Cost of the Cervical Cancer Screening Program at the Mexican Social Security Institute

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Abstract
Objective. To estimate the annual cost of the National Cervical Cancer Screening Program (CCSP) of the Mexican Institute of Social Security (IMSS). Materials and methods. This cost analysis examined regional coverage rates reported by IMSS. We estimated the number of cytology, colposcopy, biopsy and pathology evaluations, as well as the diagnostic test and treatment costs for cervical intraepithelial neoplasia grade II and III (CIN 2/3) and cervical cancer. Diagnostic test costs were estimated using a micro-costing technique. Sensitivity analyses were performed. Results. The cost to perform 2.7 million cytology tests was nearly 38 million dollars, which represents 26.1% of the total program cost (145.4 million). False negatives account for nearly 43% of the program costs. Conclusion. The low sensitivity of the cytology test generates high rates of false negatives, which results in high institutional costs from the treatment of undetected cervical cancer cases.

Key words: costs and cost analysis; cytology; screening; cervical cancer; Mexico

Resumen
Objetivo. Estimar el costo anual del Programa Nacional de Detección Oportuna de Cáncer Cervical en el Instituto Mexicano del Seguro Social (IMSS). Material y métodos. Este análisis de costos examinó las distintas coberturas por región reportadas por el IMSS. Se estimó el número de citologías, colposcopías, biopsias y evaluaciones de patología y los costos de pruebas de diagnóstico y de tratamientos por neoplasia cervical intraepitelial de grado II y III (NIC 2/3) y cáncer cervical. Los costos de las pruebas de diagnóstico se estimaron utilizando una técnica de microcosteo. Se llevó a cabo un análisis de sensibilidad. Resultados. El costo de realizar 2.7 millones de citologías fue de 38 millones de dólares, lo que representa 26.1% del costo total del programa (145.4 millones). Los falsos negativos corresponden a casi 43% de los costos del programa. Conclusiones. La baja sensibilidad de la citología genera un alto número de falsos negativos que resultan en costos elevados para la institución por el tratamiento de estos casos no detectados.

Palabras clave: costos y análisis de costos; citología; detección; cáncer cervical; México

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For most countries around the world, including Mexico, cervical cytology, or the Papanicolaou (Pap) test, serves as the principal diagnostic tool for the detection of cervical cancer. The health and economic implications of this test have been analyzed for health care systems throughout Latin America.\textsuperscript{1-4} Although the Pap test has helped to significantly reduce the burden of disease from cervical cancer in a number of high-income countries, as suggested by strong epidemiologic data,\textsuperscript{5-7} high incidence rates and related deaths persist in many middle to low-income Latin American nations.\textsuperscript{8,9} In some cases, these findings may be explained by the socioeconomic disparities and high levels of marginalization throughout the region.\textsuperscript{10,11}

A cytology program has large infrastructural and resource requirements. On top of specialized training for technicians and pathologists, as well as managing appropriate follow-up and treatment, an effective quality assurance program is necessary. Since cervical cytology is largely a subjective test, both an internal and external quality control program is essential to assure the proper clinical performance of the test. Cytology is also labor intensive, adding to the resource requirements of such a program. For these reasons, public health programs have historically struggled to maintain effective cervical cancer control programs that employ the Pap test in settings with limited resources and competing priorities.\textsuperscript{12}

Although numerous studies suggest that screening programs can reduce the rates of cervical cancer by 60 to 90%,\textsuperscript{13,14} cervical cancer remains the second leading cause of death for Mexican women due to cancer\textsuperscript{11} despite the fact that Mexico instituted a screening program in 1974. Overall, the number of cervical cancer related deaths in Mexico peaked in 1989 and have decreased since, settling at 9.2 deaths per 100,000 women in 2008.\textsuperscript{15}

We performed a cost analysis of the IMSS national CCSP taking into account that approximately 2.7 million Pap tests were performed in a population of 9.16 million women between the ages of 25 and 64, who were insured by IMSS in 2010.\textsuperscript{9} The coverage rates of the IMSS CCSP in the north, center and south were also used to examine possible cost variations by region. The direct medical costs of the IMSS CCSP were calculated considering the following: a) screening costs, which include the costs to obtain the cervical sample and the laboratory costs to determine and report the cytology diagnosis; b) the costs to confirm a positive cytology test, which include the costs to perform a colposcopy exam and taking a biopsy if necessary, and the laboratory costs to determine a biopsy-confirmed diagnosis, c) the cost to treat cervical intraepithelial neoplasia (CIN) 2/3 or cervical cancer cases resulting from the true positive (TP) or false negative (FN) diagnoses.

Materials and methods

We performed a cost analysis of the IMSS national CCSP taking into account that approximately 2.7 million Pap tests were performed in a population of 9.16 million women between the ages of 25 and 64, who were insured by IMSS in 2010.\textsuperscript{9} The coverage rates of the IMSS CCSP in the north, center and south were also used to examine possible cost variations by region. The direct medical costs of the IMSS CCSP were calculated considering the following: a) screening costs, which include the costs to obtain the cervical sample and the laboratory costs to determine and report the cytology diagnosis; b) the costs to confirm a positive cytology test, which include the costs to perform a colposcopy exam and taking a biopsy if necessary, and the laboratory costs to determine a biopsy-confirmed diagnosis, c) the cost to treat cervical intraepithelial neoplasia (CIN) 2/3 or cervical cancer cases resulting from the true positive (TP) or false negative (FN) diagnoses.

Estimates of outcomes and costs were obtained using previously published information\textsuperscript{17,20,21} and from IMSS CCSP administrative sources\textsuperscript{*} (table I). This analysis was conducted from the perspective of IMSS with a time horizon of one year, during which all the screening and follow-up activities were assumed to occur. Because the study’s timeframe is a single year, health outcomes and costs were not discounted. Estimates were calculated assuming that each woman had only one Pap test and that 37.1% of the women who received a TP or false positive (FP) diagnosis were lost to follow-up, based on previous findings.\textsuperscript{21} Additionally, although screening coverage rates varied by region, we used the same sensitivity, specificity, and cervical cancer prevalence to determine our cost and outcome estimates.\textsuperscript{20,21}

Cost of diagnostic tests

A retrospective, observational study design was used to measure the goods and services used for each cost category and process. Micro-costing techniques, which included a time and motion (TAM) study, were employed to identify the time, quantity, labor, and equipment costs associated with each of the cervical cancer diagnosis processes at IMSS. Data were obtained at the IMSS Hospital General Regional No. 1 in the state of Morelos during 2007. The following categories were used to determine the cytology, colposcopy, biopsy and pathology costs: a) staff or personnel costs; b) supply costs, which include medical supplies, treatment materials, etc.; c) capital costs; and d) overhead costs.

Staff costs were calculated by multiplying the amount of time spent on each task by each worker, by the hourly rate that each employee is paid to perform the task. Rates of pay were obtained from the Integrated System of Personnel Administration (Sistema Integral de Administración de Personal, or SIAP) of the IMSS Personnel Department in Morelos. We assumed that 10% of the salary cost of the personnel involved in the CCSP can be attributed to administrative personnel. Supply costs were determined by multiplying the units or amounts of goods consumed, by the price paid to purchase each good. These prices were obtained from the IMSS purchasing catalog of items, which is issued by the institutional supply system, and market prices when necessary. The IMSS information system for acquisitions was used to determine the annual equipment and furniture costs, at a discount rate of 3%. The annual building costs, including the costs of land and construction (as well as insurance costs) minus the depreciation costs were also estimated. Land values were estimated using the District Catalog of Real Estate and Supplies for the General Directorate of Works and Real Estate Assets for IMSS. Capital and overhead costs were obtained from the IMSS Office of Construction, Conservation, and Equipment, from the Morelos IMSS administrative offices. A discount rate of 3% over 50 years was used to annuitize capital expenditures. Fixed costs were allocated to the hospital services based on the percentage of space used in each area where CCSP activities take place. The average cost of the cytology, colposcopy, and biopsy procedures were estimated by dividing the total costs to perform each test by the number of procedures performed. The number of procedures was obtained from the monthly hospital productivity reports. All costs are reported in 2013 USD.

Cost to treat CIN 2/3 and cervical cancer cases

We also estimated the associated cost to treat women with precancerous lesions (CIN 2/3) or cervical cancer. To calculate the treatment costs of the IMSS CCSP, we estimated the number of CIN 2/3 and cervical cancer treatments and assigned them a cost based on previously published cancer treatment costs.

Costs based on cytology test performance

The number of true positives (TP), false negatives (FN), false positives (FP) and true negatives (TN) and the associated costs of these outcomes were calculated. We used previously reported estimates of the sensitivity (40%) and specificity (97%) of the Pap test, the rate of TP and FP cases that are lost to follow-up at IMSS, as well as the reported prevalence of cervical cancer at IMSS (13 cases per 1 000 women) to estimate these outcomes (table I).

The number of TP was obtained by multiplying the prevalence rate of 0.013 times the total number of women screened (n= 2 705 436), to determine the number of women with CIN 2/3 or cervical cancer in this population (n= 35 171). This number was then multiplied by the reported sensitivity of the Pap test (0.40) to obtain the number of women who should be correctly identified as having disease (n= 14 068). The number of colposcopies and biopsies associated with TP were estimated assuming that 62.9% of women in this group returned for these follow-up procedures and treatment (n= 4 049) and 37.1% did not. Additionally, we assumed that among the total TP cases, 88% of women received a diagnosis of CIN 2/3 and 12% received a cervical cancer diagnosis, based on previously published findings. To estimate the costs of the TP cases, we determined the prevalence rate of cervical cancer at IMSS (13 cases per 1 000 women) to estimate these outcomes (table I).
or CIN 2/3. Again, we assumed 88% of women would have CIN 2/3 and 12% would have cervical cancer. We multiplied the estimated number of cases by their respective treatment cost, and then added the total screening costs. The number of FP was estimated by subtracting the TN from the total number of women without disease (n= 2,670,265). To estimate the FP costs we assumed that 39% of women had a colposcopy with biopsy, as well as the corresponding pathology procedures and 24% had a colposcopy evaluation without a biopsy. Additionally, we assumed that 62.9% of women in this group returned for these follow-up procedures and treatment (n= 50,388) and 37.1% (n= 29,640) did not.

Sensitivity analyses

A deterministic sensitivity analysis was conducted to investigate the effects of certain parameters on the total costs of the IMSS CCSP. We examined the effect that changes in the coverage of the program (ranging from 20 to 40%) and variations in the sensitivity of the Pap test (ranging from 35 to 60%) have on the number of FN, TP, TN and FP diagnoses. We also varied the total and staff costs of the cytology, colposcopy and biopsy tests to determine the extent to which these variations (±20%) affect the total program costs. A three-way sensitivity analysis was also conducted that considered high vs. low costs of tests and treatment, a range of 20 to 40% for the coverage rate of the IMSS CCSP, as well as a Pap test sensitivity that ranged from 35 to 60% based on previously published results. We did not use the IMSS unitary costs lists for this analysis because they do not report the costs of colposcopy and biopsy. Due to a lack of information on the variability of the cost to treat CIN 2/3 and cervical cancer cases, we used a lower and upper range of ±20% for the base case treatment costs.
Results

The cost of a single cytology test, colposcopy without biopsy, colposcopy with biopsy, and pathology were estimated to be 14.04, 39.80, 69.01 and 26.27 USD, respectively. Staff costs were found to be the most important component for each of these four procedures, representing between 73-79% of the total cost of these diagnostic tests. The second most important contributor to the cost of these tests were supply costs for cytology (11%), overhead costs for colposcopy, and capital costs (10%) for pathology (table II). The total cost to perform approximately 2.7 million Pap tests was almost 38 million USD, which represents 26.1% of the total IMSS CCSP costs, estimated to be 145.4 million USD per year. We estimated that 99,248 confirmatory tests were performed with a cost of nearly 4.6 million USD, representing 3.1% of the total costs of the IMSS CCSP. The cost to treat the estimated 35,171 cases of CIN 2/3 or cervical cancer was 102.8 million USD, which accounts for the largest proportion (70.7%) of the costs of the program (table III).

The cost of the IMSS CCSP was also examined based on the resulting outcomes from the performance of the cytology test. The total cost to treat the 21,103 false negatives was nearly 62 million USD, which represents the largest proportion (42.6%) of the total program cost. The cost to diagnose and treat the 14,068 true positives was estimated to be 42.2 million USD (29% of the total program costs). The 2,590,157 women who were found to be true negatives cost 36.37 million USD, representing 25.1% of the total program costs, and finally the 80,108 women who received a false positive diagnosis and had unnecessary follow-up procedures cost a total of 4.85 million USD (3.3% of the total IMSS CCSP cost) (table III and figure 1).

Sensitivity analysis

The one-way sensitivity analysis shows the relationship between the number of TP, FP and FN, and the coverage rate of the IMSS CCSP. When we varied the program coverage between 20 and 40%, these outcomes ranged...
Table II

PROPORTION OF EACH COST CATEGORY FOR CYTOMETRY, COLPOSCOPY AND BIOPSY

<table>
<thead>
<tr>
<th>Cost category</th>
<th>Cytology*</th>
<th>%</th>
<th>Colposcopy without biopsy*</th>
<th>%</th>
<th>Colposcopy with biopsy*</th>
<th>%</th>
<th>Biopsy*</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Staff</td>
<td>11.02</td>
<td>78</td>
<td>28.99</td>
<td>73</td>
<td>52.18</td>
<td>76</td>
<td>20.71</td>
<td>79</td>
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<tr>
<td>Supply</td>
<td>1.48</td>
<td>11</td>
<td>1.05</td>
<td>3</td>
<td>2.37</td>
<td>3</td>
<td>0.87</td>
<td>3</td>
</tr>
<tr>
<td>Capital</td>
<td>0.49</td>
<td>4</td>
<td>2.40</td>
<td>6</td>
<td>5.00</td>
<td>7</td>
<td>2.59</td>
<td>10</td>
</tr>
<tr>
<td>Overhead</td>
<td>1.04</td>
<td>7</td>
<td>7.35</td>
<td>18</td>
<td>9.45</td>
<td>14</td>
<td>2.10</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>14.04 USD</td>
<td>100</td>
<td>39.80 USD</td>
<td>100</td>
<td>69.01 USD</td>
<td>100</td>
<td>26.27 USD</td>
<td>100</td>
</tr>
</tbody>
</table>

* Costs are in 2013 USD

Table III

NUMBER OF SCREENING TESTS, TREATMENTS AND ASSOCIATED COSTS BY REGION: RESULTS OF THE CERVICAL CANCER (CC) SCREENING PROGRAM

<table>
<thead>
<tr>
<th>Number of women screened and treated by region (2010 year)</th>
<th>Northern zone</th>
<th>Central zone</th>
<th>Southern zone</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women in the program</td>
<td>3 194 907</td>
<td>4 594 269</td>
<td>1 371 857</td>
<td>9 161 033</td>
</tr>
<tr>
<td>Pap tests performed</td>
<td>955 596</td>
<td>1 361 741</td>
<td>388 099</td>
<td>2 705 436</td>
</tr>
<tr>
<td>Colposcopy without biopsy</td>
<td>6 791</td>
<td>9 677</td>
<td>2 758</td>
<td>19 226</td>
</tr>
<tr>
<td>Colposcopy with biopsy</td>
<td>14 133</td>
<td>20 139</td>
<td>5 739</td>
<td>40 011</td>
</tr>
<tr>
<td>Pathology (biopsies)</td>
<td>14 133</td>
<td>20 139</td>
<td>5 739</td>
<td>40 011</td>
</tr>
<tr>
<td>CIN 2/3</td>
<td>10 933</td>
<td>15 578</td>
<td>4 440</td>
<td>30 951</td>
</tr>
<tr>
<td>Cervical Cancer</td>
<td>1 490</td>
<td>2 125</td>
<td>605</td>
<td>4 220</td>
</tr>
<tr>
<td>Total CIN 2/3 and CC cases treated</td>
<td>12 423</td>
<td>17 703</td>
<td>5 045</td>
<td>35 171</td>
</tr>
</tbody>
</table>

Performance of cytology test (In numbers of women)

| True positives                                            | 4 969         | 7 081        | 2 018         | 14 068 |
| False negatives                                           | 7 454         | 10 622       | 3 027         | 21 103 |
| False positives                                           | 28 295        | 40 321       | 11 492        | 80 108 |
| True negatives                                            | 9 148 878     | 1 303 717    | 37 1 562      | 2 590 157 |

Costs to screen and treat by region

| Pap tests                                                 | 13 416 568    | 19 118 843   | 5 448 910     | 37 984 321 (26.1%) |
| Colposcopy without biopsy                                 | 270 282       | 385 145      | 109 768       | 765 195 (0.5%)    |
| Colposcopy with biopsy                                     | 975 318       | 1 389 792    | 396 048       | 2 761 158 (1.9%)  |
| Total cost of pathology (biopsy)                          | 371 274       | 529 050      | 150 764       | 1 051 088 (0.7%)  |
| Treatment CIN 2/3                                         | 22 948 367    | 32 698 222   | 9 319 560     | 64 966 149 (44.7%)|
| Treatment cervical cancer                                 | 13 371 260    | 19 069 750   | 5 429 270     | 37 870 280 (26.1%)|
| Total costs                                               | 51 353 069    | 73 190 802   | 20 854 320    | 145 398 191 (100%)|

Costs based on cytology test performance

| True positives                                            | 14 895 041    | 21 230 563   | 6 048 775     | 42 174 379 (29%)  |
| False negatives                                           | 21 896 850    | 31 210 333   | 8 891 797     | 61 998 980 (42.6%)|
| False positives                                           | 1 716 291     | 2 445 718    | 697 018       | 4 859 027 (3.3%)  |
| True negatives                                            | 12 844 887    | 18 304 187   | 5 216 730     | 36 365 804 (25.1%)|
| Total costs                                               | 51 353 069    | 73 190 801   | 20 854 320    | 145 398 190 (100%)|

* Costs are in 2013 USD
from -32 to 35%. As the program coverage increases, we observe a corresponding increase in the number of FN and TP results, and a substantial increase in the number of FP (data not shown). Improving the sensitivity of the cytology test from 40 to 60% would help reduce the number of FN diagnoses, which is especially important to consider if the IMSS CCSP coverage were to increase from 20 to 40%. When the coverage is 20%, a sensitivity increase from 40 to 60% reduces the number of FN by 13%. At a coverage of 40% and a sensitivity of 60% the number of FN is reduced by 38.5% (data not shown). This reduction in FN does not result in a corresponding decrease in costs, but rather a slight increase of 0.37% is observed (from 196.79 to 197.51 million USD). This is because a higher Pap sensitivity also increases the number of TP cases and their treatment costs.

Figure 2 presents the results of a three-way sensitivity analysis that examined how varying the coverage rates (20, 30 and 40%), sensitivity (35 vs. 60%) and costs (low, no change, and high) affects the base case total cost estimates. Our findings suggest that the scenario of high coverage (40%) and high sensitivity (60%) costs approximately 197.6 million and the scenario with high coverage (40%) and low sensitivity (35%) costs slightly less (196.7 million). FN make up the largest portion of total costs when the test sensitivity is low, and TP are the largest portion of total program costs, when the test sensitivity is high. If unitary costs are assumed to be low, total costs are reduced by 27.3% and if costs are high, total costs increase by 20 percent.

Discussion

We estimated the total annual cost of the IMSS CCSP, which currently relies on cervical cytology as its primary diagnostic tool. To determine the total cost of the program, we considered the costs to perform a cytology test, follow-up procedures such as colposcopy and biopsy, as well as treatment costs. We also determined the number of TP, FN, FP and TN and calculated the costs associated with
these outcomes. Our results indicate that the annual cost of the IMSS CCSP is approximately 145.4 million USD and that FN account for nearly 42.6% of the total program costs. We used the national coverage rate reported by the IMSS CCSP (29.53%) to estimate that 2.7 million Pap tests were performed in 2010, at a cost of nearly 38 million USD, which represents 26.1% of the total IMSS CCSP costs. The cost of the follow-up tests that were performed on women who received a TP diagnosis was estimated to be 4.9 million USD which is only 3.3% of the total program costs. As expected, we found that the high cost of treating women with CIN 2/3 or cervical cancer (102.8 million USD) is the greatest contributing factor to the cost of the IMSS CCSP (70.7%). The cost of cervical cancer-related diagnostic tests, consultations, hospitalizations, and medicines reported by IMSS to the President and Congress was estimated at 53.60 million USD. This amount is higher than our estimate of 37.87 million USD, which is likely conservative since it is 27% less than the official amounts reported by IMSS.

One of the main goals of this study was to provide precise estimates of the outcomes and costs associated with cytology, colposcopy and biopsy testing, and how they contribute to the total costs of the IMSS CCSP. The main expenditures include staff wages, followed by supply, overhead and capital costs. However, when we examined the aggregated costs and economic effect of the program, we found that the largest expense of the program is incurred by the treatment of FN and TP. The two main parameters allowing for variation of total costs were the sensitivity of cytology and the coverage of the program. Increasing coverage while maintaining a sensitivity of 40% leads to a corresponding increase in program costs. Although increasing the sensitivity of cytology reduces the cost of FN, it does not change the overall costs of the program significantly, due to the added cost of treating TP cases.

The results of our three-way sensitivity analyses suggest that higher coverage rates increase program costs due to additional diagnostic tests and increased treatment costs for both TP and FN. When the sensitivity of the cytology test is low, the FN cases represent the greatest proportion of program costs; but when the test sensitivity is high, the TP make up the largest portion of total program costs. These findings indicate that the performance of the IMSS CCSP could be improved without a significant cost increase.

The results of our study may be useful in determining ways to improve the cost management in the diagnosis of cervical cancer; however, the present study has some limitations. One limitation is that we did not estimate the costs associated with the time in which staff are not performing tasks explicitly for the program, i.e. “lost” time. We also did not estimate the total cost of the personnel involved in IMSS CCSP activities (not just the time they dedicate to program activities) based on different methods (such as number of personnel in a defined physical area or the step down method). This would have allowed us to determine the effect that the productivity of the IMSS CCSP staff has on the costs of the program. Another limitation of the study is that all information to determine costs was collected at one IMSS hospital. In order to investigate the effect of modifications of the costs of staff on total costs of the program we conducted a one way sensitivity analysis and found that the variation of total costs by varying staff costs by 20% appear to be not significant (4.7%).

Further studies that collect information from different IMSS hospitals may help determine any possible differences in costs and cervical cancer prevalence. An additional limitation is the lack of information on the methodology used to determine treatment costs. This information was taken from a previous study and we do not know the methods used, and therefore cannot determine the quantity of goods and the individuals costs used for these estimations. We are, therefore uncertain as to how these costs are comparable to the costs of the diagnostic tests. As a result, we recommend additional studies to validate the treatment costs we used. Finally, one of our main assumptions is that cases are distributed in the same portions (88% for CIN 2/3 and 12% for cervical cancer), whether they are TP or FN. However, additional studies are needed to determine if FN cases are more likely to be advanced and more expensive.

The results of our cost analysis suggest that the Pap test may not be an efficient screening strategy for the IMSS CCSP. Although the Pap test is not necessarily expensive at 14.00 USD per test, its notoriously low sensitivity generates high numbers of false negative diagnoses that result in high treatment costs, which represents the largest percentage of the annual IMSS CCSP cost (42.6%). Our findings confirm those of other studies, which report that conventional cytology is less accurate and effective than the HPV test or liquid-based cytology, which results in higher program costs in the long run. Finding ways to improve the impact of the IMSS CCSP is very important, especially because cervical cancer is a leading cause of death in Mexico. Our study shows that improvements such as increasing the sensitivity of the cytology test to 60% and the extending the coverage of the IMSS CCSP to 40%, would detect a much greater number of women with disease, without a substantial increase in program costs. Achieving these improvements is very unlikely, which is why policy and decision makers at IMSS should consider other options, such as incorporating HPV test-
ing into the national CCSP to help reduce the burden of cervical cancer in Mexico.

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Declaration of conflict of interests. The authors declare that they have no conflicts of interest.

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