

# The Appropriateness of Recommendations for Hysterectomy

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**Objective:** To evaluate the appropriateness of recommendations for hysterectomies done for nonemergency and non-oncologic indications.

**Methods:** We assessed the appropriateness of recommendations for hysterectomy for 497 women who had the operation between August 1993 and July 1995 in one of nine capitated medical groups in Southern California. Appropriateness was assessed using two sets of criteria, the first developed by a multispecialty expert physician panel using the RAND/University of California–Los Angeles appropriateness method, and the second consisting of the ACOG criteria sets for hysterectomies. The main outcome measure was the appropriateness of recommendation for hysterectomy, based on expert panel ratings and ACOG criteria sets.

**Results:** The most common indications for hysterectomy were leiomyomata (60% of hysterectomies), pelvic relaxation (11%), pain (9%), and bleeding (8%). Three hundred sixty-seven (70%) of the hysterectomies did not meet the level of care recommended by the expert panel and were judged to be recommended inappropriately. ACOG criteria sets were applicable to 71 women, and 54 (76%) did not meet ACOG criteria for hysterectomy. The most common reasons recommendations for hysterectomies considered inappropriate were lack of adequate diagnostic evaluation and failure to try alternative treatments before hysterectomy.

**Conclusion:** Hysterectomy is often recommended for indications judged inappropriate. Patients and physicians should work together to ensure that proper diagnostic eval-

uation has been done and appropriate treatments considered before hysterectomy is recommended. (*Obstet Gynecol* 2000; 95:199–205. © 2000 by The American College of Obstetricians and Gynecologists.)

Several studies suggested that physicians might use surgical procedures inappropriately, with some patients not receiving necessary care and others exposed to unwarranted risk.<sup>1,2</sup> To improve the quality of patient care, there has been a concerted effort to develop guidelines and other criteria for physician practice. An equivalent effort to implement and disseminate those guidelines has been lacking.

The Agency for Health Care Policy and Research, a branch of the US Department of Health and Human Services, sponsored a series of studies to improve the process. One of those studies, the Women's Health and Hysterectomy Project, is designed to develop and disseminate recommendations for hysterectomy. We chose to focus this project on hysterectomy because it is the second most common major operation women have and there are significant concerns among researchers and the public that it might be overused.<sup>3–5</sup> In this study, we report the appropriateness of recommendations for hysterectomies in a cohort of women at nine Southern California managed-care organizations before the dissemination of clinical recommendations on use of hysterectomy.

## Methods

We measured appropriateness of recommendations for hysterectomy using two sets of criteria: 1) a set developed for the Women's Health and Hysterectomy Project by an expert panel using the RAND/University of Southern California–Los Angeles appropriateness method, and 2) three recent ACOG criteria sets de-

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*Funded in part by grant no. R18HS07095 from the Agency for Health Care Policy and Research, and in part by the Robert Wood Johnson Clinical Scholars Program.*

*The views expressed herein are those of the authors and do not necessarily reflect those of the Agency for Health Care Policy and Research or the Robert Wood Johnson Foundation.*

*The authors thank the members of the expert panel (Bruce Bagley, Constance Bohon, Vivian Dickerson, Karen Freund, Joseph Gambone, Frank Ling, Anne Moulton, Herbert Peterson, and Marian Swinker) for their assistance in developing the ratings, and Stanley Zinberg of ACOG for assistance with revising the criteria.*

signed “to evaluate the appropriateness of hysterectomy.”<sup>6</sup>

The RAND appropriateness method has been well described.<sup>1,2,7</sup> For this study, we reviewed the literature on hysterectomy to examine its efficacy and risks.<sup>8</sup> Based on that review, we developed a comprehensive list of 2332 potential indications for hysterectomy (excluding cancer or emergency) that we divided into eight groups: leiomyomata, pelvic pain, pelvic relaxation, abnormal uterine bleeding, adnexal mass, cervical dysplasia, endometrial hyperplasia, and miscellaneous. The indications were composed of explicitly defined factors necessary for considering hysterectomy (eg, menopausal status, degree of functional impairment, degree of anemia, prior treatment).<sup>9</sup>

An expert panel of five obstetrician-gynecologists, two internists, and two family physicians was selected from nominations by the relevant specialty societies. The panel included four women and both academic and private practitioners. The panelists first independently rated the appropriateness of hysterectomy on a 1 to 9 scale, with 1 representing a highly inappropriate indication and 9 a highly appropriate one. The panelists then met, discussed their ratings, and again independently rated the indications. The final appropriateness rating was based on the median of the nine ratings and the degree of agreement among panelists. If there was disagreement among panel members, we considered an indication of uncertain appropriateness. If there was no disagreement, we considered an indication inappropriate if the median panel rating was from 1 to 3, uncertain if the rating was from 4 to 6, and appropriate if the rating was from 7 to 9. Details of the panel process were published.<sup>7</sup>

These appropriateness ratings are difficult to use in clinical practice because of their detail and comprehensiveness. Therefore, they were simplified into a set of recommendations for hysterectomy by grouping similar indications with equivalent ratings and eliminating redundancy. Owing to the absence of outcome data for most indications for hysterectomy, it was not possible to base those ratings solely on evidence from the medical literature.<sup>10</sup> Thus, the recommendations represent the group judgment of the panel regarding appropriateness of referring for hysterectomy an average woman who presents with specific clinical characteristics that define an indication. They are not the product of a rigorous risk-benefit analysis because the data for such an analysis do not exist. They cannot be followed blindly, nor should they be considered standards of care. Rather, they are recommendations, based on evidence and experience, for women who are possible candidates for hysterectomies. In general, women with indications for which the median panel rating was 4 or

greater (or for which the panel disagreed about the final rating) were considered possible candidates for hysterectomy, whereas those with indications with a median rating of 3 or less without disagreement were considered inappropriate candidates. For example, the panel considered it inappropriate to recommend hysterectomy to a premenopausal woman with leiomyomata and bleeding without first evaluating the endometrium (eg, with an endometrial biopsy). In individual cases there might be other factors crucial to the decision, not included in the recommendation, that might influence appropriateness for a particular woman. The reason for making the recommendations as comprehensive as possible is to minimize that possibility.<sup>10</sup>

The ACOG criteria sets were designed to identify cases of hysterectomy that should be peer reviewed. We used three of the criteria sets as an additional method of judging appropriateness of recommendations for hysterectomy.<sup>6,11,12</sup>

We identified a convenience sample of nine capitated medical groups in Southern California. From those organizations' member lists we identified 1089 women who had hysterectomies between August 1, 1993, and July 31, 1995. We excluded 310 women because the procedure codes for their surgeries did not meet our criteria (International Classification of Diseases, 9th Revision, codes 68.3–68.8); surgery was emergent or for a previously diagnosed cancer; or the women did not speak English, or were cognitively impaired or deceased. We obtained informed consent from 539 of the remaining 779 women. An additional 42 were excluded because we were unable to obtain all data required to evaluate appropriateness, leaving 497 women. Ninety-seven physicians did the 497 operations. The study was approved by the RAND Institutional Review Board. Per institutional review board requirements, we collected data only on those patients who agreed to participate.

To collect all data necessary to assess the appropriateness of the recommendation for hysterectomy, we did a structured chart review and interviewed each woman by telephone. Trained abstractors examined inpatient and outpatient medical records for each patient and photocopied all admitting and discharge notes, operative reports, laboratory results, and pathology reports. Trained nurses conducted telephone interviews using a prepared script. Before data entry, nurse overreaders reviewed all forms for completeness and accuracy. If there was evidence in the medical record or interview that a woman was offered but refused a given intervention or medication before her hysterectomy (eg, refusing a laparoscopy) or had a contraindication to a particular intervention (eg, migraine headaches worsened by hormone replacement), that intervention was

considered to have been done for the purpose of the appropriateness analysis.

Trained physicians then reviewed the data and assigned patients to specific diagnostic categories. A computer algorithm classified each woman as a possible candidate for hysterectomy or as having an inappropriate recommendation for hysterectomy based on her medical characteristics. Each patient could be assigned to multiple diagnoses (eg, a woman with pelvic pain and endometrial hyperplasia), and each assignment received an appropriateness rating. When evaluating appropriateness, a patient was given the highest appropriateness rating of all the ratings she received.

Two reviewers independently reviewed a 5% ( $n = 27$ ) subsample of charts. The kappa statistic was .82 for assignment of diagnostic category and .89 for the final appropriateness rating, indicating almost perfect agreement.<sup>13</sup>

When ACOG criteria required information we did not collect (eg, negative cervical cytology before hysterectomy for chronic pain), we assumed that all care would have met that standard. When ACOG listed criteria without specific definitions, we applied the equivalent definition from the RAND panelists (eg, failure of conservative measures to control symptoms).

We compared the expert panel's appropriateness ratings and those of ACOG using the  $\chi^2$  statistic. We conducted several sensitivity analyses, examining how our findings would be affected by inaccuracies in the reporting of symptoms or treatment. We did all statistical calculations using Stata statistical software (version 5.0; Stata Corp., College Station, TX).

## Results

Patients had a mean age of 46 years and a median of two children (Table 1). Two thirds were white, 14% were Hispanic, and 13% were black. More than half the women had household incomes between \$31,000 and \$75,000 per year. One third had prior tubal sterilization. The study physicians did 375 hysterectomies abdominally (75%), 107 vaginally (22%), and 15 vaginally with laparoscopic assistance (3%). Of the 97 physicians in the study, 30 did one of the hysterectomies, 22 did two or three, and 17 did ten or more (data not shown).

Three fifths of all hysterectomies were for uterine leiomyomata (Table 2). Women with leiomyomata causing pain accounted for one fourth of all cases, women with leiomyomata and bleeding but no pain accounted for an additional 13% of cases, and women with leiomyomata and bleeding and pain made up 16% of cases (data not shown).

The percentage of women considered possible candidates for hysterectomy varied substantially by clinical

**Table 1.** Demographic and Clinical Characteristics

| Characteristic               | No. of cases | % of cases |
|------------------------------|--------------|------------|
| Age (y)                      |              |            |
| <40                          | 94           | 19         |
| 40–49                        | 272          | 55         |
| 50–59                        | 82           | 16         |
| >59                          | 49           | 10         |
| No. of children              |              |            |
| 0                            | 89           | 18         |
| 1                            | 94           | 19         |
| ≥2                           | 313          | 63         |
| Race                         |              |            |
| White                        | 324          | 65         |
| Hispanic                     | 68           | 14         |
| Black                        | 63           | 13         |
| Other                        | 42           | 8          |
| Menopausal status            |              |            |
| Premenopausal                | 403          | 81         |
| Postmenopausal               | 94           | 19         |
| Annual income                |              |            |
| <\$10,000                    | 9            | 2          |
| \$10–30,000                  | 115          | 23         |
| \$31–50,000                  | 144          | 29         |
| \$51–75,000                  | 124          | 25         |
| >\$75,000                    | 88           | 18         |
| Employment status            |              |            |
| Full-time                    | 333          | 67         |
| Part-time                    | 45           | 9          |
| Unemployed                   | 45           | 9          |
| Retired                      | 35           | 7          |
| Homemaker                    | 40           | 8          |
| Highest education level      |              |            |
| Did not complete high school | 30           | 6          |
| High school                  | 144          | 29         |
| Some college                 | 199          | 40         |
| College graduate             | 124          | 25         |
| Marital status               |              |            |
| Married                      | 342          | 69         |
| Never married                | 40           | 8          |
| Widowed, divorced, separated | 114          | 23         |

condition (Table 2). For example, only one fifth of women with leiomyomata were considered possible candidates for hysterectomy, but more than half of those with cervical dysplasia were considered candidates. Overall, 70% of cases did not meet the expert panel's criteria, and the decision to recommend hysterectomy was considered inappropriate. Four common indications are shown in Table 3.

Most cases for which recommendations for hysterectomy were judged inappropriate lacked one or more diagnostic or therapeutic interventions. For example, neither a laparoscopy nor a laparotomy was done before hysterectomies on 158 of 204 women (77%) with pelvic pain. The panel believed such an evaluation was necessary in most cases to exclude other causes of pain before hysterectomy. One hundred ten of 246 women (45%) with abnormal uterine bleeding did not have

**Table 2.** Appropriateness of Recommendations for Hysterectomy by Diagnostic Category

| Diagnosis               | Total no. of hysterectomies |                | Appropriateness rating* |                |               |                |
|-------------------------|-----------------------------|----------------|-------------------------|----------------|---------------|----------------|
|                         |                             |                | Possible candidate      |                | Inappropriate |                |
|                         | No.                         | % <sup>†</sup> | No.                     | % <sup>‡</sup> | No.           | % <sup>‡</sup> |
| Leiomyomata             | 298                         | 60             | 64                      | 21             | 234           | 79             |
| Pelvic relaxation       | 55                          | 11             | 24                      | 44             | 31            | 56             |
| Pain                    | 45                          | 9              | 23                      | 51             | 22            | 49             |
| Abnormal bleeding       | 41                          | 8              | 18                      | 43             | 23            | 57             |
| Cervical dysplasia      | 20                          | 4              | 11                      | 55             | 9             | 45             |
| Adnexal mass            | 22                          | 4              | 6                       | 27             | 16            | 73             |
| Endometrial hyperplasia | 10                          | 2              | 3                       | 30             | 7             | 70             |
| Miscellaneous           | 6                           | 1              | 0                       |                | 6             | 100            |
| Total <sup>§</sup>      | 497                         | 99             | 130                     | 30             | 367           | 70             |

\* Appropriateness for cases with multiple indications based on highest (most appropriate) rating.

<sup>†</sup> Column percentage.

<sup>‡</sup> Row percentage.

<sup>§</sup> Percentages may not add to 100 because of rounding.

endometrial sampling before hysterectomy. Seventy-one of 340 women (21%) with pain or bleeding did not receive (or were not offered) a trial of medical treatment for pain or bleeding. In one third of cases that required intervention, two or more interventions were omitted.

Of 497 women we studied, 71 had hysterectomies for

endometriosis, chronic pelvic pain, or premenopausal abnormal bleeding, conditions covered by three recent ACOG criteria sets. The recommendation for hysterectomy was judged inappropriate for 53% of that subset of women by the expert panel criteria and 76% of those did not meet ACOG criteria (Table 4). Although ACOG criteria sets explicitly state that required data should be found in the medical record, we also used data found only in patient interviews.

Inadequate medical records or faulty patient recall might lead to incorrect analyses, so we conducted two sensitivity analyses. The women in this study did not have hysterectomies for cancer or emergencies, so their surgeries were primarily done to improve the quality of their lives. As a result, the expert panel usually required evidence that a woman suffered some type of impairment of daily function to be a possible candidate for hysterectomy. If we assumed that all women were impaired, the percentage of cases judged inappropriately recommended fell from 70% to 66%. The high rate of inappropriate recommendations for hysterectomies despite significant impairment was because women had not had diagnostic or therapeutic interventions that were considered necessary before hysterectomy. Documentation and recall of medication use might be less accurate than recall of procedures, so we examined the effect of assuming that all women had trials of medical treatment before surgery. In that case, the inappropriate rate fell to 66%.

### Discussion

We found that the care leading recommendations of hysterectomies in our cohort was suboptimal. Seventy percent of those cases did not meet standards of expert panel recommendations. In addition, 76% of women

**Table 3.** Common Indications for Hysterectomy by Panel Rating

| Indication   | No. of cases | % of all cases |
|--|--------------|----------------|
| Possible candidate for hysterectomy  |              |                |
| Premenopausal woman with leiomyomata and bleeding without pain who had a trial of medical therapy (or was offered and refused such a trial); has significant anemia or major impairment from bleeding; and has no significant disease on endometrial sampling        | 12           | 2              |
| Postmenopausal woman with persistent or recurrent abnormal bleeding who has been given a trial of hormone therapy (or had hormone therapy adjusted) and has no significant disease on endometrial sampling   | 10           | 2              |
| Inappropriate  |              |                |
| Premenopausal woman with leiomyomata, bleeding, and pain who has significant anemia or major functional impairment but has not undergone endometrial sampling  | 44           | 9              |
| Premenopausal or postmenopausal woman with cervical intraepithelial neoplasia 2 confirmed by biopsy without trial of conservative treatment (eg, loop electrosurgical excision procedure/large loop excision of the transformation zone, cryotherapy, or conization) | 5            | 1              |

**Table 4.** Hysterectomy Appropriateness Judged by Expert Panel Recommendations and by ACOG Criteria Sets

| Condition                               | No. of cases | Cases that did not meet criteria |    |      |     | P     |
|---|--------------|----------------------------------|----|------|-----|-------|
|   |              | Expert panel                     |    | ACOG |     |       |
|   |              | No.                              | %  | No.  | %   |       |
| Endometriosis                           | 23           | 4                                | 17 | 15   | 65  | <.001 |
| Premenopausal abnormal uterine bleeding | 31           | 18                               | 58 | 22   | 71  | .210  |
| Chronic pelvic pain                     | 17           | 16                               | 94 | 17   | 100 | .150  |
| Total                                   | 71           | 38                               | 53 | 54   | 76  | <.001 |

with conditions covered by ACOG criteria sets would have been referred for peer review because their care did not meet ACOG criteria.

Our finding that many diagnostic steps are not done before hysterectomy is not unique. In the Maine Women's Health Study, fewer than half of women with abnormal uterine bleeding had endometrial sampling before hysterectomy and only two thirds of those with pelvic pain had pre-hysterectomy laparoscopies.<sup>14</sup> Our findings do not mean that had all the recommended steps been followed only 30% of the hysterectomies would have been done. Several frequently omitted diagnostic or treatment steps necessary for women to be considered possible candidates for hysterectomy probably would not have affected the eventual outcome. For example, endometrial sampling is often done to rule out uterine cancer, but hysterectomy is commonly done regardless of the results of that sampling. The expert panel ratings and ACOG's criteria sets provided an objective standard by which the quality of recommendations for hysterectomy could be judged, and can provide a benchmark with which to compare care in a variety of settings.

The rate of inappropriate recommendations for hysterectomy in this study is higher than the rates reported for coronary angiography, tympanostomy tubes, and upper gastrointestinal endoscopy, which have ranged from 2% to 44%; however, it is in the range found for carotid endarterectomy.<sup>2,15-17</sup> It is also significantly higher than the 10-27% inappropriate rates found for hysterectomy in previous studies of managed care organizations using similar methodology.<sup>4</sup> However, the previous study examined appropriateness of the procedure itself, rather than the recommendation for hysterectomy. In the current study, 14% of women had clinical characteristics such that, regardless of diagnostic or therapeutic steps before surgery, the panel would have considered the procedure inappropriate (eg, surgery for pelvic relaxation in a woman with first-degree uterine prolapse and no incontinence or pain). The majority of recommendations for hysterectomy were judged inappropriate, so we must consider whether our criteria were too strict, or if the appropriateness method

itself was flawed. We believe our criteria were reasonable for several reasons. A national, multispecialty, expert panel developed the criteria using a well-established methodology.<sup>15-18</sup> For example, Shekelle et al found moderate reliability (ie,  $\kappa = .51$ ) across three expert panels who rated appropriateness of hysterectomy using identical methodology.<sup>19</sup> That level of reliability is significantly better than individual surgeons regarding need for hysterectomy.<sup>20</sup> Significantly more cases met our own panel's criteria than those in ACOG's criteria sets, which might have been because our criteria were biased toward fewer inappropriate ratings than ACOG criteria (ie, we classified cases with multiple indications by the indication with the highest appropriateness score). We ignored whether critical steps were followed for other indications. Using the expert panel ratings, a woman with chronic pelvic pain and abnormal bleeding could have been considered a possible candidate for hysterectomy for pain, despite inadequate evaluation for bleeding. The ACOG hysterectomy criteria set for chronic pain, on the other hand, requires that if bleeding is present, it must also be properly evaluated.<sup>6</sup> In cases in which a particular therapy or intervention was required before hysterectomy, our rules reduced the number considered inappropriate by accepting evidence that women were offered such treatment as the equivalent of actually receiving it.

Our findings depended on how accurately we measured the care the women received, so we took several steps to enhance the accuracy and completeness of the data. We obtained all relevant in- and outpatient records. We conducted independent abstractions for a subsample of women and showed excellent inter-rater reliability. We also interviewed each woman, collecting data not routinely reported in the medical record. We conducted sensitivity analyses and found that our results would not be materially affected even by large errors in recording data, such as use of medical therapy or degree of impairment.

Our data appeared to be accurate and the standards for assessing appropriateness of recommending hysterectomy reasonable, so what caused the large difference

between actual practice and those standards? There are several potential answers. Hysterectomy is a relatively safe procedure that effectively cures abnormal uterine bleeding and often resolves other gynecologic symptoms.<sup>14,21</sup> Thus, many women or their physicians might perceive that the benefits of hysterectomy outweigh its risks, even in situations when the panel felt that the risk/benefit ratio suggested otherwise. The lack of randomized controlled trials (RCTs) that evaluated hysterectomy might lead to professional uncertainty about indications for hysterectomy. When our panel met, there was only a single RCT that compared hysterectomy to an alternative treatment for menorrhagia, and none that compared it to alternative treatments for leiomyomata.<sup>22</sup> Reimbursement policies (eg, paying more for surgery than medical treatment) might contribute to the gap between clinical practice and the recommendations.

There were several limitations to this study. We could not identify underuse of hysterectomy. Although we found underuse of medical treatment and conservative surgeries among women who eventually had hysterectomies, we did not examine care for women with the same gynecologic conditions who did not undergo hysterectomy, and there might be substantial underuse among those women.

Our study focused on practices in Southern California during a 2-year period, and the results might not be generalizable to other regions or times. Rates of hysterectomy vary markedly across regions, and it is not known whether the proportion of women who receive inappropriate recommendations for hysterectomy also varies by region.<sup>23-25</sup> In addition, care might vary among physicians; however, the hysterectomies examined in this study were done by 97 physicians working at nine different medical groups, and the majority of them did three or fewer hysterectomies in the study. Thus, this study did not represent the care of only a few physicians. After controlling for diagnosis, there were no significant differences among medical groups with regard to appropriateness ratings. We had too few cases per physician to examine a specific physician effect.

The recommendations used in this study represent the group judgment of experts (the expert panel and ACOG) on the appropriateness of recommendations for hysterectomy for the average woman who presented with specific clinical characteristics. The recommendations were designed to examine the care given to populations of patients, not individual women, and the criteria sets were designed to identify cases that should be peer reviewed. These types of ratings can best be thought of as screening tests that suggest the need for physician review of cases not meeting guidelines.<sup>19</sup>

Studies such as this can be useful for internal and

external quality evaluations. For example, we found substantial evidence of underuse of established diagnostic and therapeutic regimens before proceeding to hysterectomy. We are working with the medical plans to determine whether providing this information to the physicians will improve the quality of care for women with conditions leading to hysterectomy.

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*Received February 24, 1999.*  
*Received in revised form July 21, 1999.*  
*Accepted August 5, 1999.*

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