The Health and Economic Burden of Genital Warts in a Set of Private Health Plans in the United States

Ralph P. Insinga,1 Erik J. Dasbach,2 and Evan R. Myers3
1Department of Population Health Sciences, University of Wisconsin–Madison; 2Department of Health Economic Statistics, Merck Research Laboratories, Blue Bell, Pennsylvania; and 3Department of Obstetrics and Gynecology, Duke University Medical Center, Durham, North Carolina

We estimated the prevalence of and costs associated with genital warts among privately insured individuals from the perspective of a private health plan in the United States. Health care claims data were derived from a sample of 3,664,686 privately insured individuals. The database was limited to cases of disease for which an insurance claim was generated, with costs reflecting inpatient, outpatient, and pharmacy payments from all sources. We identified 5095 cases of genital warts (1.7 cases per 1000 person-years) billed through the health plans during 2000. The prevalences of and health plan costs associated with genital warts were highest among women aged 20–24 years (6.2 cases and $1692 in costs per 1000 person-years) and men aged 25–29 years (5.0 cases and $1717 in costs per 1000 person-years). On average, individual episodes of care for genital warts involved 3.1 physician visits and incurred costs of $436. These are the first age- and sex-specific estimates of the prevalence and cost of genital warts for a US health plan.

Genital warts (condyloma acuminatum) are caused by infection with the human papillomavirus (HPV), which is estimated to be the most commonly occurring sexually transmitted disease (STD) in the United States [1]. Clinical symptoms, when present, may include itching, burning, and tenderness at the wart site and anal, urethral, or vaginal bleeding or discharge [2]. In addition, the diagnosis and treatment of genital warts have been found to produce anxiety, embarrassment, anger, and shame among patients and to negatively affect sexual enjoyment and activity [3–5].

In treatment settings, genital warts are seen regularly at STD clinics, where 4%–13% of patients have been found to manifest them [6]. A lower prevalence was reported among women aged 16–50 years who attended a university student health clinic during 1984–1987 (1.5%) and among women aged 21–29 years who were examined through a Washington state health management organization (HMO) in 1984 (0.8%) [6]. Very few studies, however, have assessed the diagnosis of genital warts in a broader population within a general health care setting. The most recent study of the incidence of genital warts in a general population in the United States reported an overall rate in the Rochester, Minnesota, area of 1.1 cases per 1000 persons during 1975–1978 [2].

Data on genital wart–associated costs in general health care settings are similarly limited. To date, no study has estimated the actual costs incurred in providing genital wart care within a general US patient population. A number of studies have attempted to model the costs of various genital wart therapies, often on the basis of data from clinical trials [7–9]. Modeled cost estimates may not be generalizable to clinical settings, however, because they may not reflect actual practice patterns, rates of adherence to therapy, and the
frequency with which the myriad of available genital wart therapies are used individually and in combination [10]. In the present study, we examine the prevalences of and costs associated with genital warts among privately insured individuals generating claims within a set of health plans in the United States.

METHODS

Data for the year 2000 were derived from the Medstat Marketscan database, which contains information on inpatient, outpatient, and pharmacy claims for 3,664,686 privately insured individuals in the United States. The scope of the database was limited to cases of disease for which a health insurance claim was generated, with analyses conducted from the perspective of a private health plan. Thus, data for privately insured individuals with undiagnosed genital warts and for those who seek treatment without insurance reimbursement in other settings, such as STD clinics, are not captured by this database.

We developed a case definition encompassing both external and internal genital warts by use of the diagnosis codes of the International Classification of Diseases, Ninth Revision (ICD-9), and Current Procedural Terminology (CPT) procedure codes. The steps used for selecting genital wart cases for the analyses of prevalence, physician visits, and costs are summarized in figure 1 and are described in detail in the remainder of this section.

As has been reported elsewhere [11], 3 different ICD-9 codes are alternately used for billing for genital wart care (078.11, for condyloma acuminatum; 078.10, for viral warts, unspecified; and 078.19, for other specified viral warts). All 3 codes are specific to warts caused by HPV; however, although ICD-9 code 078.11 is specific to genital warts, the other 2 codes are also commonly used to denote other wart types, including flat warts and plantar warts. The prevalence of genital warts was estimated in 4 steps on the basis of this coding schema.

Prevalence. We tabulated data on the following individuals: (1) those with a principal or secondary genital wart—
performed to enhance generalizability.

Health plan costs. The age- and sex-specific health plan costs associated with genital wart care in 2000 were estimated per 1000 person-years for individuals with a confirmed genital wart diagnosis code of 078.11 (condyloma acuminatum). This subset of patients was chosen to reflect a balanced distribution of individuals with and without a genital-specific procedure code. Costs reflect payments from all sources (including patient copayments) for medical services and drugs commonly prescribed to treat genital warts (i.e., imiquimod, fluorouracil, podoflox, and podophyllin) [10]. Cost data were obtained from outpatient, inpatient, and pharmacy records.

The cost analysis was restricted to 1919 individuals with a genital wart–specific diagnosis code of 078.11 (condyloma acuminatum) and fee-for-service medical and prescription drug coverage through their health plan. Individuals with capitated insurance coverage through an HMO were excluded from this analysis because the source and methods used for deriving cost data for these persons could not be verified. Those without prescription drug coverage through their health care plan were excluded, because data on insurance and out-of-pocket payments for individuals who obtain prescription drug coverage through a different plan or who lack coverage are not included in the Medstat database; inclusion of data on these persons would lead to an underestimation of costs for the study group.

Individual episodes of care. An “individual episode of care” for genital warts was defined as an episode preceded by a 12-month interval free of genital wart care, and the episode ended once a 12-month interval had lapsed without evidence of a genital wart diagnosis or pharmacy code. To allow for an adequate window of observation, cases were selected from the 1998 Medstat population. Selection criteria for cases (n = 536) were the same as the criteria used in the analysis of health plan costs, with the additional requirement that an individual’s health plan and insurance enrollment be recorded in the Medstat database for the period of 1997–2000. Estimates of the mean duration, the mean number of physician visits, and the mean costs associated with individual episodes of care for genital warts are reported for male and female subjects, along with the percentage of cases treated with patient-applied therapies (imiquimod and podoflox) versus physician-applied therapies (all other therapies). Costs were adjusted to 2002 US dollars with use of the medical care component of the Consumer Price Index [14].

RESULTS

Genital wart prevalence estimates (per 1000 person-years) are shown in table 1. The 3,664,686 individuals in the 2000 Medstat population contributed 3,076,474 person-years and accounted for an estimated 5095 cases of genital warts. Overall rates for male subjects (1.67 cases per 1000 person-years) were nearly identical to those for female subjects (1.65 cases per 1000 person-years). Genital warts were observed least frequently among individuals aged <15 years (<0.50 cases per 1000 person-years), with similar rates observed for male and female subjects. For patients aged ≥15 years, changes in wart prevalence among male subjects lagged behind those among female patients by a few years. Although the prevalence among male subjects aged
Table 1. Genital wart prevalence within a set of private health plans in the United States.

| Age group, years | Male subjects | | Female subjects | |
|------------------|---------------|------------------|------------------|
|                  | No. of person-years | No. of cases | Rate per 1000 person-years | No. of person-years | No. of cases | Rate per 1000 person-years |
| 0–4              | 75,082         | 10             | 0.13                         | 72,172         | 5              | 0.07                         |
| 5–9              | 100,437        | 34             | 0.34                         | 95,145         | 24             | 0.25                         |
| 10–14            | 117,707        | 48             | 0.41                         | 112,847        | 48             | 0.43                         |
| 15–19            | 128,468        | 83             | 0.65                         | 121,926        | 350            | 2.87                         |
| 20–24            | 94,502         | 277            | 2.93                         | 95,111         | 590            | 6.20                         |
| 25–29            | 71,945         | 361            | 5.01                         | 84,321         | 333            | 3.94                         |
| 30–34            | 97,591         | 378            | 3.88                         | 111,970        | 297            | 2.65                         |
| 35–39            | 119,943        | 303            | 2.52                         | 139,820        | 278            | 1.99                         |
| 40–44            | 137,124        | 259            | 1.89                         | 161,180        | 223            | 1.39                         |
| 45–49            | 140,406        | 180            | 1.28                         | 170,061        | 246            | 1.44                         |
| 50–54            | 149,887        | 176            | 1.18                         | 175,766        | 161            | 0.92                         |
| 55–59            | 125,967        | 108            | 0.86                         | 138,739        | 120            | 0.86                         |
| 60–64            | 103,875        | 103            | 1.00                         | 109,010        | 83             | 0.76                         |
| >65              | 12,701         | 11             | 0.87                         | 12,772         | 7              | 0.55                         |
| Total            | —              | 2331           | 1.67                         | —              | 2764           | 1.65                         |

* Rates for total are age-adjusted to the 2000 privately insured population of the United States.

15–19 years remained quite low (0.65 cases per 1000 person-years), the rates for female subjects increased >6-fold between the 10–14-year-old and 15–19-year-old age groups, from 0.43 to 2.87 cases per 1000 person-years. The prevalence was highest among women aged 20–24 years (6.20 cases per 1000 person-years), while the rates for male subjects peaked during the ages of 25–29 years (5.01 cases per 1000 person-years). Rates for both sexes decreased gradually with age thereafter.

Genital wart–associated costs to the health plan (per 1000 person-years) are presented in table 2. Overall health plan costs were approximately $700 per 1000 person-years and were similar for male and female patients. The economic burden of genital warts was greatest among female patients aged 15–24 years and men aged 25–34 years, for whom costs were approximately $1700 per 1000 person-years.

Data for genital wart–associated episodes of care are presented in table 3. On average, episodes of care lasted 3 months. However, 70% of cases concluded care within a 10-week period, with the data skewed by a small minority of persistent wart episodes with duration of care of >1 year. Genital wart episodes involved 3.1 physician office visits on average, with costs of $436. The average cost per visit was $135. There was a trend towards slightly more costly episodes of care for male than female patients, but this difference did not achieve statistical significance. Treatment regimens involved patient-applied therapies for ~40% of individuals, and slightly more than one-half of these individuals were also treated with physician-applied therapies.

**DISCUSSION**

This study represents, to our knowledge, the first age- and sex-specific estimates of the prevalence of and costs associated with genital warts in a broad privately insured population in the United States. Genital warts were detected among male and female subjects of all age groups, and overall prevalence rates were similar across sex groups. This contrasts somewhat with results from the 1975–1978 study of the incidence of genital wart diagnoses in Rochester, Minnesota, in which the ratio of female patients to male patients was 1.4:1 [2]. It is interesting to note, however, that in both the Rochester study and in our analysis, the respective incidence and prevalence rates for female patients aged 15–24 years were greater than those for male patients aged 15–24 years, but the rates for men topped those for women in nearly all age groups beyond the 15–24-year-old group.

One explanation for our finding may relate to the general aging of the population since the 1970s, with a shift in cases toward age groups in which men are more predominantly affected. Another contributing factor may be the changing patterns of exposure to genital warts across age cohorts. There is evidence of a large absolute increase in the number of cases of genital warts among young adults from 1965 to 1974 [2, 15]. Because these young adults have aged during the past 30 years, the prevalence of genital warts among older cohorts of adults may have experienced a general upswing as well. Such a trend would lead to larger absolute differences in genital wart rates between men and women in older age groups and a reduction...
in the differential in wart cases across sexes. The observed age
lag in male rates behind female rates may be explained by sexual
mixing patterns in the population, in which STDs are trans-
mitted from older men to younger women [16].

The highest prevalence of genital warts was found among
young adults, with peak rates among women aged 20–24 years
and men aged 25–29 years. Consistent with previous reports,
genital warts were seen relatively rarely among children in the
Medstat population [2, 10, 11]. The proliferation of genital
warts among middle-aged individuals and particularly among
elderly individuals, however, was higher than might have been
expected on the basis of prior accounts.

For instance, although the prevalence rate of genital warts
among individuals aged 15–24 years reported in Medstat was
relatively similar to the incidence rate reported in the
1975–1978 Rochester study, among the Medstat population
aged ≥50 years, the prevalence rate was 3 times higher among
men and 5 times higher among women [2]. This widening gap
with age between reported rates of incidence and prevalence
may reflect the sustained development of genital warts among
individuals who received initial diagnoses at an earlier age [17,
18]. In addition, individuals currently aged ≥50 years have
lived through a period of increased sexual activity relative to
cohorts from 25 years ago, with the potential for increased risk
of incident or recurrent HPV infection [19].

Health plan costs associated with genital wart care during
2000 reflected a total economic burden of more than $700 per
1000 person-years of enrollment, with a burden observed
among young adults that was >2 times higher. To place these
results in some perspective, using data from Tao et al. [20], we
estimated that the overall cost of treating genital herpes in 1999
was approximately $750 per 1000 person-years of follow-up
across the entire US population.

Costs for an individual episode of care for genital warts were
estimated to be $477 for male and $404 for female patients.
This pattern of costs is reversed from those based on modeled
treatment protocols reported by Strauss et al. [7]. In that study,
reimbursed costs across 5 therapies were estimated to be higher
for female patients than male patients by $10–$130, depending
on the therapy. In the present study, mean costs were also found
to be substantially higher than those reported from the only
other study of genital wart costs based on actual patient treat-
ment patterns, which was from The Netherlands [21]. In that
study, which was limited to external genital warts, costs aver-

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Male patients (n = 237)</th>
<th>Female patients (n = 299)</th>
<th>All (n = 536)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of episode, mean days (95% CI)</td>
<td>102.6 (77.8–127.4)</td>
<td>84.8 (67.5–102.1)</td>
<td>92.7 (85.3–100.2)</td>
</tr>
<tr>
<td>Mean no. of physician visits (95% CI)</td>
<td>3.1 (2.8–3.5)</td>
<td>3.1 (2.8–3.4)</td>
<td>3.1 (2.9–3.3)</td>
</tr>
<tr>
<td>Cost, mean US$ (95% CI)</td>
<td>477 (365–590)</td>
<td>404 (316–492)</td>
<td>436 (365–508)</td>
</tr>
<tr>
<td>Therapy, % of patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient applied</td>
<td>37</td>
<td>41</td>
<td>39</td>
</tr>
<tr>
<td>Physician applied</td>
<td>62</td>
<td>58</td>
<td>60</td>
</tr>
<tr>
<td>Patient and physician applied</td>
<td>21</td>
<td>21</td>
<td>21</td>
</tr>
</tbody>
</table>

* Includes imiquimod and podofilox and reflects use of patient-applied therapy alone or in combination with physician-
applied therapy.
aged just over $200 per episode of care. However, in that study, costs were based on Dutch resource unit valuations, with nearly 80% of patients treated with podophyllin or cryotherapy.

The estimated number of physician visits per episode of care (3.1) is lower than that reported in previous studies that used modeled treatment protocols, because full compliance with therapy is often assumed in these studies [7, 9]. Coding in the Medstat database was not sufficiently precise to identify the exact therapy used to treat each case of genital warts, because general outpatient procedure codes, such as CPT 56501 (destruction of simple vulvar lesion, any method), were often used. With use of pharmacy data, however, it was determined that nearly 40% of genital wart treatments involved patient-applied therapies, which were often used in conjunction with traditional physician-applied therapies.

Several limitations should be noted in interpreting these results. First, consistent with a health plan perspective, our analysis focuses on cases of genital warts diagnosed by a physician. There are likely a substantial number of individuals with genital warts who do not receive physician care. In many cases, these warts are subclinical and remain undetected by the patient and physician [22]. In others, patients with clinically apparent genital warts may elect to forgo medical care because of embarrassment, inconvenience, or fear of treatment. Although these cases do not impact the health plan, they may result in physical or emotional distress for the affected individual [2, 4].

Second, because of the stigma associated with an STD diagnosis, some privately insured individuals may elect to seek genital wart treatment outside of their health plan at a public STD, family planning, or college student health clinic [23]. Although no direct estimates currently exist regarding the proportion of privately insured individuals who seek care for genital warts outside of their health plan, supporting data indicate that a relatively small proportion of wart cases would be omitted from the Medstat database for this reason.

A national study of genital herpes found that only 20% of herpes-related health visits were to public clinics providing STD-related services [20]. If a similar distribution of visits were assumed for genital warts, one would likely find that an even smaller fraction of all visits by privately insured individuals were made to public clinics, because these sites receive a disproportionate share of their visits (60%–70%) from uninsured persons and individuals with Medicaid [24, 25]. Furthermore, there is evidence that a proportion of out-of-plan STD care may be paid for through private insurance and thus would be included in the Medstat database. For instance, among STD clinic attendees with health insurance in 5 major urban centers, only 33% indicated that they would not use their insurance coverage to pay for their visit [25]. Thus, we believe that the vast majority of genital wart diagnoses occurring among this privately insured population are reported in the Medstat database, although there may be a degree of underestimation in the results for individuals aged 18–34 years, who are most likely to seek alternate sources of health care [24].

Third, in this study, cases of genital warts were identified through administrative billing codes, frequently without histologic confirmation. Although there exists the potential for misclassification, no studies in the literature have documented the accuracy of a clinical diagnosis. An American Medical Association consensus conference, however, reported that the clinical diagnosis of external genital warts was reliable on the basis of a strong correlation between physical findings and the results of histologic studies [26].

Finally, because of the nonspecificity of genital wart billing codes, a proportion of cases were imputed for this analysis (e.g., 20% of cases were used to estimate prevalence). This imputation was based on the assumption that physicians treat a genital wart similarly, regardless of the diagnostic code selected by the medical coder. To the extent that such coding practices vary, results for this study would change to a modest degree.

This article has reported estimates of the prevalence of and costs associated with genital wart care in a privately insured population from the perspective of a set of private health plans in the United States. HPV transmission and associated cases of genital warts remain a major public health concern. In 2000, there were an estimated 200 million Americans with private health insurance [12, 13]. To the extent that results for the Medstat population are generalizable to the privately insured population of the United States, estimates from this study would indicate an annual health and economic burden to private health plans of 330,000 cases of genital warts and $140 million in associated costs for their privately insured populations.

References