

Cover Sheet

Trust Board Meeting in Public: Wednesday 8 September 2021

TB2021.74

Title: Proposal to use on the day lateral flow testing (LFT) for patients undergoing local anaesthetic lower GI and ophthalmology day case procedures

Status: For Decision
History: TME 26 August 2021

Board Lead: Chief Medical Officer
Author: Dr Katie Jeffery – Director of Infection Prevention and Control
Confidential: No
Key Purpose: Strategy; Performance

Executive Summary

1. Patients are reluctant to attend for pre-operative COVID swabbing, making the booking procedure more onerous, and reducing the capacity of the Trust to deliver diagnostic and therapeutic procedures.
2. Safe systems of work for low-risk patients undergoing low risk procedures can be designed using lateral flow testing rather than COVID-19 PCR testing.
3. The proposal for using lateral flow testing (LFT) is detailed in the paper. The proposal represents a derogation from national guidance (COVID-19 rapid guideline: arranging planned care in hospitals and diagnostic services, NICE guideline [NG179] Published: 27 July 2020) (written prior to the introduction of vaccination, and the availability of lateral flow testing).
4. Other local Trusts within the ICS have ceased the requirement for a pre-procedural COVID-19 PCR. The continuation of the OUH infection prevention and control (IPC) hierarchy of controls to reduce the transmission of infection would remain.
5. This derogation and proposal has been approved by TME, subject to the addition of the scientific evidence supporting this proposal. Evidence has now been added (Section 4).
6. The risk of failing to detect a patient with a moderate to high viral load is **low** and is mitigated by IPC measures which are the same as would be used in the clinical setting to manage COVID-19 positive individuals

Recommendations

The Trust Board is asked to:

- Note that this paper has been considered by the Trust Management Executive and recommended to the Trust Board for approval.
- Approve the proposal and derogation from existing national guidance to replace pre-procedural COVID-19 PCR with lateral flow testing for certain categories of patients in the best interests of both patient care and productivity at OUH.

Proposal to use on the day lateral flow testing (LFT) for patients undergoing local anaesthetic lower GI and ophthalmology day case procedures

1. Purpose

- 1.1. This paper details the proposal to replace pre-procedural COVID-19 PCR with lateral flow testing for certain categories of patients.

2. Background

- 2.1. As of the 18 August, 75.7% of UK adults over the age of 16 have received two COVID-19 vaccinations, with higher percentages in older age groups and healthcare workers. Vaccination reduces the risk of acquiring infection, and the risk of becoming seriously unwell requiring hospitalisation.
- 2.2. A recently completed audit in OUH demonstrated a 14% success rate when booking for appointments in endoscopy. An important reason for patients declining an appointment was the need for an additional visit to the hospital for swabbing prior to the procedure. The continued requirement for swabbing is reducing the Trust's ability to offer diagnostics in cancer pathways and surveillance programmes, and to re-mobilise clinical services. Failure to re-mobilise services is compromising the quality of life for patients.
- 2.3. As well as showing only a 14% success rate in booking appointments in endoscopy, additional logistical issues around the co-ordination of swabbing and the procedure added 10-15 minutes per booking, estimated to amount to 16 hours of booking time per day. This had an enormous impact on the capacity of booking staff, further reducing the ability to fill lists.
- 2.4. Other local Trusts within the ICS no longer require a COVID-19 PCR within 72 hours of certain day case procedures.
- 2.5. It is proposed that for low risk patients a negative lateral flow test (LFT) taken on the day of the procedure, together with continuation of the infection prevention and control (IPC) hierarchy of controls to reduce the transmission of infection, will allow the Trust to safely remobilise essential services for the benefit of patients.
- 2.6. The OUH is currently looking to reprovide services for pre-op swabbing, as staff are re-deployed back to their usual workplace. The current home testing service is not a viable option as too few results are received in a

timely manner. If the Trust can reduce the number of swabs required by no longer requiring low risk patients to have a swab, then the swabbing services become more viable, and the pressure on the OUH microbiology laboratory is also reduced.

3. Proposal

3.1. This proposal replaces a pre-procedural COVID-19 PCR test with an 'on-the day' LFT, either self-taken by the patient prior to arrival, or taken on arrival by the clinical team. The proposal would initially apply to the two groups of patients detailed below, undergoing low-risk local anaesthetic non-aerosol generating day-case procedures:

- Patients undergoing lower GI investigations such as colonoscopy and flexible sigmoidoscopy procedures (approx. 20-30 per day)
- Patients undergoing cataract surgery, lid surgery, retinal surgery or glaucoma surgery (approx. 20-25 per day)

3.2. The Patients must meet the inclusion criteria detailed below:

- Patients must have received 2 vaccinations with the 2nd dose at least 14 days prior to the procedure
- Patients must have no symptoms consistent with COVID-19, and must not be a contact of someone with COVID-19 within the 10 days prior to the procedure

3.3. In addition, the clinical units must ensure:

- Patients are screened to exclude symptoms or exposure to COVID-19 at booking and on attendance for the procedure
- Patients produce evidence either on their NHS App or via an email from the test and trace system, that they have performed an LFT on the day of the procedure, and that it is negative

OR

- In the event of a patient unable to self-test at home, an LFT is performed on arrival by the clinical team and it is negative
- Patients who have symptoms, fever or have had a contact with a case within the prior 10 days on the day of procedure are cancelled and re-booked

3.4. The proposal represents a derogation from national guidance. (COVID-19 rapid guideline: arranging planned care in hospitals and diagnostic services, NICE guideline [NG179] Published: 27 July 2020) (written prior to

the introduction of vaccination, and the availability of lateral flow testing). As detailed above, other local Trusts within the ICS no longer require a COVID-19 PCR within 72 hours of certain day case procedures.

- 3.5. All IPC procedures will remain in place according to the hierarchy of controls – including social distancing, ventilation, and PPE. Patient would be required to wear masks if practical at all times.

4. Evidence to support the use of lateral flow devices (LFD) for asymptomatic testing for SARS-CoV-2 prior to low-risk procedures

- 4.1. Approximately one in three people never develop symptoms following SARS-CoV-2 infection. Asymptomatic testing supports finding and identifying infectious cases to reduce community transmission and is also used in healthcare settings such as maternity units and emergency settings. Patients attend out-patient settings without any prior testing, and the risk of infection to staff and other patients is managed using a hierarchy of controls including PPE. The controls required for low-risk procedures are the same as in the out-patient setting - the addition of LFD prior to these low-risk procedures provides an extra-safeguard.
- 4.2. The DHSC published evidence from LFD performance data (Oct 2020 – May 2021) in July 2021 (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/999866/asymptomatic-testing-for-SARS-CoV-2-using-antigen-detecting-lateral-flow-devices-evidence-from-performance-data-Oct-2020-to-May-2021.pdf). Results of validation experiments performed by Public Health England and the University of Oxford show these LFD antigen tests have suitable sensitivity and specificity for use within the community setting across the range of viral prevalence levels likely to exist.
- 4.3. High viral loads are more infectious than low or minimal viral loads. Therefore, the amount of virus present (viral load) can be used to assess an individual's infectious state and their likelihood to spread the virus. Evaluations performed show that the sensitivity of the test increases as the viral load (and chances of infectiousness) increases:
 - For people with high sample viral loads above 1,000,000 copies per millilitre, 96% (66/69) were detected by the LFD antigen test;
 - For individuals with moderate sample viral load between 10,000 – 1,000,000 copies per millilitre, 92% (180/195) were detected;
 - For those with low sample viral loads under 10,000 copies per millilitre, 43% (55/127) were detected.

- 4.4. The risk of failing to detect a patient with a moderate to high viral load is **low and** is mitigated by IPC measures which are the same as would be used in the clinical setting to manage COVID-19 positive individuals.
- 4.5. Recent DHSC analysis of real-world positivity rates from approximately 25,000 Innova LFD Antigen tests delivered in the community as part of NHS Test and Trace testing, combined with mathematical modelling suggests that the specificity of the Innova LFD device is greater than 99.97%.

5. Conclusion

- 5.1. This paper proposes that for patients who are double vaccinated attending for the low-risk non-aerosol generating procedures as specified above, the requirement for a negative COVID-19 PCR within 72 hours of the procedure is replaced by a requirement for a negative LFT on the day of the procedure.

6. Recommendation

- 6.1. The Trust Board is asked to
 - Note that this paper has been considered by the Trust Management Executive and recommended to the Trust Board for approval.
 - Approve the proposal and derogation from existing national guidance to replace pre-procedural COVID-19 PCR with lateral flow testing for certain categories of patients in the best interests of both patient care and productivity at OUH.