NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

Lifelight First for monitoring vital signs

1 Technology

1.1 Description of the technology

Lifelight First is software designed to spot-check monitor 4 parameters of physiological health: blood pressure, pulse, respiratory rate and oxygen saturation. Lifelight First does not require any direct contact with patients, and the measurements are taken by pointing the camera that is incorporated in digital devices on the person's face for 40 to 60 seconds. The camera acts as a sensor to detect tiny colour changes in facial skin each time the heart beats and the software incorporates fixed algorithms to analyse the data to provide the measurement outputs. These data can be used for the scoring system (e.g. early warning system) that alerts the clinical team to potentially important changes in a person's clinical condition.

Lifelight First is intended for adult patients who need vital signs monitoring. It has been designed to be used by qualified healthcare providers and the most likely locations are hospitals, clinic and other healthcare environments. Lifelight First uses a camera so the subject must be visible in a well-lit situation and must remain still during the measurement. Contraindications are listed in the instructions for use.

For the Evidence Standards Framework, Lifelight First is classified as active monitoring and so has a tier 3b evidence level.

1.2 Regulatory status

Lifelight First has not yet received a CE-mark. The technology is currently undergoing regulatory approval for use in the UK.

1.3 Relevant diseases and conditions

This technology could be used in a number of different scenarios. Typical examples include use in a GP surgery and use for people with mental illness, who may not tolerate or possibly become distressed by traditional methods of vital sign measurements.

Vital signs are an important component of patient care. GPs routinely use them in detecting or monitoring people's health conditions. For example, GPs will use blood pressure measurements to identify people with hypertension. High blood pressure is a major risk factor for stroke, myocardial infarction and heart failure.

One in four adults is diagnosed with mental illness in any given year in the UK (NHS England). Between April 2017 and March 2018 over 13,000 people were admitted to hospitals under the Mental Health Act in England (Office statistics, Mental Health Act Statistics, Annual Figures, England, 2017-2018). Mental illness has a profound impact on people's lives. In particular people with severe mental illness such as schizophrenia, bipolar illness and addictions have a greater risk of poor physical health and are likely to die younger compared with the general population.

1.4 Current management

In current practice, contact-based methods are used to measure the blood pressure, pulse and oxygen saturation measurements. These methods may not be tolerated by some patients and may cause distress.

Since the introduction of the Quality and Outcome Framework (QOF) in 2014, GPs review people with some common chronic conditions such as asthma, diabetes, obesity and hypertension on a regular basis. The review involves monitoring any change in blood pressures, pulse and respiratory rates.

The NICE guideline on acutely ill adults in hospital: recognising and responding to deterioration provides best practice advice on the care of adult patients admitted to hospital. The guideline recommends that adult patients in acute hospital settings should have physiological observations recorded at the time of their admission or initial assessment. After admission, these physiological measurements should be monitored regularly (tracked) with predetermined response criteria to changes (triggers) in order to identify deteriorating physiological status or risk of deterioration. NICE recommends the use of a tool (National Early Warning Score) based on an aggregate score made up of the measures of respiratory rate, oxygen saturation, blood pressure, pulse rate, level of consciousness and temperature to improve the detection and response to patients' physiological deterioration.

1.5 Claimed benefits

The benefits to patients with mental illness claimed by the company are:

- Reduction in distress while taking vital sign measurements
- Improvement in compliance with physiological observations
- Improved identification of physical health deterioration and the risk of deterioration
- Improvement in management and treatment of co-morbidities

The benefits to patients vising a GP surgery claimed by the company are:

- Provides a convenient, portable means of measuring vital signs
- Reduction of spurious blood pressure reading due to white coat syndrome
- Early identification of hypertension or heart rhythm abnormalities
- Quick referral for treatment

The benefits to the health and social care system claimed by the company are:

- Reduction in staff time spent taking vital sign measurements
- Improvement in compliance with physiological observations

- Reduction in the number of unsuccessful vital sign measurements
- Reduction in the need for GPs' appointments
- Reduction of GP consultation time
- Reduction of hospital admission for common chronic diseases

2 Statement of the decision problem

Population	Adults aged 18 years or older who need monitoring of vital signs
Intervention	Lifelight First
Comparator(s)	Measurement of vital signs using contact-based methods for example using a sphygmomanometer, manual pulse palpation and pulse oximeter
Outcomes	The outcome measures to consider include: Patient outcomes: • Accuracy of individual vital sign measurements (blood pressure, respiratory rate, pulse, and oxygen saturation) • Rates of compliance with vital sign measurements • Rates of successful and unsuccessful vital sign measurements • Rates of patient distress while taking measurements • Rates of detecting physiological status changes indicating physical health deterioration or the risk of deterioration • Rates of incidence of co-morbidities (such as hypertension and other cardiovascular disease) System outcomes: • Time spent to take vital sign measurement, including time taken to manage any resulting patient distress Device-related adverse events
Cost analysis	Costs will be considered from an NHS and personal social services perspective. Separate cost analysis may be needed to illustrate use of the technology in different setting. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include

	scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	People with different health indications.	
Special considerations, including those related to equality	People with long term conditions including mental illness for more than 12 months are likely to be considered disabled under the Equality Act 2010. Disability is a protected characteristic under the Equality Act.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable	

3 Related NICE guidance

Published

- Acutely ill adults in hospital: recognising and responding to deterioration. NICE Clinical Guideline CG50 (2007).
- Psychosis and schizophrenia in adults: prevention and management. NICE Clinical Guideline CG178 (2014).
- Pneumonia in adults: diagnosis and management. NICE Clinical Guideline CG191 (2014).
- Multimorbidity: clinical assessment and management NICE guideline NG56 (2016).
- Asthma: diagnosis, monitoring and chronic asthma management. NICE guideline NG80 (2017).
- Care and support of people growing older with learning disabilities. NICE guideline NG96 (2018).
- Dementia: assessment, management and support for people living with dementia and their carers. NICE guideline NG97 (2018).
- Chronic obstructive pulmonary disease in over 16s: diagnosis and management NICE guideline NG115 (2019).
- Hypertension in adults: diagnosis and management NICE guideline NG136 (2019).

4 External organisations

4.1 Professional organisations

The following societies have been alerted to the availability of the draft scope for comment:

- Addiction Recovery Foundation
- British Association for Immediate Care
- British Geriatrics Society
- Dementia Action Alliance
- Institute of Mental Health
- Institute of Psychiatry
- Royal College of Physicians
- Royal College of Psychiatrists
- Royal College of Nursing
- Royal Society for Public Health

The following societies have been alerted to the evaluation at the publication of the scope:

- Royal College of General Practitioners
- British cardiovascular Soceity
- British and Irish Hypertension Society
- British Journal of Primary Care Nursing & Primary Care Cardiovascular Journal
- Primary Care Cardiovascular Society

4.2 Patient organisations

The following patient organisations have been alerted to the evaluation at the publication of the scope:

- Addaction
- Alzheimer's Society
- Big White Wall
- Bipolar UK
- BPDWORLD
- British Heart Foundation
- Campaign Against Living
- Cardiomyopathy UK
- Centre of mental Health
- Dementia Action Alliance
- Dementia UK
- Depression UK
- Headway
- Heart UK
- Mental Health Foundation
- Mind
- Mind Wise New Vision
- National Survivor User
- PAPYRUS
- PTSD UK
- Rethink Mental Illness
- Revolving Doors Agency
- SANE
- Turning Point