

**Diagnostic Testing
Potential PURL Review Form
PURL Jam Version
Version #12 Sept 20, 2010**

**PURLs Surveillance System
Family Physicians Inquiries Network**

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

1. Citation Sharman JE, Blizzard L, Kosmala W, Nelson MR. Pragmatic Method Using Blood Pressure Diaries to Assess Blood Pressure Control. Ann Fam Med. 2016 Jan;14(1):63-9.

2. Hypertext link to PDF of full article <http://www.ncbi.nlm.nih.gov/pubmed/26755785>

3. First date published study available to readers 01/14/2016

4. PubMed ID 26755785

5. Nominated By Other Other: Kate Rowland

6. Institutional Affiliation of Nominator Other Other: Rush Copley

7. Date Nominated 01/12/2016

8. Identified Through Other Other: TOC

9. PURLS Editor Reviewing Nominated Potential PURL Kate Rowland

10. Nomination Decision Date 01/21/2016

11. Potential PURL Review Form (PPRF) Type Diagnostic Test

12. Other comments, materials or discussion

13. Assigned Potential PURL Reviewer Corey Lyon

14. Reviewer Affiliation Other Other: Colorado

15. Date Review Due 04/07/2016

16. Abstract

PURPOSE:
Twenty-four-hour ambulatory blood pressure (ABP) is the reference standard of blood pressure control. Home blood pressure (HBP) is superior to clinic blood pressure for assessing control, but a barrier to its use is the need for physicians to calculate average blood pressure from patient diaries. We sought to develop a quick and pragmatic method to assess blood pressure control from patients' HBP diaries.

METHODS:
Seven-day HBP and 24-hour ABP were measured in 286 patients with uncomplicated treated hypertension (aged 64 ± 8 years; 53% female). We determined the optimal ratio of home systolic blood pressure readings above threshold (≥135 mm Hg) for the last 10 recorded that would best predict elevated 24-hour ABP. Uncontrolled blood pressure

was defined as 24-hour ABP systolic blood pressure ≥ 130 mm Hg or 24-hour ABP daytime systolic blood pressure ≥ 135 mm Hg. Validation by corroborative evidence was tested by association with markers of end-organ disease.

RESULTS:

The best predictor of 24-hour ABP systolic blood pressure above treatment/target threshold was having 3 or more ($\geq 30\%$) of the last 10 home systolic blood pressure readings ≥ 135 mm Hg (area under the receiver operating characteristic curve = 0.71). Importantly, patients meeting this criterion had evidence of target organ disease, with significantly higher aortic stiffness, left ventricular relative wall thickness, and left atrial area, and lower left ventricular ejection fraction, compared with those who did not meet this criterion.

CONCLUSIONS:

To facilitate uptake of HBP monitoring, we propose that physicians can determine the percentage of the last 10 home systolic blood pressure values ≥ 135 mm Hg for a patient and tailor management accordingly.

17. Pending PURL Review Date 4/26/16

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

1. Is the spectrum of severity of patients' illness comparable to the patient group typically seen by family physicians and other primary care clinicians?

yes

2. Is the proportion of patients with the target illness comparable to the patient group typically seen by family physicians and other primary care clinicians?

yes

3. The nature of the test being studied is clearly specified.

- | | |
|--|---|
| <input checked="" type="checkbox"/> Well covered | <input type="checkbox"/> Not addressed |
| <input type="checkbox"/> Adequately addressed | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> Poorly addressed | <input type="checkbox"/> Not applicable |

Comments:

4. The test is compared with an appropriate gold standard.

- | | |
|--|---|
| <input checked="" type="checkbox"/> Well covered | <input type="checkbox"/> Not addressed |
| <input type="checkbox"/> Adequately addressed | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> Poorly addressed | <input type="checkbox"/> Not applicable |

Comments: Twenty-four-hour ambulatory blood pressure (ABP) is the reference standard of blood pressure control.

5. Where no gold standard exists, a validated reference standard is used as comparator.

- | | |
|---|--|
| <input type="checkbox"/> Well covered | <input type="checkbox"/> Not addressed |
| <input type="checkbox"/> Adequately addressed | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> Poorly addressed | <input checked="" type="checkbox"/> Not applicable |

Comments:

6. Patients for testing are selected either as a consecutive series or randomly, from a clearly defined study population.

- | | |
|--|---|
| <input checked="" type="checkbox"/> Well covered | <input type="checkbox"/> Not addressed |
| <input type="checkbox"/> Adequately addressed | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> Poorly addressed | <input type="checkbox"/> Not applicable |

Comments: nonpregnant adults receiving antihypertensive therapy for noncomplicated essential hypertension and taking no more than 3 antihypertensives.

7. The test and gold standard are measured independently (blind) of each other.

- | | |
|--|---|
| <input checked="" type="checkbox"/> Well covered | <input type="checkbox"/> Not addressed |
| <input type="checkbox"/> Adequately addressed | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> Poorly addressed | <input type="checkbox"/> Not applicable |

Comments:

8. The test and gold standard are applied as close together in time as possible.

- | | |
|--|---|
| <input checked="" type="checkbox"/> Well covered | <input type="checkbox"/> Not addressed |
| <input type="checkbox"/> Adequately addressed | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> Poorly addressed | <input type="checkbox"/> Not applicable |

Comments: seven day HBP and 24-hour ABP

9. Results are reported for all patients that are entered into the study.

- Well covered
 Adequately addressed
 Poorly addressed

- Not addressed
 Not reported
 Not applicable

Comments:

10. A pre-test diagnosis is made and reported.

- Well covered
 Adequately addressed
 Poorly addressed

- Not addressed
 Not reported
 Not applicable

Comments:

11. How many patients are included in this study?

Please indicate number of patients included, with inclusion/exclusion criteria used to select them.

286

Inclusion criteria: nonpregnant adults receiving antihypertensive therapy for noncomplicated essential hypertension and taking no more than 3 antihypertensive drugs.

Exclusion criteria: severely abnormal left ventricular mass index (women >59 g/m².7 and men >64 g/m².7); clinical history of coronary artery disease or renal disease; serum creatinine exceeding 1.6 mg/dL; secondary causes of hypertension; uncontrolled hypertension (clinic brachial blood pressure >180/100 mm Hg); aortic valve stenosis; or upper limb obstructive atherosclerosis.

12. What is the prevalence (proportion of people with the disease being tested for) in the population from which patients were selected?

the prevalence was not stated in this study.

13. What are the main characteristics of the patient population?

Include all relevant characteristics – e.g. age, sex, ethnic origin, comorbidity, disease status, community/hospital based

286 patients with uncomplicated treated hypertension (aged 64 SD +/- 8 years; 53% female).

14. What test is being evaluated in this study?

Consider whether the technology being described is comparable / relevant to the test being considered in the guideline. i.e. make sure the test has not been superseded by later developments.

Seven-day HBP and 24-hour ABP

15. What is the reference standard with which the test being evaluated is compared?

Indicate whether a gold standard, or if not how this standard was validated.

Twenty-four-hour ambulatory blood pressure (ABP) is the reference standard of blood pressure control.

16. What is the estimated sensitivity of the test being evaluated? (state 95% CI)

Sensitivity = proportion of results in patients with the disease that are correctly identified by the new test.

Sensitivity of the ≥ 3 cut point were 62.1% for mean 24-hour ABP systolic blood pressure ≥ 130 , and 64.6% for 24-hour ABP daytime systolic blood pressure ≥ 135 mm Hg.

- 17.** What is the estimated specificity of the test being evaluated? (state 95% CI)
Specificity = proportion of results in patients without the disease that are correctly identified by the new test
- Specificity of the ≥ 3 cut point was 80.2%, for mean 24-hour ABP systolic blood pressure ≥ 130 , and 77.2% for 24-hour ABP daytime systolic blood pressure ≥ 135 mm Hg.
- 18.** What is the positive predictive value of the test being evaluated?
Positive predictive value = proportion of patients with a positive test result that actually had the disease.
- The positive predictive value of ≥ 3 elevations was 0.85 (95% CI, 0.78-0.91) for 24-hour ABP systolic blood pressure ≥ 130 mm Hg, and 0.79 (95% CI 0.72-0.86) for 24-hour ABP daytime systolic blood pressure ≥ 135 mm Hg.
- 19.** What is the negative predictive value of the test being evaluated?
Negative predictive value = proportion of patients with a negative test result that actually did not have the disease.
- The negative predictive value of ≥ 3 elevations was 0.56 (95% CI 0.48-0.64), for 24-hour ABP systolic blood pressure ≥ 130 mm Hg, and 0.63 (95% CI 0.55-0.71), respectively, for 24-hour ABP daytime systolic blood pressure ≥ 135 mm Hg.
- 20.** What are the likelihood ratios for the test being evaluated?
If not quoted in the study, a number of tools are available that simplify calculation of LRs. Please indicate where results are calculated rather than taken from the study.
- 21.** How was this study funded? Does the funding source raise issues of conflict of interest or bias?
List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.

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

- 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** The American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association (AHA/ASH/PCNA) joint scientific statement on HBPM(1) have developed the following parameters: target BP goal < 135/85 mm Hg, or < 130/80 mm Hg in high-risk patients. If average home BP > 135/85 mm Hg, then 85% probability that ambulatory blood pressure monitoring (ABPM) will be high and decision to begin treatment can be made.

The European Society of Hypertension (ESH) practice guideline on HBPM(2) suggested normal values for home BP 130/80 mm Hg. Findings of a mean SBP \geq 135/85 mm Hg and/or DBP $>$ 85 mm Hg are considered elevated. Borderline or abnormal home BP measures should be confirmed by ABPM (ambulatory blood pressure monitoring).

Some studies show increasing home systolic BP is associated with increasing risk of cardiovascular mortality and cardiovascular events, independent of office BP.

2. DynaMed citation/access date

Title. Blood pressure measurement and monitoring Author. In: DynaMed [database online]. Available at: www.DynamicMedical.com Last updated: 2015 Dec 31. Accessed 25 April 26, 2016

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

Home blood pressure monitoring is more effective than in office blood pressure monitoring

4. UpToDate excerpts

5. UpToDate citation/access date

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

Title. Blood pressure measurement in the diagnosis and management of hypertension in adults Author. Norman M Kaplan, MD and (George Thomas, MD, MPH, FACP, FASN and Marc A Pohl, MD) In: UpToDate [database online]. Available at: <http://www.uptodate.com>. Last updated: Dec 17, 2014. Accessed

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

Ambulatory blood pressure monitoring has the limitations of cost and limited availability. Therefore, increasing attention is being given to home monitoring with inexpensive (40 to 60 US dollars) semi-automatic devices. If the blood pressure (BP) is taken at home to establish the diagnosis of hypertension or to assess BP control, the optimal schedule is unclear. Increasing evidence suggests that at least 12 to 14 measurements should be obtained, with both morning and evening measurements taken, over a period of one week.

Home BP measurements taken at home or work and self-recorded correlate more closely with the results of 24-hour or daytime ambulatory monitoring than with office-based measurements. Therefore, when home BP monitoring is used, hypertension is defined as a BP greater than or equal to 135/85 mmHg, identical to the definition used for ABPM.

Home BP monitoring is also useful in the management of patients with an established diagnosis of hypertension. Various trials have shown that home monitoring can improve BP control and compliance.

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; Revised by the Pending PURL Reviewer as needed]

1. **Validity:** How well does the study minimize sources of internal bias and maximize internal validity?

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?

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 findings represent 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.

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?

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?

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

Prior evidence has shown home b/p tend to be 5-7 pts lower than the clinic; so the ranges for normal b/p are good in this trial.

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

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

The new practice recommendation would be to implement HBP monitoring for management of hypertension. This is currently a Grade A recommendation by USPSTF (to do HBP). The target population would be patients with a diagnosis of hypertension on antihypertensive therapy.

This provides a more standard way of interpreting home b/p checks and how to make treatment decisions, whereas now, we are just using a gestalt.

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

Could be easily implemented, but need to consider how to get b/p machines to pts and assure they are using them correctly. - provide standard instructions.

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

Is the service, device, drug or other essentials available on the market?

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?

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

Some questions about is this for all populations, who were the excluded patients. Do we know that these resources will be better controlling blood pressure than other treatments (possibly still unknown).

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

SECTION 4.1: Diving for PURLs

[optional for the potential PURL reviewer -if you wish to be the author on the summary]

1. Study Summary-

Please summarize the study in 5-7 sentences

2. Criteria- note yes or no for those which this study meets

RELEVANT -
VALID -
CHANGE IN PRACTICE-
MEDICAL CARE SETTING -
IMMEDIATELY APPLICABLE -
CLINICALLY MEANINGFUL -

3. Bottom Line- one –two sentences noting the bottom line recommendation

4. Title Proposal

SECTION 5: Editorial Decisions

[to be completed by the FPIN PURLs Editor or Deputy Editor]

1. FPIN PURLs editorial decision (select one)

- 1 Pending PURL Review—Schedule for Review
 2 Drop
 3 Pending PURL

3. Follow up issues for Pending PURL Reviewer

3. FPIN PURLS Editor making decision

- 1 Bernard Ewigman
 2 John Hickner
 3 Sarah-Anne Schumann
 4 Kate Rowland

4. Date of decision

5. Brief summary of decision

SECTION 6: Survey Questions for SERMO, PURLs Instant Polls and Other Surveys

[To be completed by the PURLs Survey Coordinator and PURLs Editor]

1. Current Practice Question for Surveys

2. Barriers to Implementation Question for Surveys

3. Likelihood of Change Question for Surveys

4. Other Questions for Surveys

SECTION 7: Variables for Secondary Database Analyses

1. Population: Age, gender, race, ethnicity

2. Diagnoses

3. Drugs or procedures

SECTION 8: Pending PURL Review Assignment [to be completed by PURLs Project Manager]

1. Person Assigned for
Pending PURL Review

2. Date Pending PURL Review is due

SECTION 9: Pending PURL Review [to be completed by the Pending PURL Reviewer]

1. Did you address the follow up issues identified at the PURL Jam (Section 5.2). Add comments as needed.

Yes
 No
 Not applicable
Comments:

2. Did you review the Sermo poll & Instant Poll results (if available)? Add comments as needed.

Yes
 No
 Not applicable
Comments:

3. Did you modify Sections 2, 3, or 4? Add comments as needed.

Yes
 No
 Not applicable
Comments:

SECTION 10: PURL Authoring Template
[to be completed by the assigned PURL Author]

Author Citation Information (Name, Degrees, Affiliation)

1. Practice Changer

2. Illustrative Case

3. Background
Clinical Context
Introduction
Current Practice

4. Study Summary

5. What's New

6. Caveats

7. Challenges to Implementation

8. Acknowledgment Sentence

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.

If using UHC data:

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

9. References