

VRM Update May 29th, 2022 OFFICIAL: SENSITIVE: PERSONAL <i>This is a draft document produced for internal processes</i> Not for onward circulation without prior permission from NHS England & NHS Improvement Patient Safety team	
PSI reference	PSI 010.2021
Issue title	Oxehealth/Oxevision for inpatient suicide prevention
Previous NRLS Review	 20210527 - NRLS review oxehealth oxi
Actions agreed last time the issue was at VRM	Update provided at VRM on 17/3/2022: <i>Email summary on file. Key actions have been in MHRA's gift and they are steadily making progress on making changes to how oxehealth should be used to prevent suicide and falls etc. MHRA is going to share the miniscope with Oxehealth as they would like to learn from our findings - this may instigate a regular feed of data via a DSA. [I/S] is keeping on top of the quality of materials produced by Oxehealth. Although not currently at the point for future action, it was suggested that leaflets and training materials/guides could be produced - taking into consideration that those trusts who already use the device may not pick up on new materials/resources. The question of potential need for research was posed in the miniscope but not a formal VRM action but Taofikat may consider as a potential policy research application stream for MTM to consider for next publication.</i> NOTE: [I/S] - NHSE lead nurse for mental health within CNO Actions: All complete [I/S] to raise with MHRA mismatch between medical claims on website and IfU using only the vital signs tracker is a medical device; especially active risk to patient safety if website materials imply to patients or staff it has automatic alerting functionalities it does not have [I/S] to raise with MHRA difficulty accessing IfU, which even at the technical level of how to use the vital signs risk reliance of users on website which does not include cautions and contraindications [I/S] to raise with MHRA no information on safe fitting of monitors to avoid ligature risk when monitors linked to the medical device; incident of unsafe fitting reported and providers would be unable to check if no information on safe installation made available outside company. If this is not fruitful, may have to take through Estates and Facilities route [I/S] to take forward discussion with MHSIP how to best take forward; likely initial meeting with MHSIP plus one or more MH Chief Nurses supporting the MHSIP programme to discuss how to make users and future users of Oxehealth more aware of challenges of avoiding unintended consequences, and risks of staff and patient belief mismatch with device functionality leading to false reassurance that help will be automatically summoned. Best routes and timings need to be considered, but VRM supports findings of miniscope being fully understood by senior leaders in all organisations using or introducing the device. - Potential for alert to be revisited if any other workstreams identify clear constructive actions
Reason for bringing back to VRM	To log additional developments and to understand whether we hold this item on the TL with updates from the MH SIP?
Is issue still clearly in NHSE/I remit	Yes, although under the guidance of the Mental Health teams now.

Evidence of harm threshold met  Oxehealth Field Safety Notice-FSN-G	Oxehealth/Oxevision have been fully engaged in our discussions and concerns. Regulatory intervention from the MHRA as a result of our intervention has led to Oxehealth/Oxevision issuing a FSN for an issue that had been resolved however correct procedure had not been followed in notifying users. Changes to their website and training and educational resources and materials are now also being reviewed. As a result of these changes and oversight from the national Mental Health leads at NHS England, the level of harm is likely to be less than when this was identified.
Possible options available for addressing risk at source	Specifically, for the Oxehealth/Oxevision product: • Oxehealth issued a FSN following intervention from the MHRA • national Mental Health leads are involved in a working group to assess and evaluate training and education materials and Oxehealth/Oxevision is the first working example. For wider monitoring of vision based patient monitoring technologies • [I/S] have met with Christina Farrow – lead at NHS England for the Innovations team to discuss how PS team are more involved in the review of products selected for the innovation process • I requested that MHRA consider sharing learning on digital health technologies (DHT) with their Notified Bodies using the Oxehealth/Oxevision product as an example • Formation of a MH working group with the following objectives: Objectives of the group The purpose of this Group is: • To gather lessons learned and good practice from use of vision-based patient monitoring across mental health wards • To develop a report on recommendations that will support safe use for patients, staff and organisations. This may include the development of national guidance on appropriate use and system monitoring to support with local adoption and implementation • To identify and share best practice for patient engagement and education, and develop a framework for consent that supports local decisions on the most appropriate consent model • To look at opportunities for future engagement and research in the field to inform future developments and continuous improvement.
Is this still apparently new/under recognised	DHTs are growing exponentially and therefore although this may have been considered new or under-recognised this intervention has led to both increased regulatory awareness through the MHRA and also within the mental health arena. The Working Group to review vision based patient monitoring technologies will hopefully establish standards for such products to ensure there is full review of training and education materials, the purpose of the technology and also the process for consent and patient awareness and understanding.
Has constructive action been identified	Yes – this has been very constructive and has exposed the need for wider oversight of this type of product by the regulator and within the mental health setting.
Are new national resources or interventions available/possible (Y/N/M/unclear)	Membership of the Working Group for vision based patient monitoring technologies has membership including: • clinical nursing advisors (from the Nurse Directors Forum) • experts in patient, carer and family engagement • an expert in technical knowledge, data and information governance • an expert in human rights and law • representation from a supplier of vision based patient monitoring

Proposal	Discussion with the wider PS team within the Mental Health SIP programme has been beneficial and they (Heather Pritchard) is happy to join the Working Group and monitor the outputs from this as much as capacity allows. Heather P is also linked to [redacted] as per the email extract which will be put on file: <i>I am happy to support as discussed. I will need to understand the expectation in relation to the length and amount of involvement that will be needed from me. I am meeting with Heather Caudle about Suicide in a couple of weeks, I will take the opportunity to understand the progress in relation to sharing the learning from the mini scope with the forum members.</i> Consideration therefore whether this should remain on the TL in order to receive feedback from the MH SIP team?
Completed by	[redacted] Patient Safety clinical lead for medical devices, May 12th 2022