CERVICAL CANCER IN PENNSYLVANIA: EASING THE BURDEN

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General Assembly of the Commonwealth of Pennsylvania
JOINT STATE GOVERNMENT COMMISSION
108 Finance Building
Harrisburg, Pennsylvania 17120

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TO THE MEMBERS OF THE GENERAL ASSEMBLY:

The Joint State Government Commission is pleased to present this staff report, *Cervical Cancer in Pennsylvania: Easing the Burden.* The report details the causes of cervical cancer and the threat it poses to women's health. It provides some insight into prevention and treatment options, many of which are available through Commonwealth funded programs. The report concludes with recommendations that could help reduce the incidence of cervical cancer in Pennsylvania and ease the burden it places on the public.

The Commission is grateful for the assistance of the Department of Health, and its HealthyWoman Program and the Family Planning Council, Inc. of southeast Pennsylvania.

Respectfully submitted,

Roger A. Madigan
Chair

TABLE OF CONTENTS

INTRODUCTION

Cervical cancer had been one of the most common causes of death for women in the United States up until the mid-1950s. Since then, cervical cancer deaths and incidence rates have been in steep decline primarily because of improved gynecological care. Between 1955 and 1992, the number of cervical cancer deaths in the United States decreased by 74 percent.[1] Pap tests, for example, provide early detection of cervical cell damage, and early diagnosis is vital for successful treatment of cervical cancer.

Despite the progress made in reducing the incidence of the disease, it remains a significant threat to women's health. To combat this threat, public health efforts are varied and widespread, and initiatives strive to reach out to as many women as possible. Programs exist at the state and federal levels to fund and conduct research and provide tests and treatments for women. Individually, women are urged to obtain regular gynecological care, especially screenings for cervical cancer.

The first chapter of this report describes the threats posed by Human Papillomavirus (HPV), which is related to nearly all cases of cervical cancer. The report discusses the types of HPV, how it is spread, its symptoms, and the processes by which the virus can lead to cervical cancer. The ensuing chapter describes the anatomy of the cervix and provides some insight into the process that leads from cervical cell damage (dysplasia) to cancer.

The next chapter discusses data and compares cancer incidence and death rates of the U.S. and Pennsylvania.

The report next addresses cervical cancer prevention. It begins with a discussion of the risks that women face with regard to their reproductive health. The report provides some details on the numbers of women affected by these risks for both the U.S. and Pennsylvania populations.

The chapter on prevention has a strong focus on the steps women need to take to reduce their risk of falling victim to cervical cancer. Pap tests are discussed in depth, along with the recommended guidelines for gynecological care from several national health organizations. The chapter describes the various

[1] Pennsylvania Commission for Women, *Cervical Cancer,* http://www.pcw.state.pa.us/pcw/cwp/view.asp?a=458&q=150440 (November 10, 2004).

federal and Pennsylvania programs that endeavor to reduce the incidence of cervical cancer.

The next chapter focuses on cancer treatment. It describes each stage of cancer and how the body is affected by it. The prognosis of each stage is offered as well. Treatment options are discussed in detail, with likely treatments linked to each cancer stage. The chapter provides both a description of what a woman with cervical cancer can expect to endure and an overview of coping strategies for women who are battling the disease.

The final chapter describes legislation at the federal and state level that is targeted at cervical cancer as a matter of public health and also as a means of assisting individual women both through prevention and treatment.

The report concludes with recommendations.

HUMAN PAPILLOMAVIRUS

Human papillomavirus (HPV) is a common pathogen that affects the lives of millions of people around the world. It is also the leading cause of cervical cancer. It is estimated that 95 percent of cervical cancer cases are related to HPV.[2] Approximately 6.2 million new cases of HPV are diagnosed each year in the U.S. alone, with at least 20 million Americans currently infected.[3] At least 50 percent of sexually active men and women acquire a genital HPV infection at some point in their lives, and almost 80 percent of women will have acquired genital HPV by age 50. The annual cost of treating HPV infections is estimated at $1.6 billion and the cost of Pap tests is between $5 billion and $6 billion. One survey, found that 70 percent of women are unaware that HPV causes cervical cancer and 76 percent had never heard of HPV.[4]

At latest count, 130 different types of HPV have been identified, about 30 of which are spread by skin-to-skin sexual contact.[5] Doctors and researchers divide the many HPV strains into two broad categories, those that cause cancer and those that are very unlikely to cause cancer. Most HPV viruses are harmless and many people who are infected show no symptoms at all. Of those HPV strains that are symptomatic, common and plantar warts are the most obvious signs of infection. The more dangerous strains of sexually transmitted HPV can cause genital warts, which appear within weeks or months of contracting an infection. In fact, HPV is one of the most common causes of sexually transmitted infection (STI) in the world.

Because HPV is spread through skin-to-skin contact, traditional methods of blocking the spread of STIs are not effective in preventing the spread of HPV. In other words, because condoms do not cover all genital skin they are not effective at blocking transmission of HPV between partners. Most people have been exposed to cell-changing types of HPV at some point in their lives and most

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[2] Information-On-Cervical-Cancer.Com, *How HPV Contributes to the Risk of Developing Cervical Cancer*, http://www.cervical-cancer-causes.com/html/human-papillomavirus-hpv.php3 (November 12, 2004).

[3] American Social Health Association, National HPV & Cervical Cancer Prevention Resource Center, http://www.ashastd.org (September 30, 2004).

[4] Ibid.

[5] Gregory Henderson, M.D., Ph.D., and Batya Swift Yasgur, M.A., MSW with Allan Warshowsky, M.D., *Women at Risk: The HPV Epidemic and Your Cervical Health*, (Avery: New York, 2002), page 13.

of these people will not show any signs of cell dysplasia (potentially precancerous cell damage). The cell-changing types of HPV are most likely to be spread when dysplasia is present. It appears that a person with an active genital HPV infection might reduce transmission by refraining from sexual activity until the dysplasia is effectively treated.[6] Doctors diagnose genital warts on sight, although some genital warts are small enough as to have no abnormal coloration and are not visible to the naked eye. These warts are diagnosed after being swabbed with acetic acid (vinegar), which turns them white and increases their visibility. Genital warts affecting women are a strong indication that a cervical HPV infection is present.[7]

Different types of HPV affect different areas of the body. For example, the HPV strain that causes plantar warts can latch onto certain cells in the feet. Table 1 lists HPV strains and the body parts that are commonly infected by them. HPV 16, a particularly dangerous cancer causing strain, can infect cells of the cervix, anus, mouth fingernails and toenails.[8]

TABLE 1
TYPES OF HPV STRAINS AND
CORRESPONDING CONDITIONS

Condition	Most Common HPV Strain
Plantar warts	1
Common raised and flat warts	2, 3, 19, 27
Cancers and warts of fingernails and toenails	16
Genital warts	2, 6, 11, 16
Laryngeal and upper airway warts and cancers	6, 11, 16, 18, 35
Cervical, vaginal, vulvar, penile, and anal cancers	6, 10, 11, 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 55, 56, 58, 59, 66, 68
Oral cancers	16, 18, 36, 57

SOURCE: Gregory Henderson, M.D., Ph.D., and Batya Swift Yasgur, M.A., MSW with Allan Warshowsky, M.D., *Women at Risk, The HPV Epidemic and Your Cervical Health*, (Avery : New York, 2002).

[6] American Social Health Association, National HPV & Cervical Cancer Prevention Resource Center, *supra* note 3.
[7] U.S. Department of Health and Human Services (HHS), National Institutes of Health (NIH), National Cancer Institute (NCI), "What You Need to Know About Cervical Cancer," http://www.cancer.gov/cancertopics/types/cervical/ (October 5, 2004).
[8] Ibid.

While all types of HPV can lead to abnormal Pap test results, only 10 of the 30 sexually transmitted HPV strains have been linked to cancer. Ninety percent of women who contract a cervical HPV infection show no signs of the infection two years later. Those who suffer persistent infections with high risk HPV strains have an increased chance of developing cervical cancer.[9]

Two types of HPV vaccines are being researched and tested on people. One type would prevent infection or disease (genital warts and precancerous conditions). The other type would treat cervical cancers after they sicken patients.

There is one HPV test approved by the FDA, the Hybrid Capture II™. The test is used as a follow-up in instances when a Pap test result is inconclusive but indicates the presence of abnormal cells. These cells, called atypical squamous cells (ASCUS), may be the result of HPV infection or affected by some other cause. If HPV is shown to be present, then the ASCUS are assumed to be precancerous. Hybrid Capture II™ can also be used in tandem with Pap tests in women over age 30. Research shows that using both tests increases the chances of early detection of problems. The Hybrid Capture II™ is not used when the Pap test clearly shows cervical dysplasia or precancerous cells, in which case HPV is assumed to be present. It is also not used on women under age 30 unless a Pap test reveals ASCUS .

CERVICAL DYSPLASIA[10]

Abnormal cells on the cervix are not necessarily cancerous, though it is believed that some abnormalities in cervical cells are precancerous. Abnormal or precancerous cells that appear on Pap test results are referred to as "cervical dysplasia." The dysplastic cells have undergone changes that usually indicate the presence of HPV. The HPV strains that lead to cervical dysplasia are considered "high risk" for developing cervical cancer.

In instances where cervical dysplasia is observed, the health care provider will closely monitor the patient's cervix over time and possibly treat the patient. Cervical dysplasia does not mean that cancer is imminent, and cancer can take years to progress. Early detection of cervical dysplasia followed by appropriate treatment are almost always able to prevent the development of cervical cancer.

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[9] HHS, NIH, Centers for Disease Control and Prevention (CDC), National Center for HIV, STD and TB Prevention, Division of Sexually Transmitted Diseases, *STD Prevention: Genital HPV Infection Fact Sheet*, http://www.cdc.gov/std/HPV/STDFact-HPV.htm (September 30, 2004).

[10] American Social Health Association, National HPV & Cervical Cancer Prevention Resource Center, *supra* note 3.

VIRUSES

Viruses are the smallest known forms of life, consisting almost entirely of deoxyribose nucleic acid (DNA) and ribonucleic acid (RNA). Viruses have survived the millennia as parasites, relying on higher life forms for survival and often destroying them in the process. A person can become infected with a virus when the virus attaches itself to a cell in the person's body and injects its genetic material into that cell. The infected cell's own reproductive machinery can begin to reproduce the virus's genetic material, thereby creating millions of new virus cells that spread out to continue the infection.

There are three types of relationship that viruses have with host cells: latency, productive infection, and integration. In a *latent* relationship, the virus' genetic material enters the cell and does nothing else. It does not replicate itself by engaging the cell's reproductive system. In what is termed a *productive infection*, the virus's genetic material engages the host cell's reproductive system to reproduce the virus but does not interfere enough with the host cell to kill it. This situation is often the one where a person is a carrier of a particular disease without showing any symptoms, and unknowingly can infect other people.

A productive infection that ends with the death of the host cell is called a *productive infection with cytopathic effect*.

In the virus-host relationship known as *integration*, the virus senses that the body's immune system is trying to destroy it. To escape detection it integrates itself in its host cell by splicing its DNA directly into the host's DNA. It is this arrangement that has the potential to lead to cancer.

CERVICAL CANCER

Cancer refers to a group of over 100 different diseases. Although these diseases affect disparate parts of the body, they share common characteristics: they affect individual cells, causing those cells to divide and grow without control or order. The three mechanisms that govern a cell's life, growth, maturation, and death, are compromised by cancer. A cancer cell reproduces at an abnormal rate, grows to an abnormal size, and does not self-destruct at the appropriate time.[11] Cancer exerts its deleterious effect on the body by destroying the surrounding tissues and can spread from its original site to other parts of the body. For example, it can compress nerves, erode blood vessels, or cause perforation of organs.[12]

Cells that continue to propagate when new cells are not needed by the body form a mass of tissue referred to as a tumor. Tumors can be benign or malignant. Benign tumors are not cancer, do not affect other parts of the body and do not lead to a life threatening condition. Benign growths of the cervix include polyps, cysts, and warts.

Polyps are growths that protrude from mucous membranes. Cysts are fluid filled sacks or capsules in the body and are almost always benign. Warts are growths on the surface of the skin or organs. Any of these three types of benign tumors can be found on the cervix.

A malignant tumor is a mass of cancer cells.[13] The cancer cells can damage tissues and organs near the tumor and can break from it and enter the blood stream or lymphatic system. From there, the cancer cells can spread to other parts of the body. If they do spread (or metastasize) beyond the cervix, the cancer cells typically affect the rectum, bladder, spine, and lungs. Cervical cancer that spreads to other parts of the body is known as metastatic cervical cancer.

Cancers of the cervix are named for the type of cell in which they begin. Squamous cells, the thin, flat cells that form on the surface of the cervix, are the most common cervical cells to be affected by cancer. Thus, most cervical cancers are squamous cell carcinomas.

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[11] Henderson et al., *supra* note 5.

[12] Hyperdictionary, http://www.hyperdictionary.com/dictionary/malignant+tumor (October 27, 2004).

[13] Henderson et al., *supra* note 5.

THE CERVIX

The cervix is the lower portion of the uterus. It is the juncture between the main body of the uterus and the vagina and functions as the doorway between the two. The portion of the cervix near the vagina is the ectocervix and the portion of the cervix near the uterus is the endocervix. Made up of muscular tissue, the cervix is normally tightly closed except for a small, four to five millimeter opening at the vagina. The opening to the vagina is referred to as the os. The os serves two purposes: to protect the uterus from bacteria and viruses; and to hold fetuses in the uterus. The tunnel from the os to the uterus is the endocervical canal, or endocervix.[14]

The lining, or epithelium, of the endocervical canal is covered with a mucosal substance secreted by glandular cells. The mucus of the epithelium fills the cervical canal and seals the os. The first stages of cervical cancer are normally found in the epithelium.[15]

Cervical Epithelial Cells

Generally, there are two types of cells, squamous and glandular, that form the epithelium that lines the reproductive tract. The ectocervix, vagina, and vulva are protected by the squamous epithelium; that is, squamous cells are the primary components of the epithelium in those areas. At the cervix, these squamous cells reside atop a membrane, known as the basement membrane, which separates the epithelium from the underlying cervical tissue.

Squamous cells are tough, densely packed cells. They are relatively hard to penetrate and function as a sort of armor for the organs they cover.[16] Under a microscope, squamous cells appear to be symmetrically shaped, have a centralized nucleus, and are arranged one on top of another like building blocks. During a normal squamous cell's lifetime, it will grow, mature, and divide in two. One cell will remain at the basement membrane while the other will grow and move outward. As the squamous cell moves outward, it begins to replace its cytoplasm with keratin, its nucleus shrinks, and it firmly anchors itself to the other squamous cells around it. Thus, a strong barrier is formed at the surface of the squamous epithelium.[17]

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[14] Ibid.
[15] Mary Calvagna, MS, Rose Medical Center, *Cancer in Depth: Cervical Cancer*, http://ehc.healthgate.com (October 7, 2004).
[16] Henderson et al., *supra* note 5.
[17] Ibid.

Glandular cells line the fallopian tubes, interior of the uterus, and the endocervical canal, and are continually secreting mucus. The mucus acts as a lubricant for the vagina, and is also an antibiotic. A glandular cell is column-like in appearance with its nucleus at one end while the balance of the cell contains cytoplasm. The cytoplasm secretes the cervical mucus. Glandular cells do not move outward as they mature. Rather, they remain in a single layer on the basement membrane. Most glandular cells secrete cervical mucus while the remainder serve to divide and replenish the rank of secreting glandular cells. (The area where the two types of cells meet is called the transformation zone.)

SQUAMOUS INTRAEPITHELIAL LESIONS

Abnormal changes to the cells on the surface of the cervix are referred to as squamous intraepithelial lesions (SILs). Lesion refers to the area of abnormal tissue, and intraepithelial means the cells are only on the surface.

Low-Grade Squamous Intraepithelial Lesions (LGSIL)

Low-grade SIL refers to an early change in the size, shape, and number of cells that form the surface of the cervix, typically showing up as genital warts. Some lesions disappear without treatment. Such lesions are caused by cells reproducing at an abnormally faster, but not uncontrolled, rate. This type of lesion is caused by low-risk HPV strains and is considered low grade because it is unlikely to lead to cancer. The virus can use host cells to reproduce itself but cannot integrate with the host's DNA and affect the cell's ability to self-destruct (activate tumor suppressor genes).[18]

While some lesions disappear, others will continue to grow, and the number of abnormal cells may increase. Precancerous low-grade lesions may be called mild dysplasia or cervical intraepithelial neoplasia I (CIN I). These early changes to the cervix are most common in women ages 25 to 35, but can appear in others as well.

High-Grade Squamous Intraepithelial Lesions (HGSIL)[19]

High-grade SIL means there are many precancerous cells, appearing as lesions on the surface of the cervix. With HGSIL, viral DNA invades the cervical cells and turns off their self-destruct mechanism. In addition, the cells will

[18] Ibid.
[19] Ibid.

reproduce at an abnormally high rate. If the lesion is untreated, it will in all likelihood progress to invasive cancer. In other words, HGSIL is cancer that has not yet developed the ability to cross the basement membrane of the cervix. HGSIL may be called moderate or severe dysplasia, CIN II or III, or referred to as carcinoma in situ. They are most common in women ages 30 to 40 but can occur at other ages as well. High risk HPV strains can lead to both LGSIL and HGSIL and in fact, the majority of LGSIL are caused by high risk HPVs. Low risk HPV causes about ten percent of LGSIL cases.

Ninety percent of women who are infected with HPV develop no lesions. Of the ten percent who develop lesions, low-risk HPV has a nearly zero chance of developing into HGSIL or invasive cancer. Approximately 90 percent of women will clear the virus after two years, and virtually all cases of infection are cleared by the body after three years. In the case of high risk HPV infections that produce squamous intraepithelial lesions, approximately two-thirds of women clear the infection within five years. The other third are at risk for developing invasive cancer.

INVASIVE CANCER

Cancerous epithelial cells (carcinomas) reproduce in a chaotic fashion, piling on top of one another and pushing healthy cells aside. In the early stages of cancer, the rapid growth of the cancer cells happens above the basement membrane of the cervix. During these stages the disease has not yet penetrated the basement membrane and entered the woman's system. The cancer is highly localized and goes by a number of names: precancer, noninvasive cancer, carcinoma in situ, and intraepithelial lesion.[20] If abnormal cells invade deeper into the cervix, or move to other tissues or organs, the disease is properly referred to as cervical cancer. Women over the age of 40 are more likely than others to be affected by it.

The carcinomas, unless they are removed, will eventually move off of the surface of the basement membrane, cross over the mucosa and begin growing in the submucosa. These migrating carcinomas are referred to as subclones. After the subclones breach the submucosa they are able to enter the lymphatic and blood systems and are invasive cancer.[21] In other words, they have metastasized.

[20] Ibid.
[21] HHS, NIH, NCI, *supra* note 7.

Adenocarcinoma In Situ (AIS)

AIS (or simply Adenocarcinoma) may occur when a high risk HPV infects the glandular cells of the endocervix. The process by which this occurs is not clearly known.

DATA AND DATA ANALYSIS: PENNSYLVANIA AND UNITED STATES CERVICAL CANCER

Cancer data is collected by the North American Association of Central Cancer Registries (NAACCR). NAACCR is a collaborative umbrella organization for U.S. cancer registries, governmental agencies, professional associations, and private groups interested in enhancing the quality and use of cancer registry data.[22] This chapter presents data for the incidence of cervical cancer cases and deaths for Pennsylvania and the United States. The data, as obtained from NAACCR, are shown in five-year groups.

When comparing Pennsylvania's cancer statistics for 1995-1999 to 1996-2000, it is appropriate to use the age-adjusted figures. The age-adjusted rates should be utilized instead of actual numbers because age-adjusted rates control for the effects of age across populations with different age structures.[23] For example, when comparing Pennsylvania's cancer rates to the U.S. rates the age-adjusted rates provide a more accurate picture than do the unadjusted figures. Age-adjusted incidence and death rates are computed using the 2000 U.S. standard population.

In Pennsylvania, for the years 1996-2000, the cervical (cervix uteri) cancer incidence rate was 9.6 per 100,000 people and for all types of cancer the incidence rate was 428.5 per 100,000. During the same period, the cervical and total cancer incidence rates for the United States were 10.0 and 419.9 per 100,000 people, respectively. All of these rates have decreased slightly from the previous five-year period. Black women had a lower incidence rate of total cancer than both the female population as a whole and white women between 1996 and 2000. However, black women had a significantly higher rate of cervical cancer than the overall female population and white women. See Table 2.

[22] NAACCR, "About NAACCR, Inc.," http://www.naaccr.org/index.asp?Col_SectionKey=9&Col_ContentID=41 (October 20, 2004).
[23] NAACCR, *Cancer in North America*, "Executive Summary," http://www.naaccr.org/filesystem/pdf/2004%20Publication/Volume%20III/incd.v3.sec0.pdf (October 20, 2004).

TABLE 2
FEMALE CANCER CASES AND AVERAGE ANNUAL AGE-ADJUSTED
CANCER INCIDENCE RATES BY RACE
PENNSYLVANIA AND THE UNITED STATES 1995-2000

	Years							
	1995-1999				1996-2000			
	PA		U.S.		PA		U.S.	
	Cases	Rate	Cases	Rate	Cases	Rate	Cases	Rate
Cervix uteri								
White	2,720	9.1	30,163	9.5	2,677	9.0	38,194	9.4
Black	458	16.0	6,012	15.5	431	14.2	7,082	14.6
All races	3,309	10.0	39,353	10.4	3,237	9.6	48,597	10.0
Total Cancer								
White	149,579	425.4	1,445,894	424.4	151,283	424.5	1,905,174	424.7
Black	12,478	435.2	140,888	393.4	12,621	419.3	173,362	387.9
All races	164,993	430.0	1,657,563	420.1	167,312	428.5	2,163,096	419.9

NOTE: Rates are per 100,000 and are age-adjusted using the 2000 U.S. population standard.

SOURCE: North American Association of Central Cancer Registries, *Cancer in North America*, various years, http://www.naaccr.org/index.asp?Col_SectionKey=11&Col_ContentID=50 (September 30, 2004).

Table 3 shows that between 1996 and 2000 the cervical cancer death rate was 3.0 per 100,000 for both Pennsylvania and the United States. These rates have decreased from 3.1 per 100,000 for the 1995-1999 period. Cervical cancer death rates account for about one-third of cervical cancer incidence rates. On average, black women had a cervical cancer death rate of more than double the rate of white women. Also, even though black women had a lower incidence rate of total cancer than white women, they had a higher cancer death rate.

TABLE 3
FEMALE CANCER DEATHS AND AVERAGE ANNUAL AGE-ADJUSTED
CANCER DEATH RATES BY RACE
PENNSYLVANIA AND THE UNITED STATES 1995-2000

	Years							
	1995-1999				1996-2000			
	PA		U.S.		PA		U.S.	
	Deaths	Rate	Deaths	Rate	Deaths	Rate	Deaths	Rate
Cervix uteri								
White	881	2.7	16,708	2.8	868	2.6	16,507	2.7
Black	200	7.0	4,614	6.2	194	6.5	4,488	5.9
All races	1,095	3.1	22,086	3.1	1,077	3.0	21,783	3.0
Total Cancer								
White	66,812	175.2	1,131,602	169.8	67,011	171.9	1,139,305	166.9
Black	6,656	232.3	141,905	203.5	6,665	222.2	143,309	198.6
All races	73,754	179.0	1,296,473	171.4	73,969	175.2	1,306,629	168.3

NOTE: Rates are per 100,000 and are age-adjusted using the 2000 U.S. population standard.

SOURCE: North American Association of Central Cancer Registries, *Cancer in North America*, various years, http://www.naaccr.org/index.asp?Col_SectionKey=11&Col_ContentID=50 (September 30, 2004).

Table 4 compares different cancer rates of the female genital system, which includes the cervix, uterus, and ovaries. The rates of total cancer types of the female genital system decreased from 1995-1999 to 1996-2000. Incidence rates for cancer of the cervix and ovary decreased for both Pennsylvania and the U.S. from the years 1995-1999 to 1996-2000. Pennsylvania rates for cancer of the uterus (corpus uteri) increased between 1995-1999 and 1996-2000, while the rate for the U.S. fell slightly. Cervical cancer had the third highest incidence rates behind specified cancers of the corpus uteri and ovary. However, cervix uteri cancer incidence rates for black females were second behind corpus uteri cancer rates. Incidence rates of the total female genital system in Pennsylvania were generally higher than the United States, while all cervical cancer rates were lower. Despite a slight drop in rates for black women in Pennsylvania, overall rates of unspecified cancers of the uterus edged higher from 1995-1999 to 1996-2000.

TABLE 4
FEMALE GENITAL SYSTEM CANCER CASES AND AVERAGE
ANNUAL AGE-ADJUSTED CANCER INCIDENCE RATES BY RACE
PENNSYLVANIA AND THE UNITED STATES 1995-2000

	Years							
	1995-1999				1996-2000			
	PA		U.S.		PA		U.S.	
	Cases	Rate	Cases	Rate	Cases	Rate	Cases	Rate
Female genital system								
Cervix uteri								
White	2,720	9.1	30,163	9.5	2,677	9.0	38,194	9.4
Black	458	16.0	6,012	15.5	431	14.2	7,082	14.6
All races	3,309	10.0	39,353	10.4	3,237	9.6	48,597	10.0
Corpus uteri								
White	10,054	29.9	84,661	25.5	10,229	30.1	108,863	24.8
Black	535	18.6	6,230	17.5	526	17.5	7,820	17.8
All races	10,762	29.1	94,837	24.5	10,968	29.3	121,317	24.0
Uterus, NOS[1]								
White	87	0.2	2,243	0.6	97	0.2	3,134	0.7
Black	13	0.5	471	1.3	12	0.4	627	1.4
All races	102	0.2	2,841	0.7	111	0.3	3,898	0.8
Ovary								
White	6,098	18.5	57,932	17.5	6,111	18.3	75,367	17.3
Black	384	13.3	4,333	11.8	370	12.1	5,222	11.4
All races	6,581	18.1	65,090	16.8	6,597	17.8	83,901	16.6
Total[2]								
White	20,404	61.8	188,156	56.9	20,549	61.5	242,573	55.9
Black	1,492	51.9	18,323	49.7	1,448	47.9	22,319	48.6
All races	22,339	61.5	217,206	56.2	22,496	60.9	277,021	55.0

1. NOS: Not otherwise specified.
2. Detail does not sum to total because the total includes other unspecified cancer of the female genital system.

NOTE: Rates are per 100,000 and are age-adjusted using the 2000 U.S. population standard.

SOURCE: North American Association of Central Cancer Registries, *Cancer in North America*, various years, http://www.naaccr.org/index.asp?Col_SectionKey=11&Col_ContentID=50 (September 30, 2004).

Table 5 shows cancer deaths for different types of cancer that affect the female genital system. Corpus uteri and uterus (NOS)[24] deaths are combined as corpus and uterus (NOS). For all races, cervical cancer had the lowest death rate of the female genital system at 3.1 and 3.0 per 100,000 for the years 1995-1999

[24] NOS is an abbreviation for Not Otherwise Specified.

and 1996-2000 respectively. From 1995-1999 to 1996-2000, corpus and uterus death rates remained static, while cervix uteri and ovary decreased slightly. Black women had a higher death rate than white women, except for cancer of the ovary.

TABLE 5
FEMALE GENITAL SYSTEM CANCER DEATHS AND AVERAGE ANNUAL AGE-ADJUSTED CANCER DEATH RATES BY RACE PENNSYLVANIA AND THE UNITED STATES 1995-2000

	Years							
	1995-1999				1996-2000			
	PA		U.S.		PA		U.S.	
	Deaths	Rate	Deaths	Rate	Deaths	Rate	Deaths	Rate
Female genital system								
Cervix uteri								
White	881	2.7	16,708	2.8	868	2.6	16,507	2.7
Black	200	7.0	4,614	6.2	194	6.5	4,488	5.9
All races	1,095	3.1	22,086	3.1	1,077	3.0	21,783	3.0
Corpus and uterus, NOS[1]								
White	1,743	4.5	26,401	3.9	1,796	4.6	26,505	3.8
Black	206	7.1	4,732	6.9	206	6.8	4,928	7.0
All races	1,955	4.7	31,624	4.1	2,009	4.7	31,972	4.1
Ovary								
White	3,611	9.9	60,678	9.3	3,573	9.6	61,241	9.1
Black	188	6.6	5,267	7.6	205	6.8	5,348	7.4
All races	3,805	9.6	67,026	9.0	3,787	9.3	67,745	8.8
Total[2]								
White	6,635	18.1	110,098	16.9	6,651	17.8	110,718	16.6
Black	632	22.0	15,305	21.7	643	21.4	15,462	21.3
All races	7,294	18.3	127,840	17.1	7,325	18.0	128,768	16.8

1. NOS: Not otherwise specified.
2. Detail does not sum to total because the total includes other unspecified cancer of the female genital system.

NOTE: Rates are per 100,000 and are age-adjusted using the 2000 U.S. population standard.

SOURCE: North American Association of Central Cancer Registries, *Cancer in North America*, various years, http://www.naaccr.org/index.asp?Col_SectionKey=11&Col_ContentID=50 (September 30, 2004).

Readers should be aware that the data shown in Tables 2-5 for white and black women include women of Hispanic origin.

National data for Hispanic women (from all races) are drawn from the years grouped 1995-2000. Hispanic woman suffered 151,395 incidences of cancer at an age adjusted rate of 313.0 per 100,000 during those years. Cancers of

the female genital system affected 25,893 women, a rate of 49.3 per 100,000. Cervical cancer affected 9,398 women, a rate of 16.0 per 100,000.[25] Because Hispanic women are included in the categories black and white, in Tables 2 through 5, these figures are not directly comparable with data found in those tables.

The American Cancer Society (ACS) publishes annual reports, *Cancer Facts & Figures*, which include the probabilities that an individual will develop invasive cancer during his or her lifetime.[26] Women from birth to age 39 have a 0.16 percent, (or 1 in 632), chance of developing invasive cervical cancer. Women between the ages of 40 and 59 experience a .31 percent (1 in 322) probability of developing invasive cervical cancer. Women between 60 and 79 have a .27 percent (1 in 368) chance of developing invasive cervical cancer. Overall, from birth to death, a woman has a .78 percent (1 in 128) chance of developing invasive cervical cancer. See Table 6.

TABLE 6
PROBABILITY OF DEVELOPING INVASIVE CERVICAL CANCER
BY AGE GROUP
1998 – 2000
IN PERCENTAGES

Birth to 39	40 to 59	60 to 79	Birth to death
.16 (1 in 632)	.31 (1 in 322)	.27 (1 in 368)	.78 (1 in 128)

SOURCE: American Cancer Society, *Cancer Facts & Figures 2004,* http://www.cancer.org/downloads/STT/CAFF_finalPWSecured.pdf (November 29, 2004), page 14.

[25] NAACCR, "Total Cancer and Average Annual Age-adjusted Cancer Incidence Rates NAACCR (U.S.) Combined, 1995-2000, Hispanic/Latino All Races," *United States-Combined Incidence III-5*, http://www.naaccr.org/filesystem/pdf/2004%20Publication/Volume%20III/incd.v3.sec0.pdf

[26] American Cancer Society (ACS), *Cancer Facts & Figures 2004*, http://www.cancer.org/downloads/STT/CAFF_finalPWSecured.pdf (November 29, 2004), page 14.

PREVENTION OF CERVICAL CANCER

While cervical cancer is very curable in the early stages, if it is not caught early enough the chances of a patient's survival decrease dramatically. Unfortunately, the early signs of cancer usually do not cause pain and cause very few or no symptoms. Symptoms usually do not appear until abnormal cervical cells become cancerous and begin to spread to nearby tissue.[27] At that point, the chances of recovery and survival are greatly diminished.

This chapter is divided into several sections including a section on the risk factors for cervical cancer; a section on the most common test for detecting precancerous cells, the Pap test (or Pap smear); a section on other screenings for cervical cancer; a very brief section on Medicare coverage for cervical cancer screening; and finally a section on just a few of the organizations dedicated to preventing cervical cancer.

RISK FACTORS FOR CERVICAL CANCER

Although there is no one cause of cervical cancer, there are a number of risk factors that can increase a woman's chances of developing cervical cancer. These risk factors are summarized below.

Age

Although age is not a risk factor that can be prevented, it should be noted that the average age of women diagnosed with cervical cancer is between 50 and 55 years, but it normally begins to appear in women in their twenties. Cervical cancer is rarely found in girls younger than 15.

[27] HHS, NIH, NCI, *supra* note 7.

Human Papillomavirus (HPV) Infection

As was discussed in a previous chapter, HPV is one of the most common causes of STI. Unlike many other STIs, HPV can be spread through skin-to-skin contact, not just through bodily fluids. The virus itself can lie dormant in a person's body for years before it produces any symptoms, and therefore people who are infected may not know they are infected and may continue to infect others without knowing it. In the United States, it is estimated that about 20 million people are currently infected with some type of HPV and about 50 percent to 75 percent of theses cases are high-risk types of HPV (the types known to be linked to cervical cancer).[28] It is estimated that 60 to 80 percent of people in the United States will be infected with HPV sometime in their lifetime.[29] Women who have HPV have a much higher chance of developing cervical cancer than those who do not have HPV. Although contracting HPV does not necessarily mean that a woman will develop cervical cancer, it is estimated that between 95 and 99 percent of all cervical cancers are related to HPV infection.

Giving Birth to Many Children

Giving birth to many children is often listed as a possible risk factor for cervical cancer.

Having Many Sexual Partners

Because there is a large number of adults currently infected with HPV, the more sexual partners a woman has, the greater the risk that she will contract HPV.

Having First Sexual Intercourse at a Young Age

Adolescent girls who begin to have sexual contact at a young age are more susceptible to infection than those who refrain until a later age. There are two reasons adolescent girls are at a higher risk of contracting HPV. First, the immune system of adolescents is not fully developed and therefore may not be as adept as adults in overcoming HPV exposure. Second, as discussed previously, there are two types of cells that line a woman's reproductive tract, squamous and glandular cells.[30] Squamous cells are tough and hard and are used by the body as a barrier to keep infections out of the body, while glandular cells are more porous

[28] HHS, CDC, *Report to Congress: Prevention of Genital Human Papillomavirus Infection*, January 2004, http://www.cdc.gov/std/HPV/2004HPV percent20Report.pdf (October 18, 2004).
[29] Henderson et al., *supra* note 5, page 3.
[30] Ibid., page 21.

and allow some necessary substances from the body to pass through.[31] When a girl is going through puberty, both her uterus and cervix enlarge significantly, causing the central portion of the cervix to be covered with only glandular cells instead of the stronger, tougher squamous cells.[32] This leaves the area particularly vulnerable to infection, including HPV.[33] Over time, the body gradually re-covers this area with squamous cells.[34]

According to the *Health, United States 2000 with Adolescent Chartbook* report compiled by the Centers for Disease Control and Prevention (CDC), 32.5 percent of female 9th graders surveyed indicated that they had had sexual intercourse some time in their lifetime. This figure gradually increased for female survey respondents in 10th, 11th, and 12th grade to 42.6 percent, 53.8 percent, and 65.8 percent, respectively.[35]

Smoking

Although smoking is normally thought to cause lung cancer, it is also linked to many other cancers, including cervical cancer. Tobacco by-products have been found in the cervical mucus of women who do smoke, and researchers believe that these by-products can damage the DNA of cells and may increase the chance of the development of cervical cancer.[36] In fact, women who smoke are about two times more likely to develop cervical cancer than nonsmokers.[37]

In the 2003 *Behavioral Risk Factor Surveillance System State Questionnaire: December 2002* survey, respondents nationwide and in Pennsylvania were asked a series of questions relating to if they had smoked in the past and if they currently smoke (and how much).[38] Figure 1 details the percentage of females in the United States and Pennsylvania that currently or used to smoke. As shown in the figure, over half of females have never smoked and therefore do not have an increased risk of cervical cancer due to smoking.

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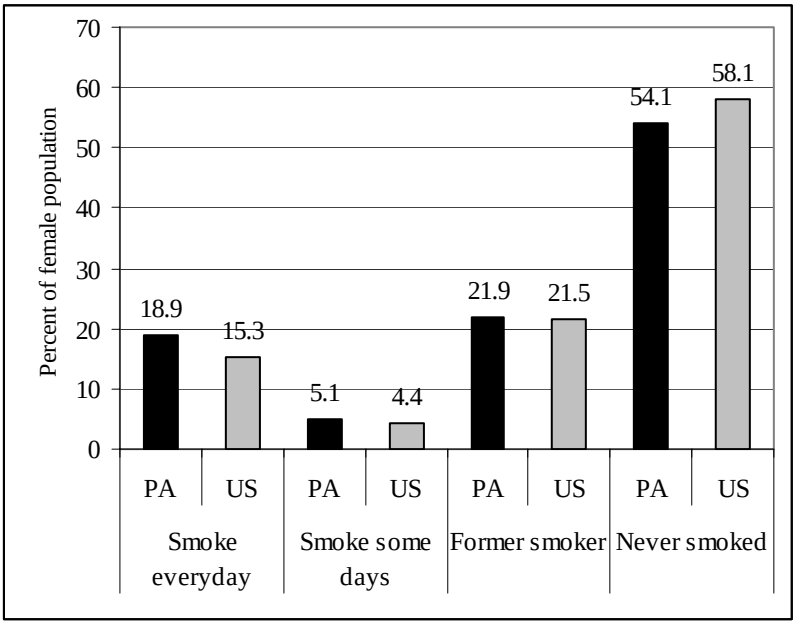
[31] Ibid.
[32] Ibid., pages 25-26.
[33] Ibid., page 26 and 50.
[34] Ibid., page 26.
[35] HHS, CDC, National Center for Health Statistics, *Health, United States, 2000 with Adolescent Health Chartbook*, (U.S. Government Printing Office: Washington, DC, July 2000), page 110.
[36] ACS, *Cervical Cancer: Prevention & Early Detection*, December 2003, http://www.cancer.org/docroot/PED/content/PED_2_3X_Pap_Test.asp?sitearea=PED (September 9, 2004).
[37] Ibid.
[38] HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, *Behavioral Risk Factor Surveillance System State Questionnaire: December 2002*, 2003, http://www.cdc.gov/brfss/questionnaires/pdf-ques/2003brfss.pdf (October 8, 2004).

FIGURE 1
PERCENTAGE OF FEMALE SMOKERS



SOURCE: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, *Behavioral Risk Factor Surveillance System State Questionnaire: December 2002*, 2003, http://www.cdc.gov/brfss/questionnaires/pdf-ques/2003brfss.pdf (October 8, 2004).

Poor Nutrition

Vitamins A, C, and E are known to have antioxidant properties that protect DNA from damage.[39] Therefore women who do not get enough of these vitamins in their diet are at increased risk of developing various types of cancers, including cervical cancer.[40] Additionally, some studies have shown that women whose diets lack folic acid have an increased chance of getting precancerous lesions within the squamous cells.[41] Finally, poor nutrition can also cause two female hormones, estrogen and progesterone, to become unbalanced. Estrogen levels that are too high (sometimes called estrogen dominance) have been linked to cervical dysplasia.[42]

[39] Henderson et al., *supra* note 5, page 49.
[40] Ibid.
[41] Squamous cells are one of two types of cells that line the female reproductive tract, including the outer portion of the cervix, called the ectocervix. Henderson et al., *supra* note 5, pages 21, 24, and 49.
[42] Cervical dysplasia is a precancerous stage of cervical cancer. Henderson et al., *supra* note 5, pages 33, 49, and 119.

Oral Contraceptive Use

Although there is no definite evidence that the use of oral contraceptives (birth control pills) increases a woman's risk for cervical cancer, some studies have shown that long-term use of oral contraceptives may slightly increase a woman's risk of developing the disease.[43] That being said, "the American Cancer Society believes that a woman and her doctor should discuss whether the benefits of using OCs [Oral Contraceptives] outweigh this very slight potential risk."[44] Additionally, on March 11, 2002, the World Health Organization's (WHO) Department of Reproductive Health and Research convened an international group of experts to review the recent information regarding the possible link between the long-term use of OCs and the increased risk of developing cervical cancer.[45] Following that meeting, WHO released the following statement:

> Pending the results of new studies in progress, the experts present at the 11 March 2002 meeting recommended no changes in oral contraceptive prescribing practice or use. Among women who use oral contraceptives, the number of cervical cancers that result from this use is likely to be very small. All methods of contraception, including oral contraceptives, carry risks and benefits. For young, healthy, non-smoking women, the health benefits of oral contraceptive use (including a reduced risk of endometrial and ovarian cancers) far exceed the health risks.[46]

According to the United States Census Bureau, in 1995, around 17.3 percent of women in the United States were using oral contraceptives.[47]

Human Immunodeficiency Virus (HIV) Infection

HIV is a virus that weakens the body's immune system and therefore puts women who have HIV at greater risk for cervical cancer in two ways. First, because of the weakened immune system, women are much more susceptible to contract HPV.[48] Second, the immune system is the body's primary method for

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[43] ACS, *Cervical Cancer: Prevention & Early Detection*, *supra* note 36.
[44] Ibid.
[45] World Health Organization (WHO), Department of Reproductive Health and Research, *Cervical Cancer, Oral Contraceptives and Parity*, April 3, 2002.
http://www.who.int/reproductive-health/cancers/cacx-ocs.en.html (October 8, 2004).
[46] Ibid.
[47] U.S. National Center of Health Statistics, special tabulations from the *1995 National Survey of Family Growth*, as quoted in U.S. Census Bureau, *Statistical Abstract of the United States: 2003, Vital Statistics*, page 81, http://www.census.gov/prod/www/statistical-abstract-03.html (October 14, 2004).
[48] ACS, *Cervical Cancer: Prevention & Early Detection*, *supra* note 36.

destroying cancer cells and slowing their growth.[49] Therefore, if precancerous cells are present in the cervix, the cells might develop into invasive cancer quicker than in women who do not have a weakened immune system.[50]

According to the CDC, as of 2002, there were nearly 72,000 female adults and adolescents (age 13 and older) who were thought to be living with HIV.[51] In Pennsylvania, there are 15,223 adults and adolescents (male and female) age 13 and older living with HIV.[52]

Chlamydia Infection

Chlamydia is a sexually transmitted bacterial infection that can infect the female reproductive system.[53] Unfortunately, many women do not know they are infected with chlamydia unless samples are taken during a Pap test and analyzed for this type of bacteria.[54] Some recent studies have shown a positive correlation between women who have blood test results indicating past or current chlamydia infection and an increased risk of developing cervical cancer.[55] However, more research needs to be done to confirm this result.[56]

In recent years the incidence of reported chlamydia infection in the United States by state health departments has gradually increased. In 1998, there were 614,250 reported cases of chlamydia infection. The number had increased to

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[49] Ibid.
[50] Ibid.
[51] This figure includes adult and adolescent females diagnosed with HIV, with HIV and a later diagnosis of AIDS, and with HIV and AIDS concurrently. AIDS stands for acquired immunodeficiency syndrome and is the disease caused by HIV. Additionally, this figure is only an estimation of the number of female adults and adolescents age 13 years and older who have HIV. HHS, CDC, National Center for HIV, STD, and TB Prevention, Division of HIV/AIDS Prevention-Surveillance and Epidemiology, *HIV/AIDS Surveillance Report: Cases of HIV Infection and AIDS in the United States, 2002*, vol. 14, page 18, http://www.cdc.gov/hiv/stats/hasrlink.htm (October 18, 2004).
[52] This figure includes adults and adolescents diagnosed with HIV, with HIV and a later diagnosis of AIDS, and with HIV and AIDS concurrently. AIDS stands for acquired immunodeficiency syndrome and is the disease caused by HIV. Additionally, this figure is only an estimation of the number of adults and adolescents age 13 years and older who have HIV in Pennsylvania. HHS, CDC, National Center for HIV, STD, and TB Prevention, Division of HIV/AIDS Prevention-Surveillance and Epidemiology, *HIV/AIDS Surveillance Report: Cases of HIV Infection and AIDS in the United States, 2002*, vol. 14, page 21, http://www.cdc.gov/hiv/stats/hasrlink.htm (October 18, 2004).
[53] ACS, *Cervical Cancer: Prevention & Early Detection*, *supra* note 36.
[54] Ibid.
[55] Ibid.
[56] Ibid.

662,647 in 1999, 709,452 in 2000, and 783,242 in 2001.[57] In 2002, the number increased to 834,555, including 31,791 cases within Pennsylvania.[58]

Low Socioeconomic Status

Many women with low incomes often do not have health insurance and therefore do not have regular access to adequate health care services, including Pap tests and methods for treatment of precancerous cervical disease.[59] These women may also not be receiving adequate nutrition, which can increase their risk for cervical cancer.[60]

Diethylstilbestrol (DES)

DES is a hormonal drug that was used between 1940 and 1971 to help prevent miscarriages.[61] Women whose mothers took DES when pregnant have a slightly increased risk of developing clear-cell adenocarcinoma[62] of the vagina or cervix; however, clear-cell adenocarcinoma is more common in the vagina than in the cervix.[63] The risk of developing this type of cancer appears to be the greatest in those whose mothers took DES during their first 16 weeks of pregnancy.[64] The average age of diagnosis of DES-related clear-cell adenocarcinoma is 19 years old, and since DES daughters are now between ages 30 and 60, the number of new cases of DES-related cervical and vaginal clear-cell adenocarcinoma has been decreasing during the past 2 decades.[65] Additionally, some studies suggest that DES daughters are also at an increased risk of developing squamous[66] cell cancer of the cervix and precancerous changes of cervical squamous cells.[67]

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[57] For 1998 and 1999, the figure does not include New York residents outside of New York City. HHS, CDC, National Center for Health Statistics, *Health, United States, 2003 with Chartbook on Trends in the Health of Americans*, (U.S. Government Printing Office: Washington, DC, September 2003), page 199.

[58] HHS, CDC, *Morbidity and Mortality Weekly Report: Summary of Notifiable Diseases - United States 2002*, April 30, 2004, vol. 51 (53), http://www.cdc.gov/mmwr/PDF/wk/mm5153.pdf (October 18, 2004).

[59] ACS, *Cervical Cancer: Prevention & Early Detection*, *supra* note 36.

[60] Ibid.

[61] Ibid.

[62] Adenocarcinoma is a "cancer that develops in the lining or inner surface of an organ." MedicinceNet.com, March 26, 1998, http://www.medterms.com/script/main/art.asp?articlekey=2144 (September 23, 2004).

[63] ACS, *Cervical Cancer: Prevention & Early Detection*, *supra* note 36.

[64] Ibid.

[65] Ibid.

[66] Recall that squamous cells are tough outer layer of cells lining the female reproductive tract. Henderson et al., *supra* note 5, pages 20-21.

[67] ACS, *Cervical Cancer: Prevention & Early Detection*, *supra* note 36.

Substance Abuse

There are a number of reasons why substance abuse (particularly alcohol abuse) increases a woman's risk of cervical cancer. First, prolonged alcohol abuse weakens the liver.[68] The liver is a very important organ that, among other things, processes female hormones that are used by the body to maintain a healthy female reproductive tract.[69] If the liver is unable to adequately produce these hormones, there is an increase in the risk of developing cervical cancer.[70] Second, some drugs other than alcohol weaken the immune system so that the body is less likely to fight off various infections, including HPV.[71] Third, abusing alcohol and other drugs impairs a person's judgment.[72] There is an increased chance that individuals who abuse drugs may find themselves being less discriminating about sexual partners.[73]

Family History of Cervical Cancer

Several recent studies suggest mothers and sisters of those who have had cervical cancer are more likely to also develop cervical cancer.[74] Researchers believe the reasoning behind this tendency is due to an inherited condition that makes some women less able to fight off HPV than others.[75]

PAP TEST

As mentioned before, cervical cancer is very curable if caught in the early stages. Currently, the best test available to detect cervical cancer and pre-cancerous cervical cells is the Pap test (sometimes called a Pap smear). Pap test is an abbreviation of Papanicolaou test, named after the physician who developed the test, Dr. George Papanicolaou, in 1949.[76] Since the test first began to be used, the incidence of cervical cancer in the United States has fallen by about 75 percent.[77]

A Pap test is a relatively quick and painless procedure that helps detect abnormal changes in a woman's cervical cells. During the procedure, a woman

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[68] Henderson et al., *supra* note 5, page 51.
[69] Ibid., pages 51-52.
[70] Ibid., page 51.
[71] Ibid.
[72] Ibid.
[73] Ibid.
[74] ACS, *Cervical Cancer: Prevention & Early Detection*, *supra* note 36.
[75] Ibid.
[76] Henderson et al., *supra* note 5, page 54.
[77] Ibid.

lies on her back with her knees bent and feet placed in stirrups at the end of the examination table. The doctor then inserts a lubricated, usually warmed speculum[78] into the woman's vagina, which spreads the walls of her vagina and allows the practitioner to see the woman's cervix.[79] The practitioner uses a device similar to a very small spatula to scrape a small portion of cells from the surface of the woman's cervix and then uses a brush-like instrument to collect the cells.[80] During a traditional Pap test, the collected cells are applied to a glass slide and preserved with a fixative solution to preserve the cells for transportation to a laboratory for analysis.[81]

In May of 1996, the FDA approved a new Pap test, called monolayer cytology testing under the brand name ThinPrep.[82] The ThinPrep Pap test still uses the spatula and brush to collect cervical cells.[83] However, instead of putting these cells directly on a slide, the collected cells are first dipped in a solution that preserves the cells and breaks down extraneous materials such as mucus and blood cells.[84] The preserved cells are then put into a machine that evenly distributes them into a single layer on a slide and sent to the laboratory for analysis.[85] The benefit of a ThinPrep test is that it provides a clear view of the cervical cells without the interference of extraneous matter. Thus, diagnoses which are more accurate than those resulting from traditional Pap tests are sometimes possible.

Frequency of a Pap Test

Although the American Cancer Society (ACS) and the American College of Obstetricians and Gynecologists (ACOG) have very similar recommendations when it comes to how often women should have a Pap test, these two organizations' recommendations differ slightly. Below is a summary of what both organizations recommend.

- Both ACS and ACOG recommend that all women should have their first cervical cancer screening three years after they begin having vaginal intercourse or at age 21, which ever comes first.[86] ACS

[78] A speculum is "a metal or plastic device that spreads the vaginal walls, allowing the practitioner to see and gain easier access to the upper portion of the vagina and the cervix." Ibid., page 57.
[79] Henderson et al., *supra* note 5, page 57.
[80] Ibid.
[81] Ibid.
[82] Ibid., page 64.
[83] Ibid.
[84] Ibid.
[85] Ibid., page 65.
[86] ACS, *ACS Cancer Detection Guidelines*, January 6, 2004,

recommends that screening should be done once a year if the conventional Pap test is used and every other year if the newer liquid-based Pap test, or ThinPrep Pap test, is used.[87] ACOG does not distinguish between the two Pap tests and recommends that a Pap test be done every year.[88]

- Both ACS and ACOG recommend that at age 30, women who have had three consecutive, normal Pap tests can decide to take one of two options: get a Pap test every two to three years or get a Pap test every three years plus a HPV DNA test.[89] Again, ACS states that the Pap test can either be the conventional Pap test or the new, ThinPrep Pap test while the ACOG does not distinguish between the two Pap tests.[90]

- ACS recommends that women age 70 or older who have had three or more normal Pap tests in a row and no abnormal Pap test results in the last ten years may choose to stop having cervical cancer screening. Women who have a history of cervical cancer, DES exposure before birth, HIV infection, or a weakened immune system should continue to have annual Pap tests as long as they are in good health.[91] ACOG does not give a certain age as to when the Pap tests can be discontinued. Instead, ACOG recommends that physicians should determine on an individual basis when an older woman should stop having cervical cancer screening, based on her medical history and the physician's ability to monitor the patient in the future.[92]

- Both ACS and ACOG recommend that women who have had a total hysterectomy (removal of the uterus and cervix) not related to having cervical cancer may also choose to stop having Pap tests. Women who have had a hysterectomy without removal of the cervix should continue to get a Pap test.[93]

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http://www.cancer.org/docroot/PED/content/PED_2_3X_ACS_Cancer_Detection_Guidelines_36.asp?sitearea=PED (September 9, 2004); and The American College of Obstetricians and Gynecologists (ACOG), *Cervical Cancer Screening: Testing Can Start Later and Occur Less Often Under New ACOG Recommendations*, July 31, 2003, http://www.acog.org/from_home/publications/press_releases/nr07-31-03-1.cfm (September 9, 2004).

[87] ACS, *supra* note 86.

[88] ACOG, *supra* note 86.

[89] ACS and ACOG, *supra* note 86.

[90] Ibid.

[91] ACS, *ACS Cancer Detection Guidelines*, *supra* note 86.

[92] ACOG, *Cervical Cancer Screening: Testing Can Start Later and Occur Less Often Under New ACOG Recommendations*, *supra* note 86.

[93] ACS, *ACS Cancer Detection Guidelines*, *supra* note 86.

In addition to these recommendations, ACOG also notes that all women age 18 and older and sexually active adolescents younger than age 18 still need annual gynecologic examinations.[94] These annual gynecological examinations should include a discussion of the patient's health history and reproductive health care needs, a physical examination (including a weight and blood pressure check), a clinical breast examination, and various tests depending on the women's age and risk factors for various diseases.[95] For the most part, the United States Preventive Services Task Force's (USPSTF) recommendations regarding the frequency of a Pap test are almost identical to that of ACOG and very similar to ACS's with one notable exception. While ACOG does not give an age where routine Pap tests should be discontinued and the ACS states that routine Pap tests should be stopped once a woman reaches the age of 70 (and is not a high risk for cervical cancer), USPSTF recommends that women age 65 or older who have had recent normal Pap tests and are not at high risk for cervical cancer discontinue getting routine Pap tests.[96]

Figures 2 and 3 show the percent of women who have never had a Pap test and of those who have had a Pap test, how long it has been since their last test. In both Pennsylvania and nationwide, about 95 percent of women have had a Pap test done at some point. Unfortunately, in addition to the approximately 5 percent of women who have never had a Pap test, approximately 12.8 percent of women in Pennsylvania and 11.7 percent of women in the United States who stated that have had a Pap test sometime during their life have not had a Pap test during the past three years.

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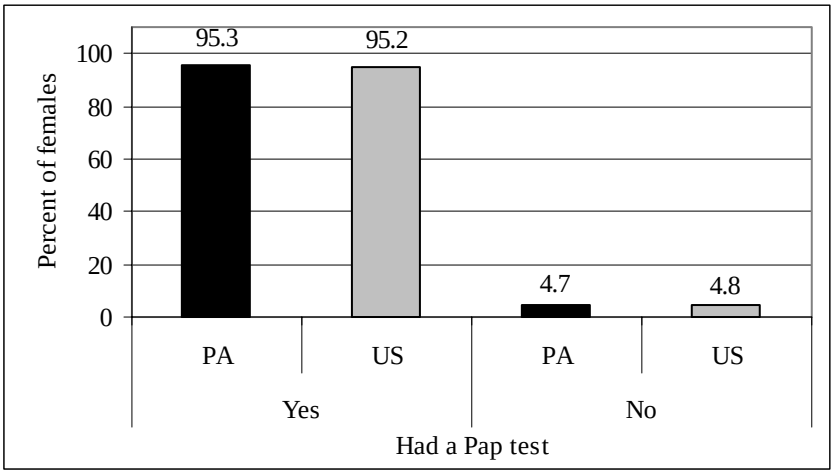
[94] Ibid.

[95] ACOG, *Revised Cervical Cancer Screening Guidelines Require Reeducation of Women and Physicians: All Women Should Have an Annual Pelvic Exam But Not All Women Need Annual Pap Tests*, May 4, 2004, http://www.acog.org/from_home/publications/press_releases/nr05-04-04-1.cfm (September 9, 2004).

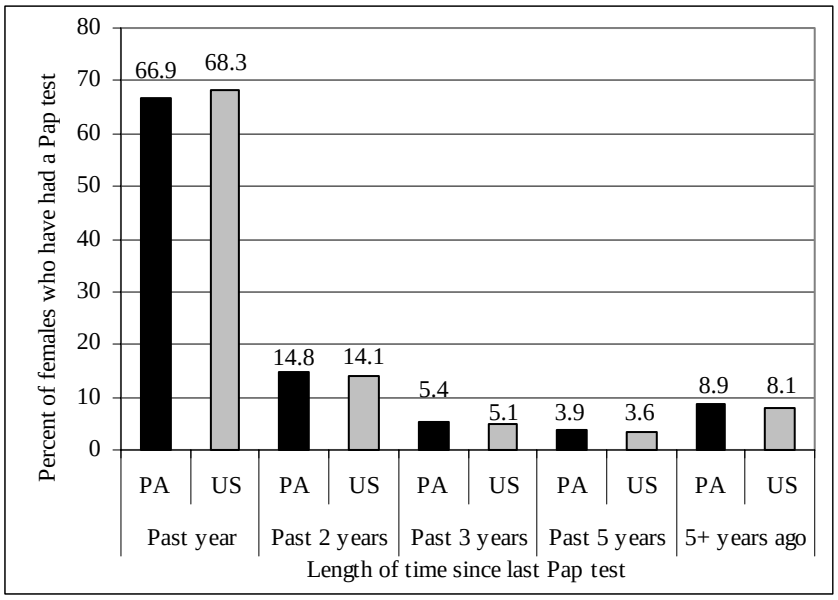
[96] HHS, Agency for Healthcare Research and Quality (AHRQ), United States Preventive Services Task Force (USPSTF), *Screening for Cervical Cancer: Recommendations and Rationale*, January 2003, http://www.ahcpr.gov/clinic/3rduspstf/cervcan/cervcanrr.pdf (September 9, 2004), page 1.

FIGURE 2
PERCENT OF WOMEN WHO HAVE HAD A PAP TEST
PENNSYLVANIA AND UNITED STATES



SOURCE: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, *Behavioral Risk Factor Surveillance System Survey Data*, http://apps.nccd.cdc.gov/brfss/ (October 8, 2004).

FIGURE 3
LENGTH OF TIME SINCE LAST PAP TEST BY PERCENT
(OF WOMEN WHO HAVE HAD A PAP TEST)
PENNSYLVANIA AND UNITED STATES



SOURCE: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, *Behavioral Risk Factor Surveillance System Survey Data*, http://apps.nccd.cdc.gov/brfss/ (October 8, 2004).

Results of a Pap Test

The Bethesda System (TBS) for describing Pap test results was first developed in 1988 and later revised in 1991 and 2001.[97] There are three general categories that Pap test results can be categorized as, including: negative for intraepithelial lesion or malignancy; epithelial cell abnormalities; and other malignant neoplasms.[98] These three categories are described below.

Negative for intraepithelial lesion or malignancy: Pap test results that are categorized as negative for intraepithelial lesion or malignancy mean that there were no signs of any cancer or precancerous changes or other significant abnormalities found.[99] Pap tests that show evidence of other reproductive system infections such as yeast, herpes, or Trichomonas and therefore may show reactive cellular changes in response to these types of infection or other irritations but do

[97] ACS, *Cervical Cancer: Prevention & Early Detection*, *supra* note 36.
[98] Ibid.
[99] Ibid.

not show any signs of cancer or precancerous changes are also categorized as negative for intraepithelial lesion or malignancy.[100]

Epithelial cell abnormalities: Pap test results that are categorized as epithelial cell abnormalities mean that cells were found that might indicate cancer or a precancerous condition.[101] Results falling within this category are further divided into several groups for squamous cells and glandular cells.[102] These groups are detailed below.

The first group is called atypical squamous cells, and this categorization is used when it is not possible to tell whether the abnormal cells were caused by an infection, irritation, or by a precancerous condition.[103] Oftentimes, a repeat Pap test is recommended within several months after this type of abnormal cell is found.[104] However, depending on the patient's history and results of previous Pap tests, the healthcare provider may also recommend a colposcopy, biopsy, or HPV DNA test (all explained below).[105]

The second group within epithelial cell abnormalities, SILs, is sub-divided into LGSILs and HGSILs.[106] While HGSILs are less likely than LGSILs to go away without treatment, a Pap test alone cannot determine for certain if the SILs are low-grade or high-grade.[107] The healthcare provider will most likely recommend that various further testing and examination be done to determine what type of SIL is present.[108]

The third group of epithelial cell abnormalities is called squamous cell carcinoma and indicates that there is a high probability that the woman has invasive squamous cell cancer.[109] Once further testing is done to confirm these results, the healthcare provider will then recommend treatments such as radiation therapy, cheomotherapy, and surgery.[110]

The fourth group of epithelial cell abnormalities is called adenocarcinomas and describes cancerous glandular cells.[111] Sometimes

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[100] Ibid.
[101] Ibid.
[102] Ibid.
[103] Ibid.
[104] Ibid.
[105] Ibid.
[106] Ibid.
[107] Ibid.
[108] Ibid.
[109] Ibid.
[110] Ibid.
[111] Ibid.

pathologists examining the cells can suggest whether the cancer began in the endocervix, endometrium (the upper part of the uterus), or elsewhere in the body.[112] At this point the healthcare provider will recommend various treatment options.

The fifth and final group of epithelial cell abnormalities is called atypical glandular cells.[113] Like the name suggests, these are glandular cells that may or may not be cancerous, but do not look like typical glandular cells.[114] Further testing will be necessary to determine if these cells are cancerous or not.[115]

Other malignant neoplasms: In some cases, a Pap test can find other cancers on and around the cervix including malignant melanoma, sarcomas, and lymphoma. Any of these other cancers would be classified as other malignant neoplasms. However, compared with epithelial cell abnormalities, these cancers very rarely affect the cervix.

OTHER SCREENINGS FOR CERVICAL CANCER

In addition to the Pap test, there are other screening methods that can be used to determine if a woman has cervical cancer. Among these tests are a pelvic exam, an HPV DNA test, a colposcopy, biopsy, and endocervical curettage. All are explained in detail below.

Pelvic Exam

A pelvic exam is almost always done at the time of a Pap test and is a procedure used to check for any abnormalities in the shape or size of the uterus, vagina, ovaries, fallopian tubes, and bladder.[116] The doctor or clinician normally does this procedure by inserting two fingers in the woman's vagina and placing one hand on the women's abdomen to feel for any abnormalities.

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[112] Ibid.
[113] Ibid.
[114] Ibid.
[115] Ibid.
[116] James N. Parker (ed.) and Philip M. Parker (ed.), *The Official Patient's Sourcebook on Cervical Cancer: A Revised and Updated Directory for the Internet Age*, ICON Health Publications, San Diego, 2002, page 13.

HPV DNA Test

In HPV DNA test (sometimes called an HPV test) is a procedure that tests for various types of HPV including the high-risk types most likely to cause cervical cancer. Since about 99 percent of all cervical cancers are related to HPV infection,[117] it is sometimes useful to know if a woman has an HPV infection (particularly if the women has had a recent abnormal Pap test result). For the patient, an HPV test is almost identical to a Pap test, and in some cases, an HPV test can be done using the same sample of cells collected for a Pap test.[118]

When a woman has had a recent abnormal Pap test, some doctors will begin further testing by doing an HPV test. If the test is negative for HPV, then there is a strong possibility that the abnormal cells present in the Pap test were due to a reactive cause, such a hormonal changes or the presence of a different kind of infection, and most likely do not reflect a precancerous condition.[119] If the test is positive for one of the high-risk strains of HPV, then there is sufficient evidence to warrant a slightly more invasive procedure such as a colposcopy or biopsy to determine if a precancerous condition is present.[120] Finally, if the test is positive for one of the low-risk strains of HPV, the doctor and patient must decide if further tests are necessary. In this case, the low-risk HPV could have caused the abnormal cells, but since it is low-risk, the probability that the abnormal cells indicate a precancerous condition is very low.[121]

Colposcopy

A colposcopy is a procedure in which a doctor uses a small lighted microscope, called a colposcope, that allows the doctor to look at the vagina and cervix very closely.[122] In most cases a colposcopy is done after a Pap test has detected something abnormal.[123]

Biopsy

A doctor may do a biopsy when abnormal cells are found during a colposcopy.[124] A biopsy is a procedure that is usually done in the doctor's office

[117] Henderson et al., *supra* note 5, page 3.
[118] Ibid., page 76.
[119] Ibid., page 76-77.
[120] Ibid., page 77.
[121] Ibid.
[122] Henderson et al., *supra* note 5, page 75.
[123] Ibid.
[124] Ibid.

where a small amount of tissue is removed or cut from the cervix for further analysis.[125] In some cases the removal of a larger, cone-shaped sample of cervical tissue, called a cone biopsy, may need to be preformed in a hospital setting.[126]

Endocervical Curettage

An endocervical curettage is a procedure where a curette, or a spoon-shaped instrument, is used to collect cervical canal cells and is sometimes done in conjunction with a colposcopy.[127] The cells are then analyzed further to determine if cancer or precancerous cells are present.

MEDICARE COVERAGE FOR CERIVCAL CANCER SCREENING

According to ACS, Medicare provides 100 percent insurance coverage for a Pap test and 80 percent insurance coverage for a pelvic examination once every two years. Women at high risk for cervical or vaginal cancer, or who are of childbearing age and have had an abnormal Pap test in the past three years, receive Medicare coverage for 100 percent of the cost of the Pap test and 80 percent of the cost of a pelvic examination once every year.[128]

ORGANIZATIONS DEDICATED TO THE PREVENTION OF CERVICAL CANCER

There are numerous organizations that are involved in trying to prevent and cure cervical cancer. A brief description of several of these organizations is provided below. Please note that the list should not be interpreted as an exhaustive list of all organizations involved in cervical cancer prevention. The list simply provides a few examples of some of the more well-known organizations dedicated to cervical cancer prevention (or dedicated to general women's health issues, including cervical cancer).

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[125] James N. Parker (ed.) and Philip M. Parker (ed.), *supra* note 116, page 13.
[126] Ibid.
[127] Ibid.
[128] ACS, *Cancer Screening - Medicare Coverage*, September 23, 2003, http://www.cancer.org/docroot/PED/content/PED_2_3x_Cancer_Screening_-_Medicare_Coverage.asp?sitearea=PED (September 9, 2004).

United States Department of Health and Human Services (HHS)

National Breast and Cervical Cancer Early Detection Program (NBCCEDP): NBCCEDP is a program run through the CDC, "to provide critical breast and cervical cancer screening services to underserved women in the United States, the District of Columbia, 4 U.S. territories, and 13 American Indian/Alaska Native organizations."[129]

NBCCEDP was created by the passage of the Breast and Cervical Cancer Mortality Prevention Act of 1990.[130] The program was established in 1991 and provides screening and diagnostic services including clinical breast examinations, mammograms, Pap tests, surgical consultation, and diagnostic testing for women whose screening outcome is abnormal.[131] In 2000, Congress passed the Breast and Cervical Cancer Treatment and Prevention Act to help make these services more accessible to women enrolled in NBCCEDP.[132] The program received $210 million in fiscal year 2004 appropriations to provide these services.[133] To date, NBCCEDP has served 1.9 million women, has provided 4.6 million screening examinations, and has diagnosed 17,009 breast cancers, 61,474 precancerous cervical lesions, and 1,157 cervical cancers.[134]

NBCCEDP also provides funding to states to create and disseminate educational resources to women, especially those who are rarely or never screened.[135] It also develops materials for the states to use to provide public education and outreach on the benefits of early detection of cervical cancer.[136] The Pennsylvania program funded by the NBCCEDP is called the HealthyWoman Program. In addition to partnering with the 50 states, 4 U.S. territories, the District of Columbia, and 13 American Indian/Alaska Native Organizations, NBCCEDP also helps create partnerships and coalitions with other private groups to increase public education on breast cancer and cervical cancer.[137]

The NBCCEDP also assists in educating a wide range of health care professionals, including physicians, nurses, radiologic technologists and cytologists and provides national guidance on screening, diagnostic follow-up,

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[129] HHS, CDC, *National Breast and Cervical Cancer Early Detection Program Website*, http://www.cdc.gov/cancer/nbccedp/ (October 20, 2004).
[130] HHS, CDC, *The National Breast and Cervical Cancer Early Detection Program: Saving Lives Through Screening*, http://www.cdc.gov/cancer/nbccedp/about2004.htm (October 26, 2004).
[131] Ibid.
[132] Ibid.
[133] Ibid.
[134] Ibid.
[135] Ibid.
[136] Ibid.
[137] Ibid.

and case management to ensure that the best practices and current techniques are used in caring for the women it serves.[138]

National Cancer Institute (NCI): The NCI is directly under the National Institutes of Health (NIH), which is one of eight agencies under the Public Health Service (PHS) within the United States Department of Health and Human Services (HHS).[139] NCI was established under the National Cancer Act of 1937 and is primarily responsible for general cancer research and training, including cervical cancer.[140] The NCI coordinates the National Cancer Program, "which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and continuing care of cancer patients and the families of cancer patients."[141] More specific to cervical cancer, NCI's website provides the general public and health care providers with information about treatment, prevention, clinical trials, cancer literature, research, and statistics pertaining to cervical cancer.[142]

Office on Women's Health (OWH): The OWH is an office under HHS that "is the government's champion and focal point for women's health issues, and work[s] to redress inequities in research, health care services, and education that have historically placed the health of women at risk."[143] The OWH created and currently sponsors a website specifically targeting women's health information called the National Women's Health Information Center (NWHIC).[144] This website allows the public, health care professionals, medical researchers, educators, and the media to search for specific women's health topics, such as cervical cancer, and includes links to both private and public organizations who have information pertaining to a specific topic.[145]

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[138] Ibid.
[139] HHS, PHS, NIH, NCI, *NCI Mission Statement*, http://www.cancer.gov/aboutnci/overview/mission (October 27, 2004).
[140] Ibid.
[141] Ibid.
[142] HHS, PHS, NIH, NCI, *Cervical Cancer*, http://www.cancer.gov/cancertopics/types/cervical/ (October 27, 2004).
[143] HHS, Office on Women's Health, *OWH Mission*, http://www.4woman.gov/owh/about/mission.htm (October 28, 2004).
[144] HHS, Office on Women's Health, *Welcome*, http://www.4woman.gov/owh/about/ (October 28, 2004).
[145] Ibid.

Pennsylvania Department of Health (PADOH)

HealthyWoman Program (HWP):[146] HWP is funded by the Commonwealth and through the CDC's Breast and Cervical Cancer Early Detection Program.[147] The state-run program contracts with eight contractors, who subcontract with over 200 service delivery sites for mammograms, Pap tests and pelvic examinations.[148] The program targets woman who are between the ages of 50 and 64,[149] have little or no health insurance, and have income levels under 250 percent of the Federal Poverty Income Guidelines.[150] Women meeting these guidelines are eligible for free clinical breast examinations, mammograms, pelvic examinations, Pap tests, education of breast self-exam, and follow-up diagnostic care for abnormal results.[151]

During fiscal year 2003-2004, the HWP provided breast and cervical cancer screening services to 6,072 women, 4,708 of whom received Pap tests. These figures are close to HWP's yearly average according to the HWP, but are showing some signs of increasing.

The HWP is able to reach out to these women through the success of its media and marketing programs. The program, through contracts with direct marketing firms and local media outlets, targets its outreach efforts at distressed communities, areas that are medically underserved, and communities that are affected by plant closings and job losses. For example, invitations were mailed to 18,000 women in Allegheny County and the program experienced a relatively high response rate of 5 percent for this effort. HWP recently was featured in an article in a physician's newsletter funded through Medicare.

The CDC provided slightly more than $2 million for fiscal year 2003-2004, which continued a pattern of funding reductions. The amount appropriated for fiscal year 2004-2005 is $2,089,000, which is lower still. The program receives $500,000 per year from the Commonwealth in the form of a Maintenance of Effort appropriation, which is a federally mandated appropriation from the

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[146] Unless otherwise noted, information in this section was obtained via conference call between Commission staff and HWP staff, November 10, 2004.

[147] Pennsylvania Department of Health (PADOH), *Breast and Cervical Cancer Projects, HealthyWoman Program*, http://www.dsf.health.state.pa.us/health/cwp/view.asp?a=174&q=198271 (October 27,2004).

[148] Ibid.

[149] Women under the age of 50 are also eligible if they have had symptoms of breast or cervical cancer. PADOH, *HealthyWoman Project, Breast and Cervical Cancer Early Detection Project*, http://www.dsf.health.state.pa.us/health/cwp/view.asp?a=174&q=200875 (October 27, 2004).

[150] PADOH, *HealthyWoman Project, Breast and Cervical Cancer Early Detection Project*, http://www.dsf.health.state.pa.us/health/cwp/view.asp?a=174&q=200875 (October 27, 2004).

[151] Ibid.

state. The HWP faces a double-edged sword: as funding is being reduced, it is at the same time trying to increase the numbers of women served by the program.

The HWP has several suggestions that may improve its ability to serve its constituency:

- Increased funding would allow it to provide services to as many uninsured and underinsured women as are in its target populations.

- More facilities and improved access to care, especially in medically underserved areas, would allow services to reach more women.

- The development of special outreach efforts directed at specific minority groups, such as Latino and Amish, could reach women that traditionally shy away from such medical services.

- A programmatic separation of cervical cancer from breast cancer, would help raise people's awareness of cervical cancer.

The HWP is administered for the primary grantee, the Alliance of Pennsylvania Councils, by the Family Health Council. The Family Health Council oversees four regional subcontractors, which work with a network of providers in their respective regions to facilitate access for women to receive breast and cervical cancer screening services. The four subcontractors are

- Family Health Council of Central Pennsylvania, Inc (Adams, Bedford, Blair, Cambria, Centre, Clinton, Columbia, Cumberland, Dauphin, Franklin, Fulton, Huntingdon, Juniata, Lancaster, Lebanon, Lycoming, Mifflin, Montour, Northumberland, Perry, Snyder, Somerset, Union, and, York);

- Family Planning Council, Inc. serving southeastern Pennsylvania (Bucks, Chester, Delaware, Montgomery, and, Philadelphia);

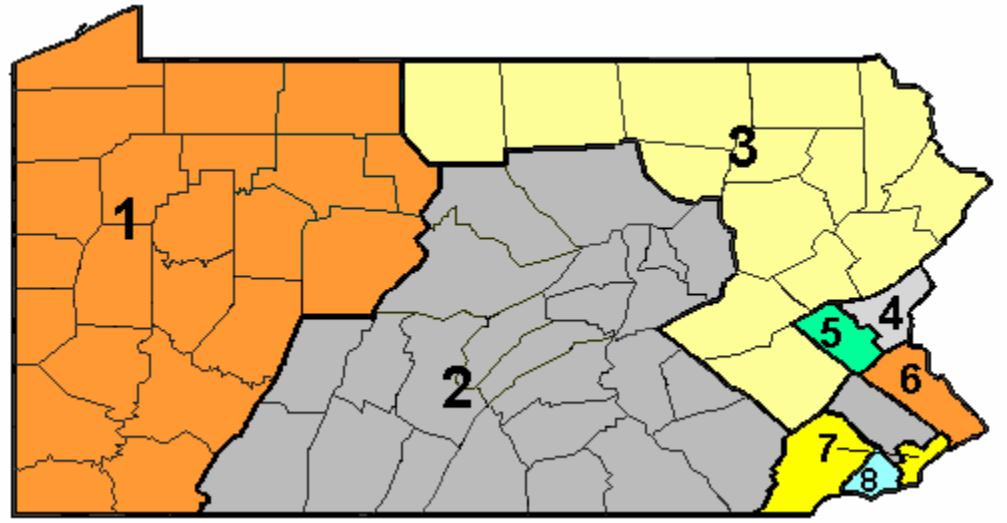
- Maternal and Family Health Services, Inc. serving northeastern Pennsylvania (Berks, Bradford, Carbon, Lackawanna, Lehigh, Luzerne, Monroe, Northampton, Pike, Schuylkill, Sullivan, Susquehanna, Tioga, Wayne, and Wyoming); and

- Family Health Council, Inc. serving western Pennsylvania (Allegheny, Armstrong, Beaver, Butler, Cameron, Clarion, Clearfield, Crawford, Elk, Erie, Fayette, Forest, Greene, Indiana,

Jefferson, Lawrence, Mercer, McKean, Potter, Venango, Warren, Washington, Westmoreland).

These four regional subcontractors coordinate the activities of the eight contractors that provide services through the HWP. They are active in 250 locations in 65 counties and serve an estimated 320,000 people. Early detection of cervical cancer has been an integral part of their operations since 1972.[152] See Figure 4 for a county map and list of the eight contractors.

FIGURE 4
HEALTHYWOMAN PROJECT'S EIGHT CONTRACTORS[153]



Key:

1 - Family Health Council, Inc.
2 - Family Health Council of Central PA
3 - Maternal & Family Health Services
4 - Bethlehem Bureau of Health
5 - Allegheny County Health Department
6 - Bucks County Department of Health
7 - Philadelphia Department of Public Health
8 - Crozer Keystone Health System

[152] Dorothy Mann, Executive Director of Family Planning Council, Inc., to Joint State Government Commission, memorandum, November 10, 2004.
[153] PADOH, *HealthyWoman Project*, http://www.health.state.pa.us/php/HW/hltwmap.htm (November 23, 2004).

To illustrate the workings of the four regional contractors, consider the Family Planning Council, Inc. (FPC).[154] FPC receives $1 million annually through PADOH's Chronic Disease and Injury Prevention Program. The program is in the third year of the five-year period for which it was originally established. The agency provides risk factor education, HPV-typing tests, colposcopies, and treatment procedures for pre-cancerous conditions. The centers utilize the new ThinPrep liquid tests mentioned earlier in this report and can perform limited cryrosurgery, cone-biopsies, and LEEP for women suffering cervical dysplasia. Women who are found to have cancerous conditions are referred to the Breast and Cervical Cancer Prevention and Treatment Program. It is estimated that in 2003, the FPC performed 145,000 Pap tests. The results of these tests led to 40,000 treatments for pre-cancerous conditions.

The FPC's constituency does not overlap with those served by the HWP. The FPC targets a younger population, ages 18-54, but it does, like HWP, serve women who are uninsured or underinsured and not eligible for Medicaid.

Breast and Cervical Cancer Research Fund: The Breast and Cervical Cancer Research Fund is a fund designed to provide grants to Pennsylvania researchers currently studying breast and cervical cancer.[155] The Fund began in 1997 with the signing of Act 7 that enabled individuals to contribute to breast and cervical cancer research by either donating a portion of their state tax refund or contributing directly to the Pennsylvania Department of Health.[156] In the first four years of operation, the Fund awarded over $1 million in grants to more than thirty Pennsylvania researchers at seven institutions for peer-reviewed studies to address the incidence and mortality of breast and cervical cancer. The Fund only provides grants to researchers who have applied for funding and have had their proposals peer-reviewed through the American Cancer Society, National Cancer Institute, Department of Defense, or the Susan G. Komen Foundation but did not receive funding through these groups.[157]

Pennsylvania Cancer Control Consortium (PAC^3): PAC^3 is a consortium of health care providers, researchers, cancer survivors, advocates, insurers, and representatives from the PADOH and the ACS formed in 2001 to develop the first statewide Comprehensive Cancer Control Plan.[158] The plan was released in

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[154] Information about FPC, Inc., obtained via telephone conversation between Commission Staff and Sarah Grambs of the FPC, Inc., November 10, 2004.
[155] PADOH, *Breast and Cervical Cancer Projects, HealthyWoman Program*, *supra* note 150.
[156] Ibid.
[157] Ibid.
[158] Pennsylvania Cancer Control Consortium (PAC^3), *The Pennsylvania Comprehensive Cancer Control Plan*, December 2003,

December of 2003 and includes numerous goals for Pennsylvania under the following general categories:

- cancer prevention and healthy lifestyles;
- cancer screening and diagnostic follow-up;
- cancer treatment and care delivery;
- quality of life: survivorship through end-of-life;
- access (to primary care, cancer prevention/screening, and cancer care);
- research (related to cancer prevention, early detection, and disease management);
- cancer-related information management and dissemination; and
- implementation (of the Comprehensive Cancer Control Plan).[159]

More specifically to cervical cancer, the PAC^3's Goal H under cancer prevention and healthy lifestyles states that "all women in Pennsylvania at higher risk for cervical cancer will have the knowledge and the resources to have Pap smears according to evidence-based guidelines and to receive appropriate follow-up of abnormal screening results."[160] PAC^3 went on to further detail the potential actions that could be taken to meet this goal. Below is a summary of these potential actions.

- Since HPV DNA is present in nearly all cases involving cervical cancer and precancerous lesions, there must be increased awareness among women on how HPV is spread and what types of sexual behavior increase the risk of becoming infected with HPV.[161]
- There should be an effort made to increase women's access to cervical cancer screening and follow-up services with the state. PAC^3 explains that this can be accomplished with a combination of

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http://www.dsf.health.state.pa.us/health/lib/health/pac3/pac3mainbook.pdf (November 1, 2004), page 1.

[159] Ibid., pages 5-8.

[160] Ibid., page 22.

[161] Ibid., page 60.

public funding, employee groups, etc., that would help address cultural and geographic boundaries to cervical screening.[162]

- There should be an effort to "[i]ncrease statewide training and support for the implementation of coordinated school health programs designed to increase knowledge of the risk associated with sexually transmitted diseases and cervical cancer by:

    - Collaborating and partnering with the American Cancer Society's School Health Leadership Institutes.

    - Sharing information on sexual health education curriculum best practices.

    - Increasing to 50 percent the proportion of school districts with active school health councils by conducting targeted awareness campaigns and implementing school-related partnerships.

    - Developing culturally relevant and age-appropriate educational approaches addressing healthy lifestyle issues and disparities by accessing relevant information from the Pennsylvania Department of Health, the American Cancer Society, the Department of Education, and other organizations."[163]

- There should be an increase in "healthy lifestyles recommendations for office practices by developing materials/tools for state healthcare professionals to use in their practices and providing applicable training and education, technical assistance, and resources."[164] This should include promoting "updated educational campaigns targeting healthcare providers and family planning professionals about Human Papillomavirus (HPV)-prevention messages, new developments in testing and treatment, and patient counseling for sexually active patients, especially those with HPV infection and their partners."[165]

- Pennsylvania should obtain "important baseline information on risk behaviors and provide a benchmark for future intervention

[162] Ibid.
[163] Ibid.
[164] Ibid.
[165] Ibid.

> efforts by working with the Centers for Disease Control and Prevention to implement the Youth Risk Behavior Surveillance System in all public school districts in Pennsylvania by 2005."[166] This includes disseminating survey-derived research and evaluation information, incorporating survey data to seek public funding for sexual health programs, and targeting increased awareness in specific high-risk populations.[167]

National Cervical Cancer Coalition (NCCC)

The National Cervical Cancer Coalition (NCCC) is a non-profit organization dedicated to serving women who have or who are at risk for developing cervical cancer.[168] Coalition members include women and family members/caregivers battling cervical cancer, women's groups, cytotechnologists, pathologists, laboratories, technology companies, cancer researchers, hospitals, organizations providing cervical cancer screening programs, and other cervical cancer related organizations.[169] The Coalition's primary goals include gaining nationwide recognition as one of the nation's primary sources for clinical and public education resources on cervical cancer, advocating for women's access to regular testing to prevent cervical cancer, and maintaining a support system for those who have cervical cancer.[170] NCCC priorities include developing professional and public education programs to inform people about current trends, technology, and research related to cervical cancer; engaging professionals, the public, health care institutions, public policymakers and the media in cervical cancer discussions to further the education process; identifying needs and programmatic gaps to guide organizational development and fundraising; and developing organizational partnerships to further NCCC's mission and goals.

Some of the examples of NCCC outreach, prevention and educational projects include the:

- development of the nation's first Cervical Cancer Phone Lifeline for women who have cervical cancer and their family members;

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[166] Ibid.
[167] Ibid., page 61.
[168] National Cervical Cancer Coalition (NCCC), *Welcome to the National Cervical Cancer Coalition Website: What is the National Cervical Cancer Coalition (NCCC)?*, April 4, 2002, http://www.nccc-online.org/index.asp (September 9, 2004).
[169] Ibid.
[170] Ibid.

- organization of The Quilts Project, which is a quilt that travels the country and helps place a personal face in the battle against cervical cancer;

- organization of the Free Cervical Cancer Screening day to provide free Pap tests for women who have not had a Pap test in the last three years;

- co-sponsorship of two conferences with the National Ovarian Cancer Coalition (NOCC) on gynecologic cancers as well as co-sponsorship of various educational research conferences on cervical and other cancers with groups such as the National Cancer Institute (NCI) and the Centers for Disease Control and Prevention (CDC);

- development of a website containing information on NCCC (http://www.nccc-online.org);

- co-sponsorship of a fundraising conference on cervical cancer issues; and

- organization of various cervical cancer prevention education fundraisers.[171]

American Cancer Society (ACS)

The ACS "is the nationwide community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives, and diminishing suffering from cancer, through research, education, advocacy, and service."[172] The Society consists of the National American Cancer Society, chartered Divisions throughout the county, and more than 3,400 local units.[173] In total, the ACS has more than two million volunteers nationwide.[174] The ACS fights cancer in a number of ways, including:

- supporting research efforts to prevent and cure cancer;

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[171] Ibid.
[172] ACS, *ACS Mission Statements*, http://www.cancer.org/docroot/AA/content/AA_1_1_ACS_Mission_Statements.asp?sitearea=AA (October 27, 2004).
[173] ACS, *About ACS: Fact Sheet*, http://www.cancer.org/doroot/AA/content/AA_1_2_2000_Fact_Sheet.asp (October 27, 2004).
[174] Ibid.

- educating people about the causes of cancer, what screening options are available, and how early detection of cancer can increase the patients chance of recovery;

- offering patient and family support for those diagnosed with cancer; and

- working with policy makers at all levels of government to influence public policies relating to:

    - controlling the use, sale, distribution, marketing, and advertising of tobacco products;

    - improving access for poor and underserved Americans to health care services for the prevention, early detection, diagnosis, and treatment of cancer;

    - increasing federal funding and incentives for research to prevent and cure cancer; and

    - fighting for the rights of cancer survivors.[175]

More specifically related to cervical cancer, ACS's website contains information pertaining to the risk factors and causes of cervical cancer, the screening methods for cervical cancer, and the treatment of cervical cancer.[176]

Gynecologic Cancer Foundation (GCF)

According to GCF website, the mission of the Foundation "is to ensure public awareness of gynecologic cancer prevention, early diagnosis and proper treatment as well as support research and training related to gynecologic cancers."[177] In order to accomplish these goals, GCF advocates "increasing public and private funds that aid in the development and implementation of programs to meet these goals."[178]

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[175] Ibid.
[176] ACS, *All About Cervical Cancer*, http://www.cancer.org/docroot/CRI/CRI_2x.asp?sitearea=&dt=8 (October 27, 2004).
[177] Gynecologic Cancer Foundation (GCF), *About GCF*, http://www.thegcf.org/about/default.htm (October 28, 2004).
[178] Ibid.

More specific to cervical cancer, GCF is the National Cervical Cancer Public Education Campaign's lead partner.[179] This campaign's primary goal is to educate women and the public about the causes of cervical cancer as well as preventing and detecting the cancer.[180] Along with GCF, other campaign partners include the American Cancer Society, American College of Obstetricians and Gynecologists, American Medical Women's Association (the founding lead partner), CDC, National Cervical Cancer Coalition, Nation Cancer Institute, Society of Gynecologic Oncologists, and over 20 other organizations.[181]

Society of Gynecologic Oncologists (SGO)

SGO is a national organization of "physicians who are trained in the comprehensive management of women with malignancies of the reproductive tract."[182] The primary goal of the Society is to improve the care of women with various gynecologic cancers by encouraging research, disseminating information to health care providers, and cooperating with other organizations interest in women's health care, oncology and related fields.[183] According to GCF's website, GCF and SGO can be viewed as complementary organizations because all members of SGO are automatically members of GCF. The primary difference between GCF and SGO is that SGO works primarily with physicians and other health professionals while GCF directs its efforts more towards the public.[184]

American College of Obstetricians and Gynecologists (ACOG)

ACOG is an organization of professionals providing health care for women and is "dedicated to the advancement of women's health through education, practice, research and advocacy."[185] More specifically, ACOG works primarily in four areas:

- serving as a strong advocate for quality health care for women;

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[179] National Cervical Cancer Public Education Campaign, *National Cervical Cancer Public Education Campaign, You Need to Know: About the Campaign*, http://www.cervicalcancercampaign.org/about/about.htm (October 28, 2004).
[180] Ibid.
[181] Ibid.
[182] Society of Gynecologic Oncologists (SGO), *About SGO*, http://www.sgo.org/about/ (October 28, 2004).
[183] Ibid.
[184] GCF, *supra* note 177.
[185] ACOG, *Scope* of *Practice of Obstetrics and Gynecology*, http://www.acog.org/from_home/acogscope.cfm (October 28, 2004).

- maintaining the highest standards of clinical practice and continuing education for it members;

- promoting patient education and stimulating patient understanding or and involvement in medical care; and

- increasing awareness among its members and the public of the changing issues facing women's health care.[186]

With regard to cervical cancer, ACOG occasionally releases statements regarding the current practices of prevention, detection, and treatment. For example, on September 30, 2004, ACOG Office of Communications released a statement that clarified ACOG's position on recommendations on cervical cancer screening in adolescents.[187] The news release stated that ACOG issued a committee opinion that stated that, although ACOG recommends that a women's first Pap test does not have to be administered until she is 21 or three years after she becomes sexually active, ACOG strongly recommends that an adolescent girl's first visit to a gynecologist for health guidance, screening, and preventive health be between the ages of 13 and 15.[188]

American Medical Women's Association (AMWA)

The AMWA "is an organization of over 10,000 women physicians and medical students dedicated to serving as the unique voice for women's health and the advancement of women in medicine." Along with supporting the general advancement of women in medicine, AMWA also works to improve women's health through developing advocacy, education, expertise, mentoring, and strategic alliance. For example, the AMWA has developed a number of educational projects for both member and non-member physicians on issues such as heart disease in woman, tobacco control, reproductive health, and breast and cervical cancer screening. AMWA also publishes a quarterly Journal of the American Medical Women's Association (JAMWA) that focuses on women's health issues. Directly related to cervical cancer education, AMWA was the founding lead partner in the National Cervical Cancer Public Education Campaign.[189] As mentioned before, this campaign's primary goal is to educate

[186] ACOG, *The American College of Obstetricians and Gynecologists Celebrating 50 years of Improving Women's Health*, http://www.acog.org/from_home/acoginfo.cfm (October 28, 2004).
[187] ACOG, "ACOG Clarifies Recommendations of Cervical Cancer Screening in Adolescents," http://www.acog.org/from_home/publications/press_releases/nr09-30-04-1.cfm (October 28, 2004).
[188] Ibid.
[189] National Cervical Cancer Public Education Campaign, *National Cervical Cancer Public Education Campaign, You Need to Know: Campaign Partner Profiles*,

women and the public about the causes of cervical cancer as well as preventing and detecting the cancer.[190]

Cancer Research and Prevention Foundation

The mission of the Cancer Research and Prevention Foundation "is the prevention and early detection of cancer through scientific research and education."[191] According to the Foundation's website, the Foundation "focus[es] on cancers that can be prevented through lifestyles changes or early detection followed by prompt treatment. These include breast, cervical, colorectal, lung, prostate, skin, oral and testicular cancers."[192] The Foundation's website contains information about cervical cancer as well as other types of cancer.

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http://www.cervicalcancercampaign.org/partneters/partners.htm (October 28, 2004).

[190] National Cervical Cancer Public Education Campaign, *National Cervical Cancer Public Education Campaign, You Need to Know: About the Campaign*, *supra* note 179.

[191] Cancer Research and Prevention Foundation, "Our Mission," http://www.preventcancer.org/ (October 28, 2004).

[192] Ibid.

TREATMENT

The three standard treatment options for cervical cancer are surgery, chemotherapy, and radiation. Each of these treatments may be used alone or in combination with one or both of the others.[193] Many issues are considered in developing a treatment plan for a particular woman, including the stage and size of the cancer, how old the woman is, and whether she wants to have children.

Most of the information in this chapter is taken from the websites of the American Cancer Society,[194] Imaginis[195] (an independent resource of physician-edited information on women's health issues), and the National Cancer Institute.[196] Other sources are cited throughout the chapter.

STAGING

Staging is the process by which it is determined how far cancer has spread. In the case of cervical cancer, staging determines if the cancer is confined to a certain part of the cervix, has spread to other parts of the cervix or has spread to other parts of the body. It is important to know the stage of the cancer in order to plan treatment.

Cervical cancer staging differs from staging for other cancers in that it is clinically, rather than surgically, based. This means that the stage of the cancer is determined by physicians through physical examination and a few tests and does not rely on surgery. This system was developed by the International Federation of Gynecology and Obstetrics (FIGO) and is called the FIGO System of Staging. If surgery is later performed and shows that the cancer has spread further than initially thought, the treatment plan might change, but its rank on FIGO stage does not.

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[193] Each of these treatments is provided by, or under the supervision of, an oncologist. A cancer patient is often treated by a cancer care team, which may include a surgical oncologist, a radiation oncologist and a medical (chemotherapy) oncologist, along with radiation technicians and oncology nurses.

[194] ACS, *Cervical Cancer*, http://documents.cancer.org/115.00/115.00.pdf (September 3, 2004).

[195] Imaginis, *Women's Health: Cervical Cancer*, http://www.imaginis.com/cervical-cancer/introduction.asp (October 14, 2004).

[196] HHS, NIH, NCI, *Cervical Cancer (PDQ®): Treatment Patient Version*, http://www.cancer.gov/cancertopics/pdq/treatment/cervical/patient/allpages/print (September 8, 2004).

Tests and Studies Used in Staging

The following tests and imaging studies may be used in the staging of (and may have been used in the initial diagnosis of) cervical cancer:

Cystoscopy: A procedure during which a small tube with a light on its tip is inserted through the urethra so that the physician can examine the urethra and bladder. The physician may perform a biopsy on this tissue to determine whether cancer cells are present.

Proctoscopy: A procedure during which a small tube with a light on its tips is inserted through the rectum so that the physician can check for cancer and perform a biopsy of this tissue if necessary to confirm that the cervical cancer has spread to the rectum.

Chest x-ray: X-ray technology is an imaging procedure during which an energy beam passes through the body and onto film, making an image of areas inside the body. An x-ray of the organs and bones inside the chest helps determine if the cancer has spread to the chest – and, particularly, to the lungs.

Computed tomography (CT or CAT scan):[197] An x-ray procedure during which the x-ray scanner circles the body, taking many pictures that are combined by a computer to make a series of detailed cross-sectional images of the body. A dye may be injected into a vein or swallowed by the patient to help the organs or tissues show up more clearly.

Lymphangiogram: A procedure used to x-ray the lymph system in order to determine whether cancer has spread to the lymph nodes. A dye is injected into the lymph vessels in the feet. The dye travels upward through the lymph nodes and lymph vessels, and x-rays are taken to see if there are any blockages.[198]

Pretreatment surgical staging: Surgery is done to find out if the cancer has spread within the cervix or to other parts of the body. In some cases, the cervical

[197] This procedure is also called computerized tomography and computerized axial tomography.

[198] This procedure was found on the website of NCI, *supra* note 196, but not on the websites of the American Cancer Society or Imaginis.

cancer can be removed at the same time. Pretreatment surgical staging is usually done only as part of a clinical trial.[199]

Ultrasound: A procedure in which high-energy sound waves (ultrasound) bounce off internal tissues or organs and create echoes. The picture of body tissues formed by the echoes is called a sonogram.

Magnetic Resonance Imaging (MRI): A procedure that uses radio waves and strong magnets, rather than x-rays, to make a series of detailed pictures of areas inside the body. The energy from the radio waves is absorbed by body tissues and then released, forming patterns that are translated by a computer to form very detailed cross-sectional images (like a CT scan) and lengthwise cross-sectional images. This procedure is also called nuclear magnetic resonance imaging (NMRI).

Stages of Cervical Cancer

The results of the physical examinations and any tests and studies that were performed are viewed together with the results of the biopsy, if one was performed, to determine the cervical cancer stage. The stages of cervical cancer are numbered 0 through IV, with stages I through IV being further divided into substages as shown below. The divisions within stages I through IV are not based on the same criteria: divisions in stage I are based on how much cancer is found, while divisions in stages II through IV are based on how far the cancer has spread. The stages of cervical cancer are as follows:

Stage 0: Cancer is found only in the surface layer of cells lining the cervix and has not invaded the deeper tissues of the cervix. Stage 0 is also called carcinoma in situ or noninvasive cervical cancer.

Stage I: Cancer has invaded deeper tissues of the cervix, but has not spread elsewhere. Stage I is divided into stages IA and IB, based on the amount of cancer that is found.

Stage IA – A very small amount of cancer that can only be seen with a microscope is found in the tissues of the cervix.

[199] Ibid.

Stage IA1 – The area of cancer invasion is less than 3 millimeters deep and is less than 7 millimeters wide.

Stage IA2 – The area of cancer invasion is between 3 millimeters and 5 millimeters deep and is less than 7 millimeters wide.

Stage IB – This stage mostly includes cancers that can be seen without a microscope. However, it also includes cancers that can only be seen with a microscope, where the area of invasion is deeper than 5 millimeters or wider than 7 millimeters.

Stage IB1 – The cancer is 4 centimeters or smaller.

Stage IB2 – The cancer is larger than 4 centimeters.

Stage II: Cancer has spread beyond the cervix but not to the pelvic wall (the tissues that line the part of the body between the hips). Stage II is divided into stages IIA and IIB, based on how far the cancer has spread.

Stage IIA – Cancer has spread beyond the cervix to the upper portion of the vagina, but not to the lower third of the vagina.

Stage IIB – Cancer has spread beyond the cervix to the upper portion of the vagina and to the tissues next to the cervix called the parametrial tissue.

Stage III: Cancer has spread to the lower third of the vagina or to the pelvic wall. Stage III is divided into stages IIIA and IIIB, based on how far the cancer has spread.[200]

Stage IIIA – Cancer has spread to the lower third of the vagina but not to the pelvic wall.

Stage IIIB – Either cancer has spread to the pelvic wall, or the tumor has become large enough to block the ureters (the tubes through which urine flows from the kidneys to the bladder) or both. This blockage can cause the kidneys to enlarge or stop working.[201]

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[200] The American Cancer Society notes that the American Joint Committee on Cancer developed an alternate staging system under which stage III is defined by the fact that the cancer has spread to lymph nodes in the pelvis. The National Cancer Institute also mentions spread to these lymph nodes under stage III.

[201] Sharlene Bence, R.N. and office manager for Andrews & Patel Associates, P.C. Hematology and Medical Oncology, Harrisburg, advised Commission staff on September 9, 2004 that the early

Stage IV: Cancer has spread to the bladder, rectum, or other parts of the body. Stage IV is divided into stages IVA and IVB, based on how far the cancer has spread.

Stage IVA – Cancer has spread to the bladder or rectum.

Stage IVB – Cancer has spread beyond the pelvis to other parts of the body, such as the lungs.

TYPES OF TREATMENT AND THEIR RISKS AND SIDE EFFECTS

The three standard types of cancer treatment are surgery, radiation, and chemotherapy.[202] Surgery and radiation are localized treatments designed to control – and hopefully eliminate – the cancer at its site of origin. Chemotherapy may also be used locally, but is generally used systemically to fight cancer cells which may have metastasized (migrated) to other parts of the body. In later stage or recurrent cervical cancer where a cure is not expected, treatment may be given in an attempt to alleviate symptoms and improve quality of life. Treatment regimens are tailored for each patient and may involve one, two, or all three types of treatment. For many patients, a combination of localized and systemic treatments provides optimal cancer control. Each type of treatment involves certain risks and side effects. The most common risks and side effects of each treatment – along with suggested treatments for the side effects – are included at the end of each of the following treatment descriptions.[203]

Surgery

Surgical treatment of cervical cancer involves the actual removal of the cancer. Surgery may also be used on pre-cancerous conditions to prevent them from developing into cervical cancer. The following surgical procedures may be used.

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spread of cervical cancer is generally up the cervix to the uterus and then bilaterally to the fallopian tubes and ovaries. However, many women who die with more advanced stages of cervical cancer die of renal failure, as the cancer spreads, blocks the ureter tubes and causes the kidneys to stop functioning.

[202] Other types of treatment, combinations of treatments and new drugs are being developed and tested in clinical trials across the country. American Cancer Society, *Cervical Cancer*, *supra* note 194.

[203] Most of the information provided on risks and side effects associated with surgical treatment of cervical cancer is from Imaginis, *supra* note 195. Most of the information provided on the risks and side effects of radiation therapy and chemotherapy is from Imaginis and the ACS, *Cervical Cancer*, *supra* note 194.

Cauterization: Cauterization is the use of heat, electricity or chemicals to burn off abnormal cervical cells. Cauterization is most often used on pre-cancerous conditions and can be performed in a doctor's office or on an outpatient basis in a hospital. Side effects of cauterization are minimal, as little discomfort is involved. However, there is a risk that cauterization will cause scarring that makes interpretation of future Pap tests difficult.

Conization; cone biopsy: Conization is a surgical procedure to remove a cylindrical or cone-shaped piece of tissue from the cervix and cervical canal so that a pathologist can examine the tissue under a microscope to look for cancer cells. Conization may be used to diagnose cervical cancer or as a treatment if the cancer is small enough to be removed during the procedure. The procedures commonly used in conization are loop electrosurgical excision procedure (LEEP; see below), for which local anesthesia is required, and using a surgical scalpel or laser, which requires general anesthesia. Conization by LEEP is usually performed in a doctor's office, and conization by scalpel or laser is performed in a hospital, usually on an outpatient basis.

Side effects include cramping, discomfort and mild to moderate bleeding for several weeks after conization. Sexual intercourse, tampons and douching must be avoided until the cervix is completely healed, which normally takes several weeks. Risks involved with conization include those for other surgeries, including infections and problems related to the administration of anesthesia.

Cryosurgery; cryotherapy: Cryosurgery is a treatment in which a metal probe is positioned so that it touches the cervical lesion. Liquid nitrogen is then sent through the probe at a temperature cold enough to freeze and destroy the tissue. Cryosurgery is usually performed by a gynecologist in the doctor's office.

Most women are able to resume normal activities immediately after cryosurgery, however they must refrain from sexual intercourse and douching for several weeks after the procedure. Mild cramping and several weeks of a watery discharge are the most common side effects of cryosurgery.

Bilateral salpingo-oophorectomy: This is a surgical procedure to remove both ovaries and both fallopian tubes. Removal of the ovaries causes sudden menopause with symptoms that can be more severe than those of natural menopause.[204]

[204] Henderson et al., *supra* note 5, page 93.

Simple hysterectomy: Simple hysterectomy is the surgical removal of the uterus and cervix. The surgery involves a hospital stay of several days. In a simple hysterectomy, the uterus can be removed through the vagina or through an abdominal incision. An abdominal hysterectomy requires a hospital stay of three to five days, while the hospital stay for a vaginal hysterectomy is sometimes shorter.

Risks involved with simple hysterectomy include excessive bleeding, infection and damage to the urinary and intestinal systems. A permanent result of simple hysterectomy is the inability to have children.

Radical hysterectomy: Radical hysterectomy is a surgical procedure to remove the uterus, cervix, the tissues near the uterus (parametria and uterosacral ligaments) and the upper part of the vagina. Nearby lymph nodes may also be removed. The ovaries and fallopian tubes are usually left in place, unless a reason to remove them is discovered during the surgery.

A radical hysterectomy involves a hospital stay of five to seven days. The most common risks of radical hysterectomy are excessive bleeding, infection and damage to the urinary and intestinal systems. Because the vagina is shortened during the surgery, side effects may include problems with sexual functioning. However, many women find that their sexual function is improved after the surgery because they no longer have pain or bleeding (which was caused by cancer) during intercourse. Again, the inability to have children is a permanent result of hysterectomy. If the ovaries are removed during the surgery, the woman will go into immediate menopause with very strong symptoms.

Laser surgery: Laser surgery uses a focused laser beam (a narrow beam of intense light) to remove tissue. It can be performed in a physician's office or on an outpatient basis in a hospital, and recovery is usually fast. Laser surgery is generally used to obtain a tissue sampling for testing in a pathology laboratory and on patients with pre-cancerous conditions or noninvasive (stage 0) cervical cancer.

Side effects include cramping, discomfort and mild to moderate bleeding for several weeks after surgery. Sexual intercourse, tampons and douching must be avoided until the cervix is completely healed, which normally takes several weeks. Risks involved with laser surgery include those for other surgeries, including infections and problems related to the administration of anesthesia.

Loop electrosurgical excision procedure (LEEP): LEEP is a treatment that uses a thin wire loop heated by an electrical current as a knife to remove abnormal tissue or cancer. Local anesthesia is used, and the procedure can be performed in a physician's office.

Side effects include cramping, discomfort and mild to moderate bleeding for several weeks after LEEP. Sexual intercourse, tampons and douching must be avoided until the cervix is completely healed, which normally takes several weeks. Risks involved with LEEP include those for other surgeries, including infections and problems related to the administration of anesthesia.

Pelvic exenteration: Pelvic exenteration is a surgical procedure to remove the bladder, lower colon, rectum, cervix, vagina, ovaries and nearby lymph nodes. Several additional surgeries may be necessary to form openings for urine and stool to flow from the body to a collection bag and to form an artificial vagina.

Pelvic exenteration involves making major changes to the body. Risks involved include those for other surgeries, including infections and problems related to the administration of anesthesia. Because pelvic exenteration surgery is so extensive and is almost certainly followed by more surgical procedures, the risks are somewhat greater than for one-time surgeries. Most women do not feel "normal" until at least six months after the surgery, with many noting that it took two years to completely adjust to the changes.

Radiation Therapy

Radiation therapy is a cancer treatment that uses high-energy x-rays or other types of radiation to kill cancer cells. There are two types of radiation therapy: external and internal. External radiation therapy uses a machine outside the body to send radiation toward the cancer. External radiation therapy is somewhat comparable to having a diagnostic x-ray but at a higher dose, for a longer period of time and for a certain number of days.[205] Before external radiation therapy begins, a radiation oncologist measures the correct angles for aiming the radiation and marks the skin accordingly with ink. To ensure that the marks do not fade away and that the radiation is always directed at the proper area, the ink marks are usually made permanent by tattooing. While cancer cells are the target of external radiation therapy, healthy cells in the field of radiation are also effected. Internal radiation therapy uses a radioactive substance sealed in needles, seeds, wires or catheters that are placed directly into or near the cancer.

[205] External radiation therapy is usually given once a day, five days a week for six or seven weeks.

Internal radiation therapy is completed in just a few days. Whether external or internal radiation therapy is given depends on the type and stage of the cancer being treated.

If external radiation therapy is used, the targeted area eventually becomes dry and looks and feels like it is sunburned. Moisturizing lotion applied after each treatment can help make the burn bearable. It takes six months to a year for the treated area to feel and look normal again. Most patients undergoing external radiation therapy also experience fatigue, which increases with each treatment and may lead to curtailing normal activities, including work, during the later weeks of treatment. Upset stomach, diarrhea, and problems urinating are side effects experienced during a regimen of radiation therapy that improve with time after the conclusion of the treatment. Side effects of radiation therapy that might be permanent are premature menopause and vaginal stenosis (narrowing caused by scar tissue), which might make sexual intercourse painful. Vaginal dilators may help enlarge the vagina in an attempt to alleviate such pain.

Internal administration of radiation therapy is the most common method for treatment of early cervical cancer. Side effects of internal radiation therapy include vaginal and cervical dryness and problems with the intestinal and urinary systems.[206] These side effects often fade away when treatment ends, but they sometimes last for a long time. Artificial lubricants and exercise may help alleviate these problems.

Chemotherapy

Chemotherapy is a cancer treatment that uses drugs to slow or stop the growth of cancer cells, kill cancer cells, stop cancer from spreading to other parts of the body, or relieve symptoms of cancer. Combination chemotherapy involves the administration of two or more drugs and is believed to be the most effective approach for cervical cancer patients, as it uses lower doses of each drug than would be required if only that drug were used and achieves greater cancer control with fewer side effects. There are two types of chemotherapy: systemic and regional. Whether chemotherapy is given systemically or regionally depends on the type and stage of the cancer being treated.

Systemic chemotherapy enters the bloodstream and reaches all the tissues and organs, with the intent of fighting cancer cells wherever they exist in the body. Systemic chemotherapy is commonly given intravenously through a catheter that is implanted in a large vein and remains there until the physician is sure that no further chemotherapy treatment will be required. It may also be

[206] Henderson et al., *supra* note 5, page 92.

given intravenously through a smaller vein, which involves the insertion of an intravenous catheter (commonly called an IV needle) for each treatment. Systemic chemotherapy may also be injected into a muscle or administered orally, by pill or liquid. Regional chemotherapy is placed directly in the cancer area through injection or topical application, so that the drugs mainly affect cancer cells in that region of the body.

Because chemotherapy, especially systemic chemotherapy, damages or kills normal cells as well as cancer cells, there is a wide range of side effects. The side effects experienced depend on which drugs are used, how much is administered, and the length of time of the chemotherapy regimen. Temporary side effects include nausea, vomiting, loss of appetite, weight loss, mouth sores, fatigue, weakness, hair loss, cognitive impairment, and dry, delicate, sensitive skin. Nausea and vomiting are generally worse during the first few days after each chemotherapy treatment, but can occur at any time during the treatment regimen, as the loss of appetite is often coupled with a "sick feeling" at the smell of food. Other common side effects of chemotherapy are lowered white and red blood cell counts, resulting in increased chance of infection, easy bleeding and bruising, and shortness of breath. Chemotherapy for cervical cancer may also result in premature menopause and the inability to have children, both of which are permanent. In addition to these side effects, the entire experience of chemotherapy and its side effects may be so difficult that it results in depression – if depression is not already present because of the stress of having cancer – and a desire to forego further treatments. Counseling may be necessary to help the woman through the experience of cancer treatment.

It has long been known that patients experience cognitive impairment, which is commonly known as "chemo-brain," during the time period when chemotherapy treatments are being given. Cognitive impairment manifests itself in many ways, including the inability to concentrate (which has many consequences, including inability to work, losing the train of thought in the middle of a sentence and the inability to follow or participate in a conversation), poor memory, using common words incorrectly, inability to find a word, inability to juggle multiple tasks, unsteady movement and poor hand-eye coordination. For some patients, cognitive impairment gradually clears up within six months or a year after chemotherapy ends. However, many patients still experience cognitive impairment two years or more after chemotherapy ends. During the last few years, more attention has been given to long-lasting cognitive impairment.[207]

[207] ACS, "Seeking Solution to 'Chemo-Brain,'" http://www.cancer.org/docroot/NWS/content/NWS_2_1x_Seeking_Solutions_to_Chemo-Brain.asp (October 22, 2004).

Antinausea drugs may be given along with each chemotherapy treatment in an attempt to alleviate nausea and vomiting. Antinausea medication may also be given in the form of pills to be taken as needed during the chemotherapy regimen. Premature menopause may be treated with hormone replacement therapy. Patients often sleep for exceptionally long periods of time, especially in the days following a chemotherapy treatment. This sleep is often therapeutic. Patients with loss of appetite are often told to "eat what you can when you can." This may help minimize weight loss.

To lower or eliminate the risk of infections, patients are often advised to avoid activities in which they may be accidentally cut or bruised (e.g., shaving with a razor blade and flossing). A simple paper cut can be dangerous for a chemotherapy patient. Patients must also avoid dental exams and treatment during the chemotherapy regimen, as germs easily enter the bloodstream during dental exams and procedures. For that reason, patients are often advised to have a thorough dental exam and have any necessary dental work done before chemotherapy begins. Patients should also stay away from individuals who are sick if at all possible, as any illness can be dangerous for a patient with a limited immune system. Because skin may become dry, sensitive and easily damaged during chemotherapy, patients are also advised of certain behaviors they should adopt, including keeping the feet covered and protected, staying out of the sun or covering the skin completely (including wearing gloves) and wearing a broad-brimmed hat when in the sun. Care must also be taken to keep the body clean; this involves thorough cleansing after each visit to the bathroom.

Injections may be given to boost both white and red blood cell counts. Improving white blood cell count reduces the risk of infection, and improving red blood cell count reduces shortness of breath and may reduce fatigue. However, not all patients can tolerate these drugs.

Making lists,[208] decreasing workload, avoiding multiple tasks and getting more sleep may help alleviate some of the symptoms of short-term cognitive impairment. Studies are in process to learn more about the causes of long-term cognitive impairment, who may be susceptible to it and how it can be treated or avoided.

[208] Making lists is not foolproof, as the patient may forget to write something down immediately after realizing it should be written down. The patient may also be unable to find a list, even if it is in plain view.

TREATMENT OPTIONS AND PROGNOSIS BY STAGE

Staging and the types of treatment available for cervical cancer were discussed in the preceding sections. This section explains which treatment options may be appropriately considered for each stage of cervical cancer. Stage of the cancer is the most important factor in deciding which treatment to use. Other factors include the exact location of the cancer, the type of cancer (squamous cell or adenocarcinoma), the patient's age, other physical conditions the patient has and whether the patient wants to have children.

A prognosis is a prediction regarding the probable outcome of disease. Where cancer is concerned, a prognosis predicts the chances of surviving the cancer for a certain period of time based on the past experience of numerous patients. Prognosis is sometimes expressed as a "cure rate." The cure rate basically states the percentage of past patients who were still alive five years after diagnosis.[209] Prognosis for cervical cancer is closely tied to the stage of the cancer at the time of diagnosis and treatment.

Each of the following subsections lists and discusses the treatment choices and possible prognoses for each stage of cervical cancer.

Stage 0

Loop electrosurgical excision procedure (LEEP)
Laser surgery
Conization
Cryosurgery
Simple hysterectomy
Internal radiation therapy

Any of the first four types of treatment may be appropriate for a patient with Stage 0 cervical cancer. Simple hysterectomy may be performed if the cancer returns, particularly for women who cannot or no longer want to have children. For women who cannot have surgery, internal radiation therapy may be used.

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[209] Patients who die of other diseases during the five years after their diagnosis are not included in determining five-year survival rates. Because a five-year survival rate is based on the outcomes for patients diagnosed five years before the rate is determined, the prognosis may actually be more favorable for newly diagnosed patients than the rate indicates due to possible improvements in treatment during those five years. American Cancer Society, *Cervical Cancer*, *supra* note 194.

All stage 0 cervical cancers are considered curable, making the prognosis excellent. However, the cancer can recur, so close follow-up care after treatment is important.

Stage IA

Simple hysterectomy with or without bilateral salpingo-oophorectomy
Conization
Radical hysterectomy and removal of lymph nodes
Internal radiation therapy

If the cancer is very superficial and the patient wants to have a child, conization is an option. However, close follow-up care is necessary, because the cancer can recur. The most common treatment for stage IA1 cervical cancer is simple hysterectomy. For stage IA2 cervical cancer, or if the cancer has spread to the blood or lymph systems, a radical hysterectomy and removal of lymph nodes in the pelvis is necessary. Tissue removed during hysterectomy will be examined to determine if the cancer has spread to the parametrium or lymph nodes or if it appears that some cancer was left behind. If any of these are found, radiation will likely be recommended. Radiation is also used if the patient cannot undergo surgery.

The five-year survival rate for patients treated at this stage is more than 95 percent.

Stage IB

Internal radiation therapy coupled with external radiation therapy
Radical hysterectomy and removal of lymph nodes
Radical hysterectomy and removal of lymph nodes followed by radiation therapy plus chemotherapy
Radiation therapy plus chemotherapy

There are two standard treatment options for stage IB cervical cancer. One is radical hysterectomy and removal of lymph nodes in the pelvis and a few lymph nodes higher up in the body to see if the cancer has spread. If cancer is found in the edges of the organs removed or in the lymph nodes, radiation therapy – possibly combined with chemotherapy – may be recommended. The other treatment option for stage IB cervical cancer is high-dose internal and external radiation. The treatment decision should be based on how the woman feels about the side effects of each treatment and whether she has any other medical conditions that might make surgery dangerous.

The cure rate for stage IB cervical cancer, using either treatment option, is about 85 percent to 90 percent. However, recent clinical trials show that combining radiation and chemotherapy with cisplatin, (a common chemotherapy drug), is more effective than radiation alone, prompting the National Cancer Institute to recommend that chemotherapy be considered for all patients receiving radiation for cervical cancer larger than four centimeters.

Stage IIA

Internal radiation therapy coupled with external radiation therapy
Radical hysterectomy and removal of lymph nodes
Radical hysterectomy and removal of lymph nodes followed by radiation therapy plus chemotherapy
Radiation therapy plus chemotherapy

There are two standard treatment options for stage IIA cervical cancer. The treatment most often recommended by doctors is high-dose internal and external radiation combined with chemotherapy with cisplatin. The other option, in cases where the cancer has not grown far into the vagina, is radical hysterectomy and removal of lymph nodes in the pelvis and a few lymph nodes higher up in the body to see if the cancer has spread. If cancer is found in the edges of the organs removed or in the lymph nodes, radiation therapy – possibly combined with chemotherapy – is usually recommended. The treatment decision should be based on how the woman feels about the side effects of each treatment and whether she has any other medical conditions that might make surgery or radiation dangerous.

The cure rate for stage IIA cervical cancer, using either treatment option, is about 75 percent to 80 percent. However, as noted above, recent clinical trials show that combining radiation and chemotherapy with cisplatin is more effective than radiation alone. Therefore, patients given radiation therapy after surgery may also be given chemotherapy with cisplatin or a combination of cisplatin and other drugs.

Stage IIB

Internal and external radiation therapy combined with chemotherapy

The usual treatment for stage IIB cervical cancer is combined internal and external radiation therapy. The cure rate for stage IIB cervical cancer, using combined internal and external radiation therapy is about 65 percent. However, recent clinical trials show that combining radiation and chemotherapy with

cisplatin is more effective than radiation alone. Therefore, patients receiving radiation therapy for stage IIB cervical cancer may also be given chemotherapy with cisplatin or a combination of cisplatin and other drugs.

Stages III and IVA

Internal and external radiation therapy combined with chemotherapy

Most doctors combine stages III and IVA together. Recent clinical trials have shown that combining radiation therapy with chemotherapy with cisplatin – and possibly other drugs – is more effective than radiation alone. The cure rate in the clinical trials of combined radiation therapy and chemotherapy was about 50 percent.[210] However, these trials did not include women whose cancer had spread to lymph nodes above the pelvis. The prognosis for them is not as bright.

Stage IVB

Palliative treatment[211] using radiation or chemotherapy

The current treatment for stage IVB cervical cancer is palliative treatment using radiation or chemotherapy. The intent of the treatment is to prolong life and improve the quality of life as much as possible.

The prognosis for stage IVB cervical cancer is not positive, as it is usually not considered curable. However, clinical trials of new anticancer drugs, drug combinations and other experimental treatments are being performed. For example, researchers are working to develop a vaccine that would help women who have advanced cervical cancer that has recurred or metastasized. The intent is to induce an immune reaction in the parts of the human papillomavirus that contribute to the abnormal growth of cervical cancer cells. The goal is for that immune reaction to kill the cancer cells or at least keep them from growing.[212]

Recurrent Cervical Cancer

Pelvic exenteration
Palliative treatment using radiation or chemotherapy

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[210] Combined internal and external radiation was the recommended treatment for stages III and IVA cervical cancer before the clinical trials, and the cure rate was as low as 20 percent to 40 percent.

[211] Palliative treatment is given to offer relief from symptoms when a cure is not expected.

[212] American Cancer Society, *Cervical Cancer*, *supra* note 194.

Recurrence means that the cancer has returned after treatment. The cancer may appear in the pelvic area or in other parts of the body, indicating that the disease spread through the blood or lymph system.

If cervical cancer has recurred only in the pelvis, the available treatments are pelvic exenteration or palliative treatment using radiation or chemotherapy. Pelvic exenteration may successfully treat the cancer in 40 percent to 50 percent of patients who undergo it.

If cervical cancer has recurred elsewhere in the body, palliative treatment using radiation or chemotherapy is considered the only option at this time. The intent of the treatment is to prolong life and improve the quality of life as much as possible. However, while chemotherapy improves the quality of life for some women, it diminishes the quality of life for others. It is estimated that about 15 percent to 25 percent of patients receive benefit from chemotherapy.

Clinical trials are underway to evaluate new treatments for women with distant recurrence of cervical cancer. As noted under stage IVB, research is underway to develop a vaccine that would kill or stop the growth of cervical cancer cells wherever they are in the body.

Cervical Cancer During Pregnancy

A small number of women who are pregnant are found to have cervical cancer. If the cancer is stage IA, most doctors believe the woman's life will not be endangered by continuing the pregnancy and then treating the woman for cancer. For stage IA1 cervical cancer, a cone biopsy may be performed several weeks after the woman gives birth. For most women, it will be recommended that a hysterectomy be performed several weeks after the birth.

If a pregnant woman is found to have stage IB cervical cancer, she must decide whether to continue the pregnancy. If she decides to continue the pregnancy, delivery should be done by cesarean section as soon as the baby is able to survive, and cancer treatment should begin as soon as possible after the delivery. If it is decided that the pregnancy should not continue, the treatment is a radical hysterectomy or radiation or both.

For cervical cancer beyond stage IB, immediate treatment offers the woman the best chance of surviving the cancer.

LEGISLATION

Federal and state legislation regarding cervical cancer addresses research, public education and awareness, and the provision of screening services to needy women. This chapter begins with an overview of selected federal statutes regarding cancer generally and a summary of federal statutes regarding cervical cancer. The section on federal enactments is followed by a brief summary of selected types of statutes regarding cervical cancer that have been enacted in other states. Next is a summary of Pennsylvania statutes that relate to cancer generally or to cervical cancer specifically. Finally, a proposal is provided for a bill to be introduced in Pennsylvania's coming legislative session.

FEDERAL ENACTMENTS

Selected Statutes Regarding Cancer Generally

National Cancer Institute Act of 1937: The National Cancer Institute Act of 1937 (P.L. 244) established the National Cancer Institute (NCI),[213] authorized annual funding for cancer research and established the National Advisory Cancer Council to review all research.[214] The federal statutes relating to the National Research Institutes originally related solely to the National Cancer Institute.[215] The director of the National Cancer Institute is appointed by the President, while

[213] National Cancer Legislation Advisory Committee (NCLAC). *National Cancer Policy Legislative History*, http://www.cancersource.com/nclac/leghistory.htm (October 22, 2004). NCLAC is a group of 21 experts formed to develop a comprehensive report of recommendations the federal government could follow in its role in the conquest of cancer. NCLAC's report *Conquering Cancer: A National Battle Plan to Eradicate Cancer in our Lifetime* included the input of more than 250 individuals, including cancer survivors, scientists, patient advocates, healthcare providers, leaders of non-profit organizations and biotechnology executives. NCLAC is co-chaired by Vincent T. DeVita Jr., M.D., Director of the Yale Comprehensive Cancer Center, and John R. Seffrin, Ph.D., Chief Executive Officer of the American Cancer Society. NCLAC, *Conquering Cancer: A National Battle Plan to Eradicate Cancer in our Lifetime*, September 10, 2001,
http://www.cancersource.com/nclac/NCLAC_report.pdf (November 1, 2004).

[214] HHS, NIH, NCI, *Closing in on Cancer*: *The National Cancer Institute is Founded*, http://press2.nci.nih.gov/sciencebehind/cioc/nci/nciframe.htm (November 3, 2004).

[215] "Historical and Statutory Notes" preceding 42 U.S.C.A. § 281.

the directors of the other national research institutes are appointed by the Secretary of the Department of Health and Human Services.[216]

National Cancer Act of 1971: The National Cancer Act of 1971 (P.L. 92-218) directed NCI to develop a coordinated national cancer research program,[217] authorized the first cancer centers and established the President's Cancer Panel and the National Cancer Advisory Board.[218] The function of the National Cancer Advisory Board is to advise the Secretary of the Department of Health and Human Services and the Director of the National Cancer Institute regarding their activities and to recommend certain grants and cooperative agreements after technical and scientific peer review.[219] The function of the President's Cancer Panel is to "monitor the development and execution of the activities of the National Cancer Program and report directly to the President."[220]

Cancer Control Month: In 1998, Congress passed a law asking the President to annually issue a proclamation designating April as Cancer Control Month.[221] The law also asks the President to invite the governors of the states to issue such proclamations.[222] Finally, Congress suggests that the President and governors invite the medical profession, the media and all agencies and individuals interested in a national cancer control program to "unite during Cancer Control Month in a public dedication to the program and in a concerted effort to make the people of the United States aware of the need for the program."[223]

Statutes Regarding Cervical Cancer

Breast and Cervical Cancer Mortality Prevention Act of 1990: The Breast and Cervical Cancer Mortality Prevention Act of 1990 (P.L. 101-354) amended the Public Health Service Act[224] by adding Title XV – Preventive Health

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[216] 42 U.S.C.A. § 284(a).
[217] HHS, NIH, NCI, *Closing in on Cancer: Molecular Biology Comes of Age*. http://press2.nci.nih.gov/sciencebehind/cioc/molecular/molecularframe.htm (November 3, 2004).
[218] NCLAC, *National Cancer Policy Legislative History*, *supra* note 214.
[219] HHS, NIH, NCI, "National Cancer Advisory Board: Charter Summary," http://deainfo.nci.nih.gov/advisory/ncabchr.htm (November 3, 2004).
[220] HHS, NIH, NCI, "President's Cancer Panel: Function Statement," http://deainfo.nci.nih.gov/advisory/pcp/pcpfo.htm (November 3, 2004).
[221] 36 U.S.C.A. § 103(a)(1).
[222] 36 U.S.C.A. § 103(a)(2).
[223] 36 U.S.C.A. § 103(b).
[224] 42 U.S.C.A. § 201 *et seq.*

Measures with Respect to Breast and Cervical Cancers. The Act authorized the Director of the Centers for Disease Control and Prevention (CDC) to make grants to states, based on a competitive review process, for the purpose of carrying out programs to do the following: screen women for breast and cervical cancer; provide referrals for medical treatment and ensure, to the extent practicable, provision of follow-up services; disseminate information and education programs about the detection and control of breast and cervical cancer; improve the education, training and skills of health professionals in the detection and control of breast and cervical cancer; monitor the quality of screening procedures; and evaluate the programs.[225] In order to accomplish the goals of the Act, CDC established the National Breast and Cervical Cancer Early Detection Program (NBCCEDP).[226]

Congress appropriated $150,000,000 for the grant program for fiscal year 2003.[227] In order to receive a grant, a state must agree to provide a matching contribution in cash or in kind of at least $1 for each $3 of federal funds provided.[228] Throughout the period of the grant, 60 percent or more of the grant must be expended to screen women for breast and cervical cancer and to provide referrals for medical treatment and ensure, to the extent practicable, the provision of follow-up services.[229] Screening for cervical cancer must include both a pelvic examination and "the screening procedure known as a Pap smear."[230] However, a state receiving a grant must agree that, if a screening procedure superior to a Pap smear is recommended and becomes commonly available, any entity providing screening procedures under the grant will use the superior procedure rather than the Pap smear.[231]

A grant may not be awarded to a state unless it agrees to give priority to the provision of services to low-income women[232] and agrees that, if a fee is imposed for services, the fee will be according to a schedule, will be adjusted to reflect the woman's income and will not be imposed on a woman with income below the poverty line established by the Office of Management and Budget.[233]

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[225] 42 U.S.C.A. § 300k(a).
[226] HHS, CDC, "2004/2005 Fact Sheet – The National Breast and Cervical Cancer Early Detection Program: Saving Lives Through Screening,"
http://www.cdc.gov/cancer/nbccedp/about 2004.htm (October 28, 2004).
[227] 42 U.S.C.A. § 300n-5.
[228] 42 U.S.C.A. § 300*l*(a).
[229] 42 U.S.C.A. § 300m(a)(1).
[230] 42 U.S.C.A. § 300m(a)(2)(B).
[231] 42 U.S.C.A. § 300m(b).
[232] 42 U.S.C.A. § 300n(a).
[233] 42 U.S.C.A. § 300n(b).

Upon the request of a state, supplies, equipment and services may be provided to the state in lieu of grant funds in an amount equal to the fair market value of the supplies, equipment and services plus the personnel costs involved.[234]

The Department of Health and Human Services is required to provide for annual evaluations of programs established under the Act[235] and annually submit a report summarizing the evaluations and making recommendations to specified standing committees of the Senate and House of Representatives.[236]

Intensified Research Regarding Breast and Gynecological Cancers: The National Institutes of Health Revitalization Act of 1993 (P.L. 103-43) required the National Cancer Institute to expand, intensify and coordinate its activities regarding research on breast cancer and gynecological cancers.[237] Among other things, NCI must conduct or support the following: research regarding the etiology and causes of the cancers; clinical research into the causes, prevention, detection and treatment of the cancers; and information and education programs regarding the cancers.[238] The director of NCI must prepare a report about these activities to be included in the biennial report submitted by the Department of Health and Human Services to the President and Congress.[239]

Breast and Cervical Cancer Prevention and Treatment Act of 2000: The Breast and Cervical Cancer Prevention and Treatment Act of 2000 (P.L. 106-354) makes treatment services more accessible to women enrolled in and screened through NBCCEDP.[240] The Act provides states the option of providing Medicaid coverage for the treatment of breast cancer, cervical cancer or a related precancerous condition for women who are not otherwise eligible for Medicaid, are under the age of 65 years, do not have creditable health insurance and have been screened through NBCCEDP.[241]

Breast and Cervical Cancer Information: Federal law provides that certain entities[242] receiving federal assistance must provide, to their clients as appropriate,

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[234] 42 U.S.C.A. § 300n-3(b)(2).
[235] 42 U.S.C.A. § 300n-4(a).
[236] 42 U.S.C.A. § 300n-4(b).
[237] 42 U.S.C.A. § 285a-6(a).
[238] 42 U.S.C.A. § 285a-6(d).
[239] 42 U.S.C.A. § 285a-6(e).
[240] HHS, CDC, "2004/2005 Fact Sheet," *supra* note 226.
[241] 42 U.S.C.A. § 1396a(aa) and 42 U.S.C.A. § 1396a(a)(10)(A)(ii)(XVIII).
[242] These entities include community health centers, migrant health centers and entities involved in the prevention, control and elimination of and public education about tuberculosis, sexually transmitted diseases and AIDS. 42 U.S.C.A. § 256d(c).

information about screening and treatment for breast and cervical cancer in the language and cultural context most appropriate for the client.[243]

OTHER STATES

All 50 states have implemented NBCCEDP and receive support from CDC for cervical cancer screening under the program.[244] All 50 states have also enacted statutes or adopted agency policies which use Medicaid or public assistance programs to provide testing for cervical cancer either on a routine basis or upon a physician's recommendation.[245] As of May of 2000, 23 states required private health insurers to cover testing for the early detection of cervical cancer.[246] In addition to these common statutes and policies, Maryland requires hospitals to offer all adult female inpatients a Pap test, unless the attending physician orders otherwise or the patient had a Pap test within the preceding year.[247]

PENNSYLVANIA

The Pennsylvania Cancer Law

The Act of August 14, 1963 (P.L. 824, No. 402) is known as "The Pennsylvania Cancer Law."[248] Among other things, Act 402 requires the Department of Health to investigate "any preparation, device or diagnostic procedure held out . . . to be of value in the diagnosis, treatment, mitigation or cure of cancer."[249] If the department determines that the subject of an investigation "is not efficacious in the diagnosis, treatment, mitigation or cure of cancer," it is required to order all persons to cease and desist manufacturing, selling, giving away, advertising, prescribing, recommending or using the subject of the investigation.[250] If the majority of the members of the Pennsylvania Advisory Health Board decide that "the use of any preparation or device in the diagnosis, treatment, mitigation or cure of cancer constitutes an imminent danger to health or a gross deception of the public, the department may take appropriate

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[243] 42 U.S.C.A. § 256d(b).
[244] HHS, CDC, "2004/2005 Fact Sheet," *supra* note 226.
[245] ACS, "Coverage for Cervical Cancer Early Detection Tests," http://www.cancer.org/docroot/mit/content/mit_3_2x_coverage_for_cervical_cancer_early_detection_tests.asp (October 28, 2004).
[246] Ibid.
[247] Md. Code Ann., Health – General, § 19-348.
[248] Act of August 14, 1963 (P.L. 824, No. 402), section 1. The act is hereafter referred to and cited as Act 402.
[249] Act 402, section 3(3).
[250] Act 402, section 4.

steps to publicize the same."[251] Act 402 also prohibits individuals who are not licensed physicians or licensed dentists from undertaking the diagnosis, treatment, mitigation or cure of cancer by the use of drugs, surgery or radiation.[252]

A violation of any of the provisions of Act 402 is a misdemeanor, punishable by either imprisonment for not more than one year or a fine of not more than $5,000 or both.[253] Third and subsequent violations are punishable by either imprisonment for not more than five years or a fine of not more than $10,000 or both.[254]

Pennsylvania Cancer Control, Prevention and Research Act

The Act of December 18, 1980 (P.L. 1241, No. 224) is known as the "Pennsylvania Cancer Control, Prevention and Research Act."[255] The Act created, in the Department of Health, the Pennsylvania Cancer Control, Prevention and Research Advisory Board.[256] The board consists of eleven members: the Secretary of Health and ten members, meeting specified requirements, appointed by the Governor with the consent of the Senate.[257] The board must meet at least four times each year.[258] Its duties include advising the Secretary of Health on cancer control, prevention and research in the Commonwealth;[259] recommending to the Secretary the award of grants and contracts in nine categories, including registry, screening, community outreach, rehabilitation, education and research;[260] and annually approving a program for cancer control, prevention and research to be known as the Pennsylvania Cancer Plan.[261]

A partnership of nearly 200 individuals with expertise in various areas, including cancer survivors, researchers and representatives of academia, government, non-profit organizations, insurers and the business and healthcare

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[251] Act 402, section 9.
[252] Act 402, section 5.
[253] Act 402, section 6(a).
[254] Act 402, section 6(b).
[255] Act of December 18, 1980 (P.L. 1241, No. 224), section 1. The act is hereafter referred to and cited as Act 224.
[256] Act 224, section 3(a).
[257] Ibid.
[258] Act 224, section 3(d).
[259] Act 224, section 4(b).
[260] Act 224, section 4(d) and (e). During the 2001-2002 fiscal year, $279,998 in state funds were awarded for breast and cervical cancer research. PADOH, *Cancer Prevention and Control Section, 2001-2002 Annual Report*, page 10, http://www.dsf.health.state.pa.us/health/lib/health/cancer/2002/CancerAnnualReport01-02.pdf (October 29, 2004).
[261] Act 224, section 4(c).

communities – called the Pennsylvania Cancer Control Consortium (PAC^3) – developed the cancer plan over the course of two years and released it in December of 2003.[262] The name of the plan has been expanded slightly from the Pennsylvania Cancer Plan, which was specified in Act 224, to the Pennsylvania Comprehensive Cancer Control Plan.[263]

The Pennsylvania Comprehensive Cancer Control Plan notes that the Centers for Disease Control and Prevention (CDC) defines "comprehensive cancer control" as an integrated and coordinated approach to reducing cancer incidence, morbidity and mortality through prevention, early detection, treatment, rehabilitation and palliation.[264] The seven priority goals of the plan fall under the categories of tobacco-free lifestyle and environment, physical activity and nutrition, skin cancer prevention and cervical cancer screening and follow-up.[265] The plan's goal for cervical cancer screening and follow-up is that "all women in Pennsylvania at higher risk for cervical cancer will have the knowledge and the resources to have Pap smears according to evidence-based guidelines and to receive appropriate follow-up of abnormal screening results."[266] Four objectives have been established to reach the goal: increasing the understanding women have regarding the importance of regular screening for cervical cancer, delivering effective health education programs to school-aged children, promoting educational campaigns targeting healthcare providers and family planning professionals about HPV and obtaining baseline information on risk behaviors and working with the CDC to implement the Youth Risk Behavior Surveillance System in all public school districts by 2005.[267]

Women's Preventative Health Services Act

The Act of April 22, 1994 (P.L. 136, No. 20) requires health insurance policies to provide coverage for an annual gynecological examination, including a pelvic examination and breast examination, and "[r]outine Pap smears in accordance with the recommendations of the American College of Obstetricians and Gynecologists."[268] The Act's declaration of policy states, among other things, that "[n]ine out of ten deaths from cervical cancer could be prevented if more women had regular Pap smears."[269]

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[262] PAC^3, *The Pennsylvania Comprehensive Cancer Control Plan*, *supra* note 158, page 2.
[263] Ibid.
[264] Ibid., page 4.
[265] Ibid., page 5.
[266] Ibid., page 22.
[267] Ibid.
[268] Act of April 22, 1994 (P.L. 136, No. 20), section 4. The act is hereafter referred to and cited as Act 20.
[269] Act 20, section 2(6).

Contribution of Income Tax Refund by Checkoff

The Act of March 4, 1971 (P.L. 6, No. 2), known as the Tax Reform Code of 1971, was amended in 1997 to allow individuals to check a box on the Pennsylvania individual income tax return form to designate part or all of the income tax refund due to be contributed for the specified purpose. One of the three checkoffs authorized in 1997 was for breast and cervical cancer research.[270] Each year, the Department of Revenue totals the amount designated for breast and cervical cancer research, keeps a reasonable amount to cover its administrative costs, and reports the remaining amount to the State Treasurer, who transfers the amount from the General Fund to the Pennsylvania Cancer Control, Prevention and Research Advisory Board established in the Department of Health under Act 224 (see above).[271] The Department of Revenue must also publicize the checkoff and include with the checkoff instructions an address to which contributions may be sent for by a taxpayer who is not due a refund.[272]

RECOMMENDED LEGISLATION

Senate Bill 1046, Pr.'s No. 1454, of 2004 proposes to establish a separate fund in the State Treasury, called the "Cancer Screening Fund," to be funded by appropriations.[273] The Department of Public Welfare would give an eligible claimant a voucher "obligating the department to pay the health care provider a stated amount[274] for performing a mammogram or a prostate specific antigen test.[275] To be eligible for a voucher, a claimant would have to earn "less than the income specified by regulations of the department," not be eligible for medical assistance, not have medical insurance coverage for the screening and be at least 40 years old for women and 50 years old for men.[276]

A bill modeled on Senate Bill 1046, to provide for screening for cervical cancer, should be considered during the coming legislative session.

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[270] Act of March 4, 1971 (P.L. 6, No. 2), section 315.2. The act is hereafter referred to and cited as Act 2. The other two checkoffs added to the individual income tax return form in 1997 are for the Wild Resource Conservation Fund, section 315.3, and the Olympics, section 315.5. The only other checkoffs added since 1997 allow contributions to the Governor Robert P. Casey Memorial Organ and Tissue Donation Awareness Trust Fund, section 315.4, and to the Korea/Vietnam Memorial National Education Center, section 315.6.

[271] Act 2, section 315.2(c).

[272] Act 2, section 315.2(d).

[273] Senate Bill 1046, Pr.'s No. 1454, of 2004, section 4. Hereafter referred to and cited as Senate Bill 1046.

[274] Senate Bill 1046, section 5(d).

[275] Senate Bill 1046, section 2.

[276] Senate Bill 1046, section 5(b).

RECOMMENDATIONS

Despite the declining numbers of diagnoses, cervical cancer remains a potentially deadly threat to women of all ages. A number of public health programs and initiatives are striving to continue to reduce the rate of incidence both across the U.S. and in Pennsylvania, but it seems that reductions in funding may affect their ability to reach vulnerable women. Without ongoing efforts to ensure that each woman receives regular gynecological care, the incidence of cervical cancer would surely increase. The primary cause of cervical cancer, HPV, is rampant and shows no signs of abating.

Experience has proven that cervical cancer is treatable if diagnosed early and medical intervention begins promptly. By some accounts, cervical cancer is the only cancer that is 100 percent curable if detected early and treated properly.

The report offers the following recommendations:

- The General Assembly should consider legislation modeled on 2004 SB1046, which would provide for state assistance for cervical cancer screening.

- The General Assembly should formally recognize by resolution the HealthyWoman Program in an effort to raise awareness of the importance of prevention and treatment of cervical cancer.

- The General Assembly should continue to fund the cervical cancer prevention and treatment efforts of the HealthyWoman Program and the contractors affiliated with it.

- The Department of Health should consider the merits of programmatically separating cervical cancer from breast cancer. In the experience of cervical cancer service providers, the public's widespread recognition of breast cancer can overshadow the significance of cervical cancer.

- The HealthyWoman Program should continue to develop initiatives aimed at serving women in minority populations, such as Latinos and the Amish, who are less likely to access regular gynecological care.

- Because many of the risk factors associated with cervical cancer begin to affect women early in their lives, the Department of Health should consider cervical health awareness programs aimed at females younger than those served by the HealthyWoman Program and its contractors.

APPENDICES

Appendix 1

PRINTER'S NO. 3912

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 745 Session of 2004

INTRODUCED BY HARHART, WEBER, MACKERETH, ADOLPH, BEBKO-JONES, BELARDI, BELFANTI, BISHOP, BOYD, BUNT, CAPPELLI, CORRIGAN, CRAHALLA, DALEY, DALLY, DeLUCA, DENLINGER, DeWEESE, DiGIROLAMO, DONATUCCI, EGOLF, FABRIZIO, FLEAGLE, FRANKEL, GABIG, GEIST, GILLESPIE, GINGRICH, GOODMAN, GRUCELA, HARHAI, HARPER, HENNESSEY, HERSHEY, JAMES, KENNEY, LAUGHLIN, LEACH, LEDERER, LEH, LEWIS, MAJOR, MARKOSEK, MELIO, MILLARD, S. MILLER, MUSTIO, PALLONE, PAYNE, PHILLIPS, PICKETT, PISTELLA, READSHAW, REICHLEY, ROBERTS, ROSS, RUBLEY, SATHER, SCAVELLO, SCHRODER, SEMMEL, SHANER, B. SMITH, STERN, R. STEVENSON, E. Z. TAYLOR, TIGUE, TRUE, TURZAI, WALKO, WATSON, WOJNAROSKI, YOUNGBLOOD AND YUDICHAK, MAY 25, 2004

REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES, MAY 25, 2004

A RESOLUTION

Directing the Joint State Government Commission to investigate and report on the prevalence and burden of cervical cancer.

WHEREAS, Cervical cancer is still a prevalent disease among women; and

WHEREAS, It is estimated that during 2003 about 12,200 women in the United States were diagnosed with cervical cancer; and

WHEREAS, It is estimated that during 2003 about 4,100 women died of cervical cancer; and

WHEREAS, Each year more than 5 million people acquire human papillomavirus, which is linked to cervical cancer in high-risk cases; and

WHEREAS, Because cervical cancer is often asymptomatic, it is

important to eliminate risk factors; and

WHEREAS, If found early, cervical cancer is highly curable, but testing is required for early detection; therefore be it

RESOLVED, That the House of Representatives direct the Joint State Government Commission to investigate and report on the prevalence and burden of cervical cancer, identify the risk factors and recommend appropriate steps toward creating awareness and elimination of this deadly disease; and be it further

RESOLVED, That the Joint State Government Commission report its findings and recommendations to the General Assembly by November 30, 2004.

Appendix 2

GLOSSARY

NCI = National Cancer Institute Dictionary of Cancer Terms
(http://www.cancer.gov/templates/db_alpha.aspx?expand=A)

Medicine.net = Medicine.net Medical Dictionary
http://www.medterms.com/script/main/hp.asp

Adenocarcinoma: Cancer that begins in cells that line certain internal organs and that have glandular (secretory) properties. [NCI]

Anesthesia: Drugs or substances that cause loss of feeling or awareness. Local anesthetics cause loss of feeling in a part of the body. General anesthetics put the person to sleep. [NCI]

Benign: Not cancerous. Benign tumors do not spread to tissues around them or to other parts of the body. [NCI]

Biopsy: The removal of cells or tissues for examination under a microscope. When only a sample of tissue is removed, the procedure is called an incisional biopsy or core biopsy. When an entire lump or suspicious area is removed, the procedure is called an excisional biopsy. When a sample of tissue or fluid is removed with a needle, the procedure is called a needle biopsy or fine-needle aspiration. [NCI]

Bladder: The organ that stores urine. [NCI]

Cancer: A term for diseases in which abnormal cells divide without control. Cancer cells can invade nearby tissues and can spread through the bloodstream and lymphatic system to other parts of the body. There are several main types of cancer. Carcinoma is cancer that begins in the skin or in tissues that line or cover internal organs. Sarcoma is cancer that begins in bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue. Leukemia is cancer that starts in blood-forming tissue such as the bone marrow, and causes large numbers of abnormal blood cells to be produced and enter the bloodstream. Lymphoma is cancer that begins in the cells of the immune system. [NCI]

Carcinoma in situ: Cancer that involves only the cells in which it began and that has not spread to nearby tissues. [NCI]

CAT scan: A series of detailed pictures of areas inside the body, taken from different angles; the pictures are created by a computer linked to an x-ray machine. Also called computerized axial tomography, computed tomography (CT scan), or computerized tomography. [NCI]

Catheter: A flexible tube used to deliver fluids into or withdraw fluids from the body. [NCI]

Cauterization: The destruction of tissue with a hot instrument, an electrical current, or a caustic substance. [NCI]

Cervical: Relating to the neck, or to the neck of any organ or structure. Cervical lymph nodes are located in the neck; cervical cancer refers to cancer of the uterine cervix, which is the lower, narrow end (the "neck") of the uterus. [NCI]

Cervical Dysplasia: Dysplasia is abnormal growth and development of the cells of the lining of the cervix. It can range from mild to moderate or severe depending on the spread of the abnormal cells. Severe cases can lead to cancer.[277]

Cervical intraepithelial neoplasia (CIN): A general term for the growth of abnormal cells on the surface of the cervix. Numbers from 1 to 3 may be used to describe how much of the cervix contains abnormal cells. [NCI]

Cervix: The lower, narrow end of the uterus that forms a canal between the uterus and vagina. [NCI]

Chemoradiotherapy: Treatment that combines chemotherapy with radiation therapy. Also called chemoradiation. [NCI]

Chlamydia: Chlamydia is a common sexually transmitted disease (STD) caused by the bacterium, Chlamydia trachomatis, which can damage a woman's reproductive organs.[278]

Clear-cell adenocarcinoma: A rare type of tumor, usually of the female genital tract, in which the inside of the cells look clear when viewed under a microscope. Also called clear cell carcinoma and mesonephroma. [NCI]

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[277] Walter Reed Army Medical Center, *Women's Health, Cervical Dysplasia,* http://www.wramc.amedd.army.mil/education/pat_edu/womenhlth/Cervical/Dysplasia.htm (November 10, 2004).

[278] HHS, CDC, STD Prevention, Chlamydia, http://www.cdc.gov/std/Chlamydia/STDFact-Chlamydia.htm#WhatIs (September 29, 2004).

Clinical trial: A type of research study that uses volunteers to test new methods of screening, prevention, diagnosis, or treatment of a disease. The trial may be carried out in a clinic or other medical facility. Also called a clinical study. [NCI]

Colposcope: A lighted magnifying instrument used for examination of the vagina and cervix. [NCI]

Colposcopy: Examination of the vagina and cervix using a lighted magnifying instrument called a colposcope. [NCI]

Condylomata acuminate: Genital warts caused by certain human papillomaviruses (HPVs).

Cone biopsy: See conization. [NCI]

Conization: Surgery to remove a cone-shaped piece of tissue from the cervix and cervical canal. Conization may be used to diagnose or treat a cervical condition. Also called cone biopsy. [NCI]

Corpus: The body of the uterus. [NCI]

Cryosurgery: Treatment performed with an instrument that freezes and destroys abnormal tissues. [NCI]

Cyst: A sac or capsule in the body. It may be filled with fluid or other material. Cysts are almost always benign. [NCI]

Cystoscopy: Examination of the bladder and urethra using a thin, lighted instrument (called a cystoscope) inserted into the urethra. Tissue samples can be removed and examined under a microscope to determine whether disease is present. [NCI]

Diathermy: The use of heat to destroy abnormal cells. Also called cauterization or electrodiathermy. [NCI]

Diethylstilbestrol (DES): A synthetic form of the hormone estrogen that was prescribed to pregnant women between about 1940 and 1971 because it was thought to prevent miscarriages. DES may increase the risk of uterine, ovarian, or breast cancer in women who took it. DES also has been linked to an increased risk of clear cell carcinoma of the vagina or cervix in daughters exposed to DES before birth. [NCI]

Dilation and curettage (D&C): A minor operation in which the cervix is expanded enough (dilation) to permit the cervical canal and uterine lining to be

scraped with a spoon-shaped instrument called a curette (curettage). Also called dilatation and curettage. [NCI]

Douche: A procedure in which water or a medicated solution is used to clean the vagina and cervix. [NCI]

Epithelial: Refers to the cells that line the internal and external surfaces of the body. [NCI]

Endocervical curettage: The scraping of the mucous membrane of the cervical canal using a spoon-shaped instrument called a curette. [NCI]

Endometrium: The layer of tissue that lines the uterus. [NCI]

Estrogen: A hormone that promotes the development and maintenance of female sex characteristics. [NCI]

Fallopian tube: Part of the female reproductive tract. There are two long slender fallopian tubes through which eggs pass from the ovaries to the uterus. [NCI]

Glandular cells: Cells that secrete substances and are porous to allow substances To pass through to the organs that lay below. Glandular cells in the cervix secret cervical mucousa.[279]

Gynecologic: Having to do with the female reproductive tract (including the cervix, endometrium, fallopian tubes, ovaries, uterus, and vagina). [NCI]

Gynecologic cancer: Cancer of the female reproductive tract, including the cervix, endometrium, fallopian tubes, ovaries, uterus, and vagina. [NCI]

Gynecologic oncologist: A doctor who specializes in treating cancers of the female reproductive organs. [NCI]

Gynecologist: A doctor who specializes in treating diseases of the female reproductive organs. [NCI]

Human Immunodeficiency Virus (HIV): The cause of acquired immunodeficiency syndrome (AIDS). [NCI]

Human Papillomavirus Virus (HPV): A virus that causes abnormal tissue growth (warts). Some types of HPV are associated with cervical and other types of cancer. [NCI]

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[279] Henderson et al., *supra* note 5.

Hysterectomy: An operation in which the uterus is removed. [NCI]

Intraepithelial: Within the layer of cells that form the surface or lining of an organ. [NCI]

Intravenous pyelogram (IVP): A series of x-rays of the kidneys, ureters, and bladder. The x-rays are taken after a dye is injected into a blood vessel. The dye is concentrated in the urine, which outlines the kidneys, ureters, and bladder on the x-rays. [NCI]

Invasive cervical cancer: Cancer that has spread from the surface of the cervix to tissue deeper in the cervix or to other parts of the body. [NCI]

Laser surgery: A surgical procedure that uses the cutting power of a laser beam to make bloodless cuts in tissue or to remove a surface lesion such as a tumor. [NCI]

Lesion: An area of abnormal tissue. A lesion may be benign (noncancercous) or malignant (cancerous). [NCI]

Liver: A large organ located in the upper abdomen. The liver cleanses the blood and aids in digestion by secreting bile. [NCI]

Local therapy: Treatment that affects cells in the tumor and the area close to it. [NCI]

Lymph node: A rounded mass of lymphatic tissue that is surrounded by a capsule of connective tissue. Lymph nodes filter lymph (lymphatic fluid), and they store lymphocytes (white blood cells). They are located along lymphatic vessels. Also called a lymph gland. [NCI]

Lymphatic system: The tissues and organs that produce, store, and carry white blood cells that fight infections and other diseases. This system includes the bone marrow, spleen, thymus, lymph nodes, and lymphatic vessels (a network of thin tubes that carry lymph and white blood cells). Lymphatic vessels branch, like blood vessels, into all the tissues of the body. [NCI]

Magnetic resonance imaging (MRI): A procedure in which radio waves and a powerful magnet linked to a computer are used to create detailed pictures of areas inside the body. These pictures can show the difference between normal and diseased tissue. MRI makes better images of organs and soft tissue than other scanning techniques, such as CT or x-ray. MRI is especially useful for imaging the brain, spine, the soft tissue of joints, and the inside of bones. Also called nuclear magnetic resonance imaging. [NCI]

Malignant: Cancerous. Malignant tumors can invade and destroy nearby tissue and spread to other parts of the body. [NCI]

Menopause: The time of life when a woman's menstrual periods stop permanently. Also called "change of life." [NCI]

Metastasis: The spread of cancer from one part of the body to another. A tumor formed by cells that have spread is called a “metastatic tumor” or a “metastasis.” The metastatic tumor contains cells that are like those in the original (primary) tumor. The plural form of metastasis is metastases. [NCI]

Oral Contraceptives: A birth control pill taken by mouth. Most oral contraceptives include both estrogen and progesterone. When given in certain amounts and at certain times in the menstrual cycle, these hormones prevent the ovary from releasing an egg for fertilization. [Medicine.net]

Ovary: One of a pair of female reproductive glands in which the ova, or eggs, are formed. The ovaries are located in the pelvis, one on each side of the uterus. [NCI]

Pap smear: The collection of cells from the cervix for examination under a microscope. It is used to detect changes that may be cancer or may lead to cancer, and can show noncancerous conditions, such as infection or inflammation. Also called a Pap test. [NCI]

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Pathologist: A doctor who identifies diseases by studying cells and tissues under a microscope. [NCI]

Physician Data Query (PDQ): PDQ is an online database developed and maintained by the National Cancer Institute. Designed to make the most current, credible, and accurate cancer information available to health professionals and the public, PDQ contains peer-reviewed summaries on cancer treatment, screening, prevention, genetics, and supportive care; a registry of cancer clinical trials from around the world; and directories of physicians, professionals who provide genetics services, and organizations that provide cancer care. Most of this information is available on the Cancer.gov Web site. More specific information about PDQ can be found at http://cancer.gov/cancer_information/pdq/. [NCI]

Polyp: A growth that protrudes from a mucous membrane. [NCI]

Precancerous: A term used to describe a condition that may (or is likely to) become cancer. Also called premalignant. [NCI]

Progesterone: A female hormone. [NCI]

Prognosis: The likely outcome or course of a disease; the chance of recovery or recurrence. [NCI]

Radiation: Energy released in the form of particles or electromagnetic waves. Common sources of radiation include radon gas, cosmic rays from outer space, and medical x-rays. [NCI]

Radiation oncologist: A doctor who specializes in using radiation to treat cancer. [NCI]

Radiation therapy: The use of high-energy radiation from x-rays, gamma rays, neutrons, and other sources to kill cancer cells and shrink tumors. Radiation may come from a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy, implant radiation, or brachytherapy). Systemic radiation therapy uses a radioactive substance, such as a radiolabeled monoclonal antibody, that circulates throughout the body. Also called radiotherapy. [NCI]

Rectum: The last several inches of the large intestine. The rectum ends at the anus. [NCI]

Remission: A decrease in or disappearance of signs and symptoms of cancer. In partial remission, some, but not all, signs and symptoms of cancer have disappeared. In complete remission, all signs and symptoms of cancer have disappeared, although cancer still may be in the body. [NCI]

Sexually Transmitted Disease (STD): See Sexually Transmitted Infection (STI).

Side effect: A problem that occurs when treatment affects tissues or organs other than the ones being treated. Some common side effects of cancer treatment are fatigue, pain, nausea, vomiting, decreased blood cell counts, hair loss, and mouth sores. [NCI]

Speculum: An instrument used to widen an opening of the body to make it easier to look inside. [NCI]

Squamous cells: Flat cell that looks like a fish scale under a microscope. These cells cover inside and outside surfaces of the body. They are found in the tissues

that form the surface of the skin, the lining of the hollow organs of the body (such as the bladder, kidney, and uterus), and the passages of the respiratory and digestive tracts [NCI]

Squamous cell carcinoma: Cancer that begins in squamous cells, which are thin, flat cells that look like fish scales. Squamous cells are found in the tissue that forms the surface of the skin, the lining of the hollow organs of the body, and the passages of the respiratory and digestive tracts. Also called epidermoid carcinoma. [NCI]

Squamous intraepithelial lesion (SIL): A general term for the abnormal growth of squamous cells on the surface of the cervix. The changes in the cells are described as low grade or high grade, depending on how much of the cervix is affected and how abnormal the cells appear. [NCI]

Sexually Transmitted Infection (STI): An infection that can be transmitted from one person to another through sexual contact. STI corresponds to and is meant to replace the older term sexually transmitted disease (STD).

Stage 0 cervical cancer: Cancer is found in the first layer of cells lining the cervix only and has not invaded the deeper tissues of the cervix. Also called carcinoma in situ. [NCI]

Stage I cervical cancer: Cancer is found in the cervix only. Stage I is divided into stages IA and IB, based on the amount of cancer that is found. In stage IA, a very small amount of cancer that can only be seen with a microscope is found in the tissues of the cervix. The cancer is not deeper than 5 millimeters and not wider than 7 millimeters. In stage IB, the cancer is still within the cervix and either (1) can only be seen with a microscope and is deeper than 5 millimeters or wider than 7 millimeters; or (2) can be seen without a microscope and may be larger than 4 centimeters. [NCI]

Stage II cervical cancer: Cancer has spread beyond the cervix but not to the pelvic wall (the tissues that line the part of the body between the hips). Stage II is divided into stages IIA and IIB, based on how far the cancer has spread. In stage IIA, cancer has spread to the upper two thirds of the vagina but not to tissues around the uterus. In stage IIB, cancer has spread to the upper two thirds of the vagina and to the tissues around the uterus. [NCI]

Stage III cervical cancer: Cancer has spread to the lower third of the vagina and may have spread to the pelvic wall (the tissues that line the part of the body between the hips), and nearby lymph nodes. Stage III is divided into stages IIIA and IIIB, based on now far the cancer has spread. In stage IIIA, cancer has spread to the lower third of the vagina but not to the pelvic wall. In stage IIIB, cancer has

spread to the pelvic wall and/or the tumor has become large enough to block the ureters (the tubes that connect the kidneys to the bladder). This blockage can cause the kidneys to enlarge or stop working. Cancer may also have spread to lymph nodes in the pelvis. [NCI]

Stage IV cervical cancer: Cancer has spread to the bladder, rectum, or other parts of the body. Stage IV is divided into stages IVA and IVB. In stage IVA, cancer has spread to the bladder or rectal wall and may have spread to lymph nodes in the pelvis. In stage IVB, cancer has spread beyond the pelvis and pelvic lymph nodes to other places in the body, such as the abdomen, liver, intestinal tract, or lungs. [NCI]

Staging: Performing exams and tests to learn the extent of the cancer within the body, especially whether the disease has spread from the original site to other parts of the body. It is important to know the stage of the disease in order to plan the best treatment. [NCI]

Surgery: A procedure to remove or repair a part of the body or to find out whether disease is present. An operation. [NCI]

Systemic: Affecting the entire body. [NCI]

Systemic chemotherapy: Treatment with anticancer drugs that travel through the bloodstream, reaching and affecting cells all over the body. [NCI]

Systemic therapy: Treatment using substances that travel through the bloodstream, reaching and affecting cells all over the body. [NCI]

Tumor: A mass of excess tissue that results from abnormal cell division. Tumors perform no useful body function. They may be benign (not cancerous) or malignant (cancerous). [NCI]

Ultrasonography: A procedure in which high-energy sound waves (ultrasound) are bounced off internal tissues or organs and make echoes. The echo patterns are shown on the screen of an ultrasound machine, forming a picture of body tissues called a sonogram. Also called ultrasound. [NCI]

Uterus: The small, hollow, pear-shaped organ in a woman's pelvis. This is the organ in which a fetus develops. Also called the womb. [NCI]

Vagina: The muscular canal extending from the uterus to the exterior of the body. Also called the birth canal. [NCI]

Wart: A raised growth on the surface of the skin or other organ. [NCI]

X-ray: A type of high-energy radiation. In low doses, x-rays are used to diagnose diseases by making pictures of the inside of the body. In high doses, x-rays are used to treat cancer. [NCI]