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	Uranga A, España PP, Bilbao A, Quintana JM, Arriaga I, Intxausti M, Lobo JL, Tomás L, Camino J, Nuñez J, Capelastegui A. Duration of Antibiotic Treatment in Community-Acquired Pneumonia: A Multicenter Randomized Clinical Trial. JAMA Intern Med. 2016 Sep 1;176(9):1257-65. doi: 10.1001/jamainternmed.2016.3633.
2. Hypertext link to PDF of full article	http://www.ncbi.nlm.nih.gov/pubmed/?term=27455166
3. First date published study available to readers	9/1/2016
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5. Nominated By	Jim Stevermer Other:
6. Institutional Affiliation of Nominator	University of Missouri Other:
7. Date Nominated	8/29/2016
8. Identified Through	Other Other:
9. PURLS Editor Reviewing Nominated Potential PURL	Other Other: Corey Lyon
10. Nomination Decision Date	9/13/2016
11. Potential PURL Review Form (PPRF) Type	RCT
12. Other comments, materials or discussion	
13. Assigned Potential PURL Reviewer	Jennie Jarrett
14. Reviewer Affiliation	Other Other: UPMC St. Margaret's
15. Date Review Due	11/1/2016
16. Abstract	IMPORTANCE: The optimal duration of antibiotic treatment for community-acquired pneumonia (CAP) has not been well established. OBJECTIVE: To validate Infectious Diseases Society of America/American Thoracic Society guidelines for

duration of antibiotic treatment in hospitalized patients with CAP.
DESIGN, SETTING, AND PARTICIPANTS:
This study was a multicenter, noninferiority randomized clinical trial performed at 4 teaching hospitals in Spain from January 1, 2012, through August 31, 2013. A total of 312 hospitalized patients diagnosed as having CAP were studied. Data analysis was performed from January 1, 2014, through February 28, 2015.
INTERVENTIONS:
Patients were randomized at day 5 to an intervention or control group. Those in the intervention group were treated with antibiotics for a minimum of 5 days, and the antibiotic treatment was stopped at this point if their body temperature was 37.8°C or less for 48 hours and they had no more than 1 CAP-associated sign of clinical instability. Duration of antibiotic treatment in the control group was determined by physicians.
MAIN OUTCOMES AND MEASURES:
Clinical success rate at days 10 and 30 since admission and CAP-related symptoms at days 5 and 10 measured with the 18-item CAP symptom questionnaire score range, 0-90; higher scores indicate more severe symptoms.
RESULTS:
Of the 312 patients included, 150 and 162 were randomized to the control and intervention groups, respectively. The mean (SD) age of the patients was 66.2 (17.9) years and 64.7 (18.7) years in the control and intervention groups, respectively. There were 95 men (63.3%) and 55 women (36.7%) in the control group and 101 men (62.3%) and 61 women (37.7%) in the intervention group. In the intent-to-treat analysis, clinical success was 48.6% (71 of 150) in the control group and 56.3% (90 of 162) in the intervention group at day 10 (P = .18) and 88.6% (132 of 150) in the control group and 91.9% (147 of 162) in the intervention group at day 30 (P = .33). The mean (SD) CAP symptom questionnaire scores were 24.7 (11.4) vs 27.2 (12.5) at day 5 (P = .10) and 18.6 (9.0) vs 17.9 (7.6) at day 10 (P = .69). In the per-protocol analysis, clinical success was 50.4% (67 of 137) in the control group and 59.7% (86 of 146) in the intervention group at day 10 (P = .12) and 92.7% (126 of 137) in the control group and 94.4% (136 of 146) in the intervention group at day 30 (P = .54). The mean (SD) CAP symptom questionnaire scores were 24.3 (11.4) vs 26.6 (12.1) at day 5 (P = .16) and 18.1 (8.5) vs 17.6 (7.4) at day 10 (P = .81).
CONCLUSIONS AND RELEVANCE:
The Infectious Diseases Society of America/American Thoracic Society recommendations for duration of antibiotic treatment based on clinical stability criteria can be safely implemented in hospitalized patients with CAP.
TRIAL REGISTRATION:
clinicaltrialsregister.eu Identifier: 2011-001067-51.

17. Pending PURL Review Date	11/1/2016

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

1. Number of patients starting each arm of the study?	A total of 539 patients were assessed for eligibility (Figure). Before randomization, 227 patients did not meet the selection criteria, leaving 312 patients. Of these, 150 patients were randomized to the control group and 162 to the intervention group.
2. Main characteristics of study patients (inclusions, exclusions, demographics, settings, etc.)?	Themean (SD) age of the patients was 66.2 (17.9) years and 64.7 (18.7) years in the control and intervention groups, respectively. There were 95 men (63.3%) and 55 women (36.7%) in the control group and 101 men (62.3%) and 61 women (37.7%) in the intervention group.Baseline demographics and characteristics were similar in the control and intervention groups (Table 1). Mean (SD) PSI scores were 83.7 (33.7) and 81.8 (33.8) in the control and intervention groups, respectively (P = .55). Vital signs at day 5 were similar in both groups (eTable 1 in Supplement 2). Nearly 80% of patients in both groups underwent treatment with quinolones, whereas less than 10% were treated with a β-lactam plus macrolide. Etiologic diagnosis was made in 35 individuals (26.5%) in the control group and 28 (20.5%) in the intervention group (P = .25). No differences were found in terms of age, sex, comorbidities, Katz Index, and severity of disease between those who violated the protocol or were unavailable for

	follow-up and those who did not.
3. Intervention(s) being investigated?	Patients in the intervention group were treated with antibiotics for a minimum of 5 days, and the antibiotic treatment was stopped at this point if their body temperature was 37.8°C or less for 48 hours and they had nomore than 1 CAP-associated sign of clinical instability, defined as systolic blood pressure less than 90mmHg,heart rate greater than 100/min, respiratory rate greater than 24 /min, arterial oxygen saturation less than 90%, or PaO2 less than 60 mm Hg in room air.
4. Comparison treatment(s), placebo, or nothing?	In contrast, duration of antibiotics in the control groupwas determined by physicians as in clinical practice.
5. Length of follow up? Note specified end points e.g. death, cure, etc.	Patinets were followed for 30 days. Patients were assesed at day 10 and again at late follow-up (day 30) since admission
6. What outcome measures are used? List all that assess effectiveness.	The primary outcomes were clinical success rate at day 10 and late follow-up (day 30) since admission, defined as resolution or improvement in signs and symptoms related to pneumonia without further antibiotics,23 and CAP-related symptoms at day 10 measured with the 18-item CAP symptom questionnaire,24 a specific and validated patient-reported outcome measure on which higher scores indicate more severe symptoms (range, 0-90).Secondary outcomes were time until clinical improvement, defined as the number of days patients took to feel better after discharge, provided by a question asked of patients at day 30 about how long it took them to feel better; time to return to normal activity, defined as the number of days before patients returned to their routine, reported by patients at day 30 after hospital admission; radiographic resolution at day 30 after hospital admission, based on assessment of chest radiography performed at least at baseline and late follow-up; in-hospital mortality; mortality at day 30 after hospital admission; CAP recurrence, defined as new or worsening symptoms related to pneumonia or appearance of a new respiratory infection in a patient classified as cured at day 10; hospital readmissions up to day 30 from hospital admission; complications during hospitalization; number of days with adverse events (such as diarrhea or headache) attributable to antibiotics up to day 30 from hospital admission; and length of hospital stay, measured by subtracting date of admission from date of discharge.
7. What is the effect of the intervention(s)? Include absolute risk, relative risk, NNT, CI, p-values, etc.	Clinical success rate at day 10 was 48.6% (71 of 150) in the control group and 56.3% (90 of 162) in the intervention group (P = .18) in the intent-to-treat analysis and 50.4% (67 of 137) in the control group and 59.7% (86 of 146) in the interventiongroup (P = .12) in the per-protocol analysis. At day 30, it improved to 88.6% (132 of 150) and 91.9% (147 of 162) in the control and intervention groups, respectively, in the intent-to treat analysis (P = .33) and to 92.7% (126 of 137) and 94.4% (136 of 146) in the control and intervention groups, respectively, in the per-protocol analysis (P = .54). The CAP symptom questionnaire scores were similar in the 2 groups on day 5 (24.7 [11.4] and 27.2 [12.5] in the control and intervention groups, respectively;P = .10 in the intent-to-treat analysis; and 24.3 [11.4] and 26.6 [12.1] in the control and intervention groups, respectively; P = .16 in the per protocol analysis). At day 10, the CAP symptom questionnaire scores decreased in both groups (18.6 [9.0] and 17.9 [7.6] in the control and intervention groups, respectively; P = .69 in the intent-to-treat analysis; and 18.1 [8.5] and 17.6 [7.3] in the control and intervention groups, respectively, P = .81 in the per protocol analysis) (Table 2).Within different PSI severity groups, clinical success rate at day 10 was comparable in the 2 groups. In the intent-to treat analysis, patients withmore severe disease achieved clinical success at day 30 more frequently in the intervention group than in the control group. No differences were observed in the per-protocol analysis (Table 3).
8. What are the adverse effects of intervention compared with no intervention?	Time receiving antibiotic treatment was significantly longer in the control than the intervention group (median, 10 days [interquartile range, 10- 11] vs 5 days [interquartile range, 5-6.5], respectively;P < .001). Four patients (2.9%) and 101 patients (70.1%) from the control and intervention groups, respectively, were receiving antibiotics for only 5 days (P < .001). No significant differences were found between groups in time until clinical improvement and days to return to normal activity measured at day 30, radiographic resolution at day 30, or adverse effects by day 30 (Table 4). Furthermore, no significant differences were found between groups using Kaplan-Meier survival curves of return to normal activity (eFigure in the Supplement 2) until day 30 (mean time to return to normal activity, 16.6 and 15.4 days in the control and intervention groups, respectively; logrank test, P = .16). In-hospital and 30-day

mortality, in-hospital complications, recurrence by day 30, and length of hospital stay were similar in the 2 groups (Table 4). However, readmission by day 30 was significantlymore common in the control group than in the intervention group (9 [6.6%] vs 2 [1.4%]; P = .02). Callingby telephone after discharge was less common in the control group than the intervention group (38 [27.7%] vs 58 [39.7%]; P = .03).

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: However, the supplemental appendix notes the study was allocation concealed and double blinded.

11. Concealed allocation to comparison groups

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

Comments: This study was not allocation concealed.

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

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

Comments: However, the supplemental appendix notes the study was allocation concealed and double blinded

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

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

Comments: No statistical differences noted.

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:

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

Yes, resolution or improvement in signs and symptoms related to pneumonia without further antibiotics, duration of treatment. Although all-cause mortality or major complications were planned as a primary outcome, as well as clinical cure, we found that there were too few events after day 5 to make this a good choice for the primary outcome

17. What percent dropped out, and were lost to follow up? Could this bias the results? How?	8.6% in the control group and 9.9% in the intervention group. Unlikely to bias results.
18. Was there an intention-to-treat analysis? If not, could this bias the results? How?	Yes, ITT was performed.
19. If a multi-site study, are results comparable for all sites?	Unknown.
20. Is the funding for the trial a potential source of bias? If yes, what measures were taken to insure scientific integrity?	No, study was grant supported.
21. To which patients might the findings apply? Include patients in the study and other patients to whom the findings may be generalized.	This article would apply to patients admitted to the hospital for community acquired pneumonia treatment.
22. In what care settings might the findings apply, or not apply?	Any inpatient settings.
23. To which clinicians or policy makers might the findings be relevant?	This would apply to a variety of clinicians in various specialties as CAP is a common reason for admission.

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

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.

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.}

For DynaMed, use the following style:
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

duration of 3-7 days for some antibiotics (generally azithromycin) may be as effective as longer antibiotic courses for adults with mild-to-moderate community-acquired pneumonia (level 2 [likely reliable] evidence)

- based on systematic review limited by clinical heterogeneity
- systematic review of 15 randomized trials of short course (7 days or less) vs. extended course (> 7 days) of antibiotic monotherapy in 2,796 patients (≥ 12 years old) with radiographically confirmed mild-to-moderate community-acquired pneumonia
- antibiotic studied varied across trials

- 10 trials with 1,093 patients evaluated short-course azithromycin (3 days in 6 trials, 5 days in 4 trials), of which 8 trials compared it to extended course of other macrolide
- 2 trials with 848 patients evaluated short-course fluoroquinolones (compared to same fluoroquinolone in 1 trial, compared to amoxicillin-clavulanate in 1 trial)
- 2 trials with 296 patients evaluated short-course beta-lactams (compared to extended course for same beta-lactams)
- 1 trial with 559 patients evaluated short-course ketolide (telithromycin) compared to extended-course clarithromycin
  - time to outcome assessment ranged from 10 days to 42 days
  - 26.1% short-course vs. 25.6% extended-course patients failed to improve clinically in meta-analysis of 15 trials with 2,796 patients
    - not statistically significant (risk ratio 0.89, 95% CI 0.78-1.02)
    - no significant differences in subgroup analyses by class of short-course antibiotic
    - 3 trials suggested improvement with short-course antibiotic (all using azithromycin for 3 days), 12 trials suggested no differences
    - no significant differences in subgroup analysis of 8 higher-quality trials
  - no significant differences in overall mortality
    - 7 trials had no deaths
    - overall mortality rate 1.7%, range 0.9% to 6.7% in trials with deaths
    - risk ratio 0.81 (95% CI 0.46-1.43) in meta-analysis of 8 trials reporting deaths
  - Reference - Am J Med 2007 Sep;120(9):783, commentary can be found in J Fam Pract 2007 Dec;56(12):1003
  - DynaMed commentary -- most trials evaluating 3 day duration used azithromycin, which has a prolonged half-life, with therapeutic tissue concentrations maintained for extended periods beyond last dose. This may have skewed results to favor shorter courses overall. (Infect Control Hosp Epidemiol 1992 Jun;13(6):357)

2. DynaMed citation/access date

Title. Antibiotics for adult outpatients with community-acquired pneumonia Author. Paritosh Prasad, MD In: DynaMed [database online]. Available at: www.DynamicMedical.com Last updated: Feb 2016. Accessed Oct 2016

3. Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences)

duration of 3-7 days for some antibiotics (generally azithromycin) may be as effective as longer antibiotic courses for adults with mild-to-moderate community-acquired pneumonia (level 2 [likely reliable] evidence)

4. UpToDate excerpts

DURATION OF THERAPY — Duration is difficult to define, since some antibiotics are administered for a short time yet have a long half-life at respiratory sites of infection (eg, azithromycin). Most patients become clinically stable within three to four days of starting antibiotic treatment [108-110].

Based upon the available data, we agree with the Infectious Diseases Society of America/American Thoracic Society (IDSA/ATS) guidelines that patients with community-acquired pneumonia (CAP) should be treated for a minimum of five days if they are afebrile for 48 to 72 hours and have no more than one CAP-associated sign of clinical instability; because of the prolonged half-life of azithromycin, a shorter duration may be indicated for this agent. Two meta-analyses support this recommendation. The first meta-analysis, which included 15 randomized controlled trials of almost 2800 patients with mild to moderate CAP, found comparable clinical outcomes with less than seven days compared with more than seven days of antimicrobial therapy; only two of these trials were limited to hospitalized patients [111].

A subsequent meta-analysis evaluated five randomized trials of adult outpatients

and inpatients with CAP not requiring care in the intensive care unit (ICU) [112]. No differences were found in clinical or microbiological outcomes between short (3 to 7 days) and long (7 to 10 days) regimens.

Treatment trials using a variety of antibiotics have used different durations of therapy, as illustrated in the following observations:

●Azithromycin has been used as monotherapy for 7 to 10 days in patients initially hospitalized (intravenously for the first two to three days with the option of changing to oral therapy to complete the course) [34,113]. In outpatients, azithromycin has been used for three days (at a dose of 500 mg daily) [36] or five days (at a dose of 500 mg for the first dose, followed by 250 mg daily) [114]; the 2 g microsphere formulation has been given as a single dose [42].

●The anti-pneumococcal fluoroquinolones (eg, levofloxacin, moxifloxacin, gemifloxacin) have been used for 5 to 14 days in inpatients and outpatients with CAP, with most patients having a good clinical response within 2 to 3 days. Using a higher dose of a levofloxacin may decrease the duration of therapy; 750 mg for 5 days was as effective as 500 mg for 10 days and was associated with a more rapid resolution of fever [115]. Gemifloxacin for five days was found to be as effective as seven days for the treatment of mild-to-moderate CAP in a randomized multicenter double-blind trial [116].

●In a randomized trial that included 186 inpatients with mild to moderate-severe CAP (Pneumonia Severity Index [PSI] score ≤110) (calculator 1), patients who had improved substantially after an initial three days' treatment with intravenous amoxicillin were randomly assigned to receive oral amoxicillin or placebo three times daily for an additional five days [110]. In the three- and eight-day treatment groups, there was no difference in clinical success rates at day 10 (93 percent for both groups) or day 28 (90 versus 88 percent, respectively).

●In a randomized trial of 860 patients with PSI risk class II, III, or IV community-acquired bacterial pneumonia, a five-day course of oral solithromycin was noninferior to a seven day course of oral moxifloxacin in achievement of early clinical response (78.2 versus 77.9 percent) [46]. (See 'Macrolides versus other drugs' above.)

Procalcitonin has been evaluated for guiding the decision to stop antibiotics since the procalcitonin level appears to correlate with the likelihood of a bacterial infection. In addition, with successful treatment and reduction of bacterial load, there is a rapid reduction of procalcitonin levels. This is discussed in detail separately. (See "Treatment of community-acquired pneumonia in adults who require hospitalization", section on 'Duration of therapy'.)

Recommendations for the duration of therapy in ambulatory and hospitalized patients with CAP are presented separately. (See "Treatment of community-acquired pneumonia in adults in the outpatient setting", section on 'Treatment duration and response' and "Treatment of community-acquired pneumonia in adults who require hospitalization", section on 'Duration of therapy'.)

5. UpToDate citation/access date

Always use Basow DS as editor & current year as publication year.

Title. Treatment of community acquired pneumonia in adults who require hospitalizationAuthor. Basow DS In: UpToDate [database online]. Available at: http://www.uptodate.com. Last updated: 10/27/16. Accessed11/1/16

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

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

could not log on - password/login didn't work

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.)

Patients with CAP should be treated for a minimum of 5 days (level I evidence), should be afebrile for 48–72 h, and should have no more than 1 CAP-associated sign of clinical instability (table 10) before discontinuation of therapy (level II evidence). (Moderate recommendation.) at IDSA on August 14, 2011 cid.oxfordjournals.org Downloaded from IDSA/ATS Guidelines for CAP in Adults • CID 2007:44 (Suppl 2) • S31 33. A longer duration of therapy may be needed if initial therapy was not active against the identified pathogen or if it was complicated by extrapulmonary infection, such as meningitis or endocarditis. (Weak recommendation; level III evidence.)

11. Citations for other excerpts

Mandell LA1, Wunderink RG, Anzueto A, et al.Infectious Diseases Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults.Clin Infect Dis. 2007 Mar 1;44 Suppl 2:S27-72.

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

At least 5 days of treatment and until clinically stable.

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 affect the results?

real world approach to the methods, they did many things upfront with a non-inferiority approach.

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.

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.

this would be a change in practice, but would be specifically for flouroquinolones - unclear if you could utilize for beta-lactams

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.

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

- 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