

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Are self-reported telemonitored blood pressure readings affected by end digit preference: a prospective cohort study in Scotland
<b>AUTHORS</b>	Parker, Richard; Paterson, Mary; Padfield, Paul; Pinnock, Hilary; Hanley, Janet; Hammersley, Vicky; Steventon, Adam; McKinstry, Brian

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Raj Padwal University of Alberta, Edmonton, Canada
<b>REVIEW RETURNED</b>	10-Sep-2017

<b>GENERAL COMMENTS</b>	<p>This is a well written paper and the subject matter is important and of interest to investigators in this field. The authors take advantage of two datasets to assess for terminal digit preference and bias in the self-reporting of home BP readings. The conclusion is appropriate and I agree with the interpretation of the data. I am a little surprised that there was not more terminal digit preference.</p> <p>One limitation that should be added is that these data are specific to two studies conducted in Scotland and generalizability to other jurisdictions is not fully possible at this time, in the absence of more data.</p> <p>Thanks for the opportunity to review.</p>
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<b>REVIEWER</b>	Associate Professor Dr Adina Abdullah University of Malaya, Malaysia.
<b>REVIEW RETURNED</b>	06-Oct-2017

<b>GENERAL COMMENTS</b>	<p>This paper aims to determine the occurrence of end digit bias and specific value preference in BP readings between patient transcribed and transmitted data versus automatically transmitted data. It utilised data from 2 different patient cohorts, collected at different time. The first concern I have is to do with validity of comparing the two different cohorts with differing distributions. There are restrictions put on the patient transcribed and transmitted data that was not put on the automatically transmitted data that is also of concerns. The main concern however is the importance of the findings.</p>
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	<p>Although the end digit preference was proven but we really have no idea if this is a rounded up or rounded down figures, and how it would or did influence patient management. The authors raised a question of validity when comparing the frequency of readings BP134/84, and excluded certain groups which may have lower target level e.g. CKD. Would the same argument not apply for the whole population? As a clinician, I am not sure if the results from this study would change my practice. There are many other reasons for using automatic transmission such as patients' capability and ease of use that may influence my decision and this study had not presented a convincing argument that end-digit preference and preference to BP of 134/84 led to significant difference in management received by patients. There are many more published studies that had shown the benefits of telemonitoring than referenced in this study. Also the data shown a preponderance of similar digit preference for both systolic and diastolic readings (highlighted in the table), is this statistically significant? I would suggest, a relook at the data and maybe be more clear on the aim of this study, esp to do with the clinical significance of the study. If there are evidence of validity to current approach, please explain in detail in your methods section and quote some references. Thank you</p>
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### VERSION 1 – AUTHOR RESPONSE

We thank reviewer 1 for the encouraging and positive comments. We accept that the single country location of the study is a limitation and have now added it to the discussion section.

We also wish to thank reviewer 2 for their comments.

Reviewer 2 writes: "The first concern I have is to do with validity of comparing the two different cohorts with differing distributions. There are restrictions put on the patient transcribed and transmitted data that was not put on the automatically transmitted data that is also of concerns. ....The authors raised a question of validity when comparing the frequency of readings BP134/84, and excluded certain groups which may have lower target level e.g. CKD. Would the same argument not apply for the whole population?"

Response: We agree with reviewer 2 that there are some difficulties with comparing the two cohorts due to the differing distributions, and indeed have already identified this as a limitation in our discussion section: "However, because of differences in the eligibility criteria, our patient populations had significantly different levels of BP control making comparison challenging, especially for the analysis of specific-value preference. In particular, patients with CKD (stages 3-5) or who had diabetes were included in the patient-texted cohort but were excluded from the automatic-transmission cohort." Although the comparison is not perfect, this is already a step forward since almost all studies in the literature do not have any comparison group at all and have to rely on within-sample methods to detect end digit preference. Moreover, although the distribution of blood pressure readings is slightly different, we would expect that the distribution of blood pressure end digits will be the same. In particular, it is unlikely that the probability of observing zero end digits varies between the populations due to differences in distribution. Therefore, this limitation applies to the specific-value analysis and not the end digit preference analyses.

Nevertheless, we tested this assumption in statistical analysis by restricting the combined data used for the GEE analysis (Table 3, first three outcomes) to include only patients with median systolic blood pressure above 120 AND median diastolic blood pressure above 80 (i.e. clear hypertensive patients) and our conclusions were unchanged. Also, as stated “our GEE analysis attempted to address this by confining the samples in both group to include only patients with median BPs within a restricted range and using a standard protocol (i.e. excluding CKD and diabetic patients).” In summary, we used restricted sampling methods to address this issue, and we have clarified this on page 11.

Reviewer 2 writes: "The main concern however is the importance of the findings. Although the end digit preference was proven but we really have no idea if this is a rounded up or rounded down figures, and how it would or did influence patient management. As a clinician, I am not sure if the results from this study would change my practice. There are many other reasons for using automatic transmission such as patients' capability and ease of use that may influence my decision and this study had not presented a convincing argument that end-digit preference and preference to BP of 134/84 led to significant difference in management received by patients. There are many more published studies that had shown the benefits of telemonitoring than referenced in this study."

Response: Many of the telemonitoring studies the reviewer refers to made use of automatically transmitted data. Low cost solutions which require the patient to input data have been tested less frequently and there have been concerns that, as has been found to be the case with blood glucose monitoring, results may be altered, particularly to avoid increases in medication. Our results provide some reassurance that although there is some evidence of tampering with patient transmitted data, that this is minimal. In the discussion section we are clear that the end digit preference is unlikely to be clinically important. Rather than reference a long list of studies to show the benefits of telemonitoring and add to what is already a long reference list, we chose to cite an overall meta-analysis of studies assessing home blood pressure monitoring [Omboni et al. Clinical usefulness and cost effectiveness of home blood pressure telemonitoring: meta-analysis of randomized controlled studies. *J Hypertens* 2013;31(3):455-67.]. In addition, we have now cited in our revised manuscript an individual patient data meta-analysis study published this year by Tucker et al. [Self-monitoring of blood pressure in hypertension: A systematic review and individual patient data meta-analysis. *PLoS Medicine* 2017, 14(9), e1002389.] which showed little or no evidence for the benefits of blood pressure self-monitoring when implemented alone; although benefit was shown when accompanied with co-interventions. In the revised version of our paper, we have cited this new meta-analysis to ensure that our citations cover the many studies to which the reviewer refers.

Reviewer 2 writes: "Also the data shown a preponderance of similar digit preference for both systolic and diastolic readings (highlighted in the table), is this statistically significant? I would suggest, a relook at the data and maybe be more clear on the aim of this study, esp to do with the clinical significance of the study. If there are evidence of validity to current approach, please explain in detail in your methods section and quote some references."

Response: Due to the clustered nature of the data (readings are clustered within patients), standard significance tests such as Chi-squared tests are not valid when applied to Table 2 or comparison of proportions, which is why we perform the advanced GEE analysis which takes into account the clustering.

We assess the clinical significance of the study in the discussion section. For example, we write: “Nevertheless, despite the statistically significant results, they are unlikely to be clinically relevant: in the patient-texted group the overall percentage of double zero readings was still below 2%, and occurrences of specific-value selection of systolic 134 and diastolic 84 were still within 4% of the automated system.”

The finding that end-digit preference is uncommon and unlikely to adversely affect clinical decisions, is a clinically important negative finding as it lends confidence in the use of the cheaper patient-texted approach. We highlight this on page 13: 'The extent of end digit preference is not so great as to warrant the use of more expensive systems that allow the automatic transfer of BP readings, and so telemonitoring services can continue to use manual entry systems.'

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Raj Padwal Director, Hypertension Clinic Professor of Medicine University of Alberta Edmonton, Alberta, Canada
<b>REVIEW RETURNED</b>	25-Oct-2017

<b>GENERAL COMMENTS</b>	My concern was addressed satisfactorily.
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<b>REVIEWER</b>	Associate Professor Dr Adina binti Abdullah University of Malaya, Kuala Lumpur, Malaysia
<b>REVIEW RETURNED</b>	02-Nov-2017

<b>GENERAL COMMENTS</b>	The authors had addressed and responded to my comments.
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