



Virtual ward platform technologies for acute respiratory infections

Health technology evaluation Published: 12 October 2023

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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

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1 Recommendations

- 1.1 Virtual ward platform technologies can be used in the NHS while more evidence is generated to monitor people over 16 with acute respiratory infection in their usual place of residence. They can be used for people who have been:
 - referred for hospital admission or
 - admitted to hospital and their condition is stable or improving but needs ongoing monitoring.

These technologies can only be used once they have appropriate regulatory approval, including CE mark, and Digital Technology Assessment Criteria (DTAC) approval.

- 1.2 Virtual ward platform technologies should have these key features:
 - interoperability with electronic patient record systems and associated medical devices
 - appropriate regulatory approval for associated medical devices (devices must also meet local testing standards and be validated for use in a place of residence)
 - validated accuracy in people with black or brown skin for devices that measure oxygen saturation
 - risk-stratified alerts (for example, red, amber or green) for healthcare professionals for when readings go outside of the agreed range (alerts can be based on device-measured vital signs or questionnaire responses)
 - trend-based alerts (to increase specificity) if they are using continuousmonitoring wearable devices
 - patient interface with an easy to use, user-centred design.
- 1.3 Further evidence should be generated on the following key clinical and cost outcomes:

- length of virtual ward or hospital stay
- hospital admission and readmission rates
- number of alerts when using a virtual ward (including false-positive and falsenegative alerts)
- costs and resource use (including virtual ward service delivery costs)
- patient and carer experience and acceptability (including carer burden)
- demographics of the people admitted to a virtual ward (including information relating to health inequalities)
- healthcare professional experience and acceptability
- number of contacts with other healthcare providers, such as GP visits, home visits and calls to 111.

Potential benefits

- System benefit: virtual wards allow people to be cared for in their home or usual place of residence while also reducing pressure on hospital inpatient care. Virtual ward platform technologies allow this treatment setting to be scaled.
- Clinical benefit: clinical evidence suggests similar outcomes to hospital inpatient care with high reported levels of patient and healthcare professional acceptability. Limitations of the evidence are discussed in section 3.15.
- **Resources:** economic evidence suggests that there is potential for virtual ward platform technologies to be cost saving because people are having their healthcare managed at home or in their usual place of residence instead of in hospital.

Managing risk

- Clinical review: a clinical assessment of suitability for admission to a virtual ward should be done in person by a healthcare professional. Plans relating to monitoring, escalation of care and discharge must be made on admission to a virtual ward. Any alerts should be followed up by a healthcare professional.
- Individual choice: some people may choose not to be on a virtual ward or may not feel comfortable using the technology and may prefer treatment in hospital. Everyone has the right to make informed decisions about their care.
- Equality: some companies can loan a smart device and provide internet access for those who do not have it. They can also provide different accessibility features including devices with large screens and buttons, screen-reading software, translation services and apps in multiple languages. Some devices that measure oxygen saturation (pulse oximetry devices) have been reported to overestimate oxygen saturation levels in people with black or brown skin. So, pulse oximetry devices should be validated for accuracy in people with black and brown skin. Limitations should be recognised for any test and a range of outcome measures should be considered.

• **Costs:** results from the early economic analysis suggest that the technologies could be cost saving based on current prices and evidence. But, the model uses a number of assumptions and is based on limited clinical evidence. This should be taken into account when negotiating the licence costs.

The <u>evidence generation plan</u> gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

2 The technology

Technologies

- A virtual ward platform technology comprises a patient-facing app or website, medical devices for measuring vital signs and a digital platform for healthcare professionals. The aim of these technologies is to expand the capacity of the acute care sector by monitoring people, who would otherwise be in hospital, remotely in their home or usual place of residence. Several virtual ward platform technologies are available in the NHS. NICE identified 20 companies as part of the scoping process. Of these, the following 13 companies provided information on their technology:
 - Clinitouch (Spirit Health)
 - Current Health (Current Health)
 - Doccla Virtual Ward solution (Doccla)
 - DOC@HOME (Docobo)
 - Feebris (Feebris)
 - Huma (Huma)
 - Inhealthcare Digital Health Platform (Inhealthcare)
 - Lenus COPD Support Service (Lenus Health)
 - Luscii (Luscii Healthtech)
 - RespiraSense Hub (PMD Solutions)
 - Virtual Ward Technologies (Virtual Ward Technologies Ltd)
 - VitalPatch remote patient monitoring solution (MediBioSense Ltd)

Whzan Blue Box (Solcom).

Of these 13 technologies, 11 are currently used in the NHS. See table 2.1 in the assessment report for details of the features offered by the virtual ward platforms technologies evaluated. This includes technologies with risk-stratified alerts and those that can do continuous monitoring using wearable devices and have trend-based alerts. Table C 3 in the assessment report lists the interoperability of the virtual ward platforms technologies evaluated. The list of technologies included in this evaluation is not exhaustive and other virtual ward technology platforms may be available. One eligible technology, Masimo SafetyNet (Masimo), was identified during consultation.

2.2 Technologies can be used once they have appropriate regulatory approval, including CE mark, and meet the standards within NHS England's Digital Technology Assessment Criteria (DTAC). Any associated medical devices needed to measure clinical parameters must also have appropriate regulatory approval and meet local testing standards. The Medicines and Healthcare products Regulatory Agency (MHRA) advise that the virtual ward platform technologies evaluated will likely be classified as class IIa or higher under the UK Medical Device Regulations 2002 (UK MDR 2002, as amended) based on the scope of the project. For software platforms that continuously or automatically monitor vital signs and provide specific warnings of a person's condition, particularly when there may be guick deterioration, are likely to be class Ilb. When a virtual ward platform technology is connected to associated medical devices, the software should be classified at the highest classification of the associated medical device(s). Classification of device will be product specific and based on the intended medical purpose that is stated by the manufacturer in their device's labelling, instructions for use and promotional materials and its mode of action in conjunction with the definition of a medical device as stated in the UK MDR 2002. Information on the classification of medical devices, including virtual ward software platform technologies, can be found on the MHRA's public access registration database.

Care pathway

2.3 NHS England's guidance on acute respiratory infection (ARI) virtual

wards provides a framework for the setup of virtual wards for people with an ARI, including information on staffing and out-of-hours care. People can be admitted to a virtual ward either from a hospital setting as an early discharge, as an alternative to hospital admission, or via direct patient-NHS contact. A clinical assessment of suitability for admission to a virtual ward should be carried out in person by a healthcare professional. It should include a review of symptoms, function, clinical observations, appropriate diagnostics, clinical severity scoring, overall clinical trajectory and a shared decision-making discussion about any support the person or their carers may need. Suitability of the person's usual place of residence should also be considered, such as whether there is access to a fixed or mobile telephone line, running water, heating, electricity and access to meals. The person or their carers would also need the confidence, motivation and skills to be able to use a virtual ward platform and the associated medical devices. On admission to a virtual ward, plans relating to monitoring, escalation of care and discharge should be made.

Comparator

Virtual ward platform technologies would be used as an alternative to inpatient secondary care, care in the community or care in the person's usual place of residence without the use of a virtual ward platform technology.

3 Committee discussion

NICE's medical technologies advisory committee considered evidence on virtual ward platform technologies for acute respiratory infections (ARIs) from several sources, including an assessment report by the external assessment group (EAG) and an overview of that report. Full details are in the project documents for this guidance.

Unmet need

There is an increased demand on NHS services for respiratory conditions. The NHS has set up a number of ARI hubs and ARI virtual wards to relieve pressure on other parts of the local healthcare system. Virtual wards allow people to be cared for in their home or usual place of residence while also reducing the pressure on hospital inpatient care. Virtual wards could also potentially reduce pressure on other aspects of the care system, including primary care appointments and emergency hospital attendance. Clinical experts highlighted that although remote care has existed for a long time, the digitisation of virtual wards supports scalability.

Population

3.2 The committee acknowledged that the admission criteria for a virtual ward for ARI should be based on NHS England's guidance on ARI virtual wards. This NHS England guidance includes the consideration of symptom severity, such as National Early Warning Score 2 (NEWS2) scores and oxygen saturation, as well as clinical trajectory and comorbidities. Clinical experts stated that population creep (such as people having treatment who would not usually need hospital care) could be a potential problem with virtual wards. The EAG highlighted population creep as a key area of uncertainty for the economic analysis. They reported that population creep can reduce the potential cost savings with virtual wards. Clinical experts stated this problem is likely to be limited if local services develop clear admission and discharge criteria using NHS England's guidance.

Virtual ward platform technology features

- 3.3 Virtual ward platform technologies comprise 3 key parts: a patient-facing app or website, associated medical devices and a digital platform for healthcare professionals. The committee acknowledged that in addition to the core functions of a virtual ward platform, the technologies offer a range of additional features. These include variation in the monitoring devices offered, such as spot monitoring devices and continuous monitoring using wearable devices. The companies also offer a range of additional services including the delivery and maintenance of the associated medical devices and in-house healthcare professionals to support implementation and operation of virtual ward platforms.
- The committee agreed that key aspects of a virtual ward are a user-3.4 centred design, the ability to allow multidisciplinary team working and interoperability with electronic patient records. Associated medical devices also need appropriate regulatory approval in addition to meeting local testing standards and must be validated for use in a home or place of residence. The platform also needs to provide risk-stratified alerts to healthcare professionals for when readings go outside of the agreed range. These alerts can be based on the person's device-measured vital signs or responses to questionnaires they submit themselves. When using wearable devices for continuous monitoring, it was acknowledged that alerts should be trend-based to prevent over-notifying, which could otherwise increase the overall time healthcare professionals spend reviewing and responding to alerts. Because of the limitations in the clinical evidence, the committee acknowledged that there is no evidence to show whether one platform is better than another. The EAG noted that the variation in cost and resource use relating to the features offered by virtual ward platform technologies is a key area of uncertainty in the economic model.

Implementation

3.5 Virtual ward platform technologies for ARIs are available in some NHS sites. Expansion of these wards is needed to support the increasing demand on hospital beds for treating ARIs. Clinical experts said that good communication with the community and local hospitals would help

- support implementation and awareness of virtual wards. They also stated that multidisciplinary teams and patient involvement are needed during the setup of a virtual ward.
- 3.6 Clinical experts and companies stated that a key barrier to implementation was interoperability of the virtual ward platforms with electronic patient records. They highlighted the importance of information being accessible to the people who need it, including the multidisciplinary team running the wards and any out-of-hours services providing support. Companies said that the platforms have software to access NHS systems such as electronic patient records, but funding availability to cover the cost of that connection is the main barrier. Electronic patient record suppliers would also need to work with the companies to support the interoperability. The committee concluded that interoperability with electronic patient records systems and associated medical devices would be a key feature needed in a virtual ward platform technology.
- 3.7 Clinical experts stated that training for staff was essential for implementing virtual ward platforms. Staff must be trained on the different features of the platforms and how to train patients to use the technologies (if training is delivered by NHS staff). Companies state that there are different training options, including online or physical face-to-face sessions, videos and user manuals. Technical support should also be made available to patients and their carers and healthcare professionals.

Patient and carer considerations

3.8 Virtual ward platform technologies can increase treatment options available to people with an ARI that needs hospital-level care. A patient expert said that being able to have care at home allows people to have their home comforts and freedom, and to interact with family, friends and pets. They also stated that you can get undisturbed rest and more easily get fresh air at home compared with a hospital. Clinical and patient experts also highlighted that being at home reduces the risk of getting a hospital-acquired infection. It also reduces the risk of deconditioning because the person can move about and exercise more easily.

- 3.9 People admitted to a virtual ward or their carers need to have clear information and support to use the technology and manage their condition. They should also be given time to ask any questions or express any concerns about using the technology before being admitted to a virtual ward. A patient expert noted a concern that people may not know what to do if part of the technology, such as the oxygen supply, stops working. Clinical experts agreed that people need to feel empowered to reach out for help and escalate care if needed.
- 3.10 Admittance to a virtual ward should involve shared decision making with patients and their carers. Patients and their carers need the confidence, motivation and skills to be able to use a virtual ward platform technology and the associated medical devices. Family support may be needed to help people who are being monitored at home. Carer burden should also be considered. Although some people may feel reassured by monitoring their readings, others may find this increases anxiety. Suitability of the person's usual place of residence should also be considered. For example, does the residence have a fixed or mobile telephone line, running water, heating, electricity and have access to meals. People with no fixed address, no privacy, or with a lack of physical space may find it hard to use a virtual ward. Other considerations may also be needed such as a person's level of frailty or whether they live alone, or have any cognitive impairment or learning disability that may make a virtual ward less suitable. The committee concluded that a range of factors need to be considered when offering a virtual ward. Any treatment offered should be patient centred and specific to their condition.

Equality considerations

3.11 Virtual ward platform technologies are delivered through a patient-facing app on a smart device. People on a virtual ward need regular access to a device with internet access to use the technologies. Additional support and resources may be needed for people who are unfamiliar with digital technologies or who do not have access to smart devices or the internet. Companies state that people who do not have access can be provided with smart devices and mobile internet access for the duration of their virtual ward stay. Additional considerations in relation to connectivity would be needed in areas where there is limited internet access.

Companies should use simplified patient interfaces to make it easier for people who are not familiar with using digital technologies.

- 3.12 Additional support and resources may also be needed for people with visual or hearing impairments, problems with manual dexterity, or who are unable to read or understand English. The companies said that they have taken steps to improve the accessibility of their technologies. This includes providing tablets or monitoring devices with large screens and buttons for people with visual impairments or problems with manual dexterity. Screen-reading software can also be offered to people with visual impairments. Some companies also offer translation services or provide the app in multiple languages for people with English as a second language. Simple user instructions in multiple languages should be made available.
- 3.13 The committee recognised that some pulse oximetry devices have been reported to overestimate oxygen saturation levels in people with black and brown skin. This may lead to their condition not being treated when treatment is needed. Clinical experts stated that limitations should be recognised for any test and that a person's condition would be treated using a range of outcome measures rather than relying on 1 parameter. Pulse oximetry devices should be tested and validated for use in people with black and brown skin. Companies noted that some devices, such as those that continuously monitor respiratory rate, are not affected by skin colour.

Clinical-effectiveness overview

The EAG prioritised 19 studies, including 6,129 people. These included 2 randomised controlled trials (RCTs), 1 prospective cohort study, 11 prospective case series (including 2 cohort studies extracted as case series) and 5 retrospective case series. The prospective cohort study was done in the UK and compared a technology-enabled virtual ward with a telephone-based virtual ward or historical hospital control. But, the RCTs were done outside the UK, so the evidence considered was limited by a lack of UK-based comparative studies. The EAG also noted that the virtual ward admission criteria in the studies were unclear and 16 of the prioritised studies were limited to only people with COVID-19.

- 3.15 The evidence reported on length of stay, admissions, readmissions and escalation of care. The results suggested similar outcomes to inpatient care. However, this evidence was limited because of the lack of comparative studies and heterogeneity in outcome reporting. None of the evidence suggested that virtual wards were unsafe and reported mortality rates were low. The evidence showed that there was a high level of adherence to use of the technology as well as high acceptability for both healthcare professionals and people admitted to virtual wards. Studies reported barriers that included digital literacy, technical issues or inadequate demonstration or explanation of the technology, language barriers and digital exclusion.
- Clinical evidence on 8 in-scope technologies (Clinitouch, Inhealthcare, Doccla, Luscii, Whzan Blue Box, Virtual Ward Technologies, Huma, Current Health) was identified in 15 of the studies. One additional technology identified during consultation (Masimo SafetyNet) has 1 UK study on a chronic obstructive pulmonary disease virtual ward and 1 US study on remote monitoring of people with COVID-19. The UK study is limited by uncertainty in the relevance of the included population. There is no evidence comparing the different platform technologies with each other. The EAG concluded that the evidence could not distinguish whether different features of virtual ward platforms affected clinical or service outcomes. See the assessment report in the project documents for this guidance for more details.

Costs and resource use

3.17 A simple cost-comparison model showed that virtual ward platform technologies are potentially cost saving to the NHS. The technologies were cost saving by an estimated £872 per person compared with inpatient care, and by £115 per person compared with care at home without a technology-enabled virtual ward. This cost model was platform agnostic and so the range of savings could vary depending on the technology considered. The base-case savings were supported by sensitivity and scenario analysis results. The economic model used a 30-day time horizon and included the costs associated with a virtual ward, such as:

- licence costs
- monitoring
- equipment delivery, maintenance and home setup
- home visits
- outpatient appointments
- emergency hospital attendances
- hospital admissions
- calls to 111.
- 3.18 The EAG acknowledged that because of limitations in the available evidence, the early economic model used simplifying assumptions. This meant there was some uncertainty in the extent of the cost saving. These assumptions included considering a virtual ward and its comparators as being equally effective and that training, implementation and treatment costs per person were directly scalable to any virtual ward size. An assumption around staffing of a virtual ward was also used due to the known variation in set up of these services in the NHS. The EAG noted that the main cost drivers of a virtual ward include the length of stay, hospital admission rates, number of alerts and the cost of the platform.
- The committee acknowledged that the variation in features offered by virtual ward platform technologies could lead to differences in costs and resource use. The EAG noted that the incremental cost of a given platform will most likely be impacted by any additional features offered by the platforms (such as company-provided support for monitoring), the effectiveness of continuous monitoring, interoperability with other NHS systems and ease of use of the virtual ward platform. The committee concluded that there was enough evidence to recommend the virtual ward platform technologies while further evidence is generated. Evidence on measures of clinical effectiveness, service outcomes and resource use are needed to reduce uncertainty in the economic modelling.

Transferability

3.20 This evaluation focused on ARI. The EAG concluded that no included evidence directly addressed transferability of virtual ward platform technologies from other settings to an ARI setting, or vice versa. The committee acknowledged that virtual ward platforms would be purchased for use in multiple populations and that usability across populations would need to be considered when deciding which platform to use.

Evidence gap overview

- The committee concluded that there was enough evidence of a potential benefit of virtual ward platform technologies for them to be used in the NHS while further evidence is generated. The main evidence gaps for these technologies are:
 - **Population:** The EAG stated that the virtual ward admission criteria reporting in studies was unclear and that 16 of the prioritised studies were limited to only people with COVID-19. Further evidence generation should clearly report admission criteria and evaluate a range of ARIs.
 - Comparator: There was a lack of comparative studies done within the NHS setting. Evidence generation on virtual ward platform technologies compared with hospital care or care at home without the use of a virtual ward platform technology would be needed to quantify the benefits of virtual wards.
 - Outcomes: Published evidence was not available for some outcomes listed in the scope of this evaluation. There was also some heterogeneity in how outcomes were reported, especially those relating to escalation, admission and readmission. Further evidence generation should collect the key outcomes to assess clinical effectiveness of virtual ward platforms as well as service-level outcomes and data on patient and healthcare professional experience.
 - Technologies: The committee acknowledged that there was variability in the
 features offered by virtual ward platform technologies. The EAG concluded that
 there was not enough evidence to determine which features could provide
 additional clinical, service or cost benefits. Further evidence generation is
 needed to address these uncertainties.

• Economic modelling: The EAG noted that the economic modelling is limited by a lack of comparative clinical evidence. The key gaps identified included implementation costs, use of the different technology features and impact of use of the technology in different population subgroups. These were in addition to the clinical and service-level outcome measures identified as key cost drivers (see section 3.18). For further evidence generation, the committee also noted that the costs of adopting and implementing virtual wards need to be captured in more detail. This includes costs of training and staffing as well as delivery and maintenance of equipment. Differences in costs and resource use between step-up and step-down care should also be captured, as well as the lead time for adoption of a new virtual ward platform technology.

4 Committee members and NICE project team

Committee members

This topic was considered by <u>NICE's medical technologies advisory committee</u>, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The <u>minutes of the medical technologies advisory committee</u>, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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ISBN: 978-1-4731-5433-9

Accreditation

