# RCT
# Potential PURL Review Form
# PURL Jam Version
**Version #11 October 29, 2009**

**PURLs Surveillance System**
**Family Physicians Inquiries Network**

**SECTION 1: Identifying Information for Nominated Potential PURL**
**[to be completed by PURLs Project Manager]**

| | |
|---|---|
| **1.** Citation | Schollhammer M, Brenaut E, Menard-Andivot N, Pillette-Delarue M, Zagnoli A, Chassain-Le Lay M, Sassolas B, Jouan N, Le Ru Y, Abasq-Thomas C, Greco M, Penven K, Roguedas-Contios AM, Dupré-Goetghebeur D, Gouedard C, Misery L, Le Gal G.Oxybutynin as a treatment for generalized hyperhidrosis: a randomized, placebo-controlled trial. Br J Dermatol. 2015 Nov;173(5):1163-8. doi: 10.1111/bjd.13973. Epub 2015 Oct 14. |
| **2.** Hypertext link to PDF of full article | http://www.ncbi.nlm.nih.gov/pubmed/26114588 |
| **3.** First date published study available to readers | 11/1/2015 |
| **4.** PubMed ID | 26114588 |
| **5.** Nominated By | Jim Stevermer Other: |
| **6.** Institutional Affiliation of Nominator | University of Missouri Other: |
| **7.** Date Nominated | 6/5/2016 |
| **8.** Identified Through | InfoPOEMs Other: |
| **9.** PURLS Editor Reviewing Nominated Potential PURL | Other Other: Corey Lyon |
| **10.** Nomination Decision Date | 7/8/2016 |
| **11.** Potential PURL Review Form (PPRF) Type | RCT |
| **12.** Other comments, materials or discussion | |
| **13.** Assigned Potential PURL Reviewer | |
| **14.** Reviewer Affiliation | Other Other: |
| **15.** Date Review Due | 09/28/2016 |
| **16.** Abstract | BACKGROUND:<br>Hyperhidrosis is a disorder that can impair quality of life. Localized treatments may be cumbersome and ineffective, and no systemic treatments have proven to be significantly beneficial. |

OBJECTIVES:
To evaluate the effectiveness and tolerance of low-dose oxybutynin for hyperhidrosis.
METHODS:
We conducted a prospective, randomized, placebo-controlled trial. From June 2013 to January 2014, 62 patients with localized or generalized hyperhidrosis were enrolled. Oxybutynin was started at a dose of 2·5 mg per day and increased gradually to 7·5 mg per day. The primary outcome was defined as improvement of at least one point on the Hyperhidrosis Disease Severity Scale (HDSS). Dermatology Life Quality Index (DLQI) and tolerance were also reported.
RESULTS:
Most patients (83%) in our study had generalized hyperhidrosis. Oxybutynin was superior to placebo in improving the HDSS: 60% of patients treated with oxybutynin, compared with 27% of patients treated with placebo, improved at least one point on the HDSS (P = 0·009). The mean improvement in quality of life measured by DLQI was significantly better in the oxybutynin arm (6·9) than in the placebo arm (2·3). The most frequent side-effect was dry mouth, which was observed in 43% of the patients in the oxybutynin arm, compared with 11% in the placebo arm.
CONCLUSIONS:
Treatment with low-dose oxybutynin is effective in reducing symptoms of hyperhidrosis in generalized or localized forms. Side-effects were frequent but minor and mainly involved dry mouth.

**17.** Pending PURL Review Date

**SECTION 2: Critical Appraisal of Validity**
**[to be completed by the Potential PURL Reviewer]**
**[to be revised by the Pending PURL Reviewer if needed]**

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|---|---|
| **1.** Number of patients starting each arm of the study? | 62 total patients. 32 in treatment and 30 in placebo |
| **2.** Main characteristics of study patients (inclusions, exclusions, demographics, settings, etc.)? | Private dermatology outpatients 18 yrs or older in France with generalized or localized primary hyperhidrosis and HDSS score of 2 or higher. Relevant exclusion: pregnancy, breastfeeding, prostate disease, colonic disease, myesthenia gravis, glaucoma. |
| **3.** Intervention(s) being investigated? | Oxybutynin (low dose) 2.5mg daily uptitrated to 7.5mg daily |
| **4.** Comparison treatment(s), placebo, or nothing? | Placebo |
| **5.** Length of follow up? Note specified end points e.g. death, cure, etc. | 6 weeks |
| **6.** What outcome measures are used? List all that assess effectiveness. | Primary: change in HDSS score. Secondary: Change in DLQI. Side effects were recorded. |
| **7.** What is the effect of the intervention(s)? Include absolute risk, relative risk, NNT, CI, p-values, etc. | 60% in tx ar, vs 27% in placebo arm had at least one point improvement in HDSS for ARR of 33% and NNT of 3. NNT for 2 point improvement was 2.7. DLQI improved by 6.9 in oxy group vs 2.3 in placebo ($p<0.01$) |
| **8.** What are the adverse effects of intervention compared with no intervention? | Dry mouth 43% treatment group. No patients stopped med due to SE |

**9.** Study addresses an appropriate and clearly focused question - ***select one***

☒ Well covered
☐ Adequately addressed
☐ Poorly addressed
☐ Not applicable

Comments:

**10.** Random allocation to comparison groups

☒ Well covered
☐ Adequately addressed
☐ Poorly addressed
☐ Not applicable
Comments:

**11.** Concealed allocation to comparison groups

☒ Well covered
☐ Adequately addressed
☐ Poorly addressed
☐ Not applicable
Comments:

**12.** Subjects and investigators kept "blind" to comparison group allocation

☐ Well covered
☐ Adequately addressed
☐ Poorly addressed
☐ Not applicable
Comments:

**12.** Comparison groups are similar at the start of the trial

☒ Well covered
☐ Adequately addressed
☐ Poorly addressed
☐ Not applicable
Comments:

**14.** 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
☐ Adequately addressed
☐ Poorly addressed
☐ Not applicable
Comments:

**15.** Were all relevant outcomes measured in a standardized, valid, and reliable way?

☐ Well covered
☒ Adequately addressed
☐ Poorly addressed
☐ Not applicable
Comments: The outcomes were subjective, but validated tools and what I would consider POE, but there were no true objective tools for comparison.

**16.** Are patient oriented outcomes included? If yes, what are they?

yes- as above

**17.** What percent dropped out, and were lost to follow up? Could this bias the results? How?

3%, 2 patients from treatment group, 1 lost to follow up and one dropped out prior treatment. none of the dropouts received medication.

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| **18.** Was there an intention-to-treat analysis? If not, could this bias the results? How? | yes |
| **19.** If a multi-site study, are results comparable for all sites? | Assume sites were similar |
| **20.** Is the funding for the trial a potential source of bias? If yes, what measures were taken to insure scientific integrity? | French Society of Derm funded it |
| **21.** To which patients might the findings apply? Include patients in the study and other patients to whom the findings may be generalized. | Adults with localized or generalized primary hyperhidrosis. The N was not high enough to draw conclusions about whether it works better for generalized or localized disease. Young to middle age adults are studied in this article, older adults would probably be more likely to experience intolerable side effects. |
| **22.** In what care settings might the findings apply, or not apply? | Outpatient derm or primary care. |
| **23.** To which clinicians or policy makers might the findings be relevant? | primary care, dermatology |

**SECTION 3: Review of Secondary Literature**
**[to be completed by the Potential PURL Reviewer]**
**[to be revised by the Pending PURL Reviewer as needed]**

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| **Citation Instructions** | For UpTo Date citations, use style modified from http://www.uptodate.com/home/help/faq/using_UTD/index.html#cite & AMA style. Always use Basow DS as editor & current year as publication year.<br><br>EXAMPLE: Auth I. Title of article. {insert author name if given, & search terms or title.} In: Basow DS, ed. UpToDate [database online]. Waltham, Mass: UpToDate; 2009. Available at: http://www.uptodate.com. {Insert dated modified if given.} Accessed February 12, 2009. {whatever date PPRF reviewer did their search.}<br><br>For DynaMed, use the following style:<br>Depression: treatment {insert search terms or title}. In: DynaMed [database online]. Available at: http://www.DynamicMedical.com. Last updated February 4, 2009. {Insert dated modified if given.} Accessed June 5, 2009.{search date} |
| **1.** DynaMed excerpts | |
| **2.** DynaMed citation/access date | Title. Author. In: DynaMed [database online]. Available at: www.DynamicMedical.com Last updated: . Accessed |
| **3.** Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences) | |
| **4.** UpToDate excerpts | Oral oxybutynin – The efficacy of oxybutynin for hyperhidrosis was documented in a six-week randomized trial of 50 patients with palmar or axillary hyperhidrosis [81]. At six weeks, great or moderate improvement in symptoms occurred in 48 and 26 percent of patients treated with oxybutynin (2.5 mg per day for one week, 2.5 mg twice daily for two weeks, and 5 mg twice daily for three weeks), respectively. In contrast, great or moderate improvement was reported by 0 and 27 percent of |

patients treated with placebo, respectively. Uncontrolled studies performed by the same authors also support the efficacy of oxybutynin for facial, palmar, and axillary hyperhidrosis [86-88]. In addition, a placebo-controlled randomized trial in which most study participants had generalized hyperhidrosis involving more than one body area (among palms, plantar feet, axillae, face, and trunk) demonstrated efficacy of oxybutynin for primary hyperhidrosis [82]. Typical adult doses of oxybutynin are 5 to 10 mg per day; however, doses up to 20 mg per day have been utilized [85].

**5.** UpToDate citation/access date

Always use Basow DS as editor & current year as publication year.
Title. Author. In: UpToDate [database online]. Available at: http://www.uptodate.com. Last updated: . Accessed

**6.** Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences)

2 RCT's and some uncontrolled studies show reduction in symptoms when using oxybutynin.

**7.** PEPID PCP excerpts
www.pepidonline.com
username: fpinauthor
pw: pepidpcp

**8.** PEPID citation/access data

Author. Title. In: PEPID [database online]. Available at: http://www.pepidonline.com. Last updated: . Accessed

**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
☐ No, this topic is current, accurate and up to date.
If yes, which PEPID Topic, Title(s):

2. Is there an EBM Inquiry (HelpDesk Answers and Clinical Inquiries) as indicated by the EB icon (EB) that should be updated on the basis of the review?
☐ Yes, there is important evidence or recommendations that are missing
☐ No, this topic is current, accurate and up to date.
If yes, which Evidence Based Inquiry(HelpDesk Answer or Clinical Inquiry), Title(s):

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

**11.** Citations for other excerpts

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

## SECTION 4: Conclusions
## [to be completed by the Potential PURL Reviewer]
## [to be revised by the Pending PURL Reviewer as needed]

**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 ☐3 ☐4 ☐5 ☐6 ☐7

**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

Small overall population. Not all patients had generalized hyperhydrosis (83%). It was Intention to treat analysis.

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 ☒2 ☐3 ☐4 ☐5 ☐6 ☐7

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

They were all dermatology patients. Possible discrepancy in male vs female numbers in the treatment group. No ethnicity of patients reported. Predominantly young population.

**5. Practice changing potential:** If the findings of the study are both valid and relevant, does the practice that would be based on these 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)
☐1 ☐2 ☒3 ☐4 ☐5 ☐6 ☐7

**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.

Itt is an additional therapy but unlikely to be first line ahead of topical medications and may still be 3rd after botox.

**7. Applicability to a Family Medical Care Setting:** 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)
☒1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

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

**9. Immediacy of Implementation:** 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)
☒1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

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

**11. Clinical meaningful outcomes or patient oriented outcomes:** 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)
☒1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

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

**13.** In your opinion, is this a Pending PURL?
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

Give one number on a scale of 1 to 7
(1=definitely a Pending PURL; 4=uncertain; 7=definitely not a Pending PURL)
☐1 ☒2 ☐3 ☐4 ☐5 ☐6 ☐7

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

Well designed small study, using POEMs that is feasable and easy to implement in a primary care setting. Would probably still be second or third line option.