HPV COMMUNICATION OUTREACH

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Division of Sexually Transmitted Disease Prevention
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INTRODUCTION

The Health Communications group within the Centers for Disease Control and Prevention's Division of Sexually Transmitted Diseases (DSTD) contracted with ORC Macro to conduct formative research on the sexually transmitted infections caused by genital Human Papillomavirus (HPV). The formative research being conducted is designed to inform DSTD of the critical issues and factors that influence and affect the prevention, diagnosis, counseling, and patient education for individuals at risk for, or currently diagnosed with, clinical manifestations of genital HPV infection. The findings from this research will be used for the following purposes:

- To identify existing communication gaps and delineate strategies for improving communication of HPV to the various target audiences
- To inform the development of a national survey of clinicians regarding their practices and clinical care experiences related to identification, diagnosis, counseling, and communication of information to patients and their sexual partners about genital HPV
- To support the development of a DSTD communications database.

Ultimately, these findings will help guide the development of educational materials for health care providers, patients, and the general public.

METHODOLOGY AND SELECTION CRITERIA

Qualitative research is particularly well suited to situations where in-depth information is needed on a specific topic or where the depth of information on a particular topic is limited. As compared to quantitative research, which is a process of measurement and is most useful in answering questions such as how much, how many, or how often, qualitative research is a process of enlightenment, on questions such as what and why. For this reason, a combined interview/focus group methodology was employed to explore the knowledge, attitudes, and beliefs from a variety of audience perspectives concerning HPV. The research was also designed to identify emerging technologies or issues that may impact the way this sexually transmitted infection is addressed in clinical practice.

ORC Macro and DSTD project staff developed a two-stage approach, the first of which consisted of initial key informant interviews with different audiences. The results from Stage One were then used to inform the second stage, which included both focus groups and in-depth interviews with audiences. ORC Macro collaborated with DSTD staff to identify target audiences to understand the different perspectives of the various stakeholder groups associated with genital HPV research, development, and practice. Once the target audiences were identified, project staff developed the qualitative research design with respect to the number of interviews and/or focus groups per audience. The resulting design included the following:

Table 1: Focus Group and In-depth Interview Target Audiences

Target Audience	Stage 1	Stage 2	
	Key Informant Interviews	Focus Groups	In-depth Interviews
Primary Care Clinicians (i.e., family practice, general practice, adolescent medicine, college health, and internal medicine)	1 individual per specialty	2 focus groups (7–9 participants)	N/A
Health Care Professionals (i.e., physicians assistants, nurse practitioners, and nurse midwives)	2 individuals per specialty	2 focus groups (7–9 participants)	N/A
Expert clinicians	5–7 individuals	N/A	N/A
HPV researchers	5–7 individuals	N/A	N/A
Developers of HPV prevention/counseling materials	4–5 individuals	N/A	N/A
Representatives of laboratories and HMOs	3–5 individuals	N/A	N/A
Developers/marketers of HPV-specific products and services (i.e., diagnostic tests, medications, vaccines, etc.)	3–5 individuals	N/A	N/A
Obstetrics/gynecology, gynecologic oncology	N/A	N/A	7–9 individuals
Colorectal surgery, dermatology, urology, HIV/AIDS care	N/A	N/A	7–12 individuals

TARGET AUDIENCES

- Primary Care Clinicians (i.e., family practice, general practice, adolescent medicine, college health, and internal medicine)
- Health Care Professionals (i.e., physician's assistants, nurse practitioners, and nurse midwives)
- Clinicians with expertise in HPV issues
- Professionals currently involved in HPV research
- Developers of HPV prevention or counseling materials
- Representatives of major laboratories and HMOs
- Representatives of organizations/agencies involved in the development or marketing of HPV-specific products and services (i.e., diagnostic tests, medications, vaccines, etc.)
- Clinicians specializing in obstetrics/gynecology and gynecologic oncology
- Clinicians specializing in colorectal surgery, dermatology, urology, and HIV/AIDS care.

STAGE ONE METHODOLOGY

With the exception of the primary care clinicians and the health care professionals, individuals identified for the key informant interviews were selected based on information provided by DSTD staff as well as results from the literature search. Through a literature search, ORC Macro project staff identified a variety of organizations, associations, agencies, events, and companies well versed in the HPV field. Within each of these entities, ORC Macro targeted advisory boards, related departments or divisions, positions, or specific individuals that specifically focused on HPV-related issues. Individuals were then cross-referenced across the various sources so that those who appeared more prevalent in the HPV arena were selected for inclusion in the list of key informants for review by the DSTD staff. DSTD project staff reviewed the key informant list and ranked the individual key informants in terms of priority. If a particular key informant recommended or referred ORC Macro staff to another colleague, ORC Macro attempted to contact that individual for an interview.

For the purposes of Stage One of this study, the primary care clinician and health care professional key informants were defined as those specializing in family practice, general practice, adolescent medicine, college health, and internal medicine; or were identified as physician's assistants, nurse practitioners, or nurse midwives, respectively. Efforts were made to recruit clinicians and health care professionals from a variety of settings, such as private practice, managed care, public hospitals, and clinics. The primary goal of conducting these key informant interviews with these two target audiences was to ensure that the most value was attained from the Stage Two focus group discussions.

Participants in these two key informant audiences were identified through a recruitment firm that utilized the American Medical Association list to identify names, specialties, addresses, and phone numbers. The firm was responsible for contacting and scheduling the telephone interview appointments with those who a) expressed interest in participating in the project and b) met the demographic characteristics identified through a screening tool developed by ORC Macro. Interviews were scheduled according to participant availability and took place primarily during office hours. All participants received a reminder telephone call the day before the scheduled interview to confirm the appointment. All participants received a $75 incentive.

A screener and structured interview guide was developed for each of the initial seven key informant audiences. This allowed the project staff to ensure that the interviewee was the most appropriate person to speak with regarding the topic and to tailor the instrument to each key informant audience. After receiving CDC approval of the key informant instruments, ORC Macro coordinated an interviewer training session to ensure all project staff sufficiently understood the project objectives and were knowledgeable about the interview topics. ORC Macro project staff then began conducting telephone interviews with the various informant audiences. It should be noted that, due to the CDC's request that the interviews be audiotaped (to ensure the accuracy of notes), ORC Macro interviewers reminded all participants of the request to audiotape the interview and attained their verbal permission prior to recording. All participants were also informed that the conversations were anonymous, their names would not be attributed to any statements, and that the audiotapes would be destroyed at the end of the project. In addition, interviewers took notes during the discussions, which were used (in combination with the audiotapes) to analyze the results.

STAGE TWO METHODOLOGY

For Stage Two of the formative research, ORC Macro conducted four focus groups and in-depth telephone interviews with the audiences identified previously. Both focus group and interview participants were identified and recruited by a professional recruiting firm. ORC Macro developed both an interview and a focus group moderator guide to ensure that all discussions followed a consistent structure and to enhance the comparability of responses. The guides were submitted to CDC project staff for review and all suggestions and changes were incorporated into the final version. In-depth interview participants received incentives of $100. Focus group participants who were MDs received $175; RNs, PAs, and NPs received $100.

The in-depth interviews were held the weeks of February 11, 2002, through February 18, 2002. All of the interviews were audiotaped and transcribed. The focus groups took place on February 13 and February 14, 2002, in Atlanta, GA, and were videotaped, audiotaped and transcribed. The transcriptions were provided in electronic and hard copy.

Results from the focus groups and interviews were categorized by target audience group and reviewed and analyzed by ORC Macro staff. The findings from the interpretive analysis of the Stage Two discussions can be found in the next section, directly following the Stage One Key Informant Interview Results.

INTERPRETIVE ANALYSIS: STAGE ONE KEY INFORMANT INTERVIEW RESULTS

I. HPV RESEARCHERS

ORC Macro conducted telephone interviews with individuals identified as HPV Researchers who are knowledgeable of current HPV research regarding prevention, detection, patient management, and the potential impact of that research on clinical practice. Key informants represented public, private, and academic institutions. These individuals had typically published or presented research on a variety of topics relating to genital HPV.

Overall Findings for HPV Researchers

- Key informants expressed the need for explicit guidelines relative to more effective and efficient HPV screening practices as well as appropriate management of women with Atypical Squamous Cells of Undetermined Significance (ASCUS). However, a number of those interviewed were aware of, or had participated in, the recent multisociety consensus meeting sponsored by the American Society for Colposcopy and Cervical Pathology (ASCCP). These consensus guidelines have been submitted to the Journal of the American Medical Association (JAMA) for joint publication with the Bethesda 2001 terminology recommendations. Many of the interviewees felt that these guidelines would have the most impact on clinical practice in the near future.

- With respect to new technological advances in the HPV arena, most of the key informants identified recently improved cytology techniques (e.g., ThinPrep Pap) and HPV tests (e.g., Hybrid Capture II, DNA tests) as being the most likely to have a significant impact on practice. The impact most frequently identified by informants was the decreased number of patients who would need to be referred for follow-up procedures due to the increased sensitivity of these new advances. Other impacts mentioned by informants included decreased costs, improved quality of life (e.g., intrusiveness of follow-up procedures), and clearer diagnostic pictures for clinicians.

- Differences in how HPV should be framed within the larger context of health were apparent among this key informant audience. This controversy appeared to center on whether HPV should be framed and communicated to the public as a public health issue, an STD issue, or as a precursor to cervical cancer.

Screening

- Most of the key informants in this group cited the need for efficient and effective screening procedures as a high priority.

- HPV researcher indicated a need for tools or scientific technologies (e.g., biomarkers/precursors) that are not only sensitive enough to detect the presence of HPV (i.e., DNA test) but have the specificity to distinguish low-risk HPV types from high-risk HPV types. A number of informants expressed that until this is accomplished, the majority of clinicians may continue to practice more aggressive follow-up as a cautionary measure.

- The patient populations that typically have a lower risk of acquiring high-risk HPV types are the same populations that adhere to screening recommendations (e.g., yearly Pap smears). Patient populations at higher risk of infection are often less likely to be screened on a regular basis, if at all. Some of the informants in this group indicated that yearly Pap smears among low-risk populations are unnecessary and negatively impact quality of life. They also identified factors that typically inhibit high-risk populations from obtaining appropriate screening as including limited access to medical services (e.g., cost, location, insurance), socioeconomic status, transience (geographically or among health care providers/plans), cultural norms, awareness of sexual health issues, and attitudes/beliefs toward sexually transmitted diseases (STDs).

New Technologies

- Informants expressed differences in opinion regarding the most effective combination and implementation of cytology techniques and HPV tests to reach at-risk patient populations. A few informants identified a need for more research to be conducted with respect to the knowledge, attitudes, and behaviors toward HPV among high-risk populations.

- Informants acknowledged the value provided by HPV DNA tests for ASCUS readings, which was the understanding of the advantage of increased sensitivity to the presence of the HPV infection at this point in the process (e.g., prior to colposcopy). At the same time there was general concern at the lack of increased specificity of high- vs. low-risk types. There was less agreement with the idea of using the same technology as a primary screening tool, especially in the United States, given the well-established usage of the Pap Smear as a primary screening tool.

- Although the consensus around the development of HPV vaccines was positive, most felt that the implications for clinical practice were at least 10 years away for prophylactic vaccines. Specific areas that needed more research, specifically for the U.S. population, included how to maximize coverage, and the advantages and disadvantages of prophylactic (i.e., produces antigens to prevent adoption of infection) vs. therapeutic (i.e., designed for those already infected with HPV) vaccines.

- Some respondents were involved in or familiar with FDA activities relative to reviewing HPV prophylactic vaccines.

- Relative to FDA approval, there was considerable interest in whether a therapeutic vaccine would be viewed as an STD vaccine or as a vaccine against cancer. Some informants familiar with the FDA review feel they may be tending toward an anti-cancer vaccine view, with attendant ramifications for the time and size of the trials.

- The male population as a whole tends to receive less attention from the respondents relative to HPV prevention, screening, and detection. However, despite this awareness there was no consistency between this informant group in terms of whether or not they should be a priority.

Knowledge, Attitudes, and Behaviors

- Overall there was a general consensus among this audience that more research needs to be conducted around the knowledge, attitudes, beliefs, and behaviors concerning HPV both among clinicians and the general public. Many indicated that they had also looked for literature on this topic and had found little information, if any. Specific gaps in clinician knowledge noted by the informants included appropriate screening procedures/guidelines, general knowledge of the connection between HPV and cervical cancer, an understanding of the role of the Pap smear vs. the HPV tests, and an understanding of how to communicate effectively with clinicians and patients on these topics.

- Some key informants indicated a need for the CDC to be more willing to acknowledge what is known and what is still unknown about HPV, and to be willing to communicate both to the larger community.

- Nearly all informants acknowledged the limited amount of behavioral research that has been conducted to date on HPV and the prevention of HPV. They agreed that once the research has been conducted, effective interventions need to be developed using the research.

- There is a need to educate/inform the public about the nature of HPV infection because it is not clearly understood. In the process, it is important to acknowledge the controversial areas regarding prevention (e.g., effectiveness of condoms, safe sex practices, methods of transmission).

- There has been very little publicly available research about how clinicians should communicate with patients on this topic, or about audience research that identifies patients' preferences for effective communications.

Public Awareness

- One of the most frequently identified areas of controversy among the researcher audience is understanding and facilitating the appropriate level of awareness among the general population about HPV infection. There was general acknowledgement that defining and identifying the appropriate level of awareness would be difficult given issues related to stigma, lack of knowledge related to transmission and progression of the infection, and the high prevalence of the infection, much of which would regress naturally.

- Some key informants expressed concern that increased awareness of the prevalence of HPV in the population might lead to an increased demand from women for HPV testing despite the fact that the majority of those who have the infection will eliminate it on their own.

- Concern that establishing a link with HPV (a sexually transmitted infection) might inadvertently result in stigmatization of both cervical cancer and the Pap smear was expressed by a few of the informants.

Guidelines

- Most key informants acknowledged the importance of appropriate and updated guidelines. The continuing advances in understanding the natural history of HPV and introduction of new diagnostic technologies create a constantly evolving environment where appropriate guidelines for prevention, detection, and management of HPV should be consistently monitored and updated. Several informants mentioned a 2-year update period.

- The health care community currently lacks a definitive set of guidelines (screening and detection) that all clinicians adhere to. Various organizations and professional societies have their "own" set of guidelines that may speak to their own priorities or agendas.

- Guidelines do not address/acknowledge the significance of the recommendations with respect to their impact on resources, cost, time, and quality of life.

- Guidelines to date have done a poor job of helping providers and the public really understand the role of the Pap smear, its appropriate usage, and how to communicate these guidelines to patients.

- Many of the informants in this audience expressed a need to establish and promote a universal/uniform terminology, to set guidelines for screening and detection, and to get endorsement of these guidelines from the various organizations and professional societies that are primarily involved in clinician education/communications. A number of informants, however, noted that the forthcoming ASCCP guidelines might effectively resolve this issue.

Advances Most Likely to Impact Clinical Practice in the Near Future (1 to 2 years)

- The Hybrid Capture II, similar DNA tests, and improved cytology techniques are likely to have the most immediate impact on clinical practice. Many informants expressed the hope that these newer, more accurate technologies would cut down on the number or frequency of Pap smears or, at the least, reduce the percentage of referrals to follow-up.

- It is believed that the establishment and dissemination of guidelines (i.e., National Cancer Institute (NCI) Bethesda System 2001 and ASCCP) that incorporate these new screening, detection, and management techniques may also significantly impact practice.

- Though not technically an advance, an increased awareness and knowledge about HPV among the public may also alter the way that clinicians approach HPV.

Communications

- The speed with which HPV-related information is changing necessitates that clinicians be updated on a continual schedule utilizing a channel mode that allows for quick dissemination of information to large audiences.

- There is a need to establish one definitive source [e.g., CDC or American Social Health Association (ASHA)] of information about HPV that is endorsed by other organizations and institutes and is accessible by many. This source must provide information about the facts that are known as well as areas of continued debate and discovery. The annual HPV conference and its proceedings was identified as one such current comprehensive review of what is currently known about HPV, but impactful dissemination is limited due to the need to be physically present at the conference or be willing and able to review all the proceedings in order to stay informed.

- The information being developed should be concise, easy to digest, and developed at both the clinician and the patient level.

- The researcher population typically relies on peer-reviewed, reputable academic journals for sources of information, and also to disseminate their information. Researchers also commended ASHA as a credible source of information.

- Many identified the need to develop a better understanding of how to communicate information to clinicians and the public in a way that will affect behavior change. Researchers acknowledged that there is little HPV-specific public research on this topic available today.

II. CLINICIANS AND HEALTH CARE PROFESSIONALS

ORC Macro conducted telephone interviews with individuals identified as either practicing clinicians or health care providers who were 30 years of age or older, who had been practicing medicine for 3 or more years, who held valid certifications, and who currently saw patients infected with HPV. The clinicians and health care professionals represented a wide variety of patient populations and specialty areas (see Methodology).

In Stage One, primary care clinicians and health care professionals were placed in the same key informant category. The analysis of the interview discussions revealed that, while the two audience groups often share similar characteristics and behaviors relative to HPV prevention, detection, and management, there were also important differences. The differences that were most noteworthy between the primary care clinicians and health care professionals included in this section. Findings relative to these two audience segments were first analyzed collectively (i.e., primary care clinicians and health care professionals) for consistencies and then at the individual level to highlight the unique characteristics and perspectives.

Overall Findings Common to Clinicians and Health Care Professionals

Screening, Detection, and Management Protocols

- Clinicians and health care professionals both appear to implement similar screening practices for HPV and other STDs. HPV screening is typically part of a larger STD screen, which primarily consists of taking a medical/sexual history. In the case of an OB/GYN or STD clinic, this may also include a pelvic exam.

- One area of controversy within the clinician/health care professional informant group was whether or not they should conduct screening (whether HPV or STD) every time a patient came for a visit or only if they believed the person to be engaging in at-risk behaviors.

- Despite the consistent implementation of HPV-screening techniques, clinicians and health care professionals felt that the majority of HPV-infected patients were detected either though an abnormal Pap smear or the patient's report of some external manifestation of the infection (i.e., genital wart).

- Most informants reported taking a relatively aggressive attitude toward monitoring and managing a patient that received an ASCUS result from a Pap smear, admitting a "better safe than sorry" mentality.

- Clinicians and health care professionals also reported consistent techniques in the management of patients diagnosed with clinical manifestations of HPV, including referrals to OB/GYN for females, and treatment and monitoring follow-up for males.

Patient Education

- Overall respondents agreed that patients have minimal awareness of HPV, with few differences among the different target audiences.

- Overall, clinicians and health care professionals acknowledged a wide gap in both the amount and quality of patient-focused HPV materials/resources available for dissemination. Issues that seemed particularly prevalent were the lack of materials in other languages and the complex writing style typically used in existing materials. The cost of materials was also an issue. Informants did not have the resources to develop their own communication materials, nor did they feel they could buy communication materials. When informants indicated familiarity with HPV materials, the majority cited drug companies, ASHA (the Web site), or CDC as the primary source of the information. The ASHA Web site received high marks from this audience as it did from all other audiences.

- Clinicians and health care professionals alike acknowledged the need (but varied on the detail) to proactively teach prevention and healthy sexual behaviors to youth beginning at an earlier age, primarily due to the increasingly younger onset of sexual intercourse or other risky sexual behaviors.

- Clinicians and health care professionals often described confusion among adolescents and young adults with respect to understanding what constitutes risky behavior. Several cited that young females did not equate having multiple monogamous relationships with having multiple sex partners, as well as denying or being unaware of the risks associated with oral/anal sex, heavy petting, or other sexual behaviors outside of intercourse.

Patient Communications

- Patients, as a whole, do not initiate discussions about HPV. The topic tends to be brought up by the clinician or health care professional either (a) in the larger context of risk behaviors or STDs or (b) after a diagnosis. Patients were described as being generally unaware of HPV issues. Instead, they focused on their symptoms.

- After diagnosis, respondents generally reported having relatively frustrating conversations with patients. Patients immediately seemed to focus on questions about the acquisition, transmission, regression, and management of the infection for which clinicians cannot provide definitive answers. There was general support for the development of communication materials that would help clinicians and health care professionals deal with some of these "difficult" questions.

Challenges/Areas of Controversy

- Numerous participants expressed frustration as a result of having to balance patient confidentiality with ensuring that the infected person receives the recommended follow-up care. This was especially prevalent among informants who frequently worked with adolescents who were on their parents' medical insurance and Latin American women who often feared repercussions from their husbands.

- Cultural norms of the patient populations appear to significantly impact the ability or willingness to seek out the appropriate prevention, screening, detection, and/or management behaviors. These cultural norms can also impact the ability to inform partners. Again, respondents working with Latin American women cited the "machismo" culture as making it difficult to deal with this sexually transmitted infection.

Priority of HPV in the Clinical Environment

- Informants working in OB/GYN practices, publicly funded clinics, and other traditional women's healthcare settings reportedly placed greater emphasis on HPV and STDs relative to other health issues compared to clinicians and health care professionals in family or general practice.

- Clinicians in family or general practice settings reported viewing HPV as very low on their radar screen.

Preferences for Communicating with Clinicians

- The one preferred and most often utilized channel for receiving medical information mentioned consistently by both clinicians and health care professionals was through their specific professional societies [e.g., American College of Obstetricians and Gynecologists (ACOG), American Academy of Family Physicians (AAFP)].

- The extent of time and resources available to the clinicians and health care professionals for skills development and information gathering varied widely and was often dependent on the workplace environment and patient population.

Choice of Area for Skill Development

- When asked to select one of three areas for further skill development, clinicians most often chose prevention or detection. Prevention was identified because it had the most positive connotation (contraction of HPV was viewed as negative) while detection was often identified as important after recognizing the difficult realities of prevention.

II-A. Health Care Professionals (Physician's Assistants, Nurse Practitioners, Nurse Midwives)

In addition to the findings presented above, the following provides some additional insights specific to the health care professional informant group, which was defined in this project as Physician's Assistants, Nurse Practitioners, and Nurse Midwives.

Roles and Responsibilities

- Health care professionals appear to typically serve as the initial interface with patients and are often responsible for such screening tasks as taking down medical and sexual histories. Health care professionals also indicated that they are frequently responsible for contacting and communicating results from tests (e.g., abnormal Pap smears) to patients and scheduling follow-up appointments.

- Although not always the case, some of the informants indicated that they are responsible for conducting post-diagnosis discussions with patients, which often focuses on educating them about the nature of HPV, potential ramifications of such a diagnosis, and next steps.

Patient Communications

- The informants in this particular group appear to be more comfortable discussing both HPV- and STD-related issues with patients than the clinician population, and then often expressed a desire to establish more of an open dialogue with patients around these issues.

- A number of health care professionals noted the importance of establishing a comfortable rapport with their patients when addressing both HPV- and STD-related issues.

- Many also expressed the desire to keep the patient from feeling overwhelmed or bombarded with information. In this situation, they prefer to provide the patient with hard copy materials during the discussion that patients can review at their own pace and then contact them with any additional questions or concerns.

- Many of the informants have developed an HPV "spiel" that seems to work well for them with their particular patient population.

- There was a wide range with respect to the amount of time that this informant group was willing or able to spend on patient education about HPV.

HPV Priorities in the Clinical Environment

- Many of the informants in this group identified partner issues as an important priority. For example, many reported being proactive with respect to encouraging and facilitating the provision of diagnostic and treatment services to the partners of infected persons.

- Though most health care professionals acknowledged widespread lack of awareness around HPV within the patient population, a few noted a slight increase in HPV awareness over the past 1-2 years. Possible explanations offered for this increase in awareness included recent references to HPV in popular magazines and newspapers. Most respondents supported increasing the level of awareness.

- Educating the patient on the importance of regular screening and follow-up was identified as a priority by nearly all the individuals interviewed in this audience segment. This was mentioned as a particular challenge for those who worked with minority and low socioeconomic patient populations. Maintaining accurate medical histories was also noted as a challenge due to transient populations and lack of medical coverage.

II-B. Clinicians

Findings exclusive to the clinician key informants are presented here. Clinicians in this group were representative of family, general, internal, adolescent, and college medicine.

Skill Development

- A number of clinicians indicated that they tend seek out additional information about HPV if they are not able to answer a patient's question. No other specific event was identified that would initiate HPV-focused information gathering activity. When they would seek additional information, the majority cited peer-reviewed journals and information provided by their professional society as their primary sources of information.

- Many of the clinicians expressed interest in focused, credit-related classes (CME courses) as the preferred method for improving their knowledge about HPV. Some indicated an interest in developing a better understanding of the colposcopy process/procedure in order to advise patients of next steps.

Patient Communications

- Many clinicians expressed a willingness to respond to questions, but less of a desire to initiate discussions. This finding seemed to reflect a certain level of discomfort in discussing this type of sensitive topic.

- Many of the clinicians indicated a desire for more materials on HPV that they can simply provide to the patient, but seemed less interested in using these materials to engage in a two-way dialogue with the patient.

- The concept of partner communications appeared to be largely dependent on the environment in which the clinician practices. For example, a clinic might be very supportive of reaching out to the partner, while an HMO may be less proactive as the partner may not be covered under the same health care plan.

- A number of the clinicians indicated that the clinician population as a whole is not comfortable dealing with issues of HPV. Some believed this discomfort is due to the lack of definitive information about HPV, which in turn, makes it difficult to provide good, solid answers to patients and their partners. Others indicated that clinicians feel uncomfortable delving into sexual issues with their patients.

III. EXPERT CLINICIANS

Telephone interviews were conducted with individuals identified as expert clinicians—individuals with extensive experience in HPV clinical care (often influencers of practice) or key opinion leaders who have published articles or studies on HPV-related issues. Key informants represented a wide variety of public, private, non-profit, and academic institutions.

Education of both patient populations and clinicians was an underlying theme in the responses to many of the questions regarding challenges, critical issues, and improving care relative to HPV. Expert clinicians continued to stress the need to provide clinicians with better education about HPV, beginning with a better understanding of the role of the Pap Smear. Expert Clinicians also focused on the area of communications, believing that clinicians need to better communicate with patients regarding HPV issues.

Challenges

- Educating clinicians and the public with an accurate understanding of HPV and appropriate screening, diagnostic and management activities was mentioned frequently. Specific areas of concern included instilling a more accurate understanding of the nature of HPV, HPV in relation to other STDs, the important relationship of certain HPV types to cancer, and the purpose and role of the Pap Smear (and, in the future, HPV tests) as a tool.

- This audience recognized a need to establish a definitive set of guidelines that would apply across the spectrum of clinicians. Optimally, these guidelines would take into account cost, quality of life, and appropriate screening intervals. These guidelines could subsequently be used to train health care professionals.

- Another significant challenge is the implementation of efficient screening techniques/guidelines that ensure hard-to-reach patient populations are receiving the appropriate care, but not overly aggressive based on assumptions that they will not return for follow up, etc.

Critical Issues for the Next 5 Years

- Some clinicians felt that shifting the focus to more adequately address prevention and management of HPV was a critical issue. Prevention and management was described by this audience in a variety of ways including patient-centered education, improved cytology techniques, appropriate applications for HPV tests, and the development of preventive and therapeutic vaccines.

Improvements in Care for HPV Patient Populations

- Informants expressed a need for significant improvement in the education provided to the general public (those at risk) about HPV. Areas specifically mentioned included symptoms of HPV, along with differences and similarities to other STDs with respect to transmission and consequences. A few individuals distinguished between primary and secondary educational opportunities, but acknowledged a need for both.

- The majority of individuals in this audience highlighted significant room for improvement in the provision of support and training to clinicians on identifying risk factors, communicating with patients, and counseling patients on issues related to HPV and other STDs.

- A few expert clinicians felt that the treatment modalities offered to patients were limited to those known or most easily available to the clinician. These individuals expressed a desire to expand clinicians' understanding of the range of modalities available. At the same time they recommend developing patient educational materials so that they are a part of the decision-making process.

- Acknowledging some of the psychosocial aspects associated with genital warts, some expert clinicians identified counseling around partner communication as an area of improvement.

NCI Bethesda System 2001

- There was general agreement by those aware of the NCI Bethesda System 2001 that the recommended terminology will help simplify the information provided to the clinician population.

Hybrid Capture II & DNA Test as Primary Screen

- Many informants felt that there was potential for both the Hybrid Capture II and HPV DNA tests to be utilized in a self-monitoring capacity. The ability to self-sample was especially attractive to many of the informants.

- There appears to be some controversy over the use of either tool as a primary screen, with some advocating this only in certain populations where the risk is higher (e.g., underserved, clinics). Some informants were concerned that, if they were used as a primary screen for the general population, there would be an excessive number of women unnecessarily referred for colposcopy.

- The informant population believed the new technologies would be more effective with a defined algorithm for management. For example, use after an abnormal Pap smear to determine referral for colposcopy.

Areas of Improvement

- Overwhelmingly, this informant audience felt that the area most in need of research and development was the counseling and education that is available for HPV patients.

IV. DEVELOPERS OF HPV PREVENTION, EDUCATION, AND COUNSELING MATERIALS

Organizations involved in developing and disseminating HPV-related information were identified and contacted to participate in telephone interviews. ORC Macro staff spoke with individuals within these organizations who were familiar with either the different types of materials or the process through which they are created.

Overall Findings for Developers of HPV Materials

- The majority of organizations that develop prevention, educational, or counseling materials take a more holistic approach to STDs, as opposed to focusing exclusively on individual diseases or infections such as HPV.

- While HPV has received more attention in the healthcare community over the past 12 months, it is still not considered a priority and is discussed more in terms of Pap smears and cervical cancer than as an infectious disease.

- HPV prevention, educational, and counseling materials are few and far between. The American Social Health Association, is widely recognized as the authority on the topic.

- The majority of materials and support that is made available to the public and health care community is designed to address the psychosocial impacts of HPV diagnosis.

- Overall, there appears to be a widespread lack of awareness of HPV both among public and general healthcare provider communities. There is also concern that there are misconceptions about the prevention, diagnosis, and management of HPV.

- Having resources that would provide effective counseling and patient communication strategies for the health care community was identified as one of the biggest priorities as well as a significant gap.

Content

- Most informants felt the materials that exist are too complex for the general public and at-risk populations to easily understand. There is a strong need to develop a broader range of materials that target a range of populations (e.g., Latino, African American, young female, male) and educational levels (less than high school).

- The majority of existing materials focus on individual aspects associated with HPV (e.g., Pap smears, genital warts, cervical cancer) without really addressing them in relation to the broader context of the infection.

- There are huge gaps in the availability of information and materials around areas of HPV research that remain unclear or inconsistent (prevention, lifespan, regression, diagnosis).

Channels

- While the informants' perspective varied with respect to the most effective communication channels for the health care community relative to HPV, they all recognized that a multi-pronged approach to information dissemination and skills training is imperative. Suggestions included the development of CME courses, coordination with drug representatives, conferences, professional society publications, and peer-reviewed journals.
- Materials are available in a wide variety of formats but primarily take the form of brochures, fact sheets, and newsletters.

Source/Development

- Organizations that are responsible for the development of existing HPV materials typically rely on an advisory committee that consists of medical researchers and scientists to identify and guide development of topics and review products for accuracy.

- Some informants felt that effective HPV materials design requires that the underlying research on which they are based is representative of the whole community.

Challenges

- Informants felt that many organizations are unwilling to publicly address and disseminate information on controversial issues because they are unsure how they will handle it.

- Many organizations are constantly challenged to increase the awareness and utilization of the HPV resources that they currently provide.

- While most informants feel that the media plays an important role in building awareness, they are also frustrated with the lack of control over the accuracy and manner (e.g., "scare tactics") with which it is presented.

- This informant audience is struggling with how to build awareness around the prevention and management of HPV given the areas of controversy and areas of inadequate knowledge.

V. DEVELOPERS/MARKETERS OF DIAGNOSTIC TOOLS AND TECHNIQUES

ORC Macro conducted telephone interviews with representatives of organizations involved in the development and marketing of diagnostic tests, medications, vaccines, and medical equipment used for diagnostic procedures.

Overall Findings for Developers/Marketers of Diagnostics

- Some of the recently introduced technologies, which have significantly impacted clinical practice, are the thin-prep cytology as well as the Hybrid Capture II test.

- The deciding factor in whether or not a new product is successful, once the medical benefits are proven superior, is an analysis that proves the cost effectiveness of the products for health care plan reimbursement. After these two hurdles, clinician demand and patient demand for a particular product will have the most impact.

- Impact in the near future will result from improving and disseminating existing technologies rather than the introduction of new technologies.

- The biggest challenges identified by the diagnostic company audience include the following:

    - The FDA's approval and re-approval process, which occurs with every change instituted during the clinical trial phase of development

    - Attaining the support and confidence of clinicians to persuade them to order the product and influential organizations to promote it among patient populations

- ➢ Developing the evidence-based, cost-benefit analyses that will support decisions by Medicare and HMOs to reimburse the increased costs associated with the product

- ➢ The need for ownership of the intellectual property on which the new product or service is based.

Organization's Perspective On-Target Audiences

- For the insurance organizations to reimburse a new product, FDA approval is considered cost of entry. Additional requirements include evidence-based studies that demonstrate efficacy and cost effectiveness, and then the advocacy of influential clinicians.

- The acceptance of a new diagnostic product among laboratories typically relies on their financial profit forecast. This forecast is based on the assessment of clinician demand, relationships with health plans to ensure they will be reimbursed by the insurance organizations, as well as up-front costs associated with equipment and training.

- Adoption of a product begins with the larger labs and then eventually spreads to the smaller local laboratories depending upon their desire to retain more profitable revenue sources in-house.

- To influence the clinician audience on the advantages of a new product, informants cited peer-reviewed publications (e.g., JAMA) and the ability to obtain support from independent opinion leaders (clinicians and researchers). They will also encourage independent research that will hopefully further validate prior findings. Informants recognize the need for independent verification of efficacy by respected opinion leaders.

New HPV Technologies of the Future

- Critical areas for further development included better tools to understand the likely progression or regression of the infection using more sophisticated HPV typing techniques, or use of biomarkers. Vaccines, both prophylactic and therapeutic were also mentioned.

- Concerns about the ability of HPV vaccines to eliminate HPV were expressed by informants who mentioned problems with acceptability (e.g., religious and social grounds), implementation, and coverage (access among high-risk populations).

Education

- Informants acknowledged a widespread lack of awareness about HPV among the public and clinicians who, in their views, are often misinformed as well as uninformed.

- Some informants expressed that the lack of information available on HPV has had a negative influence on both the demand for more advanced technologies and on emotional stress associated with diagnosis.

- Informants acknowledged a significant gap in the amount of research that examines the impact of HPV diagnosis on patients and whether it is similar or dissimilar to diagnosis of other STDs.

- To effectively inform clinicians of their new technologies, informants advocated a multi-pronged communication strategy including articles in the most reputable peer-reviewed publications (i.e., JAMA, New England Journal of Medicine) and the publications of key professional societies, sponsoring influential speakers at major national and regional conferences, and sponsoring dinner meetings for clinicians.

VI. REPRESENTATIVES OF LABORATORIES AND HMOS

Overall Findings for Representatives of Laboratories and HMOs

- HPV is a very low priority in the health plan environment because current methods are effective at relatively low cost.

- To make HPV a priority, some measurable activity would need to be integrated into the Health Employer Data Information Set (HEDIS) measures so that the health care organizations are graded accordingly. Informants felt that the benefit managers often use this data to help them make the decisions of which health care plans to offer their employees.

- Some HMOs currently communicate little to clinicians. Some have, or are developing targeted communication campaigns for health plan participants (e.g., women's issues).

New Technologies

- HMOs appear to consider a variety of factors in evaluating new HPV technologies, the most significant of which is the cost effectiveness of a new technology over existing technologies. Additional factors might include the application of the product, efficacy, safety, the side-effect profile, and outcomes.

- Some informants indicated that the clinician population would need to accept into practice a specific algorithm using a positive cancerous HPV screen as the "requirement" before referral to colposcopy. Until that time, the Pap Smear would remain the most cost effective approach for HMOs because the alternative might cause too many women to be referred for colposcopy.

- The informants believe that clinicians have both the financial, medical, and legal incentives to continue to recommend colposcopy for an abnormal Pap smear, which could create hurdles for the adoption of the soon-to-be-released guidelines.

Communication

- Though not true for all HMOs, some health plans already develop targeted communications for audiences, which might include information about HPV. In most cases, the priority audience is health plan participants (typically women), however other target audiences mentioned by informants included benefit managers and hospitals. Targeted communication strategies to participating clinicians have been tried, but are less of a priority.

- Informants indicated that the primary method for communicating new information concerning HPV to the clinician audience is to build it into CME courses.

- Mail was identified as one of the least effective channels of communication for the clinician audience.

- Channels most frequently utilized by HMOs when communicating to their participant population included birthday cards, telephone outreach, and targeted mailings.

RECOMMENDED TOPICS BASED ON STAGE ONE FINDINGS

I. THE IMPORTANCE AND IMPACT OF GUIDELINES ON CLINICAL PRACTICE

Almost all of the key informants identified as a priority the need for definitive and cross-specialization guidelines relative to the appropriate screening and management of patients infected with genital HPV. Many were also aware of (and supportive of) the recommendations and guidelines resulting from the Bethesda NCI 2001 and the ASCCP Consensus Meetings, feeling that these consensus-based recommendations and guidelines will have a significant impact on clinical practice. Per several of the key informants, a joint paper has been submitted to JAMA and publication should occur in the near future. There are many issues that could be explored which would help the CDC to better understand the issues surrounding the effective dissemination and implementation of these guidelines.

- What are the typical clinical practices conducted today and how closely do they match the existing guidelines? (Do clinicians tend to be more aggressive than the current recommended guidelines in certain instances?)
- How are the different clinician groups most likely to hear about the new guidelines?
- What communication vehicle will most likely cause the clinician groups to adopt the new guidelines?
- What are the facilitators and barriers to adoption of these guidelines (financial, legal, behavior change, concern relative to cancer)?
- What materials would support the adoption and understanding of these guidelines by clinicians? By the public? What would help make these materials easy to understand?

II. CLINICIANS' ATTITUDES TOWARD HPV RELATIVE TO OTHER STDS AND/OR AS A PRECURSOR TO CANCER

One area of controversy that may have a continuing impact on clinical practice revolves around framing HPV as a sexually transmitted infection or focusing messages and attention on its role as a precursor to cancer. Topic areas could include—

- What is the attitude of different clinician groups to Pap Smears and abnormal Pap Smears?
- What is the attitude toward patients diagnosed with HPV who have clinical manifestations of HPV?
- What is the attitude toward patients diagnosed with cervical cancer?
- How have clinicians internalized the controversy toward looking at HPV as a sexually transmitted infection or a precursor to cervical cancer?

III. CLINICIAN'S COMMUNICATION WITH PATIENTS (PREFERENCES, OPPORTUNITIES, AND BEHAVIORS)

As was discussed in the findings from Stage One research, there appear to be distinct differences in the patient-clinician communications between clinicians grouped as health care professionals (Physician's Assistants, Nurse Practitioners, and Nurse Midwives) and General Clinicians (Family Practice, General Practice, Adolescent, College Health, Internal Medicine). Improving patient-clinician communication was also identified as a high priority among expert clinicians. Areas of exploration could include—

- What is their willingness to discuss sexual practices?
- What are the time constraints or availability to provide information/counseling around this complex topic?
- What kinds of conversations are most likely? How does the topic arise?
- Given time and other constraints, what are reasonable expectations relative to communications with patients about HPV?
- What is their level of comfort acknowledging the unknowns relative to HPV infection and responding to questions that cannot be easily answered?
- What training and materials could help support better communications?

IV. THE CDC'S ROLE IN COMMUNICATION RELATIVE TO HPV

Many of the key informants felt that CDC could play a major role in helping clinicians better understand the changing knowledge about HPV. There is currently no single source of HPV information that brings together current research results, the introduction of new technologies, changes in guidelines, etc. The HPV conference was mentioned as a focal source, but those familiar with the conference felt that it was a better source for those interested in the topic, rather than clinicians in general. There was also not a strong consensus about the best channel to reach clinicians, which could also be explored.

- What are some near-term communication needs relative to HPV (new guidelines, research results, etc.)?
- What are some long-term communication needs relative to HPV (vaccine introduction, biomarkers, etc.)?
- What communication channels and strategies would have the most impact?
- What would be the value of such communications to the various clinician groups?

V. THE IMPORTANCE AND IMPACT OF NEW TECHNOLOGIES ON CLINICAL PRACTICE

While some Key Informant Groups (Expert Clinicians and HPV Researchers) were highly aware of the new technologies available to clinicians to screen and better manage HPV, awareness among the general clinician population was more difficult to gauge. There was some concern that clinicians do not fully understand the role of the Pap Smear. This might make it more difficult for clinicians to understand or appreciate the recommended changes in practice based on the new technologies available. More research could be done among these populations to understand their awareness of new technologies and the impact of these new technologies on clinical practice.

INTRODUCTION TO STAGE 2

Stage Two of this project is designed to focus in-depth on selected topics identified in the findings of the Key Informant Interviews conducted in Stage One. The audiences for Stage Two are health care clinicians who provide primary and/or specialty care for persons at risk for genital HPV infection and persons infected with HPV (including persons with genital warts or abnormal cervical cytology). Specifically Stage Two research will focus on the following individuals.

2 Focus Groups:	Primary Care Clinicians (Family Practice, General Practice, Adolescent Medicine, College Health, and Internal Medicine)
2 Focus Groups:	Mid-Level Clinicians or Health Care Professionals (Physicians Assistants, Nurse Practitioners, and Nurse Midwives)
7-9 In-Depth-Interviews:	Specialty Clinicians (Obstetrics/gynecology, gynecologic oncology)
7-9 In-Depth-Interviews:	Specialty Clinicians (Colorectal surgery, dermatology, urology, HIV/AIDs Care)

INTERPRETIVE ANALYSIS: STAGE TWO IN-DEPTH INTERVIEW FINDINGS

Using the findings from the initial interviews, ORC Macro conducted in-depth interviews with clinicians practicing in the specialty areas identified in the methodology section and included in the chart below. An interview guide, which addressed areas of interest identified by CDC project staff, was created by ORC Macro and can be found in the attached appendix. A recruiting firm was utilized to identify and schedule interviews with clinicians in each of the specialty areas. Each of the interviews, which lasted approximately 30 minutes, were audiotaped and later transcribed. Both the audiotapes and transcriptions have been provided to the CDC. The sections that follow provide a review of significant findings from these in-depth interviews.

It should be noted that the dermatology and HIV/AIDS specialist audiences contain noticeably fewer findings than the other target audiences shown below. The explanation is based on the understanding that these particular audiences generally did not perceive themselves as a primary provider of HPV related services. As a result, their familiarity with the issues and willingness to actively participate in the discussion were noticeably limited.

Target Audience	In-depth Interviews
Specialists in Gynecology, Obstetrics/ gynecology and Gynecologic Oncology	7-9 individuals
Specialists in Colorectal Surgery, Dermatology, Urology and HIV/AIDS care	7-12 individuals

I. OBSTETRIC GYNECOLOGISTS

Overall Findings

- Conversations specifically about HPV tend to arise as a result of a patient presenting with an external manifestation (e.g., genital warts), after an abnormal Pap smear, or if the patient is otherwise diagnosed. Otherwise most of the OB/GYN audience seems to address HPV in the broader context of STDs or STIs without providing specific details relative to HPV.

- The OB/GYN audience indicated that adolescent populations often represent the most difficult patient population to communicate with. Often this target group doesn't appear to understand or be concerned with the risks, consequences, or manifestations associated with the HPV infection.
- While there appears to be some level of awareness among OB/GYNs regarding the HPV tests, they identify very limited access and cost as significant barriers to incorporating its use into their clinical practice.

- The OB/GYN audience appeared to view HPV as an important issue, however, the majority of the research participants indicated that they see a high percentage of HPV-related cases (e.g., dysplasia, abnormal Pap). Therefore, this emphasis may not accurately reflect all clinician work environments or patient populations.

Communication

- The majority of OB/GYNs indicated that HPV discussions are typically instigated by themselves rather than patients. Most felt that patients are simply not coming in and asking about HPV.

- OB/GYNs indicate that patient concerns typically focus on how they got it, from whom they got it, the ramifications, and how it might affect childbirth.

- Most OB/GYNs use both face-to-face discussion format as well as provide some kind of written materials. Materials utilized by the OB/GYN audience vary from ACOG pamphlets to materials retrieved from individual research or publications.

- The OB/GYN audience indicated that the complex history and epidemiology of HPV make it difficult for them to ensure their patients comprehend the information that is being provided.

- There is not a lot of communication between the OB/GYN clinicians and other clinicians. The only real exception is if a primary care doctor refers a patient to the OB/GYN and has specific questions or concerns.

Framing HPV

- Most OB/GYNs indicated that they do not discuss the role of the Pap smear as a screening tool for identification of HPV (and therefore an STD) until a patient is diagnosed with cervical dysplasia.

- How the OB/GYN audience frames HPV for their patients appears to occur on an individual basis, however for the most part, they are more likely to frame HPV as a precursor to cancer if the patient's Pap smear indicates dysplasia. Framing HPV as an STD is more common with patients that exhibit external manifestations (e.g., genital warts or lesions) or if abnormalities are shown in the Pap smear.

Practice

- Consistencies exist among the OB/GYN clinicians with respect to recommendations and follow-up for patients with ASCUS (e.g., repeat Pap in 3-6 months) and low-grade squamous intra-epithelial lesions (LSIL), or dysplasia (e.g., colposcopy or biopsy). However, in some cases a clinician differed slightly from standard practice based on other factors such as the sexual history of the patient (e.g., participation in a monogamous relationship).
- This clinician group felt that female patients may utilize their OB/GYN as their primary care physician and therefore are not exposed to any information regarding HPV prior to their visit.

- While the OB/GYN audience understands the limits of the condom with respect to HPV transmission, they still appear to actively promote its use among their patient populations because of its effectiveness relative to other STDs.

II. GYNECOLOGIC ONCOLOGISTS

Overall Findings

- Gynecologic oncologists do not consider HPV to be as serious a problem as compared to other issues such as gonorrhea, AIDS, syphilis, because there is a smaller risk for developing high-risk outcomes.

- If prevention discussions do occur, they appear to address STDs in general, rather than pinpointing individual diseases or infections. The gynecologic oncologists indicated that they felt a realistic goal is not to prevent HPV in women, but to prevent the development of dysplasias or cancers. Therefore, any discussion around prevention focuses on barrier methods that minimize the likelihood of transmission of HPV, and therefore the diminution of dysplasias and cancers.

- This clinician group seemed to place less importance on HPV than on other health issues and STDs because the chances of it developing into a serious health complication are less probable than those associated with syphillis or chlamydia, for example.

Barriers and Facilitators

- The tendency for people to associate HPV with some of the other STDs conjures up a lot of the same stigma that is attached to those STDs.

- The two biggest facilitators to discussing HPV is a) simply establishing an open environment for the patient to talk and b) helping them understand that HPV is very, very common.

- One clinician in this group indicated that it is easier for patients with the physical manifestation of the infection (i.e.., genital warts) to cope with the diagnosis because it is a concrete thing that can be seen and treated as opposed to a nebulous notion that may or may not manifest itself.

Framing HPV

- One clinician in this group felt that framing HPV as an STD was not useful because they felt that there is very little opportunity to prevent contracting it unless you are abstinent.

Communication

- Similar to other clinician groups, the gynecologic oncology group felt that the vast majority of patients referred from primary care clinicians are inadequately, and sometimes incorrectly, informed. Incorrect information often centers around the effectiveness of condoms in preventing transmission of HPV from one partner to another.

- It appears that the majority of communication that occurs between the gynecologic oncologists and their patients is focused on allaying the fears of the patient and combating the stigmas and emotional anxiety that often accompanies a diagnosis.

New Technology

- The development and implementation of an HPV DNA test appeared to be less significant to this clinician group as the majority of their patients have already been determined to have a high-risk type of HPV (e.g., pre-cancerous). However, they mentioned that there might be some applicability for OB/GYNs with respect to distinguishing Pap smears that are mildly abnormal and are HPV-related versus those that are not.

III. UROLOGISTS

Overall Findings

- The urologist audience indicated their patients are primarily men that have either been referred by their partner's OB/GYN, have visible manifestations, or are identified by the urologist during routine examination.

- Due to the minimal interaction that occurs between OB/GYNs and urologists, it is unclear what proportion of patients that are referred or recommended by other clinicians actually come in for examination.

- Urologists expressed concern over whether or not women are getting the information necessary from their OB/GYNs to say to their partner "you have HPV" or whether they are just being treated for the disease process. If the latter is true, women are operating at a higher risk because their partners still haven't been treated and may be repeatedly exposing them to the virus.

- The urologist audience appears more concerned with the potential risk to the male's partner (i.e., women's potential risk for cervical cancer) than they are of the man contracting penile cancer. However, the patients' sexual history and risky behavior will raise concerns for attracting other STDs that the urologist will address with the patient.

Practice

- This clinician audience indicated that they typically take a sexual history of patients (e.g., number of partners and exposure to other STDs), which serves as a screening tool for at-risk behaviors. However this may not always be effective as some men will not disclose homosexual or bisexual behavior.

- Depending on the results of a male patient's diagnosis, there appear to be two very different tracks that a urologist might follow. For example, if a male patient shows no sign of HPV, the urologist will often counsel the patient on the natural history of the disease (e.g., not necessarily from infidelity) and precautions for preventing transmission. However, if a male patient shows positive for HPV, the urologist audience will often counsel on how, as a carrier of the virus, they need to take certain precautions so that they are not continually exposing their partner(s) to risk of infection.

Communication

- Many in the urologist audience felt that the conversation about HPV was easier with male patients compared to female patients.

- Concerns often arise if the patient is in a monogamous relationship (e.g., what does this diagnosis mean). In such circumstances the urologists often explain that HPV is unlike gonorrhea in that it can be dormant in an individual and therefore does not indicate infidelity. Other common patient concerns often encountered by the urologists are the probability of passing the infection on, means for protecting themselves (if partner is diagnosed but patient does not have), or how HPV may have originally been introduced into the relationship.

- Urologists indicated that they spend a significant amount of time addressing the emotional issues that go along with an HPV diagnosis and demonstrated a sensitivity to the male dynamic (e.g., how it impacts their relationship with their partner).

- Urologists felt that patients that are referred to their practice are often very open to discussion about HPV and come with a lot of questions. Often, patients want to know whether they are a carrier or a transmitter of the infection.

New Technology/Guidelines

- The urologist group indicated that the HPV test would only be valuable in its ability to diagnose the HPV strains that cause cervical cancer so that male carriers of these strains could be identified and made aware of this issue. Otherwise, no real advantage over existing techniques was identified.

- While the existing guidelines currently in existence were described as good, the urologists acknowledged that, in reality, everyone does things their own way, especially with respect to treatment. Furthermore, guidelines should address which treatment modalities are most effective for specific circumstances as well as patient counseling.

IV. COLORECTAL SURGEONS

Overall Findings

- The colorectal surgeon audience recognized the importance of HPV in terms of its connection to various cancers, but overall appeared to view it as a relatively benign infection that should be monitored for prevention and early treatment.
- Due to the nature of this particular clinician group, emphasis falls more on the treatment and prevention of further transmission to partners than on traditional prevention or diagnostic aspects.

Context for Discussion

- Due to the nature of colorectal surgery, which provides surgical services for patients with existing warts, this particular audience group indicated that they rarely, if ever, discuss HPV in terms of prevention.

- The colorectal surgeon audience appeared to take a more reactionary role in patient education related to genital HPV. For example, it was mentioned that the clinician will answer a patient's questions about the infection when they arise but that they do not discuss HPV with patients who present with a different problem.

Communication

- Because patients referred to colorectal surgeons tend to present with existing lesions, the communication generally begins at this point. Consistent with other clinician groups, colorectal surgeons indicated that their patients tend to raise questions focused on the origin of the infection and how they contracted it. In addition to answering these types of questions, the colorectal surgeons highlight the likelihood of recurrence, the need for lifelong surveillance and screening for other STDs, and the increased risk for anal cancer.

- The colorectal surgeon audience felt that, overall, patients do not appear to express many concerns or questions but are more focused on 'clearing' the genital warts. They expressed that this may result from the patients' unwillingness to change their lifestyle or simply because the patient has an existing understanding of HPV from a past diagnosis.

- The colorectal surgeons felt that among those patients who were referred by primary care physicians, most were not very well informed and estimated that more than half their patients were hearing about an HPV diagnosis for the first time from them.

- Colorectal surgeons felt that the primary care clinicians generally do not take responsibility for informing and educating patients about HPV, but were unsure whether this was due to lack of understanding or a lack of comfort on the part of the primary care clinician. Interestingly, one of the colorectal surgeons noted a difference between the patients referred from inner-city clinicians versus suburban doctors, explaining that the former appeared to be better at educating the patients.

- Effective communication is evidenced by a patient that understands HPV as an STD, the risks associated with cancer, the necessity of therapy, barrier protection and the ramifications for partners.

- Outside of routine letters to primary care clinicians, there is very limited interaction with other types of clinicians regarding HPV-related issues.

Barriers and Facilitators to Communication

- This clinician audience identified a number of barriers that may impede an open HPV dialogue between patient and clinician, such as the lack of comfort with a clinician other than their primary care provider, first-time patients, and concerns about privacy or sexual orientation. Facilitators to communication mentioned by the colorectal surgeons focused primarily on establishing a comfortable situation and ensuring the privacy of their patients (e.g., asking the parent or partner who accompanies the patient to leave the room).

Partner Issues

- The colorectal surgeon audience acknowledged addressing specific aspects of HPV infection with their patients as it relates to their partners. Topics typically addressed by this audience included transmission via sexual activity, opportunity for recurrence, the danger of repeated exposure via an infected partner, and presence of the infection despite any outward physical manifestations. In addition, they also stressed the importance of having a partner tested.

Condom Effectiveness

- The colorectal surgeons in this audience group demonstrated a lack of understanding of the effectiveness of condoms in preventing transmission of HPV, however, this did not appear to deter them from advising patients that it does offer some protection.

New Technologies/Guidelines

- The colorectal surgeon audience appeared to be less aware of the HPV DNA test than other clinician populations and its relative impact on clinical practice. This audience said that unless the new technologies lead to significant changes in patient care, they did not see any value in such an endeavor.

V. DERMATOLOGISTS

Overall Findings

- Very little education, communication, and counseling about HPV is initiated by this clinician group as the primary focus appears to be on the removal of physical manifestation (i.e., genital warts)
- The dermatology group indicated that they do not conduct HPV screening and are not involved with Pap smears. For the most part, their involvement begins when a patient with

genital warts is referred to them by their general clinician although, occasionally, physical manifestations may be identified during an examination.

- Most of the dermatologists expressed a greater tendency to address the topic of HPV in instances where the wart burden is more severe.
- Male patients that present with genital warts are often counseled to inform their female partners to see an OB/GYN.

VI. HIV/AIDS SPECIALISTS

Overall Findings

- HPV is not considered a critical issue among HIV/AIDS-focused clinicians as it is not perceived as a big risk factor compared to other health risks that the patient must be cognizant of.

- Discussions around safe sex typically touch on generalized topics as opposed to the nuances associated with individual STDs or STIs.

- This clinician group indicated that patients are not actively initiating conversations about HPV primarily because their focus is elsewhere.

STAGE 2: FOCUS GROUP FINDINGS

The two target audiences for the focus groups were—

- Primary Care Clinicians (i.e., family practice, general practice, adolescent medicine, college health, and internal medicine)
- Health Care Professionals (i.e., physician's assistant, nurse practitioners, and nurse midwives)

In Stage Two, primary care clinicians and health care professionals were recruited for separate focus groups to better identify the similarities and differences between these two groups. The analysis of the focus group discussions indicated that there were indeed differences between these two clinician populations that should be understood and incorporated into any HPV communication campaign. We recommend that these differences be further explored and validated in the quantitative survey of clinicians to be fielded in the near future. For the purposes of this report we will first identify those areas of similarity and difference, then each of the two clinician population audiences will be analyzed separately to explore their relevant characteristics and perspectives.

Overall Findings Common to Primary Care Clinicians and Health Care Professionals

- For those "at risk for HPV," participants felt that HPV was incorporated indirectly in any discussion relative to STDs or safe sex; HPV was rarely mentioned individually.

- As a first response to the question "Who do you think is most at risk for genital HPV?" most participants initially seemed to think of the younger patients, specifically teenagers or those younger.

- There was agreement in recommending condom use to their patients but with many comments across all groups of "it's better than nothing" and reflecting the condom's importance as a good method of protection against other STDs rather than a good protection method against HPV.

- Both audiences identified the partner or marital relationship impact of HPV as a major barrier to conversations. The emotional impact on the relationship came up during many of the different questions, not just those specifically related to the topic.

- HPV's link to cancer does dominate the discussion of critical issues relative to HPV.

- The questions that the primary care clinicians and health care professionals hear from their patients are very consistent: How did I get it? Who gave it to me? Implicit in these questions and the number of times they were brought up indicates that potentially the patient may feel the need to identify the source of their infection or affix blame on someone for their condition.

- For many patients the diagnosis of HPV and what that means (STD, lack of cure, etc.) could be emotionally overwhelming for a patient and inhibit their ability to "hear" anything. "If devastated [you] can't educate." Clinicians then feel unable to educate or counsel patients appropriately.

- Telling patients individually about the high prevalence of the disease and emphasizing in a mass media campaign the point that "it happens to people" was a common theme throughout the focus groups. While language around reducing stigma was not used as a reason to highlight prevalence, participants generally found that it made it easier for patients to accept the diagnosis.

- Similarly there was strong consensus around what would not be useful in a mass media campaign: a discussion of all the different types of HPV. There was general agreement that this would be more confusing than helpful. Indeed, participants indicated that they tended to talk about HPV as a whole, versus explaining the different types.

- There was relatively low awareness of the HPV DNA test among participants of all focus groups.

- Both audiences liked the idea of guidelines, finding that they can help create a standard of care as well as help convince HMOs and insurance companies to pay for tests and treatment. There was, however, also fairly widespread concern with how these guidelines could also become "tool[s]" for lawyers.

- It was generally observed that there was a lot of different language used in the discussion of HPV and how it presents: CIN, SIL, ASCUS type 1, etc.

Overall Findings Highlighting Differences between Primary Care Clinicians and Health Care Professionals

- In general, the health care professional group seemed much more comfortable talking about their practices and conversations relative to HPV. Many indicated (with some humor) that this comfort was due to the fact they deal with patients with HPV every day.

- Primary care clinicians, in general, seemed less comfortable dealing with the lack of certainties with HPV. They liked to provide concrete information, guidance, and answers to patients.

- On certain topics, the health care professionals seemed more knowledgeable about HPV than the primary care clinicians. Examples include conversations relative to the effectiveness of condoms, new technologies, etc.

- The primary care clinicians seemed to prefer keeping discussions centered more around the technical aspects of the disease, steering the conversations away from the emotional aspects. The health care professionals seemed more willing to understand and deal with the emotional aspects of the diagnosis.

- The health care professionals indicated that HPV had a greater degree of importance in their practice, but that may be more dependent on their practice setting with more of the participants from the health care professional group working in clinics and hospitals serving low-socioeconomic areas.

FINDINGS EXCLUSIVE TO HEALTH CARE PROFESSIONALS

This section of the report will highlight findings exclusive to the health care professional target audience (nurse practitioners and physician's assistants). This group was predominantly female (one male in the two groups combined) and relatively skewed toward serving lower socioeconomic groups.

Overall Findings for Health Care Professionals

- The volume and repetition of cases and conversations these participants have experienced relative to HPV were apparent in their ease in discussion of the topic and their insights about the patients that they served.

- These professionals were relatively up-to-date on the natural history aspects of this rapidly evolving disease, with some citing articles and information. By the same token, they were not generally aware of the new HPV DNA testing technology.

- In many of the discussions about conversations, certain overarching themes appeared:

    - The initial conversations after diagnosis could be shocking and overwhelming, thereby inhibiting the patient's ability to take in information.
    - Conversations with patients when HPV was diagnosed relative to warts was easier than conversations when HPV was diagnosed due to abnormal Pap smear or cervical dysplasia. Participants indicated that it was harder to convince them of the diagnosis and its importance because there was nothing for them to see, no symptoms, so they had to go on "trust" with a clinician with whom they may or may not have a relationship.
    - Patients appear to need to affix blame. The question of who gave it to them would occur in more than one counseling conversation. It seems that, for the patients, the idea of finding out who gave it to them is almost irresistible.
    - Many participants had developed certain spiels and analogies they used in their conversations. They also had found certain visual aids (posters, pamphlets, drawings) to help the patient understand this complex disease. These visual aids were designed to support conversation in the clinical practice setting, as well as for the patient to take with them and use for themselves and/or to explain the situation to their partner.
    - There are a myriad of complex issues relative to relationships for which these clinicians may have a spiel, but do not feel like they have a good answer:

        - If HPV is present in a monogamous couple where one or both have HPV, is protection really warranted?
        - What do you say about using a condom if the woman is in a relationship where they want to have a child?
        - There is a general and pervasive specter of suspicion that HPV raises in every relationship: "Who gave it to whom? When did they get it—before or during our relationship?" This suspicion causes heavier damage to fragile relationships.
        - If the female presents with warts and the male does not, it seems hard for the female to believe that the male may have had it first, if they believe that the male has it at all.

- The barriers to reducing HPV transmission in certain cultures are very high:

  - Cultures where condom use is not accepted by males (Asian and Latin American)
  - Cultures where females are highly dominated by men and will not or do not feel they can insist on protection for themselves. There was some discussion of the need to target the men in these cultures with messages about HPV that would resonate with them.

CURRENT PRACTICES

The first group of questions surrounded the clinicians' current practices relative to HPV, including types of patients, the context in which HPV is discussed, condom issues, and their practice relative to genital warts vs. cervical abnormalities. These have been grouped into major categories to make it easier for reporting purposes.

Populations at risk

- Most of the participants in both groups identified young people, people with multiple partners, those who engage in early sexual intercourse, lower socioeconomic groups, and "anybody's who's had sex—it's a crapshoot."

- One group had some discussion about the general focus on women—"it's just any women having unprotected sex"—but they also felt that there needed to be thought given to men as well. "We have to be aware that men have [HPV], and even when they don't have the lesions, they carry the virus."

- One member also cited seeing more women "40-plus, who are finding themselves single again and…not accustomed to using condoms."

Context of HPV discussions with patient

- Without a trigger that would cause a conversation to focus on HPV (abnormal Pap smear, lesions), HPV would be discussed in the context of STDs. Some would distinguish between STDs, highlighting the danger of the viral STDs—"the four H's: HIV, HSV, HPV and Hepatitis…once you've got it, you've got it."

- There did seem to be a focus on ensuring that the conversations about STDs occurred with younger patients, this focus decreasing with the age of the patient, unless that patient's history showed they were at higher risk.

- The type of contraception might also trigger the conversation. Many of the participants in this audience wanted to ensure that patients realized that using non-barrier methods of contraception did not protect them from STDs.

Barriers to discussing HPV—General

Many barriers to good conversations about HPV included—

- Lack of awareness of HPV. "They know syphilis, they know gonorrhea. HPV is like, huh, what is that." They may even have had warts for years and thought they were moles.
- The lack of complete answers on the natural history of HPV. "I think I feel bad sometimes because it's not that I don't know the answer. It's that the answer is not known. And you have to make that clear."
- Overall complexity of HPV came up in any number of situations such as the many different types and the progression—HPV types that could lead to warts, others that might lead to cancer, some people might slough off the disease themselves, some might have warts, some might not.
- The fact and importance of having HPV can be difficult to explain if it does not have a physical manifestation, e.g., a lesion. It is hard to convince the patient (never mind the partner) of the existence of something that has no manifestation or symptom. This also leads to confusion about when the lesions go away—often leading the patient to believe the virus has also gone away.

Barriers to discussing HPV—Partner Issues

- This audience indicated that often the female will have lesions and the male may not because the tissue on the penis is less likely to produce lesions. Sometimes this causes difficulty in the relationship in a greater likelihood to place blame on the person with the lesions.
- If a patient believes they are in a "mutually monogamous, long-term relationship" that makes the discussion harder because clinicians have to handle the "who" and "how" questions. Many of the participants seemed to use the tactic of trying to imply that they probably got the disease well before the current partner was in the picture.

Facilitators to discussing HPV

The discussion that focused on facilitators of discussions about HPV was a lot shorter in both groups.

- Many respondents seemed to focus their conversations on helping patients get over their inability to know how they had got the disease, stressing the very long incubation periods. Their tactic was to try and get the patient to focus on the present need for treatment and management: "Let's just go from this point and move on."
- Many had developed specific spiels, e.g. talking points, catchy phrases, etc., to help them emphasize the importance of taking HPV seriously. For example, one participant likened STDs to dogs, with some "like collies and poodles…some barking and all, but they won't really hurt you. Then you move on to the Rotweilers and Pit Bulls and you become cancerous."

- Many liked to provide them with facts about how widespread HPV is to combat the patient's feelings of guilt and isolation.

- Participants had different pamphlets or posters they recommended for which they identified many uses:

    - Help the patient ask questions about HPV they might not otherwise ask
    - To provide information to a recently diagnosed patient too overwhelmed to take in the clinician's information
    - To support the patient's further conversations about HPV with their partner. Some even had specific letters or literature designed to be given to the partner of a recently diagnosed patient.

Condom Issues

Both groups had robust discussions regarding condom issues and cited the deficiencies of condom protection relative to HPV, with comments such as "they are not perfect," and "they are not foolproof." One group had a participant who had initially promoted the female condom but found that it was too complicated and expensive.

- *Deficiency relative to lack of coverage*: Both groups understood that the condom does not cover the entire area that might be infected and could therefore transmit the virus.

    - "A condom will protect her if the warts are on the penis, itself. But it doesn't necessarily mean that she would get protection if they are beyond the condom."
    - Barrier protection won't work unless they "are going to wrap themselves in Saran Wrap."

- *Deficiency relative to timing*: There is concern that people are not aware or thinking about the need to use a condom during foreplay. Some have found that people are apt to put the condom on at the time of intercourse, however this would not offer protection from HPV as contact with infected areas may occur during foreplay.

    - One participant tells his patients, "Put the condom on when the pants come off."
    - Constant use is also required. If the patient decides not to use it because she is protected from pregnancy by the "time of the month" then there is, of course, no protection from STDs at that time.
    - There was also some discussion that male partners try and sneak the condom off during intercourse.

- *Deficiency relative to patient's purpose*: Some participants felt that condoms were used more as a backup for the preferred birth control method versus being primarily used as a protection from STDs.

Both groups do, however, recommend condom use to their patients providing the same reason that we heard from all groups: "It's a lot better than nothing." One group did offer a reason that recommended condom use relating to protection from HPV. They felt that using a condom would protect the cervix from infection. One had recommended female condoms thinking they might possibly give "more vulvar coverage." Another teaches proper condom use "so if I can protect the mucosal linings, at least I'm one step ahead, maybe protecting the cervix." Neither noted any literature that indicated that protecting the cervix relative to other areas from HPV would decrease the impact of HPV on the patient.

Typical clinical practices relative to patients diagnosed with genital warts:

In general, everyone indicated very similar practices when dealing with a patient diagnosed with genital warts.

- The conversation has three main components, a) education about HPV, b) treatment options, and c) counseling relative to maintaining follow up.

- Many participants identified the importance of discussing the different treatment options available. Identifying the right treatment options for the patient could include factors like cost and pain associated with different treatments. They also noted the need to convince patients that if the treatments were successful and the lesions went away, it did not mean that the virus was gone.
- Women who are pregnant are very interested in treatment, as the warts really tend to grow during pregnancy and can become unsightly.

- One group indicated that the diagnosis of HPV associated with genital warts meant that the patient now had increased possibility of getting cancer. One participant advocated that "patients get Pap smears every single year from now on." Another talks to them about cancer: "Some types can cause cancer." This did seem balanced with the need to reassure patients: " I want them to be cautious but I don't want to scare them too much, either, because they may not come back."

Typical clinical practices relative to patients diagnosed with cervical abnormality

The intensity of this conversation might vary depending on the cervical abnormality and where it would fall relative to progression towards cancer. There was general agreement that in every case it is important that the patient understand the seriousness of the diagnosis.

- Everyone indicated that they discussed the link to cancer. The intensity of the discussion relative to the implied threat of cancer was increased or decreased depending on whether the clinician thought the patient was taking the diagnosis seriously enough (as defined by appropriate followup).

- There was general agreement that use of Pap smears to monitor HPV should increase.

- There was a lot of discussion about counseling patients with this type of diagnosis. Patients need to understand the role and importance of Pap smears as a screening tool. They need to understand dysplasia and HPV. Some patients have been known to say "dysplasia runs in my family."

- The type of clinical followup would depend on the degree of dysplasia, with more extensive dysplasia requiring more intensive followup.

Importance of HPV relative to the practice

HPV seemed relatively important to these respondents. The respondents understood that their practice settings in urban areas serving lower SES might have impacted their view. Others also noted that the degree of importance of HPV was increased by its link with cancer.

Identification of critical issues relative to HPV

During this conversation a number of different issues arose, without much discussion of them.

- The high prevalence of HPV in the population
- Treatment—having all patients receive the "gold" standard of care. Some concern arose that some patients are not receiving this high quality.
- Treatment—properly identifying the right genital wart treatment for the patient given the number and quality of those available.
- Controversies relative to population segment or culture.
- Insurance—ensuring that insurance companies allow proper treatment and followup.

HPV COMMUNICATION

This section focused on the conversations participants have with patients who are either at risk for HPV or diagnosed with HPV, both in the context of genital warts and cervical abnormalities. The purpose of this section was to understand typical conversations, patient concerns, the framing of HPV as a cancer or STD, and finally, communication campaigns and tools that might help clinicians in their work.

How does the topic of HPV arise for patients at risk for HPV?

For the at-risk population, HPV is not singled out unless there is a reason to do so. HPV is part of an overall discussion of STDs as it relates to safe sex. For example, the clinician will ask what type of contraception is being used. If condoms are not being used for contraception, they will talk about the need for condoms to protect from STDs.

How does the topic of HPV arise for patients diagnosed with genital warts?

This was a short discussion with both groups, since the topic of HPV would naturally arise from the presence of the genital warts. The groups indicated that the presence of genital warts would inform them of the nature of the HPV virus. One group again linked the presence of warts with the need for increased Pap smear screening.

How does the topic of HPV arise for patients diagnosed with cervical abnormalities?

Patients are not automatically aware of the link between an abnormal Pap smear and HPV. Participants felt that making this link for the patient is an important education process. Part of the education process would be to help patients understand the role of the Pap smear as a screening tool. Once an abnormality had been detected, more diagnostic tests would be required. The focus group participants also made the following points:

- Conversations regarding cervical abnormalities seem more difficult than ones about genital warts. Participants felt that this may be because the cervical abnormality cannot be seen or felt. It seems that without the ability to visually confirm the problem, it is harder for the patient to believe something is truly wrong. "They don't want to believe you." This problem is especially pronounced if there is not already established trust between the patient and the clinician: "It's their word against yours."

- Patients also seem to feel that if they cannot see it, they probably cannot transmit it. "It's like well, I don't have any lesions, so I didn't give you anything."

- Participants also noted patients resisting the need to tell partners, bringing up many of the partner issues already noted in this report, e.g., distrust of the partner, fear of telling the partner, shame.

What concerns do patients typically express and how do health care professionals address them?

The questions and concerns patients typically express when finding out they have been diagnosed with HPV continue to be very consistent (from these focus groups and to the interviews conducted during Stage One of this project). Patients tend to be very focused on the past, in terms of how they got the disease, especially with whom gave it to them. Specifically, they seem to want to know whether their current partner is responsible. They may keep asking this question in different ways in the various conversations they have with the health care professional. A finding of HPV seems to engender strong feelings of suspicion in the relationship. "They mostly want to know if their current partner gave it to them." This finding results from the participants' answers in this part of the focus group as well as discussions that occurred in other areas of the focus group.

- The first set of questions a patient typically asks contains the following: How did I get it? How long have I had it? Who gave it to me? How did he get it? How do I get rid of it? We note that this first set of questions is also THE set that cannot be answered because the answers are not known.

- The second set of questions (after the first concerns have been voiced) might contain: Why doesn't my partner show it? Is my baby going to get it? Did I get it from my current partner? Is there any other way (besides physical contact) that they might have got it? Will it go away?

- What is interesting is also the concern that they do not immediately express. They do not seem to ask a lot about health care relative to their partners, how to protect them or how to talk with them. These questions may come, but tend to be later in the conversation and triggered by something the clinician will say.

The health care professionals that participated in the focus groups seemed very understanding of these conversations and had developed ways to respond:

- Health care professionals indicated that they emphasize that the virus can be dormant for a very long period of time before manifesting itself. They use the fact that there is no way to know when the virus was transmitted and could have been transmitted a long time ago to imply that the transmission probably did in fact take place a long time ago. They want to relieve the patient's suspicions toward their current partner and help them focus on what they need to do about the virus versus how they got it.

- Health care professionals also understand how overwhelming the diagnosis can be. They used words like "overwhelmed" and "upset." "A lot of times they're so upset that they've got something that they don't always hear you." To counter this, health care professionals prefer to give patients written materials that they can absorb on their own. Materials should be in several languages for those who do not speak English.

- The health care professionals also seemed to understand that some patients might not be in control of their ability to protect themselves. In some cultures, females are not empowered to insist on protection.

HOW DO HEALTH CARE PROFESSIONALS TEND TO FRAME HPV—AS AN STD OR AS A PRECURSOR TO CANCER?

The following analysis is based on the conversations that occurred directly in response to the above question, as well as responses to questions about clinical practice relative to the diagnosis of genital warts or cervical abnormality.

- In the case of a female where there is a cervical abnormality, the discussion of HPV's link with cancer always occurs.

  - The emphasis on cancer depends on the clinician's perception of the individual and the seriousness with which they take the diagnosis. The clinicians are trying to balance the desire not to scare the patient with the "cancer word" with the need for future monitoring to be seen as important. "I want them to get the seriousness of this in there. If left untreated, chances are this will become cancer, and it's the kind of cancer that could kill you."
  - They seem sensitive to how they frame the seriousness of the diagnosis because depending on the population, HPV might be one of "so many problems, this is just one of a list of many things—I'm not talking just physical problems, [but] social and economic problems as well."

- They may also discuss cancer relative to a diagnosis of genital warts, discussing HPV's link with cancer and the need for them or their partners to get increased screening.

- Universally, they seem to frame HPV as an STD, "every time, everybody."

- Participants noted the need to have conversations about safe sex, especially if patients are not using condoms for birth control purposes.
    - The viral STDs as a group, the four "Hs," were brought up again as being particularly virulent and difficult to control or cure.
    - The STD discussion again seemed easier to accept by patients if it related to a diagnosis of warts versus cervical abnormality.

What communications would support the clinicians' conversations with their patients?

Lots of good ideas were thrown out about what would or would not be useful if someone were to undertake a national media campaign. Not much discussion occurred around these different ideas.

Areas to emphasize

- How common it is
- There is no age differentiation—need to show older people they could have picked it up a long time ago.
- Focus on early age groups—teenagers
- Easily treated at early stages
- Just because you don't have warts doesn't mean you don't have HPV
- Genital warts can harm babies as they are born
- Have sex—get checked
- HPV's link to cancer
- Transmission can occur during fondling, not just intercourse.

Areas that would not be useful in a communication campaign include—

- The complexity relative to the number of and differentiation between strains.
- DNA testing.
- Confusion relative to the different viral STDs, many of which are three-letter acronyms beginning with H. (HPV, HIV, HEP-b)
- Anything that would increase stress felt by patients.

Communication materials that would be helpful for patients

- There should be different materials developed for different audiences based on cultures, gender, and age.
- Materials should be easy to read and kept simple, with pictures and big print
- Materials should tell stories that would feature common situations (teen, couples, etc.)
- Billboards might help raise awareness—one participant remembered a billboard campaign designed to increase awareness of Hepatitis. It featured a teen with yellow eyes. It seemed to be effective with increasing awareness without increasing stigma.

Communication support for colleagues

Participants felt that their own ease and ability to have good conversations with patients depended to a large degree on the frequency of these conversations, something that would be difficult to manufacture artificially for clinicians who did not have similar exposure. Suggestions to counter these issues included—

- Training sessions where clinicians would have a chance to role-play. This would be attractive since clinicians are always looking for CEUs. Training should also encompass sensitivity training and knowledge of what is happening on the street.

- Materials that would support patients whose clinicians have trouble communicating. Suggestions included videos that could be provided to patients or watched by the patient prior to having a conversation with the doctor. A similar suggestion included developing a video that could be run on a health channel.

- Understanding of cultural issues among the clinician population and ways to compensate for these issues. For example, a Hispanic doctor would not want to ask certain questions of a female patient. However, if these questions were incorporated into the medical history, the clinician would have the information they needed.
- The provision of increased awareness of HPV facts to clinicians, especially relative to its prevalence.

IMPACT OF NEW TECHNOLOGY

Neither group indicated much familiarity with the new HPV DNA testing. Only one person in both groups had used the DNA test. Others had used biopsy as a way to further test lesions. This unfamiliarity made the next exercise of asking the participants to identify how they would use the HPV DNA test less useful.

When the test was described, most participants felt that they might use the test as a method to determine the management of a patient after an ASCUS Pap smear. Others also indicated some interest in the test's use as an STD screen for women or men who may have no cytoligic abnormalities. No one in either group thought that the test should be used as a primary cervical cancer screen instead of a Pap smear. "As an adjunct to the Pap." "Yeah, but not instead of." All shared a feeling that the Pap smear was useful relative to screening for HPV and showed other things in addition to HPV. Participants also felt that the introduction of this type of technology would need to be accompanied by literature for the patient to help explain the technology and resulting information and management recommendations. This literature would also be needed to deal with the potential higher anxiety that this type of test might cause and the associated questions about the different strains.

The discussion did bring up many concerns that the respondents wanted to understand about the new technology before they would know how to implement it within their practice, including—

- How much would it cost?
- What about false positives?
- What are the implications for medical treatment?
- What are the legal implications?
- How would this impact the "standard of care?"—a very important concept for the group.
- Would this help them diagnose cervical cancer or could it cause a failure to diagnose cervical cancer?—Another very important concept. No one wanted to have failed to diagnose cancer.

Opinions about Guidelines

Because the participants were not very aware of the HPV test, the question about the role of guidelines in clinical practice became more general, but was still insightful. There was general agreement in both groups about the usefulness of guidelines in many areas, including—

- Guidelines should be evidence-based and cost effective, in other words, they needed to provide care guidelines in the context of the insurance and HMO environment.

- Guidelines should be issued by ACOG or CDC (both names given by both groups). CDC was cited because of its knowledge and because "CDC gives us our STD guidelines."

- Guidelines are important as they help create "standards of care" from credible institutions "working in the public health arena. If it's not mandated that this is what you're going to do, then we don't necessarily have that option available to us because of costs."
- Participants felt that they should provide guidelines that would allow them to still make decisions appropriate to their individual patients.

- One participant was concerned that national guidelines might not be appropriate, due to regional variances.

FINDINGS EXCLUSIVE TO PRIMARY CARE CLINICIANS

This section of the report will highlight findings exclusive to the primary care clinician target audience (family practice, general practice, adolescent medicine, internal medicine, and college health). The two groups comprised both males and females with relatively wide range of years in practice, primarily in private practices.

OVERALL FINDINGS FOR PRIMARY CARE CLINICIANS

- These groups tended not to have the same high exposure to patients with HPV as the participants in the health care professional groups.

- These groups seemed somewhat less informed about HPV, its natural history, and appropriate management.

- These groups were less comfortable in their conversations about HPV with their patients, especially those conversations that might be of an emotional nature, or that might discuss the impact or issues relative to the marriage or partner.

- Doctors expressed more concern about how the diagnosis would affect their own relationship with their patients.
- Doctors seemed to want to keep the conversation fairly technical (to keep the emotion out) or found it difficult to find non-technical language to explain the disease.

- In the college health environment, students are beginning to come in to get checked out for STDs, without experiencing any symptoms. Often they want a clean bill of sexual health before beginning a new relationship.

CURRENT PRACTICES FOR BOTH HEALTH CARE PROFESSIONALS AND PRIMARY CARE PHYSICIANS

The first group of questions surrounded the clinicians' current practices relative to HPV including types of patients, the context in which HPV is discussed, condom issues, and their practice relative to genital warts vs. cervical abnormalities. These have been grouped into major categories to make it easier for reporting purposes.

Populations at risk

Similar to the health care professional audience, the primary care clinicians' first response provided a fairly wide age range and included anyone having sex (Group One: 14–40, Group Four: 16–30). Continued comments seemed more focused on the younger age groups.

- Some had seen dysplasia in the younger teens—even in 12 and 13
- There was a general agreement on a focus around teenagers; the clinicians talked about "young people having sex" and those not practicing safe sex.

Context of HPV discussions with patient

There was general agreement that HPV was incorporated into discussions about STDs in general, whether mentioned specifically or not. There were different views offered here—

- Some indicated that they incorporated an STD discussion in the context of doing a routine Pap smear, when diagnosing another STD, or taking a sexual history. Others indicated they did not bring up STDs unless there was a specific trigger for this kind of conversation—an understanding that the patient was sexually active, or if they presented with symptoms of another STD. One participant noted whether the patient was "promiscuous."

- There was general agreement that conversations took place more with the younger patients (pre-teen or teenagers) with one participant noting that conversations tended to decline with older audiences due to the fact that older people "aren't giving me the same kind of audience." This decline runs counter to the statement that this participant made: "I'm probably seeing, in my own particular practice, a higher incidence of STDs in people between 20 and 35 or so."

- Participants acknowledged feeling pressured with the amount of time they could spend on this topic with patients during their visit—"there's not enough office time to discuss every aspect."

Barriers to discussing HPV—General

Both groups mentioned a number of barriers:

- Partner issues were raised consistently and with emphasis by both groups. One clinician in particular wanted to talk about partner issues. He felt that he was always "in the middle, no matter how you word it or what you do." Further discussion of partner issues mentioned can be found in the section dedicated to that topic.

- Embarrassment on the part of the patient, especially if they are young. This also seemed to make it hard for the clinician to introduce sexually related topics "asking a young girl, are you sexually active? They look at me like, you know."

- Ignorance and lack of awareness among all patients. "They know what HIV is…Males know what gonorrhea is… but specific diseases are very vague."

- Difficulty in getting patients to take this type of STD seriously. "Contracting a virus that's going to hurt them in 20 years from now is like talking to people about hypertension."

- Difficulty in reaching teenagers. "It's very hard to convey the seriousness to a young person because they are bulletproof."

- Difficulty in finding the right kinds of words to explain the disease. "I'm still trying to find the words to explain to lay people [about] biodiseases."

Barriers to discussing HPV—Partner Issues

Some of the clinicians in family practice settings with established relationships with patients and their families had a much harder time dealing with the partner issues. They found it difficult to counsel the patient relative to their partner issues and also found it difficult relative to the strain that it caused in the relationship between the doctor and the patient.

- One participant (family doctor) was very concerned about these discussions "the counseling kills me," the "partners can turn on you."

- The family or partner situations make it difficult for them to know how to counsel. "it's not as much a problem with my HIV patients as it is with my married couples."

- These doctors seemed to want to avoid the "emotional overlay," either related to the patient's reaction to the diagnosis or in their relationship with their patients. Without explicitly saying it, they seemed to feel their own emotional toll when a marriage would break up, or a grandmother they had known for years all of a sudden had to deal with the disease.

- The unknowns about transmission and who has the virus make it very complicated. Sometimes one partner will have it and the other won't. Doctors, similar to the health professionals, try to take the focus off the current partner. "I always tell them it's not necessarily the current partner. It's hard to know who they got it from just because of the long incubation period."

- The complexity of the disease is a further barrier to good communication. One college health doctor indicated that while her population is pretty aware and knows the different STDs "genital warts is the hardest to understand."

- Some patients with genital warts don't "buy-in" to the seriousness, especially if they have had it for a long time without any other symptoms that would tell them it is serious.

- These primary care clinicians also found it difficult because there are no good answers, either to protect a patient from it, or cure it once they contracted it. "That's what makes it so devastating: that you can't fix it, you can't protect against it.

Facilitators to Discussing HPV

Similar to the participants in the health care professionals focus groups, the discussion that focused on facilitators of discussion of HPV was shorter than the one about barriers to discussion:

- Some mentioned trying to make the patients feel more comfortable.

- Another technique involved keeping the conversation technically oriented, as a way to keep out the emotion. "So you take out some of the personal issues and…try to stabilize the emotional content of the discussion with some of the technical issues."

- Emphasizing the widespread prevalence of HPV seemed to make patients feel better.

CONDOM ISSUES

Condom effectiveness

The two groups had different levels of awareness relative to the effectiveness of condoms on HPV. One group was concerned that condoms might not be effective because they might break, or that the membrane of the condom was insufficient to keep out the virus. Another respondent felt that abstinence from sex was "the only thing, the best way to prevent sexually transmitted disease and HPV," although others in the group did not accept that statement as a realistic approach.

Participants in the other group all had a clear understanding of the issue relating to the condom's inability to cover all of the potentially infected area. "There can be lesions in places that can't even be seen, so it's just not an effective [way]..only for what it can cover." The second group also indicated concerns that contact would already have occurred before the condom was put on.

Recommendations relative to condom usage

- Condom use for self-protection: As we have found with all respondents, all groups advise patients to use condoms, if not to protect from HPV, at least to protect from other STDs.

- Encouraging patients with HPV to encourage the use of condoms (themselves or their partner as appropriate) is more complicated. One participant cited a female patient with HPV who was not able to maintain a relationship once she completely advised her potential partner of the risk of getting HPV, even with condom use.

- Later, one group also cited the difficulty of recommending condom use for married couples trying to conceive.

Typical clinical practices relative to patients diagnosed with genital warts

The focus groups had basic clinical practices in common, including—

- Both focus groups indicated that with such a diagnosis, they would discuss STDs and perhaps test for other STDs as appropriate.

- For males, depending on the severity of the diagnosis and their practice's capabilities the clinicians would either treat them at their office or make a referral to a specialty provider.

- For females, clinicians would discuss HPV's linkage with cancer and generally refer for treatment to gynecologist.

Group One had a greater discussion of clinical practice and their points are worth noting:

- There was not general agreement in the group as to the importance of HPV. In the case of one participant, he had thought until very recently that HPV could be cured. "I thought you could have some effective eradication of the virus."

- There was also concern that male populations, due to age or cultural background, are not willing to use condoms. They want females to use birth control for contraception purposes. "maybe a seventh of my population probably actually uses a condom." Many females are in situations where the male has significantly more power and the female is not willing or able to insist on a condom.

- Some clinicians want to be able to say concrete, positive things—even if they may not exactly be true (for example, one doctor spoke of telling a young female patient recently diagnosed with warts that "[your] body is going to build up antibodies to protect you after I burn these off. That's a bit of a lie, okay? But it's a way to get her into some sort of safe equilibrium."

- Clinicians also wanted to have something that would make patients pay attention. Cancer will "put the fear of God in them," it's the "only thing I've got," a "final bombshell."

Typical clinical practices relative to patients diagnosed with cervical abnormality

Both groups had relatively similar clinical practices for their female patients diagnosed with cervical abnormalities. They would counsel them as to the importance of the diagnosis. They would tell them they have HPV and explain what that means. Then they would explain the link with cancer and counsel them to have increased surveillance through Pap smears. Health care professionals and clinicians would either continue to monitor these patients or refer them to gynecologists or a specialist for colposcopy.

One respondent in Group One indicated the need to sound positive and be able to control the disease, echoing a concept that this group had introduced earlier. "This [dysplasia] was probably caused by a virus, and we can do something about it."

Importance of HPV

The importance of HPV in their practice—

- There are hurdles to focusing time on HPV for primary care clinicians. In the managed care environment there is limited time to deal with a complex issue like HPV. "It's going to take a lot appointment time to deal with that particular problem."

- HPV does not come out at the top of the importance scale given the spectrum of medical conditions the primary care physician sees. "With chest pains and myocardial infarctions at the top…[HPV] is probably closer to the bottom part."

- The link with cancer does ensure that it has some important elements to it. "With HPV it looks innocuous but it may not be."

The importance of HPV from the patients perspective

- The importance of an HPV diagnosis can depend on the patient and the patient's overall health condition. If it's one of 10 medical problems a patient has, then you deal with it relative to all the other things going on.

- There is a feeling that it is easier to try and make it an important issue with a young person because they "don't have a long list of medical problems."

Identification of critical issues relative to HPV

There were a lot of individual ideas expressed in response to the question of "what do you feel are the most critical issues in your practice relating to HPV and its clinical manifestations?"

- Prevention, education, and treatment
- Issues that relate to sexual partners
- Relationship with other STDs through risky sexual activity
- The difficulty of getting rid of it—it is a "scourge"
- Ensuring that the proper management is undertaken to stop the dysplasia.

Identification of controversial issues relative to HPV

- There is a great danger in people not seeing it as important, in "treating it carelessly"
- Lack of awareness—leads to lack of understanding that it is important
- The recent research into HPV typing, is it useful? When should it be done?
- Should anal Pap smears be done for those who engage in anal intercourse.

HPV COMMUNICATION

This section focused on getting participants to discuss the kinds of conversations they had with patients who are either at risk for HPV or diagnosed with HPV, both in the context of genital warts and cervical abnormalities. The purpose of this section was to understand typical conversations, patient concerns, the framing of HPV as a cancer or STD, and communication campaigns and tools that might help clinicians in their work.

How does the topic of HPV arise for patients at risk for HPV?

As a common finding, HPV does not arise separately with patients at risk for HPV. It comes up as one of many STDs for those who are sexually active and those not practicing safe sex.

- Some seemed to bring up the risk of STDs and the need to practice safe sex as often as possible, often in the context of taking a sexual history or a general physical exam. Others only bring up STDs if they think there is a reason the patient has been exposed.

- The college physician indicated that there is a current trend with college students coming in periodically asking to be tested for everything, wanting a "clean slate before they start with a new partner." This seemed especially applicable for males.

How does the topic of HPV arise for patients diagnosed with genital warts?

As with the other groups, this seemed fairly obvious to most participants in that patients coming in who are diagnosed with genital warts already have an idea that something is wrong.

How does the topic of HPV arise for patients diagnosed with cervical abnormalities?

- The topic of HPV generally arises with an abnormal Pap smear result. This generally begins a series of questions.

- There were differing views as to how the subject of cancer might arise. "When you're talking abnormal Pap smear with a woman, immediately she's concerned about cancer." Other participants indicated that they might not bring up either cancer or HPV. They indicate the need for further tests versus bringing up HPV or cancer.

- The clinicians also indicated that they refer these patients onto specialists: gynecologists, oncologic gynecologists or colorectal specialists.

What concerns do patients typically express and how do health care professionals address them?

- Patients don't seem to express a concern unless something is triggering that concern. Once they have had a diagnosis there are some initial questions that patients seem to ask immediately:
    - Where did I get it/who gave it to me?
    - Will a condom protect against it?
    - How long will I have it/does it go away?
    - Could I give it to anyone?

Group One had a more robust discussion about the impact of the diagnosis on the relationship. The typical situation seems to revolve around a female in a monogamous or seemingly monogamous relationship. The clinician emphasizes that the patient probably "picked it up when you were younger, some way." Clinicians want to avoid the suspicion that the current partner is fooling around. "That's my white lies when they come for that [HPV]. I never destroy relationships with stories like that."

- Then there seems to be a second set of questions that focus more on what the virus means to the patient:

    - What does it mean in terms of cancer?
    - What does it mean for future relationships?
    - What does it mean for my ability to have babies?
    - What does it mean if you have active lesions or not? – Can you give the virus to a partner if you don't have active lesions?

- Some clinicians seem to defer the discussion, preferring to avoid these complicated and time-consuming conversations relative to HPV and STDs and allow the specialist to whom they have referred the patient to deal with these issues. "I spend a lot of time explaining that it's not just a lesion; it's an infection. And that takes a lot of time."

- Some clinicians have found that in the initial diagnosis the patient is overwhelmed and cannot take anything in. "If they're sitting there crying and all that, you're not going to get through a whole lot of the time…they're devastated."

How do primary care clinicians tend to frame HPV—as an STD or as a precursor to cancer?

CANCER

There does seem to be a difference in nuance depending on the patient and the type of diagnosis. "If it's in the STD climate you're going to focus more on the sexually transmitted disease, and you may mention it can lead to cervical dysplasia and ultimately cancer. If you've got a patient with cervical dysplasia, you're going to frame it that this can lead to cancer, and it's caused by something that is sexually transmitted."

The level of emphasis placed on the "big C" seems to depend on the clinician's sense of the patient's willingness to follow through with the appropriate followup and/or treatment. If the patient's attitude is "it's just a bump; it doesn't bother me," the clinician will use cancer as a word that has the power to provoke a change in attitude. We note that in this example the clinician used the threat of cancer to help the patient pay attention to genital warts— the type of HPV that is generally not linked with cancer. On the other hand if clinicians feel that the patient is "compliant," they will not "beat them over the head about cancer."
Another trend is that some clinicians are now beginning to write down that they did tell the patient of the risk of cancer so that there is a documented warning in case of problems down the line.

STD

There was general agreement among both groups that HPV should always be framed as a STD. "That's how you get it straight. It's not like hypertension…You've got to frame it".

What media communication campaign would support the clinicians' conversations with their patients?
Many different ideas were contributed about what would be useful and what would not. Not much discussion occurred around these individual ideas.

Areas to emphasize

- To prevent HPV, practice safe sex
- Abstinence, with condoms as a back up
- Condoms don't always protect against HPV
- Show graphic pictures of the STDs, warts, and cervical cancer
- The prevalence of HPV
- Fear of cancer
- For teens, try fear of getting warts
- Tell married couples they have the possibility of having HPV. They are, by definition, sexually active.

Areas that would not be useful in a communication campaign include

- Discussion of sub-types
- Areas of complexity that could increase the confusion

Communication materials that would be helpful for patients

- There was an acknowledgement that different populations would need to be approached differently. There was a difference of opinion as to whether the materials should be tailored to the different populations or whether the materials should be the same, allowing the clinician to deal with the cultural or other specifics.
- For kids, some suggested videotapes with cool kids as models, but also felt that focus groups would be required to identify the best approaches to this population.
- Understanding the different cultural hurdles would be important; one participant indicated that Asians do not wear condoms.
- Different languages such as Spanish and English.
- Pamphlets can be very helpful, as they will answer the typical questions. Participants noted prior conversation where they had talked about some patients' inability to hear anything else once they received their diagnosis.

Communication support for colleagues

- CME classes. Participants felt the curriculum should be fairly prescriptive: give direction, help with attitudes, provide way to open discussion. Another respondent noted that females as well as males should lead these classes.
- Increase physician's knowledge so they are more comfortable.
- There was a request that if someone did do a public information campaign, to let the clinicians know first!
- Information and materials that would help clinicians understand and deal with nationalities where males are more in control.

IMPACT OF NEW TECHNOLOGY

The conversation in this section was less robust, given the general lack of awareness of the HPV DNA test. Of participants in both groups, none had used it and only one participant had some level of awareness of it.

Once they had discussed the test, there was a general indication that respondents might use it either as a method to determine management of a patient after an ASCUS Pap smear, or as an STD screen. None thought that it should replace the Pap smear. The groups also indicated a need for a lot more information before making an informed decision that focused on cost and relevance to practice. They also felt that it might increase patients' fear of cancer and therefore targeted materials for counseling and education would need to be provided along with the new test.

Opinions about guidelines

Similar to the other focus groups, the discussion about guidelines became more general in nature, given the low level of awareness of the group to the HPV DNA technology and its potential to impact guidelines. The group had very strong feelings about guidelines, which will be useful in the development of HPV-related guidelines at the appropriate time.

Both groups were in general agreement as to the need for, and usefulness of guidelines

- Guidelines helpful in convincing HMOs and insurance companies.
- "Guidelines really help us," they are a "cookbook."
- "The future is guidelines."
- Guidelines can help set the "standards of care."

They should also meet the following standards

- Must show they are cost effective
- They must be based on research and refer to literature
- They should contain algorithms
- They should be issues by organizations that have the weight to influence HMOs and insurance companies.
- It should be clear that they are mandating a "standard of care" or that they are suggestions.

Guidelines also have their drawbacks

- Concern that attorneys also refer to guidelines. "Physicians make guidelines but lawyers follow them." "They are a tool for lawyers.
- Some are out of hand, e.g., hypertension guidelines so restrictive now that next year everyone will fall within the new guidelines.

Suggestions for organizations that could issue Guidelines that carry weight and credibility

- One: CDC for STDs they are the "quintessential organization"
- ASCPR—they are the big folks that make guidelines
- NCS, AMA.

PREFACE

A literature review was conducted to identify and determine the effectiveness of communications and behavioral interventions designed to reduce the transmission of human papillomavirus (HPV), the primary cause in the development of cervical cancer. A comprehensive search was conducted to identify relevant research as it related to the four aspects of HPV prevention, diagnosis, and management identified below:

- Critical issues, controversies or areas of consensus relative to those infected with or at-risk of genital HPV
- Examples of effective interventions, best practice, campaigns, results, and impact related the target audiences
- Most effective mediums, tone, format, etc. for HPV-related communications (as applicable)
- Existing gaps in information or research.

This review presents an overview of current literature findings and conclusions based on the variety of issues, ideas, or research that were available in the literature. It should be noted that while every effort was made to limit the review to evidence-based literature, the overall lack of such research caused us to expand the original criteria for inclusion. As a result, when applicable, this report often references the validity or framework for the research cited.

INTRODUCTION

The cause of one of the most common sexually transmitted infections in the United States today is Human Papillomavirus (HPV). In recent years, research has shown that HPV infection is even more common than originally believed. It has been estimated that as many as one in five American adults has a genital HPV infection and another 5.5 million more people become infected with HPV each year.

Primarily recognized as the cause of genital warts, an increasingly large body of research that has developed over the past 20 years has demonstrated its relation to a variety of anogenital cancers. In fact, as a result of this research, over the past few decades a concerted national effort was made to implement and promote cervical cancer screening programs for sexually active women. As a result, a dramatic reduction in the incidence of cervical cancer in the United States and other industrialized nations has been achieved. However, despite the important successes that have been achieved in the prevention of cervical and other anogenital cancers, genital HPV continues to present many challenges to both clinicians and patients. Due to the many manifestations that genital HPV can take, from outwardly visible genital warts to invisible subclinical infection, a patient's knowledge of HPV and their emotional and sexual health can be significantly impacted in very different ways.[64]

Aside from the stigma associated with STDs, there are many factors that often limit the public's awareness of HPV. For example, health care professionals know that because HPV can be present for years with no symptoms, a person may be infected with it or transmit it to others without ever knowing it. In addition, because condoms cannot guarantee protection against infection with HPV, it can be passed from person to person with any skin-to-skin contact with an HPV-infected area that is not covered by the condom. The complexities associated with genital HPV therefore make it the responsibility of the health care community to not only address patients' physical needs, but also their educational and psychosocial needs throughout the entire process.

These findings have increased the public health importance of improving efforts relative to effective primary preventive efforts and understanding the community's awareness and perception of HPV infection.[95] In order to create a successful prevention or management program for HPV infection, it is imperative that the health community understand both the clinician's and public's knowledge and perceptions of genital HPV, identify the most effective methods to prevent and manage the infection, and have a real appreciation of the complexities of the greater community health beliefs relative to sexually transmitted infections.[6]

The purpose of this review was to identify existing literature that provided evidence-based research associated with the prevention, detection, or management of genital HPV infection. Upon researching this topic, one of the biggest realizations was the very limited amount of evidenced-based studies that have been published to date. However, the information that was available was collected and reviewed to see whether it met the criteria for inclusion. The publications that met the established criteria were then analyzed for content. The analysis yielded four primary categories in which research has been conducted regarding genital HPV: 1) knowledge, attitudes, behaviors, and practices of at-risk and patient populations, and health care professionals; 2) patient communication, counseling, and prevention; 3) genital HPV prevalence and risk factors; and 4) evidenced-based behavioral interventions for genital HPV screening and followup. At the request of CDC, ORC Macro was asked to include in this review two additional types of information—HPV-related guidelines for clinicians and health care professionals and articles or stories providing genital HPV-related information found in popular lay press publications. However, these two additional areas of interest are presented individually as they cannot be considered empirically based research.

METHODS

Selection of literature for inclusion in the final report was primarily designed to examine communication or behavioral interventions, patient/clinician knowledge, attitudes, behaviors, practices, HPV prevention, counseling, education, outreach, and awareness as they relate to the prevention, detection, or management of HPV infection.

A series of searches was conducted to identify any relevant studies and/or related literature. Both library personnel and project staff utilized a variety of medical and social science databases such as PubMed, MEDLINE, PsycLIT, ERIC, and reviewed resources and information made available from a variety of organizations, associations, or agencies providing HPV-related information. The following includes a list of terms, used both individually and in combination, to identify pertinent literature.

Key Terms Used in Search Strategy

- cervical
- guidelines
- recommendations
- human papillomavirus
- HPV
- genital warts
- prevention
- screening
- assessment
- management
-
- counseling
- interventions
- patient education
- communication
- outreach
- adolescents
- anogenital
- ASCUS, AGUS, HSIL, LSIL, CIN
- Pap smear (abnormal)
- messages
- sexually transmitted diseases (STDs)
- sexually transmitted infections (STIs)
- channels
- evaluation
- media

Once the publications were collected, results from the search were then evaluated for inclusion in the literature review according to the following criteria:

- Data referenced was collected post 1985.
- Studies of behavioral interventions based on the presence of the following five methodological qualities:
    - Clear description of the objective(s) of the intervention or study.
    - Utilizing a control/comparison group equivalent to the intervention group on socio-demographic and outcome variables at baseline.
    - Existence of pre-intervention data for both control and condition groups.
    - Existence of post-intervention data for both control and condition groups.
    - Reporting on outcomes targeted as indicated in the study objective(s).
- Literature based on reviews of previous studies, formative research, or anecdotal information.
- Literature drawing direct comparisons between STDs or HIV/AIDS research and HPV. Also literature attempting to apply effective interventions that are specific to STDs or HIV/AIDS to HPV, due to their similar characteristics.
- ORC Macro also collected and analyzed available literature that referenced HPV guidelines or that was published in lay press vehicles. However, as previously noted, because this information cannot be considered evidence-based, it is not included in the primary analysis.

OVERALL FINDINGS

After reviewing all of the HPV-specific research, ORC Macro identified key overall findings in an effort to better characterize the literature that currently exists and identified where large gaps in information remain.

- A very limited amount of evidence-based research on HPV infection exists. The majority of the research that does exist focuses primarily on the knowledge, attitudes, behaviors, and psychosocial or psychosexual aspects of HPV diagnosis or prevention among the patient populations.
- A good portion of the work in the identified literature appeared to be based on previous HPV studies, anecdotal information, or other evidence-based STD studies to develop recommendations, model/theories, or discussion around HPV-related issues.
- Nearly all of the research collected exclusively referenced or focused on the female population.
- There appears to be little consistency in the way that research functionally defines Human papillomavirus. In different studies, HPV infection might be portrayed as the presence or absence of genital warts, pre-cancerous lesions, abnormal Pap smears, CIN, etc., which often prevents direct comparisons to be made across the research.
- The majority of prevention activities, as it is described in much of the literature, tends to focus on secondary prevention (e.g., screening, followup) as opposed to primary prevention (e.g., education to prevent infection).
- The presence of HPV-related information in lay media channels primarily appears in popular women's magazines (e.g., Glamour, Vogue, Redbook) or news publications. The information contained in these publications seem to be relatively accurate and typically provide basic information related to the transmission, consequences, and treatment options available, although some provide guidelines for communicating with clinicians.
- Few evidence-based studies currently exist that measure the effectiveness of behavioral or educational HPV interventions. Operationalized definitions of effectiveness were typically measured by adherence to follow-up procedures, increased HPV knowledge, self-reported increase in safe sexual practices, or the presence or absence of sexually transmitted infections.

KNOWLEDGE, ATTITUDES, BEHAVIORS, AND PRACTICES

General Public & Patient Populations

Studies examining the knowledge of and psychosocial and behavioral aspects associated with genital HPV constituted the largest portion of existing literature. Among these studies, research focused exclusively on patient populations or clinician populations and typically utilized a variety of quantitative and qualitative methods for data collection. Research on specific patient populations represents the majority of existing literature.

Assessments of knowledge or awareness among the general population reveal that individuals are often ignorant of HPV infection and its identification as a sexually transmitted disease. Findings from research investigating HPV-related knowledge among college women have indicated that the vast majority have never even heard of HPV.[38] In a study of college women conducted by Vail-Smith & White, more than four fifths of the respondents reported no awareness of HPV or its specific signs, symptoms or risk factors[101]. More recent studies, including a study of college women conducted by Baer, Allen & Braun, continued to find that the majority of college-level students are ignorant about HPV infection, the modes of transmission, and its prevalence in society[6].

Some of the research examining public awareness of HPV infection reveals a greater familiarity with genital warts than with HPV infection (e.g., they do not associate the two). A study of college students revealed a significant difference in the number of students who indicated they had heard of genital warts—more than 95 percent, versus those who had heard of HPV infection of either the cervix (less than one third) or HPV infection of the penis (approximately one fifth). [6] Similar to Vail-Smith & White's research, other areas where students were particularly misinformed included how the infection is transmitted, what organism is responsible, and HPV prevalence relative to other STDs. For example, nearly half of all respondents thought genital warts could be transmitted through blood or semen. Approximately two thirds reported they didn't know what caused genital warts, while more than one fourth cited herpes as the cause.

Perceived risk of HPV infection and actual risk associated with genital HPV infections have also been explored among the college population. A study of college-age women also indicated that the majority possessed negative feelings in relation to HPV infection, which may impact their decision to be tested for HPV. The actual risk of HPV infection, which was defined as a positive HPV test, was not associated with women's personal perception of risk. [88] Similarly, a more recent study demonstrated that despite the prevalence of HPV, a majority of the college students surveyed did not afford the same level of concern for HPV as they did for other STDs (e.g., HIV/AIDS, syphilis, gonorrhea), which might indicate a lower perception of risk for either acquiring HPV infection or the consequences associated with infection. [6]

Another area of focus has been the identification of barriers to educational messages about healthy sexual practices and preventive screening practices, such as the Pap smear. Often this line of research focuses on target audiences that are considered to be at high risk for HPV infection due to their cultural or religious background and beliefs, socioeconomic status, locale, sexual orientation, education, or language proficiency.[38] In particular, low rates of Pap smear screening have been documented among Latinas, Asians[72, 100, 103], Native Americans, and rural African American populations. In contrast, little difference has been found in screening rates between African American women and Anglo American women in urban settings. The 1997 Behavioral Risk Factor Surveillance System identified those least likely to ever obtain a Pap smear as those with an income of less than $15,000 a year, women with less than a high-school education, women over 65 years, and Latin American women.[11]

A number of studies have identified factors including fatalism, fear, hopelessness regarding a diagnosis of cancer, and embarrassment for the screening process as particularly prevalent among specific cultural groups such as Latin Americans and Vietnamese Americans.[38] However, other studies have found that adherence to an annual Pap smear schedule may just as easily be dictated by factors such as forgetfulness, transportation, or job-, school-, or family-related conflicts.[72]

Access to healthcare is often presented as one of the primary predictors in obtaining adequate HPV screening for financially disadvantaged individuals. In fact, the cost of screening has been shown to repeatedly predict lower rates of screening across a variety of populations, however if the financial barriers are controlled, the rates of utilization often become more comparable.[88]

The widespread lack of HPV-related knowledge, mentioned earlier in the report, may serve as a barrier to accessing preventive HPV screening, although research on the relationship between HPV-related knowledge and adherence to screening guidelines has been contradictory. For example, some studies have found that heightened knowledge of cervical cancer may be associated with increased anxiety, and individuals experiencing high levels of anxiety were less likely to adhere to screening regimes[66], while other studies report increased knowledge as positively associated with higher levels of screening.

In addition, familiarity with genital HPV may vary greatly by gender, largely due to the fact that most HPV information focuses on its relation to cervical cancer, portraying it as more of a "woman's issue" than a global problem. In addition, women are more likely to schedule annual exams (often with an obstetric gynecologist) than men are, thereby creating more opportunities for the health community to communicate with the individual about genital HPV and other STDs as well. Similarly, Baer demonstrated some significant differences in the sources that males and females use to obtain STD-related information, particularly a tendency for women to rely more on magazines and men to rely on television more.[6] However, both genders indicated health education classes or books as their primary sources for information.

Most of the research around attitudes, frequently referred to as psychosocial aspects in the literature, demonstrates that the majority of patients exhibit a wide range of negative emotions upon learning that they have been exposed to the STI, but may differ slightly depending on how the infection manifests itself. People often report feelings of anger, depression, guilt, confusion, and lowered self-esteem related to their infection with HPV. The American Social Health Association (ASHA) conducted a survey of people with HPV of which one component addressed personal impact. More than 75 percent of respondents reported feelings of depression and anger and two thirds experienced feelings of shame

(Clarke, Ebel, Catotti, Stewart, 1996). Additional studies (Lamont, 1994; Reed, Ruffin, 1999, Baer, 2000) have reported similar characteristics, as well as changes in the level of self-esteem and sexual behavior of infected individuals, typically defined by less physical intimacy or a decreased desire for physical intimacy.[61, 91, 22, 6]

Some of the research suggests, however, that the psychosocial impact of HPV infection on an individual may lessen with time. Taylor, Keller, and Egan conducted a descriptive study in which HPV-infected persons responded to open-ended questions in which most described a reduction in the intensity of emotional responses between the time at which they were diagnosed to 1 year after they were diagnosed. [98] In one study of HPV-infected females, 86 percent of survey respondents reported the diagnosis affected their ability to approach a new partner, 73 percent were less spontaneous in their sexual activity, and 72 percent had sex less frequently, although these percentages decreased over the course of the next 12 months. [22]

Research also indicates that the reactions of infected individuals may differ depending on the type of HPV that they have, specifically whether or not the infection manifests itself externally or at the sub-clinical level. For example Reed, Fuffin, Gorenflo, Zazove conducted a cross-sectional study comparing the reactions of sexually active women diagnosed with genital HPV with those not infected. [91] They found that the emotional reactions of infected patients who did not have physically apparent external genital warts (e.g., sub-clinical) were more similar to the reactions of those who were not infected than to those exhibiting external manifestations. However it should be noted that the particular patient population studied consisted largely of females considered very low-risk for contracting the infection.

As mentioned earlier, very little research on the psychosocial impacts of HPV infection on men exists, and it is often contradictory. Some research reports similar reactions among men and women to HPV diagnosis, with respect to expressing emotions such as anger, fear, and concern. [92] Other studies have found gender differences with respect to the cause of their concern, reporting that men appear more focused on the effects of HPV on sexual performance or the concern for the potential for treatment to result in visible scarring. Some studies have even portrayed men as more prone to avoidance reactions. In contrast, women may be more focused on the physical appearance of genital warts and its potential effects on sexual attractiveness, and concern about transmission of the infection to children. Overall the research suggests that women have a more difficult time coping with the infection than males do.

Clinicians and Health Care Providers

A very limited amount of research has been conducted that specifically examines the knowledge, attitudes, or clinical practices relative to HPV among clinicians. However the research that was identified relied on two primary methods for evaluating these factors: directly measuring the clinician population, and measuring patient reports or satisfaction of their experience(s) with clinicians.

While measuring the psychosocial aspects of HPV infection on patients, Clarke et al.[29] also measured seven service-related issues that evaluated different aspects of HPV communication. Results showed that nearly two thirds of all patients reported some level of dissatisfaction with the communications strategies employed by their diagnosing clinician. In particular, patients indicated higher dissatisfaction with the lack of advice on emotional issues and not asking enough sexual practice–related questions. Additionally, more than 80 percent of the respondents reported not being referred to other sources of information and 60 percent were provided no written materials. However, it should be noted that higher levels of satisfaction were reported by patients who subsequently saw a different clinician than the one providing the initial diagnosis.

Assessments of clinician knowledge, attitudes, and behaviors relative to genital HPV are somewhat inconsistent. While some studies indicate comparable levels of HPV knowledge among clinicians of different ages, gender, and years in practice, there appear to be more inconsistencies in HPV-related attitudes and practices demonstrated within the clinician population. In order to identify trends and variations in medical, educational, and counseling practices, a group of college-based primary care clinicians was surveyed.[65] Both clinicians and health care providers demonstrated a solid understanding of basic HPV epidemiology, diagnostic-, and treatment-related information, but were less consistent with respect to issues associated with transmission (e.g., skin vs. semen) and most effective confirmative diagnostic techniques (e.g., acetowhitening vs. biopsy or DNA hybridization).

Clinician attitudes and practices represent greater variance. A study that surveyed 180 clinicians in Southwest U.S., suggests that there may be significant uncertainties or variations in opinion specifically related to appropriate follow-up intervals and treatment decisions.[29] Other studies indicate that female clinicians may be more likely to acknowledge the effectiveness of prevention and address it in communication with patients. Other characteristics that have been associated with proactive screening practices included younger clinicians and longer patient consultation periods.[67] Not surprisingly, obstetric gynecologists recommend screening practices more than doctors in any other specialty field.

Other research has posed that the differences in clinician procedures and protocols may be attributed to the differences that exist in the HPV-related guidelines that are produced by individual medical associations. Overall, studies indicate that clinicians tend to implement more aggressive approaches to the management of HPV, for example, calling for more frequent Pap smears than recommended by the CDC guidelines for those exhibiting external manifestations.[65] Another possible explanation for variance in the recommendation for colposcopy is the clinicians' access to either colposcopy or colposcopists, often a problem in areas that service high-risk populations. Despite the variance in application of diagnostic practices, the studies consistently identify the Pap smear, visual inspection, or acetic acid washes as the most common techniques used to identify HPV infection.

II. PATIENT COMMUNICATION/COUNSELING/PREVENTION

Counseling patients about STDs is difficult, however the impact of HPV diagnosis creates a unique set of challenges that often make it uncomfortable for both the patient and the clinician. Research that explores effective communication about genital HPV typically is based on interpretive analysis of the knowledge, attitudes, and behaviors that patients diagnosed with HPV infection have been shown to exhibit. Other research may rely more on the effective techniques that have been proven to be effective for other STDs.

Research suggests that a patient's knowledge, attitude, and behavioral characteristics, as described earlier, are very often the same obstacles that clinicians must address in order to effectively communicate about genital HPV with patients. The stigma associated with having an STD—embarrassment, shame, guilt and sense of injustice—may cause a patient to avoid clinical settings where they fear disapproval. Misconceptions and lack of information, which are often conveyed by both the media and professionals, can create unrealistic fears or hysteria among patients. On the other hand, barriers commonly exhibited by clinicians include feelings of uneasiness or discomfort in dealing with sexual matters, often as a result of their own personal stereotypes and biases concerning STDs. Additional factors that have been suggested to negatively impact the effectiveness of HPV-related communications include a predominantly female patient population and predominantly male clinician population, the lack of time due to HMO-enforced constraints, the complexity of information and resulting confusion that may exist as a result, and the difficulty in translating complex information into simpler terminology for their patients.[92]

The current research is fairly consistent in identifying the primary objectives of patient-clinician communication. Reitano illustrates four goals for counseling patients with genital HPV, including collectively identifying the most appropriate treatment for the patient, helping patients understand the relationship between HPV and cervical cancer, reducing the risk of transmission, and alleviating or preventing the onset of significantly negative emotional and psychosocial reactions that result from an HPV diagnosis.[92]

Linnehan and Groce suggest that the health care community adopt the intervention paradigm used for chronic disease patients due to the similarities, such as threats of symptom recurrence, partner transmission, and the potential for disease progression.[64] Chronic disease research has shown that in order to effectively manage infected individuals, the patients themselves need to take an active role in monitoring their disease to ensure that the disease does not progress. Therefore, in order to move the patient from the initial state of shock, to acceptance and eventually integration into their daily life, the clinician must instill a sense of empowerment that can only be accomplished by establishing an on-going and open relationship between the clinician and the patient.

Although not empirically tested, much of the research examining barriers to effective patient-clinician communications has led to recommendations such as acknowledging the complexity of information, facilitating an open environment for patients to ask questions, developing a structured format for screening processes, and providing both written and oral information.

Some of the anecdotal literature suggests that health care professionals (nurse practitioners, physician's assistants) are often responsible for patient education, communications, and counseling than are physicians. Furthermore, some of the literature indicated that they are well suited to the task since they often already interact with patients of reproductive age and therefore are already discussing preventive care. Coughlin suggests that nurse practitioners may be more competent at tasks such as taking sexual histories and patient counseling.[28]

III. RISK FACTORS/PREVALENCE

Human papillomavirus is recognized as the most prevalent STI among sexually active individuals residing within the United States, with estimates ranging anywhere from 10 percent to 40 percent at any one time and may vary even more, depending upon the particular population.[68]. Truly accurate accounts of genital HPV prevalence are difficult to ascertain for a variety of reasons, including no existing requirement to report the incidence of this type of data and the nature of the infection, which often goes undetected or can regresses spontaneously.

Most of the research conducted to date is relatively consistent with regard to the risk behaviors and demographic characteristics associated with genital HPV infection. Risk behaviors that are typically associated with the development of cervical cancer include early onset of sexual activity, the total number of sexual partners, and the total number of his/her sexual partners. Acknowledging the link between cervical cancer and HPV infection, it might be tempting to assume these risk behaviors apply to the latter as well. However, while several studies have strongly linked high-risk HPV types to multiple sex partners and the age of first intercourse, low-risk types are much more common and not always correlated with sexual behavior.[38]

Peyton et. al. conducted a study of more than 3,500 women that demonstrated the relationship of age and sexual history to the prevalence of low-risk, high-risk, and uncharacterized HPV types.[87] Results showed an increasing prevalence of all three types of HPV with the number of lifetime and recent sex partners and a decreasing prevalence of low- and high-risk HPV types. The relationship between age and HPV prevalence indicated a higher prevalence of high- and low-risk HPV types other than older women, however, the prevalence of low-risk of HPV varied less with age than high-risk types, despite the number of lifetime or recent sexual partners.

In addition to age and the number of sexual encounters, several studies have highlighted specific demographic characteristics that often include ethnicity, education, marital status, ever having used birth control pills or a diaphragm, number of live births, a history of chlamydia, and ever having a sex partner with genital warts.[60, 87, 38, 77] In contrast, cigarette smoking, long touted as a risk factor associated with cervical cancer and HPV, has been questioned in more recent studies due to its close association with sexual behavior.[40, 87]

A study of risk factors associated with high- and low-risk HPV types also emphasize that casual sex should not be considered a deciding factor for HPV acquisition. In fact, the significant risks often associated with sexual activity in noncasual relationships, such as more frequent sexual exposure and a reluctance to use condoms, are more prevalent within the context of an on-going, monogamous relationship.[77]

IV. BEHAVIORAL INTERVENTIONS FOR HPV SCREENING AND FOLLOW-UP

As mentioned previously, the majority of HPV behavioral interventions focused on increased adherence to HPV screening and follow-up as a measurable outcome. Studies have suggested that women without a regular source of care are less likely to engage in cervical cancer screening. One study showed that women enrolled in a state Medicaid program were more likely to undergo cervical cancer screening (i.e., a Pap test) if they were referred to a specific physician (name and telephone number) as opposed to no referral at all. This supports other studies that have found a positive relationship between having a regular source of care and completion of Pap tests.[44]

Studies have demonstrated that individuals at greatest risk for pre-cancerous cervical disease are least likely to engage in regular Pap smears and recommended diagnostic procedures. Miller et al. evaluated a preventive telephone counseling strategy designed to enhance adherence following an abnormal Pap smear.[74] Results showed that the counseling intervention, which included questions relative to ability to encode factual information, affective/emotional state of the patients, and self-regulatory/practical barriers, significantly impacted adherence to follow-up recommendations among minority women who either received a reminder call or received nothing. Factors that appeared to mitigate lower adherence included forgetfulness; scheduling conflicts; and child-, job-, or school-related conflicts or transportation.

A variety of studies suggest that patient education (both peer and instructor-led) may increase the likelihood of certain at-risk populations to engage in safer sexual practices or secondary prevention practices. Research identifies a variety of modalities that appear somewhat effective including various channels (lecture, videos, slide shows) and formats (one-on-one, written and oral).

V. LAY PRESS

A review of popular lay press publications reveals that women's magazines, and particularly those that target late adolescents and young adults, are the most frequent publishers of information about genital HPV infection. In fact, such vehicles have been publishing HPV information at least as far back as 15 years. However, as our knowledge of the natural history of the infection has greatly improved and the emergence of new technologies has occurred, the content and focus has changed dramatically.

Earlier literature published in these types of publications appeared to focus more heavily on HPV's association with cervical cancer and appropriate preventative measures, prevalence within the U.S. population, or methods for detection and treatment. Articles published in the more recent past seem to provide more detailed information that focuses in on the modes of transmission, advances in screening instruments, awareness of HPV among broader population, and the natural history of HPV. In addition, they will often provide guidance on how to communicate more effectively with their clinician.

In addition to the women's magazines, the past 2 to 3 years have revealed a marked increase in the presence of HPV-focused articles in more broadly read news publications (e.g., U.S. News & World Report, USA Today, Time, etc.). The information provided in these types of vehicles typically relates to improvements in screening tools, new diagnostic techniques, and occasionally, patient-clinician communications. The information provided in both the news and women's magazines appears relatively accurate. However, areas such as appropriate level of cervical cancer risk, natural regression, and appropriate applications for new screening procedures do not seem to be adequately addressed.

VI. GUIDELINES

Guidelines for HPV infection have been developed by a variety of professional associations. Existing guidelines primarily provide recommendations for prevention, screening, management, counseling/education, and treatment of HPV, anogenital warts, cervical cancer, sub-clinical lesions. Some of these guidelines have been adapted from sources such as the Centers for Disease Control and Prevention (CDC), which addresses selected public health topics affecting women's health, or the American Society for Colposcopy and Cervical Pathology (ASCCP), which discusses management guidelines for followup of atypical squamous cells of undetermined significance in addition to cervical cancer screening procedures. Still other guidelines appear to have been created by some other individual, private panel, or non-profit organization, and have not been adapted from another source, making the validity of such publications questionable.

Most guidelines address treatment options and discuss long-term implications for the health of patients and their partners. General advice promoting condom use, regular health exams, especially Pap smears for women, and referrals for counseling for the psychological distress or psychosocial dysfunction associated with HPV, are outlined throughout many publications.

The research on HPV to date has mainly been done in developed countries. Very little data, if any, exists from the developing countries concerning the epidemiology, determinants, and regional variations of HPV types. There are currently 37 studies in 26 countries currently being conducted by the members of the International Network on Control of Gynecological Cancers (INCGC). These are feasibility studies to evaluate "best practices" for cervical cancer screening and treatment in different resource settings. Approximately seven of these studies have added HPV detection components to be incorporated into future guidelines.

The following provides a brief look at the different organizations that have published guidelines related to the screening, management, and counseling of at-risk populations for HPV infection. These guidelines reportedly have not adapted these guidelines from another source:

Screening

- *The Canadian Task Force on Preventive Health Care, 1994.*—Developed by a task force consisting of experts in family medicine, geriatric medicine, pediatrics, psychiatry, and epidemiology. Recommends screening for HPV infection depending on grade and level of evidence resulting from periodic health exams.

- *The Institute for Clinical Systems Improvement, 1994.*—Developed by a private non-profit organization. This guideline acknowledges education and outreach efforts in helping increase the number of age-appropriate women who present themselves for regular cervical Pap smear screening.

- *The United States Preventive Services Task Force, 1996.*—Developed by an independent expert panel of physicians. Recommends testing techniques and frequency for cervical cancer screening and HPV detection.

- *The American Medical Association/Department of Adolescent Health, 1997.*— Developed by the AMA Medical Specialty Society and members of the Guidelines for Adolescent Preventive Services (GAPS) National Scientific Advisory Board. Recommends health guidance for adolescents concerning sexual responsibility, STD screening for sexually active adolescents, and counseling regarding sexual history and risk behaviors that may result in STDs.

Management

- *The American Society of Colposcopy and Cervical Pathology, 1996.*— Developed by the ASCCP Practice Guidelines Committee. Recommends the Pap smear should be performed first before any testing for gonorrhea, chlamydial infection, or HPV is undertaken. Practitioners should choose from one of the four management arms: repeat Pap, colposcopy, adjunctive test, and subdivision of ASCUS patient groups. It also discusses management issues related to the quality of the smear.
- *The Institute for Clinical Systems Improvement, 1999.*—Developed by a private non-profit organization. Recommends verbal notification of abnormal Pap result, provision of written materials specific to the diagnosis, and provision of information and resources for recommended procedures/followup.
- *The Association for Genitourinary Medicine/Medical Society for the Study of Venereal Diseases, 1999.*—Developed by the Clinical Effectiveness Group of AGM. Recommends advice for the diagnosis, treatment, and management of anogenital warts and sub-clinical lesions.

Counseling

- *The United States Preventive Services Task Force, 1996.*—Developed by an independent expert panel of physicians. Recommends that all adolescent and adult patients should be advised about risk factors for STDs and counseled appropriately about effective measures to reduce risk of infection. Recommendations are based on the proven efficacy of risk reduction.

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RECOMMENDATIONS FOR FURTHER RESEARCH OR COMMUNICATION STRATEGIES RELATIVE TO HPV

The following recommendations indicate future actions the Division of Sexually Transmitted Disease could undertake based on the findings of this research project. Any of these recommendations would require further, in-depth audience research as part of the development and implementation process.

1. **CDC should support the development and dissemination of Guidelines that will support the appropriate clinical practices and patient communications relative to the diagnosis and management of patients with HPV.**

   Participants in the Focus Groups conducted as part of Stage Two were relatively unaware of the newer technologies (HPV DNA Tests) and how these technologies might impact clinical practice and standards of care. They were, however, favorable to receiving and putting into practice guidelines that they did receive from a trusted source, identifying their particular association as well as CDC as appropriate sources. These guidelines and materials that are developed to help promote and support these new guidelines should incorporate the following aspects:

   - Show the evidence basis for the new guidelines from a health and cost effectiveness basis, thus providing clinicians and insurance companies with the reassurance that the guidelines also promote clinical practice that is cost effective
   - Identify whether these are recommendations or new standards of care, including algorithms as appropriate
   - Understand the legal implications of these guidelines
   - Provide appropriate collateral materials to help patients understand these guidelines.

2. **CDC, in collaboration with other key stakeholders, should consider a nomenclature system that would more clearly express the HPV infections relative to the individual HPV sub-types within HPV.**

   As every audience has expressed, HPV is a highly complex infection in any number of ways. The body of knowledge about the natural history of HPV has grown substantially in the past decade given the increasing research being done by public health agencies and the private sector. From the research with key informants and clinicians, we have identified one overarching issue: the confusion caused by the various sub-types. There are more than 70 different sub-types of the HPV virus that are all labeled by number. Some types cause genital warts, while some high-risk types (16, 18, 31 and 45) account for 80 percent of cervical cancers (Bosch, 1995; Shah, 1997). As can be seen, this categorization of HPV sub-types does not provide an easy identification of the two or more categories of HPV that clinicians are interested in—those that cause genital warts and those that can lead to cancer.

   We recommend that CDC, along with key stakeholders, consider developing a nomenclature system that would group similar types of HPV together—those that can lead to cancer would be one category, those that cause genital warts would be another category.

3. **CDC, in collaboration with other key stakeholders, should consider how to better clarify HPV as a sexually transmitted infection.**

   One of the difficult communication issues facing clinicians is that HPV, when framed as a sexually transmitted infection, causes certain reactions and expectations in the minds of patients that are not necessarily accurate because HPV is unlike other sexually transmitted infections. For example, the disease is transmitted from contact with the skin, not the fluids. The virus can be present in the skin surrounding the penis or vaginal area. Clinicians indicated that the patients believe, and they recommend, that patients use condoms to protect them from infection, mostly because condom use will protect against other STIs. They are mostly aware that condoms, as typically used, will not necessarily protect against HPV because contact with infected areas can and often does occur during foreplay and the condom is generally used at the moment of intercourse. And the condom may not cover the entire infected area. CDC must grapple with the issues this represents. How does HPV, which is not transmitted through sexual intercourse, similar to or different from other sexually transmitted infections, and is the categorization of HPV as an STI the most appropriate categorization of this infection?

4. **Improving Primary Care Clinicians' Communication With Patients**

   Based on the findings from the focus groups and in-depth-interviews, there are lots of potential improvements that would support the patient understanding of HPV and benefit the patient-clinician relationship. The preliminary research would indicate that the first target audience should be primary care clinicians (family practice, general practice, adolescent, college health, internal medicine) as they see a wide range of patients at-risk for, and possibly infected with, HPV. Findings from this group that would need to be validated with more research indicates that this group—

   - May not be completely up-to-date on understanding the infection and the different sub-types.
   - Is less comfortable with the unknowns relative to the infection (How did I get it? How do I get rid of it? How can I protect others?), preferring to appear to have the answers for their patients.
   - Is less comfortable with the emotions that this diagnosis can cause, the suspicions it raises relative to patients' relationships, the feeling of isolation.
   - Feels time constrained and, therefore, less willing to start what they perceive will need to be a long and involved conversation.

   We recommend that CDC identify ways to improve these clinicians' ability to have informative and supportive conversations about HPV with their patients through training programs and educational materials. We also recommend that CDC develop materials for patients (as discussed below) that will ensure that the patient receives the information they need, regardless of the ability of the clinician to communicate.

5. **Targeted Patient Materials**

   The need to develop materials directed to patients at risk for, or diagnosed with, HPV is not simply due to the clinicians' difficulties in communication. A significant finding from this research project is that upon hearing the diagnosis of HPV, patients are overwhelmed and cannot take in much more. They simply do not seem to hear the rest of the information that is presented to them. Developing patient materials that would help patients understand and manage their HPV infection is an important, but complex undertaking. Materials could include pamphlets, frequently asked questions, videos, Web sites, Health Channel segment. Again, given the complexities of the infection, the different manifestations, and ramifications of the infection, we recommend researching and identifying priority target audiences and evidence-based materials based on the following categories:

- *HPV Type:* Materials that focused on the different types (e.g., those that lead to genital warts and those that are a precursor to cancer)

- *Ethnic or group culture:* Many clinicians and key informants talked about the different ethnic or group cultures that created barriers to protection from or good management of the infection. These were primarily cultures in which the male dominated the female.

- *Gender:* Separate communication strategies would seem appropriate for men versus women, since women are at risk for cervical cancer from HPV, receive periodic screening through pap smears, have issues related to HPV and pregnancy. Other gender-related issues that would need further research included the difference between how men and women accept the diagnosis (some clinicians thought men were easier to deal with than women) and trends that occurred in their follow-up care.

- *Age:* There were some very interesting age-related issues that arose from this research. Clinicians tended to focus their conversations on younger patients engaging in risky sexual behaviors from a prevention standpoint. Yet clinicians are beginning to see the manifestations of the infection in older, divorced men and women who are beginning to date again. They are at risk for, or being diagnosed with, the infection, yet conversations about HPV prevention are not taking place with their primary care physician. Another interesting trend in young people (college age) is those who are coming in without symptoms but are asking for a clean bill of health.

- *Relationship Situation:* Those who have been diagnosed with HPV and are in a monogamous relationship need more information to help them handle the suspicions that this diagnosis engenders. They also need to know how to manage the infection within the ongoing relationship, including the issue of conception.

- *Lingual:* Materials need to be made available in multiple languages.

APPENDIX

HPV Communication Outreach – Formative Research
Key Informant Interview Guide: Clinicians in Family Practice, General Practice, Adolescents, College Health, Internal Medicine, Physicians Assistants, Nurse Practitioners, Nurse Midwives

Introduction

Thank you for agreeing to participate in this interview. The insights gained from these interviews and a national survey of clinicians will be used by CDC to guide how we communicate with clinicians, patients and the public about HPV and other STDs. I want to remind you that any identifiable information will be removed and the responses you provide cannot be linked to you in any way, so we would like for you to be as candid as possible. However if you do not feel comfortable answering any specific questions, please let me know and we will move on. We will be audiotaping the interviews to ensure the accuracy of our notes. These tapes will be in the sole possession of the researchers and will be destroyed at the end of the project.

1. Could you tell me a little bit about your practice? **(Listen for patient populations, specialization, and general environment in which he/she practices.)**

First we would like to spend a few minutes on bacteria sexually transmitted disease like gonorrhea, chlamydia or syphilis.

2. Aside from treatment, could you very briefly describe what you do when you have a patient that is *at risk* for bacterial STD? . **(Listen for risk assessment, screening, patient education - not interested in treatment)**

3. Now could you briefly describe what you do for a patient that is *diagnosed* with a bacterial STD **(Listen for risk assessment, counseling, partner services, patient education, referrals etc.)**

These next few questions will become more specific to HPV

4. *How common are manifestations of HPV, i.e. genital warts, abnormal paps, cervical dysplasia, anogenital cancers, etc. in your practice?*

5. Briefly, describe what you do when a patient is *at risk* for HPV infection **(Listen for risk assessment and screening, patient education,) (Probe for similarities and differences with other bacterial STDs ….)**

6. Now please tell me what you do when your patient is *diagnosed* with clinical manifestations of HPV infection. **(Listen for risk assessment, counseling, partner services, patient education, etc.) (Probe for similarities and differences with other bacterial STDs)**

7. Tell me what you feel are the critical or controversial issues in your practice relating to HPV and its clinical manifestations, other than treatment? **(Listen for**

detection, clinical management, counseling, prevention) Probe for policy or practice level controversies or critical issues?)

8. How important are HPV and its clinical manifestations in your practice in relation to other health issues you deal with? **(Listen for: where HPV fits in the big scheme of their practice) - If this is difficult try a ranking from 1-5 with 5 very important.**

Now we would like to gain a better understanding of the different kinds of conversations that may occur with patients. In your responses please consider the different patient populations (adolescent men or women, people with or without genital warts, people with or without other manifestations).

9. How does the topic of HPV and its clinical manifestations typically come up with your patients? **(Listen for: who raises the issue) (Probe: Are there any issues that you particularly raise?)**

10. What concerns do patients typically express to you regarding HPV? **Probe: What are patients asking about prevention issues? Probe: What are patients asking about their sex partners? Listen for prevention messages and methods, counseling and patient education.**

11. How do you respond to the issues they raise?

Now we'd like to ask a couple of questions about where you go for information:

12. How do clinicians like yourself obtain more information, improve skills, etc. regarding HPV? Where do you go for additional information?
    - *What would cause you to seek additional knowledge/skills?*

13. What sources of new information (person, organization, literature) regarding this challenging issue would you most value and trust? Why?

14. If you had time to improve your knowledge, skills or practices regarding one of the three following areas of HPV which one would you choose and why? Prevention, diagnosis, counseling

15. What are the areas of greatest difficulty in dealing with HPV with your patients? (relative to Screening, diagnosis, treatment, counseling, dealing with sex partners, other?)

16. What would make these challenges easier? Relative to Screening, diagnosis, treatment, counseling, dealing with sex partners, other?

    (listen for Insurance coverage, guidelines, and understanding of HPV, new techniques)

Closing

That is the extent of my questions. I would like to reiterate that we greatly appreciate your willingness to spend your time assisting us with this research project.

Before we end this interview, do you have any additional information that you feel would be helpful to provide?

Do you have any questions you would like to ask of me?

HPV Communication Outreach – Formative Research
Key Informant Interview Guide: Representatives of Organizations
Involved in Development/Marketing of Diagnostic Tests, Medications, etc.

Introduction

Thank you for agreeing to participate in this interview. The insights gained from these interviews and a national survey of clinicians will be used by CDC to guide how we communicate with clinicians, patients and the public about HPV and other STDs. I want to remind you that any identifiable information will be removed and the responses you provide cannot be linked to you in any way, so we would like for you to be as candid as possible. However if you do not feel comfortable answering any specific questions, please let me know and we will move on. We will be audiotaping the interviews to ensure the accuracy of our notes. These tapes will be in the sole possession of the researchers and will be destroyed at the end of the project.

Let's go ahead and begin.

1. First, I would like for you to briefly describe your work relative to the detection, management and/or prevention of genital HPV
   - *Do your work tend to focus on any specific patient populations?*
   - *Do you interact with clinicians or clinical specialty organizations? In what ways? What types of clinicians?*
   - *Do you work with some of the commercial companies that are developing vaccines, or new diagnostic tools, etc*
   - *Do you interact with lab experts, commercial or governmental labs and laboratory organizations*
   - *At what point(s) in the process do you start interacting with any government or regulatory agencies? (For example, FDA, Health Insurance Commissions)*

The next few questions are designed to help us understand the perspective of those involved in developing new products relative to the latest genital HPV detection/prevention technologies.

2. What do you consider are some of the highest priorities concerning the development of new products and services in the prevention, detection, management and prevention of genital HPV? (diagnostic procedures, provider education, counseling, new technologies)
   - *Why are these priorities?*
   - *Which of these would you say are areas of general agreement and which are areas of controversy? Why?*

Note: Does your answer change when you consider different patient populations (adolescent men or women, people with or without genital warts, people with or without other manifestations)

3. What are the biggest hurdles in getting these products/services in use by clinicians?

- Are you aware of any research being done with clinicians or patients that would focus on patient-clinician interactions, such as patient counseling, patient attitudes or quality of life issues?

Let's talk about new developments in genital HVP detection and prevention technologies that are on the market, have recently been introduced to the market or are likely to become available within the next year.

4. When you think about some of the newer products/services (diagnostic tools/procedures/vaccines, medications) currently available for the detection, management and prevention of genital HPV (e.g., Pap smears, DNA test, liquid cytology, etc) *What factors contribute most to their widespread usage or lack of acceptance?*
   - *What are some of the advantages/disadvantages of these tools*
   - *How do these factors differ for different patient populations (adolescent men or women, people with or without genital wards, people with or without other manifestations)?*
   - *NCI Bethesda System 2001 Terminology recommendations.*

5. Looking ahead to the next 12 months, are you aware of any new products, vaccines, or services currently in development that may become available?
   - What factors will contribute to their acceptance or lack of acceptance in clinical care?
   - What is the timeframe for vaccine? What is your view as to the type of vaccine that would have the best opportunity for widespread acceptance and usage?
   - How will a vaccine impact clinical practice

6. Who are the primary/priority audiences for the products/services being developed for genital HPV prevention, detection, and management?

Information Management

7. What are your preferred ways to disseminate findings from your work?

8. How do the pharmaceutical companies prefer to disseminate their findings?

9. Given the rapid evolution of knowledge in this area – what would be some of the best ways to disseminate new information that would impact clinical practice to clinicians quickly?

10. What sources (person, organization) of new information do you think clinicians value and trust most? Why?

Closing

That is the extent of my questions. I would like to reiterate that we greatly appreciate your willingness to spend your time assisting us with this research project.

Before we end this interview, do you have any additional information that you feel would be helpful to provide?

Do you have any questions you would like to ask of me?

Is there someone else you recommend that we speak to?

HPV Communication Outreach – Formative Research
Key Informant Interview Guide: Candidates With Extensive Experience in HPV Clinical Care—Influencers, Key Opinion Leaders

Introduction

Thank you for agreeing to participate in this interview. The insights gained from these interviews and a national survey of clinicians will be used by CDC to guide how we communicate with clinicians, patients and the public about HPV and other STDs. I want to remind you that any identifiable information will be removed and the responses you provide cannot be linked to you in any way, so we would like for you to be as candid as possible. However if you do not feel comfortable answering any specific questions, please let me know and we will move on. We will be audiotaping the interviews to ensure the accuracy of our notes. These tapes will be in the sole possession of the researchers and will be destroyed at the end of the project.

Today we are going to focus on your work relative to HPV manifestations aside from treatment.

1. Briefly describe your work with HPV in clinical practice? Please describe your work on HPV other than in clinical practice? **Probe: work in developing policy or guidelines, recommendations, standards of practice, etc.**

2. Tell me, what are the most challenging issues about HPV in clinical practice today?

3. Looking to the future what do you believe will be some of the critical issues about HPV in clinical practice the next 5 years?

Now, I'd like to look at three different population categories: patients at risk for genital HPV, patients with genital warts and patients with cervical cytological abnormalities.

4. Aside from treatment, what are the areas that are most in need of improvement for patients who might be at risk for genital HPV infection? **(Listen for prevention issues, such as sexual history taking, (i.e. what is sexual history), patient counseling, patient education, prevention method messages, dealing with sex partners, and HPV testing issues) Probe: What are some solutions or changes that you think should be made?**

5. Now, for patients with genital warts associated with HPV, what areas could be most improved for the care of these patients? **(Listen for prevention issues, such as sexual history taking, (i.e. what is sexual history), patient counseling, patient education, prevention method messages, dealing with sex partners, and HPV testing issues) Probe: What are some solutions or changes that you think should be made?**

6. Now, could you give me your thoughts for patients with cervical cytological abnormalities associated with HPV? **(Listen for prevention issues, such as sexual history taking, (i.e. what is sexual history), patient counseling, patient education, prevention method messages, dealing with sex partners, and HPV testing issues) Probe: What are some solutions or changes that you think should be made?**

7. What do you think has been or will be the implications of the new approved FDA tests for management of Paps classified as ASCUS readings. (This is the Hybrid Capture II Digene test question)

8. Are you familiar with the NCI Bethesda System 2001? How do you think the NCI Bethesda System 2001 Terminology and Recommendations for cervical cytology will impact clinical practice?

9. How about if the FDA approved a HPV DNA test for primary HPV screening? How do you think that would impact clinical practice?

10. What other factors besides guidelines may influence use of a HPV DNA test? (Probe: factors such as insurance companies, coverage, marketing forces, available lab options.)

11. Think about clinicians that care for persons at risk for or with clinical manifestations of genital HPV infection. Where would you recommend they go to obtain more information, skills, etc. regarding HPV? Are these the sources you most often use?

12. What sources of information (person, organization, literature) regarding this challenging issue do you think clinicians would most value and trust? Why?

13. If clinicians had time to improve their knowledge, skills or practices regarding one of the three following areas of HPV which one would you choose and why? Prevention, diagnosis, counseling

Closing

That is the extent of my questions. I would like to reiterate that we greatly appreciate your willingness to spend your time assisting us with this research project.

Before we end this interview, do you have any additional information that you feel would be helpful to provide?

Do you have any questions you would like to ask of me?

HPV Communication Outreach – Formative Research
Key Informant Interview Guide: Labs, HMOs

Introduction

Thank you for agreeing to participate in this interview. The insights gained from these interviews and a national survey of clinicians will be used by CDC to guide how we communicate with clinicians, patients and the public about HPV and other STDs. I want to remind you that any identifiable information will be removed and the responses you provide cannot be linked to you in any way, so we would like for you to be as candid as possible. However if you do not feel comfortable answering any specific questions, please let me know and we will move on. We will be audiotaping the interviews to ensure the accuracy of our notes. These tapes will be in the sole possession of the researchers and will be destroyed at the end of the project.

1. For starters, I would like for you to very briefly describe what you do and how it specifically involves or relates to working with practitioners to support their work with patients relative to genital HPV.
   - *How do you interact with practitioners? In what ways? What types of practitioners?*
   - *Do you interact with any other types of stakeholders (government agencies, researchers, and pharmaceutical companies?*

The next few questions will focus on better understanding the process by which new tests, diagnostic procedures, vaccines, etc. can be brought into the market. This will help us understand the hurdles involved in the diffusion of new services.

2. Please tell me about the process your organization goes through in approving the provision of, or payment of, a **new** service or diagnostic procedure.

3. Are you aware of new HPV related products/services that are currently or soon to be available?

> Note: If not addressed probe for different patient populations, adolescent men and women, people with or without genital warts, people with or without other manifestations

4. How does your organization implement new products like these?
   - *How long does it take*
   - *What are difficulties?*

5. In your opinion, how much of a priority is the detection, management and prevention of HPV among healthcare insurance providers? Why?
   - *How does this compare with STDs in general?*

6. Who are your the priority audiences when you approve a new products/ services?
    - *How do you identify the needs of these audiences?*
    - *How do you communicate with these audiences?*
    - *What kinds of messages do you find most effective with these audiences?*

7. Where do practitioners currently get information regarding what detection and diagnostic services are available and approved? (source, channel) How frequently do they receive information? Under what circumstances do they receive it?

8. What sources (person, organization) of new information do you think practitioners value and trust most? Why?

9. What is the best way to communicate information on this issue to the practitioner population? To other priority audiences? (print, internet, CME courses, word of mouth, academic detailing)

Closing

That is the extent of my questions. I would like to reiterate that we greatly appreciate your willingness to spend your time assisting us with this research project.

Before we end this interview, do you have any additional information that you feel would be helpful to provide?

Do you have any questions you would like to ask of me?

Is there someone else you recommend that we speak to?

HPV Communication Outreach – Formative Research
Key Informant Interview Guide: Developers of HPV Counseling and Prevention Materials

Introduction

Thank you for agreeing to participate in this interview. The insights gained from these interviews and a national survey of clinicians will be used by CDC to guide how we communicate with clinicians, patients and the public about HPV and other STDs. I want to remind you that any identifiable information will be removed and the responses you provide cannot be linked to you in any way, so we would like for you to be as candid as possible. However if you do not feel comfortable answering any specific questions, please let me know and we will move on. We will be audiotaping the interviews to ensure the accuracy of our notes. These tapes will be in the sole possession of the researchers and will be destroyed at the end of the project.

Let's go ahead and begin.

1. Briefly describe what you do, and specifically, how it involves or relates to the detection, management and/or prevention of genital HPV.
    - *How long have you been involved in the development of HPV counseling and prevention materials?*
    - *Describe the particular aspect(s) of HPV that you are focused on (practice, communication, marketing, education, medical research)*
    - *Do you focus on any specific patient populations?*
    - *Do you interact with healthcare providers? In what ways? What types of providers?*
    - *Do you interact with HPV researchers? In what ways?*

The CDC is very interested in understanding the different types of prevention and counseling materials, specifically related to genital HPV, that currently exist for providers, patients and partners. We would also like to better understand how and when these materials are used. The following questions focus on the prevention and counseling materials that are available.

2. Please describe the various types of prevention/counseling materials that exist related to the detection, management and prevention of genital HPV.
    - *Who are the target audiences for the different types of materials (providers, at-risk patients, patients' partners, the general public, teachers)?*
    - *Are there materials for different patient populations? (adolescent men or women, people with or without genital warts, people with or without manifestations)*

3. How and why were these materials developed (i.e., who was the source of information) for the different audiences? Was there a particular need they were designed to fulfill?
   - What were the major information sources for these materials?
   - Are they designed to be used in any specific way (interactive vs. take-away)

4. In general, describe how these materials are used today?
   - *In what environments are they most likely to be utilized (schools, clinics, hospitals, and doctor's offices)?*
   - *When are they most likely to be used (what would trigger their usage?)*
   - *How are these materials helpful? What benefit do they provide providers? What benefit do the provide patients?*
   - *Is there anything about these materials that is of concern? (outdated, incomplete)*

5. What topics related to detection, management and prevention of genital HPV, do these materials typically address? What are the core messages?
   - *Why were these topics chosen? Why are they important?*
   - *For providers? For patients?*
   - *Why do you feel these core messages are important?*

6. What types of communication materials are missing? Where is there the biggest need for materials? Why?
   - *For different patient populations? (adolescent men or women, people with or without genital warts, people with or without manifestations)*

7. What are the biggest challenges that you face in developing and getting providers to use these communication materials for their target audiences? Why? What would help reduce or eliminate these barriers?
   - *Which communication channels or methods are typically used to deliver communication materials to providers?*
   - *Which channels are most effective?*
   - *What would help improve the provision of support materials to providers?*

8. Based on what we have already discussed what would you do to improve genital HPV materials?

HPV Communication Outreach – Formative Research
Key Informant Interview Guide: Developers of HPV Counseling and Prevention Materials

Note: If not addressed probe for different patient populations, adolescent men and women, people with or without genital warts, people with or without other manifestations

9. Think about clinicians who care for persons at risk for acquiring genital HPV infection and those with clinical manifestations of genital HPV infection. Where would you recommend they go to obtain information, prevention/counseling materials, skills, etc. regarding HPV?

10. What sources of information (person, organization, literature) regarding this challenging issue do you think clinicians would most value and trust? Why?

Closing

That is the extent of my questions. I would like to reiterate that we greatly appreciate your willingness to spend your time assisting us with this research project.

Before we end this interview, do you have any additional information that you feel would be helpful to provide?

Do you have any questions you would like to ask of me?

Is there anyone else you would recommend that we speak to?

HPV Communication Outreach – Formative Research
Key Informant Interview Guide: HPV Researchers

Introduction

Thank you for agreeing to participate in this interview. The insights gained from these interviews and a national survey of clinicians will be used by CDC to guide how we communicate with clinicians, patients and the public about HPV and other STDs. I want to remind you that any identifiable information will be removed and the responses you provide cannot be linked to you in any way, so we would like for you to be as candid as possible. However if you do not feel comfortable answering any specific questions, please let me know and we will move on. We will be audiotaping the interviews to ensure the accuracy of our notes. These tapes will be in the sole possession of the researchers and will be destroyed at the end of the project.

Let's go ahead and begin.

1. First, I would like you to briefly describe your research with genital HPV or its clinical manifestations such as anogenital neoplasia or genital warts. **Probe:** ***How long have you been involved in this research?***

   Probe: Describe the particular aspect(s) of HPV research that you are focused on. Listen for clinical practice (specific populations,) medical research, (vaccines, microbicides, other prevention methods, treatment), natural history, diagnostic testing, epidemiology and public health issues, prevention and patient education.

2. What do you consider to be the clinical or public health issues of highest priorities related to HPV or its clinical manifestations such as anogenital neoplasia or genital warts? ***Listen for clinical practice (specific populations,) medical research, (vaccines, microbicides, other prevention methods, treatment), natural history, diagnostic testing, epidemiology and public health issues, prevention and patient education.***

3. How could current and future research about HPV or its clinical manifestations such as anogenital neoplasia or genital warts address these issues? ***Listen for clinical practice (specific populations,) medical research, (vaccines, microbicides, other prevention methods, treatment), natural history, diagnostic testing, epidemiology and public health issues, prevention and patient education.***

4. To what extent do you think existing national clinical guidelines (clinical specialty organizations such as ACCP, IDSA, ACOG, government organizations such as USPSTF, CDC, NIH, and non-governmental such as ACS,) for the prevention, detection, and management of HPV infection have been based on solid scientific evidence? Where are the gaps in the scientific basis for guidelines that most urgently need to be addressed?

Let's talk about advances in the prevention, detection or management, counseling, patient education, and partner services of HPV infection or its clinical manifestations such as anogenital neoplasia or genital warts.

5. Are you aware of any advances that are available to clinicians for detection or management, counseling, patient education, and partner services of HPV infection or its clinical manifestations such as anogenital neoplasia or genital warts? **Listen for: New applications of existing tests, new tests, new vaccines, new microbicides, new condoms or barrier methods, patient educations, and counseling materials (written, videos, websites, books), patient support services, support groups, hotlines, treatment, etc.**

6. Which of these do you feel have influenced practice or are most likely to in the near future?

7. Looking ahead, are you aware of any advances that are available to clinicians for detection or management, counseling, patient education, partner services of HPV infection or its clinical manifestations such as anogenital neoplasia or genital warts currently in development that may become available in the next 2 years? **Listen for: New applications of existing tests, new tests, new vaccines, new microbicides, new condoms or barrier methods, patient education, and counseling materials (written, videos, websites, books), patient support services, support groups, hotlines, treatment, etc**)

   Probe: ***What companies/organizations are currently involved in the development of these products?***

   Probe: Where is the research being conducted?

Note: If not addressed probe for different patient populations, adolescent men and women, people with or without genital warts, people with or without other manifestations

8. How could clinicians or public health specialist best find out about advances in research regarding HPV or its clinical manifestations such as anogenital neoplasia or genital warts? Probe: What are the best (most influential, most efficient) sources or channels for finding out about these advances. Why?

9. How have or how could researchers like you use these channels to disseminate research findings?

Closing

That is the extent of my questions. I would like to reiterate that we greatly appreciate your willingness to spend your time assisting us with this research project.

Before we end this interview, do you have any additional information that you feel would be helpful to provide?

Do you have any questions you would like to ask of me?

Is there anyone else you would recommend that we speak to?

HPV FOCUS GROUPS
February 13, 14, 2002
Moderator's Guide

I. Introduction of Moderator

A. Independent consultant hired to moderate these discussions
B. No vested interest in receiving any particular point of view
C. This project is not funded by any drug or diagnostic company, it receives no commercial funding.

II. Ground Rules

A. You have been asked here to offer your views and opinions; participation from everyone is important
B. Audio and videotaping/observers
C. Speak one at a time
D. No side conversations
E. No right or wrong answers
F. It is OK to be critical. If you dislike something or disagree with something that is said, I want to hear about it.
G. All answers are confidential, so feel free to speak your mind.
H. The group does not need to reach consensus, differing opinions are OK.
I. Please know that any identifiable information used to bring this group together or that you share during the focus group will be removed and destroyed before the information is summarized for future use. In addition, all your comments and information will be completely confidential and your name will not be associated with the focus group or research in any way
J. Quotations may be used in the communications database, however any identifiers will be removed from transcribed audiotapes.

Brief Explanation of the Focus Group Purpose/Introduction of Topic

ORC Macro, who has been contracted by CDC to conduct interviews and focus groups to better understand the factors that affect the prevention, diagnosis and counseling, and patient education for people at risk for acquiring genital HPV infection, or those diagnosed with clinical manifestations of genital HPV infection such as genital warts, cervical dysplasia, and cervical cancer.

- The specific purpose of this study is to inform the development of a national survey that will be conducted with clinicians regarding their practices, and clinical care experiences in identifying, diagnosing, counseling, and communicating information to patients or their sex partners about HPV. The data that is gathered from both this discussion and the national survey on clinicians' opinions & practices will help in developing educational materials for clinicians, patients & the general public. This information will become part of a CDC STD communication database that will assist and guide how we communicate with clinicians, patients, and the public about HPV and other STDs.

HPV FOCUS GROUPS
February 13, 14, 2002
Moderator's Guide

GROUP DISCUSSION TOPICS

With that, I would like to begin by having each of you introduce yourself. Please tell us your name, setting in which you practice, your specialty, and how long you have been practicing in your current environment.

Section A: Current Practices

1. Who do you think is most at risk for genital HPV?

2. In what context do you discuss HPV prevention screening, diagnosis with your patients?

    - *Do you feel it is more important to discuss with particular types of patients?*
    - *What are the barriers to discussing HPV (probe for comfort in discussing sexual practices, acknowledging unknowns relative to HPV, time and other constraints)?*
    - *What are the facilitators to discussing HPV?*
    - *How do you deal with partner issues?*

3. What is your view of condom effectiveness relative to HPV?

4. How do you advise your patients regarding condom use relative to HPV prevention?

5. Now please describe your typical clinical practice when your patient is diagnosed with clinical manifestations of HPV infection (probe for genital warts, cervical abnormalities separately).

6. First, can you describe what you do when your patient is diagnosed with genital warts?

    Probe for:

    - Counseling
    - Partner services
    - Patient education
    - Gender differences

    Next can you describe what you do when your patient is diagnosed with cervical abnormalities?

    Probe for:

    - Counseling
    - Partner services
    - Patient education
    - Gender differences

We are interested to know how important HPV and its clinical manifestations is in your practice in relation to other health issues you deal with.

7. Where does HPV fit in the big scheme of your practice?

8. How does HPV fit relative to your patients' other health care problems and screening tests?

9. Tell me what you feel are the critical or most important issues in your practice relating to HPV and its clinical manifestations.

10. Tell me what are the controversial issues relating to HPV and its clinical manifestations.

Section B: HPV Communication

Lets now talk about how you discuss HPV with, patients who may be at-risk for HPV or have clinical evidence of HPV infection, that is, cervical neoplasia or genital warts.

11. How does the topic of HPV and its clinical manifestations typically come up with your patients (probe for similarities and differences between patients at risk for HPV, patients with genital warts, patient with cervical abnormalities)?

- ♦ *First, patients at risk for HPV*
  Probe:
    - ▪ *Who raises the issue?*
    - ▪ *Are there any issues that you particularly raise?*
    - ▪ *Does the role of Pap Smears come up and if so, how?*

- ♦ *Now for patients for genital warts*

  Probe:
    - ▪ *Who raises the issue?*
    - ▪ *Are there any issues that you particularly raise?*
    - ▪ *Does the role of Pap Smears come up and if so, how?*

- ♦ *Now for patients with cervical abnormalities*
  Probe:
    - ▪ *Who raises the issue?*
    - ▪ *Are there any issues that you particularly raise?*
    - ▪ *Does the role of Pap Smears come up and if so, how?*

12. What concerns do patients typically express to you regarding HPV or its clinical manifestations – genital warts and abnormal pap smears (Listen for any particular prevention messages and methods, counseling and patient education)?

    Probe:
    - *What are patients asking about prevention issues?*
    - *What are patients asking about how they became infected, their risk of infecting others, prevention methods such as condoms?*
    - *What are patients asking about what they should tell their sex partners?*
    - *What are patients asking for in terms of education materials for self and/or sex partners?*

13. How do you respond to the issues they raise?

14. Are there differences in the kinds of conversations you have regarding HPV?

15. Do you have conversations where you frame HPV as a precursor to cancer? When, how often and to whom?

16. Do you have conversations where you frame HPV as an STD? When, how often and to whom?

Now, if there were a mass media campaign to increase awareness in U.S. adults about HPV…

17. What information (about HPV) should be emphasized in such a campaign? Why?

18. What information would not be useful (or would be confusing) to provide the patient/public? Why?

Section C: Impact of New Technology

There is a new diagnostic test – an HPV DNA test - available that can detect the presence of high-risk types of HPV, although it does not distinguish which type (or types)is/are present. Currently FDA has approved this test for screening of women with ASCUS Paps. The manufacturer of the test may seek FDA approval of the test as a primary screening test either in conjunction with, or in lieu of the Pap smear.

18. Have you used this type of test in your practice? (if any focus group member answers "yes" probe for how they used the test.)

19. How might you use this type of test in your practice?

Probe:

- *What would be some of the advantages or disadvantages of utilizing this test?*
- *Where do you think this test would be most appropriately used? Moderator suggests 3 choices:*
  - *(1) As a method to determine management of a patient after an ASCUS Pap smear*
  - *(2) As a primary cervical cancer screen instead of Pap smears*
  - *(3) As an STD screen for women or men who may have no cytologic abnormalities*

- *Do you think using the HPV test in any of these ways might change the kinds of services, counseling, or education you might provide patients (at risk for HPV, with genital warts, with cervical cytologic abnormalities)*
- *Do you think using the HPV test in any of these ways might change the types of issues patients might raise?*

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Section D: Guidelines

We are also interested in your opinions about the issue of HPV DNA testing and its role in clinical practice.

20. Do you think guidelines should be issued regarding HPV DNA testing?

Probe:

- *What should be the focus of guidelines regarding HPV DNA testing?*
- *Who should issue them?*
- *How do you decide whether such guidelines are appropriate for your patients?*
- *How would you decide whether or not to start using the new guidelines/ information in your practice?*
- *What would be the barriers and facilitators to you adopting HPV guidelines?*

V. Closing

HPV In-depth Interviews
Specialty Clinicians

Introduction

Thank you for agreeing to participate in this interview. The insights gained from these interviews and a national survey of clinicians will be used by CDC to guide how we communicate with clinicians, patients and the public about HPV and other STDs. I want to remind you that any identifiable information will be removed and the responses you provide cannot be linked to you in any way, so we would like for you to be as candid as possible. However if you do not feel comfortable answering any specific questions, please let me know and we will move on. We will be audiotaping the interviews to ensure the accuracy of our notes. These tapes and transcripts will be in the sole possession of the researchers and will be destroyed at the end of the project.

Section A: Introduction

1. *Please tell me a little bit about your particular practice.*

   Probe for:
   - Areas of specialization
   - Different patient populations (males/females, adolescents, SES)
   - Setting in which they practice

2. *How common are manifestations of genital HPV, i.e. genital warts, abnormal Paps, cervical dysplasia, anogenital neoplasia, etc. in your practice?*

Section B: HPV Communications

The CDC would like to gain a better understanding of the different kinds of conversations that may occur between clinicians like yourself and patients. Please consider the different patient populations (adolescent men or women, people with or without genital warts, people with or without other manifestations).

3. *In what context do you discuss HPV prevention, screening, and diagnosis with your patients?*
   - Do you feel it is more important to discuss with particular types of patients?
   - What are the barriers to discussing HPV (probe for comfort in discussing sexual practices, acknowledging unknowns relative to HPV, time and other constraints)?
   - What are the facilitators to discussing HPV?
   - How do you deal with partner issues?

4. *What is your view about condom effectiveness relative to HPV? How do you advise your patients regarding condom use relative to HPV prevention?*

HPV In-depth Interviews
Specialty Clinicians

Lets now discuss how you discuss HPV with patients who may be at risk for HPV or have clinical evidence of HPV infection, that is, cervical neoplasia or genital warts.

5. *How does the topic of HPV and its clinical manifestations typically come up with your patients (probe for similarities and differences between patients at risk for HPV, patients with genital warts, patient with cervical abnormalities)?*

   Probe:
   - Who raises the issue?
   - Are there any issues that you particularly raise?
   - Does the role of Pap Smears come up and if so, how?

6. *What concerns do patients typically express to you regarding HPV or its clinical manifestations – genital warts and abnormal Pap smears?*

   Probe:
   - What are patients asking about prevention issues?
   - What are patients asking about how they became infected, their risk of infecting others, prevention methods such as condoms?
   - What are patients asking about what they should tell their sex partners?

7. *How do you respond to the issues they raise?*

8. *Are there differences in the kinds of conversations you have regarding HPV?*

9. *Do you have conversations where you frame HPV as a precursor to cancer? When, how often and to whom?*

10. *Do you have conversations where you frame HPV as a STD? When, how often and to whom?*

11. *How similar or different are the conversations you have with patients from those they might have with their primary/other clinician?*

    Probe:
    - Do you feel that the patients you see are adequately informed (re: HPV) when they come to see you?

    - What specific information should primary care clinicians (e.g., general, internist, and adolescent medicine) be providing patients at risk for HPV? For patients exhibiting clinical manifestations of HPV (ask for differences/similarities between genital warts and cervical abnormalities?

Section C: Current Practices

12. *Now please describe your typical clinical practice when your patient is diagnosed with (a) an abnormal Pap classified as ASCUS, (b) cervical neoplasia classified as LSIL on Pap through invasive cervical cancer, (c) genital wart?*

    Probe for:
    - Assessing a patient's risk for HPV through a sexual history
    - Counseling about future Pap smears, colposcopy, HPV testing
    - Counseling (what, who, when, format) concerning HPV infection
    - Partner Services
    - Patient Education about abnormal Pap, HPV specifically
    - Are there any differences re: males/females as appropriate

13. *How do you interact with other types of clinicians in HPV prevention, diagnosis, and, education of patients? (look for interactions in which they seek guidance)*

    Probe for:
    - Under what circumstances do you interact with them?
    - What type of clinicians
    - Who initiates the communication?
    - For what reasons do they/you interact? [e.g., topics, questions, referrals, consults]

14. *How important is HPV and its clinical manifestations in your practice in relation to other health issues you deal with? [*Interviewer probe for how HPV fits in the big scheme of their practice or ask to rank from 1-5 with 5 very important]

    Probe for:
    - Do you feel that other clinicians share your point of view? What are some of the similarities/differences that exist?
    - Do you feel that you influence other clinicians views toward HPV? In what ways?

15. *Excluding treatment for genital warts or cervical neoplasia, please tell me what you feel are the most critical issues in your practice relating to HPV and its clinical manifestations?*

    Probe for:
    - Assessing patient risk for HPV through sexual history
    - Detection of HPV infection through testing
    - Clinical management of persons with genital warts, cervical neoplasia, or HPV+ test
    - Counseling and education of patients
    - Prevention methods, including condoms

Section D: Guidelines

We are also interested in your opinions about the issue of HPV testing and its role in clinical practice.

16. *Under what circumstances in your practice would you or would you not test your patients for HPV?*

17. *What are the advantages of testing?*

18. *What are the disadvantages of testing?*

19. *Do you think guidelines should be issued regarding HPV testing?*

Probe:
- What should be the focus of guidelines regarding HPV testing?
- Who should issue them?
- How would you decide whether such guidelines are appropriate for your patients?
- How would you decide whether to translate those guidelines/information into your practice?
- What are the barriers or facilitators to your adopting HPV guidelines?
- What factors do you think influence use of guidelines for ASCUS and HPV testing for clinicians like yourself?

Closing

That is the extent of my questions. I would like to reiterate that we greatly appreciate your willingness to spend your time assisting us with this research project.

Before we end this interview, do you have any additional information that you feel would be helpful to provide?

Do you have any questions you would like to ask of me?