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NRLS analysis summary

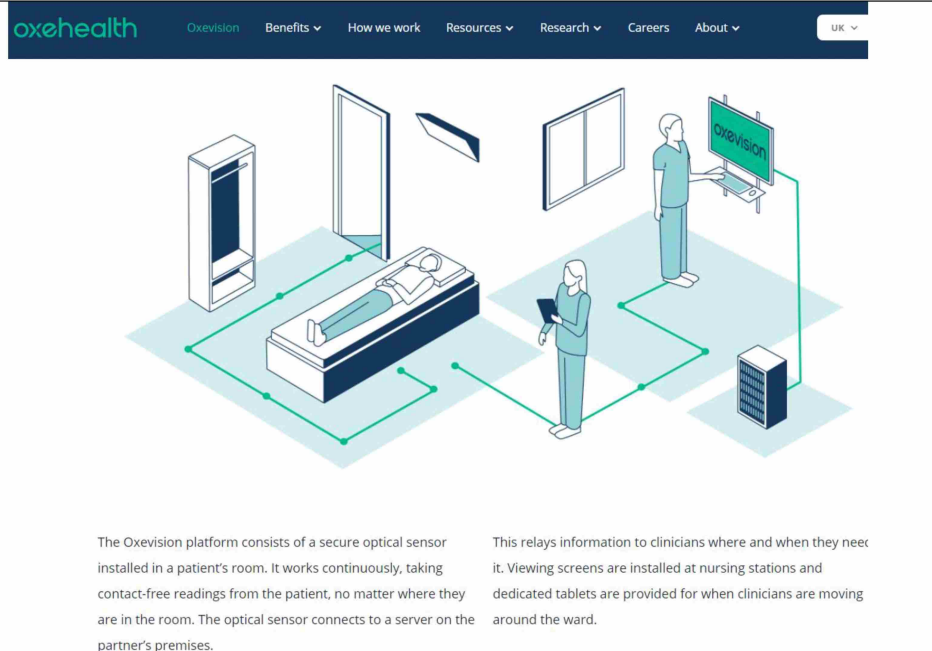
PSI010.2021

Oxehealth/oxevision

Trigger	Trigger: StEIS incident 2021/1743 <i>".....the patient was seen to be absent from the communal area on the ward. Staff member 1 used the oxehealth software to check if the patient was in their bedroom. The patient was observed to be sitting behind the bedroom door, possibly in an attempted ligature. Staff member 1 immediately responded to the bedroom, [report goes on to describe finding a ligature jammed into the door frame and the patient unconscious, blue and with no discernable breathing or pulse, and the resuscitation efforts that followed, including by ambulance staff. The patient was transferred to an acute hospital, intubated and admitted to ITU at the point of reporting, but did later recover. Insights from reported incident were added to by regional contacts supporting local investigation]."</i> In trigger incident, different perspectives on whether viewing monitor rather than going to bedroom once patient observed to be missing had sped or delayed response. It was clear device had not alerted staff to patient who had been near to a door and was unconscious, hypoxic and not breathing, but unclear whether the device would have been expected to do so.
Brief background information	Trigger incident and website information on the oxehealth/oxevision device discussed at VRM on 18 February 2021. VRM steer was to find out more about the device (including functionality and medical device indications/instructions for use) and review NRLS to look for indications of how it is being used, if staff using the device clearly understood what it could and could not do, and whether there were any indications of it affecting staff or patient behaviour in ways that may not have been intended, as we appreciate any new technology can influence safety behaviours within a complex system. An earlier CQC report on the device under its past name Digital Healthcare Assistant is on Oxehealth's 5f7e056d00b0daf56610505d_Digital_care_assistant_Care_Quality_Commission.pdf (website-files.com) MH&LD Nurse Directors' forum exchanges suggest significant and growing investment in use, with some mentions of similar devices from other companies also being tested.

**Functionality
(summarised
from Oxehealth
website**

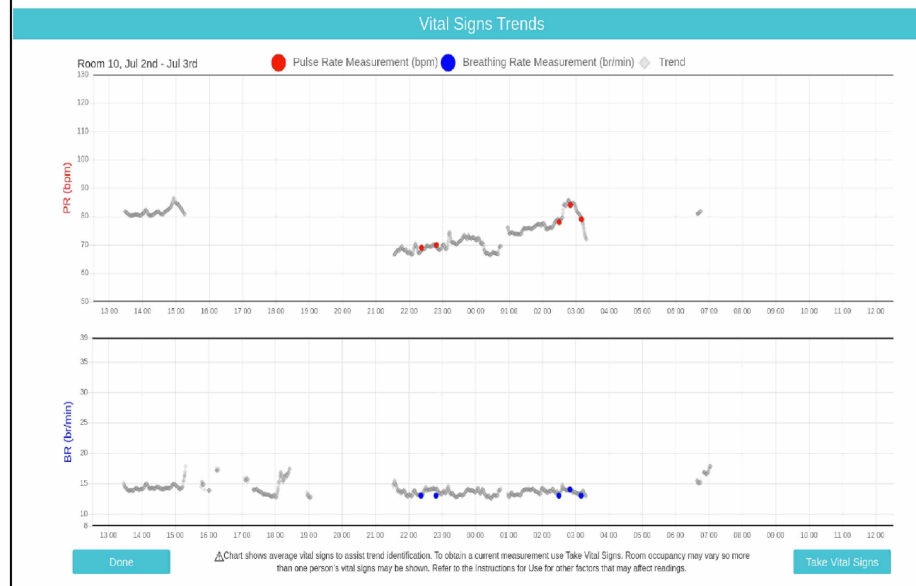
[Oxevision -
Oxehealth](#)



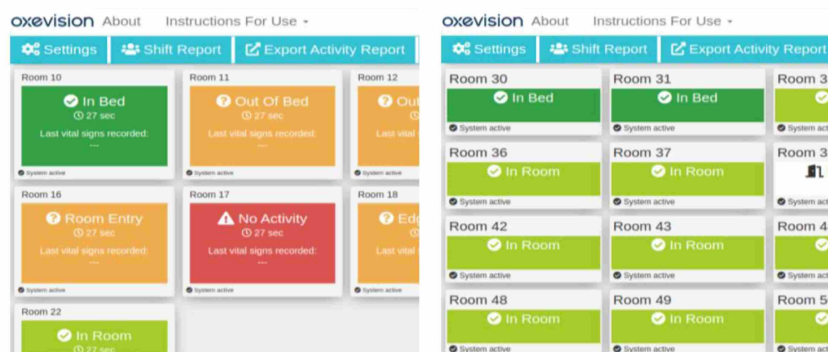
Interlinked components provided as a service; functionality appears to be:

- CCTV – 15 seconds of live video. Not continuously live to protect privacy - staff select to view, like a conventional visual observation round at level 1 (all patients typically hourly) or level 2 (typically every 15-30 minutes)
- Recording of CCTV is continuous – brief replays possible after locally agreed authorisation (e.g. moment when self-harm or fall occurred)
- Remote pulse and breathing – uses tiny oxygenation-related skin colour changes for pulse, and chest movement for respirations (first non-contact medical device to be registered to do so). The key benefit to this emphasised in the mental health unit context is that at night it allows staff to check that someone who appears unmoving in bed has a normal pulse/respiration without coming close enough to disturb their sleep
- Although IfU note only accurate when 'spot' (staff press to take, like a conventional physiological observation round after checking patient is not moving and two screen sensors have correctly located patient's body rather than another item in the room) also takes automatically every 75 seconds and charts for review later. Appears these charts have to be selectively viewed (no suggestion they 'alarm' outside certain parameters in IfU). Note on these charts that this may include the obs of anyone in room (e.g. staff)

refer to the previous section on [Viewing Vital Signs History](#).) You will then see the **Vital Signs Trends** screen below:



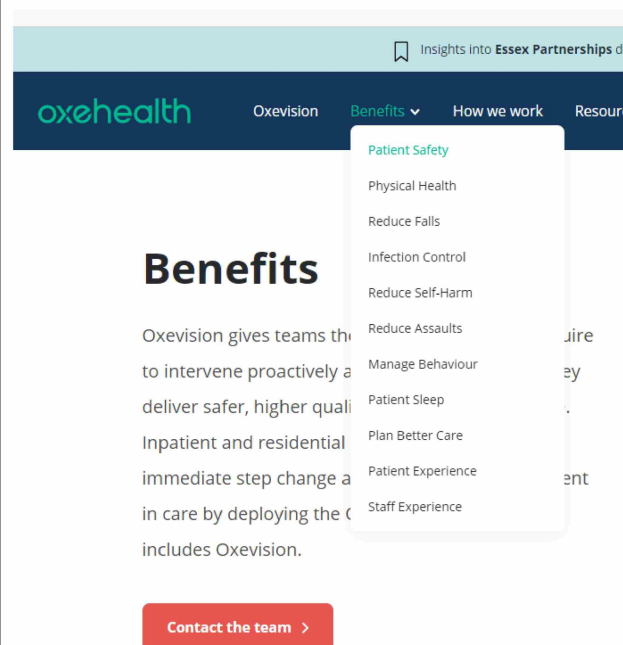
- Whilst some website materials might be read as implying can be set to alarm if patient in blind spot in room or risky areas (presumably near doors) more than x minutes, IfU suggest only settings are in bed/out of bed, in room/no activity detected/door open. Incident reports described later suggest location 'alarm' timings can be locally set for individual patient's room (e.g. alarm if in bathroom more than x minutes with x decided locally). It seems likely these alarms relate to movement trackers rather than the vital signs functionality.
- Website might be read as implying falls prevention 'algorithm' that alerts to sitting on side of bed/exiting bed and appears to require turning on once patient has settled in bed. IfU has an 'edge of bed' alert.
- 'room entry' alert sounded if extra person in bedroom



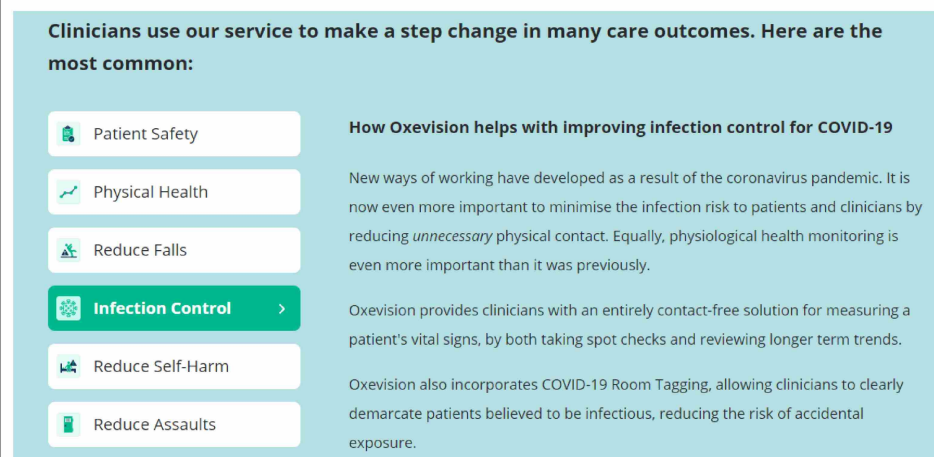
Instructions for Use (formal IfU and website advice)

The MHRA does not routinely hold IfU. An enquiry direct to Oxehealth for IfU did not result in a copy of the IfU, but MHRA since requested one on our behalf.

	It is focused on the part that is the CE marked device (spot measurement of vital signs) and for end users rather than installers. Oxehealth website information on use: Previously noted this caveat as footnote within one PDF on Oxehealth website but unsure if it is current: <i>The Oxehealth Vitals Signs device is a certified medical device in Europe. It is intended for non-invasive spot measurements of pulse rate and respiratory rate. It is a fixed-installed device for use within single occupancy rooms within hospitals, general care, domestic and secured environments where a framework exists which mandates period checks by a trained professional to ensure subject safety. See Instructions for Use for intended use, contraindications, warnings, cautions, usage directions and maintenance. The activity detection, fall risk, activity tracker and sleep products are activity trackers and do not have a medical purpose or functionality. They are not patient monitors or vital signs monitors. They cannot be used to make a medical or clinical decision.</i> Current IfU states <i>The Oxehealth Vital Signs device is intended for noninvasive spot measurement of pulse rate and breathing rate. It is a fixed-installation device for use within single occupancy rooms within hospitals, general care, domestic and secured environments where a framework exists which mandates periodic checks by a trained professional to ensure subject safety. The Oxehealth Vital Signs device is indicated for use on humans 12 years of age or older with all skin types, who do not require critical care.</i> Website evidence sources Has some staff/patient questionnaire data/quotes collected from single trusts mainly in PDFs, but one as a journal article on perceived impact on sleep quality; Introducing artificial intelligence in acute psychiatric inpatient care: qualitative study of its use to conduct nursing observations - PubMed (nih.gov). Also has locally reported falls data from one trust's dementia unit. Website indications: overall list
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Website indications: Covid-19 patient monitoring information



Note the devices can only collect pulse and respiration whereas temperature and O2 sats would usually be considered key for patients with suspected Covid-19.

Website indications: Self-harm information

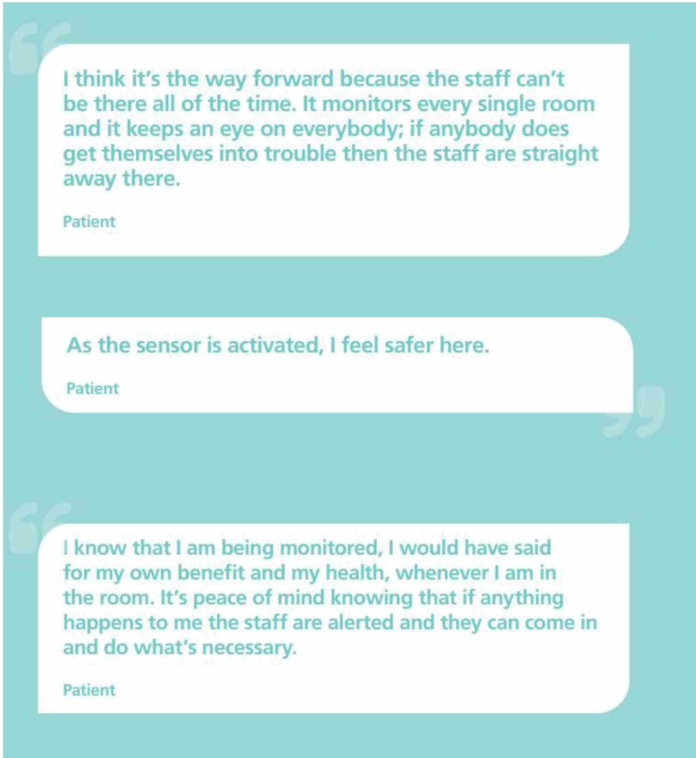
	Reduce Self Harm Clinical impact 88% Staff reported that the system enabled them to prevent incidents of self-harm 66% Reduction in bathroom ligatures 22% Reduction in self-harm in bedrooms 15% Reduction in bedroom ligatures Nothing found on website that could be source for the 66%/22%/15% figures. 88% figure may be from one of the single trust PDFs undertaking surveys of staff but not clear which one. Falls prevention information: Reduce Falls Clinical impact 92% Staff reported that the system helped them to prevent a fall 82% Reduction in harmful falls 68% Reduction in A&E 49% Reduction in emergency service visits 48% Reduction in bedroom falls at night Speak with an expert > Perhaps source is this associated PDF from Coventry and Warwickshire Trust 2017/2018 but numbers do not match (e.g. describes 33% reduction in falls in bedroom at night) 5f7dd0a836242101825e6c2b_safer_dementia_care.pdf (website-files.com)
Patient Safety Question	Can incidental or direct mentions of oxehealth/oxevision within NRLS give indications of purposes for which it is being used, if staff using the device clearly understood what it can and cannot do, and whether there were any indications of it affecting staff or patient behaviour in ways that positively or adversely affect patient safety.
Search strategy	Start incident date 1 September 2018 (the month it secured medical device registration) Date of extraction 23/2/2021

	AND All_Standard MAP ★ Start incident date 01 September 2018 (E) ★ Free text search % oxehealth % ★ Free text search % oxyvision % ★ Free text search % oxe - health % ★ Free text search % oxihealth % ★ Free text search % oxyhealth % ★ Free text search % oxe - vision % ★ Free text search % oxivision % ★ Free text search % oxevision % ★ Free text search % digital care assist%
Number of relevant incidents	This search strategy generated 136 incidents and these were all reviewed. Apart from the trigger incident all were reported as no harm or low harm, although some described inpatient self-harm requiring ED attendance. Reports came from 11 different MH trusts; most reports (N=98) came from 2020, probably reflecting wider adoption.

	Because the search was intended to answer multiple questions, findings of relevance are presented in relation to those questions below.
Themes:	Apparent patterns of use The spot checks of pulse and respirations were being used for patients in seclusion after physical restraint (N=11) or after rapid tranquilisation (N=2). Some reports suggested staff recognised a more extensive set of observations including BP and temperature was desirable (as per https://www.nice.org.uk/guidance/ng10) but patient would not have cooperated; in some it appeared assumed as the norm for seclusion rooms with these fitted. They were also used after medication error (N=1) and for an older patient in context of general health (N=1) with no clear indication why more complete physiological obs could not have been taken instead. The CCTV 15 seconds of live video function was being used to conduct all patient checks and planned intermittent frequent checks for patients in their bedrooms (N=57). Conducting observations via the device appeared routine practice in daylight hours as well as at night (75% of mentions with time stated were between 08:00 and 22:00). CCTV checks appeared to be mainly made from office monitor not iPads although reporting language is not always clear. The falls prevention function was mentioned in 25 reports of falls, generally in context of where it was used for replay to see how the patient fell, or a mention that it would be in use at night as parts of actions to prevent future falls. These reports came from only three MH trusts. Incident reports would not encompass occasions it helped staff assist patients without falling. Two of these reports suggested the systems had alarmed to alert staff of a fall: <i>Bang heard to come from bedroom and oxyhealth activated simultaneously. Upon checking patient was found on bedroom floor wrapped up in bedding.</i> <i>Oxehealth alert system sounded alert for room of patient A. Staff members L and R checked alert and it appeared patient A was on floor in bedroom.</i> Some of these reports implied it did not alert staff to patients who had fallen in their bedroom (typically describing that the patient had rolled out of bed and was found on the floor during routine in-person checks). These reports were unclear whether system was on and didn't detect this (only detecting sitting on side of bed) or the system was not turned on (as even at night, staff would turn on only once patient had settled in bed). One report implied that it had not been turned on <i>"Importance of having Oxe-Health activated for those at risk of falls."</i> One report was clear the system did not detect standing from chair <i>"Discussed with Oxehealth around adjusting algorithms to include chairs."</i> The falls replay function used to see if no potential head injury therefore no need for neuro obs (as per past NPSA Rapid Response Report) and to understand what they were doing at time of fall for future care planning.

	Setting of local location time limit alarms was mentioned in 4 reports – two referred to an alarm sounding because patient had been in the bathroom for 3 minutes, one an alarm sounding because they had been in it for 10 minutes. One report did not appear to have an alarm set, but oxehealth log of time out of bedroom was checked once staff were concerned: <i>During one of the rounds [at 01:00] a staff member reported that the shower is running on one of the shower room. Patient in bedroom 11 has been out of her room for 10 minute according to OXEHEALTH , I rushed to the shower room , along with two female staff member . The client was sat under the shower, her wrist was bleeding....</i> No reports referred to the system alarming if a patient was by a door for an excess time period.
Themes:	<u>Staff understanding of and response to device limitations</u> IfU has a range of cautions around unable to take pulse and respiratory rate measurement with any movement or tremor and if sufficient skin surface not exposed. Staff appeared to appreciate the spot checks of pulse and respirations did not function when patients were moving, for example <i>“Patient was informed that staff were going to lock his door as he needed to calm himself. Patient accepted this. Patient CD was placed on eyesight observations for the initial hour. Attempts to utilise oxehealth to record physical observations, however as he was moving this was unable to be gained.”</i> 13 reports described being unable to take these because patients had covered themselves with sheets, normal blankets, anti-tear blankets etc. Anti-tear blankets were mentioned most frequently. Some reports suggested staff expected this <i>“lying on the floor in bed space covered by a blanket such that it was not possible to take vitals”</i> other reports suggested staff needed to be made aware <i>“For staff to be aware that when blankets are over the head the Oxehealth team will not support vital signs.”</i> The inability of the device to take pulse and respiration when the patient is moving may be unlikely to be a problem in the normal MH ward environment where movement is in itself reassuring, but might be an issue post restraint/rapid tranquilisation/seclusion when agitation can accompany physiological deterioration. Two reports suggested staff believed the device would alert them automatically to a change in breathing rate: <i>“staff were completing level 2 checks and had also gone to ask patient a question to find she had hidden behind her chair and self-strangulated with an item. staff pulled alarm for assistance as initially patient did not appear to be responding if patient breathing rate had altered then the Oxehealth system would have alerted staff by alarm in the office.”</i>

	<i>"Staff one was doing random Oxyhealth check and observed person having covered her face with a pillow and writhing. Staff 1 went to check and found that she had tied a ligature using <u>an item of clothing</u>. The ligature was very tight, her face was blue and purple and she appeared to be struggling to breath wheezing and gasping for air; consequently vomited. Staff 1 pulled the alarm and staff 2 , 3 and 4 responded to the alarm. The ligature was freed from her [neck] and she appeared to be unconscious but responding to voice and touch - Oxyhealth did not alert staff."</i> Other reports suggested staff understood if they obtained abnormal physiological signs the device was not automatically alerting anyone else, and they would need to contact medical assistance. Just as with other means of taking observations, reports suggested this sometimes did not happen, although the report below may be ambiguous as to whether these were the automatic but not necessarily accurate continuous recording that may not have been seen by staff, or 'spot' measurements that would have been seen. <i>Patient had a marked increase in RR recorded on the observation chart [from 15 to 26]. OxeHealth then recorded consistent recording of 25-32. This was not escalated to the medical team and was picked up in handover when the charts were checked by the doctors. Unfortunately I do not know who recorded the observations.</i> Note NEWS2 scores cannot be calculated if only pulse and respirations are taken.
Themes	<u>Unintended impact on patient behaviour</u> One incident described a patient as 'testing' it (without harm as in constant staff presence) <i>"Patient on 1:1 observations was in her bed area talking about the oxyhealth system that had been installed and told the staff member observing her that she was "wanted to test it". Patient pulled <u>an item of clothing</u> from her pocket and wrapped it around her neck in an attempt to self-strangulate herself."</i> Website patient quotes suggest patients may believe it automatically and immediately alerts staff to any self-harm attempt (and through providing these quotes on the website, this may also give staff the impression that it does so):

	 "I think Oxehealth makes us very safe. It calls for help when you need it, but also when you don't think you need help. I find it hard to ask for help or admit I might need help, but with Oxehealth you know it alerts staff when you need them and they will come and help you."
Themes:	<u>Unintended impact on staff behaviour</u> Most information here was collected from incident reports the described the patient trying hide themselves or hide materials that might be used for self-harm or was found self-harming or attempting to self-harm (N=58). These were similar in style to typical incident reports of self-harm in the NRLS, with the difference that where a typical report might begin '<i>when doing level two observation round I saw that the patient was....</i>' these reports were identified because they used wording such as '<i>when doing level two oxehealth obs I saw that the patient was....</i>' or '<i>when doing routine obs via oxehealth I saw that....</i>' In addition to the trigger incident there were two additional reports of staff going to check the monitor to view the bedroom, rather than going direct to the bedroom, when patient noticed missing from communal areas. Whilst we can't be totally sure from incident reports, context suggested staff used the term 'monitor' or 'machine' to mean the screen in the staff office rather than an iPad they were carrying with them. <i>"During the time staff was conducting level one observations staff checked all communal areas however did not find the patient , the staff member checked the</i>

	<i>oxehealth machine and noticed the patient had appeared to have tied a ligature around her neck whilst she was in her room . Alarm was activated and staff members attended and cut the ligature.”</i> Depending on local ward layouts this could be appropriate (e.g. if monitor nearer than bedroom and the ward has other rooms or unobserved spaces that the patient may be vulnerable in). Other reports suggested staff went away to check the monitor even when outside the bedroom and concerned the patient was at risk inside: <i>“Staff member knocked on patients bedspace door, patients response was agitated and they refused to attend to medication. Staff reported this to qualified staff and both staff utilised oxihealth system to remotely monitor patient, where they observed that patient appeared to be self-harming to their left arm. Both staff attended patients bedspace where patient secreted the object used to harm themselves and refused to hand it to staff. They had cut their arm in multiple places with what was later discovered to be a an object.</i> <i>At around 00:05 staff took prn medication to patient A and noticed that her bedroom light was off. Staff checked on Oxe-health monitor and saw a chair placed on the bed upside down. method of suicide attempt</i> method of suicide attempt Other reports suggested staff were trying to take pulse and respiration via the Oxehealth monitor even though they could see patient was in a vulnerable situation, which may delay response (IfU implies this would take 30 seconds for respiratory rate plus time to confirm that it was identifying patient location correctly for spot measurement). For example: <i>At 16.00, staff on checks seen patient lay on the floor. Oxevision unable to read [pulse and respirations]. Staff entered patient bedroom saw patient had an item tied tightly around her neck, her face appeared grey in colour. [an item] was cut off, physical observations completed all within range.</i> <i>During routine oxehealth level 2 night checks staff noticed patient sitting by the corner in the bedspace and it was unclear what the patient was doing and oxehealth could not take vital signs. Staff entered the bedroom to investigate further, upon entering Patient was found self-strangling using an item which was attached to a ligature point and the other end tied tightly round her neck.</i> One report suggested the system was used before responding to patient call bells: <i>At around 19:58 patient pressed the assistance alarm in her bedroom. Checked on OxeHealth noticed that she was cleaning her arm in the basin. Staff attended</i>
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	patient reported that she had lacerated her left arm using an object and requested to go to A&E and this was facilitated. Note the section above suggests CCTV monitoring may be replacing at least some in-person checks during the day. One report suggested enhanced observation decisions may be specific to means of observation: <i>"[after a self-harm episode] he retired to his room extra observations started only using the Oxehealth machine."</i> Website materials suggest it might have a more general impact on staff visibility and interactions (e.g. references to able to leave just one staff member on the ward rather than several as iPad can be taken into team meetings).
Other findings	Monitor fitting as ligature risk: <i>"Ward manager received a report from staff nurse that they had received a telephone call to state that the recent work carried out for oxehealth in all bedrooms on the ward required anti - pick mastic to be put in place and that the wrong screws had been used which can be unscrewed by services users. This means there is currently potential ligature points and self - harm risks in all bed areas of the ward."</i> This report was followed up at our request by regional team to ensure this had been remedied in the reporting trust. Whilst this report refers to faulty fitting, general design suggests anti-ligature properties have been considered but may have complexities of interaction with room design/ceiling height.  Other miscellaneous reports related to a data breach, device faults, devices being damaged by patients, device being used to observe 'permitted' self-harm and device being used to detect illicit drug use.
Actual harm as derived from incident narrative	None of the incident reports of self-harm other than the trigger incident involved a need for emergency or critical care, so there is no evidence of past harm meeting alerting thresholds even if (as is not always clear) any delay in locating the patient/removing ligatures occurred through taking observations/checking the monitor rather than going immediately into the patients' rooms once concerned. However, use of the devices was relatively limited through most of the period under review and is increasing.
Summary	There appears to be some mismatch between the medical device authorisation and 'Instructions for Use' for the system, and the website materials suggesting how it can be used to prevent falls, prevent self-harm, monitor COVID-19 patients, etc. It is unclear if the fitting instructions are sufficiently clear to avoid creating ligature anchor point risk since no fitting instructions have been located. Whilst Oxehealth appears to undertake fitting with its own engineers, they would still need clear instructions and trusts would have responsibilities for ensuring these were safe even if they had not installed them themselves.

	There are indications that only pulse and respiratory rate is being taken in circumstances when full physiological observations should be taken, and unclear whether this is always because this was the only possible observations that could be taken. Its limitations when the patient is moving are clear, but it is less clear if all users understand the pulse detection aspect of the system will not work if all skin is covered, and that respiration rate will also be affected by some coverings. Whilst movement alarms for falls prevention are not recommended by NICE CG161, and the website materials do not make any claims for the device to be a falls detection monitor, there appeared to be a number of patients found on their bedroom floor without the system alarming, either because it could not detect rolling out of bed or because staff had not switched it on. There are some indications that staff may expect the device to perform functions it cannot actually perform (e.g. automatically alerting them to significant changes in respiratory rate). There would be a significant risk to patient safety if even a small minority of staff misunderstood this functionality. There are some indications patients may expect it to automatically and immediately alert staff if they have self-harmed, which may lead to risks that they may attempt self-harm believing staff intervention will save them from severe consequences. There would be a significant risk to patient safety if even a small minority of patients misunderstood this functionality. Ability to check the patient is alive and well without turning on the light or entering the bedroom at night is a genuine need within mental health unit environments to balance sleep quality and safety. The need to check wellbeing of the patient in seclusion rooms, when entering the seclusion room to do so may not be a safe option for staff, is also a genuine need. In common with other technology introduced in healthcare systems, there are indications that staff behaviour may change in ways that were not as intended, and potential that patients' behaviour may also change.
Planned action	To discuss at VRM • Whether MHRA would have a role in relation to promotion in lines with IfU and more clarity on what the device cannot do and/or whether direct contact with manufacturers • Whether MHRA would have a role in relation to specific fitting instructions to avoid ligature anchor point risk (and/or potentially an area to refer for Estates and Facilities colleagues' action) Other potential actions may be more in safety improvement programme (SIP) or research influence zone: • Whether the MHSIP (including in its role supporting MH&LD Nurse Directors' forum advice on new technology for prevention of self-harm) can support improved local adoption planning to help reduce unintended consequences [Note to MHRA this has since been discussed with forum

	leads who expect to provide some guidance on local adoption as part of a suite of material; aimed at reducing inpatient ligature events] • The expenditure on these types of systems is such that it might be considered a policy research question under the umbrella of “broader research aimed at testing interventions to maximise benefits whilst reducing unintended consequences” [note to MHRA the potential to propose research remains under consideration but likely it would relate to any type of remote monitoring/CCTV in MH environment]
Reviewed by	[I/S], RH, RN-MH, PhD, Deputy Director of Patient Safety (Insight)
Date completed	25 May 2021 extra redaction before sharing with MHRA undertaken 1 Sept 2021