them in their clinical practices. They imagined using it to help determine appropriate follow-up approaches for patients with abnormal Pap results and when providing information to patients and answering their questions. Some commented that they always refer patients with abnormal Pap results to a gynecologist. But even though these providers do not personally handle the follow-up procedures for these patients, they still appreciated having the information so they can discuss the test results and reinforce appropriate follow-up procedures with their patients.

- *"Being that there is an algorithm that I can refer to very quickly to reassure myself that I'm following the guidelines…And that I'm taking good care of my patients, I guess. That I'm providing them with what is considered the standard of care." (Nurse Practitioner, African-American patient population)*

- *"[I would use this information] when counseling a patient or when trying to be sure that I'm giving them the most up-to-date information because some of this information is very new." (Physician, Native American patient population)*

Registered nurses were less likely to think this information would be useful in their clinical practices. Several said they found the section informative and liked having the information, but that it was not relevant to the work that they do.

A few participants had made comments suggesting that they see some variability among their colleagues, or even in their own practices, with respect to the approaches used for follow-up of abnormal Pap results. These providers commented that the algorithms in this section make it very clear how the results should be handled.

- *"I think they're useful. They delineate a lot more clearly what the actual process should be instead of just kind of winging it." (Physician, Native American patient population)*

None of the participants reported finding anything in this section inappropriate.

E. Reactions to Pamphlet Designs

The providers reviewed two pamphlet designs, labeled as Design A and Design B, and were asked to comment on specific elements, including overall design, organization, colors, images, graphics, formatting, and paper preferences. *Both pamphlet designs are provided in Appendices F1-F2.* In general, Design A was the preferred approach among all provider types, selected as the favorite design by 26 of the 37 respondents. Table 4 provides the breakdown of votes by provider type.

Table 4: Participant Design Preferences

Provider Type	Design A	Design B
Physicians	12	5
Nurse Practitioners	10	4
Registered Nurses	4	2
Total	**26**	**11**

The respondents who selected Design A cited the cover design, size, and color as their primary reasons for preferring this approach. They described Design A as "eye-catching," "easy to read," and “effective.” The participants felt that the information was well organized and that the color combination stood out, making the design more aesthetically appealing. To improve the design, they suggested adding specific pictures and graphic elements, such as bullet points, tables, and charts to enhance the utility of the pamphlet. When asked about formatting preferences for Design A, participants were split between whether or not to include tabs, but did not want to use a heavier stock paper. In addition, most respondents believed that a perforated algorithm sheet would be a useful tool, however, many were hesitant or against the idea because the sheet would inevitably become separated from the pamphlet with use or damaged once it was removed from the pamphlet.

While B was not the preferred design, many participants reacted favorably to some of its key elements, such as the listing of contents, CDC logo, and cover images. However, the participants expressed that Design B did not capture their attention and was less appealing than Design A. In spite of their general preference for Design A, the respondents appreciated the organizational elements of Design B, noting that it presents the information in a clear and concise manner. In addition, many respondents felt that the color scheme is suitable. Participants also liked the selection of images, for which they offered additional suggestions. The respondents were split regarding whether or not to include tabs in Design B.

In general, physicians, nurse practitioners, and registered nurses all expressed similar overall opinions regarding the various design elements. The views provided by the participants are discussed in greater detail below.

1. Design A

As mentioned above, the majority of respondents from each provider group selected Design A as their favorite design.

i. Overall Design Look. The layout and color scheme in Design A immediately attracted the respondents to this version, eliciting a variety of positive reactions. In addition, a few of the registered nurses noted that it is a good size and appears more “inviting.”

- *“…It goes more in the context of what we’ve seen coming out of CDC in the bulletins that we’ve had. It’s easier to read and it gives you more bang for the buck on a page. (Physician, Asian American patient population)*

- *“It’s more inviting at the very front end of it. It looks easier to read because the headings are very easy to look at.” (Registered Nurse, Native American patient population)*

ii. Organization. Most participants reacted favorably to the organizational elements of Design A, noting that the information is “well organized,” “concise,” and easy to navigate.

- *“It says in the very beginning why it’s important, what it is, how common it is, how it’s transmitted. So, it hits the highlights right off the bat.” (Nurse Practitioner, Hispanic patient population)*

iii. Colors. When asked about their reactions to the color of Design A, almost all of the participants reported that they favored the gold color and felt that it is a good choice for the brochure. Specifically, nurse practitioners and registered nurses liked the colors used in Design A because they are "bright" and "catchy."

➢ *"I like the colors. It caught my eye when I first opened up the packet." (Registered Nurse, Native American patient population)*

iv. Images. While almost all participants felt that images should be incorporated into the pamphlet, responses were mixed regarding the number and type of photos that should be included. For example, those who wanted more images generally requested very specific ones, such as those depicting cervical lesions; infections at different stages; changes in the cervix (going from an ASCUS to cancer); additional African Americans; a penis and cervix; and a cross-section of histology that illustrates the membrane and cervical cancer. In addition, some commented on the graphic nature of the images, but agreed that they were appropriate for the HPV subject matter. In fact, the picture of the cervix received a very positive response, while images of the health care providers received mixed reviews.

➢ *"I didn't really care for the genital warts and the penis. But, obviously, we see these all day long. So, it doesn't really bother me too much." (Physician, Caucasian patient population)*

➢ *"I don't like the pictures on the top. I don't think you have to put pictures of doctors and nurses in there." (Nurse Practitioner, African-American patient population)*

v. Graphic Elements. The graphic elements in Design A received very favorable responses, ranging from "well placed" to "excellent." Many respondents noted that they were much more likely to read information presented graphically as opposed to plain text. In fact, many physicians suggested adding more bullets, highlights, and charts to the brochure to make it even more interesting and easier to understand.

➢ *"I like when they highlight something because it gets my eyes right there. I read the bullets. So, this is meaningful for someone like me who may be looking at lots of journals every day and lots of reading materials." (Nurse Practitioner, Caucasian patient population)*

➢ *"They stand out. It catches your eye. I'm more apt to read the bullets because they are highlighted there or they're in different colors." (Registered Nurse, African-American patient population)*

vi. Formatting. Overall, respondents were divided over the preferred size of the pamphlet. For example, despite the fact that some commented positively about the size and shape of Design A, some requested that it be larger (journal size), while others felt it was too large and inconvenient to use.

➢ *"I just don't like the size of it. I would say the size is better for a patient. For doctors, I prefer the smaller one because… it would be easier to handle if the size fits into the pocket of your gown." (Physician, Hispanic patient population)*

In addition, none of the participants expressed a strong preference for whether or not to include tabs, although several noted that including them could be useful.

➢ *"Section tabs are helpful. It depends on whether you intend this to be a pocket guide. If it's to be a pocket guide, then section tabs are going to be a drag. If it's just a small reference guide that's intended to be used as sort of a desktop guide and not carried about in the pocket, then it would be okay. But I don't think it's necessary." (Nurse Practitioner, Hispanic patient population)*

2. Design B

Overall, participants responded well to specific elements of Design B, but only 11 individuals chose it as their favorite.

i. Overall Design Look. Participants who favored the overall look of Design B preferred the smaller size, front cover layout, and inclusion of the CDC logo on the cover. Those who did not prefer this design believed that the small size and thick, dense appearance would make the information and layout too crowded.

➢ *"I like the way you've got the HPV and then you've got the different things you're going to cover in the pamphlet. And then the CDC—that's very important because people want to know that they're reading reputable information and I want to know I'm giving reputable information." (Nurse Practitioner, African-American patient population)*

➢ *"[Design B does not appeal to me because] it's a smaller pamphlet. It's narrow. More things are crammed into it." (Physician, African-American patient population)*

ii. Organization. All of the respondents expressed a positive impression of the organizational elements. Many noted that they felt this design has a more concise approach to organizing the material, which makes the information presented easier to read and more succinct.

➢ *"I think it's well organized. I think that the relationship between the pictures and the wording are good. I think it's easy to read." (Physician, African-American patient population)*

iii. Colors. Comments addressing the color of Design B were lukewarm at best. Several respondents said that they liked the color, stating that it was "okay" or "fine." However, nearly just as many people expressed a negative reaction, such as "it doesn't stand out" or it is "dreary."

iv. Images. When asked about the images in Design B, most responded that the pictures improved the quality of the pamphlet. In fact, several participants noted that the graphic nature of the pictures was helpful and similar images should be added. Specifically, respondents suggested including pictures of genital warts; different stages of the disease; normal and infected tissue; normal and abnormal cells; and clinicians. One physician reacted negatively to the picture of the infected penis, stating that she was "offended" by the image because HPV primarily is a female disease. However, none of the other providers expressed similar feelings toward the image.

- ➢ *I actually would like to see more. The pictures [I use] are really, really old. I don't have very good current pictures of HPV." (Nurse Practitioner, Caucasian patient population)*

v. Graphic Elements. The graphic elements of Design B were well received by participants. Several nurse practitioners and registered nurses commented that they particularly liked the "Types of HPV" table included in this version.

vi. Formatting. The format of Design B garnered a mixture of responses, ranging from those who did not like the format and thought it looks "dense" and "squashed," to those who believed it is an appropriate size and good choice of font. One nurse practitioner noted that they "get a lot of literature in this format, and it's just not something [they] may want to read." The participants were divided when asked whether or not they preferred tabs.

3. Paper Stock Preferences

Overall, the respondents did not want the pamphlet printed on heavier paper. Although there were several exceptions, most did not believe that the value or usefulness of the pamphlet would be increased by using a heavier stock paper for the algorithms. Preferences regarding the inclusion of a tear-out algorithm sheet were divided between those who wanted a tear-out because they could carry it around or post it in their office, and those who did not want a tear out because the sheet would become worn and the pamphlet would no longer be as valuable.

- ➢ "[*Perforated* pages] might be helpful. Or maybe a fold-out." (Physician, Asian American patient population)

- ➢ *"…if it was a perforated tear-out page, people would tend to tear it out and then throw the book away and the book has so much useful information in it otherwise." (Physician, African-American patient population)*

F. Alternative Material Considerations

The participants were questioned about the types of HPV materials they would need or use in their practices. In addition to probing about the pocket guide tested during the interview, the moderators asked about a variety of other materials CDC could produce, such as a patient counseling tip sheet or memo pad.

The most requested items overall were a Web site, algorithm wheel/chart, tip sheet, memo pad, and patient materials. Nurse practitioners and registered nurses were also very interested in the toolkit option. The participants were very interested in materials to help them counsel patients, as well as to give to patients to prompt a discussion or use during a discussion. Although the poster was not a popular item, many participants said they wanted a version of the algorithm to place on the wall or in an exam room. Several providers, particularly physicians, also requested a small, laminated version of the algorithms. Other suggestions for new materials from registered nurses included a laminated pocket card with counseling tips and a videotape for patients.

The preferences for materials only varied slightly by provider type. The physicians generally preferred the Web site, algorithm wheel or chart for the wall, and a tip sheet; while the nurse practitioners preferred the patient materials, memo pad, Web site, algorithm wheel/chart, and tip sheet. The registered nurses were most interested in the algorithm wheel/chart, toolkit, and tip sheet.

1. Pocket Guide

Participants first were asked whether they would use the information they just evaluated in a pocket guide format, and what qualities the guide would need to encourage them to keep the material rather than discard it. Most participants said they would keep and use the material tested, and were enthusiastic about having it. Only a few physicians stated they would not be interested in keeping it due to the large amount of materials they already have. However, the pocket guide format was one of the least popular material options among all participants, who were more interested in using the material as a reference guide or keeping it in exam rooms than carrying it around in their pockets.

A few physicians and nurse practitioners liked the idea of the pocket guide. None of the registered nurses requested it, but said they would keep the material and use it as a reference piece. In particular, several registered nurses said they would keep it if it contained patient counseling information or other information to share with patients.

- ➢ *"Our pockets are only so big. There's too many pocket-sized things. So, no, I wouldn't use it." (Physician, Caucasian patient population)*

2. Other Materials

i. Algorithm/Decision-tool Wheel or Chart. The participants were asked whether they would use an algorithm or a decision-tool wheel or chart in their practice. Most participants (26 of 27) said they would use this type of material, particularly if they could post it on the wall in the patient exam rooms. As mentioned above, several providers requested a small, sturdy, laminated pocket card with the algorithms. The respondents expressed a need for a durable tool that could also be used to share information with patients.

- ➢ *"…[algorithm charts] would be better if they were flowcharts that were able to be put on a chart for the wall in the exam room." (Physician, Asian American patient population)*

- ➢ *"I like the idea of the laminated algorithms. Those are really helpful." (Nurse Practitioner, Hispanic patient population)*

ii. Patient Brochures. The participants were asked if they would use patient brochures, and whether the brochures would need to take into account literacy levels or cultural issues. The patient brochures were extremely popular, with 28 participants requesting them. The participants noted that they are always looking for useful patient materials. In particular, several nurse practitioners requested shorter, one-page brochures for patients that contain a bullet-point format and are easier to read than a typical patient brochure.

Low-literacy Materials: Almost all participants noted a need for low-literacy materials. Although the exact level of literacy requested varied considerably both across and within provider types – and ranged from elementary school to high school – all agreed that it should be at or below high school-level.

One Hispanic nurse practitioner requested separate materials for her lower-literacy Hispanic populations than for higher-income patients, noting that the higher-income patients would want more statistical, complex information.

Culturally sensitive Materials/Languages: Many participants acknowledged a need for materials translated in other languages. Spanish was the language most requested, when one was specified. Other specific requested languages were Chinese, Hmong (Cambodian), Farsi, and Hebrew.

In addition, physicians serving Native Americans and Asian Americans specifically noted a need for culturally sensitive and multilingual materials. One registered nurse, who works with an African-American population, said she'd like to see more races represented in the material, especially Native Americans, African Americans, and Hispanics.

- *"…we'd like to see different races in anything we get. There's not that many brochures or literature that are out that are mainly specific to Native Americans. So, if there's some way to develop these brochures that are specific to Native Americans and for African Americans or the Hispanics that would really help us out." (Registered Nurse, African-American patient population)*

- *"It should be in a variety of different languages. The literacy level should be fairly simple – an elementary education." (Physician, Asian American patient population)*

iii. Patient Counseling Tip Sheet/Guide. The participants were asked if they would use a patient counseling or interpersonal relationship tip sheet or guide. Many participants (23) across provider types were interested in this type of material. As mentioned previously, one registered nurse requested a laminated card with counseling tips to carry around and use during patient interactions. In addition, one physician raised concerns about offending patients with cultural beliefs or practices that conflict with the recommendations being given and asked for that issue to be addressed within the counseling materials. In general, the respondents were encouraged at the prospect of receiving materials that would "be helpful" in assisting them with patient counseling on HPV-related subject matter.

- *"I know my patients who come in and say, well, I think we're supposed to do this and this and this, I'm more apt to go get the rest of the information and [use the tools to] make sure I'm not missing anything." (Nurse Practitioner, Caucasian patient population)*

iv. Memo Pad. The participants were asked if they would use a memo pad with key points about HPV or clinical algorithms printed on it. Overall, the providers were interested in the memo pad material, with 21 saying they would find it useful. The nurse practitioners and registered nurses were more enthusiastic about this idea, while the physicians generally were not as interested in it.

- *"That might be helpful. I'm always interested in any kind of educational material that I can share with my patients and anything that might be helpful. So, that might work out. A tear-off sheet might work out well and help with documentation also in the patient record in terms of what the plan is." (Nurse Practitioner, Hispanic patient population)*

v. *Web Site or CD-ROM.* The participants were asked whether they would use a Web site or CD-ROM in their practice. Most participants preferred the Web site to the CD-ROM, with 25 saying they would use the Web site and 12 wanting to use the CD-ROM. One physician commented that a Web site is no longer optional – it is a requirement. Most participants said that a Web site would be quicker and easier to access, and has an additional advantage because it can be updated regularly. A few providers liked the idea of receiving a CD-ROM, however, because they could use it with patients.

- *"More information and more accessible information is always easier. Especially if you could put it on the computer. You could pull it up immediately rather than look for something." (Physician, Caucasian patient population)*

- *"Something that we could go to immediately would be fine. So, either one." (Registered Nurse, African-American patient population)*

vi. Toolkit. The participants were asked whether they would use a toolkit containing some or all of the pieces listed above. Many participants (18) liked the idea of a toolkit and having a variety of materials available to them. All of the registered nurses said they would use a toolkit, while about half of the nurse practitioners agreed. One nurse practitioner requested that the toolkit include reproducible materials for patients. Only a few physicians were interested, however, in part because of storage and practicality issues.

- *"[With a toolkit]… you get into too much stuff. I'd rather have it all in one thing." (Physician, Caucasian patient population)*

- *"I would [use a toolkit]. I personally would use [a toolkit or a combination of multiple pieces about HPV] if they were available." (Nurse Practitioner, Hispanic patient population)*

G. Preferred Communication Methods/Channels of Dissemination

Ensuring that health care providers receive and review information can be a challenge, given their hectic daily schedules and the large amount of information they are inundated with on a regular basis. In order to determine which communication channels are most likely to capture their attention, the providers were asked to describe the best way to reach them with HPV information. More than half of all respondents said that sending e-mails or directing them to a particular Web site (especially www.cdc.gov) is the most effective way to reach them, specifically because they receive so much information in the mail. Other respondents indicated that they still preferred to receive information in the mail, particularly if the letter or package is addressed directly to them or has the CDC logo on it. Other preferred communication channels included professional journals, American Academy of Family Physician materials, continuing medical education programs, faxes, information from diagnostic laboratories, and television advertising.

➢ *"Personally, I like e-mails with a Web site link. That makes it easier for me. So, if I get an e-mail and it's in an easy format with a Web site to go to from a trusted source, then something like that is easy." (Physician, Caucasian patient population)*

➢ *"Anything that comes in from CDC is read. I personally take time out to read CDC information. So, anything that has the CDC logo on it is read. If the envelope says CDC, it's going to be read. The secretaries know it's going to be read." (Nurse Practitioner, African-American patient population)*

➢ *"Just probably the journals that nurse practitioners and physicians' assistants get. We get lots of journals. Like I said, that one called the Female Patient is all on women's health and it's a great avenue for things of this nature. It's so helpful." (Nurse Practitioner, Caucasian patient population)*

H. Reported Intentions

Following a detailed discussion of reactions to the pamphlet content, participants were asked to consider the content as a whole and to comment on what they would most likely do after receiving the information. Responses to this question varied. Many providers answered by explaining what they would do with the information, rather than with the pamphlet itself. In these instances, the majority of providers reported that the information in this pamphlet is useful and that they would likely share it with fellow providers who would also benefit. Overall, most providers believed that the pamphlet would be a valuable and useful tool, though a handful providers mentioned that it was too long and occasionally redundant.

➢ *"I'd definitely be more cognizant of the fact that it's a highly prevalent thing in the population. I wasn't aware that for sexually active individuals that you could be a carrier for this up to 80 percent of the time. That was one important point that I found in this packet." (Physician, Asian American patient base)*

- *"I will make my nurses read this and I would sit down with them and make sure they understand it. I would use this not just for the clinicians in the office, but also for the other staff members who might be involved in health education counseling." (Nurse Practitioner, Hispanic patient population)*

- *"Go schedule everyone for a Pap." (Nurse Practitioner, Hispanic patient population)*

Some providers responded to this question about reported intentions by describing what they would do with the pamphlet itself. Even though the pamphlet is designed as an educational tool for health care providers, some talked about distributing it – or sections of it – to patients as an educational handout. Others said they would use it as a reference tool or show it to patients who wanted detailed information.

- *"I'll keep it available. I might actually pull the algorithm out and put it in a plastic folder and have that available on my wall. When you're dealing with so many diseases, quick and easy references are so easy." (Nurse Practitioner, African-American patient population)*

- *"I would use it as a reference and in some cases show it to patients to go over facts and figures if they were really concerned." (Physician, Caucasian patient population)*

IV. CDC Expert Feedback

A. Reactions to Pamphlet Content

The CDC subject matter experts provided feedback on the pamphlet content with respect to scientific accuracy, scope, and appropriateness. Overall, they suggested primarily line edits and a few broad-based changes. For example, one expert felt that the content could be reduced and divided into two documents – one addressing genital warts and the other addressing cervical cancer – or that the epidemiological information could be removed. Others suggested adding more charts and figures, a page outlining treatment approaches, and more detailed cervical cancer statistics.

The CDC expert feedback was fairly diverse, with little agreement on specific revisions. Below, we provide an overview of the general comments from the experts and note specific content areas that received comments from more than one expert, indicating the need for revision. We also provide a list of more specific recommendations made by individual experts. These recommendations are described within the context of each of the four pamphlet content sections.

Section 1

Many of the comments in the first section related to removing information that was not considered relevant as well as clarifying words or phrases to improve accuracy. In particular, several experts wanted to improve the accuracy of the statement about HPV transmission. Also, in some instances, experts wanted to add more detailed information, such as definitions to clarify certain statements. In other cases, they suggested verifying references to confirm the accuracy of the information presented.

Examples of the recommendations include:
- Instead of using 80 percent of sexually active women, say "more than 50 percent of sexually active persons."
- Clarify what is meant by "good" HPV testing methods for men
- Acknowledge that nutritional deficiencies is not a definitive risk factor for HPV
- Revise the discussion about transmission by inanimate objects to acknowledge that such findings are undocumented.

Section 2

As in *section one*, comments on *section two* related primarily to adding or removing words and phrases to increase the accuracy of certain statements. There also were a few sentences that were confusing to the experts, or that were identified as needing to be moved within the document to help improve organization or removed altogether. In addition, the risk factors table was problematic for many of the experts due to their concern that many of the listed risk factors may not be well substantiated.

Examples of specific recommendations include:
- Several experts were not sure whether all of the factors listed in the risk factors table were well substantiated. Immunosuppression was noted as the strongest factor listed.
- Delete discussion of cesarean delivery since new information is expected to come out on this subject.
- Clarify whether *reducing the duration of infection* (for prevention of genital HPV) refers to reducing the viral burden or the amount of viral shedding.
- Qualify that HPV is transmitted through "direct" skin-to-skin contact.

Section 3

With respect to *section three*, several CDC experts commented on the counseling section, wanting to remove points that seemed unnecessary or to add to the existing information. In addition, they recommended clarifying several points within the "Key Messages" box and "HPV Vaccines" section to improve accuracy and ensure the information provided does appear to be official CDC recommendations. In addition, several experts noted the need to add ACOG information to the screening guidelines table.

Examples of the recommendations include:
- In the "Key Messages" box: add genital warts as a symptom; qualify Pap testing with "appropriate treatment and follow-up" as part of the process to prevent cervical cancer; delete information about the number of partners; add an explanation of why screening is beneficial.

- Revise wording on recommended vaccine use to avoid making predictions on the FDA ruling and the appearance that CDC is making an official recommendation for the vaccine.

Section 4

The CDC experts offered many suggestions for the "HPV DNA Testing" section, primarily noting a need to reorganize some information and clarify key points, including the approved and non-approved uses for this test. In the "Clinical Management" section, some experts asked for clarifications of confusing statements, references to support the information, an expanded discussion of the extended screening intervals, and for clarification of CDC's position on the recommendations or approaches listed.

Examples of the recommendations include:

- Specify that the HPV DNA test is for women only.
- Address uses for which the test is *not* approved or recommended (based on the inappropriate uses identified in CDC's national provider survey).
- Clarify that there is no HPV test for men and explain why.
- Note that the three approaches to managing women with ASCUS are not CDC positions, but have been recommended by national organizations.
- Address pros and cons of HPV DNA test

B. Reactions to Pamphlet Designs

The CDC subject matter experts expressed an overall preference for Design A over Design B. Of the seven experts who provided feedback on the design, only one preferred Design B.

The general consensus was that the color of Design A stands out more and is more eye-catching, although some were concerned that the color could confuse providers, who might think it is intended as a patient education piece. At least one expert perceived the color of Design B to be more "serious."

Many of the experts liked the variety of images depicted in Design A. One person commented, however, that the images are less serious than those in Design B, and that an image of the HPV virus should be added to help indicate that it is a higher-level material.

The experts had mixed feedback on the format of the pamphlet. One individual preferred a slim size because can fit into lab coat pocket. Another disagreed and preferred a wide format because it looks more substantive, while a third expert suggested an even larger, journal size.

V. Study Limitations

Interview methodology offers rich opportunities to garner and assess participant reactions to draft concepts and images, as well as to take note of the words they choose to express their thoughts about particular issues. The research detailed in this report provides insight into the target audiences' reactions to the pamphlet content and design, as well as needs and preferences for HPV materials. Limitations of this study are described below.

A. Generalizing Findings to the Larger Population of Health Care Providers

The qualitative nature of interview methodology and the limited number of participants mean that the findings may not be statistically significant and representative of a larger target audience. However, because the participants were recruited on the basis of their similarities to the target audiences for HPV educational materials, the findings of even this small sample are of considerable value for assessing likely target audience perceptions and attitudes. It should be noted that other audiences may have perceptions and attitudes that vary from those of the study participants. For example, this research did not explore whether OB/GYNs or health care providers in other specialty areas are also in need of HPV-related information and resources.

Because the recruitment criteria for this project were very specific and participants had to meet eligibility criteria across a range of different variables, the recruitment often was challenging in light of the project's tight timeframe. As a result, in some audience segments in which recruiting was difficult, the "hours working in direct patient care" recruitment criteria was relaxed slightly to include participants who work with patients only 16 hours a week, instead of 20. In some situations, patient population criteria was also relaxed slightly to include participants who work with the designated population for 50 percent of the time as opposed to 60 percent. We do not believe these changes resulted in the recruitment of participants who were significantly different from the rest of the study sample.

B. Time Limitations

The deadlines dictated by CDC to meet the Congressional mandate placed the project under tight time constraints for developing, testing, and finalizing the materials for health care providers. These time constraints hampered the project team's ability to incorporate feedback on the materials by CDC's SMEs in the most efficient manner possible by requiring CDC expert review to occur simultaneous with the interviews. As a result, content changes made upon the suggestion of SMEs could not be tested with the target audience(s).

Time limitations also dictated the project's approach of testing both the content and the designs in the same set of interviews, rather than testing during multiple phases of development. Doing so may have limited the project's ability to gather in-depth feedback about provider reactions to the content and the design.

In addition, time and funding constraints limited the project's ability to explore the potential advantages of developing materials targeted to smaller, more specific audience segments. For example, additional time and resources may have allowed the project to assess whether there are different information needs or preferences beyond the booklet, based on the extent to which providers practice obstetrics or perform Pap tests.

VI. Recommendations

Issued by Ogilvy Public Relations Worldwide (Ogilvy PR) and CDC, the following HPV pamphlet content and design recommendations are derived from both the health care provider and CDC SME responses. These recommendations currently are under CDC review. Once a determination is made as to which recommendations are accepted, the pamphlet content and design will be revised accordingly. Once the pamphlet is officially cleared by CDC and the U.S. Department of Health & Human Services, it will be made available to health care providers and other interested parties.

Presented by Ogilvy PR for CDC's consideration, the following recommendations for additional HPV materials and methods of dissemination are drawn from the health care provider feedback.

A. Pamphlet Content

<u>Section 1</u>

Why Is HPV Important?

- ***Revise the title of this section to "Why is it Important to Know About HPV?"*** A few health care providers suggested this clarification.

- ***Replace "80% of sexually active women" with "more than 50% of sexually active persons" and remove the reference to percentages of men.***

- ***Break the second paragraph into two sentences, and add "cases of" cervical cancer.*** We suggest revising this paragraph by removing "but it is now accepted that" and starting a new sentence at "persistent."

What Is HPV?

- ***Add detail to the second sentence to specify why human HPV is different.*** We suggest adding, "Human papillomavirus (HPV) is a DNA virus that can cause epithelial…"

Types of HPV

- ***Revise the language in the second and third sentences.*** We recommend changing the sentence to read, "They differ in terms of the types of epithelia that they infect. Some infect cutaneous sites, while others infect mucosal sites."

- ***Detail the types of HPV that account for 38 percent of cervical cancers.*** One physician stressed that it is confusing to read that HPV 16 is found in half of all cervical cancers and that HPV 18 accounts for 10 to 12 percent of cervical cancers. Since these two types account for 62 percent, the remaining 38 percent should be represented – particularly since the various other high-risk and low-risk types are presented within the table that precedes this discussion. We suggest inserting a sentence that specifies the types of HPV that the remaining 38 percent of cases generally are attributed to.

- ***Remove "types whose risk is not yet well established" from the text.*** We recommend retaining the information within the table, but removing it from the text since it does not add any informational value there.

How Common is HPV?

- ***Specify that about half of the 20 million people who have HPV are sexually active adolescents and young adults.*** Several providers commented that the draft copy currently references too many complex statistics/numbers. This change, which was proposed by two physicians, will make the first two points listed under this section easier to read and interpret.

- ***Clarify the sentence about recent prospective studies of college age women.*** We recommend specifying which population is being referred to with the 80 percent statistic and clarifying the timeframe in which this population will become infected.

- ***Change "good testing methods" to "reliable testing methods" for men.***

What Are the Risk Factors for Acquiring a Genital HPV Infection?

- ***Eliminate the "less commonly identified risk factors" cited within the "risk factors for acquiring a Genital HPV infection in women" table.*** We recommend this change since current science does not definitively suggest that active or passive cigarette smoking, oral contraceptive use, nutritional deficiencies, and lack of circumcision of male partner(s) are risk factors.

- ***Change the title of the risk factor table.*** As clarification, we recommend revising the title within the risk factors table to read, "Factors strongly associated with acquisition of HPV infection in women."

How is HPV Transmitted?

- ***Re-work the first sentence.*** We recommend revising this sentence to read, "Unlike HIV and most other sexually transmitted infections, HPV is transmitted through direct skin-to-skin contact rather than through semen or bodily fluids."

- ***Clarify the second sentence.*** We recommend revising the second to read, "However, genital HPV is most often transmitted during penetrative genital contact, usually through vaginal or anal sex."

Natural History of Genital HPV Infections

- ***Remove redundant information from the first sentence.*** We recommend removing "causing no clinical problems" from the sentence.

- ***Clarify whether 91 percent of HPV cases truly go away within two years.*** Many providers were confused by this point when they later read that "it is unclear whether women who become HPV DNA negative actually clear the virus from their bodies. It is possible that in some women the virus remains in a nondetectable dormant state for a considerable period of time and then reactivates many years later." We suggest revising the second bullet point to read, "70 percent of women with new HPV infections become HPV negative within one year, and as many as 91 percent of women become HPV negative within two years." We also suggest combining the second and fourth bullet points to address the concept of clearance in a more logical order.

- ***Clarify that women who develop persistent infections are at "greatest" risk for developing cancer precursors and cancer.***

- ***Remove the last point within the section.*** Since the reference is from 1998 and appears to be irrelevant, we recommend removing it.

Section 2

What is the Risk Associated with Genital HPV Infection?

- ***Provide a better distinction between this section and the prior discussion of risk factors.*** Several providers mistakenly believed this section provided the same content as the prior discussion, which focused specifically on the risk factors for acquiring a genital HPV infection. However, this section is drafted to address the risks that are associated with genital HPV infection, once it is contracted. We recommend modifying the opening sub-head to read, "What are Potential Outcomes Associated with Genital HPV Infection." In addition, we suggest adding a new header to the table that is provided at the top of page five, which reads, "Factors Influencing HPV Persistence and Progression to Cervical Cancer." The copy within the current table header should be moved into the table itself.

- ***Remove some of the risk factors from the table and provide appropriate scientific citations.*** Several individuals expressed concern about the elements included in the table on risk factors for developing cancer from HPV – particularly oral contraceptive use, cigarette smoking, nutritional deficiencies, and "having a mother who took diethylstilbestrol" – due to a lack of science confirming these associations. As a result, we recommend removing these factors from the table, but describing them within the text, and providing references for each of the remaining risk factors for individuals who may be concerned with the data.

- ***Clarify the "lack of adequate Pap test screening" risk factor for cervical cancer.*** One nurse practitioner did not understand the meaning of this. One physician stated that the point should explain that inadequate Pap test screening has to do with poorly performed Pap smears as well as the infrequency of screening. We recommend revising the point to "lack of adherence to recommended Pap screening and follow-up."

- ***Move the third paragraph to follow the first sentence and clarify the type of HPV as high-risk.*** We recommend moving the information in the third paragraph to the second and third sentences of the first paragraph. We also suggest inserting "high-risk" before HPV in this paragraph.

- ***Clarify the meaning of "one large case-control study reported relative risks of over 100 for cervical cancer for all of the high-risk types of HPV."*** Several physicians did not understand this statement. One asked if this point is in reference to high grade SIL. She suggested that CDC incorporate "Bethesda language" to make this more understandable. Another physician felt that the reference to relative risk distorts the information by making the cervical cancer risk sound much more serious than it actually is.

- ***Change the word, "only" in the fourth paragraph to "the vast majority."*** One subject matter expert suggested removing "only" because she was not sure whether the statement is accurate. Another expert suggested changing "only" to "the vast majority of women."

- ***Clarify that perinatal transmission occurs infrequently, and reorganize the information in this section.*** We recommend adding, "Very rarely" to the beginning of the second paragraph under "Risk to Infants," to clarify that recurrent respiratory papillomatosis is quite uncommon.

- ***If appropriate, provide additional information about perinatal transmission of HPV infection.*** Quite a few providers expressed significant interest in learning more about this presentation, specifically with respect to how it is treated and the baby's prognosis. One physician asked how it can be prevented if C-sections are not protective. Another provider requested clarification on whether C-section babies have the same rate of HPV infection during delivery as non-C-section babies. Given the pamphlet's space constraints, CDC may wish to list a Web site where providers can go for additional information on the topic.

Prevention of Genital HPV Infection

- ***Shorten this section and eliminate redundancies.*** Quite a few providers felt that this section was too long and repetitious. We recommend eliminating the paragraph that introduces the three key strategies for reducing sexually transmitted infections because it is unnecessary.

- ***Update the references.*** We suggest researching and incorporating more up-to-date references for this section since the current references are from 1996 and 1998.

- ***Incorporate messages consistent with CDC's Report to Congress within this section.*** We suggest including select messages from the individual prevention strategies section of CDC's *Report to Congress* within this section.

- ***Clarify the discussion about reducing the duration of infectiousness.*** CDC should consider clarifying whether this refers to viral burden or the amount of viral shedding.

- ***Clarify the point that "evidence indicates that currently available therapies for HPV-related cervical cell abnormalities and genital warts may reduce infectiousness, but probably do not eliminate it."*** Numerous providers were confused by this statement. CDC needs to be clarify whether the virus really clears the body or it lies dormant. One physician pointed out that a subsequent point seems to contradict this statement, by saying "approximately 70% of HPV DNA positive women with cervical cancer precursors who undergo surgical excision subsequently become HPV DNA negative." One nurse practitioner emphasized that CDC needs to more clearly explain that some cases of HPV may be lifelong.

- ***Insert language explaining that primary prevention is ideal, but difficult to impossible among sexually active adults.*** In light of provider reactions focusing on the need to prevent the acquisition of HPV rather than its consequences, we recommend adding a few sentences to put the commonness of HPV in perspective and to emphasize that clinical efforts should focus on preventing the consequences of HPV – particularly cervical cancer, since most sexually active adults will likely have HPV at some time in their lives.

- ***Clarify the second sentence in the first paragraph under number 1.*** We recommend revising this language, which states "Genital HPV infections occurring in the absence of detectable lesions are not treated," because it contradicts the prior statement. We suggest the following alternative language: "For this reason, genital HPV infections occurring in the absence of detectable lesions should not be treated."

- ***Add "direct" to the term "skin-to-skin contact."*** We recommend incorporating this change throughout the document as clarification.

Section 3

Counseling People Infected with Genital HPV

- ***Move the sections "Counseling People Infected with Genital HPV," "HPV Vaccines," and "Prevention of Cervical Cancer" to the end of pamphlet.*** Some respondents commented that this information, while important, would be more appropriately placed at the end of the pamphlet, or as an addendum. Moving this content to the end also will result in moving the HPV DNA Testing and Clinical Management Issues sections earlier in the document, which some providers felt was preferable because they perceived these to be the most useful sections.

- ***Shorten this section considerably.*** Respondents frequently commented that this section was too long and covered information they already knew. The last two paragraphs, in particular, were seen as unnecessary, particularly by the CDC experts. Therefore, we recommend reducing this section to the key educational messages box, which was well received, and a few brief statements about lack of knowledge of genital HPV and women's needs for information.

- ***Change the title of the key educational messages box to reflect the fact that the messages only apply to counseling women in the context of cervical cancer screening, as opposed to counseling patients on genital warts.***

- ***Clarify and add some of the points in the key educational messages box.*** We suggest revising the first bullet to read: "Genital HPV infection is very common among sexually active adults. Most sexually active adults will have it at some point in their lives, though most will never know it because the infection usually has no symptoms and clears on its own. Very few women with HPV will develop cervical cancer." An additional bullet will be added that reads, "Genital HPV infection is usually sexually transmitted. The incubation period (the interval between initial exposure and established infection or disease) is variable and it is often difficult to determine the timing and source of infection." For the fifth bullet, we recommend adding "appropriate treatment and follow-up" after early detection as part of the process to prevent cervical cancer. We also suggest revising the last sentence, to read: "screening using the Pap test with appropriate follow-up for all sexually active women." We also recommend adding a bullet point at the end, stating: "This screening detects abnormal cell changes that can be treated so they don't progress to cervical cancer." Finally, we also recommend adding the following bullet: "The types of HPV that cause genital warts are different from the types that cause cervical and other anogenital cancers."

- ***Add bullet points below the box of key educational messages to further clarify the relationship between types of HPV that cause genital warts and those that cervical abnormalities.*** One bullet should read: "HPV testing is not indicated for patients, or partners of patients, with genital warts." Additional bullets should be inserted to note that 1) Pap test abnormalities are not related to genital warts (or vice versa), and 2) women with Pap test abnormalities and their sex partners do not need to be screened for genital warts or specifically for HPV.

HPV Vaccines

- ***Tighten up this section by using more bullets.*** Some respondents felt it would be easier to read and pull out key points from this section if it contained more bullet points. We recommend exploring this possibility.

- ***Revise the wording of the second paragraph on recommended vaccine use.*** To avoid the appearance that CDC is making an official recommendation for the vaccine, we recommend changing the sentence to read, "…and would likely be recommended for administration before…"

- ***Revise the language about the FDA ruling in the third paragraph.*** To avoid making predictions on the FDA ruling, we recommend changing the third paragraph to read, "…by the FDA, but may be available soon."

- ***Clarify the language in the last sentence.*** We recommend changing this sentence to read, "…precancerous cells in women already infected with HPV – are also in development."

- ***Clarify whether vaccines are being developed for both men and women.*** In part because of the difficulties of testing in men, and the fourth paragraph, which lists the results of a study conducted with adolescent girls, a few providers wanted clarification about whether the vaccines under development are intended for use among males and females, or only among females.

- ***If available, provide a Web site where providers can get updates on the status of vaccine development.*** Most providers appreciated and were very interested in information about the vaccine for genital HPV. Some had heard that a vaccine is under development, but knew little about it. For others, this information was completely new. Many providers said they were interested in getting updates about the status of the vaccine as well as notification of when it will become available, preferably by visiting a Web site. We suggest listing CDC's Web site as a resource for this information at the end of the pamphlet.

Prevention of Cervical Cancer

- ***Remove the word "only" in the third paragraph.*** Some respondents commented that the word "only" is confusing because it implies the number of cases and deaths in 2005 will be lower in comparison to 2004, but the 2004 numbers are not provided as a comparison.

- ***Add the ACOG guidelines to the screening guidelines chart.***

- ***List cytological screening interval recommendations on a single row within the table.*** A few providers suggested that it was confusing to see the recommended screening intervals presented on two different rows within the table. We recommend combining them on a single row with subheads or bullets indicating differences for before and after age 30.

- ***Provide Web site(s) where providers can obtain additional details about the guidelines and get updates.*** Several providers requested a Web address for additional information pertaining to this section.

- ***Clarify the key public health message.*** We recommend changing the second sentence of the key public health message since providers cannot fully control whether patients are screened. The revised sentence should read, "Therefore, screening is very important in women who have never or rarely been screened."

- ***If appropriate, replace "high grade cervical cancer precursors" with "ASCUS."*** Two of the physicians indicated that the Bethesda classification term, "ASCUS," would be more familiar and immediately meaningful to providers.

- ***If appropriate, clarify whether the text in this section separates ASCUS from HGSIL and LGSIL.*** One physician felt this was unclear.

- ***Clarify whether the screening guidelines provide different recommendations for post-hysterectomy depending on the type of hysterectomy.*** One nurse practitioner asked for clarification on this point, questioning whether the guidelines have different screening recommendations for a woman who has a uterus versus someone with a partial uterus, etc. We believe this is an important point for clarification.

- ***Add a statement explaining that the increased sensitivity of using the Pap test with the HPV DNA test provides a high degree of assurance that a woman will not develop cervical cancer in the next three years.*** Numerous providers commented that they did not agree with the guidelines that recommend a three-year screening interval or cervical cancer.

Section 4

HPV DNA Testing

- ***Indicate the uses for which the HPV DNA test is not approved or recommended.*** Non-approved/recommended uses that should be mentioned include screening for 1) HPV status, 2) partners of female patients with cervical cell abnormalities, 3) individuals and partners of individuals with genital warts, and 4) men, among others

- ***Indicate that the test is approved only for screening of high-risk HPV (13 types).*** We suggest making this addition because low-risk HPV testing has no clinical significance or value.

- ***Re-organize this section to group related content.*** Some providers suggested re-organizing this section so that related content is grouped together in a way makes it easier to read. This includes making sure the content does not jump between discussions of the different types of HPV tests.

- ***Clarify the language in the first paragraph.*** We recommend changing this to read, “A molecular test to detect HPV DNA is approved by FDA for use in selected female patients to determine if they have HPV infection for guiding decisions about future PAP testing, follow-up of abnormal Pap tests, or follow-up of women who have been treated for abnormal cervical cells or cancer.” This change will further clarify that the test is only for use in women.

- ***Delete the third sentence in the second paragraph.*** The sentence on antibodies against genital HPV is perceived to be confusing, irrelevant, and inaccurate. Since it is providing additional information about the HPV blood tests and not the HPV DNA tests – the main point of this section – we recommend deleting it.

- ***Expand the third paragraph regarding the only FDA-approved molecular test for HPV.*** We recommend changing the sentence to read, “The only molecular test…is a solution hybridization method for testing of HPV DNA in endocervical cells.”

- ***Clarify the information provided within the fifth paragraph.*** We recommend changing ordering of words within this sentence to read, “There are no accepted clinical uses for low-risk HPV DNA testing.”

- ***Clarify the information in the second and fourth bullet points on page 10 and how they are related to each other.*** A few providers found the information in these two bullet points contradictory. We recommend changing the information in the fourth bullet to read, “The test is used to determine whether they are at risk for having or developing a CIN 2,3 lesion in the next three years. It is not used to determine whether someone is infected with HPV.” We also recommend placing these bullet points next to each other and providing clarification as to how these statements work together.

- ***Clarify the sensitivity statement in the third bullet point on page 10.*** We recommend revising the language in the third bullet from “the sensitivity of the test means” to “the fact that the test is not 100% sensitive means…”

- ***Add a statement acknowledging that the psychological impact of HPV DNA testing must be considered in decisions to use the test.*** The statement should explain that women may experience anxiety, concern, distress, or guilt in response to an HPV diagnosis and that providers should consider this potential psychological impact, both in their decision to use the test, and in how they convey the results of an HPV DNA test to patients.

- ***Clarify HPV testing in men.*** In the last paragraph on the page, we suggest adding more definitive information on HPV testing in men. In addition to an explanation of why testing is not available or recommended, we recommend adding the sentence, “Currently, there is no FDA-approved HPV DNA test for males. Testing in males is not recommended.” We also recommend keeping the original copy that explains why testing in males is not recommended: “In large part this reflects problems with collecting an adequate sample of epithelial cells from ano-genital surfaces for analysis. In order to collect sufficient material for testing, relatively abrasive methods are required. (49)”

- ***Add a statement explaining that, for primary screening, if both the Pap test and the HPV DNA test are negative, women do not need to be re-screened for three years.***

- ***Insert the table “Results obtained on cytology and DNA testing,” and emphasize key points in the copy.*** This algorithm is clear and participants expressed a preference for receiving information presented in algorithms.

- ***If appropriate, refer to a few Web sites where providers can learn more about how to conduct HPV DNA testing.*** Some physicians requested information about how the HPV DNA test is actually conducted. We recommend listing various pharmaceutical Web sites that offer instructions for performing HPV DNA tests for additional information.

Clinical Management Issues

- ***Consider adding a statement describing the extension of the screening interval to three years as a benefit and explaining that a history of Pap test results is no longer needed for risk stratification using this combined strategy.*** This statement should be pulled from ACOG's 2005 bulletin, ACS, or the interim guidance.

- ***If appropriate, provide greater information about why HPV DNA testing is preferred in the third paragraph on page 12.*** We recommend incorporating additional detail about why HPV DNA testing is performed in this scenario, with mention of both the pros and the cons.

- ***Revise the language within the section addressing concerns.*** We recommend changing the first sentence in this section to read: “…concern about the misuse of HPV DNA testing and the potential negative impacts in this group.” The first sentence in the second bullet point also should be changed to read, “about their risk.”

- ***Explain why the USPSTF found insufficient evidence to recommend for or against routine use of HPV DNA testing as a primary screening test for cervical cancer.*** Some providers said they needed additional information about why USPSTF felt there is insufficient evidence in order to know how they should react to this statement. They felt it would be important to know, for example, whether USPSTF deemed that not enough studies had been conducted or whether studies showed too many false positives. We recommend adding the following statement (from the USPSTF Web site) to the text: “The USPSTF found poor evidence to determine the benefits and potential harms of HPV screening as an adjunct or alternative to regular Pap smear screening. Trials are underway that should soon clarify the role of HPV testing in cervical cancer screening.” The reference for this statement should be included as well.

- ***Soften the language for Consensus Guideline recommendations.*** Since there are less data for the Consensus Guidelines, the language within this sentence should be softened. As such, we recommend changing "indicate" to "recommend."

- ***Clarify the three approaches to managing women with ASCUS.*** We suggest clarifying that this is not a CDC position by noting that the three approaches have been recommended as possibilities by national organizations and are not ranked.

- ***Provide references for the sentence mentioning published studies on HPV DNA testing, and rework language.*** We recommend adding these references so individuals can review these sources if they have questions about the content. The language should be revised to read, "In the published studies, HPV DNA testing appears to be more sensitive than repeat cytology and appears to result in referring fewer patients to colposcopy compared to a program of repeat cytology."

- ***Add a phrase to explain what "routine adjunctive screening" means.*** In the section discussing routine screening in women age 30 and older, two nurse practitioners commented that they had difficulty understanding the meaning of the phrase "routine adjunctive screening." We recommend adding a phrase or clause to one of the sentences in this section to clarify this meaning.

- ***Re-organize the adjunctive screening section.*** We suggest reorganizing the section to first describe why adjunctive testing is a good idea; then provide the recommendations; and finally, to summarize the data.

- ***Provide an explanation for why routine adjunctive screening with a Pap test is only recommended in women beginning at age 30.*** One physician commented that this recommendation is confusing due to prior content stating that younger women are at greater risk of genital HPV infection. As such, we recommend including a brief explanation for this recommendation.

References

- ***Create a separate "additional resources" section that provides the Web addresses of all resources that are available online.*** Several providers indicated that they liked to seek additional information online, and requested Web resources and online reference citations so they can obtain additional information.

B. Pamphlet Design

Recommended Approach: A

Design A was the preferred design by the majority of participants (26 of 36) and CDC experts. Participants responded positively to the cover design, color, and size of Design A, noting that it is eye-catching, inviting, and easier to read. While many participants commented positively about the cover of Design B, participants generally thought the design was adequate, but did not stand out due to the traditional size and "dull" color.

Design A received favorable comments about the color, design, and layout. The organization was well received, particularly due to the bolded headings and bulleted format. The wider size led participants to assume it contained less dense information and would be easier to navigate, making them more likely to want to read it. Many participants said they would use this pamphlet as a reference guide to keep at their desks – and not carry it around as a pocket guide – making the wider size preferable because it will be easier to find and use.

Participants liked the variety of images presented on the cover, although several commented that pictures of health professionals were not necessary for this audience. The graphic elements within the pamphlet received overwhelmingly positive responses. Most participants liked the clinical images in Design A and thought it contained the right number of images. A few participants requested one or two additional clinical images, which may include the depiction of a cervix with ASCUS and cancer, a penis, female genital warts, anal warts, and/or more images of the cervix.

Participants were mixed about whether to include tabs in Design A. Most felt that tabs were not needed, or they did not have a preference either way. Participants also were mixed about whether to print the algorithms on heavier paper or to include them as a tear- off. While many participants wanted a version of the algorithms to pull out and post in offices or exam rooms, they were concerned about removing the information from the pamphlet and not having it there for future reference. Only a few participants requested the algorithms on heavier paper.

We recommend using Design A with the following modifications:

- ***Replace the photos of the health care professionals on the cover with more clinical images.*** Participants did not respond well to the images of the health care professionals, commenting that it reminded them of patient material. We recommend adding one or two more serious clinical images to help ensure that providers know this is a high-level, provider-oriented piece.

- ***Incorporate popular elements – contents and CDC logo – from the cover of Design B.*** Participants responded quite favorably to the listing of the contents on the cover of Design B, with many listing that feature as the only positive aspect of the design. Participants also liked Design B's prominent use of the CDC logo, which let them know the content was produced by a scientifically reliable and reputable source.

- ***Label pamphlet cover "Clinician Reference Guide".*** Participants noted they would use this piece as a reference guide and cited this as a reason they would keep it for future use, rather than discarding it.

- ***Insert additional images into the pamphlet.*** Participants reacted well to the graphic clinical images included in both versions of the pamphlet design, either commenting that there were the right amount of images or requesting a few more. The specific images we recommend including are: the image of the penis with genital warts from Design B; an image of female genital warts; and a comparison of images showing the progression of infection, such as with ASCUS and cervical cancer.

- ***Add internal tabs.*** While participants were mixed about including tabs in Design A, many noted that the internal tabs in Design B were sufficient if tabs were needed. Since adding internal tabs will help meet the reference needs of those who requested it, and did not offend those who did not request it, we recommend including them.

- ***Develop a separate, laminated, pocket-sized piece containing the algorithms.*** Many providers requested a version of the algorithms they could post or carry with them, but were concerned about if CDC and partner organization resources permit, "losing" the information from the pamphlet if the algorithms are a tear-off piece. As such, we recommend creating a separate laminated pocket-sized guide with the algorithms, in addition to the algorithms contained within the pamphlet.

C. Additional Materials

Participants expressed interest in a range of different materials about HPV. Based on their collective feedback, the following points detail a series of elements that CDC should consider developing:

- ***Develop patient education brochures on HPV.*** When asked whether they would use patient brochures, the majority of providers reported that they would, especially if they are appropriate for use with low-literacy populations. Several providers mentioned that they only are allowed to disseminate patient brochures that are produced by their State and local health departments. As a result, we recommend that CDC develop template materials that can be customized by health departments and other third parties and to encourage their widespread dissemination and use through program partners.

- ***Create an algorithm/decision tool wheel or chart that can be posted in an exam room and used to share information with patients.*** While participants understood that the algorithms in the pamphlet were intended for providers, several commented that they could also imagine using them to discuss HPV testing and follow-up with their patients. Similarly, providers felt that a durable tool that they could use as reference would be helpful, especially if they could use it to share information with patients.

- ***Develop a memo pad with key points about HPV or clinical algorithms printed on it.*** Participants, especially nurse practitioners and registered nurses, felt these tools could be helpful.

- ***Develop a patient counseling tip sheet or guide that includes examples of the words providers can use to deliver the key educational messages to patients with cultural sensitivity.*** Many providers were interested in materials that would assist them in counseling patients on HPV. Some requested laminated cards with counseling tips and/or key messages. At least one physician requested guidance on how to counsel patients without offending those whose cultural beliefs or practices conflicted with key recommendations. Two providers suggested that the box of key educational messages would be a more useful tool if the educational messages are “translated” into the words that providers could use to deliver the key messages to patients. They felt this was important because clinicians do not always know exactly how to explain medical information to patients meaningfully and without creating more confusion and anxiety. One provider suggested that this could include instructions for adapting the messages to a patient’s particular situation. Another provider said they would like a tool that provides guidance for dealing with patients who are anxious and concerned about their diagnosis. In light of one physician’s concerns that some recommendations may conflict with patient cultural beliefs and practices, we recommend working with appropriate special audience experts throughout the course of developing and testing a patient counseling tip sheet to help ensure that it is culturally sensitive, yet effective in communicating to the target population the necessary information about condom use, the Pap, test, HPV test, and other key issues.

- ***Package HPV materials for providers in a toolkit format.*** Roughly half of the providers said they would use a HPV toolkit.

- ***Consider developing a range of patient education brochures that target different populations.*** Many providers expressed a need for patient education materials in other languages. Spanish was most frequently requested. Asian languages also were mentioned generally, in addition to Chinese, Hmong, Farsi, and Hebrew. A few participants also suggested that separate materials should be developed for patients with lower literacy levels as well as for patients with higher incomes and levels of education.

D. Methods of Dissemination

- ***Consider posting the pamphlet content, as well as additional information and resources, online for providers.*** Many participants felt that a Web site would be helpful, and quicker and easier than accessing information through a CD-ROM.

- ***Inform providers about new HPV information and materials by sending an e-mail from CDC that contains a link to a CDC Web site.*** The majority of providers indicated that they like to receive information through e-mail or by being directed to a Web site. The e-mail and Web site should come from CDC since providers indicated that they see it as a highly credible organization and, therefore, they are more likely to make an effort to read information from CDC.

- ***Consider conducting a companion print mailing to providers, in a package that prominently displays the CDC logo.*** While over half of the participants indicated that they prefer receiving and accessing information in an online environment (through e-mail or the Internet), many of the providers interviewed indicated that they do not use e-mail or the Internet regularly and that they prefer to receive information through the regular mail. Some providers requested that such mailings be addressed directly to them by name.

- ***Consider disseminating HPV information through professional journals, continuing medical education programs, and conferences.*** While only a small number of providers indicated a preference for receiving information and resources from CDC through these channels, responses to earlier questions in the interview guide indicate that, for many providers, these are the information channels that have exerted the greatest influence on their current knowledge of HPV and approaches to cervical cancer screening and clinical management.

E. Issues for Further Research/Consideration

The health care provider interviews and subject matter expert review of the pamphlet content uncovered various issues and concerns that warrant further research and consideration. Following are a series of additional suggestions concerning the brochure content, which CDC will investigate as time and resources allow.

- ***Address gay/lesbian patients within the transmission discussion.*** One physician felt strongly that the content needs to address whether gay men or women who have sex with women can transmit and/or are at higher risk of HPV. Since the current copy doesn't specifically mention gay/lesbian individuals, she felt that it only seems to apply to heterosexuals.

- ***Clarify how HPV can be transmitted by "environmental surfaces."*** A few providers wanted to know exactly which types of environmental surfaces can transmit HPV (e.g., toilet seats). They also felt CDC should specify whether HPV can be transmitted via sex toys. This section should clarify that the evidence is inconclusive.

- ***Consider incorporating a diagram to depict the natural history of Genital HPV infections.*** One physician strongly suggested that CDC incorporate a flow chart that indicates how many people can expect to acquire HPV over a lifetime; how many people can anticipate high-risk versus low-risk infection; how many people will receive abnormal Pap tests; and how many people ultimately will have cervical cancer. The provider felt this diagram would help illustrate the magnitude of the problem since the numbers currently make this difficult to grasp.

- ***If possible, specify the percentage of women who actually develop cervical cancer, among the 10 percent who develop persistent infection.*** The physician requesting this felt that the information should be presented in a flowchart or other image, to reduce the level of copy.

- ***Incorporate a section detailing the risks to men, following the discussion of risks to women.*** A few providers suggested a brief discussion or point detailing the risks concerning men – particularly for men who have sex with men – since risks to women and infants are listed.

- ***Explain the types of treatments that are available for HPV-associated diseases, in the absence of a vaccine.*** One physician wanted to know what the topical pharmacologic agents are for treating genital warts. Another nurse practitioner wanted to know about treatments for cervical dysplasia. Given the pamphlet's space constraints, CDC may wish to reference a Web site that providers can refer to for more extensive information about the available HPV treatments.

- ***Add a section explaining what patients should do to prevent transmission after learning they have HPV.*** One physician felt strongly that CDC should provide guidance on the measures HPV-positive patients should take to prevent further transmission. This issue may be more complex than space will allow in current materials. CDC should consider whether this is critical to address here, or whether it might be better addressed in a separate piece, focused on patient counseling.

- ***Consider possible ways for overcoming identified challenges to material dissemination and adoption.*** Several challenges to using these materials were identified by providers. For example, they noted the many other materials competing for their attention and the limited time they have to sift through the piles of informational materials they receive. A few of them also reported that they are restricted to using only materials that are developed by their own state or local health departments. CDC must consider ways to overcome these challenges and to promote the adoption and use of the current pamphlet, as well as any future educational materials that are developed.

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