From: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]
Sent: 3/17/2022 8:25:12 AM
To: [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]
CC: [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]; JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S] WOOD, Frances (NHS ENGLAND & NHS IMPROVEMENT - X24)
Subject: Oxehealth roundup PSI010.2021

Hi all

I said I'd bring verbal highlights to VRM today, but might help me update more clearly if Kerri/Nima could show this email as well as use for tracking log. I'll send a batch of emails evidencing the parts below to Kerri for tracking log.

We are making progress.

The first three original actions we agreed at VRM related to influencing MHRA in relation to formal and informal instructions for use (including website) and medical device status in relation to use to prevent self-harm, use to prevent falls, continuous versus spot monitoring of pulse and blood pressure, and fitting consoles to avoid ligature risk.

Sarah and me met Oxehealth once with MHRA 27 October 2021 – MHRA pursued the regulatory angle whilst I tried to appeal to their better nature and asked them to reduce the risk of staff/patients misunderstanding what the device will do, even if they were not legally required to. There have since been two rounds of MHRA posing questions to Oxehealth in writing and Oxehealth formally responding, third round about to be sent by MHRA. Each time MHRA asks us if we have any questions to add. MHRA have been steady but persistent on the regulatory angle, Oxehealth initially defensive response to MHRA but becoming more responsive now that MHRA making it clear they are on unsteady ground if saying it prevents self-harm and falls whilst stating it is not a medical device except when it takes your pulse and respiration. Oxehealth have recently begun to make some changes to website and training material – weak changes so far and need to make more, but movement now in the right direction and MHRA is clearly on the case. Sarah has stayed alongside through all these and probably just needs Sarah to continue supporting MHRA on pushing those improvements as far as they can go from a regulatory/IfU angle. We have told MHRA at this point they can share the miniscope with Oxehealth and the NRLS team would consider a data sharing application from Oxehealth for the purposes of continuous improvement should they make one.

We had a new development when a patient complained to a newspaper about Oxehealth being intrusive of their privacy once they'd recovered from an acute MH spell, with an especial concern that they'd consented to the CCTV element in their bedroom whilst not really well enough to understand what they had consented to. Because Oxehealth was something NHSE/I innovation team had supported, the national MH policy team got involved. This had benefits in that it opened out a conversation with Tim Kendall NCD for MH and MH Policy team and Innovation team. They have all had the Oxehealth miniscope. Tim was alarmed that medical device regulation is not as robust as medication regulation. Claire Murdoch (national MH Director) has Oxehealth in her trust. Going forward they plan a workshop probably in June 2022 to produce a patient consent leave for Oxehealth and similar devices. This is likely to have real value for our concerns, as the leaflet would have to explain what the device does and doesn't do for informed consent, and staff would be using the leaflet to talk to patients so would learn too. I've linked MHRA to the innovation/MH policy colleagues leading on this work.

The innovation teams acknowledge safety team involvement in their innovation selection processes had lapsed and I am hopeful that might change in future though have not seen concrete proposals for that. Something we'd need to progress separately from Oxehealth.

Other actions were:

4. HC 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.

[I/S] will be able to update at some point on where MH&LD forum work in relation to this is. I've seen one fairly reassuring local protocol via the MH policy contacts – it explains to staff some of what the device won't do or shouldn't be used for - but even that one not aware of all the limitations we are aware of, and we don't know what protocols are used elsewhere.

5. '*Potential for alert to be revisited if any other workstreams identify clear constructive actions'* – may or may not want to revisit potential at VRM today or leave until after further developments.

Supplementary research action:

The question of potential need for research was posed in the miniscope but not a formal VRM action. Even if it gets to point where local and manufacturer support materials are perfect, video monitoring is likely to create some profound changes in patient and clinical behaviour. It was included in the patient safety strategic research needs published in December 2021 *"Remote respiration and pulse monitoring devices, sometimes combined with CCTV, are used in mental healthcare settings to reduce the need to disturb patients in their bedrooms or in seclusion rooms to check their physical wellbeing. While this will have benefits in relation to supporting sleep and recovery, it may reduce patient-staff interaction and other opportunities to detect distress or vulnerability. Has reliance on automated equipment for monitoring physiological observations in mental health units reduced detection of other signifiers of patient distress or vulnerability? If so, how could the benefits of these devices be maintained without these associated risks?"* However given MH policy interest and high expenditure may be worth Taofikat considering as a possible one on the list for MTM to consider for next potential policy research application stream.

All best

Frances

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