Tees, Esk and Wear Valleys
NHS Foundation Trust

Clinical Safety Case Report

Tees, Esk and Wear Valleys NHS Trust

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Document Management

Revision History

Version	Date	Summary of Changes
1.0		First version.

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
[redacted]	Chief Information Officer		V1.0
[redacted]	Chief Clinical Information Officer		V1.0

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
DPAG	Digital Programmes Assurance Group		V1.0
[redacted]	Chief Clinical Information Officer		V1.0

Related Documents

These documents provide additional information and are specifically referenced within this document.

Ref	Doc Reference Number	Title	Version
	CRMS (V1.0)	Clinical Risk Management System	V1.0
	ODCA (V:1)	Oxehealth (DCA) - Clinical Risk Management Plan	V1.0
	ODCA (V:1)	Oxehealth (DCA) - Hazard Log	V1.0

Contents

Introduction
This document is the initial Clinical Safety Case Report developed by Tees Esk and Wear Valleys (TEWV) NHS foundation trust in relation to the Oxehealth Digital Care Assistant (ODCA). The use of ODCA in TEWV aims to improve the safety of patients and reduce the need to disturb patients' sleep and privacy.

This was produced as part of a clinical safety process to ensure ODCA is compliant with NHS Digital clinical safety requirements (as detailed in the NHS digital standards document DCB0160 (Clinical Risk Management Its Application in the Deployment and Use of Health IT Systems).

Observation of service users is by its very nature intrusive, particularly where it is for prolonged for many hours or even days, and if managed inappropriately can damage that recovery process. The use of supportive observation and engagement must not breach The European Convention on Human Rights, and in particular the right to have private life respected (Article 8). Levels should never be regarded as routine practice but must be based on assessed and current need and the use of assistive technology such as bed sensors or remote physiological observations may also be considered within the individual care plan, but it must be remembered that for some service users it may be more appropriate to retain some level of night time observation.

The Trust's Supportive Observations and Engagement Procedure (2019), is consistent with NICE Clinical Guideline 10: Violence and aggression: short-term management in mental health, a health and community setting (2015) which describes levels of observation that can be used when clinical risk levels are high; highlights TEWV's commitment to providing a safe and supportive environment to all service users recognising that the effective and appropriate implementation of supportive observations and engagement is fundamental to discharging our duty of care for people admitted into inpatient services.

A hazard workshop was held 18th August 2020 in preparation for a pilot commencing September 2020 on cedar and elm ward across four sites:

- Adult Mental Health: Psychiatric Intensive Care Unit (PICU), Cedar Ward, Darlington
- Adult Mental Health: Acute Admissions, Elm Ward, Darlington
- Medium Secure Assessment Unit for Women. Sandpiper Ward, Middlesbrough
- MHSOP: older people's acute inpatient service, Rowan Lea, Scarborough

System Definition / Overview

ODCA is a medical device that supports the observations of a patient by providing spot check pulse and breathing rate observations. ODCA technology uses an optical sensor to pay attention to a patient in a room. Oxehealth algorithms can see movement in the room, rather like a human eye would. When someone walks into a room, the Digital Care Assistant detects where they are.

It provides data to staff on high-risk activity that may lead to falls, tracks night-time behaviour, and enables nurses to measure vital signs without entering a bedroom and disturbing a patient while they sleep. There is no device connected to the patient, and the technology works even in total darkness

Salient data (raw and unblurred video footage) can be captured upon request if there is a situation that the ward would like to investigate further. Request to capture salient data must be within 24 hours via Oxehealth directly.

ODCA is being introduced across inpatient wards and seclusion rooms with the aim of improving patient care and safety, and works alongside nursing practice in order to:

- Reduce the risk of self-harm, including. ligatures and bathroom dwelling
- Reduce the risk of multiple people in room at one time
- Reducing disturbance during night-time observations

It further offers the following Alerts and Warnings.

- Out of room – where the alert is raised if the patient leaves the bedroom through the main door.
- In bathroom – where alert is raised to indicate the patient has left the bedroom and entered the bathroom / ensuite area.
- Room Entry – where an alert is raised when a second person enters an occupied room
- Activity detection – raised an alert if no activity is detected in an occupied seclusion room.

ODCA is ISO 13485 certified.

Clinical Risk Management System

The ODCA Clinical Risk Management framework is described in detail in the Clinical Risk Management Plan:

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Key personnel and their roles are identified in these documents. The key leads for the Clinical Risk Management System are the Chief Clinical Information Officer and the Clinical Safety Officers.

Any version of the Clinical Risk Management Plan and any Clinical Safety Case Reports will need to be approved by these individuals to ensure appropriate clinical safety via Digital Programmes Assurance Group (DPAG). The Clinical Risk Management Plan also documents activities and meetings associated with Clinical Risk Analysis, Evaluation and Control.

Clinical Risk Analysis

A hazard workshop was undertaken on 18th August 2020, where representatives from Experts by Experience, clinical staff involved in the pilot, the Information Department technical team, staff from supporting users and staff from the positive and safe team were invited to discuss the deployment of ODCA (Appendix One).

The Hazard workshop was compliant with the Clinical Risk Management System, and the Clinical Safety Officers completed a Hazard Workshop.

During the hazard workshop, representatives from Oxehealth gave an overview of the background and functionality of the OCDA and a guide through the process of using the device (Appendix Two)

The Structured What If Technique (SWIFT) for hazard identification was used to allow workshop attendees to identify potential hazards associated with the use of ODCA within clinical practice. Each identified hazard or cause was discussed at length during the workshop, and then following this, identified hazards were included within the hazard log and allocated a score using the Clinical Risk Matrix (Appendix Three). The potential risks have been evaluated by the clinical safety officers and discussed with key experts within the information department with conclusions logged in this Clinical Safety Case. The risk rating was difficult as the risks to patients are somewhat subjective, and it is difficult to gauge who will and who will not be adversely affected by the use of the recording sensors within their bedrooms.

20 hazards in total were identified

Technology Product - 1

People and Processes - 11

Technology product. Technology Support and People - 1

Technology product and People – 2

Technology product and Technology support, People, Process - 5

Clinical Risk Evaluation

Evaluation of any residual clinical risk has been undertaken by the Clinical Safety Officer, informed by documentation and discussion with Oxehealth system manager and TEWV CCIO. The results of this review are recorded in the final version of the Hazard Log and incorporate recommendations to mitigate the Clinical Safety Risks identified.

Technology Product

One hazard has been identified as Technology Product Hazards - ODCA07 - Secure Storage of Personal Information

Should personal Information not be stored safely, securely or encrypted this creates the potential for confidentiality breaches and a risk of a cyber-attack. The consequences of this happening could result in psychological harm to patients and would be significant however the likelihood of this happening is low, existing controls and mitigation resulting in this hazard being rated as a 2 are:

- TEWV DPIA completed (Appendix Four)
- Oxehealth has implemented an Information Security Management System (ISMS) for assessing and managing security technology and policies to ensure measured protection of all assets (including TEWV information assets).
- Oxehealth’s storage servers are within a secure facility which has strict access controls. All server room physical access and file electronic access are logged and audited.

- The facility is within an alarmed building which has 24-hour security guards.
- The Oxehealth network has a high level of electronic security to minimise the likelihood of a network based attack. It is protected with a perimeter Unified Threat Management (UTM) firewall, scanning and protecting the gateway from external threats (including intrusion prevention, anti- virus, anti-spyware and botnets).
- Staff use different sets of credentials for Virtual Private Network (VPN), remote machine access and fileserver access. Staff VPN access is granted to selected staff and is audited. Logging and pattern-based alerts are active on the firewall and VPN
- The system and network are subject to regular Penetration Testing by certified third party information security specialists.
- Whilst the data is being recorded it will be stored on the local computer equipment in the secure housing (Oxecam) or securely at TEWV (Oxeserver).
- Any data transfer over the internet will be in encrypted format.
- During transfer of the data back to Oxehealth's secure facility the servers will be always accompanied by a member of the Oxehealth team or a secure courier.
- Use of tablets have a pin code to access.
- TEWV owns the footage with Oxehealth hosting the recordings. Any recordings kept will be considered part of the patient record which is covered in the procedure.
- ISO 27001 certified
- Cyber Essentials Plus certification
- The Standard Operating Procedure (SOP) (Appendix Five) defines the process to review and delete footage including an explanation of why and who, as a minimum, is involved in the decision to capture
- Bandwidth has been fully tested across all pilot sites.

With the above existing controls, the risk has been rated as a 2 which is acceptable to proceed, no new controls identified.

People and Processes

Twelve hazards were identified as People and Process Hazards These hazards are stated as:

- ODCA01 – Triggering of Past Traumas.
- ODCA02 – Monitor May Make Patients Feel More Paranoid Dependant on Delusional Beliefs.
- ODCA03 - Loss of Patient Privacy, Dignity and Feelings of Humiliation
- ODCA09 - Optical Image Not Turned Off When Patient's Privacy And Dignity Compromised

- ODCA11 – potential negative impacts identified for six of the nine protected characteristics of the Equality Act 2010
- ODCA12 - Inappropriate location for viewing handheld mobile devises
- ODCA13 – Staff Training
- ODCA14 - Communication regarding the use of Oxevision product
- ODCA15 - Patient Leaflets in English Language Only
- ODCA18 – Mistaken Identity to Room
- ODCA19 – Consent
- ODCA20 – Observation levels

Of the 12 hazards, 8 have been rated as a 2. The potential causes of these hazards are patients past negative experiences and current vulnerable mental states, human error/misuse of the system or training issues. The consequences of these hazards occurring would be significant detrimental impact to the services user's wellbeing and recovery and on the therapeutic relationship with caregivers (ODCA01, ODCA02). Significant psychological harm and possible unlawful discrimination for six of the nine protected characteristics of the Equality Act 2010 (ODCA11). The handheld device is viewed in an unsecure environment resulting in services user's confidentiality being compromised (ODCA12). Physical harm to services users if the system is the only means of carrying out patient observations rather than augmenting patient observations (ODCA20) or if there is a case of mistaken identity (ODCA18). A common theme to all these hazards is the psychological and physical harm patients can experience due to staff not being trained or not being competent to use the system (ODCA13). The consequences for the final two hazards in this section are considerable as patients would be denied accurate and important information about their care and they would not be aware of the full scope of the system (ODCA15) and the patient could lose trust in the service which could in turn impact on therapeutic relationships and the recovery process or the patient refuses admission and therefore is detained under the mental health act (ODCA19).

Existing controls for ODCA01 - Triggering of Past Traumas and ODCA02 – Monitor May Make Patients Feel More Paranoid Dependant on Delusional Beliefs are:

- The SOP details the processes to be followed/adhered to when using the Oxehealth Oxevision system to conduct patient observations within ward patient bedrooms.
- Explanation re the use of the Oxevision monitor will be given verbally by staff during the admission process. Written information (Appendix 7) will be provided to the patients within the ward information pack provided on admission, this will detail what, when and how patient activity and vital sign measurements will be recorded in the bedroom area. Any queries the patient or family members have must be answered in full and a record documented in the patients' health record.
- Oxevision should be used as part of the care planning process with the involvement of the service user where possible. The use of Oxevision should be based on individual patient need to ensure that there is no potential for a negative impact to

occur for service users and individualised care plans will reference the discussion with the service user/carer

- Reasonable adjustments should be made for service users who require a different protocol to that outlined in the SOP, to avoid unlawful discrimination.

With the above existing controls, the risk has been rated as a 2 which is acceptable to proceed, no new controls identified.

Existing controls for ODCA11 - potential negative impacts identified for six of the nine protected characteristics of the Equality Act 2010 are:

- The device is indicated for use on adults and adolescents over 12 years old with all skin types. Oxevision WILL NOT be switched on in bedrooms where the occupant is under 12 years old. This information will be cascaded during the training.
- The SOP states that Oxevision should be used as part of the care planning process with the involvement of the service user where possible.
- The Equality Impact Assessment (Appendix Six) states that the use of Oxevision should be based on individual patient need to ensure that there is no potential for a negative impact to occur for service users with protected characteristics i.e., Age, Religion and Belief, Gender Reassignment, Sex, Sexual Orientation, Pregnancy and Maternity, Disability and Race.
- Reasonable adjustments should be made for service users who require a different protocol to that outlined in the SOP to avoid unlawful discrimination.
- This will also ensure that service users are being treated with dignity and respect and that their privacy and confidentiality is always upheld when Oxehealth is in operation.

With the above existing controls, the risk has been rated as a 2 which is acceptable to proceed, no new controls identified.

Existing controls for ODCA12 - Inappropriate location for viewing handheld mobile devises are:

- staff to access Oxevision handheld mobile device in appropriate setting to minimise risk of viewing from other parties
- staff will receive training and reach a level of competency and understanding of the correct and appropriate use to ensure that confidentiality is always maintained
- TEWV Information Governance Policy (Appendix Eight)

With the above existing controls, the risk has been rated as a 2 which is acceptable to proceed, no new controls identified.

Existing controls for ODCA15 - Patient Leaflets in English Language Only

- Verbal information upon admission and written information contained in the patient information leaflet states that the service user can request the information in alternative formats or languages.

With the above existing controls, the risk has been rated as a 2 which is acceptable to proceed, no new controls identified.

Existing controls for ODCA18 – Mistaken Identity to Room are:

- staff to ensure that patients are assigned to correct room on device
- process described in SOP.
- All staff undergo training prior to using system Staff training (see ODCA13, p.11).
- Use alternative checks to establish patient wellbeing

With the above existing controls, the risk has been rated as a 2 which is acceptable to proceed, no new controls identified.

Existing controls for ODCA19 – Consent

- Oxevision is part of routine clinical care, therefore consent is not required, and the system cannot be turned off in individual services user's bedrooms.
- Privacy notice - We do not need your consent to use your personal information for the delivery of direct care because we are an NHS Trust. We use personal information because it is necessary for us to use this to carry out our activities as an NHS organisation.
- This is not seen as a blanket restriction as the CQC have cited it as good practice in their 'Driving improvement through technology Case Study' (Appendix Nine)

With the above existing controls, the risk has been rated as a 2 which is acceptable to proceed, no new controls identified.

Existing controls for ODCA20 – Observation levels are:

- Oxevision can only be used for patients' risk assessed as being nursed on general observation and engagement observations when in their bedroom areas and is not for those that are assessed as requiring a higher level of observation and engagement. The SOP makes clear that it complements the Trusts Observations and Engagement Policy and does not replace it. This information will be cascaded as part of the training protocol.
- Staff training (see ODCA13, p.11)

With the above existing controls, the risk has been rated as a 2 which is acceptable to proceed, no new controls identified.

The remaining 4 hazards are rated as a 3, which is defined in the matrix as:

> "*Undesirable level of risk. Attempts should be made to eliminate the hazard or implement control measures to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical"*

These hazards are stated as:

- ODCA03 - Loss of Patient Privacy, Dignity and Feelings of Humiliation
- ODCA09 - Optical Image Not Turned Off When Patient's Privacy And Dignity Compromised
- ODCA13 – Staff Training
- ODCA14 - Communication regarding the use of Oxevision product

Existing controls for ODCA03 - Loss of Patient Privacy, Dignity and Feelings of Humiliation are:

- The Oxevision System is continuously on as the system is constantly working to provide real-time alerts to high-risk activity and real-time reports on patient activity/behaviour as well as the Vital Signs functionality.
- Personally identifiable salient video data, although recording on a continuous 24-hour loop, is not monitored, observed or retained unless a request for a clipped section Is made by TEWV or by engineers at Oxehealth and is automatically deleted after 24 hours if it is not requested for capture.
- There is a strict protocol in place that governs the retention and viewing of personally identifiable salient video data as detailed in the SOP. The nurse in charge will request for Salient Video Data to be "clipped" and saved before it is recorded over through the Oxehealth customer service call line that operates 24/7, 365 days a year. This request must be received within 24 hours before the Salient Video Data is automatically deleted. At the point of request, Oxehealth will acknowledge it immediately and clip the data remotely, pending review.
- A discussion will occur between the relevant Head of Nursing and The Matron/ Ward Manager to decide whether the Salient Video Data will be released from Oxehealth to the ward, this discussion will consider, reason for request, severity of the incident, patient consent and confidentiality. Outside of normal working hours the Nurse in Charge will make the request for data to be 'clipped' for review on the next working day.
- Following confirmation to Oxehealth that the Salient Video Data is required, Oxehealth will send personnel to the Server Location to collect the encrypted data, and Oxehealth will then securely deliver the data clip as encrypted video file within 72 hours of collecting it from the Server Location (if request raised Mon - Thurs) or 96 hours of collecting it from the Server Location (if request raised Fri – Sun) to the Trust in line with their Salient Data Request process – provided the Trust provides immediate access to the Location to collect and deliver the Salient Video Data. This will be received by relevant Modern Matron or Ward Manager in their absence.
- For any salient data released, any patient or staff members will need to be informed.

- Salient Video Data will be securely deleted at the end of the project or when no longer required, whichever is the earlier. In addition, TEWV can request that Oxevision delete Personally Identifiable Salient Video Data at any time. To support this, all data files are date and time stamped so that retention can be tracked.
- Oxehealth undertakes periodic reviews with TEWV to consider the Personally Identifiable Salient Video Data held, the reason for the data retention and confirmation of Personally Identifiable Salient Video Data deleted.
- At least twice per year, Oxevision provides TEWV with a Salient Video Data Report which confirms the purpose, principles and review process for any Personally Identifiable Salient Video Data collected for the Partner and a log of the personal data retained, reasons for retentions and date of next review. Oxevision will process all personal data generated in the project in accordance with the contract, DPIA and any other documented instructions from TEWV, the Data Controller.

Existing controls for ODCA09 - optical image not turned off when patients privacy and dignity compromised are:

- Staff training (see ODCA13, p.12)
- The Oxevision System is continuously on as the system is constantly working to provide real-time alerts to high-risk activity and real-time reports on patient activity/behaviour as well as the Vital Signs functionality.
- The SOP dictates that It is the responsibility of all care staff within an environment where Oxevision is installed to be familiar with the Oxevision system in their routine observation of in-patients on the ward.
- Additional resources and training are available on the Intranet and the “Instructions for Use” can be found in Appendix 1 of the SOP.

With the above existing controls, and the addition of further controls of training being expanded to include appropriate and inappropriate use of system. What to do if person is in compromising position, sharing info from individual care plans, ensuring care plans are adhered to Staff will immediately turn off the optical image if patient is in a compromising position when taking vital signs and try again later and the postponing of the taking of readings if when they access the camera, the patient is in a compromising position is referenced in the SOP the risk would be rated as a 2 for both hazards which is acceptable.

Existing controls for ODCA13 – Staff Training are:

- All new starters going forward will receive training from Oxehealth or Oxevision Champions and there is an electronic Oxevision user guide to refer to. Oxehealth champions will be identified to deliver training to new ward staff, agency workers and bank staff, this means that training can be delivered to the team in a consistent manner. Staff will be signed off as competent to use the system by the trainer.

- The SOP dictates that It is the responsibility of all care staff within an environment where Oxevision is installed to be familiar with the Oxevision system in their routine observation of in-patients on the ward.
- Staff must be trained and deemed competent on the Oxevision system before use. All direct care staff (permanent, temporary, agency and bank staff) will be given training in how to use the system. This will be via local cascade Oxevision trainers / champions
- It is the responsibility of the nurse in charge to ensure that only staff that are trained in the use of the equipment are allocated to patient observations that require its use.
- Additional resources and training are available on the Intranet and the “Instructions for Use” can be found in Appendix 1 of the SOP

With the above existing controls, the risk has been rated as a 3 which is unacceptable, however, the risk rating could be reduced to a 2 if training were expanded to include appropriate and inappropriate use of system, what to do if person is in compromising position, sharing info from individual care plans, ensuring care plans are adhered to, staff immediately turning off the optical image if patient is in a compromising position when taking vital signs and try again later.

The potential cause of hazard ODCA14 is that written, or verbal communication is not transparent and does not meet trust values of respect and responsibility.

The consequence of this would be significant as patients would not be aware of the full scope of the system. Although the Patient information Leaflet (Appendix Nine) states that the technology uses cameras, further down it refers to ‘data’ being kept for 24 hours. The system records personally identifiable salient video data. The statement on the leaflet Is not clear and transparent and does not reflect that the data stored is personally identifiable salient video data.

> *Data from Oxevision is only be stored for an agreed period. The Trust may request data to assist with incidents, however, the Trust would need to make the request within 24hrs as after that the data is not available.*

The information would be more transparent and therefore reduce the risk to an acceptable level if it were to inform patients and carers that although video recording is on a continuous 24-hour loop, it is not monitored, observed or retained unless a request for a clipped section is made by TEWV or by engineers at Oxehealth and is automatically deleted after 24 hours if it is not requested for capture.

Technology product. Technology Support and People

One hazard was identified as Technology Product, Technology Support and People Hazard, ODCA04 - Unable to obtain footage of incidents. The possible causes of this would be broken equipment, technical issues in uploading/loss of data, lack of connectivity. The consequence of this occurring would be significant in that it may not be possible to obtain footage that would provide evidence of incidents and therefore promote future patient safety.

Existing controls for ODCA04 are:

- There is a service level agreement in place to cover servicing of equipment.

- Protocol covers safety checks on monitor before issue - daily checks. A fault logging process will be agreed across pilot sites to monitor issues raised during the pilot.

The possibility of this occurring is very low and has been rated as a 1, acceptable as existing controls are robust, and no further action is required.

Technology product and People

One hazard was identified as a technology product and people hazard, ODCA10 - Safeguards to Ensure Individual Care Plans Are Adhered To. The potential cause of this hazard is that there is no individual password protection log in on the viewing monitor/handset. The consequence of this occurring could result in a negative impact for service users with protected characteristics resulting in psychological harm however the likelihood of this happening is low. Existing controls and mitigation resulting in this hazard being rated as a 2 are:

- there is a footprint of when the cameras have been activated and how long for
- the audit trail would be the completed paris documentation of recorded observation results which provides a signature and a date/time stamp

Individual log-in's could be provided for all staff members using the system. The addition of this extra security layer would reduce the risk level to a 1.

Technology product and Technology support, People, Process

Five hazards have been identified as Technology Product, Technology Support, People and Process Hazards. These hazards are stated as:

- ODCA05 - Risk to Confidentiality of Patient Information
- ODCA06 - Pulse Rate or Breathing Rate Observations Are Falsely Reassuring
- ODCA08 - Alert Not Working
- ODCA16 - Oxevision Tablet Not Working
- ODCA17 - Environmental Impact

Of the five hazards, three have been rated as a 2. ODCA06, ODCA08, ODCA17. The potential causes of these hazards are rhythmic movements (voluntary or induced by some means) of the services user's body, that the software could mistake as a pulse rate or breathing rate, failure modes in optical hardware, failure modes in hardware software or network communications, mistaken deployment of unapproved software release, malicious intrusive activity, or user error (ODCA06); equipment broken, technical issues. network issues, user error (ODCA08) or environmental factors that may introduce a reading that the software could mistake as a pulse rate or breathing rate for example oscillating fans, a shower curtain blowing in a breeze, or a second occupant in the room, creating a pulse rate or breathing rate that does not belong to the patient (ODCA17). The consequences of these hazards occurring would be significant, with crucial patient data not being available which could lead to a delay in caregiver attending the service user and therefore the service user not receiving appropriate intervention resulting in physical or psychological harm or distress.

Existing controls for ODCA06 are:

- If for any reason there is a technical failure/malfunction of the system, then staff must revert to the manual taking/recording of observations as detailed in the Trusts Observations and Engagement Policy. This may require an increase in the level of a person's observations.
- Existing physical and IT system security to prevent unauthorised access to patient data (see ODCA07, p.7).

With the above existing controls, the risk has been rated as a 2 which is acceptable to proceed, no new controls identified

Existing controls for ODCA08 are:

- Staff training (see ODCA13, p.12)
- This system is to be used in addition to routine observations, it does not replace them.
- Use of other means to establish patient wellbeing should be used as described in the SOP and defined in the Trusts Observation and Engagement policy.
- Oxehealth monitor the Oxevision System 24/7 to ensure it is running as expected. For most of the issues that arise, the Oxehealth team can undertake a remote diagnostic & fix the issue remotely.
- If the issue cannot be resolved remotely and a site visit is required, depending on the severity of the issue and site access requirements, we are typically on-site to diagnose the issue (and typically resolve) within a few days.
- Oxehealth are always in communication with the relevant teams (i.e. Estates, Ward) to ensure it is appropriate to visit, and will work around the staff and ward.

With the above existing controls, the risk has been rated as a 2 which is acceptable to proceed, no new controls identified.

Existing controls for ODCA17 are:

- Use alternative, (face to face), checks to establish patient wellbeing.
- The SOP makes it clear that Oxevision complements the Trusts Observations and Engagement Policy and does not replace it.
- This information will be cascaded as part of the training protocol (see ODCA13, p12)
- Algorithms are reviewed and issues resolved following feedback from staff

With the above existing controls, the risk has been rated as a 2 which is acceptable to proceed, no new controls identified.

The two remaining hazards ODCA05 - Risk to confidentiality of patient information and ODCA16 - Oxevision tablet not working are rated as a 1. The potential causes of these risks

Cyber-attack, malpractice, people viewing the footage in non-secure environment, malicious and intrusive activity, accidental loss, or theft of hardware containing patient data (ODCA05); no network connection, user error (ODCA16). The consequence of these hazards occurring would be significant in that service user's confidentiality would be compromised creating psychological harm or distress or there could be a delay in staff administering appropriate intervention which would result in significant physical harm to the service user.

Existing controls for ODCA05 are:

- Protocol defines the process to review and delete footage including an explanation of why and who as a minimum is involved in the decision to capture.
- TEWV DPIA (Appendix Four)
- Existing physical and IT system security to prevent unauthorised access to patient data (see ODCA07, p.7).
- Training covers appropriate and inappropriate use (see ODCA13, p.12)
- TEWV owns the footage with Oxehealth hosting the recordings. Any recordings kept will be considered part of the patient record which is covered in the procedure.

With the above existing controls the risk has been rated as a 1 which is acceptable to proceed and no further action is required.

Existing controls for ODCA16 are:

- Use of other means to establish patient wellbeing
- customers services number
- Training and training leaflets (see ODCA13, p.12 and SOP Appendix 5)

With the above existing controls the risk has been rated as a 1 which is acceptable to proceed and no further action is required.

Clinical Risk Control

Evaluation of any residual clinical risk has been undertaken by the Clinical Safety Officer, informed by documentation and review or discussion CCIO. The results of this review are recorded in the final version of the Hazard Log and incorporate recommendations to mitigate the clinical risks identified.

Design Control:

- TEWV need to consider redesigning patient information leaflets to ensure transparency in order to meet trust values of respect and responsibility. Although the Patient information Leaflet states that the technology uses cameras, further down it refers to 'data' being kept for 24 hours. The system records personally identifiable salient video data. The statement on the leaflet Is not clear and transparent and does not reflect that the data stored is personally identifiable salient video data. The information would be more transparent if it were to inform patients and carers that although video recording is on a continuous 24-hour loop, it is not monitored, observed or retained unless a request for a clipped section is made by TEWV or by engineers at Oxehealth and is automatically deleted after 24 hours if it is not requested for capture.
- TEWV could request that the system be upgraded to provide individual log-in's for all staff members using the system. The addition of this extra security layer would allow a more robust audit trail
- TEWV could ensure a range of patients and carers in addition to staff are involved in the review of the use of the monitor during the pilot. This could include interviews and/or focus groups to formally evaluate the pilot in order to identify further controls that would mitigate further against all/some risks and reduce their ratings.

Training Control:

- Training needs to be expanded to include appropriate and inappropriate use of system. What to do if person is in compromising position, sharing info from individual care plans, ensuring care plans are adhered to

Hazard Log

The Hazard Log for this Clinical Safety Case can be found on the following link:

Copy of Oxehealth- Hazard Log (V1.0) draft August 2020.xlsx

Test Issues

No outstanding test issues.

Summary Safety Statement

The Oxevision pilot commenced on 23/11/2020 on Elm, female acute and Cedar, mixed PICU, in and on 23/11/2020/ Rowan Lea, mixed older adult.

All hazards considered it is recommended the pilot continue as there is evidence that the system improves patient safety, positively impacts on risk management and least restrictive practice, and enhances patient experience and care quality. However it is recommended that TEWV consider the following mitigations in order to reduce risks further:

- Patient information leaflets are updated to ensure transparency in order to meet trust values of respect and responsibility. Currently the statement in the leaflet Is not clear and transparent and does not reflect that the data stored is personally identifiable salient video data. The information would be more transparent if it were to inform patients and carers that although video recording is on a continuous 24-hour loop, it is not monitored, observed or retained unless a request for a clipped section is made by TEWV or by engineers at Oxehealth and is automatically deleted after 24 hours if it is not requested for capture.
- Investigate the possibility of introducing individual log-in's for all staff members using the system. The addition of this extra security layer would allow a more robust audit trail
- The process and areas for evaluating the effectiveness of the pilot is determined in order that extensive evidence can be collated to support the positive findings and review the identified hazard from a patients/service user perspective in order to identify additional controls that would mitigate further against all/some risks and reduce their ratings.
- Training needs to be expanded to include appropriate and inappropriate use of system. What to do if person is in compromising position, sharing info from individual care plans, ensuring care plans are adhered to

Any issues encountered during the pilot will be recorded on Datix and or via the IT support desk and will be shared with the Clinical Safety Officer team via email [redacted]

Quality Assurance and Document Approval

This clinical safety case report is to be discussed and signed off at the Digital Programmes Assurance Group (DPAG), prior to discussion at the Senior Leadership Group and the Operational Delivery and Development Group and then the Trust Board. The report and hazard log will also be presented and considered by NHSD. This process is detailed within the Clinical Risk Management System.

Configuration Control / Management

Oxehealth Oxevision system control and management will be business as usual through corporate systems. If any major changes are made to the system, or significant issues

identified through Datix (web-based incident reporting and risk management software), the case should be reviewed with an update of the Hazard log and the Clinical Safety Case, where the case will be re-presented and discussed within the DPAG.

Appendix One

Hazard Workshop Attendees

Clinical Safety Officers

[redacted] workshop lead

[redacted]- CSO

[redacted]- CSO

Associate Director of Nursing

[redacted] – Project Lead

AMH Acute Admissions, Elm Ward West Park Hospital. Darlington

[redacted]

MHSOP: older people's acute inpatient service, Rowan Lea, Scarborough

[redacted]

Secure Inpatient Services: Sandpiper Ward female medium secure services

[redacted]

AMH: Psychiatric Intensive Care Unit (PICU), Cedar Ward, Darlington

[redacted]

Information Services

[redacted] – unable to attend

Service user/Carer Representation

7 attendees

Appendix Two

Workshop slides

T:\Clinical Safety\OXEHEALTH\Oxehealth hazard workshop slides.pptx

Appendix Three

Risk Classification Matrix

Clinical Risk Management Risk Matrix

Likelihood						
	Very High	3	4	4	5	5
	High	2	3	3	4	5
	Medium	2	2	3	3	4
	Low	1	2	2	3	4
	Very Low	1	1	2	2	3
		Minor	Significant	Considerable	Major	Catastrophic
		Consequence				

Risk Matrix key - Severity

5	Unacceptable level of risk.
4	Mandatory elimination or control to reduce risk to an acceptable level
3	Undesirable level of risk Attempts should be made to eliminate or control to reduce risk to an acceptable level. Shall only be acceptable when further risk reduction is impractical.
2	Acceptable where cost of further reduction outweighs benefits gained.
1	Acceptable, no further action required

Hazard likelihood definitions

Likelihood Category	Interpretation
Very high	Certain or almost certain; highly likely to occur
High	Not certain but very possible; reasonably expected to occur in the majority of cases
Medium	Possible
Low	Could occur but in the great majority of occasions will not
Very low	Negligible or nearly negligible possibility of occurring

Hazard Consequence definitions

Consequence Classification	Interpretation	Number of Patients Affected
Catastrophic	Death	Multiple
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Multiple
Major	Death	Single
	Permanent life-changing incapacity and any condition for which the prognosis is death or permanent life-changing incapacity; severe injury or severe incapacity from which recovery is not expected in the short term	Single
	Severe injury or severe incapacity from which recovery is expected in the short term	Multiple
	Severe psychological trauma	Multiple
Considerable	Severe injury or severe incapacity from which recovery is expected in the short term	Single
	Severe psychological trauma	Single
	Minor injury or injuries from which recovery is not expected in the short term.	Multiple
	Significant psychological trauma.	Multiple
Significant	Minor injury or injuries from which recovery is not expected in the short term.	Single
	Significant psychological trauma	Single
	Minor injury from which recovery is expected in the short term	Multiple
	Minor psychological upset; inconvenience	Multiple
Minor	Minor injury from which recovery is expected in the short term; minor psychological upset; inconvenience; any negligible severity	Single

Appendix Four

Data Protection Impact Assessment

T:\Clinical Safety\OXEHEALTH\CSI065 Oxehealth Monitoring System (DPIA) v2.doc

Appendix Five

Standard Operating Procedure

T:\Clinical Safety\OXEHEALTH_SOP for using Oxehealth v4 -.doc

Appendix Six
Equality Impact Assessment

T:\Clinical Safety\OXEHEALTH\Oxehealth EIA (002).docx

Appendix Seven

Observation and engagement policy

T:\Clinical Safety\OXEHEALTH\Supportive Observations and Engagement Procedure.pdf

Appendix Eight

Information Governance Policy

T:\Clinical Safety\OXEHEALTH\Information-Governance-Policy.pdf

Appendix Nine

Driving Improvement Through Technology Case Study

Digital care assistant | Care Quality Commission (cqc.org.uk)

Appendix Ten

Patient Information Leaflet

T:\Clinical Safety\OXEHEALTH\Draft 3 Oxevision PCI - KS RM JB (002).docx

Appendix eleven

Patient Information Posters

T:\Clinical Safety\OXEHEALTH\200611 Oxehealth Elm Ward Patient Information.pdf

T:\Clinical Safety\OXEHEALTH\200710 Oxehealth Cedar Ward Patient Information.pdf