

## *Comparative Effectiveness Research Review Disposition of Comments Report*

### **Research Review Title:** *Self-Measured Blood Pressure Monitoring: Comparative Effectiveness*

Draft review available for public comment from May 4, 2011 to June 2, 2011.

**Research Review Citation:** 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. HHS A 290-2007-10055-I.) AHRQ Publication No. 12-EHC002-EF. Rockville, MD: Agency for Healthcare Research and Quality. January 2012. Available at: [www.effectivehealthcare.ahrq.gov/reports/final.cfm](http://www.effectivehealthcare.ahrq.gov/reports/final.cfm).

### **Comments to Research Review**

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The tables below include the responses by the authors of the review to each comment that was submitted for this draft review. The responses to comments in this disposition report are those of the authors, who are responsible for its contents, and do not necessarily represent the views of the Agency for Healthcare Research and Quality.

Commentator & Affiliation	Section	Comment	Response
Beverly Green (Public Reviewer)	Abstract	<p>The conclusion really disappointed me. I would write that in general HBPM with and without other support has a modest affect on improving BP control.</p> <p>I probably would include nothing about the incremental benefit of HBPM and HBPM + other. If you feel you must say something. Then say the studies are too heterogeneous to draw any conclusions and needs more research.</p> <p>In general the interventions with the largest effect sizes include SBPM + team care (not just any kind of other care) by a nurse or pharmacist or facilitated transmission of BP data (means that someone helped make the BP data easier for physicians to respond to). Those that have used SBPM alone – have smaller benefits. Teasing apart the SBPM only and SBPM + other – the research is currently insufficient to do this, and the comparisons you lumped very heterogeneous methods and quality and size. The negative studies were all C quality and had poor external generalizability (foreign). The Community Task Force omits C grade studies in their summary statements. The incremental interventions that were ineffective in general are ineffective or weakly effective compared to UC in general (education, cards, and physician alerts). AHRQ technical review #175 states that telemonitoring interventions are most effective when a closed loop is used (measurements, sending these, feedback, readjustment of the plan, and then repeating theses).</p> <p>The studies that did show benefit of incremental interventions used teams, feedback loops, and were better quality studies and had large benefits (Green, Bosworth moderate effects and he has another study in press with similar findings). Zillich did not have a benefit on BP control but was very small and underpowered, but it did have sufficient power to show a diastolic BP decrease and trend for systolic – since you did not do a meta-analysis of effect size you missed trends and I think they would show benefit, particularly for BP reduction which is preferable, particularly if the goal of BP control is &lt;130/80 for diabetes which is controversial and being abandoned in JNC8 as there has never been any direct evidence to support it and now there is direct evidence invalidating the target. Thus I think to make this the emphasis of your conclusion of you abstract distracting and a bad idea.</p>	<p>We concur with this conclusion, that: “HBPM with and without other support has a modest effect on improving BP control”.</p> <p>The nominators were particularly interested in the role of additional support, but we agree that the studies are very heterogeneous, limiting the ability to compare the effects of SMBP with or without additional support. Also the indirect comparison across the studies comparing SMBP with or without additional support in comparison with usual care are weak. We rephrased our conclusion accordingly: “SMBP with or without additional support results in a small reduction in BP compared with usual care. Given clinical heterogeneity and limited head to head comparisons, the evidence limits our ability to draw definitive conclusions about the incremental effect of additional support”</p> <p><i>See also responses below:</i>  <i>We conducted a sensitivity analysis in the MA for the comparison of SMBP alone vs usual care after excluding all quality C studies which yielded consistent findings. We added these sentences.</i>  <i>“In a sensitivity meta-analysis that included only the three quality A or B studies, a statistically significant summary RR of 1.53 (95 percent CI 1.22-1.93) favoring SMBP was found, with no statistical heterogeneity (<math>I^2 = 0</math> percent).” p 23. “These summary estimates remained essentially unchanged in sensitivity meta-analyses that included only quality A and B studies.” p 24</i>  <i>For the comparison of SMBP plus additional support versus usual care we had already weighed qualitatively in favor of ‘good quality’ studies. “Overall, in light of the consistent findings in all five quality A trials, the strength of evidence is rated as high in favor of an improvement in BP control using SMBP with some form of additional support compared to usual care.” p74. Unfortunately, the additional support differed for each of these 5 studies.</i></p> <p>We changed this. See above.</p>
Peer Reviewer 1	Introduction	Well done	Thank you

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Peer Reviewer 2	Introduction	Appropriate framing of the issue with excellent background review	Thank you
Peer Reviewer 3	Introduction	As the number of home blood pressure monitors proliferates, the number of people using them routinely is increasing. Current guidelines such as those of the Joint National Committee do not specifically address many of the important questions involved in the choice of monitors, and the clinical utility of this increasingly popular means of outside-the-clinic blood pressure measurement. Consequently, an in-depth review of this area, such as that covered in this manuscript, is appropriate and timely.	Thank you
Peer Reviewer 4	Introduction	This report provides a relevant summary of available research.	Thank you
Peer Reviewer 5	Introduction	This section is pretty straightforward and very well written.	Thank you
Mehul Dalal (Public Reviewer)	Introduction	Abstract Pg ix – “Data Synthesis” 2nd to last sentence • Suggest mentioning that most all the studies that found reduced BP were done with automatic devices and to the extent the evidence supports SMBP, it supports SMBP provided using automatic devices. Introduction Pg 4, 4th complete paragraph • Clarify that the cost of manual devices and some automated devices are less than \$40.	We added this half sentence in the abstract “While many trials used automated devices, ...”  In the discussion, under summary of findings for Key Questions 3,4, and 5 we wrote (p. 136 “Automated electronic oscillometric devices are presently the devices most widely used for SMBP monitoring, and manual or semi-automated devices were only used in a few older studies.” We did not want to provide cost estimates, as these vary widely, based on commercial entity, device, additional features such as storage or printing and additional equipment such as a large cuff.
Peer Reviewer 1	Methods	Methods consistent with AHRQ methods and very sound.	Thank you

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 2	Methods	<p>The authors did an excellent job describing the inclusion and exclusion criteria. The appendix describing those studies not included in the analysis was very helpful.</p> <p>One might wonder whether or not studies that employed self bp measurement not at home (eg in the work setting), if available, should have been included.</p> <p>It ould also be helpful to define "grey literature", a term some readers may not be familiar with.</p> <p>I do not feel qualified to comment in detail re: the statistical methodology.</p>	<p>Thank you.</p> <p>We discussed whether we should include studies that employed self bp measurement not at home (eg in the work setting or in the physician's office) with our TEP. Our experts felt that the accessibility and frequency of self measurement would be lower and that this would not directly inform the question of whether patients should have a device at home. See Statement of work,page 5: "For the purpose of this report, BP measurement by the patient in the office/clinic/pharmacy or a health unit at work is not included under SMBP monitoring since it does not reliably overcome the problem of white coat hypertension nor provide the privacy and opportunity for more frequent measurements of home self measurement."</p> <p>On page 8 we now define the grey literature searched for this report as "unpublished or nonpeer-reviewed data, in particular the Food and Drug Administration 510(k) database and abstracts from recent relevant scientific meetings of professional societies"</p> <p>OK.</p>
Peer Reviewer 3	Methods	<p>The inclusion and exclusion criteria are well defined. Those articles that were found by the search mechanism, but not included in the actual meta-analyses, are included in the appendix with the reasons for their exclusion from data management clearly stated.</p> <p>The diagnostic criteria used for the search, and the specifics of each key question are well delineated. The meta-analytical procedures undertaken appear appropriate, and I believe the statistical methods to be valid.</p>	<p>Thank you.</p>

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 4	Methods	<p>The literature review was exhaustive and valuable in its own right.</p> <p>However, the desire to include as many trials as possible, including those of lesser quality, may have caused relevant endpoints to be diluted.</p> <p>The outcome measures chosen were largely those previously specified by included studies. They are appropriate 'hard' outcomes including changes in measurable cardiac endpoints. While these are relevant, the intervention of SMBP was not of sufficient magnitude or duration to affect them.</p> <p>Further, the chosen endpoints are probably incomplete as they did not sufficiently weight indirect effects which might have captured changes in patient perception of hypertension through self-monitoring of BP.</p>	<p>Thank you.</p> <p>We conducted a sensitivity analysis in the MA for the comparison of SMBP alone vs usual care after excluding all quality C studies which yielded consistent findings. We added these sentences.</p> <p>“In a sensitivity meta-analysis that included only the three quality A or B studies, a statistically significant summary RR of 1.53 (95 percent CI 1.22-1.93) favoring SMBP was found, with no statistical heterogeneity (<math>I^2 = 0</math> percent).” p 23. “These summary estimates remained essentially unchanged in sensitivity meta-analyses that included only quality A and B studies.” p 24</p> <p>For the comparison of SMBP plus additional support versus usual care we had already weighed qualitatively in favor of ‘good quality’ studies. “Overall, in light of the consistent findings in all five quality A trials, the strength of evidence is rated as high in favor of an improvement in BP control using SMBP with some form of additional support compared to usual care.” p74.</p> <p>We agree.</p> <p>Self perceived knowledge was indeed not an outcome of interest, however patient satisfaction and patient adherence were.</p>
Peer Reviewer 5	Methods	This section is complete and quite detailed.	Thank you

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 1	Results	<p>Excellent tables and figures. I think in at least one there is the (SD) field but no need since standard deviation not reported.</p> <p>There are two papers I am aware of that I did not see included or in the excluded list:            -Artinian NT, Flack JM, Nordstrom CK, et al. Effects of nurse-managed telemonitoring on blood pressure at 12-month follow-up among urban African-Americans. Nurs Res 2007;56:312-322.</p> <p>-Earle KA, Istepanian RS, Zitouni K, Sungoor A, Tang B. Mobile telemonitoring for achieving tighter targets of blood pressure control in patients with complicated diabetes: a pilot study. Diabetes Technol Ther 2010;12:575-579.</p> <p>When discussing the Sawicki paper (e.g., on page 88 of 204), it might be useful to add in the text that the patients were type 1 diabetics with nephropathy. It is unclear whether the lower mortality found would be generalizable.</p>	<p>We chose to keep the SD field in the table headers for consistency across tables in this report and across all reports.</p> <p>Thank you for pointing out that we had missed this study. We have now added it.</p> <p>This study was identified in our updated search and was included as well.</p> <p>In Table 2: Study characteristics we described the patient characteristics for Sawicki as “ Type 1 DM with diabetic kidney disease” We also added this on page 66 where we describe the clinical outcomes for this study. Finally we added this sentence to the summary of the findings of this study for clinical events on page 73. “This study was conducted in individuals with Type 1 diabetes and diabetic kidney disease and has limited applicability.”</p>
Peer Reviewer 2	Results	I believe the answer is yes to all of the above questions and that appropriate justification was provided for those studies included or excluded.	Thank you
Peer Reviewer 3	Results	<p>The results are covered both in the text as well as in the actual data tables and figures. I was able to follow the logic in the text and see the changes in the graphics. There was at least one time, however, when the X-axis labels are switched within a key question so that "favors X" is found on one side and one graphic and on the other side in the other graphic. For example, in figure 9 on page 119 of 204, on the left side of the figure is the following text: "Favors ASMBP alone" while in figure 10 that same text is on the right-hand side of the figure.</p> <p>There is also what I think is a simple cut-and-paste problem and that is the notation for appendix C. This is found on page 177 of 204. If you look at the title above the actual wording "appendix C" it cites "comparative effectiveness of the diagnosis and treatment of obstructive sleep apnea in adults."</p>	<p>This problem stems from the plots depicting two different BP outcome measures. The plot that uses the relative risk of “adequate” BP is set up to show the results favoring more intensive intervention on the right of the line of identity, and the plot showing net change clinic BP is set up to show results favoring more intensive intervention on the left with the greater reduction (i.e. a greater reduction resulting in a more negative number). We considered to switch the orientation for the categorical outcome but decided against it since we thought that the label of ‘relative risk of NOT achieving adequate BP’ was difficult to understand.</p> <p>Thank you. We corrected this error.</p>

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Peer Reviewer 4	Results	The characteristics of the studies were well presented both in the summary statement and in greater detail in the text. The choice of grouping of studies by additional interventions (counseling etc) was reasonable. The tables were helpful to organize the studies and weight their relative merits.	Thank you.
Peer Reviewer 5	Results	<p>Pretty straightforward section. There are important omissions that should be addressed in this section.</p> <p>1. Under the section "Comparison of SMBP alone versus usual care for BP outcomes" LINE 32: The number of studies that looked at pre-specified BP targets or BP control should be stated and a separate table created for this outcome. This is important because clinicians often think in terms of BP control rather than continuous measures.</p> <p>2. Under the section "Comparison of SMBP plus additional support versus usual care for BP outcomes" LINE 22: Similar to the evidence on use of SMBP alone, the authors need to specify the number of studies that achieved BP control and whether or not this was significant. They only reported the evidence for continuous BP rather than achievement of stated BP goals.</p> <p>3. There is very little emphasis on the comparative effects of SMBP on medication adherence. The authors may want to highlight this area given the interest from primary care practitioners. As written the evidence statements were not clear or definitive enough in this regard. The data on medication adherence should be provided even if it is non-significant. This is an important intermediate outcome for primary care providers.</p>	<p>This information is not omitted. It is already provided in text, tables and figures See p.23: "Categorical BP outcomes (Appendix D: Table 3, Figure 3) Thirteen (updated from Twelve) studies reported categorical BP outcomes"</p> <p>Again this information is provided in the section on Blood pressure outcomes p 67: "Categorical BP outcomes (Table 16, Figure 3) Ten (updated from Nine) studies reported categorical BP outcomes..."</p> <p>Medication adherence was included as an outcome in the report and all available information from the studies was provided in the respective results sections, tables and summaries. For SMBP versus control see p. 26, and 29 For SMBP plus additional support versus control see p. 70 and 74 p.99 and 102.</p> <p>We added a section summarizing the results in the discussion section: "Medication adherence is an important intermediate outcome for primary care providers. Studies used a variety of different definitions of adherence. For the comparisons of SMBP versus control and SMBP plus additional support versus control, there was weak evidence that medication adherence may be better among patients using SMBP monitoring. For the comparison of SMBP plus additional support versus SMBP alone or with another type of additional support the evidence was weak and failed to show a difference."</p>

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			<p>We also added this section in the future research needs section: “Many clinicians consider self-monitoring of BP to be an educational tool to help patients become aware of their disease process, increase their commitment to BP normalization, recognize the importance of antihypertensive therapy and increase adherence and persistence to BP lowering therapy. Therefore, another outcome of interest to be examined in future comparative studies of SMBP is patient’s understanding of disease and how this correlates with adherence to antihypertensive medication and with BP control.”</p>
Mehul Dalal (Public Reviewer)	Results	<ul style="list-style-type: none"> <li>• In the meta-analyses especially, but in all areas when possible, would suggest also presenting the results excluding quality C studies as reader can have more confidence that those results more accurately reflects true estimate of effect.</li> <li>• Suggest mentioning race/ethnicity data that was abstracted and whether any subgroup analysis by race/ethnicity was reported in the studies or could be performed through meta-analysis</li> </ul>	<p>As described above, we conducted a sensitivity analysis in the MA for the comparison of SMBP alone vs usual care after excluding all quality C studies which yielded consistent findings. We added these sentences. “In a sensitivity meta-analysis that included only the three quality A or B studies, a statistically significant summary RR of 1.53 (95 percent CI 1.22-1.93) favoring SMBP was found, with no statistical heterogeneity (<math>I^2 = 0</math> percent).” p 23. “These summary estimates remained essentially unchanged in sensitivity meta-analyses that included only quality A and B studies.” p 24</p> <p>For the comparison of SMBP plus additional support versus usual care we had already weighed qualitatively in favor of ‘good quality’ studies. “Overall, in light of the consistent findings in all five quality A trials, the strength of evidence is rated as high in favor of an improvement in BP control using SMBP with some form of additional support compared to usual care.” p74.</p> <p>We extracted race and noted this in the summary tables under “other patient characteristics” if pertinent. See for example Table 2, p 43 .</p> <p>In our literature update, we found a study (Bosworth 2011, FU report on Bosworth 2009) with analyses by race/ethnicity, which we added to the report.</p>

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Peer Reviewer 1	Discussion	<p>In a few places in the report, it is mentioned that few devices have been validated, and a paper from 2000 is cited. While there are no doubt a lot of devices on the market, actually many have been validated.</p> <p>At the end of the report, the need for a central database to serve as a reference on devices is mentioned. Did authors take a look at the dablededucational website:? The journal Blood Pressure Monitoring also publishes new validation studies nearly every issue.</p> <p>In the Future Research section, might mention the need for research in children with hypertension.</p>	<p>We removed this sentence and the ref from the report.. "However, a number of these digital BP devices have yet to undergo rigorous independent validation.{Yarows, 2000 20046 /id}" p 136</p> <p>We agree that this website looks like a good resource for consumers and have removed our research recommendation calling for a central database.</p> <p>We added the need to conduct studies in children to the research recommendations. "There is a need for for studying the role of SMBP in children." p. 140</p>
Peer Reviewer 2	Discussion	<p>While I found the results disappointing as a clinician, the analysis clearly seems to support the conclusions. Provding a synopsis of pending studies (appendix) was also helpful.</p>	<p>Thank you.</p>
Peer Reviewer 3	Discussion/ Conclusion	<p>A few general comments. I thought the manuscript quite scholarly and useful. In particular the detail of areas with deficiencies that would benefit from future trials taking into consideration the recommendations by the authors of this review is a help. I do not do a lot of this kind of research, and I'm not savvy with terms like "grey literature" found several times in the document for example on line 13 of page 4. A parenthetical comment on what grey literature refers to would help those less well informed such as myself.</p> <p>Two areas of concern I had after reading the manuscript. Number one, is there enough confidence in the validity of SMBP, or should there be (more) validation of SMBP by external procedures such as ABPM?</p> <p>Secondly, how strongly do the authors feel that the value found in nocturnal blood pressures might be important to have in addition to the daytime values that are currently accessible with existing devices? There is rumor that Omron is working on a home device that will be able to take nocturnal blood pressures with an SMBP-type approach.</p> <p>The statement on page 32, lines 35 through 39 might generate some controversy. The notion that it requires "decades" to witness the difference between improved blood pressure control and better clinical outcomes, although true on a global epidemiologic scale, is</p>	<p>Thank you.</p> <p>On page 8 we now define the grey literature searched for this report as "unpublished or nonpeer-reviewed data, in particular the Food and Drug Administration 510(k) database and abstracts from recent relevant scientific meetings of professional societies"</p> <p>The assessment of the diagnostic accuracy or the risk relationships between BP measured by SMBP and other means was not a question of interest for this report. We however recommended future research on the accuracy of SMBP: "Other important areas for future research include examining the role of various measures for improving the accuracy of and adherence with SMBP"p.139.</p> <p>Again, our review did not examine this. The ability to measure nocturnal SMBP will require research on how to use this to characterize BP pattern and burden and how this correlates with end-organ damage or future risk for CVD. We believe our generic research recommendation covers this: "Of particular importance for future SMBP research is the need to establish targets for home BP based on observational and RCT data. Observational studies should compare risk</p>

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		<p>not so true in the typical five-year randomized clinical trial done in the 1970s, 1980s and 1990s which established utility of treating blood pressure in the first place. I would recommend softening the tone of this sentiment.</p> <p>I may have missed this, but on page 36 lines 21 through 25, the authors mention a search of the food and drug administration website for measurement systems with a particular product code. Are these results reported somewhere? Did I miss them?</p> <p>Another semantic issue arises on page 94. At lines 9 and 10 the authors make a point that "the studies were too heterogeneous along a variety of axes" and I wasn't sure what this actually meant. A parenthetical comment expanding that would help (or a note that this is covered subsequently on page 144, or whatever the ultimate page would be).</p>	<p>information from home BP, ambulatory BP measurement, and clinic BP levels." p 140.</p> <p>We changed this sentence: "SMBP may actually increase cost, at least in the short term, since there is a decades-long lag between improved BP control and better clinical outcomes." to "SMBP may actually increase cost, at least in the short term, since it takes several years for improved BP control to improve clinical outcomes." p.4</p> <p>We removed this half sentence on p 139" with its risk for clinical outcomes accruing over decades"</p> <p>The searches of the FDA database were part of the grey literature searches. Figure 2 of the literature flow shows two abstracts added from the grey literature search (these came from the conference meetings). The rejects from the grey literature search were not tabulated in the appendix of excluded studies, following AHRQ reporting convention.</p> <p>We changed "axes" to "criteria" and added in parenthesis "(including populations, settings, interventions, control treatment, duration of follow-up and quality)".</p>

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Peer Reviewer 4	Discussion/ Conclusion	<p>Unfortunately, a large number of studies diluted the potential significance of the findings.</p> <p>The data for SMBP with additional interventions (pharmacist counseling and website) was strong and could have resulted in a stand-alone recommendation.</p> <p>The section on future studies was fairly reasonable, although perhaps missed the main benefit of SMBP. The emphasis on tailoring treatment to specific patient situations (avoiding overtreatment or undertreatment) is laudable, but overly ambitious. Most clinicians consider SMBP to be an adjunct to in-office BP management and use it for validation of clinical impression of BP control in willing patients (and to limit the need for repeated ambulatory BP monitoring which is more cumbersome and more expensive). The section would have benefitted from a broader look at the use of SMBP in increasing patient understanding of disease, BP goals and the role of antihypertensive therapy. Further studies to elucidate the effect of SMBP on medication adherence and persistence (not addressed in any of the short-term studies).</p>	<p>As explained above: For the comparison of SMBP plus additional support versus usual care we had already weighed qualitatively in favor of ‘good quality’ studies. “Overall, in light of the consistent findings in all five quality A trials, the strength of evidence is rated as high in favor of an improvement in BP control using SMBP with some form of additional support compared to usual care.” p74.</p> <p>Unfortunately, the additional support differed for each of these 5 studies. The findings of a single study using a unique combination of a pharmacist and a Web portal is not be sufficient to draw a conclusion. The same applies to the single study that examined SMBP with patient self titration of antihypertensive medication.</p> <p>We agree that SMBP may be used as an adjunct to in-office BP management and used for validation of clinical impression of BP control. We added this sentence in the future research section: “Further there is a need to test SMBP as an adjunct to in-office BP management and use it for validation of clinical impression of BP control in willing patients” p.139</p> <p>We also added this section: “Many clinicians consider self-monitoring of BP to be an educational tool to help patients become aware of their disease process, increase their commitment to BP normalization, recognize the importance of antihypertensive therapy and increase adherence and persistence to BP lowering therapy. Therefore, another outcome of interest to be examined in future comparative studies of SMBP is patient’s understanding of disease and how this correlates with adherence to antihypertensive medication and with BP control.”</p>

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 5	Discussion/ Conclusion	<p>While this section is very well written, the statement "establishing targets for home BP; and consistently reporting complete information on the name, type, and accreditation of the SMBP device used" is dated simply given that there are now numerous studies with regards to this point. Most importantly, most journals do not allow publication of data based on SBPM without specification of the types and validation of such monitors.</p> <p>Also, there seem to be an important literature omitted with regards to the effect of SBPM on use of antihypertensive medications. This is a review by Agarwal et al in Hypertension 2011. This omission may reflect the search period.</p>	<p>While we agree that the detail in reporting seems to be improving, unfortunately even the most recently published abstracts did not identify the device and at least one study published in 2010 did not reference information on validation. Thus we have left this recommendation in the report.</p> <p>Regarding the therapeutic targets for home BP we believe that this is still an area of uncertainty. A review by Staessen in 2008 concluded that further studies must establish what values of the self measure blood pressure are optimal and normal in terms of cardiovascular outcomes. (Stassen JA et al Blood pressure Monitoring 2008, 13:352-365). As discussed on p 138, the ongoing HOMED-BP study aims to determine an optimal target BP level on the basis of SMBP at home.</p> <p>This was not omitted: We discussed our findings in the context of Agarwal's 2011 systematic review in Hypertension in the section on "Context of findings" p 138. "Our findings are consistent with four recently published systematic reviews examining the effect of SMBP identified in our search. {Agarwal, 2011 20048 /id;Bray, 2010 8034 /id;Cappuccio, 2004 3384 /id;Glynn, 2010 8185 /id} Agarwal 2011 examined 37 trials, Bray 2010 25 trials, Cappuccio 2004 18 trials, and Glynn 2010 14 trials.</p>
Mehul Dalal (Public Reviewer)	Summary and Discussion	<p>Pg 118 – "Interpretation of findings of Key Questions 1 and 2" first paragraph, last sentence • Although some lifestyle interventions are associated with substantial reductions in blood pressure, effective lifestyle interventions must be high frequency and intensive and therefore may not be feasible in most clinical practice settings. On the other hand, SBPM could be a relatively simple intervention to introduce in the clinical setting. Suggest modifying the last sentence of this paragraph to reflect this point.</p> <p>Pg 118 – "Summary of findings of key question 3,4 and 5" • Although there were no comparative studies among types of monitors, strongly suggest indicating the lack of A- or B- rated studies using manual devices and that only 1 study, a quality C study (Mehos) in past 25 years used a manual device.</p>	<p>We added this section: "However, effective lifestyle interventions must be high frequency and intensive and therefore may not be feasible in many clinical practice settings. In comparison, SBPM may be a simpler intervention to introduce in the clinical setting."</p> <p>We added this half sentence: "and manual or semi-automated devices were only used in a few older studies." p 136 .</p> <p>Thank you for these thoughts. We believe such an endorsement of current applicability is overstating the findings.</p>

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Commentator & Affiliation	Section	Comment	Response
		<p>Pg 119 – “Applicability” • Overall, the first paragraph lists reasons that limit applicability and the second paragraph focuses on future potential applicability. Suggest adding a middle paragraph that focuses on current applicability. The following points could be made:</p> <ol style="list-style-type: none"> <li>1. Given appropriate selection of patients, providers can consider integrating SBPM with or without additional support into their clinical management of patients with hypertension. Additionally, 3rd party validation information is available online through the manufacturer specifications or 3rd party sites such as ESH, AAMI or BHS. 2. Since the potential for health impact is large if the intervention is applied across populations, public health, clinical quality organizations and payers can consider programs and policies supporting the uptake of SBPM with and without additional support. Efforts could be made to align SBPM with ongoing reform initiatives such as meaningful use, patient-centered medical home and accountable care.</li> </ol> <p>Pg 120- “Future Research”</p> <ul style="list-style-type: none"> <li>• Suggest adding a paragraph on the importance of pragmatic trials, which would inform “real-world” effectiveness and report practical information on how best to integrate SBPM into routine clinical care.</li> </ul> <p>Pg 121 – first sentence</p> <ul style="list-style-type: none"> <li>• Other subgroups of interest include racial and ethnic minorities, low SES groups and individuals receiving care in safety-net and non-academic settings.</li> </ul> <p>Pg 121 – 4th full paragraph • The language mentions that direct comparisons among different types of monitors may not be important research questions, however such comparison’s may inform 3rd party coverage, which does not universally reimburse for automated monitors.</p> <p>Pg 121 – last paragraph, last sentence • Suggest adding “race and ethnicity” as candidate variable of interest</p> <p>Pg 122 – “Conclusion” • The conclusion is missing a key finding that SBPM plus some type of additional support has highest evidence of benefit.</p>	<p>In the introduction, where we discuss validation of devices, we included a reference to the educational website dablededucational.org.</p> <p>We added this half sentence: “as well as by pragmatic trials that would inform real world effectiveness.” p.139</p> <p>We added this: “Other subgroups of interest include racial and ethnic minorities, low SES groups and individuals receiving care in safety-net and non-academic settings”</p> <p>We modified this to say: “Automated devices are widely available and require less dexterity on the part of the patient. If the question of cost difference between different types of devices is of interest, then future research on this question may be considered and should evaluate any trade offs between cost and user acceptance.”</p> <p>We added “race and ethnicity”</p> <p>We decided to de-emphasize this given the clinical heterogeneity for the additional support. See response to public reviewer Beverly Green.</p>
Peer Reviewer 1	General	The authors are to be congratulated on completing this review. Overall it is very well done, and I recognize the large amount of work that went into this!	Thank you.
Peer Reviewer 2	General	An exhaustive, well written analysis of a clinically important issue.	Thank you.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 3	General	This submission is a thorough evaluation of the clinical utility of self monitored blood pressure. To me it appears well done, and includes articles I know should be cited for the key questions proposed. The area is important and as the work shows there are clear deficits in the current knowledge base. The key questions are appropriate, well crafted, though poorly supported by the actual literature as the authors note.	Thank you.
Peer Reviewer 4	General	Many clinicians consider self-monitoring of BP to be an educational tool to help patients become aware of their disease process, increase their commitment to BP normalization, recognize the importance of antihypertensive therapy and increase adherence and persistence to BP lowering therapy. Data in this area are sparse. However, the key questions addressed in this study were limited to adherence to medication and BP outcomes, reflecting limitations in published research.	We agree. Change in patient's knowledge or attitude regarding hypertension was not an outcome of interest for this review, but it was rarely reported in otherwise eligible trials. As discussed above we added this sentence to the future research needs section: "Many clinicians consider self-monitoring of BP to be an educational tool to help patients become aware of their disease process, increase their commitment to BP normalization, recognize the importance of antihypertensive therapy and increase adherence and persistence to BP lowering therapy. Therefore, another outcome of interest to be examined in future comparative studies of SMBP is patient's understanding of disease and how this correlates with adherence to antihypertensive medication and with BP control."
Peer Reviewer 5	General	The report addresses a very important area of hypertension management that is useful for practitioners both primary care and specialty care. The questions posed are largely relevant and significant.	Thank you.

Source: <http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=893>

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Beverly Green (Public Reviewer)	General	<p>The study by Green – was not a personalized Web site, it was an existing patient Web portal – it was part of usual care and all 3 groups received this, UC was registered to receive this and got pamphlets about it, group 2 received this + HBPM and a brief tour on how to use it in conjunction with their SBPM. Group this (3) got group 1 and 2 interventions and Web based pharmacist care using the existing Web portal.</p> <p>Page 88 subgroups, this was an a priori separately randomized group, and the relative risk you provided is incorrect it was not 2.11 , but 3.33 (1.86 -5.94).</p> <p>We also looked at utilization, it is text – as there were no significant differences we did not include it in the tables, but we did report numbers and p values so it should be in the section on utilization .</p> <p>Soghikian K found decreased costs of care, as did others that used home BP measurements to reduce medications but I did not have time to check your studies on this but feel it was incomplete .</p> <p>In general the document is hard to read, a scientific writer with plain English skills would help.</p>	<p>We will make this change from “personalized Web site” to “Web training”.</p> <p>Our estimate 2.11 (1.22, 3.65) is correct. It was calculated for the comparison SMBP Web training plus pharmacy counseling vs SMBP Web training The estimate 3.32 (1.86, 5.94) is for the comparison of SMBP plus Web training plus Pharm counseling versus usual care.</p> <p>We added the information on the health care utilization outcomes to the final report. p. 71 and p 9x.</p> <p>Cost was not an outcome of interest for this report.</p>
Peer Reviewer 1	Clarity and Usability	Very clear and usable. The synthesis is well-done.	Thank you
Peer Reviewer 2	Clarity and Usability	<p>The structure and organization was excellent and exhaustive.</p> <p>The conclusion is somewhat lukewarm and vague. It is not clear what will be recommended to the policy makers and there are no specific recommendations for the clinician.</p>	<p>Thank you.</p> <p>The strength of the evidence is weak or insufficient for most outcomes except for BP which results in uncertainty about the overall benefit, especially beyond the one year follow up duration that most studies were limited to. Our charge is explicitly not to make recommendations for policy decisions.</p>
Peer Reviewer 3	Clarity and Usability	The report is well structured. The organization is easy to follow. I felt that the main point are clearly presented and that the results really will help inform future clinical trials in this area of blood pressure monitoring.	Thank you.
Peer Reviewer 4	Clarity and Usability	<p>The report is well organized and worthwhile.</p> <p>The conclusions do not recommend a change in policy.</p>	<p>Thank you.</p> <p>The report makes no recommendations on policy, since our charge was to present the evidence so that it can be used by others when making policy decisions.</p>

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Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 5	Clarity and Usability	The report is very well structured.	Thank you.
Mehul Dalal (Public Reviewer)	Tables	<p>Table 2 – suggest include study N in this table</p> <p>Table 26 – if possible consider categorizing additional support into existing taxonomy of QI interventions to facilitate comparisons: <a href="http://www.ahrq.gov/clinic/epc/qgapfact.htm">http://www.ahrq.gov/clinic/epc/qgapfact.htm</a></p> <p>Table 43 – page 110 – Key Question 1: SMBP vs. Usual Care, Blood Pressure Suggest clarifying the implications of study heterogeneity on confidence of the conclusion and/or direct reader to page and section number in text that discusses this point</p>	<p>We did not include the numbers randomized here as the numbers analyzed are included in all results tables.</p> <p>Unfortunately there is a lot of overlap across the taxonomy. For example SMBP (as a means of promotion of self-management) is used in all studies.</p> <p>None of the sections in the summary of findings table reference the corresponding text sections. However, there is an entire section on “Sources of clinical heterogeneity” in the discussion section. p 135</p>