Feedback on CEBM rapid review by Tarassenko and Greenhalgh on smartphone oximeters

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We read the rapid evidence synthesis "*Can we use smartphones to measure oxygen saturation?*", published online on the 1st April 2020 with interest. However, we would like to raise some issues with interpretation and challenge the conclusion that the scientific basis for these technologies is questionable.

DigiDoc, Tomlinson et al.

While we agree with the conclusion for the DigiDoc app, that it is not fit for purpose, there is a scientific basis for how it can measure an oxygen saturation. This may be a technical detail unrelated to the interpretation of the usability, but is important to note for accuracy.

As noted in the article SpO2 requires both a red (660μ) and an infra-red (IR) (900μ) waveform. Conventional oximetry uses a red and an IR led to distinguish the wavelengths. As observed the DigDoc uses the camera flash, a single light source. The light source is designed to be broadband so it contains both the red and the IR. The smartphone camera designed to discriminate color is used to separate the two waveforms. So in principle it may work but has never been proven to.

Samsung, Tayfur et al.

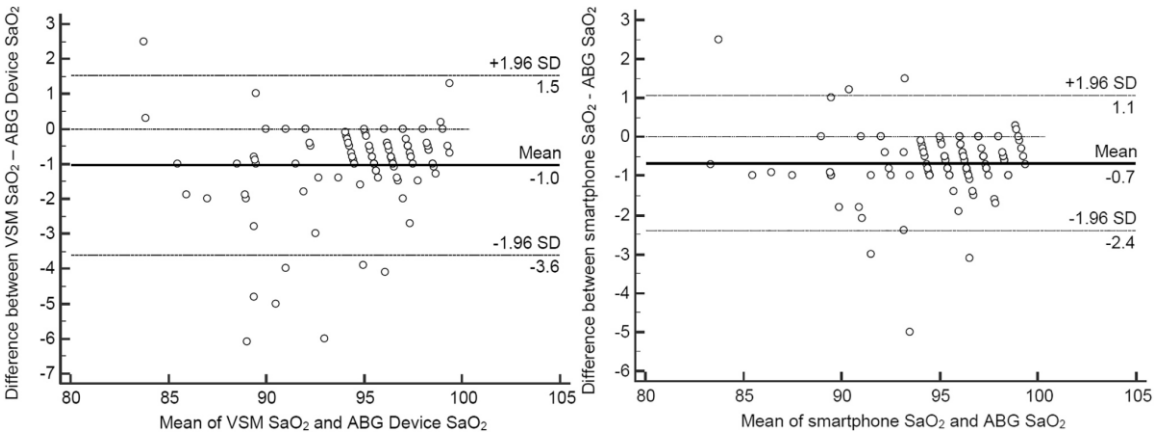
The most important point of clarification in the presentation of the Samsung phone is that it has a dedicated SpO2 sensor. It does not use the camera or the flash for oxygen saturation measurements, as stated in the Tayfur et al. article "*The feature of the Samsung Galaxy S8 smartphone used in this study is that it performs SaO2 and HR measurements using a dedicated sensor built in the device, rather than a camera and flash light*."

The integrated sensor includes both red and IR LEDs. The red is visible to the naked eye, and any smartphone camera allows one to observe the IR LED which is not visible to the human eye. The IR LED can be distinguished because it is always on, while the red LED only comes on with a finger near the sensor. Indeed, the presence of the separate IR LED is integral to the way the oxygen saturation measurement has been set-up on the Samsung devices.

The Tayfur et al. conclusion differed considerably from the one drawn in this Evidence Review. Tayfur et al. presented a Bland Altman plot of the Welch Allyn vital signs monitor – a 'traditional' oxygen saturation measurement based on Masimo or Nellcor technology - compared to the Radiometer ABL-800 blood Hemoximeter, an invasive 'gold-standard' for measuring oxygen saturation. The Samsung smartphone result was also compared to the ABL-800. About 100 subjects were tested. Visual comparison of these plots suggests the smartphone actually had slightly better agreement with the reference standard than the Welch Allyn device, with fewer outliers.

While the presence of outliers indeed means that the some of the Samsung measurements were inaccurate, the same is true for the Welch Allyn device. However, it's important to remember that all medical monitors are specified statistically as there is always a certain amount of random error in any single measurement – i.e. some outliers could always be expected, even in CE marked and ISO certified

pulse oximeters. It's also worth noting that most pulse oximeters, including the Welch Allyn only claim to be accurate within +/-2%, and accuracy is often poorer at lower saturations and in low-perfusion states.



Finally, it was stated that "*Samsung withdrew its claim of being able to measure oxygen saturation in May 2019*". This is a misinterpretation of the notice given by Samsung. Rather the statement that "*you can measure your oxygen saturation by measuring your stress*" simply means that the SpO2 measurement was moved in the phone's interface to the stress measurement location on the phone. It's important to clarify that Samsung has never made a claim that their SpO2 measurement function is a medical device. In fact, almost all consumer grade pulse oximeters, including those sold in pharmacies, are not listed as medical devices.

Conclusion

Based on the above, we do not agree with the conclusions drawn by this evidence review. Firstly, the studies presented do not demonstrate that the scientific basis for smartphone based oxygen saturation measurement is unfounded. Further our interpretation of the Tayfur et al. study, supported by the authors of the original paper, is that the smartphone performed equally well than a traditional pulse oximeter.

Finally, while the marketing of the Samsung device may not be completely clear, we feel it's important to consider the nuanced balance between scientific validity, clinical accuracy and real-world utility. Pulse oximeters are not a common household item, and there is a clear use-case for home-based self-monitoring of oxygen saturation in suspected or confirmed COVID-19 patients. All pulse oximeters are only accurate to within +/-2%, and all pulse oximeters can become inaccurate if used incorrectly. Based on this, our conclusion would be to recommend the use of smartphone pulse oximeters with a proven level of clinical accuracy, but with the support of clear instructions. In an ideal world, inbuilt pulse oximetry should come with built-in quality control and decision-support aids.

Conflicts of Interest:

MB is an independent consultant in the field of SpO2 development and validation, and a staff member of the Bickler-Ye Laboratory which is engaged in SpO2 testing and validation. He has consulted for over 50 pulse oximetry manufacturers. Both MB and CK have received research funds from the BMGF to work on pulse oximetry re-design with the Lifebox Foundation.

Authors' Reply:

The paragraph on the DigiDoc app referred to above has been superseded by the recent exchange with the principal author (Dr Eric Larson) of the paper published the November issue of the IEEE Journal of Biomedical & Health Informatics.

Samsung, Tayfur et al.

Mike Bernstein and Carina King state that the "integrated (Samsung) sensor includes both red and infra-red (IR) light-emitting diodes (LEDs). This would certainly make oxygen saturation measurement possible, but we could not find any evidence of this fact in any peer-reviewed papers.

Bernstein and King further point out in their review of the Tayfur et al paper that, although "some of the Samsung measurements were inaccurate, the same is true for the Welch Allyn device. However, it's important to remember that all medical monitors are specified statistically as there is always a certain amount of random error in any single measurement – i.e. some outliers could always be expected, even in CE marked and ISO certified pulse oximeters." We do not disagree with this statement, but the accuracy claim for the Welch-Allyn device will hold **throughout the clinical range of oxygen saturations from 70% to 100%, as this is the range required by the FDA and other regulatory bodies to approve the clinical use of pulse oximeters.** The most important part of the range for clinical use is below 90%, when patients are becoming hypoxic. There are only six data points in the Bland-Altman plot for the Samsung app with oxygen saturations below 90%, which lie between 83% and 89%. From these it is not possible to make any statements about the accuracy of the Samsung app for SpO_2 values below 90%.

We could not find any evidence, either in the Tayfur and Afacan paper or anywhere else, that the Samsung smartphone app has been tested over the full range of skin types (from Fitzpatrick skin type 1 to 6), **an essential requirement for all reflectance-type pulse oximeters**. The lack of mention of any such testing invalidates the results presented in the Tayfur and Afacan paper, even in the physiologically normal range.

Finally, in response to the point that Samsung have not removed the app from the latest version of the smartphone, we believe this interpretation is correct. In the revised review, we have omitted the section on stress measurement replacing oxygen saturation in the more modern smartphones. On the contrary, the latest Samsung smartphone still includes an app which they claim measures oxygen saturation accurately and which we believe does not do so over the required clinical range of 70% to 100% SpO2.

Conclusion

We believe that our conclusions stand: smartphone apps should NOT be used clinically for the measurement of oxygen saturation; none of the apps has the required evidence, a comparison with a calibrated device for oxygen saturations below 90%, carried out in a study with Medical Research Ethics

(or IRB) approval. In addition, there is no evidence that they work over the full range of skin types, an essential requirement for all reflectance-type pulse oximeters.

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