

**Easing the discomfort of a speculum exam. Online exclusive. *J Fam Pract.* September 2012;61(9):E1-E3.**

**Potential PURL Review Form: Randomized controlled trials**

**SECTION 1: IDENTIFYING INFORMATION**

1. Citation Hill DA, Lamvu G. Effect of lubricating gel on patient comfort during vaginal speculum examination: a randomized controlled trial. *Obstet Gynecol.* 2012;119(2 pt 1):227-231.
2. Hypertext link to PDF of full article <http://www.ncbi.nlm.nih.gov/pubmed/22270273>
3. First date published study available to readers February 1, 2012
4. PubMed ID 22270273
5. Nominated By Kate Rowland
6. Institutional Affiliation of Nominator University of Chicago
7. Date Nominated January 26, 2012
8. Identified Through Green Journal
9. PURLS Editor Reviewing Nominated Potential PURL Kate Rowland
10. Nomination Decision Date February 2, 2012
11. Potential PURL Review Form (PPRF) Type Randomized controlled trial
12. Other comments, materials or discussion
13. Assigned Potential PURL Reviewer Nina Rogers
14. Reviewer Affiliation University of Chicago
15. Date Review Due March 1, 2012
16. Abstract **OBJECTIVE:** To estimate the efficacy of lubricating gel compared with using water for pain during vaginal speculum insertion.

**METHODS:** This study was a randomized trial of nonpregnant women aged 18-50 years who required a vaginal speculum examination between February and July 2011. Patients blinded to study assignment underwent vaginal speculum examination using a standardized technique with a medium-sized plastic speculum prepared with either 0.3 mL lubricating gel or 3 mL of water used to cover both speculum blades. Patients recorded pain using a 10-cm visual analog scale immediately after speculum insertion. A pre hoc power analysis determined that 55 patients in each arm would be required to detect a difference of 0.9 cm on a 10-cm visual analog scale.

**RESULTS:** A total of 299 consecutive women requiring vaginal speculum examination were screened for enrollment and 120 women were randomized with 60 per group. There were no marked differences in the demographic characteristics of the gel (n=59) and water (n=60) participants available for final analysis. The gel group showed significantly lower pain scores for speculum insertion (mean±standard deviation: 1.41±1.55 compared with water 2.15±1.93,  $P<.01$ ). Of patients undergoing examination with gel, 20 of 59 (33.9%) marked zero on the pain scale compared with six of 60 (10%) patients receiving water ( $P=.002$ ). All 73 patients who underwent Pap screening had adequate cytology.

**CONCLUSION:** Applying a small amount of lubricating gel significantly decreases patient pain during vaginal speculum insertion.

**CLINICAL TRIAL REGISTRATION:** ClinicalTrials.gov, www.clinicaltrials.gov, NCT01289665.

**LEVEL OF EVIDENCE:** I.

## SECTION 2: CRITICAL APPRAISAL OF VALIDITY

- |  |   |
|--|---|
| <b>1.</b> Number of patients starting each arm of the study?   | 60  |
| <b>2.</b> Main characteristics of study patients (inclusions, exclusions, demographics, settings, etc.)? | Consecutive patients aged 18-50 years who presented with conditions requiring vaginal speculum examination were screened.<br><br>Exclusion criteria: Women who were menopausal (as determined by an elevated follicular-stimulating hormone level, use of hormone therapy, or amenorrhea for ≥12 months); were pregnant or within 6 weeks of delivery; had dyspareunia, vaginitis, vulvar pain, or vulvar lesions; were undergoing a vulvar, vaginal, or uterine procedure; were not fluent in English; or had never had vaginal intercourse were excluded to prevent inclusion of altered pain perception. |
| <b>3.</b> Intervention(s) being investigated?  | Lubricating gel for diminished pain during speculum insertion.  |
| <b>4.</b> Comparison treatment(s), placebo, or nothing?  | Water   |
| <b>5.</b> Length of follow up? Note specified end points e.g. death, cure, etc.                          | Examinations occurring February through July 2011.  |
| <b>6.</b> What outcome measures are used? List all that assess effectiveness.                            | Participants' marking on a 10-cm, nonhatched visual analog scale immediately after the speculum was opened to the third notch.  |
| <b>7.</b> What is the effect of the intervention(s)? Include absolute risk,                              | Absolute risk of having a pain score greater than zero was 66.9% in the gel group and 90% in the water group ( $P=.002$ ). The relative risk of pain greater than zero was 72% in the gel group, or a relative risk reduction of 28%. The number needed to treat with   |

relative risk, NNT, CI, p-values, etc.	gel was 4.18 to ensure a pain score of zero. The total mean pain scores in the gel group was 1.41 ( $\pm 1.55$ ) and 2.15 ( $\pm 1.93$ ) in the water group ( $P < .011$ ).
<b>8.</b> What are the adverse effects of intervention compared with no intervention?	There is a risk of unsatisfactory results of the Pap smear, but the authors noted all the patients who underwent screening using liquid cytology in both arms had satisfactory results.
<b>9.</b> Study addresses an appropriate and clearly focused question - <b><i>select one</i></b>	Well covered
<b>10.</b> Random allocation to comparison groups	Well covered
<b>11.</b> Concealed allocation to comparison groups	Well covered
<b>12.</b> Subjects and investigators kept "blind" to comparison group allocation	Well covered
<b>13.</b> Comparison groups are similar at the start of the trial	Well covered
<b>14.</b> Were there any differences between the groups/arms of the study other than the intervention under investigation? If yes, please indicate whether the differences are a potential source of bias.	Well covered
<b>15.</b> Were all relevant outcomes measured in a standardized, valid, and reliable way?	Well covered
<b>16.</b> Are patient oriented outcomes included? If yes, what are they?	Yes, pain.
<b>17.</b> What percent dropped out, and were lost to follow up? Could this bias the results? How?	1.7%. This is unlikely to bias the results.
<b>18.</b> Was there an intention-to-treat analysis? If not, could this bias the results? How?	No, but this is unlikely to bias the results as so few participants dropped out.

- 19.** If a multi-site study, are results comparable for all sites? N/A
- 20.** Is the funding for the trial a potential source of bias? If yes, what measures were taken to insure scientific integrity? Funding was not disclosed explicitly, but the authors did not report any potential conflicts of interest.
- 21.** To which patients might the findings apply? Include patients in the study and other patients to whom the findings may be generalized. Premenopausal patients undergoing routine speculum examinations for non-pain-related reasons.
- 22.** In what care settings might the findings apply, or not apply? Primary care settings
- 23.** To which clinicians or policy makers might the findings be relevant? Primary care physicians and clinical administrators.

### SECTION 3: REVIEW OF SECONDARY LITERATURE

#### 1. DynaMed excerpts

- 2.** DynaMed citation/access date Cervical cancer screening. In: DynaMed [database online]. Available at: [www.DynamicMedical.com](http://www.DynamicMedical.com). Last updated December 4, 2011. Accessed February 28, 2012.
- 3.** Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences) There is no mention of gel or water in relation to comfort.

#### 4. UpToDate excerpts

- 5.** UpToDate citation/access date Feldman S, Crum CP. Cervical cancer screening tests: Techniques and test characteristics of cervical cytology and human papillomavirus testing. In: Basow DS, ed. UpToDate [database online]. Waltham, Mass: UpToDate; 2012. Available at: <http://www.uptodate.com>. Last updated January 23, 2012. Accessed February 28, 2012.

- 6.** Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences) There is no mention of gel or water concerning comfort.

- 7.** PEPID PCP excerpts  
[www.pepidonline.com](http://www.pepidonline.com)  
 username: fpinauthor  
 pw: pepidpcp

There are no PEPID excerpts addressing this topic.

8. PEPID citation/access data

9. PEPID content updating

1. Do you recommend that PEPID get updated on this topic?

Yes, there is important evidence or recommendations that are missing.

10. Other excerpts (USPSTF; other guidelines; etc.)

When choosing a speculum for the examination, the patient's age, developmental status, hymenal opening, and sexual experience should influence the decision. Typically, a Pederson or Huffman speculum should be used.

11. Citations for other excerpts

The initial reproductive health visit. ACOG Committee Opinion Number 460, July 2010.  
[http://www.acog.org/Resources\\_And\\_Publications/Committee\\_Opinions/Committee\\_on\\_Adolescent\\_Health\\_Care/The\\_Initial\\_Reproductive\\_Health\\_Visit](http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Adolescent_Health_Care/The_Initial_Reproductive_Health_Visit). Accessed: February 28, 2012.

12. Bottom line recommendation or summary of evidence from Other Sources (1-2 sentences)

There is no mention of recommendations for comfort with a speculum examination.

**SECTION 4: CONCLUSIONS**

**1. Validity:** How well does the study minimize sources of internal bias and maximize internal validity? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly)

1

**2.** If 4.1 was coded as 4, 5, 6, or 7, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?

**3. Relevance:** Are the results of this study generalizable to and relevant to the health care needs of patients cared for by "full scope" family physicians? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly)

1

**4.** If 4.3 was coded as 4, 5, 6, or 7, please provide an explanation.

**5. Practice-changing potential:** If the findings of the study are both valid and relevant, does the practice that would be based on these

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findings represent a change from current practice? Give one number on a scale of 1 to 7 (1=definitely a change from current practice; 4=uncertain; 7=definitely not a change from current practice)

6. If 4.5 was coded as 1, 2, 3, or 4, please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit.

I believe that physicians are not using gel for fear of unsatisfactory Pap smear results. The new recommendation would be to use gel for every speculum examination.

**7. Applicability to a Family Medical Care Setting:** 1

Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office, hospital, nursing home, etc), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, educating or counseling a patient; or creating a system for implementing an intervention? Give one number on a scale of 1 to 7 (1=definitely could be done in a medical care setting; 4=uncertain; 7=definitely could not be done in a medical care setting)

8. If you coded 4.7 as a 4, 5, 6 or 7, please explain.

**9. Immediacy of Implementation:** 1

Are there major barriers to immediate implementation? Would the cost or the potential for reimbursement prohibit implementation in most family medicine practices? Are there regulatory issues that prohibit implementation? Is the service, device, drug or other essentials available on the

market? Give one number on a scale of 1 to 7 (1=definitely could be immediately applied; 4=uncertain; 7=definitely could not be immediately applied)

10. If you coded 4.9 as 4, 5, 6, or 7, please explain why.

**11. Clinical meaningful outcomes or patient-oriented outcomes:** 3

Are the outcomes measured in the study clinically meaningful or patient oriented? Give one number on a scale of 1 to 7 (1=definitely clinically meaningful or patient oriented; 4=uncertain; 7=definitely not clinically meaningful or patient oriented)

12. If you coded 4.11 as a 4, 5, 6, or 7 please explain why.

Although the pain reduction is statistically significant, the absolute reduction is not clinically significant. Nevertheless, in our judgment the effect would be clinically significant.

13. In your opinion, is this a Pending PURL? Give one number on a scale of 1 to 7 (1=definitely a Pending PURL; 4=uncertain; 7=definitely not a Pending PURL) 3

Criteria for a Pending PURL:

- Valid: Strong internal scientific validity; the findings appears to be true.
- Relevant: Relevant to the practice of family medicine
- Practice changing: There is a specific identifiable new practice recommendation that is applicable to what family physicians do in medical care settings and seems different than current practice.
- Applicability in medical setting:

- Immediacy of implementation

**14.** Comments on your response in 4.13.