AHRQ Systematic Review Surveillance Program

CER #45: Self-Measured Blood Pressure Monitoring: Comparative Effectiveness

Original Release Date: January 2012
Surveillance Report: November 2012
Surveillance Report: March 2016

Summary of Key Findings from Surveillance Reports:

- Key Question 1: Original systemic review conclusions are likely current.
- Key Question 1a: Original systematic review conclusions are likely current.
- Key Question 1b: Original systematic review conclusions are likely current
- Key Question 2: The conclusion that evidence fails to support a difference between self-measured blood pressure (SMBP) monitoring plus additional support versus SMBP monitoring alone or with less intense support may not be current. An individual patient data meta-analysis identified by experts, which analyzed data from 21 studies found that more intensive interventions (i.e., tailored support from study personnel, a pharmacist, or a clinician), resulted in greater reductions in systolic and diastolic blood pressure as well as blood pressure control compared to less intensive interventions.

- Key Question 3: Original systematic review conclusions are likely current.
- Key Question 4: Original systematic review conclusions are likely current.
- Key Question 5: Original systematic review conclusions are likely current.

Signal Assessment: The signals examined in this surveillance assessment suggest that some conclusions in the original systematic review may not be current.

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Conflict of Interest:
None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

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Introduction

The purpose of the surveillance process for the Evidence-based Practice Center (EPC) Program is to determine whether the conclusions of a systematic review are current. The surveillance process examines the conclusions to the key questions as written, and does not evaluate the currency of the original scope (i.e., key questions, included interventions). A small number of high-impact systematic reviews are selected for surveillance annually based on popularity, use in obtaining continuing medical education certificates, potential impact for changing the field, and use in clinical practice guidelines.

Comparative Effectiveness Review (CER) #45, titled *Self-Measured Blood Pressure Monitoring: Comparative Effectiveness*, was originally released in January 2012.[1]

The key questions for the original systematic review are as follows:

Key Question 1. In people with hypertension (adults and children), does self-measured blood pressure (SMBP) monitoring, compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes?

> **Key Question 1a**. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)?
>
> **Key Question 1b.** How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH [left ventricular hypertrophy], LVM [left ventricular mass], LVMI [left ventricular mass index]) and intermediate outcomes (BP control, BP treatment adherence, or health care process measures)?

Key Question 2. In studies of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?

Key Question 3. How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic versus manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?

Key Question 4. In studies of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?

Key Question 5. How does adherence with SMBP monitoring vary by patient factors?

Our surveillance assessment began in July 2015. We conducted an electronic search for literature published since the end date of the most recent surveillance report search date. After completing a scan of this literature to identify evidence potentially related to the key questions in the systematic review, we contacted experts involved in the original review to request their opinions as to whether the conclusions had changed.

Methods

Prior Surveillance

A surveillance report for the original systematic review was released in November 2012, and included a search for relevant literature published between January 2011 and August 2012, expert opinions, and a search of U.S. Food and Drug Administration (FDA), Health Canada, and Medicines and Healthcare Products Regulatory Agency (MHRA) surveillance alerts received from the Emergency Care Research Institute (ECRI). The findings from this report are included in our assessment.

Literature Searches

We conducted a literature search of Ovid MEDLINE (1946 to June 2015) and Ovid MEDLINE In-Process and Other Non-Indexed Citations (July 2015), using the identical search strategy of the original systematic review[1] and searching for studies published since the end date of the prior surveillance report's literature search.

The search was conducted to assess the currency of conclusions using journals from among the top 10 journals from relevant specialty subject areas and among those most highly represented among the references for the original report. We included the journals searched in the previous surveillance assessment. The included journals were five high-profile general medical interest journals (Annals of Internal Medicine, The BMJ, JAMA, Lancet, and New England Journal of Medicine) and five specialty journals (American Journal of Hypertension, Circulation, Hypertension, Journal of Human Hypertension, Journal of Hypertension). The search strategy is reported in Appendix A.

Study Selection

Using the same inclusion and exclusion criteria as the original systematic review (see Appendix B), one investigator reviewed the titles and abstracts of the 14 high-impact journal search results (Appendix C). We included systematic reviews and meta-analyses, whether or not they were included (as a study design) in the original systematic review. For systematic reviews and meta-analyses, we considered findings only if all included studies met criteria that a) all studies were not included or excluded from the original systematic review, b) all studies were not included in a prior surveillance report (if applicable), and c) all studies met inclusion criteria for the original systematic review. Reviews for which one or more study did not meet our criteria were used to identify potentially relevant primary research. Reviews of systematic reviews were not included.

Expert Opinion

We shared the conclusions of the original report and most recent surveillance assessment, findings from the literature analysis, and the newly identified studies with 12 experts in the field (five original peer reviewers and seven technical expert panel [TEP] members) to request their assessment of the currency of report conclusions and their recommendations of any relevant new studies. Two subject matter experts responded to our request. Appendix D shows the form experts were asked to complete.

Horizon Scanning

The Agency for Healthcare and Research Quality (AHRQ) Healthcare Horizon Scanning System identifies emerging health care technologies and innovations with the potential to impact health care for AHRQ's 14 priority conditions. We reviewed the Cardiovascular Disease section to identify new potentially high-impact interventions related to the key questions in this systematic review. Potentially high impact interventions were considered in the final assessment of the currency of the conclusions.

FDA Class I Recalls and Withdrawals

We searched the FDA MedWatch online database website for class I device recalls, device withdrawals, and recently approved devices relevant to the key questions in this systematic review.

Check for Qualitative Signals

The authors of the original systematic review conducted qualitative synthesis of data on the comparative effectiveness of hypertension management with or without SMBP monitoring, and of different additional support interventions with SMBP monitoring to determine predictors of adherence to SMBP monitoring. We compared the conclusions of the included abstracts to the conclusions of the original review and previous surveillance report and assessed expert opinions to identify qualitative signals about the currency of conclusions.

Compilation of Findings and Conclusions

For this assessment we constructed a summary table (Appendix E) that includes the key questions and conclusions from the original systematic review and most recent surveillance assessment, findings of the new literature search, and the expert assessments that pertained to each key question. Because we did not find any Class I device recalls or withdrawals, we did not include a column for this in the summary table. We categorized the currency of conclusions using a 3-category scheme:

- Original conclusion is still valid and this portion of the systematic review is likely current
- Original conclusion is possibly out of date and this portion of the systematic review may not be current
- Original conclusion is out of date.

We considered the following factors when making our assessments:

- If we found no new evidence or only confirmatory evidence and all responding experts assessed the systematic review conclusion as still valid, we classified the systematic review conclusion as likely current.
- If we found some new evidence that might change the systematic review conclusion, and/or a minority of responding experts assessed the systematic review conclusion as having new evidence that might change the conclusion, then we classified the systematic review conclusion as possibly not current.
- If we found new evidence that rendered the systematic review conclusion out of date or no longer applicable, we classified the systematic review conclusion as out of date. Recognizing that our literature searches were limited, we reserved this category only for

situations where a limited search would produce prima facie evidence that a conclusion was out of date, such as the withdrawal of a drug or surgical device from the market, a black box warning from FDA, etc.

Signal Assessment for Currency of the Systematic Review

We used the following considerations in our assessment of currency of the systematic review:

- **Strong signal:** A report is considered to have a strong signal if new evidence is identified that clearly renders conclusions from the original systematic review out of date, such as the addition or removal of a drug or device from the market or a new FDA boxed warning.
- **Medium signal:** A report is considered to have a medium signal when new evidence is identified which may change the conclusions from the original systematic review. This may occur when abstract review and expert assessment indicates that some conclusions from the original systematic review may not be current, or when it is unclear from abstract review how new evidence may impact the findings from the original systematic review.
- **Weak signal:** A report is considered to have a weak signal if no new evidence is identified that would change the conclusions from the original systematic review. This may occur when no new evidence is identified, or when some new evidence is identified but it is clear from abstract review and expert assessment that the new evidence is unlikely to change the conclusions of the original systematic review.

Results

Prior Surveillance

Prior surveillance[2] of the topic included one new study and consultation with six subject matter experts. While the one included study did not directly address Key Question 4, it was included in the prior surveillance report "because earlier publications of this study were referenced under the ongoing research section of the original [systematic review]." There were no qualitative signals identified, and the original review's conclusions were determined to be up to date.

Literature Search

The literature search identified 334 unique titles from the 10 selected high profile general medical and specialty journals. We examined a random selection of 200 of the 334 articles (see Appendix C). Upon abstract review, 196 of the randomly selected studies were rejected because they did not meet the original systematic review inclusion criteria (see Appendix B). The remaining four studies[3-6] were examined for potential to change the results of the original systematic review. Note, one of the four included studies,[6] was initially excluded, and was not included in the summary sent to experts.

Horizon Scanning

None of the interventions in the horizon scanning report for Priority Area 03: Cardiovascular Disease overlapped with the key questions in the original systematic review. Thus, we did not identify new interventions with high-impact potential for this topic.

FDA Class I Recalls and Withdrawals

We did not find any Class I device recalls or withdrawals relevant to the key questions in the original systematic review. We identified 21 new devices (19 automatic SMBP monitors and 2 ambulatory SMBP monitors):

Automatic

- Shenzhen Urion Technology Co. Electronic Blood Pressure Monitor
- Microlife Upper Arm Digital Blood Pressure Monitor
- Sejoy Electronics Arm Type Fully Automatic Digital Blood Pressure Monitor
- A & D Medical UA-651 Digital Blood Pressure Monitor
- A & D Medical UB-543 Digital Blood Pressure Monitor
- FORA Care Blood Pressure Monitoring System
- Belter Blood Pressure Meter
- Omron HEM 7320
- Oregon Scientific Upper Arm Blood Pressure Monitor (BPU 321)
- Omron HEM 7311
- BOSCH BLOOD Pressure Meter
- Honsun Automatic Blood Pressure Monitor
- Ageless Health Industrial Age Automatic Upper Arm Blood Pressure Monitor
- Biospace Digital Blood Pressure Monitor
- Shenzhen Arm Automatic Blood Pressure Monitor
- Health and Life Co Full Automatic Blood Pressure Monitor
- Little Doctor Electronic Digital Blood Pressure Monitor
- Transtek Blood Pressure Monitor
- Thermor Compact Digital Blood Pressure

Ambulatory

- Spacelabs Model On Trak (90227) Ambulatory Blood Pressure Non-Invasive
- ABPM7100 (I.E.M.)

Expert Opinion

We shared the conclusions of the original systematic review with 12 experts in the field (five original peer reviewers and seven TEP members) to request their assessment of the currency of systematic review conclusions and their recommendations of any relevant new studies. Two subject matter experts responded.

One expert felt that conclusions related to Key Questions 1 and 2 were current, while the other did not comment on the currency of the conclusions. One expert suggested two studies[7,8] for Key Question 1 and one study[9] for Key Question 2. In addition, both experts suggested an individual patient data (IPD) meta-analysis currently being considered for publication. This IPD meta-analysis examined individual patient data from 21 studies in 19 articles (8,931 patients total) from 2005-2014. The included studies examined the effectiveness of self-monitoring, with or without additional support, versus usual care. Outcomes included systolic and diastolic blood pressure and BP control.

Of the studies included in the IPD meta-analysis, five[10-14] were included in the original systematic review, four[3-6] were included in this surveillance report, and two[15,16] did not meet inclusion criteria, leaving five studies[17-21] meeting the original review criteria and not included in the original systematic review or identified in our literature search.

Both experts agreed that conclusions related to Key Question 3-5 were likely current, although one expert commented that the scope of Key Question 3 may be out of date because automated monitors are now used for almost all SMBP. This expert felt it would be more useful to compare the accuracy of SMBP to ambulatory SMBP, and to examine the impact of telemetry (communicating blood pressure [BP] data via phone calls) on SMBP accuracy. This expert also suggested a randomized controlled trial (RCT)[22] related to Key Question 5 which found that older age, male gender, and some college education predicted better adherence to a tele-monitoring intervention.

Experts suggested five additional studies for Key Question 1,[23] 3,[24] 4,[23] and 5[25-27] that did not meet the original systematic review inclusion criteria. One study[23] included patients with conditions other than hypertension, one[24] was not a comparative study, and three studies[25-27] did not inclusion criteria for outcomes of interest.

Identifying Qualitative Signals

Appendix E shows the original key questions, the conclusions of the original report and the most recent surveillance report, the results of the literature search, the experts' assessments, and the conclusions regarding the currency of the systematic review.

Conclusions for Key Questions 1, 3, 4, and 5 are likely current.

For Key Question 1, one expert suggested a RCT[7] that found no difference between SMBP monitoring and usual care on systolic BP at three months, and another RCT[8] that found no difference between SMBP monitoring and usual care on systolic BP or BP control at nine months. The original systematic review did not draw conclusions for three month or nine month timeframes. In addition, experts suggested an IPD meta-analysis[28] that was consistent with the original review conclusion that SMBP monitoring is associated with small improvements in BP outcomes at 6 months and shows a positive trend at 12 months when compared to usual care.

In addition, consistent with the findings of the original review, the IPD meta-analysis[28] suggested by experts and three RCTs[3-5] identified by the literature search found SMBP monitoring plus additional support to be associated with improvements in BP outcomes compared to usual care. However, two RCTs[6,9] (one[9] identified by an expert and one[6] identified by the literature search) conflict with the original review conclusions. One[9] RCT found no advantage to SMBP monitoring plus communication by phone over usual care on ambulatory daytime BP at 3 months, and the other RCT[6] found no advantage to SMBP monitoring plus patient education and monthly lifestyle coaching over usual care on BP control at 12 months. Because the strength of evidence related to SMBP monitoring plus additional support versus usual care in the original review was high, and the results of these new studies fit within the range of results found in the original systematic review, the conclusion is likely current.

For Key Question 2, the conclusion of no difference between SMBP monitoring plus additional support versus SMBP monitoring alone or with less intense support may not be current. The IPD meta-analysis[28] suggested by experts found that more intensive support (i.e., tailored support from study personnel, a pharmacist, or a clinician), resulted in greater reductions in BP

and improvements in BP control when compared to less intensive support (e.g., providing only minimal additional contact). Subgroup analyses found no differences in efficacy by sex or most co-morbidities, with the exception of stroke patients who experienced no benefit of self-monitoring. Although the original systematic review included 4 RCTs that examined subgroup differences, there was insufficient evidence from which to form a conclusion.

We identified no new studies for Key Question 3 or 4. One RCT[22] identified by an expert for Key Question 5 was consistent with findings from the original systematic review.

There were no new high-impact potential interventions for this report based on horizon scanning data, nor were there any Class I device recalls or withdrawals since the original systematic review was published.

Signal Assessment

The SRC conclusions based on the results of the prior surveillance assessment, literature published since the original report, FDA boxed warnings, horizon scanning, and expert assessment is that:

- Key Question 1: Original systemic review conclusions are likely current.
- Key Question 1a: Original systematic review conclusions are likely current.
- Key Question 1b: Original systematic review conclusions are likely current
- Key Question 2: The conclusion that evidence fails to support a difference between self-measured blood pressure (SMBP) monitoring plus additional support versus SMBP monitoring alone or with less intense support may not be current. An individual patient data meta-analysis[28] identified by experts, which analyzed data from 21 studies found that more intensive interventions (i.e., tailored support from study personnel, a pharmacist, or a clinician), resulted in greater reductions in systolic and diastolic blood pressure as well as blood pressure control as compared to less intensive interventions.
- Key Question 3: Original systemic review conclusions are likely current.
- Key Question 4: Original systemic review conclusions are likely current.
- Key Question 5: Original systemic review conclusions are likely current.

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Appendices

Appendix A: Search Strategy

Appendix B: Inclusion and Exclusion Criteria from Original Systematic Review

Appendix C: Literature Search Results

Appendix D: Questionnaire Sent to Expert Reviewers

Appendix E: Summary Table

Appendix A. Search Strategy

Database: Ovid MEDLINE(R) and Ovid OLDMEDLINE(R) <1946 to June Week 4 2015>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <July 07, 2015> Search Strategy:	
1 exp Blood Pressure Monitoring, Ambulatory/ (7329) 2 exp Blood Pressure Monitors/ (2017) 3 exp Blood Pressure/ (254223) 4 exp hypertension/ (216684) 5 exp Self Care/ (42460) 6 (3 or 4) and 5 (1198) 7 ((blood pressure or hypertens$) and self and (measure$ or monitor$ or care or manage$)).mp. (8569) 8 1 or 2 or 6 or 7 (17015) 9 randomized controlled trial.pt. (398697) 10 controlled clinical trial.pt. (89792) 11 randomized controlled trials/ (98553) 12 Random Allocation/ (83948) 13 Double - blind Method/ (131101) 14 Single - Blind Method/ (20681) 15 clinical trial.pt. (495972) 16 Clinical Trials.mp. (318039) 17 (clinic$ adj25 trial$).tw. (296784) 18 ((singl$ or doubl$ or trebl$ or tripl$) adj (mask$ or blind$)).tw. (137182) 19 Placebos/ (33055) 20 placebo$.tw. (169432) 21 random$.tw. (779195) 22 trial$.tw. (690789) 23 (latin adj square).tw. (3732) 24 Comparative Study.tw. or Comparative Study.pt. (1737041) 25 exp Evaluation studies/ (205921) 26 Follow - Up Studies/ (521880) 27 Prospective Studies/ (393517) 28 (control$ or prospectiv$ or volunteer$).tw. (3286853) 29 Cross - Over Studies/ (36320) 30 or/9-29 (5926638) 31 exp cohort studies/ or exp prospective studies/ or exp retrospective studies/ or exp epidemiologic studies/ or exp case - control studies/ (1774208) 32 (cohort or retrospective or prospective or longitudinal or observational or follow - up or followup or registry).af. (2193168) 33 case - control.af. or (case adj10 control).tw. (241145) 34 ep.fs. (1267411) 35 31 or 32 or 33 or 34 (3276128) 36 8 and (30 or 35) (12614) 37 limit 36 to humans (11910) 38 (home adj20 blood pressure).mp. (2368)	Original Search Strategy

39 (exp telemedicine/ or exp self - examination/) and (exp Blood pressure/ or exp Hypertetension/) (121) 40 or/9-37 (7389834) 41 40 and (38 or 39) (1777) 42 37 or 41 (12689)	
43 lancet.jn. (130265) 44 jama.jn. (66896) 45 "annals of internal medicine".jn. (30461) 46 bmj.jn. (62903) 47 "new england journal of medicine".jn. (72471) 48 "american journal of hypertension".jn. (6544)	Journal Limits : General Medicine
49 hypertension.jn. (13129) 50 "journal of human hypertension".jn. (4040) 51 "journal of hypertension".jn. (8834) 52 circulation.jn. (40464) 53 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 (436007) 54 42 and 53 (2077)	Journal Limits : Specialty Journals
55 limit 54 to yr="2012 -Current" **(334)**	Date Limits

Appendix B. Inclusion and Exclusion Criteria from Original Systematic Review

Populations	Included: o Adults with hypertension, defined as an untreated (or pretreatment) BP >140/90 mmHg o Children with hypertension, defined as either a BP above a cut-off for age, sex and height reference. o Any clinically reasonable definition of hypertension, including existing treatment with antihypertensive medications. Excluded: o Participants on dialysis or had gestational hypertension o SMBP was part of a comprehensive disease management for heart failure or for weight loss
Interventions	**All Key Questions** Included: o All SMBP upper arm monitors (manual, semi-automated, automated), regardless of whether they have been accredited or validated, or whether they are commercially available. o SMBP used as an intervention. o Measurement can be completed by a family member or a companion of the patient o SMBP monitoring conducted for at least 8 weeks. Excluded: o Wrist monitors except in cases where they were used as a default for selected patients with large arm circumference. o SMBP not undertaken at home, for example if the participant self-measured in the clinic, office, pharmacy, or workplace. o SMBP used as a tool for a BP outcome (e.g., a trial of antihypertensive medications where the BP outcome was measured with SMBP) **Additional Support** Included: o At least one group in study used SMBP monitoring. o Study abstract and/or title must have suggested that SMBP monitoring was used as a principle part of the intervention. o Additional support included but was not limited to educational training, reminders, nursing interventions, tele-monitoring, algorithms for medication titration, and additional physician consultation.
Comparisons	**Key Question 1** o Compared SMBP monitoring (with or without additional support) to usual care (any office or clinic BP monitoring). **Key Question 2** o Compared SMBP monitoring with additional support to either SMBP without additional support or SMBP with an alternative additional support. **Key Question 3** o Compared SMBP monitoring (with or without additional support) with one SMBP device (or type of device, e.g., manual) with another SMBP device (or type of device, e.g., automated). **Key Question 4** o Evaluated the effect of SMBP on BP control as a predictor of clinical and

	surrogate outcomes. **Key Question 5** ○ Addressed the outcome of adherence with any type of SMBP monitoring. ○ Prerequisite: studies had to evaluate adherence rates based on specific predictors, including a primary interest in patient factors (e.g., demographics, medical or comorbid conditions, care setting).
Outcomes	Clinical outcomes (Key Questions 1a, 2, 3, & 4) • Cardiovascular events (myocardial infarction, angina, congestive heart failure, stroke, transient ischemic attack, peripheral vascular disease diagnosis or events) • Cardiovascular mortality (as defined by studies) • All-cause mortality • Patient satisfaction (any measurement tool, including satisfaction specifically with SMBP device) • Quality of life • Adverse events related to treatment with antihypertensive agents (e.g., hypotensive episodes or orthostatic falls) Surrogate outcomes (Key Questions 1b, 2, 3, & 4) • Cardiac measures ○ Left ventricular hypertrophy by echocardiography ○ Left ventricular mass by echocardiography ○ Left ventricular mass index by echocardiography Intermediate outcomes (Key Questions 1b, 2, & 3) • BP control (also predictor in Key Question 4) ○ Achieving a predefined change in BP (e.g., systolic BP reduction by 10 mmHg) or a predefined threshold (e.g., systolic BP <140 mmHg) ○ Systolic and diastolic BP or mean arterial pressure which must be measured the same way in both groups. SMBP measured BP can be outcome only for Key Questions 2 & 3. ▪ Clinic or other measurement by a health care professional ▪ Ambulatory BP (as either mean wake or daytime, mean sleep or nighttime, or mean 24 hour BPs) ○ Number and dose of hypertension medications or number of medication changes • Adherence to hypertension treatment. ○ *Not:* adherence to BP monitoring (for Key Questions 1–4) • Health care process measures such health care encounters (visits or calls) ○ *Not:* ▪ Diagnosis of hypertension ▪ Diagnosis of white coat or masked hypertension ▪ Diagnostic accuracy Adherence with SMBP monitoring (Key Question 5) • Adherence (or compliance) with SMBP monitoring, including any measurements used by the studies
Settings	Self-measurement had to occur at home. If patients self-measured in the clinic, office, pharmacy, or workplace, the study was excluded.
Study Design	**SMBP Monitoring (Key Questions 1–4)** Included: ○ Comparative studies, including randomized controlled trials (RCTs), quasi-RCTs, and nonrandomized prospective studies. ○ Must have at least 8 weeks of follow up.

	○ No minimum sample size. Excluded ○ Retrospective longitudinal studies. **Adherence (Key Question 5)** Included: ○ Prospective or retrospective longitudinal studies ○ Sample size: N=100 or greater for adults/ N=10 or greater for children ○ Patients used SMBP monitoring for at least 8 weeks. ○ Adherence rates evaluated based on predictors (for example age group ≥65 versus <65 years old) ○ Both univariable and multivariable analyses. Excluded: ○ Predictor values based on adherence (for example adherers were on average X years old and non-adherers were on average Y years old).

Appendix C. Literature Search Results

1. Abdel-Kader, K., Dohar, S., Shah, N., Jhamb, M., Reis, S. E., Strollo, P., Buysse, D. and Unruh, M. L. (2012). Resistant hypertension and obstructive sleep apnea in the setting of kidney disease. *Journal of Hypertension*,30;5:960-6.
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Appendix D. Questionnaire Sent to Expert Reviewers

AHRQ Comparative Effectiveness Review Surveillance Program

Reviewer Form

Title of Original Review: Self-Measured Blood Pressure Monitoring: Comparative Effectiveness
Link to Report
Link to Surveillance

Name of Reviewer: _____

Instructions:
The AHRQ Scientific Resource Center (SRC) periodically conducts surveillance of published AHRQ reviews to assist with prioritization of reports for updating. One part of this process includes soliciting expert review of our synthesis of recently published literature and any identified FDA black box warnings.

The attached document includes a table highlighting the conclusions from the original report, conclusions from a surveillance review conducted in 2012, and our synthesis of the recently published literature. Abstracts from relevant literature are included at the end of the attached document. If you would like a list of our full search results, please let us know.
Please review the table in the attached document and provide responses to the questions for each key question below. The primary goal of this review is to identify any missing studies, drugs, interventions, or devices; and ensure the accuracy of our synthesis of the recently published literature.

Key Question 1:

In people with hypertension (adults and children), does self-measured blood pressure monitoring (SMBP), compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes?

a. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)?
b. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH, LVM, LVMI) and intermediate outcomes (BP control, BP treatment adherence, or health care process measures)?

Prior Surveillance Assessment (November 2012):

- All conclusions were up-to-date

SRC Literature Analysis:

- One primary care, unblinded RCT (McManus 2014) found a significant decrease in mean baseline blood pressure at 12 months (143.1/80.5mm Hg to 128.2/73.8 mm Hg) in the intervention group undergoing self-monitoring of blood pressure combined with an individualized self-titration of antihypertensive medication. The control group experienced a decrease in blood pressure (143.6/79.5 mm Hg to 137.8/76.3 mm Hg). There were no differences by subgroup.

Reviewer Questions:

1. Are the original report conclusions still supported by the current evidence?

Click here to enter text.

2. Are there any published or unpublished studies that you know of that we may have overlooked?

Click here to enter text.

Key Question 2:

In trials of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?

Prior Surveillance Assessment (November 2012):

- All conclusions were up to date

SRC Literature Analysis:

- SMBP plus Additional Support versus SMBP without Additional Support or With Less Intense Additional Support: BP Outcomes.
    - One cluster RCT (Margolis 2013) examining the combination of home BP telemonitoring with pharmacist case management reported control of systolic BP (<140 mm Hg and diastolic BP to <90 mm Hg) in 57.2% of patients in the telemonitoring intervention group vs. 57.1% of patients in the usual care group at 6, 12, and 18 months. Compared to the usual care group, systolic BP decreased more from baseline among patients in the telemonitoring intervention group at 6 months (-6.0 mm Hg, p <.001), at 12 months (-5.1 mm Hg, p<.001), and at 18 months (-3.0 mm Hg, p = .07).
    - One multi-center RCT (McKinstry 2013) examining the impact of telemonitoring and supervision by usual primary care providers reported a mean difference in daytime systolic ambulatory blood pressure of 4.3 mm Hg (p = .0002) between intervention and usual care. The mean difference between the two groups for daytime diastolic ambulatory blood pressure was 2.3 mm Hg (p = .001), with higher values in the usual care group. The intervention was associated with a mean increase of one general practitioner (p = 0.0002) and 0.6 (p = 0.01) practice nurse consultations during the course of the study.

Reviewer Questions:

1. Are the original report conclusions still supported by the current evidence?

Click here to enter text.

2. Are there any published or unpublished studies that you know of that we may have overlooked?

Click here to enter text.

Key Question 3:
How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic vs. manual) in the effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?

Prior Surveillance Assessment (November 2012):
- All conclusions were up to date

SRC Literature Analysis:
- No studies were identified

Reviewer Questions:
1. Are the original report conclusions still supported by the current evidence?

Click here to enter text.

2. Are there any published or unpublished studies that you know of that we may have overlooked?

Click here to enter text.

Key Question 4:
In trials of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?

Prior Surveillance Assessment (November 2012):
- All conclusions were up to date

SRC Literature Analysis:
- No studies were identified

Reviewer Questions:
1. Are the original report conclusions still supported by the current evidence?

Click here to enter text.

2. Are there any published or unpublished studies that you know of that we may have overlooked?

Click here to enter text.

Key Question 5:
How does adherence with SMBP monitoring vary by patient factors?

Prior Surveillance Assessment (November 2012):
- All conclusions were up to date

SRC Literature Analysis:
- No studies were identified

Reviewer Questions:
1. Are the original report conclusions still supported by the current evidence?

Click here to enter text.

2. Are there any published or unpublished studies that you know of that we may have overlooked?

Click here to enter text.

Original Review Conclusions and Literature Analysis

Title of Original Review: First- and Second- Generation Antipsychotics for Children and Young Adults

Link to Report

Link to Surveillance

The conclusions from the original report, conclusions from a prior surveillance assessment and an analysis of recent literature identified by the Scientific Resource Center (SRC) are summarized below. Abstracts are provided for included literature at the end of the document.

Conclusions From Original Review	Conclusions from Prior Surveillance Assessment (Nov 2012)	SRC Literature Analysis (July 2015)
Key Question 1: In people with hypertension (adults and children), does self-measured blood pressure monitoring (SMBP), compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes? a. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)? b. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH, LVM, LVMI) and intermediate outcomes (BP control, BP treatment adherence, or health care process measures)?		
SMBP Alone Versus Usual Care: Clinical Outcomes **SOE: Insufficient:** No studies reported on clinical outcomes.	The conclusions are still valid.	No studies were identified
SMBP Alone Versus Usual Care: BP Outcomes **SOE: Moderate:** The strength of evidence is based on statistically significant findings at 6 months and a trend at 12 months. Of 24 studies that compared SMBP alone versus usual care, 22 were randomized controlled trials (RCTs) and 2 were quasi-RCTs. The studies were heterogeneous in terms of the brand and type of SMBP monitor, follow up duration, and baseline BP control. Individual studies mostly found greater (although nonsignificant) rates of achieving BP control with SMBP monitoring alone than with usual care, but meta-analysis of the small number of available studies showed that SMBP alone was not associated with a significantly increased probability of achieving a predefined BP target at either 6 or 12 months. Sixteen studies reported continuous outcomes of net changes in clinic systolic BP (SBP) and diastolic BP (DBP). Meta-analyses revealed no significant	The conclusions are still valid.	One primary care, unblinded RCT (McManus 2014) found a significant decrease in mean baseline blood pressure at 12 months (143.1/80.5mm Hg to 128.2/73.8 mm Hg) in the intervention group undergoing self-monitoring of blood pressure combined with an individualized self-titration of antihypertensive medication. Likewise, the control group experienced a decrease in blood pressure (143.6/79.5 mm Hg to 137.8/76.3 mm Hg). Primary outcome data were available from 450 patients (81% of the study total). There were no differences by subgroup.

Conclusions From Original Review	Conclusions from Prior Surveillance Assessment (Nov 2012)	SRC Literature Analysis (July 2015)
effect at 2 months follow up. Statistically significant differences favoring SMBP monitoring alone over usual care were, however, found at 6 months for SBP and DBP (SBP/DBP 3.1/2.0 mmHg), but not at 12 months (SBP/DBP 1.2/0.8 mmHg). Meta-analyses showed statistical heterogeneity at 6 and 12 months. The meta-analyses for 6-and 12-month BP outcome included five and six studies, respectively, with one quality A study in each meta-analysis. Only one RCT reported follow up data beyond 12 months; significant reductions were found in SBP and DBP at 24 months with SMBP. Comparisons of SMBP alone with usual care for the outcomes of ambulatory BP measurements (24 hour, awake, and asleep) were based on a small number of studies that reported contradictory results. Meta-analysis of a small number of studies for the net changes in 24-hour ambulatory SBP and DBP at 2 months found no significant differences between SMBP alone and usual care. There were not enough studies to be subjected to meta-analysis for longer durations of follow up. The studies of awake and asleep ambulatory BP fairly consistently favored SMBP alone over usual care, although most did not find a statistically significant difference.		
SMBP Alone Versus Usual Care: Surrogate and Intermediate Outcomes **SOE: Low** Other outcomes examined included quality of life (in three trials), medication number and dosage (in eight trials), medication adherence (in seven trials), left ventricular mass index (in one trial), and patient satisfaction with health care service (in one trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.	The conclusions are still valid.	No studies were identified.
SMBP Plus Additional Support Versus Usual Care: Number of Health Care Encounters **SOE: Low** Eight studies reported on health care encounters. Results were	The conclusions are still valid.	No studies were identified

Conclusions From Original Review	Conclusions from Prior Surveillance Assessment (Nov 2012)	SRC Literature Analysis (July 2015)
mixed, with five studies finding no difference between groups, one study finding fewer visits in the SMBP plus additional support group, one finding more visits in the SMBP plus additional support group, and one reporting mixed findings. The quality of included studies for this outcome was poor, and the results were inconclusive.		
Key Question 2. In trials of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?		
SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Clinical Outcomes **SOE: Insufficient** No studies reported on clinical outcomes.	The conclusions are still valid.	No studies were identified
SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: BP Outcomes **SOE: Low** Rating is based on the findings of the majority of comparisons, which failed to show a difference for the additional support or the more intense support. In addition, the studies that indicated benefit included only one rated as quality A. Of the 12 studies, 11 were RCTs and 1 was a quasi-RCT. The studies were highly heterogeneous, primarily in the types of additional support used. Additional support consisted of a mixture of behavioral interventions or disease management by a nurse or pharmacist, medication management, educational interventions, electronic transmission of BP measurements, Web sites/training portals for patient provider communication, BP recording cards, BP and medication tracking tool, hypertension information leaflets, and home visits. Change in medication management as a result of the monitoring could be initiated by the patient, nurse, pharmacist, or primary care physician. Four trials found statistically significant benefits favoring more intense additional support for either SBP, DBP, BP control, or	The conclusions are still valid.	One cluster RCT (Margolis 2013) examining the combination of home BP telemonitoring with pharmacist case management reported control of systolic BP (<140 mm Hg and diastolic BP to <90 mm Hg) in 57.2% of patients in the telemonitoring intervention group vs. 57.1% of patients in the usual care group at 6, 12, and 18 months. Compared to the usual care group, systolic BP decreased more from baseline among patients in the telemonitoring intervention group at 6 months (-6.0 mm Hg, p <.001), at 12 months (-5.1 mm Hg, p<.001), and at 18 months (-3.0 mm Hg, p = .07). One multi-center RCT (McKinstry 2013) examining the impact of telemonitoring and supervision by usual primary care providers reported a mean difference in

Conclusions From Original Review	Conclusions from Prior Surveillance Assessment (Nov 2012)	SRC Literature Analysis (July 2015)
combinations thereof. Only one study was rated quality A. It showed consistent benefit for continuous SBP and DBP outcomes and for a categorical BP outcome. The additional support examined in this study was pharmacist counseling added to SMBP plus use of personalized Web training. The other eight trials (seven full reports and one abstract) were indeterminate. Two studies provided results beyond 12 months. These were nonsignificant or of uncertain statistical significance. Across studies, no clear patterns could be discerned to explain the heterogeneity in results. The small number of studies and their distribution across different categories of additional support make it impossible to draw conclusions regarding the potential effects of any specific additional support or its interactions with SMBP.		daytime systolic ambulatory blood pressure of 4.3 mm Hg (p = .0002) between intervention and usual care. The mean difference between the two groups for daytime diastolic ambulatory blood pressure was 2.3 mm Hg (p = .001), with higher values in the usual care group. The intervention was associated with a mean increase of one general practitioner (p = 0.0002) and 0.6 (p = 0.01) practice nurse consultations during the course of the study.
SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Surrogate and Intermediate Outcomes **SOE: Low** Outcomes examined included quality of life (two trials), mental health (one trial), medication number and dosage (five trials), medication adherence (three trials), and adverse drug reactions (one trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.	The conclusions are still valid.	
SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Number of Health Care Encounters **SOE: Low** Five trials reported number of health care encounters. Additional support included counseling by a nurse or pharmacist, behavioral intervention, medication management, and telemedicine. None of the studies found a difference in number of health care encounters through visits or hospitalizations. One study found that communication via email or telephone increased in those assigned to a pharmacist in addition to SMBP with Web training.	The conclusions are still valid.	No studies were identified

Conclusions From Original Review	Conclusions from Prior Surveillance Assessment (Nov 2012)	SRC Literature Analysis (July 2015)
Key Question 3: How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic vs. manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?		
No trial address this key question	The conclusions are still valid.	No studies were identified
Key Question 4: In trials of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?		
No trials answered this question in the original CER.	The conclusions are still valid.	No studies were identified
Key Question 5: How does adherence with SMBP monitoring vary by patient factors?		
SOE: Insufficient One study investigated predictors for adherence to SMBP monitoring (with telephonic transmission of BP measurements, hypertension education, and telephone counseling by a nurse) and its relationship to BP control in 377 middle-aged Korean Americans. Older age was independently associated with greater adherence to SMBP monitoring, and the presence of depression was independently associated with lower adherence.	The conclusions are still valid.	No studies were identified

Abbreviations: BP = blood pressure; CER = comparative effectiveness reviews; DBP = diastolic blood pressure; RCT = randomized controlled trial; SBP = systolic blood pressure; SMBP = self-measured blood pressure monitoring

Abstracts from Relevant Literature

Margolis, K.L. Asche, S.E. Bergdall, A.R. Dehmer, S.P. Groen, S.E. Kadrmas, H.M., et al. 2013
Effect of home blood pressure telemonitoring and pharmacist management on blood pressure control: a cluster randomized clinical trial

IMPORTANCE: Only about half of patients with high blood pressure (BP) in the United States have their BP controlled. Practical, robust, and sustainable models are needed to improve BP control in patients with uncontrolled hypertension.; OBJECTIVES: To determine whether an intervention combining home BP telemonitoring with pharmacist case management improves BP control compared with usual care and to determine whether BP control is maintained after the intervention is stopped.; DESIGN, SETTING, AND PATIENTS: A cluster randomized clinical trial of 450 adults with uncontrolled BP recruited from 14,692 patients with electronic medical records across 16 primary care clinics in an integrated health system in Minneapolis-St Paul, Minnesota, with 12 months of intervention and 6 months of postintervention follow-up.; INTERVENTIONS: Eight clinics were randomized to provide usual care to patients (n=222) and 8 clinics were randomized to provide a telemonitoring intervention (n=228). Intervention patients received home BP telemonitors and transmitted BP data to pharmacists who adjusted antihypertensive therapy accordingly.; MAIN OUTCOMES AND MEASURES: Control of systolic BP to less than 140 mm Hg and diastolic BP to less than 90 mm Hg (<130/80 mm Hg in patients with diabetes or chronic kidney disease) at 6 and 12 months. Secondary outcomes were change in BP, patient satisfaction, and BP control at 18 months (6 months after intervention stopped).;RESULTS: At baseline, enrollees were 45% women, 82% white, mean (SD) age was 61.1 (12.0) years, and mean systolic BP was 148 mm Hg and diastolic BP was 85 mm Hg. Blood

pressure was controlled at both 6 and 12 months in 57.2% (95% CI, 44.8% to 68.7%) of patients in the telemonitoring intervention group vs 30.0% (95% CI, 23.2% to 37.8%) of patients in the usual care group (P=.001). At 18 months (6 months of postintervention follow-up), BP was controlled in 71.8% (95% CI, 65.0% to 77.8%) of patients in the telemonitoring intervention group vs 57.1% (95% CI, 51.5% to 62.6%) of patients in the usual care group (P=.003). Compared with the usual care group, systolic BP decreased more from baseline among patients in the telemonitoring intervention group at 6 months (-10.7 mm Hg [95% CI, -14.3 to -7.3 mm Hg]; P<.001), at 12 months (-9.7 mm Hg [95% CI, -13.4 to -6.0 mm Hg]; P<.001), and at 18 months (-6.6 mm Hg [95% CI, -10.7 to -2.5 mm Hg]; P=.004). Compared with the usual care group, diastolic BP decreased more from baseline among patients in the telemonitoring intervention group at 6 months (-6.0 mm Hg [95% CI, -8.6 to -3.4 mm Hg]; P<.001), at 12 months (-5.1 mm Hg [95% CI, -7.4 to -2.8 mm Hg]; P<.001), and at 18 months (-3.0 mm Hg [95% CI, -6.3 to 0.3 mm Hg]; P=.07).; CONCLUSIONS AND RELEVANCE: Home BP telemonitoring and pharmacist case management achieved better BP control compared with usual care during 12 months of intervention that persisted during 6 months of postintervention follow-up.

McManus, R.J. Mant, J. Haque, M.S. Bray, E.P. Bryan, S. Greenfield, S.M. Jones, M.I., Jowett, S., et al. 2014.
Effect of self-monitoring and medication self-titration on systolic blood pressure in hypertensive patients at high risk of cardiovascular disease: a TASMIN-SR randomized clinical trial.

IMPORTANCE: Self-monitoring of blood pressure with self-titration of antihypertensives (self-management) results in lower blood pressure in patients with hypertension, but there are no data about patients in high-risk groups.; OBJECTIVE: To determine the effect of self-monitoring with self-titration of antihypertensive medication compared with usual care on systolic blood pressure among patients with cardiovascular disease, diabetes, or chronic kidney disease.; DESIGN, SETTING, AND PATIENTS: A primary care, unblinded, randomized clinical trial involving 552 patients who were aged at least 35 years with a history of stroke, coronary heart disease, diabetes, or chronic kidney disease and with baseline blood pressure of at least 130/80 mm Hg being treated at 59 UK primary care practices was conducted between March 2011 and January 2013.; INTERVENTIONS: Self-monitoring of blood pressure combined with an individualized self-titration algorithm. During the study period, the office visit blood pressure measurement target was 130/80 mm Hg and the home measurement target was 120/75 mm Hg. Control patients received usual care consisting of seeing their health care clinician for routine blood pressure measurement and adjustment of medication if necessary.; MAIN OUTCOMES AND MEASURES: The primary outcome was the difference in systolic blood pressure between intervention and control groups at the 12-month office visit.; RESULTS: Primary outcome data were available from 450 patients (81%). The mean baseline blood pressure was 143.1/80.5 mm Hg in the intervention group and 143.6/79.5 mm Hg in the control group. After 12 months, the mean blood pressure had decreased to 128.2/73.8 mm Hg in the intervention group and to 137.8/76.3 mm Hg in the control group, a difference of 9.2 mm Hg (95% CI, 5.7-12.7) in systolic and 3.4 mm Hg (95% CI, 1.8-5.0) in diastolic blood pressure following correction for baseline blood pressure. Multiple imputation for missing values gave similar results: the mean baseline was 143.5/80.2 mm Hg in the intervention group vs 144.2/79.9 mm Hg in the control group, and at 12 months, the mean was 128.6/73.6 mm Hg in the intervention group vs 138.2/76.4 mm Hg in the control group, with a difference of 8.8 mm Hg (95% CI, 4.9-12.7) for systolic and 3.1 mm Hg (95% CI, 0.7-5.5) for diastolic blood pressure between groups. These results were comparable in all subgroups, without excessive adverse events.; CONCLUSIONS AND RELEVANCE: Among patients with hypertension at high risk of cardiovascular disease, self-monitoring with self-titration of antihypertensive medication compared with usual care resulted in lower systolic blood pressure at 12 months.

McKinstry, B. Hanley, J. Wild, S. Pagliari, C. Paterson, M. Lewis, S. Sheikh, A. Krishan, A. Stoddart, A. and Padfield, P. 2013.

OBJECTIVE: To determine if an intervention consisting of telemonitoring and supervision by usual primary care clinicians of home self measured blood pressure and optional patient decision support leads to clinically important reductions in daytime systolic and diastolic ambulatory blood pressure in patients with uncontrolled blood pressure.; DESIGN: Multicentre randomised controlled trial.; SETTING: 20 primary care practices in south east Scotland.; PARTICIPANTS: 401 people aged 29-95 years with uncontrolled blood pressure (mean daytime ambulatory measurement > 135/85 mm Hg but < 210/135 mm Hg).; INTERVENTION: Self measurement and transmission of blood pressure readings to a secure website for review by the attending nurse or doctor and participant, with optional automated patient decision support by text or email for six months.; MAIN OUTCOME MEASURES: Blinded assessment of mean daytime systolic ambulatory blood pressure six months after randomisation.; RESULTS: 200 participants were randomised to the intervention and 201 to usual care; primary outcome data were available for 90% of participants (182 and 177, respectively). The mean difference in daytime systolic ambulatory blood pressure adjusted for baseline and minimisation factors between intervention and usual care was 4.3 mm Hg (95% confidence interval 2.0 to 6.5; P=0.0002) and for daytime diastolic ambulatory blood pressure was 2.3 mm Hg (0.9 to 3.6; P=0.001), with higher values in the usual care group. The intervention was associated with a mean increase of one general practitioner (95% confidence interval 0.5 to 1.6; P=0.0002) and 0.6 (0.1 to 1.0; P=0.01) practice nurse consultations during the course of the study.; CONCLUSIONS: Supported self-monitoring by telemonitoring is an effective method for achieving clinically important reductions in blood pressure in patients with uncontrolled hypertension in primary care settings. However, it was associated with increase in use of National Health Service resources. Further research is required to determine if the reduction in blood pressure is maintained in the longer term and if the intervention is cost effective.

Appendix E. Summary Table

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
Key Question 1: In people with hypertension (adults and children), does self-measured blood pressure monitoring (SMBP), compared with usual care or other interventions without SMBP, have an effect on clinically important outcomes? a. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant clinical outcomes (cardiovascular events, mortality, patient satisfaction, quality of life, and adverse events related to antihypertensive agents)? b. How does SMBP monitoring compare with usual care or other interventions without SMBP in its effect on relevant surrogate outcomes (cardiac measures: LVH, LVM, LVMI) and intermediate outcomes (BP control, BP treatment adherence, or health care process measures)?				
SMBP Alone Versus Usual Care: Clinical Outcomes **SOE: Insufficient** No studies reported on clinical outcomes.	Up-to-date No studies identified	No new studies identified	One expert felt the original systematic review's conclusions were current and the other did not comment on the currency.	Conclusions are likely current.
SMBP Alone Versus Usual Care: BP Outcomes **SOE: Moderate** The strength of evidence is based on statistically significant findings at 6 months and a trend at 12 months. Of 24 studies that compared SMBP alone versus usual care, 22 were randomized controlled trials (RCTs) and 2 were quasi-RCTs. The studies were heterogeneous in terms of the brand and type of SMBP monitor, follow up duration,	Up-to-date No studies identified	No new studies identified.	One expert felt the original review's conclusions were current and the other did not comment on the currency. Both experts recommended examining evidence from a new IPD meta-analysis[1] currently being considered for publication. This meta-analysis compared patients who self-monitor BP to patients receiving usual care. In general, the IPD meta-	Conclusions are likely current.

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
and baseline BP control. Individual studies mostly found greater (although nonsignificant) rates of achieving BP control with SMBP monitoring alone than with usual care, but meta-analysis of the small number of available studies showed that SMBP alone was not associated with a significantly increased probability of achieving a predefined BP target at either 6 or 12 months. Sixteen studies reported continuous outcomes of net changes in clinic systolic BP (SBP) and diastolic BP (DBP). Meta-analyses revealed no significant effect at 2 months follow up. Statistically significant differences favoring SMBP monitoring alone over usual care were, however, found at 6 months for SBP and DBP (SBP/DBP 3.1/2.0 mmHg), but not at 12 months (SBP/DBP 1.2/0.8 mmHg). Meta-analyses showed statistical heterogeneity at 6 and 12 months. The meta-analyses for 6-and 12-month BP outcome included five and six studies, respectively, with one			analysis[1] found that self-monitoring was associated with lower systolic BP compared to usual care -1.0 mmHg, [95% CI -3.3 to 1.2 mmHg] at 12 months. One reviewer suggested 3 additional studies that compared self-monitoring BP with usual care. One study was excluded because it included patients who had conditions other than hypertension.[2] The second study,[3] a primary care RCT among 108 patients with type 2 diabetes and hypertension, tested the effectiveness of in-home monitoring versus usual care. The study found no significant differences between intervention and control groups on systolic BP at 3 months. The third study was a RCT[4] that examined the effectiveness of self-	

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
quality A study in each meta-analysis. Only one RCT reported follow up data beyond 12 months; significant reductions were found in SBP and DBP at 24 months with SMBP. Comparisons of SMBP alone with usual care for the outcomes of ambulatory BP measurements (24 hour, awake, and asleep) were based on a small number of studies that reported contradictory results. Meta-analysis of a small number of studies for the net changes in 24-hour ambulatory SBP and DBP at 2 months found no significant differences between SMBP alone and usual care. There were not enough studies to be subjected to meta-analysis for longer durations of followup. The studies of awake and asleep ambulatory BP fairly consistently favored SMPB alone over usual care, although most did not find a statistically significant difference.			monitoring versus usual care among 900 predominately black and Hispanic patients at New York City community clinics. Both the intervention group and control group saw similar decreases in systolic blood pressure (-14.7 mm Hg to -14.1 mm Hg) and similar rates of blood pressure control (38.9% to 39.1%) at 9 months. Intervention and control groups also had similar rates of blood pressure control at 9 months (38.9% to 39.1%).	
SMBP Alone Versus Usual Care: Surrogate and Intermediate Outcomes	Up-to-date No studies identified	No new studies were identified	One expert felt the original review's conclusions were current	Conclusions are likely current.

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
SOE: Low Other outcomes examined included quality of life (in three trials), medication number and dosage (in eight trials), medication adherence (in seven trials), left ventricular mass index (in one trial), and patient satisfaction with health care service (in one trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.			and the other did not comment on the currency. One expert suggested an additional study, but it was excluded because it included patients with conditions other than hypertension.[2]	
SMBP Alone Versus Usual Care: Number of Health Care Encounters **SOE: Low** Six studies reported on health care encounters. The majority of studies found no difference between SMBP alone and usual care in the number of health care encounters; however, there was some inconsistency, as one study found an increase and two found a decrease in office visits in the SMBP versus usual-care groups.	Up-to-date No studies identified	No new studies were identified.	One expert felt the original review's conclusions were current and the other did not comment on the currency.	Conclusions are likely current.

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
SMBP Plus Additional Support Versus Usual Care: Clinical Outcomes **SOE: Insufficient** One quality C study reported on mortality and end-stage renal disease.	Up-to-date	No new studies were identified.	One expert felt the original review's conclusions were current the other did not comment on the currency.	Conclusions are likely current.
SMBP Plus Additional Support Versus Usual Care: BP Outcomes **SOE: High** Thirteen of 24 studies reported a statistically significant reduction in either SBP or DBP at followup favoring the SMBP with additional support intervention. All six quality A trials reported a significant mean net reduction in SBP (ranging from -3.4 to -8.9 mmHg) or DBP (ranging from -1.9 to -4.4 mmHg) in the intervention group compared with usual care at up to 12 months followup. The modalities of support added to SMBP in these six trials were telemonitoring and counseling on patient adherence to antihypertensive medications; Web-based pharmacist counseling; telemonitoring	Up-to-date No studies identified	One primary care, un-blinded RCT[5] found a significant decrease in systolic blood pressure at 12 months (143.1/80.5mm Hg to 128.2/73.8 mm Hg) in the intervention group undergoing self-monitoring of blood pressure combined with an individualized self-titration of antihypertensive medication. The control group experienced a smaller decrease in blood pressure (143.6/79.5 mm Hg to 137.8/76.3 mm Hg), indicating a clinically significant difference between intervention and care-as-usual groups. Primary outcome data were available from 450 patients (81% of the study total). There were no differences by patient	One expert felt the original review's conclusions were current, the other did not comment on the currency. Both experts recommended reviewing the IPD meta-analysis[1] for new evidence. This analysis reported that combining self-monitoring with additional interventions such as medication titration, education or lifestyle counseling resulted in greater reductions in BP. One expert commented that the RCTs[5-7] from the 2015 literature search suggest there is a benefit to adding additional support to SMBP programs. This expert also suggested 1 additional study, a	Conclusions are likely current.

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
with self-titration of antihypertensive medications; telemonitoring with nurse videoconference; behavioral management; and medication management. The remaining seven studies reporting results favoring SMBP with additional support (in both SBP and DBP) used similarly diverse modes of support. Four studies provided results after 12 months. The single quality A trial found no difference between groups at 18 months followup; the other three trials each reported statistically significant mean net BP reductions for followup periods of 18 to 60 months. Across studies, it is not possible to state with certainty whether one form of additional support is superior, as the modalities of additional support examined varied in their primary intent, ancillary equipment and educational materials, followup personnel, and algorithms for medication adjustments. In addition, no form of additional support was examined by		subgroup. One cluster RCT[6] examining the combination of home BP telemonitoring with pharmacist case management reported control of systolic BP (<140 mm Hg and diastolic BP to <90 mm Hg) in 57.2% of patients in the telemonitoring intervention group vs. 57.1% of patients in the usual care group at 6, 12, and 18 months. Compared to the usual care group, systolic BP decreased more from baseline among patients in the telemonitoring intervention group at 6 months (-6.0 mm Hg, p <.001), at 12 months (-5.1 mm Hg, p<.001), and at 18 months (-3.0 mm Hg, p = .07). One multi-center RCT[7] examining the impact of telemonitoring and supervision by usual primary care providers reported a mean difference in daytime systolic ambulatory blood pressure of 4.3 mm Hg (p	randomized, un-blinded trial[8] of 356 patients in Denmark which showed a decrease in ambulatory daytime blood pressure for both those who self-monitored with transmission of measurements and subsequent communication by phone (-8±12/-4±7 mm Hg) and those who received usual care (-8±13/-4±8 mmHg) at 3 months. Both groups also had similar rates of participants in the normal daytime ambulatory blood pressure range at 3 months (17% in intervention versus 21% in control, p=.34).	

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
more than one trial.		= .0002) between intervention and usual care at 6 months. The mean difference between the two groups for daytime diastolic ambulatory blood pressure was 2.3 mm Hg (p = .001), with higher values in the usual care group. The intervention was associated with a mean increase of one general practitioner (p = 0.0002) and 0.6 (p = 0.01) practice nurse consultations during the course of the study. One cluster RCT[9] of 1,059 African American patients found similar rates of BP control among both intervention (self-monitoring with patient education and monthly lifestyle coaching) versus usual care groups at 12 months. However, in subgroup analyses the intervention was associated with greater BP control in patients without diabetes (IC=54.0% versus		

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
		UC=44.7%; odds ratio, 1.45 [confidence interval, 1.02-2.06]); and small-sized community health centers (IC=51.1% versus UC=39.6%; odds ratio, 1.45 [confidence interval, 1.04-2.45]).* *Note: This RCT was not sent to reviewers.		
SMBP Plus Additional Support Versus Usual Care: Surrogate and Intermediate Outcomes **SOE: Low** Additional support included counseling, education, and Web support. Outcomes examined included quality of life (in 3 trials), medication number and dosage (in 11 trials), medication adherence (in 6 trials), and adverse drug reactions (in 1 trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.	Up-to-date No studies identified	One study[6] found that patient satisfaction was similar in both the SMBP with pharmacist case management group and the care as usual group.	One expert felt the original review's conclusions were current and the other did not comment on the currency.	Conclusions are likely current.

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
SMBP Plus Additional Support Versus Usual Care: Number of Health Care Encounters **SOE: Low** Eight studies reported on health care encounters. Results were mixed, with five studies finding no difference between groups, one study finding fewer visits in the SMBP plus additional support group, one finding more visits in the SMBP plus additional support group, and one reporting mixed findings. The quality of included studies for this outcome was poor, and the results were inconclusive.	Up-to-date No studies identified	No new studies were identified.	One expert felt the original review's conclusions were current and the other did not comment on the currency.	Conclusions are likely current.
Key Question 2. In trials of SMBP monitoring, how do clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence) vary by the type of additional support provided?				
SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Clinical Outcomes **SOE: Insufficient** No studies reported on clinical outcomes.	Up-to-date No studies identified	No new studies were identified.	One expert felt the original review's conclusions were current, and the other did not comment on the currency.	Conclusions are likely current.
SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: BP	Up-to-date No studies identified	No new studies were identified.	One experts felt that the original review's conclusions were current, and the other did not comment on the	Conclusions may not be current, due to one IPD meta-analysis[1] of 19 studies that found that more intensive

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
Outcomes **SOE: Low** Rating is based on the findings of the majority of comparisons, which failed to show a difference for the additional support or the more intense support. In addition, the studies that indicated benefit included only one rated as quality A. Of the 12 studies, 11 were RCTs and 1 was a quasi-RCT. The studies were highly heterogeneous, primarily in the types of additional support used. Additional support consisted of a mixture of behavioral interventions or disease management by a nurse or pharmacist, medication management, educational interventions, electronic transmission of BP measurements, Web sites/training portals for patient provider communication, BP recording cards, BP and medication tracking tool, hypertension information leaflets, and home visits. Change in medication management as a result of the monitoring could be initiated by the patient, nurse,			currency. One expert recommended reviewing an IPD meta-analysis[1] currently under review for publication. The authors of this study divided data from 21 studies (19 articles) into 4 levels according to the intensity of the co-intervention. All 4 levels included a SMBP component. Level 1 interventions provided minimal additional contact, level 2 interventions provided automated feedback or support, level 3 interventions had an active component (feedback provided to patients who take part in a regular class, etc.), and level 4 interventions provided significant tailored support from study personnel, a pharmacist, or a clinician. Results indicated that more intensive interventions resulted in greater reductions in systolic BP at 12 months (level 1: -1.0mmHg [-3.3, 1.2];	support resulted in greater reductions in BP compared to less intensive interventions.

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
pharmacist, or primary care physician. Four trials found statistically significant benefits favoring more intense additional support for either SBP, DBP, BP control, or combinations thereof. Only one study was rated quality A. It showed consistent benefit for continuous SBP and DBP outcomes and for a categorical BP outcome. The additional support examined in this study was pharmacist counseling added to SMBP plus use of personalized Web training. The other eight trials (seven full reports and one abstract) were indeterminate. Two studies provided results beyond 12 months. These were nonsignificant or of uncertain statistical significance. Across studies, no clear patterns could be discerned to explain the heterogeneity in results. The small number of studies and their distribution across different categories of additional support make it impossible to draw conclusions regarding the potential effects of any specific additional support or			level 4: -6.1mmHg [-9.0, -3.2]). In addition, subgroup analyses of the entire population found no differences in efficacy by sex or most comorbidities, with the exception of stroke patients who experienced no benefit of self-monitoring.	

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
its interactions with SMBP.				
SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Surrogate and Intermediate Outcomes **SOE: Low** Outcomes examined included quality of life (two trials), mental health (one trial), medication number and dosage (five trials), medication adherence (three trials), and adverse drug reactions (one trial). The number of studies addressing each of these outcomes was low, and there was a lack of consistency in outcome definitions.	Up-to-date No studies identified	No studies were identified.	One expert felt the original review's conclusions were current and the other did not comment on the currency.	Conclusions are likely current.
SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Number of Health Care Encounters **SOE: Low** Five trials reported number of health care encounters. Additional support included counseling by a nurse or pharmacist, behavioral	Up-to-date No studies identified	No studies were identified	Both experts agreed that the original review's conclusions were current and the other did not comment on the currency.	Conclusions are likely current.

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
intervention, medication management, and telemedicine. None of the studies found a difference in number of health care encounters through visits or hospitalizations. One study found that communication via email or telephone increased in those assigned to a pharmacist in addition to SMBP with Web training.				
Key Question 3: How do different devices for SMBP monitoring compare with each other (specifically semiautomatic or automatic vs. manual) in their effects on clinical, surrogate, and intermediate outcomes (including SMBP monitoring adherence)?				
No trial address this Key Question	Up-to-date No studies identified	No studies were identified	Both experts agreed that the original review's conclusions are current. However, one expert commented that the question itself is outdated because almost all SMBP is done by automated monitors. This expert also pointed to a systematic review supporting the U.S. Preventive Services Task Force recommendation [10] related to hypertension screening and monitoring. However, the review did not include any studies that directly answered the question of how SMBP	Conclusions are likely current, though it may be useful to reframe the question to focus on the accuracy of SMBP in comparison to ambulatory BP.

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
			monitoring devices compare to each other in terms of clinical, surrogate, and intermediate outcomes. This expert also provided 2 additional questions related to SMBP that may be more important to consider for a future review: 1) How accurate is SMBP compared to ambulatory BP, which is the gold standard? 2) How does telemetry affect the accuracy of SMBP, due to selective reporting?	
Key Question 4: In trials of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?				
No trials answered this question in the original review	Up-to-date One included did not directly answer key question 4 however it informs choice of home BP. TC BP: <125/<80 mm Hg UC BP: 125-134/80-84 mm Hg	No studies were identified	Both experts agreed that the original review's conclusions are current. One expert identified a RCT[2] that examined the effect of BP control on quality of life, but it was excluded because it included patients with conditions other than hypertension.	Conclusions are likely current.
Key Question 5: How does adherence with SMBP monitoring vary by patient factors?				

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
SOE: Insufficient One study investigated predictors for adherence to SMBP monitoring (with telephonic transmission of BP measurements, hypertension education, and telephone counseling by a nurse) and its relationship to BP control in 377 middle-aged Korean Americans. Older age was independently associated with greater adherence to SMBP monitoring, and the presence of depression was independently associated with lower adherence.	Up-to-date No studies identified	No studies were identified	Both experts felt the original review's conclusions were current. One expert suggested four additional studies. Three[11-13] were excluded because they did not examine the association between SMBP adherence and patient factors. The last study was a randomized trial[14] of 213 patients which assessed adherence to a 6-month telemonitoring program in which BP measurements were transmitted to a pharmacist case manager and patients attended case management visits via phone. 73% of patients took at least 6 BP readings per week, and 88% attended their expected case management visits. Older age, male gender, and some college education predicted better telemonitoring	Conclusions are likely current.

Conclusions From the Original Systematic Review - Link to Review	Conclusions from Most Recent Surveillance Assessment (Nov 2012 – Link to Report)	Current Literature Search (July 2015)	Expert Opinion	Surveillance Assessment
			adherence in a multivariate analysis, White non-Hispanic race/ethnicity predicted better adherence to phone visits with pharmacist case managers.	

Abbreviations: SMBP = self-measured blood pressure monitoring; BP = blood pressure; RCT = randomized controlled trial; SBP = systolic blood pressure; DBP = diastolic blood pressure

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