
From: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - T1520) [I/S]
Sent: 1/28/2022 6:20:37 PM
To: [I/S] JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520)
[I/S]
Subject: RE: Oxehealth

Hi [I/S]

For us the key concern is the risk their material makes patients or staff believe the equipment will protect people from self-harm in ways it may not be able to do.

Page 19 they say they have “Clear communication of the scope of the Activity Detection, Falls Risk and Location Risk products and their claims in sales and marketing handover material” but that is what they really don’t seem to have (all the website quotes saying it will automatically summon help if you are in trouble, or proven to prevent self-harm) page 24 likewise – they appear to be describing technical instructions for using the screens or taking spot obs correctly - not our key concern of staff understanding the equipment will not automatically alert them to changes in respiration, nor alert them if the patient is in a dangerous area of the room, unless the system has been told what areas are dangerous and how many minutes to wait before alerting. So asking more on what material they routinely provide to help patients and staff understand what it **won’t** do would be helpful

On page 7 they seem to be claiming a technically in relation to the self-harm functionality – they are saying they are not claiming it reduces self-harm, simply sharing the experiences of clinicians who have found it does. You’ll know whether that does or doesn’t count as making claims of medical purpose, but we’re still concerned that isn’t a claim supported by any evidence links on the site or in their answers here. Appreciate they call it an ‘activity tracker’ but it is clearly tracking activities that might indicate self-harm.

You will know the right regulatory questions but to me they shouldn’t be able to have it both ways – can’t say it has no medical function and also say it is proven prevent self-harm and that is clearly the purpose it is being marketed/purchased for in most cases.

Less key to us but I note page 6 is ambiguous on how the buffered video is stored or for how long in order for the trust to request a ‘short segment’ related to an incident. Presumably everything would have to be stored for quite a while to make that possible (e.g. emailing on Monday to ask if they can have the time a fall might have occurred on Friday)

Page 7 seems pretty ambiguous too – I think they are saying the observations tracker is not registered as a medical device because it is so similar to the spot obs that are registered as a medical device BSI says it counts as an extension to a medical device? From the safety perspective our worry is confusion between one mode that meets medical device standards for accuracy and one that clearly doesn’t. I know you don’t want to second-judge BSI but I’d suspect the correspondence on this all pretty confusing and I can’t really see BSI saying the bit they hadn’t assessed the accuracy of (continuous monitoring) can be treated the same as the bit they had (spot measure)

Table p 11 I’d have thought the mode intended to allow staff to intervene before they fall counts as prevention of disease as might the one detecting you on the floor? There would be lots of precedent and looks to me like the lower tech fall alarms seem to be registered medical devices. Equally they just say the activity detector isn’t intended for diagnosis – but medical devices are not limited to diagnosis and it appears to me it is intended for prevention of disease (self-harm)

Page 31 low pulse rate incident really worrying. A breathing rate higher enough to be mistaken for a pulse rate is clinically very serious, as is missed tachypnoea. Lucky no harm to that patient, but I don’t think any responsible clinician could agree that type of error is immaterial in MH patients – if we were not worried about readings at those extremes we’d not be monitoring anyone at all. Even it was hyperventilation that is far from benign.

I note their reported incidents do not include the fitting with wrong mastic we shared. I would count the mastic incident as clearly reportable – it introduced a high ligature point in the room of multiple patients deemed at high risk of suicide. I would have thought the patients on floor undetected (quite a few of those in our incident reports) would be too, it's a significant risk in frail older people though they might argue staff should not have been relying on the alarms to alert them.

Really sad there isn't even a hint of reflection as to whether any of this could be presented in ways safer for staff or patients, just total push back. Website hasn't changed. What you can do in the regulatory space would be vital as I've no hope they'll be responding to my appeals to their better nature.

All best

Frances

Dr Frances Healey, PhD, RN, RN-MH (NMC 80D1205E)

Deputy Director of Patient Safety (Insight)

NHS England & NHS Improvement

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[I/S]

From: [I/S]

Sent: 26 January 2022 15:06

To: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - T1520) <[I/S]> JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520) [I/S]

Subject: RE: Oxehealth

Dear Both,

We are finalising a list of questions in response to the document attached. Please let me know if you have any immediate thoughts or comments in regards to Oxehealth's response to our questions.

Kind regards,

[I/S]

Senior Medical Device Specialist – Software, Apps and AI

Medicines and Healthcare products Regulatory Agency

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From: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - T1520) <[I/S]>

Sent: 05 January 2022 08:54

To: [I/S]

Subject: RE: Oxehealth

Many thanks for the update and wishing you a good 2022 – we all deserve a better year

[I/S]

, PhD, RN, RN-MH (NMC 80D1205E)

Deputy Director of Patient Safety (Insight)

NHS England & NHS Improvement

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E

[I/S]

From: [I/S]

Sent: 04 January 2022 17:28

To: JENNINGS, Sarah (NHS ENGLAND & NHS IMPROVEMENT - T1520) <[I/S]> (NHS ENGLAND & NHS IMPROVEMENT - T1520) <[I/S]>

Cc: [I/S]

Subject: Oxehealth

Dear All,

I hope you had a good Christmas break.

We have now received a response to our questions from Oxehealth. We will be working through this and will be updating you soon.

Many thanks,

[I/S]

Senior Medical Device Specialist – Software, Apps and AI

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