Covid 19 – The impact of variable and 'low normal' pulse oximetry scores on Oximetry@Home services and clinical pathways: Confounding variables?

Short title - Oxygen saturation variance in oximetry@home services

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Abstract

Covid 19 Oximetry@Home services have been commissioned nationally. This allows higher risk patients with mild Covid 19 symptoms to remain at home, being supplied with a Pulse Oximeter to measure their oxygen saturation (SpO_2) two to three times daily for two weeks. Patients record their readings manually or electronically which are monitored by a clinical team. Clinical decisions, using an algorithm, are based on SpO_2 readings in a narrow range with 1-2 point changes potentially affecting care. In this article we discuss the problem that multiple factors affect SpO_2 readings, and that some 'normal' individuals will have 'low normal' scores at the threshold of clinical management, without any known respiratory problem. We discuss the potential magnitude of this problem based on the associated literature and consider how this will impact on the use of the Oximetry@home services, potentially partially confounding their purpose; to reduce face to face medical care.

Background

There are a number of advantages in managing less serious cases of COVID 19 in the community, though this limits the use of medical devices such as thermometers, stethoscopes and pulse oximeters during assessment. With the usefulness of patient performed home based pulse oximetry in both preventing unnecessary emergency department attendance (Torjesen, 2020) and in early identification of silent hypoxia however, NHS England has recommended national commissioning of 'Oximetry@Home' services (NHSE[1], 2020) where patients with mild Covid 19 symptoms but at higher risk of deterioration can be provided with a Pulse Oximeter for 14 days in order to self-monitor their oxygen saturation (SpO_2) 2-3 times a day.

Patients referred to Oximetry@Home services are usually directed to use an App or a paper diary to record their observations. The App either provides an automated response/recommendation, or data is monitored by a clinician who can contact the patient if necessary, though usually only during normal working hours. Patients are given instructions on interpreting their results so they can act

independently if they need to, such as seeking urgent care. Those aged over 65 and/or with multiple comorbidities defining them as extremely vulnerable are being targeted by the pathway due to a higher risk of deterioration (NHSE[1], 2020).

The assessment of patients within Oximetry@Home services starts with their oxygen saturation as measured by a Pulse Oximeter, SpO_2, followed by consideration of other signs and symptoms. A Red, Amber, Green (RAG) rating is used and patients are classified as Red if their SpO_2 is 92% or less, Amber if their SpO_2 is 93% or 94%, and Green if their SpO_2 is 95% or greater. Usually only Green patients are eligible for Oximetry@Home (NHSE[2,] 2020). Various non-disease related factors influence SpO_2 scores however and these may not be accounted for in the pathway. In this article we discuss the impact various factors affecting SpO_2 may have on the movement of patients in and out of Oximetry@Home services that may partially confound their purpose : to ease the pressure on face to face medical services.

The Variability of Oxygen Saturation Measurements

The accepted range of 'normal' for oxygen saturation in the blood as measured by a pulse-oximeter (SpO_2) is 95-99%. This statement is so ubiquitous that medical articles rarely reference it, though documents such as the World Health Organisation Pulse Oximetry Training Manual exist (WHO, 2011). When searching for normative data regarding SpO_2 in a non-medical population, little information can be found. In a study of 791 individuals aged 65 and over (Rodríguez-Molinero et al, 2013) the mean 5^{th} centile SpO_2 score was 92% after accounting for variables such as COPD, indicating that 5% of the measured population had a significantly low score without any known medical explanation. In another study of 458 individuals aged between 40 and 79 (Enright & Sherrill, 1998) the range of oxygen saturation before a 6-minute walk test was 92-98% at the 5^{th} centile and 93-99% at the 95^{th} centile. Neither study documented in detail the procedure used to measure SpO_2.

A population study of 5152 individuals in Norway (Vold et al, 2015) found that 11.5% had a low, or low end of normal, SpO_2 of less than or equal to 95%. In this study only a minority of the individuals with a low SpO_2 were reported to have asthma (18%) or COPD (13%), whereas a significant majority had a BMI over 25 (77%), and a large proportion were aged 70 or over (46%). In the UK, 24.4% of cases tested for Covid 19 between May and August 2020 were aged 60 or over and 15% were aged 70 or over [8] (Dept Health and Social Care, 2020). Although the Norwegian study suggests 11.5% of any population may have a low SpO_2, most of these cases having no known respiratory diagnosis, the literature suggests there may be "missing millions" with undiagnosed COPD (Bakerly & Cardwell, 2016) and a potentially high rate of undiagnosed Obesity Hypoventilation Syndrome (Massa et al, 2019). A significant proportion of unexplained 'low normal' SpO_2 scores found in population studies may have an undiagnosed respiratory condition.

In addition to population variance, specific factors regarding the protocol used to measure SpO_2 may affect outcome. Measurements taken whilst lying at rest are statistically significantly different from those taken in sitting (Ceylan et al, 2015). Further to this, and age and obesity factors, SpO_2 may drop over a period of 5-15 minutes at rest (Mehta & Parmar, 2017) and more specifically at rest during meditation (Bernardi et al, 2017). Limb temperature, associated with ambient temperature, may also have a statistically significant effect (Khan et al, 2015) as can anxiety, the presence of which may drop scores a full point (Ardaa et al, 2020). Lastly it is known that Pulse Oximeters have a standard error of measurement of +/- 2% when compared to simultaneous arterial blood gas measurement, SaO_2, (American Thoracic Society, 2018) but pragmatically, from a clinical perspective, as there is no way to account for this variance measurements must be taken and acted upon at face value.

Variability of SpO_2 over time and repeated measurement is a further issue, with little information about this in a non-medical population. One study with a small sample size (n=36) examined SpO_2

changes over an hour [16] (Bhogal & Mani, 2017) but no reports exist of variability during repeated measurement over weeks, as undertaken during Oximetry@Home.

During a 14 day Oximetry@Home monitoring period with SpO_2 taken three times a day, and potentially more frequently in an anxious patient, 42 measurements could be taken. Even assuming an identical measurement protocol is used on every occasion and a stable clinical condition, it is reasonable to suggest there will be some variability in these measurements. With the population research using one measurement taken on one occasion showing that 11.5% of individuals may have an SpO_2 of 95% or below, the probability of finding a low reading on one or more occasions during repeated measurement over time when following the Covid 19 recommendations is probably higher than 11.5%.

The Impact of SpO2 Variability on the Oximetry@Home pathway

The algorithm behind Oximetry@Home services recommends that because poor outcomes are associated with lower SpO_2 scores [17] (Shah et al, 2020); those whose SpO_2 drops to 93-94% should receive face to face medical assessment and be considered for hospital admission, and those with scores of 92% or below should receive urgent secondary medical care. With nationwide implementation of Oximetry@Home services, repeated SpO_2 measurements taken at home by patients will be an important factor in interpreting their clinical condition.

SpO_2 measurement is most frequently performed within a short time of oximeter placement with the patient in sitting and not having had a period of rest, walking from a waiting area to a clinical area physiologically interrupting rest.. With commissioning of Oximetry@Home services an NHS YouTube video (2020) has been released that recommends for home based measurement patients lie down for 5 minutes, place the Oximeter, and then take the most stable reading 1 minute after placement. This video link has been circulated via the Future NHS Collaboration Platform pages

relevant to those setting up Oximetry@Home services but no account appears to have been made regarding the potentially lower reading this can give compared to readings taken in sitting. It is noteworthy that a further Health Education England NHS video featured in the Daily Mail newspaper recommends an entirely different protocol, taking the first reading given in sitting (Daily Mail, 2020).

In an individual with an unknown usually low score of 95%, a drop of even 1 point due to Covid 19 infection could result in an Amber rating leading to direct clinical care. What is unclear is whether a single point drop in an individual with a pre-disease low score makes direct clinical care an efficient use of resources.

Although the national algorithm also mentions SpO_2 drop, with the vast majority of cases not having documented pre-disease SpO_2 scores this factor becomes impossible to assess until after any initial drop caused by the virus that led to SpO_2 assessment. It is also unclear clinically from a decision making perspective if an individual's best saturation/perfusion level in sitting should be the baseline around which care is organised, or if a reduced saturation/perfusion in lying after rest should be the baseline. No nationally agreed policy regarding this appears to exist.

Discussion

SpO_2% is an eye-catching, publicly available parameter in the evaluation of COVID 19. NHS England has acquired 370,000 oximeters for multi-patient use for distribution to services.

It is probable that the factors described may result in many single point SpO_2 measurement changes triggering face to face patient reviews either in primary care or emergency departments. Over time many thousands of patients may be treated in the community with SpO_2 monitoring, potentially leading to a significant number of unnecessary face-to-face reviews. When the effect of factors affecting SpO_2 readings in Covid 19 cases where no pre-disease SpO_2 readings are available are analysed and placed into the context of population based clinical and home based measurement, the potential impact is significant, particularly on those 'missing millions' more likely to have

borderline SpO_2. Additionally Oximetry@Home services are far more likely to select those with borderline scores by targeting the over 65's and those that may have a higher BMI associate with comorbidities. The research suggests the 'low normal' population will be at least 11.5% of all individuals, but due the selection criteria of Oximetry@Home services this percentage appears likely to be much greater than this.

With the documented factors affecting SpO_2 scores at play, those patients with usually lower scores, particularly scores of 95%, may potentially move between green and amber ratings on multiple occasions. This move could possibly even occur between usual clinical practice measurement in sitting at the time of referral to Oximetry@Home, and a patients' first measure at home if they use the lying down for 6 minutes protocol. Patient anxiety upon taking a measurement if they feel unwell could also potentially move those with a borderline score to drop below 95% and seek care. This could cause multiple unnecessary episodes of face to face care putting additional pressure on services already working at, or beyond, capacity.

Even outside commissioned Oximetry@Home pathways and medical supply of oximeters to patients, press coverage of the usefulness of pulse oximeters has been widespread and it is unknown what percentage of the population may own a pulse oximeter in response to the Covid 19 Pandemic, though with many different suppliers of relatively inexpensive devices and reports of devices selling out (CNN, 2020) the number is likely to be in the hundreds of thousands at least. The factors described in this article may also affect these individuals, putting further pressure on services.

Recommendations

1. Due to the device measurement error inherent in pulse oximeters and the narrow boundaries of the national oximetry@home algorithm it is recommended that, where possible, the mean of three measurements should be used to inform patient and/or clinical

decision making. Patients should be advised that upon taking a reading that might cause them to seek medical care, provided their condition is not obviously subjectively deteriorating, they should repeat the reading three times over a period of one hour before making a decision.

2. Unification and documentation of SpO_2 measurement protocols with a single approved national measurement protocol put in place for both patients and clinicians. Pragmatically in an out-patient and home setting this protocol should likely be in the sitting position.
3. Widespread clinical education of relevant NHS staff regarding the potential for low scores and the factors that increase the likelihood of those scores to facilitate a more nuanced approach to implementation of the national algorithm.

Ethics - As an analysis of the literature ethical approval was not required for this work

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