

The Cervical Cancer Vaccine: Coming Soon To a Doctor's Office Near You

The world's first cervical cancer vaccine is likely to arrive shortly in physicians' offices across the nation, thanks to two recent federal government endorsements. The vaccine represents an important public health advance for women in the United States, by promising to significantly reduce the incidence of cervical cancer, which currently affects nearly 10,000 women and results in 3,700 deaths each year. The vaccine is expected to have a far greater impact in resource-poor developing countries, where the incidence rates of cervical cancer are higher and where the disease is far more lethal.

On June 8, the U.S. Food and Drug Administration (FDA) approved the vaccine, known as Gardasil, as safe and effective for use among females aged 9–26. Manufactured by Merck & Company, the vaccine is virtually 100% effective in preventing infection with the types of human papillomavirus (HPV) associated with 70% of all cervical cancer cases and 90% of all cases of genital warts. HPV is an extremely common sexually transmitted infection that can lead to cervical cancer in the small proportion of cases in which a persistent infection is left untreated over many years. To achieve maximum effectiveness, the vaccine should be administered to girls and young women prior to initiation of sexual activity (related article, Winter 2006, page 6).

Three weeks after the FDA's approval, the federal Advisory Committee on Immunization Practices (ACIP), affiliated with the Centers for Disease Control and Prevention, exercised its authority to issue recommendations regarding vaccine administration and to maintain the nation's schedule of recommended vaccines. According to ACIP, the vaccine should be routinely administered to all girls aged 11–12, and to those as young as nine at a physician's discretion. In addition, ACIP recommended that two other groups of girls and women receive the vaccine: those aged 13–26 who have not been vaccinated, and those who have had abnormal Pap smears, genital warts or certain other conditions. Furthermore, ACIP voted to include Gardasil in the federal Vaccines for Children program, which provides free vaccines to certain low-income uninsured and underinsured children.

Immediately following the ACIP proceedings, at least two major nationwide insurers, Aetna and WellPoint, announced that they will cover the vaccine for the categories of girls and women included within the ACIP recommendations. In addition, Merck has announced a patient assistance program designed to provide free vaccines to uninsured adults with limited incomes visiting private physicians. (To receive free vaccines, patients will need to complete and fax forms from participating doctors' offices for processing by Merck

during the patients' visit.) Still, significant barriers to ensuring universal uptake of the vaccine remain: the relatively high cost of the vaccine, which is expected to run \$360 for the full three-dose course; the difficulty of providing individuals with the required three shots over a six-month period; and the historic challenge of reaching the target population—adolescents—through immunization programs. It will be up to the states to decide whether the vaccine will be required for students to enroll in school.

In a related development, a study published in June in the *New England Journal of Medicine* found that consistent condom use reduces the risk of HPV infection—something which had been an open question due to the fact that HPV is transmitted through skin-to-skin contact rather than through bodily fluids. According to the study, which followed more than 80 female college students at the University of Washington in Seattle who had recently become sexually active, those whose male partners used condoms every time they had sexual intercourse had less than half the infection rate of those whose partners used condoms less than 5% of the time. The study should help put to rest long-standing questions raised in both political and public health circles about condoms' ability to offer protection against HPV infection.

—Cynthia Dailard

New Medicaid Requirement to Prove Citizenship Seen as Threat to Coverage and Care

A new law, effective July 1, requires states to ensure that Medicaid enrollees who claim to be citizens provide documentary proof. The provision, enacted in February as part of the Deficit Reduction Act, is intended to prevent the “theft of Medicaid benefits by illegal aliens,” according to Rep. Charlie Norwood (R-GA), one of its lead proponents. Many health care advocates, however, assert that it threatens to delay or deny Medicaid coverage and critical services for millions of low-income American citizens.

After months of speculation and leaks, the Centers for Medicare and Medicaid Services (CMS) waited until June 9—just three weeks before the effective date—to issue a letter of guidance to the states on how to implement the new requirement. The guidelines stipulated a tiered list of documentation that states must request of both new applicants and existing recipients to prove citizenship and identity. Passports top the list, even though many low-income people do not possess one. Presenting a birth certificate, along with a driver’s license or similar photo identification, would qualify as second-tier documentation. For cases when those or similar documents are unavailable, the guidance laid out additional possibilities, but labeled them as less reliable and warned states that CMS would audit

their use of such options. Under prior law, legal noncitizens had to provide documentation of their status, but most states allowed citizens to attest to their status, without proof but under the penalty of perjury.

A week after the effective date, CMS formalized and in some ways eased these requirements by issuing interim final regulations. Notably, the regulations make clear that states may assist Medicaid applicants and recipients by using data matches with

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government agencies to document citizenship and identity—for example, checking the computer records of the state’s vital statistics agency in lieu of obtaining a birth certificate. In addition, the regulations exempt from the requirement millions of elderly and disabled Americans who have already proven their citizenship before receiving Medicare or Supplemental Security Income.

The delay in issuing any guidance and the Bush administration’s unexpectedly strict interpretation of the law left states scrambling to meet the July 1 deadline. Officials in at least two states, California and Ohio, announced that they would delay

implementation of the policy, risking the loss of their federal Medicaid funds; New Mexico will put off recertifying eligibility for current Medicaid recipients, limiting the immediate impact of the law to new applicants. In Congress, Sen. Daniel Akaka (D-HI) introduced a bill to push back implementation until next year.

For their part, health care advocates lauded the new options allowed under the formal regulations, but asserted that millions of Americans

could still be forced to delay needed care or even lose Medicaid coverage because of time, cost and other barriers to obtaining acceptable documentation. A study by the Center on Budget and Policy Priorities, revised in July in response to the regulations, estimated that between 1.2 million and 2.3 million U.S.-born citizens, mostly children, could experience serious problems. In response to the law, the Sargent Shriver National Center on Poverty Law filed a class-action lawsuit in federal court on June 28, arguing that “American citizens are about to have their health coverage denied for unconstitutional reasons.”

—Adam Sonfield

One Million New Women in Need of Publicly Funded Contraception

Between 2000 and 2004, the number of U.S. women in need of publicly funded contraceptive services and supplies increased by 6%—more than one million women—to a total of 17.4 million (see table). The overall number of women in need of contraception, regardless of financial need, increased only marginally, suggesting that broader economic trends of the period, rather than population growth, have driven the change. The increasing need for subsidized family planning comes at a time when the very programs that provide these services are facing serious economic and political challenges.

Women are defined as being in need of contraceptive services and supplies if they are of reproductive age (13–44), have ever had sexual intercourse, and are able to become pregnant but do not wish to do so. Those with an income below 250% of the federal poverty level or who are younger than 20 (and thus presumed to have a low personal income) are considered in need of publicly funded contraception.

These trends, from a Guttmacher Institute analysis released in July 2006 and funded by the Department of Health and Human Services, point toward an especially rapid increase in need for family planning services among the nation's poorest women. Over the four-year period, growth in the number of women in need was four times greater—15% compared with 3%—among those with incomes under the federal poverty line (\$15,670 in 2004) than among those with slightly higher incomes (100–250% of

poverty). Meanwhile, the number above 250% of poverty (and not deemed in need of subsidized care) actually declined by 3%. Forty-one states experienced an increase between 2000 and 2004 in the number of women in need of publicly funded contraceptive services.

The same economic difficulties that seem to have driven these trends have also posed serious budgetary problems for the federal government and, especially, the states (related articles, August 2004, page 6, and December 2001, page 8). Together with the ascendancy of conservative ideology, these difficulties threaten to undermine the public programs, such as Medicaid and the Title X family planning program, that provide the funding necessary to meet this growing need for subsidized contraceptive services and supplies (related article, February 2005, page 4). Notably, changes to Medicaid law enacted in February 2006 allow states, for the first time since 1972, to exclude family planning from the package of services offered to some Medicaid recipients (related article, Spring 2006, page 2). Notably, these trends also come at the same time as the rate of abortion in the United States has essentially stagnated after a decade of steady decline (related article, page 2).—*Adam Sonfield*

SUDDEN SPIKE

Between 2000 and 2004, the number of women in need of publicly funded contraceptive services and supplies increased by over one million.

Women in need of publicly funded contraception

	2000	2004	% change
U.S. TOTAL	16,396,050	17,396,650	6.1
Alabama	275,750	282,320	2.4
Alaska	32,230	30,960	-3.9
Arizona	314,600	360,220	14.5
Arkansas	165,250	166,250	0.6
California	2,110,740	2,316,550	9.8
Colorado	229,000	244,430	6.7
Connecticut	161,100	174,690	8.4
Delaware	39,760	44,930	13.0
Dist. of Columbia	41,260	37,440	-9.3
Florida	848,380	895,150	5.5
Georgia	472,120	522,940	10.8
Hawaii	61,390	59,920	-2.4
Idaho	80,360	86,940	8.2
Illinois	694,420	721,980	4.0
Indiana	357,070	374,930	5.0
Iowa	168,760	174,730	3.5
Kansas	157,410	166,230	5.6
Kentucky	240,430	253,850	5.6
Louisiana	309,360	298,230	-3.6
Maine	78,700	82,030	4.2
Maryland	243,480	267,650	9.9
Massachusetts	333,710	328,250	-1.6
Michigan	562,410	610,790	8.6
Minnesota	253,250	271,860	7.3
Mississippi	194,380	190,550	-2.0
Missouri	342,080	365,440	6.8
Montana	54,990	55,010	0.0
Nebraska	102,430	111,680	9.0
Nevada	110,030	143,780	30.7
New Hampshire	62,840	63,520	1.1
New Jersey	395,100	398,050	0.7
New Mexico	127,390	132,570	4.1
New York	1,195,150	1,232,660	3.1
North Carolina	455,030	505,640	11.1
North Dakota	41,810	41,370	-1.1
Ohio	657,860	678,040	3.1
Oklahoma	217,250	212,550	-2.2
Oregon	196,920	217,410	10.4
Pennsylvania	715,330	740,470	3.5
Rhode Island	66,370	72,980	10.0
South Carolina	244,440	279,820	14.5
South Dakota	47,370	51,860	9.5
Tennessee	331,390	338,290	2.1
Texas	1,303,550	1,416,570	8.7
Utah	147,120	159,280	8.3
Vermont	37,550	35,300	-6.0
Virginia	365,760	386,980	5.8
Washington	318,990	339,020	6.3
West Virginia	110,200	104,270	-5.4
Wisconsin	294,440	320,710	8.9
Wyoming	29,340	29,560	0.7

Source: Guttmacher Institute, 2006.