



# Effective Health Care Program

## Self-Measured Blood Pressure Monitoring: Comparative Effectiveness

### Executive Summary

#### Background

High blood pressure (BP), or hypertension, is a common, long-term health condition, particularly among older adults. Untreated or ineffectively treated hypertension leads to increased cardiovascular morbidity and mortality, and increased consumption of health care resources, thus levying high human and financial costs to society. In adults, hypertension is defined as a persistently elevated BP equal to or greater than 140/90 mmHg.<sup>1</sup> In children, the diagnosis is made from an average of three or more BP readings greater than the 95th percentile for age, sex, and height.<sup>2,3</sup> The Seventh Joint National Committee (JNC 7) guideline recommends a BP goal of 140/90 mmHg or less in the general population and a lower threshold of 130/80 mmHg or less in patients with diabetes mellitus or chronic kidney disease.<sup>1</sup>

The World Health Report 2002 estimates that over 1 billion people have high BP and that hypertension is responsible for 4.5 percent of the global disease burden.<sup>4</sup> Within the United States alone, about 76.4 million adults are affected.<sup>5</sup> Despite improvements in the quality of health care and life expectancy, it is expected that the prevalence of hypertension will continue to rise worldwide. The World

#### Effective Health Care Program

The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

The full report and this summary are available at [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm).



Health Organization ranks high BP as the third highest risk factor for burden of disease, highlighting the contribution of hypertension directly and indirectly to the development of numerous diseases.<sup>4</sup> Hypertension has been identified as a major risk factor for cardiovascular disease,<sup>6</sup> and is an important modifiable risk factor for coronary artery disease, stroke, peripheral vascular disease, congestive heart failure, and chronic kidney disease.<sup>1</sup> High BP directly results in 7 million deaths every year.<sup>7</sup>

Effective management of BP has been shown to dramatically decrease the incidence of stroke, heart attack, and heart failure.<sup>1,8-13</sup> However, hypertension is usually a lifelong condition, and long-term adherence to lifestyle modification (such as smoking cessation, regular exercise, and weight loss) and medication treatment remains a challenge in the management of hypertension. Thus an increasing focus has been placed on developing strategies that can improve adherence and result in satisfactory BP control with the goal of improving health outcomes for hypertensive patients.

One such proposed method is self-measured blood pressure (SMBP) monitoring. SMBP refers to the regular self-measurement of a patient's BP at home or elsewhere outside the office or clinic setting. However, while patient self-participation in chronic disease management appears promising, the sustainability and clinical impact of this strategy remain uncertain. Also its impact on health care utilization is uncertain, since it may replace office visits for BP checks but may increase overall intensity of surveillance and treatment.

## Objectives

The primary objective of this review is to evaluate whether the use of SMBP monitoring influences outcomes in adults and children with hypertension, and to what extent these changes in outcomes can be attributable to the use of self-monitoring devices alone or the use of SMBP plus additional support or attention. The intention of this report is to inform physicians' decisionmaking as to whether to encourage the use of SMBP monitoring alone or along with additional support, and to assist health care policymakers and payers with decisions regarding coverage and promotion of SMBP monitoring.

The topic nomination provided the general parameters (population, modes of treatment, alternative approaches, outcomes of interest, etc.) that defined the scope of this report. Using these parameters, Key Questions were developed to address the questions of interest. Five Key Questions are addressed in this report. Four pertain to the comparative effectiveness of using SMBP as part of

a strategy of BP monitoring (Key Questions 1–4). The remaining Key Question concerns associations between baseline patient characteristics and adherence to SMBP (Key Question 5).

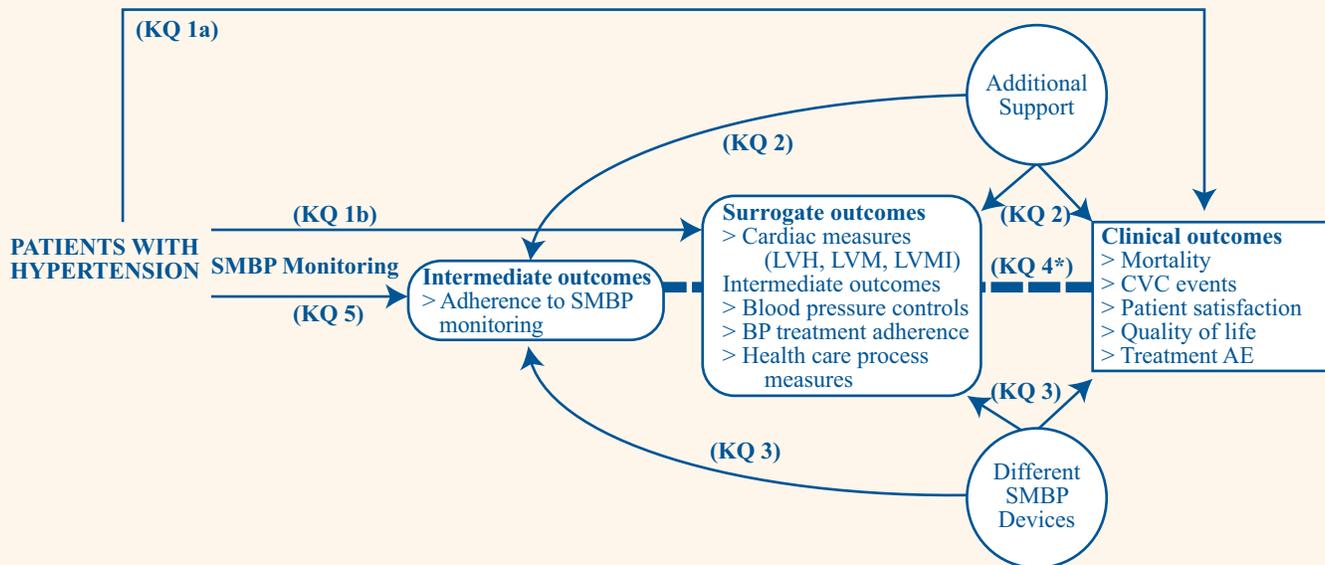
## Key Questions

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?
  - 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 [left ventricular hypertrophy], LVM [left ventricular mass], LVMI [left ventricular mass index]) and intermediate outcomes (blood pressure [BP] control, BP treatment adherence, or health care process measures)?
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?
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)?
4. In trials of SMBP monitoring, how does achieving BP control relate to clinical and surrogate outcomes?
5. How does adherence with SMBP monitoring vary by patient factors?

## Analytic Framework

To guide the development of Key Questions, we generated an analytic framework (Figure A) that maps the specific linkages associating the populations and subgroups of interest, interventions (for both diagnosis and treatment), and outcomes of interest (intermediate outcomes, health-related outcomes, compliance, and adverse effects). Specifically, this analytic framework depicts the chain of logic that evidence must support to link interventions to improved health outcomes.

**Figure A. Analytic framework for evaluation of SMBP monitoring**



\*Key Question 4 relates to the link between the intermediate outcome blood pressure control and either surrogate outcomes (cardiac measures) or clinical outcomes.

Note: AE = adverse event; BP = blood pressure; CVD = cardiovascular disease; KQ = Key Question; LVH = left ventricular hypertrophy; LVM = left ventricular mass; LVMI = left ventricular mass index; SMBP = self-measured BP.

## Methods

### Input From Stakeholders

During a topic refinement phase, the initial questions were refined with input from a panel of Key Informants. Key Informants included experts in hypertension, general internal medicine, pediatrics, and cardiology; representatives from both New York State and New York City Medicaid; and the Agency for Healthcare Research and Quality (AHRQ) Task Order Officer.

After a public review of the proposed Key Questions, the clinical experts from among the Key Informants were reconvened to form the Technical Expert Panel, which served to provide clinical and methodological expertise and comments that were considered to further refine Key Questions, identify important issues, and define parameters for the review of evidence, including study eligibility criteria.

### Data Sources and Selection

We conducted literature searches of studies in MEDLINE® (from inception through July 19, 2011) and both the Cochrane Central Trials Registry® and Cochrane Database of Systematic Reviews®. All studies enrolling human subjects were screened to identify articles relevant to each

Key Question. The search strategy included terms for self-measurement, home measurement, telemonitoring, self-care, and relevant research designs. The reference lists of related systematic reviews, selected narrative reviews, and primary articles were also reviewed, and relevant articles were screened. Following screening of abstracts, full-text articles were retrieved for all potentially relevant articles and rescreened for eligibility. A gray literature search of recent conference proceedings and of the Food and Drug Administration Web site was conducted for additional unpublished or non-peer-reviewed evidence.

For all Key Questions, we included all prospective comparative studies of SMBP versus any other intervention, including SMBP in adults or children already diagnosed with hypertension. We excluded studies of pregnant women or of patients on dialysis. We considered only arm (not wrist) SMBP monitors that were used for at least 8 weeks. For Key Question 5, we also included prospective or retrospective longitudinal studies that analyzed at least 100 adults or at least 10 children who used SMBP monitoring for at least 8 weeks.

### Data Extraction and Quality Assessment

Study data were extracted into customized forms. Together with information on study design, patient and intervention characteristics, outcome definitions, and study results, the

methodological quality of each study was rated from A (highest quality, least likely to have significant bias) to C (lowest quality, most likely to have significant bias).

## Data Synthesis and Analysis

The Comparative Effectiveness Review from which this Executive Summary is derived is a systematic review of the published scientific literature using established methodologies outlined in the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews ([www.effectivehealthcare.ahrq.gov](http://www.effectivehealthcare.ahrq.gov)). Evidence tables in the full report summarize study and baseline patient characteristics, detailed descriptions of the SMBP monitors and other interventions used, study quality, and relevant study results. For Key Questions 1 and 2, we graphed all the trial results for BP outcomes in forest plots. When there were three or more studies of SMBP alone versus usual care at any given time point, we performed random effects model meta-analyses. Sensitivity analyses were run excluding the quality C studies.

We graded the strength of the body of evidence according to the AHRQ methods guide.<sup>14</sup> We assessed the evidence for each question (or comparison of interventions) based on the risk of bias, study consistency, directness of the evidence, and precision of the findings. Based on these factors, we graded the overall strength of evidence as high, moderate, low, or insufficient for the following outcome categories: (1) BP (continuous and categorical outcomes); (2) other clinical events, other clinical outcomes such as quality of life and satisfaction, surrogate and intermediate outcomes; and (3) number of health care encounters.

## Results

We identified 48 comparative studies addressing Key Question 1 or Key Question 2 and one study addressing Key Question 5. (Please refer to the reference list in the full report for full documentation of statements contained in the Executive Summary.) No studies relevant to Key Questions 3 or 4 were found. No studies of SMBP monitoring in children were identified.

### Key Question 1

In people with hypertension (adults and children), does self-measured blood pressure monitoring, 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

The strength of evidence is *insufficient* regarding a difference between SMBP versus usual care for clinical outcomes. No studies reported on clinical outcomes.

### SMBP Alone Versus Usual Care: BP Outcomes

The strength of evidence is *moderate* for a small improvement in BP control using SMBP alone compared with usual care, 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, followup 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 effect at 2 months followup. 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 followup 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

SMBP alone over usual care, although most did not find a statistically significant difference.

### **SMBP Alone Versus Usual Care: Surrogate and Intermediate Outcomes**

The strength of evidence is *low* and fails to support a difference between SMBP alone versus usual care for surrogate and intermediate outcomes. 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.

### **SMBP Alone Versus Usual Care: Number of Health Care Encounters**

The strength of evidence is *low* and fails to support a difference between SMBP alone versus usual care for the number of health care encounters. 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.

### **SMBP Plus Additional Support Versus Usual Care: Clinical Outcomes**

The strength of evidence is *insufficient* regarding a difference between SMBP plus additional support versus usual care for clinical outcomes. One quality C study reported on mortality and end-stage renal disease.

### **SMBP Plus Additional Support Versus Usual Care: BP Outcomes**

The strength of evidence is *high* and supports an improvement in BP control using SMBP with some form of additional support compared to usual care, based on consistent findings in quality A trials. 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 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 more than one trial.

### **SMBP Plus Additional Support Versus Usual Care: Surrogate and Intermediate Outcomes**

The strength of evidence is *low* and fails to support a difference between SMBP plus additional support versus usual care for surrogate and intermediate outcomes. 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.

### **SMBP Plus Additional Support Versus Usual Care: Number of Health Care Encounters**

The strength of evidence is *low* and fails to support a difference between SMBP plus additional support versus usual care for the number of health care encounters. 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.

## **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**

The strength of evidence is *insufficient* regarding a difference between SMBP plus additional support versus SMBP without additional support or with less intense additional support for clinical outcomes. No studies reported on clinical outcomes.

### **SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Blood Pressure Outcomes**

The strength of evidence is *low* and fails to support a difference in BP effects between SMBP plus additional support versus SMBP with no additional support or with less intense additional support. This 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 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.

### **SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Surrogate and Intermediate Outcomes**

The strength of evidence is *low* and fails to support a difference between SMBP plus additional support versus SMBP without additional support or with less intense additional support for clinical, surrogate, and intermediate outcomes. 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.

### **SMBP Plus Additional Support Versus SMBP Without Additional Support or With Less Intense Additional Support: Number of Health Care Encounters**

The strength of evidence is *low* and fails to support a difference for number of health care encounters between groups receiving SMBP plus additional support versus SMBP without additional support or with less intense additional support. 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.

### **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 addressed this Key Question.

### **Key Question 4**

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

No trial addressed this Key Question.

## Key Question 5

How does adherence with SMBP monitoring vary by patient factors?

There is an *insufficient* level of evidence regarding predictors of SMBP adherence. 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.

## Discussion

### Summary

This review identified 48 comparative studies that examined the impact of SMBP with or without additional support in the management of hypertension and 1 study that evaluated predictors of adherence to SMBP. Overall, the benefit of SMBP for BP reduction appears to be modest and is not consistent across studies. We examined the role of additional support in combination with SMBP by setting up comparisons as: (1) SMBP alone versus usual care; (2) SMBP plus additional support versus usual care; and (3) SMBP plus additional support versus SMBP with no additional support or less intense additional support. Findings are summarized in Table A. Twenty-four trials compared SMBP alone versus usual care. Meta-analysis showed a statistically significant reduction in clinic SBP and DBP (SBP/DBP 3.1/2.0 mmHg) at 6 months but not at 12 months. Only one RCT reported followup beyond 12 months; findings indicated significant reductions in SBP and DBP at 24 months in favor of SMBP.

The comparison of SMBP plus additional support versus usual care was examined in 24 studies, with 11 of 21 randomized trials and 2 of 3 nonrandomized studies reporting a statistically significant benefit in BP reduction favoring SMBP plus additional support. Four studies provided results after 12 months. The only quality A trial found no difference between groups at 18 months followup; the other three trials reported statistically significant mean net BP reductions for followup periods of 18 to 60 months.

Although the observed reductions in BP with SMBP with or without additional support were small in size, they may still reflect a clinically relevant effect, since observational data on a population level show a decreased risk of

cardiovascular disease with even small differences in BP in the hypertensive range.<sup>15</sup> On the other hand, the reductions in BP found with SMBP are modest compared to those estimated to occur with other lifestyle interventions.<sup>1</sup> Evidence for other surrogate or clinical outcomes or health care processes was sparse, of low strength, or not conclusive.

Twelve trials compared SMBP plus additional support (or more intense additional support) versus SMBP without additional support (or plus less intense additional support). Only four of these trials reported a significantly greater reduction in BP in the SMBP plus additional (or more intense) support groups. Two studies provided results beyond 12 months. Both reported findings that were nonsignificant or of uncertain statistical significance.

### Clinical Heterogeneity

Despite the ostensible similarity in research questions across studies, great clinical heterogeneity across the examined publications limited the conclusions that could be drawn. There was a large degree of variability in SMBP monitoring protocols and implementation, use of and response to BP data, and types of additional support provided to patients. We grouped the additional support interventions into categories based predominantly on education, counseling, Web support, or other support. However, the types of additional support were too heterogeneous and overlapping to be neatly categorized. Further, no two studies used exactly the same mode of additional support, and even the studies that used SMBP without additional support varied in their methods.

While it should be noted that evidence from indirect comparisons is much inferior to evidence from direct comparisons within trials, the evidence appears to suggest that additional support is synergistic with SMBP to achieve BP control. However, the heterogeneity of additional support with regard to the primary intent, ancillary equipment, educational materials, followup personnel, and algorithms for medication adjustments make it impossible to draw conclusions regarding the potential effects of specific modalities or particular components of additional support or their interactions with SMBP. Further, there were too few subgroup analyses in these trials for each potential effect modifier, such as sex, race, comorbid disease, socioeconomic status, blood pressure control, or compliance at baseline, to allow detection of consistent signals for subgroups that might preferentially benefit.

## Applicability

Reviewed studies were all conducted in an outpatient setting and included only adults with uncontrolled hypertension or on antihypertensive medication. Patients had to be willing and able to participate in SMBP, or, in a small number of studies, have a companion to conduct the home BP measurement. Most studies included individuals with uncomplicated hypertension, without recent acute cardiovascular disease events, terminal illnesses, or advanced kidney disease. Most studies were conducted in Western Europe and North America. Minorities were underrepresented, although a few studies focused on African Americans.

## Limitations

Given the clinical heterogeneity stemming from the variation in the populations, interventions, and outcomes examined, in many cases only one or two studies were available for specific comparisons. Many studies were rated as quality C and likely were underpowered, even for BP outcomes. There were no studies in children. Duration of followup was limited and in most instances less than 12 months. Data on clinical event outcomes were lacking.

There are multiple possible reasons that these studies generally found no significant effects or reported relatively small effect sizes. Existing trials did not evaluate patients regarding their pattern of home and clinic BPs prior to inclusion. Each study may have included varying proportions of individuals with uncontrolled hypertension, white coat hypertension (elevated BP in the office setting but not at home), or masked hypertension (elevated BP at home but not in the office). Study participants with different patterns of BP abnormalities will differ in when they trigger treatment thresholds, depending on whether BP management in a trial is guided by home or clinic BP; thus the same treatment targets may result in different actions in terms of medication titration and achieved BP levels. Therefore, SMBP may have resulted in opposing effects on medication management and clinic BP within and across trials.

A question of interest to this review was how the type of BP device (particularly automated versus semiautomated or manual devices) impacted BP control. However, no study comparing different SMBP devices was identified. Automated electronic oscillometric devices are presently the devices most widely used for SMBP monitoring, although a number of these digital BP devices have yet to undergo rigorous independent validation.<sup>16</sup> Nevertheless, we are unlikely to get more data on this comparison due

to the widespread adoption of automatic devices, despite the difference in cost and the dilemma this presents for policymakers.

It stands to reason that adherence to SMBP is a necessary intermediate outcome in deriving any benefit from SMBP. However, observational data on predictors of adherence to SMBP were sparse, precluding any in-depth analysis.

## Future Research

On a population level, home BP is lower than clinic BP, but the exact relationship between home and clinic BP levels varies from person to person. As noted earlier, it can be expected that patients with white coat hypertension or masked hypertension will be managed differently based on SMBP than those with average BP behavior. Thus the strategies to measure and control elevated BP may need to differ based on an individual's discrepancy between home and clinic BP. Individuals with elevated BP at home and in the clinic require more intense BP treatment, while those with elevated BP only in the clinic do not. Therefore, future studies on SMBP ought to be clear as to whether their primary goals are lowering BP in individuals with uncontrolled hypertension or avoiding overtreatment in individuals with white coat hypertension. To accomplish this, patients should be evaluated regarding their pattern of BP abnormality prior to study enrollment. Subgroups of interest in studies are older persons and those with important clinical comorbidities, including cardiovascular and cerebrovascular disease, diabetes mellitus, and chronic kidney disease.

Better standardization is needed regarding how patients use SMBP and the types of additional support that are employed. While we do not suggest that incremental improvements in how SMBP is deployed should cease, we have found that it is of limited value for every study to have a unique protocol for SMBP monitoring and additional support. To reduce the heterogeneity of interventions, researchers should consider which already-investigated method of SMBP monitoring and additional support they believe is most promising and implement that protocol. Furthermore, the interpretability of future studies would be enhanced by the use of "usual care" protocols that most closely resemble the true usual care of the patients being studied, as well as by pragmatic trials that would inform real-world effectiveness.

Self-measuring BP can be burdensome over time. Future studies of SMBP should compare different monitoring schedules to determine the least burdensome protocol(s). Other important areas for future research include

examining the role of various measures for improving the accuracy of and adherence to SMBP, as well as improving the transmission of SMBP information for decisionmaking. Investigations should also be made into further use of telemedicine for patient-provider interaction regarding SMBP results and medication management. Given the paucity of data for clinical event outcomes, future studies examining the effects of SMBP on clinical events should also be made. Other recommendations for future SMBP research include examining characteristics that predict adherence to SMBP; establishing targets for home BP; and consistently reporting complete information on the name, type, and accreditation of the SMBP device used.

## Conclusion

SMBP may confer a small benefit in blood pressure control, but the BP effect beyond 12 months and the attendant long-term clinical consequences remain unclear. Future research should standardize patient inclusion criteria, BP treatment targets for home BP, and protocols for SMBP and additional support to maximize the interpretability and applicability of SMBP trials.

## References

1. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA*. 2003;289(19):2560-72. [Erratum: *JAMA*. 2003 Jul 9;290(2):197.]
2. National High Blood Pressure Education Working Group on High Blood Pressure in Children and Adolescents. The fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents. *Pediatrics* 2004;114(2 Suppl 4th Report):555-76.
3. Falkner B. Hypertension in children and adolescents: epidemiology and natural history. *Pediatr Nephrol* 2010;25(7):1219-24.
4. World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. 2002. <http://www.who.int/whr/2002/en/>. Accessed January 31, 2011.
5. Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics--2011 update: a report from the American Heart Association. *Circulation*. 2011;123(4):e18-e209.
6. Ezzati M, Oza S, Danaei G, et al. Trends and cardiovascular mortality effects of state-level blood pressure and uncontrolled hypertension in the United States. *Circulation*. 2008;117(7):905-14.
7. Whitworth JA. 2003 World Health Organization (WHO)/International Society of Hypertension (ISH) statement on management of hypertension. *J Hypertens*. 2003;21(11):1983-92.
8. Law M, Wald N, Morris J. Lowering blood pressure to prevent myocardial infarction and stroke: a new preventive strategy. *Health Technol Assess*. 2003;7(31):1-94.
9. Neal B, MacMahon S, Chapman N. Effects of ACE inhibitors, calcium antagonists, and other blood-pressure-lowering drugs: results of prospectively designed overviews of randomised trials. Blood Pressure Lowering Treatment Trialists' Collaboration. *Lancet*. 2000;356(9246):1955-64.
10. Gueyffier F, Froment A, Gouton M. New meta-analysis of treatment trials of hypertension: improving the estimate of therapeutic benefit. *J Hum Hypertens*. 1996;10(1):1-8.
11. Staessen JA, Gasowski J, Wang JG, et al. Risks of untreated and treated isolated systolic hypertension in the elderly: meta-analysis of outcome trials. *Lancet* 2000;355(9207):865-72.
12. Stamler R. Implications of the INTERSALT study. *Hypertension*. 1991;17(1 Suppl):116-20.
13. Whelton PK, He J, Appel LJ, et al. Primary prevention of hypertension: clinical and public health advisory from The National High Blood Pressure Education Program. *JAMA*. 2002;288(15):1882-8.
14. Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions--Agency for Healthcare Research and Quality and the Effective Health-Care program. *J Clin Epidemiol*. 2010;63(5):513-23.
15. Lewington S, Clarke R, Qizilbash N, et al. Age-specific relevance of usual blood pressure to vascular mortality. *Lancet*. 2003;361(9366):1391-2.
16. Yarows SA, Julius S, Pickering TG. Home blood pressure monitoring. *Arch Intern Med*. 2000;160(9):1251-7.

## Full Report

This executive summary is part of the following document: Uhlig K, Balk EM, Patel K, Ip S, Kitsios GD, Obadan NO, Haynes SM, Stefan M, Rao M, Kong Win Chang L, Gaylor J, Iovin RC. Self-Measured Blood Pressure Monitoring: Comparative Effectiveness. Comparative Effectiveness Review No. 45. (Prepared by the Tufts Evidence-based Practice Center under Contract No. HHSA 290-2007-10055-I.) AHRQ Publication No. 12-EHC002-EF. Rockville, MD: Agency for Healthcare Research and Quality. January 2012. [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm).

## For More Copies

For more copies of Self-Measured Blood Pressure Monitoring: Comparative Effectiveness: Executive Summary No. 45 (AHRQ Pub. No. 12-EHC002-1), please call the AHRQ Clearinghouse at 1-800-358-9295 or email [ahrqpubs@ahrq.gov](mailto:ahrqpubs@ahrq.gov).

**Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring**

Key Question	Strength of Evidence	Summary/Conclusions/Comments
<p><b>Key Question 1:</b>  <b>SMBP Alone Versus Usual Care</b>  <i>Overall</i></p>	<p>--</p>	<ul style="list-style-type: none"> <li>• Twenty-four studies compared SMBP alone versus usual care (22 RCTs and 2 quasi-RCTs). In total, 5,400 patients with hypertension were included. Four studies were graded quality A; 6, quality B; 13, quality C; and 1 conference abstract was not graded.</li> <li>• The studies were heterogeneous in terms of the brands and types of SMBP monitors; followup duration (2–36 months); baseline hypertension control (across studies, mean SBP/DBP: 124-167/70-109 mmHg); patient ages (across studies, mean 47–73 years). All patients were adults, most were male, and the most commonly cited comorbid conditions in these studies were type 1 or 2 diabetes, obesity, dyslipidemia, and cardiovascular disease.</li> </ul>
<p><b>Key Question 1:</b>  <b>SMBP Alone Versus Usual Care</b>  <i>Clinical Outcomes</i></p>	<p>Insufficient</p>	<ul style="list-style-type: none"> <li>• No study reported clinical outcomes.</li> <li>• <b>Conclusion:</b> There is insufficient comparative study evidence regarding clinical outcomes in trials of SMBP versus usual care.</li> </ul>

**Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)**

Key Question	Strength of Evidence	Summary/Conclusions/Comments
<p><b>Key Question 1:</b>  <b>SMBP Alone Versus Usual Care</b>  <i>Blood Pressure</i></p>	<p>Moderate (favoring SMBP)</p>	<ul style="list-style-type: none"> <li>• Twenty-three of the 24 studies that compared SMBP alone versus usual care reported BP outcomes (4 quality A, 5 quality B, 13 quality C, and 1 conference abstract that was not graded). See the “Overall” summary above regarding the study heterogeneity.</li> <li>• Thirteen studies reported categorical changes in BP control, mostly defined as achieving a BP of &lt;130-140/80-90 mmHg (sometimes with lower thresholds for patients with diabetes). Although all but one study found greater rates of achieving BP control with SMBP monitoring, meta-analyses of the subset of trials that examined achieving a BP target found no significant effects at 6- and 12-month followup.</li> <li>• Twenty-one studies reported continuous BP outcomes. Seventeen studies reported clinic BP outcomes; 5 reported 24-hour ambulatory BP; 6, awake (day) ambulatory BP; and 5, asleep (night) ambulatory BP. In meta-analyses, no significant effect was found at 2 months followup; statistically significant differences for clinic BP favoring SMBP monitoring were found at 6 months (SBP/DBP: 3.1/2.0 mmHg), but these differences were not statistically significant at 12 months (1.2/0.8 mmHg). The meta-analyses were statistically heterogeneous at 6 and 12 months. Only 1 RCT reported followup data beyond 12 months, and it found significant reductions in SBP and DBP at 24 months with SMBP. The studies reporting 24-hour ambulatory BP had inconsistent findings favoring either SMBP or usual care. However, the studies of awake and asleep ambulatory BP fairly consistently favored SMBP, although most did not find a statistically significant difference.</li> <li>• Subgroup analyses were reported by 4 trials. One study found no differences in the relative effect of SMBP monitoring in patients treated or untreated for hypertension at baseline. Another found no difference by age, sex, or diagnosis with diabetes. A third study found significant reductions in clinic and 24-hour ambulatory DBP in men but not women. A study looking at differences by race did not have consistent findings. Across studies, no clear patterns could be discerned to explain the heterogeneity in results.</li> <li>• <b>Conclusion:</b> Based primarily on the consistent findings of the quality A and B studies examining the impact of SMBP versus usual care in clinic BP measurements and the corresponding results from meta-analyses, the strength of evidence is moderate for a small improvement in BP using SMBP compared with usual care.</li> </ul>

**Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)**

Key Question	Strength of Evidence	Summary/Conclusions/Comments
<p><b>Key Question 1:</b>  <b>SMBP Alone Versus Usual Care</b>  <i>Surrogate and Intermediate Outcomes (Not Blood Pressure)</i></p>	<p>Low (failing to support a difference)</p>	<ul style="list-style-type: none"> <li>• Thirteen of the 24 studies that compared SMBP alone versus usual care reported surrogate and intermediate outcomes that were not BP. See the “Overall” summary above regarding the study heterogeneity.</li> <li>• Eight studies reported data on categorical and continuous outcomes related to number of medications and dosage (1 quality A, 5 quality B, 2 quality C). Studies variously reported increases or decreases in number of medications, medication dose, added medication classes, number of treatment modifications by physicians, physician assessment of strength of medication regimen, number of antihypertensive medications used, and medication changes. The majority of studies found no difference in medication outcomes, although a minority found significantly greater changes in medication treatment with SMBP monitoring. Weak evidence favors no difference in medication use with SMBP monitoring.</li> <li>• Three studies reported on quality-of-life outcomes (2 quality B, 1 quality C). Studies used the SF-36 quality-of-life assessment tool. In general, studies found no difference in quality of life between SMBP and usual care.</li> <li>• Seven studies reported on medication adherence using a variety of different definitions of adherence, including both categorical and continuous outcomes (3 quality B, 4 quality C). A wide variety of definitions were used for medication adherence across studies. Three studies reported some significantly better measures of adherence with SMBP (although not always for all evaluated measures of adherence); the remaining 4 studies found no difference. Overall, there was weak evidence that medication adherence may be better among patients using SMBP monitoring.</li> <li>• Only a single study each reported on patient satisfaction (quality C) and left ventricular mass index (quality B). No differences were found between SMBP and usual care. There is insufficient evidence for either of these outcomes.</li> <li>• <b>Conclusion:</b> The evidence is weak or insufficient for these outcomes. Thus, overall the strength of evidence is low and fails to support a difference between SMBP alone versus usual care for surrogate and intermediate outcomes.</li> </ul>
<p><b>Key Question 1:</b>  <b>SMBP Alone Versus Usual Care</b>  <i>Health Care Encounters</i></p>	<p>Low (failing to support a difference)</p>	<ul style="list-style-type: none"> <li>• Six of the 24 studies that compared SMBP alone versus usual care reported number of health care encounters (1 quality A, 3 quality B, and 2 quality C). See the “Overall” summary above regarding the study heterogeneity.</li> <li>• The majority of studies found no difference in number of physician visits between groups, 2 studies found no difference in number of hypertension-related telephone calls, and 1 study found no difference in number of medical procedures received for hypertension.</li> <li>• One study found that patients using SMBP had more office visits and 2 studies found that patients using SMBP had fewer visits.</li> <li>• <b>Conclusion:</b> Based on the lack of agreement in study results, the strength of evidence is low and fails to support a difference between SMBP alone versus usual care for health care encounters.</li> </ul>

**Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)**

Key Question	Strength of Evidence	Summary/Conclusions/Comments
<p><b>Key Question 1:</b>  <b>SMBP + Additional Support Versus Usual Care</b>  <i>Overall</i></p>	<p>--</p>	<ul style="list-style-type: none"> <li>• Twenty-four studies compared SMBP plus additional support versus usual care (19 RCTs, 2 quasi-RCTs, and 3 nonrandomized studies). In total, 6,187 patients with hypertension were included. Six studies were graded quality A; 5, quality B; and 13, quality C. Four of these studies also provided data for SMBP alone versus usual care.</li> <li>• The studies were heterogeneous in terms of the brands and types of SMBP monitors; followup duration (2–36 months); baseline hypertension control (across studies, mean SBP/DBP: 124-163/70-103 mmHg); patient ages (across studies, mean 47–77 years). All patients were adults, most were male, and the most commonly cited comorbid conditions in these studies were type 1 or 2 diabetes, obesity, dyslipidemia, and cardiovascular disease.</li> <li>• No form of additional support was examined by more than one trial. The studies were highly heterogeneous in the types of additional support used. They included educational materials, Web resources, telephone monitoring with electronic transmission of BP data, nurse or pharmacist visits, calendar pill packs and/or compliance contracts, and behavioral management and/or medication management. Change in medication management as a result of the monitoring could be initiated by patient, nurse, pharmacist, or primary care physician.</li> </ul>
<p><b>Key Question 1:</b>  <b>SMBP + Additional Support Versus Usual Care</b>  <i>Clinical Outcomes</i></p>	<p>Insufficient</p>	<ul style="list-style-type: none"> <li>• One quality C trial found significantly lower mortality with SMBP plus self-titration versus usual care, and lower composite mortality and end-stage renal disease. End-stage renal disease alone was not significantly different.</li> <li>• <b>Conclusion:</b> There is insufficient comparative study evidence regarding clinical outcomes in trials of SMBP plus additional support versus usual care.</li> </ul>
<p><b>Key Question 1:</b>  <b>SMBP + Additional Support Versus Usual Care</b>  <i>Blood Pressure</i></p>	<p>High (favoring SMBP)</p>	<ul style="list-style-type: none"> <li>• All 24 studies that compared SMBP plus additional support versus usual care reported BP outcomes. See the “Overall” summary above regarding the study heterogeneity.</li> <li>• All 6 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. Four studies provided results after 12 months. The only quality A trial found no difference between groups at 18 months followup; the other 3 trials reported statistically significant mean net BP reductions for followup periods of 18 to 60 months.</li> <li>• <b>Conclusion:</b> The strength of evidence is high for an improvement in BP control using SMBP with some form of additional support compared to usual care. By examination across studies, it is not possible to state with certainty whether one form of additional support is superior, as the additional supports examined across studies varied in primary intent, ancillary equipment and educational materials, followup personnel, and algorithms for medication adjustments. The studies were too heterogeneous in numerous ways to allow an explanation of differences in results across studies.</li> </ul>

**Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)**

Key Question	Strength of Evidence	Summary/Conclusions/Comments
<p><b>Key Question 1:</b>  <b>SMBP + Additional Support Versus Usual Care</b>  <i>Surrogate and Intermediate Outcomes (Not Blood Pressure)</i></p>	<p>Low (failing to support a difference)</p>	<ul style="list-style-type: none"> <li>• Fourteen of the 24 studies that compared SMBP plus additional support versus usual care reported surrogate and intermediate outcomes that were not BP. See the “Overall” summary above regarding the study heterogeneity.</li> <li>• Eleven studies reported data on categorical and continuous outcomes related to medication number and dosage (3 quality A, 2 quality B, 6 quality C). Studies variously reported increases or decreases in medication number, medication inertia (no change in regimen), physician assessment of strength of medication regimen, treatment modification by physician, discontinuation of medication, and number of medication classes used or tablets taken. Studies were split between finding no difference in medication outcomes and finding either an increase or decrease in medications with patients using SMBP with additional support. The contradictory findings in the evidence overall favor no difference in medication use with SMBP monitoring plus additional support.</li> <li>• Three studies (2 quality A and 1 quality C) reported on quality-of-life outcomes. These studies found no difference in SF-12, Consumer Assessment of Healthcare Providers and Systems score, Anxiety score, or Euro QoL 5D score. The studies all found no difference in quality of life.</li> <li>• Six studies reported on medication adherence using a variety of different definitions of adherence, including both categorical and continuous outcomes (1 quality A, 2 quality B, 3 quality C). The studies had inconsistent findings, with half finding no difference in medication adherence and half finding greater adherence with SMBP plus additional support. Overall, there was weak evidence that medication adherence may be better among patients using SMBP monitoring.</li> <li>• One study found no difference in adverse drug reactions across three groups with different forms of additional support.</li> <li>• <b>Conclusion:</b> The evidence is weak or insufficient for these outcomes. Thus, overall the strength of evidence is low and fails to support a difference between SMBP plus additional support versus usual care for surrogate and intermediate outcomes.</li> </ul>
<p><b>Key Question 1:</b>  <b>SMBP + Additional Support Versus Usual Care</b>  <i>Health Care Encounters</i></p>	<p>Low (failing to support a difference)</p>	<ul style="list-style-type: none"> <li>• Eight of the 24 studies that compared SMBP plus additional support versus usual care reported number of health care encounters. All were graded quality C.</li> <li>• The studies were highly heterogeneous, primarily in the types of additional support used. Additional support included education, alerts, medication monitoring, self-titration, Web training, pharmacist counseling, medication management, and behavioral management. All reported on number of physician (or physician and nurse) visits. One study additionally reported on telephone and Web encounters.</li> <li>• Six studies found no difference in number of visits, 1 found fewer visits, and 1 found more visits with SMBP plus additional support compared to usual care.</li> <li>• One study found mixed results with respect to telephone and Web encounters.</li> <li>• <b>Conclusion:</b> Given the discordant findings as well as the low study quality, the strength of evidence is low and fails to support a difference between groups.</li> </ul>

**Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)**

Key Question	Strength of Evidence	Summary/Conclusions/Comments
<p><b>Key Question 2:</b>  <b>SMBP + Additional Support Versus SMBP</b>  <i>Overall</i></p>	<p>--</p>	<ul style="list-style-type: none"> <li>• Twelve studies compared SMBP plus additional support versus SMBP without additional support or with less intense additional support, of which 11 were RCTs and 1 was quasi-randomized. In total, 3,311 patients with hypertension were included. Two trials were graded quality A; 4, quality B; and 5, quality C; and 1 conference abstract was not graded.</li> <li>• 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 for patient-provider communication, telemonitoring, BP recording cards or hypertension information leaflets, BP and medication tracking tool, and home visits. Change in medication management as a result of the monitoring could be initiated by patient, nurse, pharmacist, or primary care physician. Other sources of heterogeneity included the brands and types of SMBP monitors; followup duration (3–24 months, although mostly ≤12 months); baseline hypertension control (across studies, mean SBP/DBP: 126–179/70–103 mmHg); patient ages (across studies, mean 50–72 years. All patients were adults, most were male, and the most commonly cited comorbid condition was type 2 diabetes.</li> </ul>
<p><b>Key Question 2:</b>  <b>SMBP + Additional Support Versus SMBP</b>  <i>Clinical Outcomes</i></p>	<p>Insufficient</p>	<ul style="list-style-type: none"> <li>• No study reported clinical outcomes.</li> <li>• <b>Conclusion:</b> There is insufficient comparative study evidence regarding clinical outcomes in trials of SMBP versus usual care.</li> </ul>

**Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)**

Key Question	Strength of Evidence	Summary/Conclusions/Comments
<p><b>Key Question 2:</b>  <b>SMBP + Additional Support Versus SMBP</b>  <i>Blood Pressure</i></p>	<p>Low (failing to a support a difference)</p>	<ul style="list-style-type: none"> <li>• All 12 studies that compared SMBP plus an additional support versus SMBP without the additional support or with less intense additional support reported BP outcomes. See the “Overall” summary above regarding the study heterogeneity.</li> <li>• Eight studies reported categorical changes in BP control, mostly defined as achieving a BP of &lt;120-140/80-90 mmHg (sometimes with lower thresholds for patients with diabetes). Six trials showed no significant difference or were indeterminate for a difference in rates of achieving BP control. One trial of SMBP plus pharmacist counseling plus training in use of a patient Web portal vs. SMBP plus training in use of a patient Web portal found a significant effect favoring, more intensive additional support. Another trial comparing SMBP plus medication monitoring plus educational material versus SMBP plus educational material also found benefit for the more intense additional support.</li> <li>• Ten studies reported continuous BP outcomes. Six trials found no significant difference. Four favored the more intense support in addition to SMBP, comparing pharmacist counseling plus training in use of a patient Web portal versus training in use of a patient Web portal, medication monitoring plus educational material versus educational material, medication monitoring plus educational material versus educational material, and telemonitoring versus SMBP alone. Two studies provided results beyond 12 months. These studies reported findings that were nonsignificant or of uncertain statistical significance.</li> <li>• Four trials reported subgroup analyses by control of BP at baseline (controlled or not controlled), degree of adherence (lower adherence), or race (white vs. predominantly African American). Two of these studies did not provide analyses for the comparisons of SMBP plus additional support versus SMBP without additional support or with another type of additional support, and two studies did not provide complete subgroup analysis data.</li> <li>• <b>Conclusion:</b> Overall the strength of evidence is low and fails to support a difference in BP effects between SMBP plus additional support versus SMBP with no additional support or with less intense additional support.</li> </ul>

**Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)**

Key Question	Strength of Evidence	Summary/Conclusions/Comments
<p><b>Key Question 2:</b>  <b>SMBP + Additional Support Versus SMBP</b>  <i>Surrogate and Intermediate Outcomes (Not Blood Pressure)</i></p>	<p>Low (failing to support a difference)</p>	<ul style="list-style-type: none"> <li>• Seven of the 12 studies that compared SMBP plus additional support versus SMBP without additional support reported surrogate and intermediate outcomes that were not BP. See the “Overall” summary above regarding the study heterogeneity.</li> <li>• Two trials reported on quality of life or anxiety (1 quality A, 1 quality B). The studies used SF-36, SF-12, and the State-Trait Anxiety Inventory, a mental health questionnaire. Both found no differences using any quality-of-life measure.</li> <li>• Five trials reported data on categorical and continuous medication number and dosage (2 quality A, 2 quality B, 1 quality C). Studies reported numbers of patients taking 2 or more classes of medications, medical inertia (defined as no medication change vs. either an increase or decrease in medications), and number of medication drug classes. Four trials using additional support consisting of nurse counseling, home visits for BP measurement, telemonitoring, or education found no difference between SMBP plus additional support and usual care. One trial found a somewhat greater mean number of medication drug classes with SMBP plus Web training plus pharmacist counseling. Weak evidence suggests no difference in medication use.</li> <li>• Three quality C trials reported on medication adherence. Using different measures in each study, none found a significant difference in medication adherence. One trial also found no difference in a subgroup of individuals with lower baseline adherence.</li> <li>• Two trials looked at miscellaneous outcomes. One quality C trial found no difference in adverse drug reactions across four groups with different forms of additional support or usual care. One quality A trial found no difference in consumer satisfaction measured with the Consumer Assessment of Healthcare Providers and Systems instrument.</li> <li>• <b>Conclusion:</b> The evidence is weak due to inconsistency across studies or poor-quality studies, or it is insufficient. Thus, overall the strength of evidence is low and fails to support a difference between SMBP plus additional support versus SMBP without additional support or with less intense additional support for surrogate and intermediate outcomes.</li> </ul>

**Table A. Summary of findings of studies addressing Key Questions on self-measured blood pressure monitoring (continued)**

Key Question	Strength of Evidence	Summary/Conclusions/Comments
<p><b>Key Question 2:</b>  <b>SMBP + Additional Support Versus SMBP</b>  <i>Health Care Encounters</i></p>	<p>Low (failing to support a difference)</p>	<ul style="list-style-type: none"> <li>• Five of the 12 studies that compared SMBP plus an additional support versus SMBP without the additional support reported number of health care encounters. All were quality C. See the “Overall” summary above regarding the study heterogeneity.</li> <li>• All reported on outpatient primary care visits, 2 reported on hospital admissions or inpatient or urgent care/emergency use, and 3 reported on cardiac and other specialist visits.</li> <li>• None found a difference in the numbers of outpatient visits or hospital admissions between patients receiving SMBP with or without additional support.</li> <li>• One study found more electronic and telephonic communication with SMPB plus pharmacist counseling plus training in use of a patient Web portal compared to SMBP plus training in use of a patient Web portal.</li> <li>• <b>Conclusion:</b> Despite the consistency across trials, because of their small number and poor quality, overall the strength of evidence is low and fails to support a difference in number of health care encounters when using additional support with SMBP compared to SMBP without additional support or with less intense additional support.</li> </ul>
<p><b>Key Question 3:</b>  <b>Different SMBP Devices</b></p>	<p>Insufficient</p>	<ul style="list-style-type: none"> <li>• No eligible study provided data to address this question.</li> <li>• <b>Conclusion:</b> There is insufficient comparative study evidence regarding the comparison of different SMBP devices.</li> </ul>
<p><b>Key Question 4:</b>  <b>Blood Pressure Control Relationship With Clinical and Surrogate Outcomes</b></p>	<p>Insufficient</p>	<ul style="list-style-type: none"> <li>• No eligible study provided data to address this question.</li> <li>• <b>Conclusion:</b> There is insufficient comparative study evidence regarding the relationship of BP control with SMBP and clinical and surrogate outcomes.</li> </ul>
<p><b>Key Question 5:</b>  <b>Predictors of SMBP Adherence</b></p>	<p>Insufficient</p>	<ul style="list-style-type: none"> <li>• One quality B study addressed how adherence to SMBP monitoring varies by patient factors. The study included 377 middle-aged Korean Americans using SMBP with telephonic transmission of BP measurements, hypertension education, and telephone counseling by a nurse. Adherence was defined as transmitting a minimum of 12 readings per week for at least 24 weeks of the 48-week study.</li> <li>• Age <math>\geq 60</math> years was significantly associated with better adherence with SMBP, and greater depression (measured on a scale specific to Korean Americans) was significantly associated with worse adherence. Other factors explored for their relationship to adherence that did not show significant influences were marital status, education, work status, medication, duration of hypertension, comorbidity, family history of hypertension, body mass index, and knowledge and awareness regarding hypertension.</li> <li>• <b>Conclusion:</b> There is insufficient evidence regarding predictors of SMBP adherence.</li> </ul>

Note: BP = blood pressure; DBP = diastolic blood pressure; Euro QoL 5D = Euro QoL Group 5-Dimension Self Report Questionnaire; RCT = randomized controlled trial; SBP = systolic blood pressure; SF-12/36 = Short Form-12/36 Health Survey; SMBP = self-measured blood pressure (monitoring).

#### **Methodological Quality Ratings:**

A (good). Quality A studies have the least bias, and their results are considered valid. They generally possess the following: a clear description of the population, setting, interventions, and comparison groups; appropriate measurement of outcomes; appropriate statistical and analytic methods and reporting; no reporting errors; clear reporting of dropouts and a dropout rate of less than 20 percent; and no obvious bias. For treatment studies, only RCTs may receive a grade of A.

B (fair/moderate). Quality B studies are susceptible to some bias, but not sufficiently to invalidate results. They do not meet all the criteria in category A due to some deficiencies, but none likely to introduce major bias. Quality B studies may be missing information, making it difficult to assess limitations and potential problems.

C (poor). Quality C studies have been adjudged to carry a significant risk of bias that may invalidate the reported findings. These studies have serious errors in design, analysis, or reporting and contain discrepancies in reporting or have large amounts of missing information.

#### **Evidence Ratings:**

High. There is a high level of assurance that the findings of the literature are valid with respect to the relevant comparison. No important scientific disagreement exists across studies. At least two quality A studies are required for this rating.

Moderate. There is a moderate level of assurance that the findings of the literature are valid with respect to the relevant comparison. Little disagreement exists across studies. Moderately rated bodies of evidence contain fewer than 2 quality A studies or such studies lack long-term outcomes of relevant populations.

Low. There is a low level of assurance that the findings of the literature are valid with respect to the relevant comparison. Underlying studies may report conflicting results. Low rated bodies of evidence could contain either quality B or C studies.

Insufficient. Evidence is either unavailable or does not permit estimation of an effect due to lacking or sparse data. In general, when only one study was published, the evidence was considered insufficient, unless the study was particularly large, robust, and of good quality.

