

Management and cost of genital warts in Italy

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BACKGROUND

- Genital warts (GW) are common and increasing in sexually active people. Ninety percent of GW in Europe are due to Human papillomavirus (HPV) types 6 and 11¹.
- Current GW treatments are often long, painful and unsatisfactory because of the relatively high number of recurrent and resistant cases that require repeated visits and result in a noteworthy economic impact²⁻⁵.
- Randomized controlled trials show that a quadrivalent HPV vaccine is effective in preventing up to 100% of HPV 6, 11, 16 and 18 related diseases⁶.
- In order to assess the expected benefits of a hypothetical HPV vaccination programme, national public health authorities need to know the cost burden associated with HPV-related diseases.

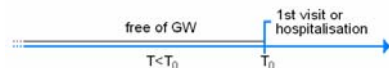
OBJECTIVES

The objective of this study was to assess treatment patterns and costs associated with the treatment of GW in Italy from the societal perspective.

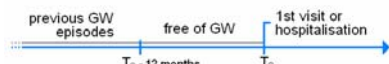
METHODS

Study design

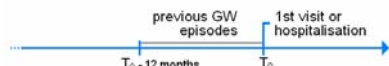
- A multi-centre, retrospective, observational study was designed to involve 40 investigators in public gynaecological, dermatological, and sexually transmitted disease (STD) centres, enrolling 360 patients with external and/or internal GW aged 14-64 years.
- GW case definition included:
 - newly diagnosed GW



recurrent GW



resistant GW



- Investigators documented medical resource utilisation and absence from work for the treatment of GW and related complications in 2005.
- Mean costs per patient were estimated from the third party payer as well as a societal perspective.

Unit costs

- Ambulatory unit costs were derived by applying the appropriate official regional fees⁷ to the local codification of medical procedures.

Table 1. Ambulatory unit costs

| Category | Item | Cost range (€) |
|-------------------------|-------------------------------------|----------------|
| Physician visits | Gynaecological | 13.6 – 23.0 |
| | Other | 11.7 – 23.0 |
| Office-based procedures | Application of Podophyllin resin | 3.6 – 4.3 |
| | Application of Trichloroacetic acid | 3.9 – 12.8 |
| | Cryotherapy | 8.4 – 18.4 |
| | Electrotherapy | 12.8 – 36.2 |
| | Laser therapy | 7.9 – 29.8 |
| | Curettage | 8.4 – 29.8 |
| Examinations | Application of Acetic acid | 3.9 – 6.2 |
| | Pap smear | 2.6 – 13.7 |
| | Colposcopy | 10.3 – 15.4 |
| | Biopsy | 13.9 – 35.0 |
| | HPV DNA detection | 14.1 – 114.1 |
| | Urethroscopy/Meatoscopy | 27.3 – 35.8 |
| | Anoscopy/Proctoscopy | 22.7 – 32.5 |

- Prices of medications paid for by the public health service or by the patients came from the national pharmaceutical formulary⁸.
- Day-hospital (DH) and inpatient admission fees were taken from the national tariffs of interregional mobility across public hospitals⁹.

Table 2. Hospitalisation unit costs

| Category | Item | Cost range (€) |
|---------------------------------|--|----------------|
| Hospitalisations (DH/Inpatient) | Operation on anus and stoma without | 1416 / 1327 |
| | Perianal and pilonidal operations | 1600 / 1500 |
| | Other operations on skin, subcutaneous tissue and breast without complications | 1403 / 1315 |
| | Operation on vagina, cervix and vulva | 1554 / 1943 |

- All medical resource fees and prices refer to 2005
- Days off work were valued according to the average daily earnings stratified by gender and age class from national labour statistics¹⁰.

RESULTS

Patient sample

- A total of 28 investigators (15 dermatologists, 7 gynaecologists and 6 specialists of STD clinics) enrolled **341 patients** (189 men and 152 women).
- Newly diagnosed, recurrent and resistant episodes were respectively 194 (56.9%), 81 (23.7%) and 66 (19.4%).
- Mean age was 33.1 years (± 10.4 sd), 49 (14.4%) patients reported previous sexually transmitted infections, and 22 (6.5%) were immunocompromised.

Treatment patterns

- 333 (97.7%) had at least one investigator visit (mean number of visits = 3.4). 8 patients were admitted directly to day-hospital.
- 267 outpatients cases (80.2 %) underwent at least one office-based procedure, mainly cryotherapy and electrotherapy.
- 124 patients (36.4%) were prescribed a self-applied therapy.
- 39 cases (11.4%) were admitted to day-hospital.
- 47 patients (13.8%) reported a medical complication related to GW treatment.

Table 3. Patients undergoing treatments and number of interventions

| | | Hospital admissions | | | | Outpatient* | | | | | |
|-------|-----------|---------------------|------|-------------|-------------|-------------|------|--------------|------|------------|------|
| | | Cases | | Medications | | Cases | | Examinations | | Procedures | |
| | | n | % | % | mean (days) | n | mean | % | mean | % | mean |
| Men | New | 109 | 8.3 | 45.9 | 26.7 | 108 | 2.9 | 38.9 | 0.82 | 74.1 | 1.6 |
| | Recurrent | 38 | 0.0 | 55.3 | 39.2 | 38 | 4.8 | 55.3 | 1.11 | 89.5 | 2.8 |
| | Resistant | 42 | 4.8 | 35.7 | 36.4 | 41 | 4.3 | 39.0 | 0.71 | 95.1 | 2.7 |
| | Total | 189 | 5.8 | 45.5 | 31.5 | 187 | 3.6 | 42.2 | 0.86 | 81.8 | 2.1 |
| Women | New | 85 | 18.8 | 18.8 | 48.3 | 81 | 3.6 | 82.7 | 4.54 | 84.0 | 1.5 |
| | Recurrent | 43 | 25.6 | 30.2 | 51.2 | 41 | 3.9 | 85.4 | 4.8 | 78.0 | 1.7 |
| | Resistant | 24 | 20.8 | 37.5 | 32.2 | 24 | 3.1 | 95.8 | 4.29 | 58.3 | 1.0 |
| | Total | 152 | 21.1 | 25.0 | 45.5 | 146 | 3.6 | 85.6 | 4.58 | 78.1 | 1.5 |
| Total | | 341 | 12.6 | 36.4 | 35.7 | 333 | 3.6 | 61.3 | 2.49 | 80.2 | 1.8 |

*Including investigator and other physicians

Sick leave

- 10 men (5.3%) and 30 women (19.7%) were on sick leave due to GW and their treatment; 8 patients (17.0%) were absent from work due to related medical complications.
- The annual mean number of days off work per patient was estimated to be 5.7 (± 4.0 sd).

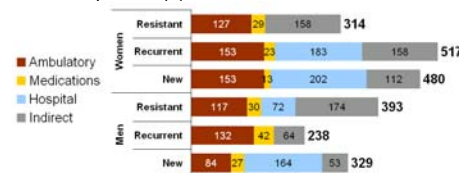
Cost analysis

- Mean direct medical costs per patient were **€42 for men** and **€32 for women**. When productivity losses are included, these costs were respectively **€25** and **€46** (Table 4).
- Visits and procedures were the main drivers of outpatient costs in men, whereas examinations and visits were the main components in women.
- Hospital admissions accounted for 47.7% of direct medical costs per patient.

Table 4. Mean costs and 95% CI

| Costs | Men | Women | Total |
|------------|---------------------------|---------------------------|---------------------------|
| Outpatient | 132.04 (118.41-145.47) | 167.20 (150.73-185.05) | 147.71 (136.68-158.37) |
| Visits | 55.48 (50.82-60.28) | 58.88 (52.85-60.02) | 57.00 (53.51-60.80) |
| | 13.08 (9.57-17.19) | 64.08 (54.09-73.25) | 35.82 (30.29-40.92) |
| | 32.51 (27.81-38.24) | 25.90 (22.25-29.56) | 29.57 (26.17-32.83) |
| | 30.96 (24.68-37.29) | 18.34 (12.47-24.60) | 25.34 (16.09-32.42) |
| | 110.43 (44.78-190.52) | 164.75 (88.62-249.13) | 134.65 (81.67-199.66) |
| Direct | 242.47 (176.14-325.89) | 331.96 (253.99-425.35) | 282.36 (230.73-342.57) |
| Indirect | 82.26 (54.55-114.27) | 132.39 (104.53-162.48) | 104.60 (83.50-126.53) |
| Total | 324.73 (248.15-418.00) | 464.35 (383.52-559.30) | 386.96 (327.20-451.17) |

Figure 1. Cost composition (€)



DISCUSSION & CONCLUSION

- This study is the first to identify therapeutic patterns and costs of GW in Italy.
- Treatment costs are in line with recent European estimates, ranging from €21 for outpatient services among men in the Netherlands⁵ to €342 for women consulting gynecologists in France².
- Self-applied therapies are less widespread than in other European countries: 34% of newly diagnosed GW episodes are managed with patient-applied therapies, whereas in the UK 77% of incident cases are treated with topical creams¹¹, and in France 53% of all cases are given imiquimod².
- A quadrivalent HPV vaccine that prevents HPV 6,11,16,18 related diseases has the potential to significantly decrease the socio-economic burden associated with GW in Italy in a very short term¹²