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	SPRINT Research Group, Wright JT Jr, Williamson JD, Whelton PK, Snyder JK, Sink KM, Rocco MV, Reboussin DM, Rahman M, Oparil S, Lewis CE, Kimmel PL, Johnson KC, Goff DC Jr, Fine LJ, Cutler JA, Cushman WC, Cheung AK, Ambrosius WT. A Randomized Trial of Intensive versus Standard Blood-Pressure Control. N Engl J Med. 2015 Nov 26;373(22):2103-16.
2. Hypertext link to PDF of full article	http://www.ncbi.nlm.nih.gov/pubmed/?term=26551272
3. First date published study available to readers	11/26/2015
4. PubMed ID	26551272
5. Nominated By	Jim Stevermer Other:
6. Institutional Affiliation of Nominator	University of Missouri Other:
7. Date Nominated	11/10/2015
8. Identified Through	Other Other:
9. PURLS Editor Reviewing Nominated Potential PURL	Kate Rowland Other:
10. Nomination Decision Date	
11. Potential PURL Review Form (PPRF) Type	RCT
12. Other comments, materials or discussion	
13. Assigned Potential PURL Reviewer	Kate Rowland
14. Reviewer Affiliation	Other Other: Rush Copley
15. Date Review Due	
16. Abstract	BACKGROUND: The most appropriate targets for systolic blood pressure to reduce cardiovascular morbidity and mortality among persons without diabetes remain uncertain. METHODS: We randomly assigned 9361 persons with a systolic blood pressure of 130 mm Hg or higher and an increased cardiovascular risk, but without diabetes, to a systolic blood-pressure target of less

than 120 mm Hg (intensive treatment) or a target of less than 140 mm Hg (standard treatment). The primary composite outcome was myocardial infarction, other acute coronary syndromes, stroke, heart failure, or death from cardiovascular causes.
RESULTS:
At 1 year, the mean systolic blood pressure was 121.4 mm Hg in the intensive-treatment group and 136.2 mm Hg in the standard-treatment group. The intervention was stopped early after a median follow-up of 3.26 years owing to a significantly lower rate of the primary composite outcome in the intensive-treatment group than in the standard-treatment group (1.65% per year vs. 2.19% per year; hazard ratio with intensive treatment, 0.75; 95% confidence interval [CI], 0.64 to 0.89; P<0.001). All-cause mortality was also significantly lower in the intensive-treatment group (hazard ratio, 0.73; 95% CI, 0.60 to 0.90; P=0.003). Rates of serious adverse events of hypotension, syncope, electrolyte abnormalities, and acute kidney injury or failure, but not of injurious falls, were higher in the intensive-treatment group than in the standard-treatment group.
CONCLUSIONS:
Among patients at high risk for cardiovascular events but without diabetes, targeting a systolic blood pressure of less than 120 mm Hg, as compared with less than 140 mm Hg, resulted in lower rates of fatal and nonfatal major cardiovascular events and death from any cause, although significantly higher rates of some adverse events were observed in the intensive-treatment group. (Funded by the National Institutes of Health; ClinicalTrials.gov number, NCT01206062.).

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]

1. Number of patients starting each arm of the study?	4678 intensive; 4683 control
2. Main characteristics of study patients (inclusions, exclusions, demographics, settings, etc.)?	age 50+ SBP 130-180 One of the following: clinical or subclinical CV disease except stroke CKD except PCKD Age >75 10year Framingham risk of 15% or greater Exclusion: DM
3. Intervention(s) being investigated?	goal SBP 120 or less
4. Comparison treatment(s), placebo, or nothing?	Goal SBP of 135-139
5. Length of follow up? Note specified end points e.g. death, cure, etc.	mean 3.26 years
6. What outcome measures are used? List all that assess effectiveness.	composite of MI, acute coronary syndrome without MI, acute heart failure or death from any cardiovascular cause
7. What is the effect of the intervention(s)? Include absolute risk, relative risk, NNT, CI, p-values, etc.	243 of 4683 (5.2%) patients in the intensive treatment group experienced the primary outcome, compared with 319/4683 (6.8%) in the standard treatment group (ARR: 1.6%, NNT: 63, p<0.001)
8. What are the adverse effects of intervention compared with no intervention?	serious AEs 38.3 vs 37.1% (p=0.25); orthostatic hypotension 4.7% intensive vs 2.5% control; risk of new kidney disease in people wthout known kidney disease: 1.21%/year intensive 0.35% control (p<0.001)

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:
16. Are patient oriented outcomes included? If yes, what are they?	No
17. What percent dropped out, and were lost to follow up? Could this bias the results? How?	111 in intensive; 134 in control
18. Was there an intention-to-treat analysis? If not, could this bias the results?	Yes

How?

19. If a multi-site study, are results comparable for all sites?	Yes
20. Is the funding for the trial a potential source of bias? If yes, what measures were taken to insure scientific integrity?	n/a
21. To which patients might the findings apply? Include patients in the study and other patients to whom the findings may be generalized.	People without diabetes at high risk of CV disease with hypertension
22. In what care settings might the findings apply, or not apply?	primary care, cards
23. To which clinicians or policy makers might the findings be relevant?	primary care, cards

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	
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	There's an entire article about it; rather than excerpt it here's the title: Goal blood pressure in patients with cardiovascular disease or at high risk
5. UpToDate citation/access date	Always use Basow DS as editor & current year as publication year. Title. Goal blood pressure in patients with cardiovascular disease or at high riskAuthor. George Bakris and William White In: UpToDate [database online]. Available at: http://www.uptodate.com. Last updated: 11/23/15.

6. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences)	Quotes SPRINT + other studies
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 ( ) 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.)	Not yet included in AHA guidelines/JNC8
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 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.

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.

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