INFORMATION BRIEF (RAPID REVIEW)

ARTIFICIAL INTELLIGENCE (AI) MONITORING MATTRESS

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Medical Development Division
Ministry of Health Malaysia
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Rapid Review
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PURPOSE

This review was requested by the Office of Health Minister upon the proposal of a company to introduce the technology of artificial intelligent monitoring mattress in the healthcare facilities within the Ministry of Health.

BACKGROUND

In 2019, WHO reported that 13.2% of the total world population of 7.7 billion people aged 60 years old and over and it is estimated that that the population will increase to approximately 2.1 billion by 2050.[1] Malaysia has become an aging nation and is heading towards aged nation by 2044 when approximately 14% of the population will reach the age of 65 years old according to World Bank Group report in 2020.[2] The Guidelines on Integrated Care for Older People introduced by WHO in 2017 emphasised that elderly are exposed to the risk of falls.[3]

In certain group of patients such as patient with the history of cardiovascular disease and sleep related, cardiovascular events and respiratory related diseases need to be monitored continuously.[4] Within health facilities, patients were continuously monitored by modalities such as electrocardiographic monitoring (telemetry), pulse oximetry and continuous end-tidal CO_2 monitoring (capnography), just to name a few.[5] However, these modalities require continuous contact of sensors and leads on the patients. Therefore, with the emerging of contactless or remote monitoring system, this provides continuous vital monitoring data that may improve patients' well-being and outcomes, even post discharge. Remote patient monitoring (RPM) is a combination of technologies and techniques that provides continuous real time data monitoring of patients' health information from outside of the health facilities.[6] There are several advantages of the RPM in managing patients' well-being among which the capacity to properly monitor patients ensuring early intervention, preventing early deaths and reducing the hospital admissions.[5,6] However, its disadvantages include the unproven accuracy of the devices employed, as well as the lack of health provider interactions.[6]

Polysomnography (PSG) is considered as gold standard in diagnosing of sleep-related disorders and monitoring sleep pattern by recording of brain wave, heart rate, muscle and respiratory activities, airflow, oxygen saturation and, eye and leg movement.[7,8] It is usually conducted at a sleep centre and requires a certified technician to position sensors, electrodes, tube and mask on the patients' body surface in order to acquire multiple signals simultaneously, as well as the monitoring of the data.[5,10] The data collected are highly accurate.[5] However, due to the highly obtrusive set up, the outcome of the sleep study may not represent the normal patient's sleeping pattern which affects the quality of sleep and it is expensive.[4,8,9,10] Electrocardiography (ECG) is the gold standard in monitoring signals from the heart used within the health facilities. However, similarly to PSG, it is expensive to operate, intrusive and is operated by certified personnel.[11]

In contrast, a contactless or remote monitoring provides minimum interference to the patient's normal sleep pattern, minimal or zero contact with patient's body, low cost, safe and easier to operate without the presence of medical personnel. This technology among which are bedside device such as radiofrequency identification, an infrared camera or under the mattress device such as pressure sensor or piezoelectric sensor placed underneath the mattress.[8] Other than that, is the ballistocardiograph (BCG) which is a non-invasive technique that creates graphical representation based on signal of the repeated motions induced by the human heartbeats, monitoring blood volume, rate of respiration.[11,12] Sumali et al. (2022) also emphasized that BCG despite its convenience set up, it could provide inaccurate signals outcome due to change in the movement of body on the mattress.[11] The advantages of contactless beside being contact less, it can be applied without the presence of medical personnel.[9]

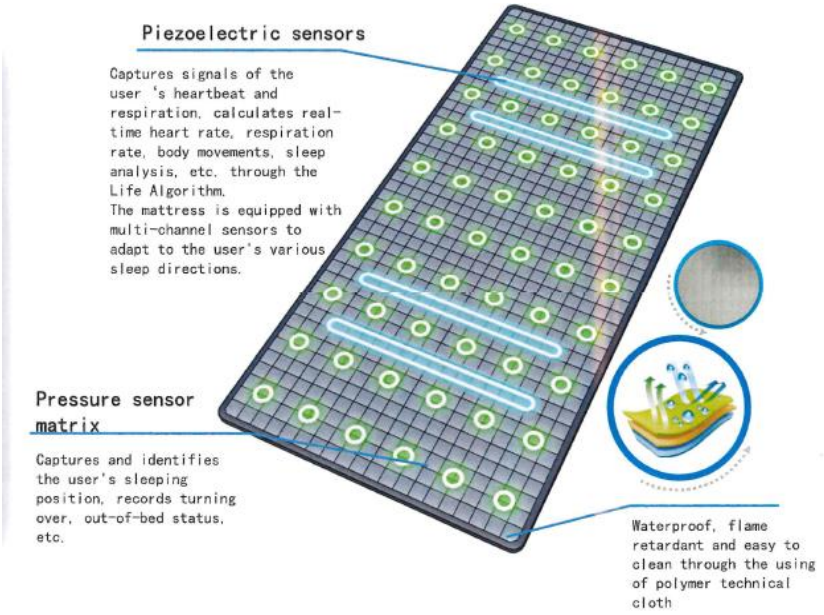

Figure 1: An example of a mattress equipped with monitoring device

EVIDENCE SUMMARY

The systematic search found **three** relevant articles (one Rapid Review Report and two randomised controlled trials) related to Artificial Intelligence (AI) Monitoring Mattress from the scientific databases such as Medline, EBM Reviews via OVID, PubMed and from general search engines up to 10 October 2023 using the following search terms: [redacted] */ ballistocardiogra* / mattress / remote monitoring.*

EFFICACY/ EFFECTIVENESS

A systematic review and meta-analysis conducted by Zhai, H et al (2023) involving 36 studies compared the effectiveness of polysomnography (PSG), actigraphy and contactless consumer sleep-tracking devices (CCSTDs) in 11 countries. CCSTDs reviewed were bedside devices and mattress-based devices which included the pressure and piezoelectric sensor placed underneath the mattress. The outcomes measured were

total sleep time (TST), wake after sleep onset (WASO), sleep onset latency (SOL), light (N1 + N2) and deep sleep (N3), rapid eye movement (REM), sensitivity, specificity and accuracy in the detection of sleep epochs. The population included were normal sleepers, periodic limbic movement of sleep (PLMS), obstructive sleep apnea, sleep-disordered breathing (SDB), central disorders of hyper somnolence (CDH), insomnia, diabetes, hypertension, arthritis, perioperative and septic shock. The findings were analysed based on subgroups of sensors, device types and device brands. In the sensor subgroups against PSG, it was reported that there was no significant difference in the estimation of TST, SOL, WASO and REM for piezoelectric electric, the estimation of sleep stages for radiofrequency sensor, the estimation of TST for infrared camera. In terms of device, it was reported that there was no significant difference for the mattress-based device in terms of SOL, WASO and sleep stages, as for bedside device in the estimation of sleep stages. A total of 24 studies involving 1200 samples in epoch – by – epoch investigation between PSG as the reference with CCSTDs in terms of accuracy, sensitivity and specificity in estimation of sleep epochs by the devices. In overall, the accuracy values involving N=22 studies between CCSTDs and PSG was between 0.68 and 0.91 (0.81 ± 0.07), whilst N=23 studies reported the sensitivity as 0.75 to 0.97 (0.90 ± 0.06) and the specificity between 0.37 to 0.80 (0.51 ± 0.12). CCSTDs detected sleeps epoch accurately, however, lesser accurate for the awake epoch based on the high degree of sensitivity (0.90 ± 0.06) and the lower specificity (0.51 ± 0.12).[8]

A controlled clinical trial by Brown et al. (2014) involved 7643 patients with 2314 of them were monitored by the intervention which is a piezoelectric motion-sensing device placed underneath the mattress against 5329 in the contemporaneous control group. The primary outcome were unplanned ICU transfers, average ICU length of stay (LOS) for transferred patients and medical-surgical LOS. The secondary outcome the Acute Physiology and Chronic Health Evaluation (APACHE II) scores for the unplanned ICU admissions, number code blue events and unexpected deaths. They found that there was no significant difference between the intervention group both pre- and post-, and the control groups in the number of ICU transfers. The result showed reduction in total ICU days for the intervention group post implementation at 63.44 days / 1000 patients compared to pre implementation at 120.11 days/1000 patients and the control concurrent group at 85.36 days / 1000 patients (P = 0.04). The LOS was significantly lower in the post implementation group as opposed to pre implementation at 3.63 and 4.00 days respectively, and significant lower in the intervention group compared with control group during the post-implementation at 3.61 and 3.8 days respectively (P < 0.01). The code blue incidences were reported significantly reduced in the post-implementation intervention group compared to the pre-implementation and concurrent post-implementation control group when 0.9/1000 patients vs 6.3/1000 patients and 2.1/1000 patients (P= .45), respectively.

A single centre prospective observational study was conducted by Klersy et al (2014) in Northeast Ohio, USA involving 29 patients with history of heart failure (HF). The purpose is to examine typical and abnormal physiological processes at home by using the under-the-mattress piezoelectric sensor (PS). The outcome was measured by hospital readmission due to HF within 30 days post discharge. It collected physiological data and ascertained changes in the physiological patterns up to 30 days for a total of 640 nights examined. The variables monitored include heart rate, respiratory rate and movement rate. They found that four out of nine readmissions were due to HF. There were 97% overall tolerance experience reported. The authors concluded that PS was well tolerated

by patients and provided consistent physiological data within 30 days for patients who are with high-risk readmission after hospitalisation due to HF and larger clinical trial could be undertaken to ascertain its effectiveness.[14]

SAFETY

As of today, there was no technology registered related to the technology of AI monitoring mattress with the Malaysian Medical Device Agency (MDA), United States Food and Drug Administration (US FDA).

Low mortality was reported by Brown et al (2014) with one non-Net Death Rate (NDR) death for each arm (both control and intervention) pre-implementation and one non-NDR from the control group during the post-implementation period.[4]

COST-EFFECTIVENESS

Klersy et al (2011) in a meta-analysis economic impact reported that the cost effectiveness and cost utility of the management of multidisciplinary heart failure between RPM and the usual care based in Europe and North America for over a year found that the remote patient monitoring (RPM) to be less expensive than usual care due to a significant decrease in hospitalisations for heart failure (HF) by a range of €300 to €1000, as well as an improvement in QALY by 0.06.[14]

CONCLUSION

Based on the review, there was limited evidence retrieved on the AI monitoring mattress technology. The limited evidence showed that th[redacted]otion-sensing device placed underneath the mattress improved in the total ICU days, length of stay and code blue incidences. It is well tolerated by patients and able to provide consistent physiological data. The economic impact study also emphasised that RPM costs lesser than the usual care in the management of heart failure.

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