Back-to-base pulse oximetry monitoring for suicidal behaviours in mental health care settings

A feasibility and acceptability study

Study Outcomes | August 2019

Dr Fiona Shand | Dr Marcia Fogarty | Dr Josephine Anderson | Dr Mark Larsen | Ms Nicole Cockayne | Mr Michael Raftery
Ms Jo Riley | Ms Margaret Balaz | Dr Sujatha Venkatesh | Mr Michael Bruce | Professor Gregory Carter | Mr Dean Martin

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Glossary

Accelerometer
Used to measure the acceleration of a moving body

AI
Artificial intelligence

Bluetooth
A wireless technology standard for exchanging data between fixed and mobile devices over short distances

COPD
Chronic obstructive pulmonary disease

ECG
Electrocardiogram, a measure of the electrical signals from the heart

GPS
Global Positioning System

Observations
The purposeful gathering of information from consumers to inform clinical decision making. It is the formal and objective assessment of a person's condition – physical, mental, social

PECC
Psychiatric Emergency Care Centre

PICU
Psychiatric Intensive Care Unit (now referred to as Mental Health Intensive Care Unit or MICU)

PPG
Photoplethysmogram, an optical technique that can be used to detect blood volume changes in the microvascular bed of tissue

Pulse oximetry
A measure of the oxygen level (oxygen saturation) of the blood and pulse rate

Sentinel event
An unanticipated event in a health care setting resulting in serious harm to or death of a patient

SmO2
Muscle oxygen saturation primarily used for athletes

SpO2
Peripheral capillary oxygen saturation, an estimate of the amount of oxygen in the blood

Vital signs
A measurement of temperature, respiratory rate, pulse, blood pressure and blood oxygen saturation

Zigbee
Communication protocols used to create personal area networks with small, low-power digital radios

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Executive Summary

Background

In 2018 the New South Wales Government introduced a Towards Zero Suicides Initiative. It is anticipated that by strengthening practices, policy, procedures, training and technology in the mental health system that suicides in care can be eliminated.

Together with changes in clinical practice, technology such as back-to-base pulse oximetry (pulse oximetry), can play a role in this initiative by monitoring patients at risk and providing an additional safety net to other initiatives, such as empathetic engagement with patients.

This study, funded by the NSW Ministry of Health, examined whether wearable devices that measure pulse and oxygen saturation are feasible and acceptable to use in inpatient mental health care settings.

In 2017, the Deputy NSW State Coroner Derek Lee, recommended to NSW Health that pulse oximetry should be investigated to help prevent suicide in inpatient mental health settings.

This was a result of a suggestion made by two psychiatrists in 2016, that pulse oximetry could be used to help prevent suicide. This suggestion was presented by an expert witness at an inquest into the death of a young person, Ahlia Raftery, in Newcastle in 2017, who recommended further investigation by NSW Health.

Suicide is a tragic loss and impacts on those close to the person, but also staff, who may be adversely affected. It has been noted (Large, Ryan et al. 2014) that psychiatric hospitalisation itself can contribute to some inpatient suicides. However, suicide within inpatient mental health settings is rare.

Patient observations are imperfect as risk assessment and frequency of observations are both limited and prone to error or misinterpretation.

Real-time monitoring to alert nursing staff to a suicide attempt is very likely to save lives, even if such events are relatively infrequent.

Pulse oximetry is not only able to monitor for suicide attempts but also to identify patient deterioration from other causes, such as drug interactions, undisclosed drug overdoses, or comorbidities that many with mental illness have, such as sleep apnoea.

Ethics approval for the trial of pulse oximetry in the 8-bed Psychiatric Intensive Care Unit (PICU) at the Mater Mental Health Services was obtained from the Hunter New England Human Research Ethics Committee in November 2018. Approval to recruit patients from the adjoining 4-bed Psychiatric Emergency Care Centre (PECC) was obtained in May 2019.

The trial was registered with the Australian New Zealand Clinical Trials Register (ANZCTR).

"Ahlia was alone for some time when she suicided. Her vital signs would have changed alarmingly. There was an opportunity for her to be saved before it was too late, but time is critical in situations such as these – minutes only. If the unfolding tragedy is discovered quickly, the nearby hospital resources can be used to save a life in the balance.

I am heartened by the forward thinking shown by witnesses and advocates during the inquest, for the findings, and that the pulse oximetry recommendation for a trial, has been taken up.

The nature of suicide is that many questions remain unanswered, but I believe that emerging technologies such as pulse oximetry, can be used to save the lives in hospital and other settings. We owe it to Ahlia and others like her, to pursue and embrace every opportunity to prevent suicide."

Michael Raftery, 2017

Trial device

Following desk research, several possible systems were identified, together with some that did not involve pulse oximetry but were designed to remotely monitor vital signs by other means (video monitoring, for example).

The system with the best fit with requirements for a mental health inpatient setting was the AliveLock RiskWatch, which was identified in the original suggestion mentioned above.

This device was used for the trial under the Therapeutic Goods Administration's Clinical Trial Notification (CTN) scheme.

How the device works

With the AliveLock system a finger sensor is attached to a watch-like device on the wrist (the RiskWatch), which transmits readings to a base station attached to a computer. The RiskWatch is secured to the wrist by a locked nylon band that can only be unlocked by staff.

System software displays devices that are being worn (up to 20) on a laptop or PC at the nursing station and monitors each device according to parameters set from an individual's baseline reading, to accommodate differences between individuals, and sleeping and active periods by the wearer. An alarm sounds at the nursing station when there is a percentage variation from the baseline readings, or if the RiskWatch is out-of-range, or the sensor removed or tampered with.

Unit staff continued to carry out mandated observations while a patient was wearing the RiskWatch.

The trial ran for 143 days in the PICU (from late February to late July 2019) and 60 days in the PECC (from late May to late July 2019).

Participation and findings

Forty-one unique patients participated in the trial, some more than once. Patients who were well enough to participate were recruited if they provided informed consent. Recruitment was primarily undertaken by a Peer Support Worker, who was employed for the study and who also wore the device while on-site.

Patient participants were aged between 17 and 72 years old, with 19 being male and 22 female.

Twenty-three were recruited in the PICU and 20 in the PECC (including two who had participated in the study previously in the PICU).

The RiskWatch was worn for an average of 24 hours in the PICU and just under 5 hours 30 minutes in the PECC. Some of this difference is due to the short-stay nature of the PECC.

Across both units there were a total of 1,390 alarms recorded in the system. The majority (83%) were for 'heart rate sensor – check for tamper'. Many of these were seen by staff as false alarms, although some were also because the sensor had moved on the finger or had been removed by the patient.

Staff found the frequency of alarms, especially because some were errors, to be annoying. The system vendor investigated the issue and replaced the base station in the PICU but this did not entirely resolve the issue with false alarms.

Nevertheless, many staff remained supportive of using pulse oximetry in the unit, especially if the number of false alarms could be reduced. Staff also suggested a number of other potential enhancements to the system, as well as better training and support from the equipment supplier.

Some participants reported issues with the lack of comfort wearing the silicone finger sensor. A small quantity of adhesive sensors were trialled and these were more comfortable although they were not waterproof like the silicone ones.

As this was a clinical trial, pulse oximetry was not incorporated in normal workflows.

Initially the study was conducted in a high-acuity unit and obtaining informed consent from very unwell people was an issue. Involvement of the PECC in the trail from late May made recruitment of patients easier.

The study also obtained the views of the Peer Support Worker, unit staff and the Executive Manager, Mental Health Services.

The general consensus was that the system showed promise, but reliability needed to be improved and other enhancements made for it to be adopted more widely.

Potential of pulse oximetry

The study identified that being able to access local support and user training is important to the acceptance of the technology. Pulse oximetry sounds straight-forward from the examples in medical settings that people are familiar with, but using back-to-base pulse oximetry in mental health care settings brings another level of complexity, especially when patients are monitored for extended periods. Staff need to have confidence in the system – that there are not too many false alarms. Ideally the system should also be integrated with other hospital systems.

Reliable pulse oximetry systems will provide a valuable backup to nursing observations and other measures to reduce suicide in mental health inpatient settings. They will also help with the earlier detection of medical deterioration of patients. Many people with mental health conditions have comorbidities, such as COPD and sleep apnoea, and pulse oximetry would be useful for monitoring these as well.

A number of issues that need to be addressed (discussed above) as well as features that would enhance the AliveLock system were identified.

An ideal device would:

- be smaller and lighter;
- be robust and waterproof;
- have a longer battery life but retain separate charging of batteries;
- have a tamper-proof sensor in the device or wristband itself;
- allow for artefacts in readings while the wearer was moving;
- incorporate a screen providing feedback to the wearer;
- sound an external alarm when relevant parameters are met;
- be integrated with other hospital systems;
- provide a secure but easy to use system interface;

and

- be compliant with Australian communication standards and meet requirements to be registered as a medical device in Australia.

The AliveLock RiskWatch has some of these features, but not all of them.

While this study suggests that the technology is not yet quite ready for wide adoption, it does have a lot of potential and would be invaluable as part of efforts currently underway to eliminate suicides in inpatient mental health care settings altogether.

Future studies and developments

Any future study should look to simplify what was attempted in this trial, i.e., reduce the number of questionnaires and their scope, as they proved difficult to administer in this study.

Once the technology is further enhanced, a scoping study and perhaps a multi-site efficacy trial could be undertaken, working with system vendors. An efficacy trial would establish if pulse oximetry is effective in detecting adverse events. A trial like this could be undertaken with other Australian jurisdictions or potentially internationally.

With other enhancements, it may be possible to use back-to-base pulse oximetry (or other monitoring systems) in community settings.

Technology does not replace good quality care, including compassion and safety planning, but it does provide a backup that would alert clinical staff to a medical emergency or possible suicide attempt quickly.

Background

NSW Health's Zero Suicides in Care initiative, which is one of the Towards Zero Suicides initiatives announced in October 2018, is designed to support staff in the mental health system to redesign procedures, reduce risks and build skills to prevent suicides among people with mental health conditions in hospital inpatient and community care.

By strengthening practices within the mental health system it is hoped to eliminate suicide by people in care. Technology, such as wireless pulse oximetry monitoring – which is the subject of this study – might supplement good clinical care and act as a comprehensive backup to assist in reducing inpatient suicides. The technology is not seen as a replacement for appropriate ongoing suicide monitoring and clinical practice in inpatient settings.

Wearable devices that monitor health are increasingly used in medical and home settings. These include blood pressure monitors, sleep monitors, and pulse oximeters. In many hospital wards, monitoring of vital health signs is routine. In psychiatric wards there are both psychological safety factors and physical health factors which point to the need to monitor vital signs with technology.

Wireless devices are likely to be more suitable in psychiatric settings, as patients may be physically well enough to be mobile, and to benefit from being mobile. Wireless monitoring devices are available in several different forms, from wristbands and straps to patches.

Suicide is a tragic loss and has serious impacts on those close to the deceased. When the person who dies by suicide is an inpatient at a health facility, staff are also often adversely impacted by the death.

As noted by Large, Ryan et al. (2014) it is likely that psychiatric hospitalisation itself contributes to some inpatient suicides. This has significant implications for the delivery of inpatient psychiatric care.

Technology can increase engagement and enhance care through increased interaction with patients and potentially less night-time disturbance. However, it should not be seen as an alternative to ongoing suicide risk management, an appropriate level of observations, developing staff rapport with patients to aid empathetic engagement (enhancing the therapeutic relationship, which consistently predicts better patient outcomes), and other suicide prevention strategies such as means restriction.

Observation is sometimes not enough to prevent patient suicide. With intermittent observations, unless they are carried out at random (which is difficult) patients are able to use the time when they are not in line of sight to attempt suicide. For example, immediately after an observation has occurred, the person has 15 or 30 minutes before the next observation is due. The process of observation and what to observe has been refined (Bjorkdahl, Nyberg et al. 2011) but the levels of observations outlined in this paper are unlikely to be done consistently across all mental health settings.

For many who attempt suicide there is little time to resuscitate them (Sauvageau, LaHarpe et al. 2011). Real-time monitoring to alert nursing staff to a suicide attempt is very likely to save lives, even if such events are relatively infrequent.

The trial of back-to-base pulse oximetry monitoring for suicidal behaviours in mental health care settings described in this report was a result of a recommendation from the NSW Deputy State Coroner to the NSW Ministry of Health following expert testimony to a 2017 inquest into the death of a young woman, Ahlia Raftery, at the Mater Mental Health Centre in Newcastle in 2015.

The initial suggestion to use back-to-base pulse oximetry to prevent inpatient suicide was made by O'Connor and Paton (2016) in a letter published in Australasian Psychiatry. It was this letter that was referred to in the expert testimony at the inquest. The letter referenced three patent applications outlining pulse oximetry systems, methods and components for monitoring for signs of suicide.

One patent was for 'Systems, methods, components, and software for monitoring and notification of vital sign changes' (US patent US9339242B2) a back-to-base pulse oximetry system that has been used in some correctional settings in the United States. One other patent application referenced in the letter was abandoned in 2019, and information about the third is no longer accessible.

A review of the literature identified several other devices, as discussed below.

As well as helping to detect attempted suicide, pulse oximetry – if feasible – is likely to have other benefits in monitoring patient welfare, as many people with mental illness have comorbidities that can compromise their wellbeing (Anderson, Curtin et al. 2018).

Suicide is relatively uncommon in inpatient settings (see Table 1) although deaths still occur, even when there is intermittent or continuous observation (Flynn, Nyathi et al. 2017). Data on attempts in mental health or other inpatient settings were not available; however, suicides in public hospital inpatient settings represented approximately 1.7 per cent of all suicides in NSW over a seven-year period. Not all of these deaths occurred in mental health inpatient settings.

Real-time monitoring to alert nursing staff to a suicide attempt is very likely to save lives, even if such events are relatively infrequent.

Table 1 – NSW Sentinel Events 2010-11 to 2016-17: Suicide of a patient in an inpatient unit

NSW Selected Sentinel Events	2010-11	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17
Suicide of a patient in an inpatient unit	12	20	15	18	15	9	4

Report on Government Services 2017 and 2019. Data for reporting periods prior to 2016-17 include events that occurred in private hospitals and day procedure centres and are therefore not comparable with data for 2016-17 2017: Table 12A:37; 2019: Table 12A.38

This study is one of the first to assess the feasibility and suitability of back-to-base pulse oximetry in mental health care settings to help reduce suicide. It highlights what aspects of the system may be feasible now and what needs to change to make systems more suitable for use in these settings.

The authors understand there is another study planned by Providence Health and Services in the Pacific North-West of the United States. This study had not yet commenced when last checked in late-May 2019.

Trial Summary

Which back-to-base pulse oximeters were most suitable?

The adoption of appropriate technologies in mental health settings will help to save lives and studies such as this should also help shorten the knowledge to practice gap.

Constant monitoring of vital signs provides a rapid alert and response, is non-intrusive and comprehensive. Monitoring can detect a suicide attempt, as well as physical deterioration due to factors that mental health inpatients are at increased risk of (e.g. medication interactions). The trial examined the use of one back-to-base pulse oximetry system, but other technologies are emerging and will continue to do so.

The system used for the trial was the AliveLock RiskWatch. This choice was confirmed following a review of wireless or back-to-base pulse oximetry systems and other technologies available in March 2018 and updated in early 2019. At the time of the review, several systems were not available commercially, were still in the development phase or otherwise considered unsuitable for extended use in a mental health care setting (such as finger clip style devices). It had been anticipated that at least one of the newer wrist-worn devices, the Oxitone 1000M would be available in time to use in the trial, but it became available too late to be incorporated, although some desk evaluation of the device was carried out.

A technical paper outlining the options and a recommended choice was prepared in early 2018. In summary, the system needed to provide reliable back-to-base monitoring of pulse and oxygen saturation measurements, be comfortable but robust, unobtrusive, reliable, incorporate an audible alarm, and minimise false alarms.

Newer technologies or approaches to monitoring patients in health settings are in development and may provide suitable systems for use in mental health care settings in future. These include wearables like the Oxitone 1000M as well as patches such as Rhythm Diagnostic Systems' MultiSense and VitalConnect's VitalPatch. Further discussion of these alternatives is below.

Other technologies reviewed included video monitoring. These were not sufficiently developed at the time to be considered, although there is some recent literature regarding their trial in an acute mental health ward. Video also has other limitations for use in a health care setting, including contravention of current privacy legislation.

How the trial device works

The RiskWatch device uses a finger sensor and a Nonin OEM circuit board inside a waterproof casing that attaches to the wrist, as shown in Figure 2. The device strap is locked once the watch is attached and can only be unlocked and removed using a key, although the nylon strap can be cut with scissors in an emergency.

The unit is powered by a rechargeable battery, giving a claimed 8-12 hours of battery life (although in practice battery life was often less).

What does the device measure?

The device sensors measure oxygen saturation, heart rate, and movement. A reading is taken approximately every 20 seconds. These data are communicated to a base station attached to a laptop or PC and displayed by the software user interface.

Figure 1: AliveLock system

Figure 2:
AliveLock RiskWatch wrist-worn device and finger sensor

Communication with the base station uses the Zigbee standard in the 2.4GHz radio frequency spectrum. This is a class licenced band used for medical or research purposes in many jurisdictions.

Figure 3:
AliveLock base station

The base station utilises two USB ports: one for power and the other to communicate with the monitoring software on the PC/laptop. It also includes a fingerprint scanner for security, enabling identification of actions by staff and administration by a suitable person.

For the trial a radiocommunications booster was used to provide wireless coverage throughout the PICU. Line-of-sight communications were possible over approximately 30 meters.

Alarm parameters are based on a percentage variation from a baseline established when the patient first wears the RiskWatch, and retaken when there is a change in activity levels, such as on going to sleep. This arrangement makes it more difficult to use the standard Clinical Excellence Commission observation charts.

Why this device was chosen for the trial

- it has a secure attachment to the wrist
- the device is robust
- several devices can be monitored using one station
- it provides a more reliable reading than wrist-only devices
- the base station emits an audible alarm to alert staff when vital signs exceed safe parameters.

Other wireless pulse oximeters

The other device considered for the trial, the Oxitone 1000M, is entirely contained within a watch-like case and band, with no separate finger sensor. The device uses Bluetooth to connect with a smartphone. Software for monitoring device is provided in a private cloud as Software as a Service (SaaS).

Figure 4:
Oxitone 1000m

It should be noted that the Oxitone 1000M was not formally included in the trial, so any observations are from use of the device by the Newcastle Lived Experience Advisory Group, study investigators [FS and DM] and the peer support worker [SL], not from use in a health care setting.

We attempted to include the Oxitone 1000M device as part of the trial but were unable to do so because it only became available late in the study and a new ethics application would have been required, which would have taken recruitment beyond the end of the project deadline.

Other devices were not considered suitable for use in mental health care settings for a variety of reasons. These included not being sufficiently robust, the need to individually pair each device with a separate smartphone, the lack of an audible alarm, gaps in the readings due to movement or misplacement of the sensors on the wrist, and a limited communications range.

Trial objectives and research questions

The study examined whether it is feasible and acceptable to patients, staff, carers and families to use back-to-base pulse oximetry to monitor suicidal behaviours in mental health care settings.

To be feasible the system and device needed to be easy to use and convenient.

To be acceptable, the system and device needed to be suitable and able to be tolerated by wearers.

Trial design

The trial used a mixed methods design to assess the feasibility and acceptability of using back-to-base pulse oximetry within mental health settings. It was not an efficacy or effectiveness trial.

Two clinical staff in the PICU were nominated as champions for the study, and the Peer Support Worker also became a champion. The use of champions will work best if they feel supported and are equipped to overcome technical issues.

Setting

Initially the trial was conducted only at the Mater Mental Health Centre's eight-bed Psychiatric Intensive Care Unit (PICU) but was extended in May 2019 to include the adjoining four-bed Psychiatric Emergency Care Centre (PECC). Patients in the PICU are more high risk for suicide than those in the PECC, which is usually short stay.

Participants

Patients admitted to the PICU (and subsequently the PECC) were eligible to be enrolled in the study. Those who provided written consent wore the device during their stay in the unit, sometimes for several days, unless they decided to withdraw or no longer participate in the study.

Measures

Participants were to be asked to complete a questionnaire at the outset, after each 24-hour period wearing the device, and on transfer to another ward or discharge (however, either there was no opportunity for this to happen or patients refused to do so).

Questions related primarily to participant views about the contribution of pulse oximetry monitoring to their safety, the comfort of the device, any interference with their routine, how well the device had been explained to them, and trust in the device working appropriately. These questions were based on a modified Whole Systems Demonstrator Service User Technology Acceptance Questionnaire (SUTAQ) (Hirani, Rixon et al. 2017).

Qualitative feedback regarding patient and staff views about wearing the device was collected.

Two clinical staff in the PICU were nominated as champions for the study, and the Peer Support Worker also became a champion for the study.

Staff continued to carry out regular observations of the patient as mandated by NSW Health Policy Directive PD2017_025, 'Engagement and Observation in Mental Health Inpatient Units' in parallel with the pulse oximetry monitoring.

Limitations

As this was a clinical trial, the use of pulse oximetry monitoring was not embedded in clinical practice in the same way as it would be if its use was routine, so data were mainly captured from those who agreed to participate, and not from those who did not participate, or who withdrew their consent. This, together with the small number of participants, leads to a degree of uncertainty regarding the study results.

With recruitment of patients in the PICU it became evident that many were too unwell to provide informed consent to participate in the study. Participation rates were low until the study was extended to the PECC, where recruitment of participants was more straightforward, and the rates improved. Nevertheless, participants were reluctant or unable to complete the questionnaires or wait to be interviewed once the discharge process commenced. It was also not possible to recruit family members or carers to obtain their views. Therefore, only limited data on acceptability of the device with patients was available and was largely drawn from unit staff comments. This reduces the confidence with which we are able to comment on acceptability of the technology to patients.

Some investigators working on this research [MF, JR and DM] together with members of the steering committee [MF] have lived experience of bereavement by suicide. This experience may bring with it an inherent bias, which is acknowledged here.

Data analysis

Data from the AliveLock systems used in the PICU and the PECC were analysed to determine the numbers of alarms, the recorded cause of the alarm and any action taken.

Consenting unit staff and the Nurse Unit Manager answered questions about the feasibility and acceptability of using the AliveLock system. Data from these are presented below.

Funding

The study was funded by a grant of $300,314 from NSW Ministry of Health to the Black Dog Institute. A portion of the funding from the grant ($60,938) was provided to the Hunter New England Local Health District, primarily to cover the cost of employing a mental health peer worker to assist with the study, especially recruitment and data collection.

Ethics and clinical trial registration

Ethics approval was given by the Hunter New England Human Research Ethics Committee on 9 November 2018 (2018/ETH00341). An amendment to include recruitment of patients admitted to the PECC was approved on 14 May 2019.

The trial was registered with the Australian New Zealand Clinical Trial Register (ANZCTR) Trial Id: ACTRN12618001844235.

The device was used under the Therapeutic Goods Administration Clinical Trial Notification (CTN) scheme.

Consent

The trial involved patients aged over 16 who consented to wearing the device. This was facilitated by the clinical staff or the Peer Support Worker explaining the study Participant Information Sheet with those who were identified as being well enough to provide informed consent. Patients were given information about the study and asked if they were prepared to be involved. Those who were prepared to be part of the study and understood what was involved were asked to sign a consent form. Informed consent was also obtained from unit staff who provided feedback.

Inclusion of lived experience

As well as some of the Investigators and project Steering Committee members having lived experience, the Newcastle Lived Experience Advisory Committee was consulted about the study on two occasions.

The first occasion, in 2018, was to demonstrate the AliveLock system. The second occasion, in August 2019, was to provide an update of the study and the opportunity to see both the AliveLock system and the Oxitone 1000M side-by-side.

Feedback has been incorporated in the study findings.

Results

Participants

A total of 41 unique patients participated in the study as well as the Peer Support Worker. The average age of patient participants was 36, ranging from 17 to 72 years old. There were 19 male and 22 female patient participants. A small number participated more than once, with two proactively asking to have the RiskWatch fitted on readmission, as it made them feel safer.

As noted, participants did not fill out the questionnaires to examine suitability of the device. This was due in part to the characteristics of the cohort involved and their general reluctance to fill in a paper questionnaire, as well as workflows in the ward. In most instances, on discharge or transfer to another unit, there was limited time for participants to complete a questionnaire, and most were reluctant and refused.

Some qualitative data about patient acceptance was noted by the Peer Support Worker and unit staff.

Five unit staff, the Peer Support Worker and the Nurse Unit Manager provided information in response to questions about their experience with the device, the system, and the study.

AliveLock system data

In the Psychiatric Intensive Care Unit (PICU), of the 52 patients recorded as having been approached to participate in the study, 23 were recruited (44%) over a 143 day period from early March to late July 2019.

The Peer Support Worker actively wore the device when in the unit. So did some of the clinical staff, for varying lengths of time, but without activating the device. This was to try to normalise its use.

Any data recorded when staff were wearing a device has been disregarded in the results presented here.

Excluding the Peer Support Worker and other staff, the AliveLock system record indicated 28 separate occasions the RiskWatch was worn by PICU participants. Some of these were when the RiskWatch was changed to another, as well as one patient who participated twice on different admissions.

The average length of time that the RiskWatch was worn by PICU patients (as indicated by the system log) was around 24 hours, ranging from 19 minutes to over 91 hours. These are likely to be under-estimates as the AliveLock system does not record when the RiskWatch was first activated for each wearer.

A total of 1,169 events where recorded by the AliveLock system in the PICU. Of these, 220 were for the RiskWatch worn by the Peer Support Worker when in the unit.

Of the total number of events, the majority (964, or 82%) were for the heart rate sensor reading being unavailable (which also could indicate that the patient had tampered with the sensor) with 328 of these being recorded by staff as errors, bad reads, faults or malfunctions.

The next highest number of events (74) were for oxygen levels being out of range.

Most of these were false positives, with only a few (7) reported as occurring when the patient had removed the sensor.

Table 2: AliveLock System Reports - Psychiatric Intensive Care Unit (PICU) and Psychiatric Emergency Care Centre (PECC)

Reported Reason for Alarm	Nº (%)	Nº (%)	Nº (%)	Average Nº.
	PICU	PECC	Both units	Both units
Battery	34 (3)	0 (0)	34 (2.5)	17
Heart Rate Sensor Reading Unavailable - Check for Tamper	963 (82)	192 (87)	1155 (83.1)	577
Heart Rate Too Low/High	11 (1)	3 (1)	14 (1.0)	7
No Motion Detected	25 (2)	1 (0)	26 (1.9)	13
O2 Out of Range	74 (6)	3 (1)	77 (5.5)	38
Radio Communication Lost	39 (3)	13 (6)	52 (3.7)	26
Sensor device change	5 (0)	1 (0)	6 (0.4)	3
Unknown	16 (1)	4 (2)	20 (1.4)	10
Other	2 (0)	0 (0)	2 (0.1)	1
TOTAL	**1169 (100)**	**221 (100)**	**1390 (100)**	**695**

Twenty patients in the Psychiatric Emergency Care Centre (PECC) participated in the study over a 60 day period from late May to late July. Two patients who participated in the study while in the PICU also participated when admitted to the PECC, making 41 unique patients in the study in total.

The AliveLock system records show that the RiskWatch was worn by patients on 20 occasions, with an average of 5 hours 27 minutes. Recorded times ranged from 41 minutes to over 30 hours. As noted previously, these are likely to be under-estimates as the system does not record when the RiskWatch was first activated for each wearer. Data from the system log files were utilised when the recorded time was very short to try to correct this.

The shorter usual length of stay of patients in the PECC means that the average time worn is less than in the PICU.

As with the PICU, the main reason for alarms was that the heart rate sensor reading was not available (192, or 87%). More than half of these were recorded as errors, malfunctions, or false alarms.

There were no medical or other events recorded while participants were wearing a RiskWatch. There was one instance of a participant in the PICU threatening to use the device as a weapon. Secure fitting of the device, ensuring the wrist strap is not loose, is therefore an important consideration that needs to be covered adequately in training.

The number of false alarms or errors is concerning. Some occurred when the sensor stopped obtaining a reading because of positioning or movement, but other causes such as communications errors were also possible. The vendor (AliveLock) endeavoured to trace the issue but was not able to resolve it, and alarms continued to occur due to tampering or bad reads where no available read was available from the sensor/s.

A small quantity of adhesive sensors (100) was obtained and these generally provided more accurate readings and were more comfortable for the wearer, although they were not waterproof like the silicone finger sensors.

It is not clear whether use of these sensors reduced the number of false alarms as their use was not recorded in the system. However, the system log would suggest that this was not the case, particularly before the faulty base station was replaced in late May 2019.

Some of the staff comments in the AliveLock System Report for the PECC indicated a level of frustration with the apparent errors:

Time Verified	Actions Taken
17/06/2019 6:30	Other: error
17/06/2019 7:29	Other: error
17/06/2019 7:33	Other: ANOTHER ERROR
17/06/2019 7:35	Other: ANOTHER ERROR
17/06/2019 7:45	Other: This is terrible
17/06/2019 7:46	Other: This is outrageous and stopping me from doing my job
17/06/2019 7:48	Risk Watch Removed;

Viewpoints - Unit staff

A number of clinical staff wore the device to better understand its potential impact on participants.

Whether they wore the device themselves or not, staff generally felt the RiskWatch was too bulky, the silicone sensors uncomfortable, and the number of alarms for no apparent reason too high. Staff also noted that training and support from the supplier could have been better, with issues taking too long to be fixed, if they were resolved.

Despite these issues, staff who responded to the questions that were asked were generally supportive of the use of pulse oximetry in the unit to help keep patients safe. This was particularly 'for patients who may be medically unstable, and for monitoring the risk of physical issues' [Medical Officer].

For some, it was more clear cut:

'Yes, [I] think it is feasible to use pulse oximetry in the PICU/PECC.'

[Nurse Unit Manager]

The caveat mentioned by most, though, was that the device needed to be more comfortable for patients to wear, with fewer alarms for no apparent reason. The increased workload from responding to false alarms was also noted.

Supports for staff were also mentioned:

'There was...
poor support and training for staff....'

[Unit staff member]

Training was provided to clinical staff by AliveLock on three separate occasions, however that was not sufficient to cover all staff, especially when the PECC also became part of the study. Staff were generally only available for training sessions during shift changeover. This needed to be 'protected time' for staff to be able to attend. Because of this, the Peer Support Worker became the main resource for assisting staff with knowledge of the AliveLock system while in the unit.

The system had limited documented training materials and other information available for staff to use, so face-to-face training was the only option. Support was available by telephone, but this was not used often, possibly because of the difficulty in communicating issues and understanding the steps required to resolve an issue.

To be feasible, better comprehensive support, documented technical information, and additional staff training would be required.

Viewpoint - Peer Support Worker

'The overall feedback... is that this is a worthwhile initiative and [staff] appreciate the efforts to assist them to provide care in a challenging environment and vulnerable cohort of patients. They recognise that these technologies [are intended to...] mitigate incidents that may have a lasting effect on them professionally and personally.'

[Peer Support Worker]

How suitable was the device?

It was difficult to determine the acceptability of the system because of the technical issues and resulting lack of staff confidence in the system, as well as the lack of quantitative data from the planned questionnaires. Some of the comments from staff about the size of the device and discomfort with the silicone finger sensors do, however, suggest that acceptability to wearers could be improved, as technology improves. Nevertheless, some patients wore the device for extended periods, in one case over 91 hours.

Two patients who returned to the unit and had worn the pulse oximeter during their previous admission requested to have the device refitted on their subsequent admission, as it helped them to feel safer.

Some patients noted that the RiskWatch looked like a monitoring device as used in the Justice sector, which may have been due in part to its origins in correctional settings in the United States. This perception was a deterrent to some patients.

Informed consent from patients to participate in the study was noted as a barrier, particularly when patients were too unwell to provide consent, as they often were when initially admitted to the PICU. Use of the system, once technological improvements have been made, as a routine part of patient care would not only help normalise it for patients but would help in staff acceptance as well.

Acceptance by staff of the system was mixed, with a number of issues with the system identified that would need to be addressed for it to be acceptable. These issues included the changes to practice needed to incorporate use of the device in the workflow (although the Peer Support Worker did help reduce this barrier).

Five staff provided an answer to the question about their level of confidence in the system (out of 10). The average score was 5.4 with a range of 2 to 8.

It was reported that this trial increased the contact between nursing staff and patients wearing the device, as it did with the Peer Support Worker too. While this was primarily around the technology and alarms, it also provided an opportunity to engage with the patient.

Is the device feasible to use?

There were ongoing issues with the technology, described below. We have suggested areas requiring improvements on page 18 to address these and other issues. Despite these issues, feedback from staff and patients indicates the potential of pulse oximetry as a suicide prevention measure.

Technological issues identified during the trial included:

- a large number of alarms relating mainly to heart rate sensor readings not being available, and with the devices being 'out of range'. Testing of the equipment identified a fault with the base station initially deployed, and this was replaced. However, there were still issues with false alarms afterwards;
- problems operating two base stations in close proximity. A second base unit was installed to cover the Psychiatric Emergency Care Centre (PECC) once this was included in the study, from 25 May 2019. When two base stations were operating together, there were times when one or more RiskWatch devices were identified by the incorrect base station;

- difficulty accessing timely technical support. The absence of 24-hour support for the system also meant that identification of issues was often delayed, sometimes until the AliveLock representative could be onsite to undertake troubleshooting;
- problems with the locking mechanism on several RiskWatches, which became inoperative due to stripping of the plastic hex nut. It was difficult to tell when the unit was unlocked, as there was not a clear physical indication;
- a number of batteries failed to charge, and battery life was not as long as expected. Faulty batteries were replaced;
- difficulty going back into the system to add or amend patient data. The security features of a system originally designed for correctional settings may not be warranted in mental health settings. Being able to re-enter the system to make amendments would be an important feature when there are many things to be attended to when a patient is first admitted;
- these issues impacted on the trial and indicate some shortcomings with the current technology. To some extent, they also meant that unit staff were less engaged with the study than they may have been if the system had been easier to use with fewer false alarms.

'[While] potentially [feasible] the system would have to work better, be a better design and not increase workloads.'

[Unit staff member]

Facilitators and barriers in psychiatric settings

The nursomg stations in the PICU and the PECC had limited room for additional equipment needed for the AliveLock system. To overcome this issue, integration with existing hospital systems would need to occur so existing computers can be used to manage the alert system.

Both PICU and PECC, while adjacent to one another, had separate nursing staff and nursing stations. This meant have two systems operating near each other, with some communications conflicts evident (i.e., a RiskWatch being detected by the wrong base station after an error). Improved pairing of a device with a base station would be necessary to overcome this issue.

As with all low power radio communications, their range is limited. Although both units in this trial were small, a communications booster was initially needed in the PICU to ensure adequate coverage. Radio communication was lost 39 times in the PICU and 13 times in the PECC.

The audible alarm volume was limited to that of the laptop used for the system. External speakers would be needed to ensure that alarms could be heard while away from the laptop although, because of the frequency of alarms in this study, it was probably just as well that alarms could not be heard everywhere.

Positive features of the system

Despite the issues that occurred in this study, the AliveLock system had features that made it more suitable for use in mental health settings than other devices that were considered and that should be maintained or included in future systems.

These features included:

- the RiskWatch was robust, and not easily broken (apart from issues with the locking mechanism);
- it could be locked and only removed by unit staff;
- it was sufficiently waterproof to enable the wearer to shower, although there were some issues with the disposable finger sensors that were used during the trial if they got wet;
- readings for multiple devices were displayed on the one computer console;
- alarms for drop in oxygen saturations or pulse were visible on the console as well as being audible;
- alarm parameters could be set, either individually or globally, using a baseline for each patient and reset depending on the level of activity or overnight;
- communication between the device and the base station over a relatively wide area was possible with a range booster (in the PICU);
- all data were kept locally with a record of wearers, events, users and administrators kept in a database on the laptop/PC used that would enable interrogation if there was a sentinel event (and enable data for this study to be collected).

'I hope future studies will benefit from technological advances not available at the time of commissioning this study and incorporate the experiences from this formative study to advance knowledge….'

[Peer Support Worker]

'The system would detect acute or gradual deteriorating medical conditions… including drug effects on the patient.'

[Executive Manager]

Lived experience

'I could imagine some people might be suspicious of the device, but others may be comforted by knowing that it would be helping to keep them safe, even when no one else was around.'

[Person with lived experience]

Comparison to other studies

The researchers are not aware of any other studies of pulse oximetry in mental health care settings to help identify suicidal behaviours, although they are aware of a study proposed in the USA that had not commenced at the date of this report (see above). This study was premised on the potential reduction in night-time disturbance of patients from nursing observations.

Limited information is available on studies involving other devices to detect suicide attempt.

As noted later, the Oxehealth video monitoring system has been trialled for night observations in a male psychiatric ward in England, with positive results.

Looking to the future

Overall, while back-to-base pulse oximetry holds promise, in practice this study found that the system we tested (AliveLock) is not yet reliable enough to be used in health care settings until issues with the high number of false alarms are dealt with. This may be as straight-forward as the redesign of the sensors to remain positioned in the right place for longer periods of time.

Potential improvements to the system noted by staff and members of the Lived Experience Advisory Group as well as the study Steering Committee included:

Device improvements

- Making the device smaller, and more like a consumer smartwatch
- Improving battery life while retaining the ability to change batteries rather than having to remove the device to charge the battery
- Providing feedback to patients on the watch itself, which could include vital signs as well as the time, steps, and other information that could be useful and engaging to a patient
- Making the device more reliable with fewer false alarms
- Not require a separate sensor on the finger and be more tamper-proof
- Allow for movement
- If possible, measure relevant metabolic risk factors such as high blood pressure, low high-density lipoprotein cholesterol (HDL-C), elevated triglycerides, and hyperglycemia.

System improvements

- Making setup of the device in the system simpler
- Making the system more user friendly for clinical staff, i.e. revising how security is built into system functions
- Enable pulse and oxygen saturation monitoring using 'Between the Flags' parameters in standard observation charts
- Recording the time in the database when a RiskWatch was fitted to a patient
- Reducing the number of system components (e.g., using existing laptop fingerprint reader)
- Ensuring 24-hour support for the system is available.

Integration and other improvements

- Using the device to identify any deterioration due to medical reasons (although it would also detect suicide attempts) meaning re-evaluating how thresholds are set
- Improvements to training of staff and information provided to staff setting up devices and using the system
- Providing an external alarm that can be heard in other parts of the unit
- Integration with other hospital IT systems, instead of being a standalone system, allowing it to be deployed across a facility
- Integrating a mechanism for patients to call staff if necessary.

As well as enhancements to the technology, to make it easier to use and more reliable, a cultural shift may also be needed for pulse oximetry to be feasible within inpatient settings.

Other issues that would need to be addressed before the technology could be used more widely include:

- Staff understanding and acceptance of the technology as an additional way to help keep patients safe
- Improvements to training and support – to enable its wider use
- Simplifying the way in which actions taken by staff can be entered in the system (this information may be important if there was a sentinel event)
- Setting alarm parameters for individual patients that reflect their 'normal' vital signs, rather than relying on predetermined parameters (although it should be noted that the AliveLock system takes an individual baseline and alarms are generally triggered when measured oxygen saturation or pulse is a percentage different).

The use of pulse oximetry may be easier to do in lower-intensity settings, although the benefits of its use are likely to be greater in intensive care settings.

While this study indicates that the technology is not ready, it has a lot of potential and would be invaluable as part of the efforts currently underway to eliminate suicides altogether in health care settings.

Issues to consider

Implementation

The current study indicates that the level of user training and technical support for a system such as AliveLock should not be underestimated. It will also be important that staff have confidence in the system, that it does not present too many false alarms, and is stable. Any back-up equipment should be easy to install and ideally the system should be integrated with other hospital systems, given that space in nursing stations is often at a premium.

Implementation and acceptance by staff and patients will need positive action, such as: using a peer support worker to champion the use of pulse oximetry as a safety measure; providing protected time for staff training in the system; providing comprehensive technical support, and providing a supportive environment with positive messages from managers.

While pulse oximetry will identify more medical episodes than suicide attempts, once the reliability of the technology has been improved it will provide a backup to intermittent observations and other measures and reduce suicide in mental health inpatient settings.

Most systems, whether wireless pulse oximeters or other devices, would need approval by the Therapeutic Goods Administration for use in Australia as medical devices. In addition, they would need to be assessed for their compliance – electrical and wireless communication – with the Australian Communications and Media Authority requirements.

Emphasising the potential of pulse oximetry to detect suicide attempts and avert the considerable distress not only to families and carers but also to staff caused by suicide is needed, even though often staff did appreciate this aspect.

There are also policy and social considerations, such as the collection of biometric data and what happens to it, and use of pulse oximetry on involuntary patients, and guardianship.

Legislative changes may be necessary, for example, to enable a pulse oximeter to be fitted securely to an involuntary patient.

Future research

Once the technology has been further enhanced to more closely meet identified requirements, there is scope to undertake an efficacy trial. This would require working with technology providers to identify opportunities to undertake a multi-site trial (with sufficient participants) to establish if pulse oximetry is effective in detecting adverse events. A trial like this could be undertaken with other Australian jurisdictions, or potentially internationally.

Other research is examining other mechanisms to keep people in mental health settings safe from suicide. Earlier articles suggested using technology to help manage risk in psychiatric settings. These have included GPS-based electronic monitoring and have not been without ethical concerns (Tully, Hearn et al. 2014). It should be noted that some patients in the current study initially thought that the AliveLock RiskWatch was an electronic monitoring device like those used in the Justice sector.

Pulse oximetry was the only back-to-base monitoring that was evaluated in this trial, partly because of the nature of the recommendation of the NSW Deputy State Coroner to the Ministry of Health. Other mechanisms to monitor the safety of mental health patients have been developed or tested, including single-lead electrocardiogram (ECG) and unobtrusive video or radar monitoring.

Within enclosed spaces such as bedrooms, systems such as the Oxehealth Digital Care Assistant, which utilises video, may be better than pulse oximetry for monitoring a person's vital signs. However, while it is designed to be relatively unobtrusive, there may be privacy concerns about the use of video in this way. Nevertheless, there may be potential to use this technology in non-medical settings, for example, in community-based respite care centres.

Other technology is emerging: second generation devices have tried to embed the sensor in the device, either worn on the wrist, like the Oxitone 1000M, or in a patch, as with the Rhythm Diagnostics System MultiSense patch, a sensor worn on the foot (see Owlet baby monitor) or single lead ECG (isansys Patient Status Engine).

Pulse oximetry monitoring in community and other settings

Without including ways to establish location, such as GPS, pulse oximetry monitoring of people in unsecured or community settings is likely to be sub-optimal. While in theory it could be done, and linked to ambulance and/or a carer, there are ethical issues in implementing technology that does this.

Technology does not replace good quality care including compassion and safety planning, and it will not by itself prevent suicide attempts.

Significant research on remote monitoring has involved systems to monitor falls and loss of consciousness in the elderly, using accelerometers and, more recently, depth sensors. Such systems may have application for monitoring suicide attempts but would be less effective for monitoring deterioration in a patient's condition from other causes. Nevertheless, these systems may be appropriate to monitor those at risk of suicide who are in community-based or non-medical settings.

There is obvious potential to use back-to-base pulse oximetry in other settings as well, including residential aged care, private hospital mental health units, drug and alcohol inpatient settings, and the in the Justice sector (police holding cells and correctional facilities).

Next steps

Achieving zero suicide in health care settings will need evidence-based ways to keep people safe – these may include improved engagement between staff and patients and safety plans but may also require better monitoring of patient vital signs or indications of suicide attempt, both in hospital and community settings. Technology, such as pulse oximetry, would provide an additional way to keep patients safe in mental health care settings.

The vision remains to see pulse oximetry technology used in mental health settings for suicide prevention.

'It would great if we could interest a big player like Apple to make something [like the Apple Watch] specific to mental health settings.'

[Person with lived experience]

To achieve this, a business case needs to be made to get the technology to the next level, to make it reliable and more comfortable for patients to wear, and to make the case for its development. There are several opportunities to enhance the potential of technology in suicide prevention that can be pursued, including modifications to existing devices or sensors to make them robust, secure, and reliable, or designing new devices that meet the requirements of the health sector.

Working with manufacturers to improve the devices

Further development by manufacturers of back-to-base pulse oximetry may be assisted by grant funding. For example, the Medical Research Future Fund (MRFF) has a Researcher Exchange and Development within Industry Initiative (REDI).

Most first generation back-to-base pulse oximetry systems are either a finger clip or have a separate finger sensor wired to a watch-like device worn on the wrist, like the AliveLock RiskWatch. Second generation devices have looked to embed the sensors in the device itself, either worn on the wrist, like the Oxitone 1000M, or in a patch, as with the Rhythm Diagnostics System MultiSense patch. These second-generation devices, however, still need to be proven in mental health settings, and may not be robust or secure enough.

In acute settings any device worn by patients should not be able to be used as a weapon.

Refining back-to-base pulse oximetry for use in mental health care settings

- Enhancing the AliveLock RiskWatch to operate more reliably, with fewer false alarms
- Working with technology vendors to ensure suitable levels of training and support
- Designing a new system, e.g., a sensor worn on the foot (see Owlet baby monitor).

Reframing the parameters for the use of unobtrusive patient monitoring

- Night-time only (to overcome issues arising from patients being mobile during the day)
- Some rooms (e.g., bedrooms) or units, not others (e.g., more open spaces, rooms where patients mix)

Evaluating other systems and settings

- Single lead ECG (isansys Patient Status Engine)
- Pulse oximetry using a patch (Rhythm Diagnostic Systems' MultiSense and VitalPatch from VitalConnect)
- Video monitoring (Oxehealth's Digital Care Assistant)
- Safe houses that are established under the New South Wales 2018 Suicide Prevention Strategy.

Establishing a technology and innovation advisor under the Towards Zero Suicides Initiative

This study established the potential of back-to-base pulse oximetry monitoring to keep patients safe in mental health settings.

The technology employed in this trial is in its infancy. Many other options are more clearly aimed at the consumer market and not suitable for mental health settings. However, advances in the technology are happening quickly, and for a coordinated approach to using pulse oximetry in mental health and other settings in future, the monitoring of those developments will be critical.

This could be advanced by:

- seeing pulse oximetry as an adjunct to other changes, included in the zero suicides initiative, that will help to reduce suicide in inpatient and other settings;
- the appointment of an advisor under the zero suicides initiative to provide leadership and evidence-informed advice to the health sector about pulse oximetry and other patient monitoring technologies;
- the running of another study (in 12 months) once the technology is more mature, to examine whether shortcomings identified in this study have been overcome, and staff receptiveness improved.

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Appendices

Project timeline

- Agreement with Ministry of Health (January 2018)
- Letter of support from the Chief Executive, Hunter New England Local Health District (HNELHD) (March 2018)
- Ethics approval (November 2018)
- Agreement with Hunter New England LHD (January 2019)
- Trial devices obtained (February 2019)
- Trial February 2019 – July 2019 (5 months)
- Final report to NSW Health (August 2019)

Trial governance

The trial was undertaken as a collaboration between the Black Dog Institute and the Hunter New England Local Health District, Mental Health Service. A project Steering Committee was established to oversee the study. Members consisted of:

Principal Project Lead: Ms Nicole Cockayne, Director Discovery and Innovation, Black Dog Institute.

Coordinating Principal Investigator: Dr Fiona Shand, Senior Research Fellow, Black Dog Institute/UNSW

Principal Investigator: Dr Marcia Fogarty, Executive Director, HNE Mental Health

Associate Investigator: Ms Margaret Balaz, Nurse Unit Manager, Psychiatric Intensive Care Unit, Mater Mental Health Service [from 12 July 2018]

Associate Investigator: Dr Sujatha Venkatesh, Clinical Director, Psychiatric Intensive Care Unit, Mater Mental Health Service [from 14 August 2018]

Associate Investigator: Mr Michael Bruce, Service Manager, Psychiatric Intensive Care Unit, Mater Mental Health Service [from 12 July 2018]

Associate Investigator: Dr Josephine Anderson, Psychiatrist, Black Dog Institute

Associate Investigator and Biomedical Engineer: Dr Mark Larsen, Research Fellow, Black Dog Institute/University of NSW.

Associate Investigator: Ms Jo Riley, Lived Experience Manager, Black Dog Institute.

Associate Investigator: Professor Gregory Carter, Conjoint Professor, Centre for Brain and Mental Health Research, University of Newcastle

Mr Stephen Scott, Principal Policy Officer, Social Policy, Mental Health Branch, NSW Ministry of Health [from 13 November 2018]

Mr Michael Raftery, Lived Experience Representative, Newcastle

Project Manager and Associate Investigator: Mr Dean Martin, Research Manager, Black Dog Institute.

Communications and Media Expert: Ms Sasha Pavey, Communications Officer, Black Dog Institute.

The Steering Committee met via teleconference on the following dates:

27 November 2017
31 January 2018
7 March 2018
12 April 2018
25 May 2018
12 July 2018
14 August 2018
18 September 2018
13 November 2018
31 January 2019
11 March 2019
4 April 2019
9 May 2019
24 June 2019
29 July 2019
28 August 2019

Summary of devices considered for the Pulse Oximetry study

Introduction

This paper is a summary of the research conducted in early 2018 that led to the identification and selection of a suitable pulse oximetry system for a feasibility and acceptability study of back-to-base pulse oximetry monitoring for suicidal behaviours in mental health care settings. This study was undertaken by the Black Dog Institute with Hunter New England Mental Health Services and was funded by way of a grant from the NSW Ministry of Health.

The study was concluded in February to August 2019.

Back to Base Pulse Oximetry trial aims

The primary aims of the trial are to examine the feasibility and acceptability (to staff, patients and families) of wireless pulse oximetry monitoring of patients at risk of suicide in a mental health setting. It is hypothesised that such monitoring will alert staff to an event so that an intervention may take place before death occurs.

The study is a result of a recommendation from the Newcastle Coroner to the NSW Government to investigate the use of pulse oximetry to monitor patients following the death by suicide of a young person in a PICU.

Additional trial purposes

While the main purpose for the trial is to use pulse oximetry in a mental health setting to monitor vital signs to help detect and respond to any patient suicide attempt, a secondary purpose is to help monitor patients (who have a high incidence of comorbidities or are on multiple medications) for other life-threatening health events, including indications of accidental or undisclosed overdose.

A further aim of the trial is to see whether there are any additional impacts or effects for patients and staff from monitoring for suicide attempts and other health events using technology.

The trial is designed to be run in parallel with existing mandated requirements for staff observations of patients, either continuously or at intervals, so aspects such as the impact of decreased overnight disturbance will not be able to be tested.

Supplementary purposes include:

- to list potential uses for the device in other settings, such as in other hospital or community settings;
- to forecast the development of this technology, to determine if and when full expectations for devices may be met by technological improvements;
- to consider patient rights for privacy against the need to prevent suicide;
- to consider limitations of the devices, such as the transmission range compared to ward sizes;
- to consider whether current legislation allows scope for the non-voluntary fitting of devices, if necessary (although the trial will be conducted with patient consent);
- to add to the body of knowledge on such devices, by reporting findings externally;
- to model what future project work and a rollout of technology might be;
- to make recommendations on next steps.

Technologies

Technology used to monitor vital signs is developing rapidly. There are several health-related wristbands (Helo, for example) that are or will soon be capable of reading SpO2 and pulse. They have the advantage of being more like fitness trackers, and more comfortable to wear. However, their accuracy is such that the companies concerned have not sought FDA approval for these functions. In addition, they can easily be removed, and may not be capable of streaming data continuously within a healthcare setting.

Video together with artificial intelligence (AI) is also being used experimentally to monitor vital signs. These technologies will continue to be developed and perhaps provide better alternatives to the currently available solutions.

Three potential wireless monitoring technologies were identified in the initial review of literature:

- back-to-base pulse oximetry (AliveLock, Oxitone 1000, Isansys Patient Status Engine with wrist worn monitor, etc);
- single lead wireless ECG (Isansys Patient Status Engine with single lead ECG sensor);
- video monitoring of vital signs (Oxehealth).

Technologies to monitor falls (accelerometers and gyroscopes) were also investigated briefly but it was determined that they would only be useful in conjunction with other sensors to monitor vital signs.

Some of the pulse oximetry devices investigated include accelerometers, primarily to pick up extended periods without movement.

For a general discussion about sensors to monitor respiration and other vital signs, including pulse oximetry, see http://breathe.ersjournals.com/content/breathe/13/2/e27.full.pdf

Requirements of the technology for the trial are to include most, if not all of the following:

- wearable/portable device;
- minimally obtrusive device which doesn't restrict movement or dexterity;
- reasonably accurate measurement of pulse/heart;
- reasonably accurate measurement of SpO2 (blood oxygen levels);
- display continuous readings (although this may be via sampling and averaging measures);
- provide wireless streaming of data from the worn sensor/monitor to a central base station;
- overcome any transmission blind spots on the ward;
- ability to monitor up to 10 patients at the one time;
- showerproof sensor and/or patient-worn device;
- reusable or inexpensive sensor/device that meets standards for sterilisation if reusable;
- robust device which is unlikely to be accidentally dislodged and is relatively tamper-proof and not able to be used as a weapon;
- individually configurable parameters for when alarms will sound (preferably in line with NSW Health 'Between the Flags' measures);
- alarms to sound loudly enough for staff away from nurses' station to be able to hear (may require computer to link to ward alarms or external speakers)
- not substantially increase the disruption of sleep etc. already experienced by those on the ward.

Because of the nature of the different technologies, not all requirements may be relevant (e.g., sterilisation should not be an issue for remote video monitoring, whereas tampering may be).

Clinical advice is that the system should identify and alarm when the following conditions are met:

- sudden change in pulse (high and low)
- change in SpO2 (low) whether sudden or gradual
- if the sensor is removed or tampered with
- if the worn device goes 'out-of-range'

Other potential situations resulting in an alarm are:

- possible sudden change in position
- possible absence of movement, or unusual movement/s.

Initial evaluation of back-to-base systems

The back-to-base pulse oximetry systems that were identified and evaluated further were:

- Oxitone 1000 (https://www.oxitone.com/)
- AliveLock Safety Monitoring System (http://www.alivelock.com/)
- Isansys Patient Status Engine (http://www.isansys.com/en/products/PSE)
- Oxehealth (http://www.oxehealth.com/)
- VinCense (http://www.vincense.com/).

Systems used in fitness, sports physiology and falls monitoring, while potentially able to meet the basic monitoring requirements, were not investigated further, due to their evident short-comings.

A report on 'Patient-Monitoring Wearables in Healthcare' was sourced from ABI Research, which also identified the four wearable devices evaluated.

A list of devices evaluated is included in Appendix A.

Contact was made with the manufacturer or supplier of each of the more suitable technologies, and (where applicable) additional information obtained about:

- sensors, metrics obtained and streamed, accuracy;
- alarms and parameters;
- durability and re-use;
- whether the wearable component is waterproof;
- how secure the wearable is (how easy/difficult is it to remove);
- battery life of the wearable when in use;
- whether the software to support the system is proprietary or not;
- wireless technology employed to stream data from the wearable to the base station;
- technical requirements for PC/laptop used with the system;
- training, documentation and help desk support;
- research involving use of the device in any setting;
- cost of a system capable of monitoring up to 10 patients at one time.

Oxitone 1000

Following initial contact, it was apparent that the Oxitone 1000 was not yet commercially available, and it had FDA approval for measuring SpO2 while the person is not moving vigorously. The device was expected to be commercially available in the Northern summer 2018, at a cost of US$250-350 per device plus a SaaS cost for Oxitone's cloud platform, analytics and 24/7 support.

The Oxitone 1000 wrist-sensor pulse oximeter has FDA 510(k) Clearance (NO: K163382).

In January 2018 Dr Leon Eisen, the Founder and CEO of Oxitone indicated that the device 'doesn't read SpO2 during intensive motion' which is physically impossible at the wrist.

The Oxitone 1000M is has been available in limited numbers from May 2019, at a cost of approximately US$450 per device.

AliveLock

The AliveLock Safety Monitor system was developed in the United States for use in correctional settings. It has been deployed in several institutions.

The AliveLock RiskWatch utilises a medical grade finger sensor to obtain a PPG reading for processing by an FDA certified Nonin OEM module and algorithm.

The system provides monitoring with SpO2 readings between 70 and 100% +/- 2 digits and pulse rate from 20 to 250 bpm +/- 3 digits. These are for someone with normal perfusion and not moving vigorously.

The RiskWatch also includes a sensor to detect movement. This allows motionlessness for a pre-determined time to be detected but is able to register normal sleeping movements so it doesn't alarm during periods of sleep.

Parameters for percentage SpO2 drop, heart rate and movement can all be set to suit individual circumstances.

The device is shower-proof but water will get into the battery compartment if it is held under the stream of water for an extended period. Wearers are advised not to do so.

The device (not the finger stall) is difficult if not impossible for the wearer to remove. In a correctional setting care is taken to ensure there is no access to sharps to cut the Velcro band that is used.

Battery life is determined in part by the number of times the device alarms but is between 8 and 12 hours of use. The monitoring page of the system includes a battery indicator for each watch being used. Two batteries plus charging cradle are supplied for each device.

The software supporting the AliveLock is proprietary.

The RiskWatch communicates with a base station that is connected to a computer or dedicated laptop in the area it is being used.

The system uses radio frequencies to communicate, rather than WiFi or Bluetooth. The monitor indicates the level of connectivity with each device.
If communication with the device is lost an alarm on the monitoring screen will be triggered.

Training for staff can be customised for the specific context and was included in an indicative cost of AU$55,000 for a 10-device system. Ongoing costs

for support and help desk access have yet to be determined. Access to the technology for the trial was provided without cost.

The current system is manufactured with US power plugs so adapters for the battery chargers are required for use in Australia.

Isansys Patient Status Engine

The Isansys Patient Status Engine (PSE) is a monitoring platform that supports multiple devices/sensors, including a wrist worn device with a finger senor to capture SpO2, which is like the RiskWatch. It is a third-party device and not part of Isansys' intellectual property.

The system is wireless and has been trialled in several medical settings and is a fully certified Class IIa CE-marked and Class II 510(k) cleared medical device.

When discussing the PSE and various options with the CEO of Isansys Keith Errey on 24 January 2018, he suggested the use of a single lead ECG monitor rather than the SpO2 watch, as the sensor is more 'wearable', and readings more reliable than the 65-70% of data obtained for pulse oximetry. It would also provide an indication of fundamental stress being experienced by the patient by intelligently measuring variation in heart rate and respiration rate.

The system is designed to help automate patient charts and is designed ultimately to be integrated into hospital IT infrastructure. However, integral to the system are critical alerts based on parameters set for each patient.

With multiple sensors the PSE can monitor heart rate (and variability) in real time, remote ECG on request, respiration rate, temperature, oxygen saturation (and PPG on request), and continuous activity/orientation.

The system utilises Bluetooth for bedside gateways (if used) and WiFi for display on other authorised devices. A central monitoring console or nurses station can also be used.

The system can be installed remotely and operates within the hospital firewall.

The cost – if a Lifetouch body-worn sensor to measure heart rate and respiration was used instead of a pulse oximetry watch – would be in the vicinity of £5,000.

Oxehealth

Oxehealth is a system that uses cameras to measure vital signs. Their Research Lead indicated in early 2018 that they have prioritised measuring heart rate and breathing rate to date, but have implemented pulse oximetry as a demonstrator, although where the user is fairly stationary.

The mental health project conducted so far have been at a high-security psychiatric hospital for monitoring seclusion rooms.

VinCense

The VinCense watch is similar to the Oxitone 1000 in that measurements are displayed on the device as well as being transmitted to monitoring software. Readings are taken from the fingertip rather than the wrist, thereby improving the accuracy in most circumstances. However, the device is not waterproof and is easily removed by the wearer.

A summary of the pros and cons of each of the pulse oximeters is given at Appendix A.

Summary

Five pulse oximetry devices or systems have been evaluated for their suitability for use to monitor patients at risk of suicide in an acute mental health setting: AliveLock, Isansys, Oxehealth, Oxitone, and VinCense. The Oxehealth video monitoring system is not yet suitable for this application as its ability to measure pulse oxygen saturation is still at the proof-of-concept stage. The Oxitone wrist-worn sensor is a promising candidate as an FDA-approved wrist only device – however at the time of this review it was approved for patients at-rest only and was not suitable for ambulatory patients. The remaining three devices (AliveLock, Isansys and VinCense) all consist of a wrist-worn device which connects to a finger probe. The AliveLock RiskWatch was considered to be the most suitable for this setting, as it has a greater degree of security (less prone to accidental or deliberate removal by the patient) and is showerproof to allow wearing while in the shower, provided it is not held directly in the stream of water for any length of time.

The Nonin OEM III module is the basis for the Isansys and AliveLock systems and is approved by the FDA for use in clinical settings (https://www.accessdata.fda.gov/cdrh_docs/pdf10/K102350.pdf).

It should be noted that the range of available devices is expected to change rapidly, and second-generation wrist-based sensors will become more accurate and potentially better suited for the purpose of monitoring for suicide attempts in mental health settings once artefacts introduced by movement can be overcome.

Update

Since this paper was first written other devices that measure pulse and oxygen saturation have been developed, although not yet commercially available. These include:

- VitalConnect's VitalPatch (https://vitalconnect.com/solutions/vitalpatch/)
- Rhythm Diagnostic Systems' MultiSense (http://rhythmdiagnosticsystems.com/technology/)

The Oxehealth video monitoring system has been trialled in a male acute inpatient mental health ward in the UK. The study assessed the use of Oxehealth's Digital Care Assistant to improve patient rest and privacy at night without compromising safety (https://www.oxehealth.com/oxford-health-report).

Appendix A:
Pulse oximeters evaluated – summary of pros and cons

Nonin WristOx2®, Model 3150 Wrist-worn Pulse Oximeter	http://www.nonin.com/OEMSolutions/WristOx23150-OEM	

PROS	CONS
Nonin SpO2 devices are ubiquitous, the technical specs are freely available. Uses an algorithm to give an accurate reading when limb in motion. Continuous Bluetooth streaming and around 24 hours battery life. Measurements displayed on face of wrist worn device.	Utilises a finger stall sensor. Not secure (easily removed). Not fully waterproof. Range of Bluetooth transmission limited.

Vincense	http://www.vincense.com/product.html	

PROS	CONS
Relatively inexpensive. Provides an accurate reading when limb in motion. Measurements displayed on face of wrist worn device.	Android only. Utilises a finger stall or clip sensor. Not secure (easily removed). Not fully waterproof.

Oxitone 1000	https://www.oxitone.com/	

PROS	CONS
FDA approval for SpO2 readings when limb is at rest. Only suitable device available with integrated sensors in wrist band. Measurements displayed on face of wrist worn device.	SpO2 reading only accurate when limb not moving vigorously. Showerproof only. Not secure (easily removed).

Isansys	http://www.isansys.com/en/products/sensors	

PROS	CONS
Utilises Nonin OEM module (see above). Integrated with cloud-based service/ Patient Status Engine (PSE) software.	Proprietary software system but APIs available.

AliveLock RiskWatch	http://www.alivelock.com/solutions/view/software/riskwatch	

PROS	CONS
Incorporates Nonin OEM III module. Secure with bracelet that cannot easily be removed. Only device with demonstrated use for suicide prevention (in correctional settings). Utilises Zigbee for radio transmission to base station. Showerproof. Provides an accurate reading when limb in motion.	Proprietary system. Manufacturer has indicated that APIs would be developed to enable integration with medical systems. Measurements not displayed on device itself.

Appendix B:
Devices or systems identified but not included

Helo LX (working on including pulse oximetry – due 2018): http://worldglobalnetwork.co/helo/

Visi Mobile: http://www.device.com.au/shop/visi-mobile-wireless-ecg-monitoring-system/

Medtronic Zephyr Performance Systems: https://www.zephyranywhere.com/system/components

Humon Hex (worn on thigh – measures SmO2): https://humon.io/science.html

BSX Insight (worn on calf – endurance testing – probably unsuitable): https://www.bsxinsight.com/

Empatica E4: https://www.empatica.com/get-started-e4

Devices/systems that detect falls/loss of consciousness – brief literature review

Fall Detection with Body-Worn Sensors: A Systematic Review

DOI: 10.1007/s00391-013-0559-8

Abstract:

Background and aims: Falls among older people remain a major public health challenge. Body-worn sensors are needed to improve the understanding of the underlying mechanisms and kinematics of falls. The aim of this systematic review is to assemble, extract and critically discuss the information available in published studies, as well as the characteristics of these investigations (fall documentation and technical characteristics). Methods: The searching of publically accessible electronic literature databases for articles on fall detection with body-worn sensors identified a collection of 96 records (33 journal articles, 60 conference proceedings and 3 project reports) published between 1998 and 2012. These publications were analysed by two independent expert reviewers. Information was extracted into a custom-built data form and processed using SPSS (SPSS Inc., Chicago, IL, USA). Results: The main findings were the lack of agreement between the methodology and documentation protocols (study, fall reporting and technical characteristics) used in the studies, as well as a substantial lack of real-world fall recordings. A methodological pitfall identified in most articles was the lack of an established fall definition. The types of sensors and their technical specifications varied considerably between studies. Conclusion: Limited methodological agreement between sensor-based fall detection studies using body-worn sensors was identified. Published evidence-based support for commercially available fall detection devices is still lacking. A worldwide research group consensus is needed to address fundamental issues such as incident verification, the establishment of guidelines for fall reporting and the development of a common fall definition.

https://www.researchgate.net/publication/259778683_Fall_Detection_with_Body-Worn_Sensors_A_Systematic_Review (accessed Feb 15 2018).

An interactive fall and loss of consciousness detector system

DOI: 10.1016/j.gaitpost.2008.04.011 Source: PubMed

https://www.researchgate.net/publication/51431023_An_interactive_fall_and_loss_of_consciousness_detector_system

Abstract: A device capable of automatically detecting a fall with loss of consciousness (FloC), and activate an alarm by means of an accelerometer sensor is presented. Four hundred trials were performed by 20 participants (10 young and 10 elderly adults). The algorithm relies on the recognition of the effects of three events characterizing a FLoC: impact of the body against the ground, lying and immobility. All FLoC cases were correctly detected as well as all activities of daily living (ADLs). This result corroborates both usefulness and applicability of the device proposed.

https://www.researchgate.net/publication/51431023_An_interactive_fall_and_loss_of_consciousness_detector_system (accessed Feb 15 2018).

Use of Information Technology for Falls Detection and Prevention in the Elderly. Ageing International 40(3) · September 2014

DOI: 10.1007/s12126-014-9204-0

Abstract

This research aims to clarify the arguments in the body of knowledge on IT use in fall prevention among the elderly, synthesize ideas to assist in the delivery of healthcare to prevent falls in older people and further add to the available body of knowledge. An extensive literature search was carried out and the information retrieved from the literature was synthesised into paragraphs using themes to structure the types of information technology used for falls prevention. The different modalities of IT used in falls prevention at the different places of care for each category were explored and inferences were drawn from the structured themes which summarized the major findings. The research found that there is potential ground for a wider use of the forms of IT used in falls prevention in the elderly in various settings and outlined the factors involved in this usage. With further refinements in larger studies, many of these forms of IT would be better explored and acceptance is likely guaranteed provided they are accessible and affordable. The need for IT use in fall prevention in the elderly is unavoidable with the trend in technology and the associated convenience. More work is needed to further define the effects of IT in falls prevention using larger prospective studies that will be more generalizable.

https://www.researchgate.net/publication/266318765_Use_of_Information_Technology_for_Falls_Detection_and_Prevention_in_the_Elderly (accessed Feb 15 2018).

Neural network based daily activity recognition without feature extraction

Conference Paper (PDF available) · April 2014

DOI: 10.1109/SIU.2014.6830292

Conference: 2014 22nd Signal Processing and Communications Applications Conference (SIU)

Abstract: In recent years, human-computer interaction systems are become one of the most exciting areas in technological development. These systems aim to obtain personal information of people and development of an automated systems managed by this information. In this study, we have been studied a faster and higher accurate system design without feature extraction for the recognition of daily human activities and falling situation. Motion data were collected under knee with a 3-axis accelerometer. After data re-arrangement, a 250 data size window was applied to collected data. 250 XYZ axis data belonged to each windowed sample were written in an array and converted to 1×750 sized array. Finally, applying data reduction with PCA, the data were simulated by MLP, SVM and Naive-Bayes classifiers. The best result without feature extraction achieved by Naive Bayes classifier.

https://www.researchgate.net/publication/269303618_Neural_network_based_daily_activity_recognition_without_feature_extraction (accessed Feb 15 2018).

Appendix C:
Technical specifications for communications

Zigbee

Zigbee is used for radio transmission in the AliveLock system. It an IEEE 802.15.4-based specification for high-level communication protocols used to create personal area networks with small, low-power digital radios, such as for home automation, medical device data collection, and other low-power low-bandwidth needs, designed for small scale projects which need wireless connection. Hence, Zigbee is a low-power, low data rate, and close proximity (i.e., personal area) wireless ad hoc network.

The technology defined by the Zigbee specification is intended to be simpler and less expensive than other wireless personal area networks (WPANs), such as Bluetooth or more general wireless networking such as Wi-Fi. Applications include wireless light switches, home energy monitors, traffic management systems, and other consumer and industrial equipment that requires short-range low-rate wireless data transfer.

Its low power consumption limits transmission distances to 10–100 meters line-of-sight, depending on power output and environmental characteristics. Zigbee devices can transmit data over long distances by passing data through a mesh network of intermediate devices to reach more distant ones. Zigbee is typically used in low data rate applications that require long battery life and secure networking (Zigbee networks are secured by 128 bit symmetric encryption keys.) Zigbee has a defined rate of 250 kbit/s, best suited for intermittent data transmissions from a sensor or input device.

Zigbee was conceived in 1998, standardized in 2003, and revised in 2006.

Advantages – encryption and ability to utilise mesh networks. Up to 100m line of sight.

Disadvantages – limited to intermittent data transmission.

Bluetooth

Bluetooth is used for most of the other pulse oximetry systems investigated. It is a wireless technology standard for exchanging data between fixed and mobile devices over short distances using short-wavelength UHF radio waves in the industrial, scientific and medical radio bands, from 2.400 to 2.485 GHz, and building personal area networks (PANs).

A master BR/EDR Bluetooth device can communicate with a maximum of seven devices in a piconet (an ad-hoc computer network using Bluetooth technology), although not all devices reach this maximum.

The Bluetooth Core Specification provides for the connection of two or more piconets to form a scatternet, in which certain devices simultaneously play the master role in one piconet and the slave role in another.

At any given time, data can be transferred between the master and one other device (except for the little-used broadcast mode). The master chooses which slave device to address; typically, it switches rapidly from one device to another in a round-robin fashion. Since it is the master that chooses which slave to address, whereas a slave is (in theory) supposed to listen in each receive slot, being a master is a lighter burden than being a slave. Being a master of seven slaves is possible; being a slave of more than one master is possible.

Bluetooth is a standard wireless communications protocol primarily designed for low power consumption, with a short range based on low-cost transceiver microchips in each device. Because the devices use a radio (broadcast) communications system, they do not have to be in visual line of sight of each other; however, a quasi optical wireless path must be viable.[17] Range is power-class-dependent, but effective ranges vary in practice.

Officially Class 3 radios have a range of up to 1 metre (3 ft), Class 2, most commonly found in mobile devices, 10 metres (33 ft), and Class 1, primarily for industrial use cases,100 metres (300 ft). Class 1 range is in most cases 20–30 metres (66–98 ft), and Class 2 range 5–10 metres (16–33 ft). The actual range achieved by a given link will depend on the qualities of the devices at both ends of the link, as well as the air conditions in between, and other factors.

Advantages – common technology, reasonable secure.

Disadvantages – limited range for most mobile devices, limit of seven slaves to one master.

Creating a mentally healthier world.

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Black Dog Institute, Hospital Rd, Randwick NSW 2031