

PURL Author Instructions

Goal: The goal of the PURLs series is to identify all new research evidence that is immediately applicable to the practices of family physicians and other primary care clinicians. The goal of each individual PURL is to communicate convincingly the need and rationale for the change in practice that is recommended.

Section 1: Instructions

1. Review the following documents, which can be found in the PURLs section of the website.
 - a. PURL Author Instructions (this document)
 - i. Instructions
 - ii. Helpful Hints
 - iii. PURL Template
 - iv. Example PURL
 - b. Potential PURL Review Form—This document has the results of the critical appraisal completed by the Potential PURL Reviewer, the PURL Editor comments, and relevant excerpts from UpToDate, DynaMed, PEPID PCP and other sources.
 - c. PURL Author Checklist (*not yet created*)
2. Please refer to the following documents as needed.
 - a. PURL FAQs – (answers common questions about the PURLs in general)
 - b. AMA Manual of Style—the official style used by the Journal of Family Practice
healthlinks.washington.edu/hsl/styleguides/ama.html
 - c. Determining Strength of Recommendation www.aafp.org/afp/20040201/548.html
 - d. Sample Published PURL Manuscripts (www.jfponline.com/purls)
3. References
 - a. Include past research studies relevant to the study generating this PURL. The study itself will often quote these; the DynaMed and UpToDate excerpts are also good sources to find relevant past research studies (and guidelines).
 - b. Include relevant guidelines and positions from national associations and government agencies.
 - c. The National Guideline Clearinghouse (<http://www.guideline.gov/>) is a good source for identifying relevant guidelines.
 - d. The US Preventive Services Task Force should be reviewed on all clinical prevention topics. (<http://www.ahrq.gov/clinic/USpstfix.htm>)
 - e. The cited references should not represent a comprehensive list of references, but rather those that are essential. Fewer are better than a lot.
4. Optional resources for critical appraisal and designating the Strength of Recommendation:
 - i. The **Strength of Recommendation (SOR)** (included in the Practice Changer) can be determined using the following guide: *Strength of Recommendation Taxonomy (SORT): A patient-centered approach to grading evidence in the medical literature*
www.aafp.org/afp/20040201/548.html
 - ii. An alternate, more detailed **levels of evidence** system than the SORT system is the *Center for Evidence-Based Medicine* system. We do not designate levels of evidence for PURLs since they are generally based on one or two studies (including meta-analyses). However, this guide can be useful for assessing level of evidence in a more detailed way than the SORT system: www.cebm.net/levels_of_evidence.asp#levels
 - iii. If you need help with **interpreting statistics**, this is a good source: *Statistical Help*
www.statsdirect.com/help/statsdirect.htm
 - iv. Other useful sites for **guidance on critical appraisal** and other EBM topics:

Centre for Health Evidence: Users' Guides to Evidence-Based Practice

www.cche.net/usersguide/main.asp

Duke University Medical Center Library: Evidence-Based Medicine

www.mclibrary.duke.edu/subject/ebm

5. PURL authors should obtain permission from authors and publishers for the use of quotes, tables, and other materials taken from previously-published works not in the public domain. Electronic or paper letters of permission should accompany the manuscript as separate attachments. Please mention the original source in the figure legend or table footnote.
6. Convert your search results into user-friendly statistics (numbers needed to treat, confidence intervals, likelihood ratios, etc.) where possible.
7. Compose the manuscript using transparency in your writing: Describe the studies, rather than just stating the results.
8. Format the manuscript according to the template below (section 3).
 - a. Small tables and figures are useful ways to represent a large amount of data in a reader-friendly manner. They should be self-explanatory, clearly organized, and supplemental to the text of the manuscript; avoid duplicating material in the text and the table.
9. List the references using the American Medical Association Manual of Style, 9th edition
healthlinks.washington.edu/hsl/styleguides/ama.html
10. If you have included analyses from the University HealthSystem Consortium, then please list the following acknowledgement just before your reference list:

“We acknowledge Sofia Medvedev, PhD, of the University HealthSystem Consortium (UHC) in Oak Brook, IL for analysis of the [National Ambulatory Medical Care Survey data] and/or [the UHC Clinical Database.”

11. Please add the following acknowledgement to the end of your PURL:

“The PURLs Surveillance System is supported in part by Grant Number UL1RR024999 from the National Center For Research Resources, a Clinical Translational Science Award to the University of Chicago. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center For Research Resources or the National Institutes of Health.”

12. Review the PURL Author Checklist to ensure all criteria are met.

Section 2: Helpful hints for an excellent PURL manuscript

1. Never use **abbreviations** in a title.
2. Always **spell out** the full phrase the first time you use an abbreviation in the text (i.e.acute otitis media (AOM)....)
3. Abbreviations like c/o are never appropriate in a scientific article.
4. In many journals, like JFP, the **superscripted number for the citation** always goes at the end of the sentence.
5. For the "background & clinical context" section, be sure to address the issue at hand.

6. Use caps only for proper names. Most diseases and generic drugs are not considered proper names (i.e. acute otitis media, lidocaine), unless named after a person (Wernicke's encephalopathy) or are a brand name (Wellbutrin).
7. Whenever possible, try to **use the active tense**, not the passive tense e.g. Physicians prescribed paracetamol, vs. Children were given paracetamol. Writing in the active tense is clearer and conveys information more powerfully. Sometime passive tense is appropriate.
8. Small sample sizes are important if the study is negative because the study may not be adequately powered. However, if the study findings are positive, power is not an issue by definition, and therefore small sample size generally is not an issue.
9. List only caveats that would threaten validity or describe important clinical exceptions to the recommendation or practice change. Describe how the validity was threatened and explain why you think that the study is actually valid. If a validity concern is a sufficiently significant one, then it is not a PURL. If there is a study design weakness, limitation or threat to validity that may undermine the findings or cause many readers to doubt the conclusions, explain what it is, how it might undermine the findings and why you think it does not undermine the findings. It is not enough list potential study flaws. Take it the next step and interpret it for the reader. If they are not significant flaws, don't mention them.

Section 3: Template FOR PRIORITY UPDATES FROM THE RESEARCH LITERATURE (PURLs)

TITLE

The objective is to draw the reader into the article. A good title is provocative but not sensational. Traits of effective titles: Concise, gives the benefit to the reader, gives information that the reader does not already know. Tells the reader what to do and why. A Lew Miller tip: Touch a nerve, especially fear, guilt, or greed.

Examples:

Vitamin D prevents cancer in postmenopausal women

(True, but does not convey an action)

Double the dose of vitamin D in postmenopausal women

(Accurate and somewhat provocative, but does not touch a nerve)

Give double-dose vitamin D to prevent cancer in women over 55

(More likely to draw readers into the text. Raises a fear: I have no excuse for not advising these patients about this)

PRACTICE CHANGER

1. A concise statement of the take-home point and how it applies to a clinical dilemma. Similar to the Conclusion in a research report, but more than a statement of the main finding; the Practice Changer explains why it matters to family physicians.
2. The SOR
3. The complete citation of the study

Example:

Practice Changer: Stop prescribing antibiotics for adults with a clinical diagnosis of acute sinusitis, unless the patient has severe symptoms. Antibiotics have little if any positive effects on the severity and duration of symptoms, and they cause adverse effects and create unnecessary expense.

CASE

A concise description of a patient who represents the clinical dilemma. Give more than 1 case if needed. In the last sentence, give the clinical dilemma in the form of a question, such as “Should you recommend that she stay on aspirin or switch to warfarin?”

Example: A 23-year-old woman presents to your office with a 1-week history of cough, purulent nasal discharge, and unilateral facial pain. You diagnose acute sinusitis. Should you prescribe an antibiotic?

FIRST PARAGRAPH

Objective: Give a compelling reason--*in the first few words if possible*--for the family physician to read further.

Explain the clinical dilemma and how/why the PURL study helps. Tell why the this study is a practice changer. May include or allude to: why the problem exists, current standard and the evidence upon which it is based, how the current standard relates to the clinical dilemma, brief summary or citation of relevant guidelines.

Example: “We have been reluctant to use warfarin in elders with atrial fibrillation for good reason: risk of hemorrhage. Since there are few trials looking at use of warfarin among elders in primary care settings, we are uncertain about the balance of benefits and harms. The BAFTA study is the first trial to compare outcomes of warfarin vs aspirin in elders specifically, in the less-than-ideal conditions of real life.”

Do not use the first paragraph to define the condition or give epidemiology.

Speak directly to the reader. Use “we” and “you” rather than “physicians” or “researchers.”

REMAINDER OF INTRO SECTION

The backstory. This is a good place to include potential impact on morbidity and mortality, quality of life, and so on.

Avoid free-floating data. When giving demographics and epidemiology, explain their meaning from the perspective of family physicians.

STUDY SUMMARY

Give the clinical question that the study investigated and how the study was designed to address that question. Summarize salient points about the design, patients, etc. Summarize outcomes.

WHAT'S NEW?

The key finding that makes this study unique in its capacity to improve patient care, if acted upon. Explains how/why this study provides solid grounds for a meaningful, worthwhile change in practice. Make the contrast with past research evidence or the standard practice and why the practice change is new and different.

CAVEATS

Downsides of the practice changer, such as risks, contraindications, monitoring. This is also a good section to

address potential threats to the validity of the study, most importantly, to describe why you think these threats are not sufficiently problematic to conclude that this research justifies a change in practice.

CHALLENGES TO IMPLEMENTATION

What are the barriers to implementation? What do you advise family physicians regarding these barriers? What is your assessment of the challenges and how hard it will be for family physicians to actually put this new information into practice?

REFERENCES

Be selective; JFP prefers 15 or fewer

Please adhere to AMA Manual of Style. For a concise version of AMA reference style, check:

<http://www.docstyles.com/amaguide.htm>

OTHER ELEMENTS

Additional content might be instructive. Examples: counseling script, additional anecdotes or cases that illustrate important variations in the clinical dilemma, list of helpful web sites, figures, tables, text boxes.

FYI

A helpful resource:

<http://www.americanscientist.org/template/AssetDetail/assetid/23947?fulltext=true&print=yes>

The Science of Scientific Writing

If the reader is to grasp what the writer means, the writer must understand what the reader needs

George D. Gopen, Judith A. Swan

This article was originally published in the November-December 1990 issue of American Scientist.

Science is often hard to read. Most people assume that its difficulties are born out of necessity, out of the extreme complexity of scientific concepts, data and analysis. We argue here that complexity of thought need not lead to impenetrability of expression; we demonstrate a number of rhetorical principles that can produce clarity in communication without oversimplifying scientific issues. The results are substantive, not merely cosmetic: Improving the quality of writing actually improves the quality of thought.

The fundamental purpose of scientific discourse is not the mere presentation of information and thought, but rather its actual communication. It does not matter how pleased an author might be to have converted all the right data into sentences and paragraphs; it matters only whether a large majority of the reading audience accurately perceives what the author had in mind. Therefore, in order to understand how best to improve writing, we would do well to understand better how readers go about reading. Such an understanding has recently become available through work done in the fields of rhetoric, linguistics and cognitive psychology. It has helped to produce a methodology based on the concept of reader expecta

Section 4: PURL Manuscript Example

What makes a great PURL Manuscript?

Below you will find an example of a great PURL and some items identified that has made this a good manuscript.

1. Title gives the benefit to reader and strongly arouses interest. (“Benefit” = resolving a clinical dilemma)
2. Emphasis on evidence in throughout, including the “dek” (immediately below the title)
 3. Lead gives the clinical dilemma and identifies with readers—not a “lecture lead” or a “demographic digression” lead
 4. Accompanying text box with art brings up the other side of the coin, and thus adds balance
 5. An intriguing Instant Poll

Patients insist on antibiotics for sinusitis? Here is a good reason to say “no”

Convincing evidence emerges from primary care trials

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Practice changer

Stop prescribing antibiotics for adults with a clinical diagnosis of acute sinusitis, unless the patient has severe symptoms. Antibiotics have little if any positive effects on the severity and duration of symptoms, and they cause adverse effects and create unnecessary expense.

Strength of recommendation

A: Based on a meta-analysis of 9 randomized trials in primary care practice.

Young J, De Sutter A, Merenstein D, et al. Antibiotics for adults with clinically diagnosed acute rhinosinusitis: a meta-analysis of individual patient data. *Lancet*. 2008;371:908-914.¹

■ CASE

A 23-year-old woman presents to your office with a 1-week history of cough, purulent nasal discharge, and unilateral facial pain. You diagnose acute sinusitis.

Should you prescribe an antibiotic?

PURLs Instant Poll

What is the likelihood that most of your patients would accept your recommendation not to use an antibiotic to treat sinusitis?

Extremely likely

Fairly likely

Fairly unlikely

Extremely unlikely

Comments?

No. Yet it's no wonder that most adults treated for acute sinusitis leave the doctor's office with a prescription for antibiotics. Until the publication of the meta-analysis by Young and colleagues¹ featured in this PURL, we have lacked A-level evidence from studies conducted in realistic settings—like your practice and ours.

Review of serial data from the National Ambulatory Medical Care Surveys (NAMCS) from 1999 through 2005 does show a slight downward trend in antibiotic prescribing for acute sinusitis: 1999-2002 data showed that 83% of cases of acute sinusitis were treated with an antibiotic.² Data from the 2004 and 2005 NAMCS reveal that family physicians prescribed antibiotics for 80% of patients with acute sinusitis in 2004 and 76% of patients in 2005 (S. Medvedev, unpublished data, NAMCS database, March 2008).

Is this continued high rate of antibiotic prescribing justified?

Do antibiotics improve symptoms and shorten the duration of illness or not?

These questions are important, obviously, not only because of the high rate of prescribing but also because sinusitis is one of the most common diagnoses: approximately 20 million cases annually in the United States, or about 21% of all outpatient antibiotic prescriptions for adults.²

Which patients might benefit from antibiotics?



Common clinical signs and symptoms cannot identify patients with rhinosinusitis for whom treatment is clearly justified, given the cost, adverse events, and bacterial resistance associated with antibiotic use

- Severity of symptoms is important only in that signs suggestive of a serious complication are the sole reason for immediate antibiotic treatment
- Purulent discharge noted in the pharynx on exam was associated with a higher likelihood of benefit from antibiotics, but NNT was 8
- Antibiotics are not justified even if a patient reports having symptoms for longer than 7-10 days

Source: Young et al.¹

■ A diagnostic dilemma

Before we discuss the evidence that is summarized in the excellent meta-analysis by Young and colleagues,¹ let's acknowledge that acute sinusitis is undeniably a diagnostic dilemma. Distinguishing bacterial from viral infection is nearly impossible on clinical grounds because the symptoms are so similar. A litany of identical upper respiratory symptoms accompanies both viral and bacterial sinus infections. Purulent nasal secretions, maxillary facial pain (especially with unilateral predominance), maxillary tooth pain (which is uncommon with sinus infection), altered sense of smell, and worsening illness after improvement constitute the short list of signs and symptoms that has some predictive value, but even the presence of all of these is not a terrific predictor of bacterial sinus infection. Plain x-rays have low accuracy in distinguishing viral from bacterial infection. Computed tomography (CT) sinus scans are better but far from perfect, are not readily available in practice, and are expensive.

■ Sinusitis in the real world

How effective are antibiotics for patients diagnosed not by sinus x-rays or CTs, but by signs and symptoms—as we typically do in daily practice?

A meta-analysis³ of 13 randomized controlled trials (RCTs) found that sinusitis improved without antibiotics, but it included trials in which patients were recruited based on results of imaging studies and cultures, which are not normally used in primary care clinical practice. That study compared antibiotic treatment to placebo for acute uncomplicated sinusitis; 35% of placebo-treated patients were clinically cured by 7 to 12 days and 73% were improved after 7 days. Antibiotic therapy increased cure rates by 15% and improvement rates by 14%, yielding a number needed to treat of 7 to achieve 1 additional positive outcome at 7 days.

FAST TRACK

Treating 15 patients with an antibiotic to possibly benefit 1 patient after 2 weeks does not seem like a good idea when one considers cost and complications

■ STUDY SUMMARY: Meta-analysis of primary care trials

Young and colleagues¹ aggregated and analyzed individual patient-level data from all known placebo-controlled, randomized, antibiotic treatment trials of adults with clinical symptoms of acute sinusitis that were conducted in primary care settings. They excluded trials that used imaging or bacterial culture as part of patient recruitment.

Studies were included that allowed the use of concomitant medication such as nonsteroidal anti-inflammatory drugs, decongestants, or nasal steroids, as long as patients in both groups had access to the same medications. All trials excluded patients with severe symptoms such as high fever, periorbital swelling or erythema, or intense facial pain, important exclusions that we will discuss below.

They identified 10 such studies and completed an intent-to-treat analysis of the 9 double-blind trials for which patient level data were available. Using individual data from 2547 patients, the odds ratio for an overall antibiotic treatment effect was 1.37 (95% confidence interval, 1.13-1.66), with a number needed to treat (NNT) of 15.

FAST TRACK

The current recommendation to use antibiotics if illness lasts more than 1 week was based on expert opinion, not clinical trials

This finding means that 15 patients needed to be given an antibiotic for 1 additional patient to be cured at 8 to 15 days after treatment commenced. Using statistical modeling, they determined that 64% of patients treated with placebo were cured at 14 days compared with 70% given an antibiotic. One patient out of 1381 treated with placebo experienced a serious complication, a brain abscess.

■ Do antibiotics benefit any subgroups?

The investigators also analyzed the prognostic value of specific signs and symptoms to answer the question: Is there any subgroup of patients who might benefit more from antibiotic treatment?

Duration. Patients with a longer duration of symptoms, more severe symptoms, or increased age took longer to cure, but were no more likely to benefit from antibiotic treatment than other patients.

Symptoms, such as a previous common cold, pain on bending, unilateral facial pain, tooth pain, and purulent nasal discharge did not have any prognostic value.

Only one sign—purulent discharge noted in the pharynx on examination—was associated with a higher likelihood of benefit from treatment with antibiotics, but the NNT was still 8 in this group. Patients with symptoms for 7 days or longer were no more likely to respond to antibiotics than those with symptoms for fewer than 7 days.¹

■ WHAT'S NEW: Realistic evidence from realistic settings

We believe this meta-analysis provides a high level of evidence against routine treatment of sinusitis with antibiotics in primary care practice. Treating 15 patients with an antibiotic to possibly benefit 1 patient 2 weeks after treatment commences does not seem like a good idea when one considers the cost and complications of antibiotic use. Diarrhea and other adverse outcomes are 80% more common among patients with sinusitis who are treated with an antibiotic compared with placebo.³ As noted above, prior meta-analyses of antibiotic treatment for acute sinusitis have been more encouraging than this meta-analysis, with a number needed to treat of 7, but those meta-analyses are clearly overly optimistic for the results one will achieve in primary care practice using clinical signs and symptoms to diagnose acute sinusitis.^{3,4} Unlike the Young study, they included trials in specialty clinics with CT scans and sinus puncture and culture used for the diagnostic standard.

■ Symptoms >1 week are not a reason to prescribe

One very important new finding in this meta-analysis that should change practice is that the duration of illness did not predict a positive response to antibiotics.

Current national recommendations are to use an antibiotic for patients with a duration of illness longer than 1 week, as these patients are presumably more likely to have a bacterial infection.⁵⁻⁷ However, that recommendation had been based on expert opinion, not on data from clinical trials. A longer duration of symptoms should not be a reason to prescribe an antibiotic for sinusitis symptoms.

■ How can you help your patient?

What to do, then, for patients with acute sinusitis? Treat the symptoms, which means recommending pain medication for facial pain or headache and saline nasal spray for the nasal discharge, not antibiotics or nasal corticosteroids. Side effects will be fewer and costs will be lower.

- **Saline irrigation.** A 2007 Cochrane review of 8 chronic and recurrent sinusitis trials showed that nasal saline irrigation is effective for reducing symptoms of chronic and recurrent sinusitis.⁸ Although we do not have high-quality RCT data on saline nasal irrigation for treatment of acute sinusitis, nasal saline irrigation is harmless and inexpensive.
- **What about nasal steroids?** The evidence is equivocal, and the most recent high-quality RCT of nasal steroids showed no effect.⁹

■ CAVEATS: Refer seriously ill patients and complicated cases

A very important caveat to our recommendation is that seriously ill patients must be managed differently. Very infrequently a patient develops a serious complication of acute sinusitis such as brain abscess, periorbital cellulitis, or meningitis. Therefore, seriously ill patients with signs and symptoms of acute bacterial sinusitis, such as high fever, periorbital erythema or edema, severe headache, or intense facial pain must be carefully evaluated

and treated with great caution and close follow-up. These patients should be referred immediately for consultation with an otolaryngologist.

Of course, mildly ill patients today may become quite ill tomorrow, so always provide advice to patients to return if they are getting worse, a good clinical practice for any condition that is usually benign but occasionally serious.

FAST TRACK

Saline nasal spray and pain medications lead to fewer side effects and lower cost

Patients who have prolonged or recurrent sinusitis symptoms need further evaluation for other diagnoses such as allergies, cystic fibrosis, fungal sinus infection, and other illnesses associated with immune compromise. These complicated patients benefit from consultation with an otolaryngologist who has a specific interest in chronic and recurrent sinusitis, and perhaps consultation from an infectious disease specialist as well.

■ CHALLENGES TO IMPLEMENTATION: The patient who wants a pill

Some patients may be accustomed to receiving an antibiotic prescription for their “sinus infections” and may resist conservative management. It may be difficult to convince them that antibiotics won’t make a difference when they attribute past resolution of symptoms to antibiotics.

Take enough time to educate your patients on the natural course of illness, the positive benefits of nasal saline, and the reasons not to use unnecessary antibiotics (eg, they are not effective, have potential adverse effects, and can contribute to future antibiotic resistance); this effort will save you time in future visits.¹⁰ A “just in case you don’t get better” prescription to be filled only if the patient is not improving in the next few days is about 50% effective in reducing antibiotic usage for upper respiratory infections.¹¹

•Acknowledgements•

We acknowledge Sofia Medvedev of the University HealthSystem Consortium (UHC) in Oak Brook, IL for analysis of the National Ambulatory Medical Care Survey data.

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FAST TRACK

Giving a prescription to be filled only if the patient does not improve is about 50% effective in reducing antibiotic usage

[PURLs methodology](#)

This study was selected and evaluated using FPIN’s Priority Updates from the Research Literature (PURL) Surveillance System methodology. The criteria and findings leading to the selection of this study as a PURL can be accessed at www.jfponline.com/purls.

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