20 Oct 21

Pulse oximetry for people with darker skin

Issue

1. Media reports that excess deaths in ethnic minority populations may in part be related to oximeter use.

Summary

2. We are not aware of any evidence that pulse oximeter inaccuracy in people with COVID and darker skin has contributed to excess deaths. The Medicines and Healthcare products Regulatory Agency (MHRA) is not aware of any incidents where skin colour has had an adverse effect on the use of pulse oximeters when providing effective clinical care.

3. NHS guidance is based on monitoring trends rather than single measures of blood oxygen to mitigate pulse oximeter inaccuracy in all patients.

4. We have asked National Institute for Health Research (NIHR) to commission rapid further research to definitively understand the accuracy of pulse oximeters for people with different skin colours.

5. Pulse oximetry is the only means of detecting silent hypoxia easily in patients at home.

6. We are concerned that some media messaging risks increasing numbers of people with darker skin who decline pulse oximetry services, thereby exacerbating inequalities.

Discussion

7. Pulse oximeters in the national supply comply with the latest ISO and CE requirements and must be within a range of ~2-3% accuracy.

8. There are some research reports[1] that pulse oximeters may not work as well in people with darker skin. The extent to which any inaccuracy may apply to COVID patients, and those on home oximetry programmes, is unknown. There are some limitations to the existing reports:

    a. The reports involve old out of date oximeters and/or there is no detail on the specific models used.
    b. They involve relatively low numbers of patients who may already have been significantly unwell
    c. No studies have involved COVID patients
    d. They generally involve reading levels that are unrelated to the ranges set out by NHS @home i.e. significantly lower which would mean the patient would likely be hospitalised
    e. There are significant questions over the validity of testing based on commonly accepted methodology e.g. time delays between comparing oximetry readings

[1] For example see example https://pubmed.ncbi.nlm.nih.gov/18048893/ or https://www.nejm.org/doi/full/10.1056/NEJMc2029240

9. Current evidence appears to suggest the following factors are likely to reduce accuracy in the general population, including people with darker skin:

    i. low perfusion
    ii. movement
    iii. nail polish
    iv. henna dye
    v. tattoos
    vi. probe mispositioning
    vii. ambient lighting hitting the sensor

10. Given the potential for inaccuracy in all patients including those with darker skin, our advice is that:

    a. Wherever possible patients record a baseline oxygen saturation at onboarding and subsequent changes in saturation readings are then compared to this established baseline.
    b. Clinicians should remain vigilant for other signs of deterioration in all patients with COVID, use their clinical judgement and monitor trends of both oxygen saturation readings and symptoms.
    c. Patients should seek help if <u>any</u> of their symptoms get worse.
    d. Publicly available safety netting guidance which includes key messages above and a section for people with brown or black skin with advice to continue to use an oximeter has been published via NHS.uk.
    e. Through engagement and regular communications with healthcare professionals distributing pulse oximeters, people have been encouraged to actively report safety issues through NHS processes for reporting incidents e.g. through local incident reporting systems, directly to the National Reporting & Learning System or through the MHRA reporting portal for device concerns (Yellow Card Scheme - MHRA) (as stated in para 2 - no reports have been received at present).

11. We are working closely with the MHRA and the Race and Health Observatory and this work has been supported by NHSEI's Health Inequalities improvement team.

12. Unfortunately, due to misleading media reports, we risk seeing increasing numbers of people with darker skin who decline pulse oximetry services, thereby exacerbating inequalities.

13. We have also kept in contact with a small study undertaken by a clinical engineer following engagement with this professional network. This involves a small number of patients in Guys and St Thomas's and various oximeter models (none used in the national supply) and initial results appear to show no greater inaccuracy in patients with darker skin and that one oximeter may show greater inaccuracy in lighter skin.

14. In January 2021, the World Health Organisation included use of pulse oximeters to identify patient who might need hospitalisation in its clinical advice for treating COVID-19. We have supported the use of pulse oximetry internationally including supporting the Indian COVID crisis.

<u>Evaluation of COVID oximetry @home</u>

15. An independent evaluation of the COVID Oximetry @home programme was commissioned through the NIHR with three research partners: Imperial, UCL and the Improvement Analytics Unit (a partnership between NHSEI and the Health Foundation) and is expected to be published in October. However, whilst this included looking at mortality and length of stay it has been limited by local variation in entry criteria and not