Topic Exploration Report [1]

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

Topic exploration report number	TER540
Topic	Contactless measurement of blood pressure using cameras on smart phones or tablets and artificial intelligence software.
Summary of findings	Blood pressure is typically measured using an electronic monitor connected to an inflatable blood pressure cuff, wrapped around the upper arm. Contactless photoplethysmography (PPG) where blood pressure is measured by an app using the camera on a smart device and algorithms derived using artificial intelligence (AI) technology may be more rapid and convenient. We identified one HTA, two systematic reviews and three primary studies, one published as a preprint. There is some evidence that contactless PPG can achieve similar mean errors and standard deviations as cuff-based measurements for blood pressure. One small validation study reported sensitivity of 70% and specificity of 72% for diagnosis of high blood pressure when compared with a gold standard reference measurement. However, the identified systems are still in development with ongoing research being conducted to improve the algorithms. An unpublished report provided by the topic proposer estimates Lifelight to be associated with life cost-savings of £136,159 - £266,212 per 10,000 patients. There are uncertainties as to how rapidly blood pressure readings are given and around how well the technology will perform if used for self-monitoring in uncontrolled conditions. The estimated cost savings are subject to uncertainties around the age of cost inputs used, the diagnostic accuracy of Lifelight for patient end-users and the compatibility of outcomes due to assumptions surrounding the conversion rates.

[1] Cyfieithu dogfennau HTW wedi'u cyhoeddi o'r Saesneg i'r Gymraeg
Translation of published technical HTW documents from English into Welsh

Introduction and aims

It is estimated that cardiovascular disease (CVD) causes 27% of all deaths in Wales. Hypertension or high blood pressure (BP) is the leading modifiable risk factor for CVD, with around a half of heart attacks and strokes being associated with high blood pressure. Around 700,000 adults in Wales live with high BP, with as many as 180,000 undiagnosed. Rapid identification of people with undiagnosed hypertension enables more rapid treatment.

BP measurements have two components: systolic BP, which is the pressure against the arteries when the heart contracts and diastolic BP, the pressure when the heart relaxes. Typically to measure BP, an inflatable blood pressure cuff is wrapped around the upper arm and connected to an electronic device that can calculate BP from oscillations in the cuff pressure as it deflates. Alternatively, auscultation, where the observer uses a stethoscope to listen for Korotkoff sounds that indicate the point of systolic and diastolic BP can be used, although this is now less common in routine practice. For an accurate reading, the person measuring blood pressure must be trained in the correct technique and use a cuff of the correct size, positioned correctly. The patient should be relaxed and seated or lying down, with a supported arm, should have avoided caffeine, exercise, and smoking for 30 mins prior to the measurement, should have an empty bladder and should not talk during measurement. Inaccurate measurement technique is common and introduces errors. BP readings in healthcare should be based on two or more measurements obtained on two or more occasions.

Contactless photoplethysmography (PPG) is a method for measuring vital signs by measuring changes in light reflected by skin using the digital camera available in smartphones and tablets. It is stated that the amount of reflected light is related to the volume of blood flowing in the blood vessels, which varies with each pulse beat. Software, including artificial intelligence (AI) technology such as machine learning or deep learning have been used to develop algorithms that combine demographics with changes in the reflected light to measure pulse rate, blood oxygenation, respiratory rate, and blood pressure. Lifelight (Xim Ltd), identified by the topic proposer, is an example of this technology. The user looks into the camera on the smart device for 40 seconds. Lifelight analyses colour changes in the face caused by each pulse beat, converts this into red, green, blue (RGB) numbers and sends the colour signal to the cloud along with the user's age, height, and sex for processing by machine learning algorithms. Once processed, values for BP, pulse rate and respiration rate are then returned to the smart device. All data is anonymised. At present Lifelight is registered as a CE / UKCA Class I medical device, with Class IIa registration pending. Lifelight is being piloted in GP practices and care homes in Hampshire Hospitals NHS Foundation Trust, by Novo Nordisk in people with type 2 diabetes and has recently partnered with iPLATO to integrate Lifelight into the myGP app. It is proposed that contactless PPG can reduce the time taken for BP readings, be used to screen people more easily for undiagnosed hypertension and facilitate home self-monitoring of BP. The topic proposer also highlighted Anura (Anura) and Binah.ai's Health Data Platform as examples of similar technology and HTW identified a contactless PPG system developed by Vastmindz. It is not clear whether these latter technologies are CE / UKCA marked.

Health Technology Wales researchers searched for evidence on the clinical and cost effectiveness of contactless PPG using smart devices for measuring blood pressure.

Evidence overview

Health Technology Assessment

In 2020 the National Institute of Health and Care Excellence (NICE) published a relevant Medtech innovation briefing, "Lifelight First for monitoring vital signs [MIB213]" (NICE 2020). The evidence was obtained from Vision D, an unpublished observational study in 8,585 patients and healthy volunteers, and an unpublished validation study in 127 healthy volunteers. There was evidence that indicated that Lifelight First showed similar accuracy to

Evidence overview

clinical-grade blood pressure monitors when compared with the Welch Allyn Connex Monitor. Key uncertainties were that the evidence did not evaluate the technology in a clinically relevant population, only reported direct comparisons with the Welch Allyn Connex Monitor and did not report diagnostic accuracy or clinical outcome data. These studies have now been published (Heiden et al. 2022).

Secondary evidence

We identified two systematic reviews. Pham et al. (2022) conducted a review that examined the effectiveness of contactless PPG using a smartphone or webcam in measuring vital signs. Searches were conducted up to September 2020. The review identified 22 studies measuring heart rate, three measuring BP and three measuring respiratory rate. No studies measured blood oxygen saturation. It was reported that most studies had a sample size of 30 or fewer participants and were conducted in laboratories. It was concluded that more studies were needed to assess accuracy of contactless BP. Limitations of contactless PPG included motion, poor lighting and lack of automatic face tracking and the authors commented on the need for validation in larger populations in clinical settings.

Haugg et al. (2022) conducted a systematic review of image processing and machine learning techniques to measure BP using smartphones. Searches were conducted up to January 2022. Seven studies were identified, of which two were also included in Pham et al. (2022). Sample sizes ranged from 17 to 5,992 with comparison with cuff-based measurements used to validate the results. The authors reported that some of the machine learning models were already used to measure BP, but improved reliability was needed in a wider range of conditions, including controlled and uncontrolled environments. It was not clear as to whether the studies were conducted in real-time or used datasets consisting of video images.

Primary studies

We identified three primary studies published since January 2022 that used contactless PPG in real-time to measure vital signs, as opposed to using video images from a pre-existing dataset.

Heiden et al. (2022) reported results from two studies, the Vital Sign Comparison Between Lifelight and Standard of Care Development (Vision-D) and Validation (Vision-V). In both studies, respiratory rate, pulse rate and blood pressure were measured using standard of care manual methods. The Vision-D dataset consisted of 17,233 measurements from 8,595 participants. Data from this study was used to refine the algorithms for validation in Vision-V, which involved 679 measurements from 127 participants. Accuracy targets were defined from a systematic literature review of vital signs technologies. The targets were deemed to have been met if the mean error and standard deviation (SD) for Lifelight at least met the target. For systolic BP the target mean error (SD) was 6.7 (15.3) mmHg and for diastolic BP the target mean error (SD) was 5.5 (8.9) mmHg. It was reported that the standards for all vital signs were met in Vision-V. For systolic BP mean error (SD) was 2.8 (14.5) mmHg and for diastolic BP it was -0.3 (7.0) mmHg. The authors describe these studies as being early-stage development studies and they were used to support certification for a Level 1 CE mark.

Talukdar et al. (2022) evaluated Vastmindz's contactless PPG technology in 463 participants with various skin tone, ethnicities, and baseline vital signs. It was reported that the technology could estimate heart rate, respiratory rate, and oxygen saturation with a mean error of ±3 units and systolic and diastolic BP with ±10 units. During this study participants had to sit completely still and look at a camera fixed to a tripod with a light source positioned 60 cm away. The scan took 60 seconds. It is not clear as to whether the data was analysed and fed back to participants immediately or collected and analysed later.

Evidence overview

Kapoor et al. (2024) reported on a validation study of Lifelight, conducted by an independent laboratory in the USA. Study procedures were reported to follow the methodology outlined in ISO 81060-2:2018/AMD 1:2020 "Non-invasive Sphygmomanometers – Part 2: Clinical investigation of automated measurement type". There were 85 participants recruited, aged 18 to 85 with a wide distribution of blood pressure. At least 20% of participants were required to have dark skin tones. Lifelight measurements were compared with dual-observer manual auscultation. Sensitivity and specificity for diagnosing BP, using the in-clinic systolic threshold was reported as 70% and 72%. The authors report that these rates are consistent with those reported for conventional blood pressure monitors in a literature review by NICE. The mean error (SD) in the normal and stage 1 hypertensive range (65 participants) was 6.48 (12.88) mmHg for systolic BP and 0.43 (10.64) mmHg for diastolic BP. This study has been published as a pre-print and has not yet been peer reviewed.

Economic evidence

The topic proposer provided an unpublished report by Mind Over Matter (date unknown) presenting a cost comparison analysis building upon the modelling approached used in NICE guideline NG136 (Hypertension in adults: diagnosis and management). The report compares lifetimes costs associated with a cohort of patients invited to use Lifelight compared with patients invited to book an NHS Health Check. The report estimates Lifelight to be associated with life cost-savings of £136,159 - £266,212 per 10,000 patients, dependant on age and sex group, with females aged 70 estimated to have the highest cost savings. This analysis is subject to uncertainties around the age of cost inputs used, the diagnostic accuracy of Lifelight for patient end-users and the compatibility of outcomes due to assumptions surrounding the conversion rates.

Ongoing studies

We identified three relevant ongoing studies.

Wiffen et al. (2023) is conducting VISION-MD (NCT04763746), an observational study of Lifelight in two hospitals in the UK. VISION-MD is a development study designed to improve the accuracy of the app by collecting data from a wider range of participants with abnormal blood pressures and blood oxygen levels, including critically ill patents. The study also aimed to recruit more people with different skin tones. The study recruited 1,869 participants and reported completion in April 2023, but results do not appear to have been published yet.

Xim Limited (2024) is conducting VISION-Real World Evaluation (NCT06325384). This is a randomised controlled trial that will recruit 500 participants from the Bart's Hospital Trust hypertension clinic patient database with a clinical diagnosis of hypertension that is treated but not well controlled. Participants will be randomised to Lifelight or a standard digital blood pressure cuff for self-monitoring at home for six months. The primary outcome is to demonstrate the non-inferiority of Lifelight for achieving blood pressure control. The secondary outcome is to determine the acceptability and adherence of Lifelight in comparison with cuff-based self-monitoring. The trial will start recruitment in July 2024 and aims to complete in August 2025.

Abdullah (2024) is conducting a prospective feasibility study of contactless PPG developed by Nervotec Ltd, in Singapore. The aim is to develop and validate a predictive model for contactless PPG to measure blood pressure. The study opened in February 2024 and aims to recruit 300 participants. Study completion is estimated to be December 2024.

Technology classification

Evidence overview

Contactless PPG is a digital health technology and was determined to be a Tier C technology according to the Evidence Standards Framework for Digital Health Technologies. Technologies within this classification provide information that will be used to aid treatment or diagnosis, to triage or identify early signs of a disease or condition or will be used to guide next diagnostics or next treatment interventions.

For technologies of this classification, it is recommended that satisfactory evidence for effectiveness is produced to demonstrate effectiveness of the technology. This includes studies conducted in a setting like the UK health and care system, peer-reviewed studies, and prospective studies. Evidence to support the claimed benefits of contactless PPG should include real-world evaluations of its clinical utility and include one or more high-quality studies that support the claimed benefits in a relevant setting, showing improvements in relevant outcomes. Similarly, appropriate assessment of the economics of contactless PPG should be undertaken.

Areas of uncertainty

The evidence for contactless PPG using smart devices for measuring blood pressure and other vital signs comes primarily from development and small validation studies.

- The apps identified are under development and the algorithms are still “learning”, making figures for diagnostic accuracy provisional.
- How well the apps perform during self-monitoring at home, in variable lighting conditions and with different users.
- Total time taken to measure BP via contactless PPG.
- Whether the AI will continue to be updated over time.
- Age of the cost inputs.

Literature search results

Health technology assessments and guidance
NICE. (2020). Lifelight First for monitoring vital signs: Medtech innovation briefing MIB213. National Institute for Health and Care Excellence. Available at: www.nice.org.uk/guidance/mib213 [Accessed 09 July 2024].
Evidence reviews and economic evaluations
Haugg F, Elgendi M, Menon C. (2022). Assessment of Blood Pressure Using Only a Smartphone and Machine Learning Techniques: A Systematic Review. Frontiers in Cardiovascular Medicine. 9. doi: https://doi.org/10.3389/fcvm.2022.894224
Pham C, Poorzargar K, Nagappa M, et al. (2022). Effectiveness of consumer-grade contactless vital signs monitors: a systematic review and meta-analysis. J Clin Monit Comput. 36(1): 41-54. doi: https://dx.doi.org/10.1007/s10877-021-00734-9
Individual studies
Heiden E, Jones T, Brogaard Maczka A, et al. (2022). Measurement of Vital Signs Using Lifelight Remote Photoplethysmography: Results of the VISION-D and VISION-V Observational Studies. JMIR Form Res. 6(11): e36340. doi: 10.2196/36340
Kapoor M, Holman B, Cohen C. (2024). Validation of the Lifelight Contactless Blood Pressure and Pulse Rate Monitor. JMIR Preprints. 13/02/2024:57241. doi: https://doi.org/10.2196/preprints.57241
Talukdar D, De Deus LF, Sehgal N. (2022). Evaluation of a Camera-Based Monitoring Solution Against Regulated Medical Devices to Measure Heart Rate, Respiratory Rate, Oxygen Saturation, and Blood Pressure. Cureus. 14(11): e31649. doi: https://doi.org/10.7759/cureus.31649
Ongoing research
Abdullah HR. (2024). Development of Predictive Remote Photoplethysmography Algorithm for Blood Pressure Assessment and Monitoring. Available at: https://clinicaltrials.gov/study/NCT06320847 [Accessed 2024/01/02/].
Wiffen L, Brown T, Brogaard Maczka A, et al. (2023). Measurement of Vital Signs by Lifelight Software in Comparison to Standard of Care Multisite Development (VISION-MD): Protocol for an Observational Study. JMIR Res Protoc. 12: e41533. doi: 10.2196/41533
Xim Limited. (2024). VISION-Real World Evaluation. Available at: https://clinicaltrials.gov/study/NCT06325384 [Accessed 2024/07/01/].
Other – provided by topic proposer
Mind Over Matter. (date unknown). Xim Lifelight Hypertension Case Detection.

Date of search	July 2024
Concepts used	Contactless photoplethysmography; photoplethysmogram; blood pressure; LifeLight

Proposed research question and evidence selection criteria (if selected)

Proposed Research question	What is the clinical and cost effectiveness of contactless photoplethysmography using cameras on smart devices?

	Inclusion criteria	Exclusion criteria
Population	People with or at risk of hypertension	
Intervention	• Contactless photoplethysmography to measure raised blood pressure • Contactless photoplethysmography to monitor blood pressure during treatment	Contact photoplethysmography
Comparison/ Comparators	Standard of care cuff-based measurements.	
Outcome measures	Diagnostic accuracy outcomes (e.g., sensitivity, specificity, positive predictive values, negative predictive values) – for high blood pressure? Changes in blood pressure Health related QoL Resource use Economic outcomes	

Proposed speciality	**Cardiovascular system**