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SARS-CoV-2 Antigen Testing Program (COVID-ATP): A longitudinal study in 14 UK cancer centers

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Abstract

Objectives: The COVID-19 pandemic has had a profound impact on population health, with the prevalence and severity of the illness being higher in cancer patients due to their immunosuppressive state. Cancer clinics should consider routine staff and patient testing as people infected with COVID-19 may have very mild or no symptoms while they can still transmit the virus to others, acting as super spreaders. The study aim is to assess the prevalence of SARS-CoV-2 in asymptomatic healthcare workers and patients and the impact of preventative measures in a UK private oncology provider.

Study design: Asymptomatic staff and patients enter a prospective screening program, the SARS-CoV-2 Antigen Testing Program (COVID-ATP), consisting of the nationally approved real time Polymerase-Chain-Reaction (RT-PCR) nasopharyngeal swab test looking for SARS-CoV-2 viral RNA. The program runs April to December 2020 and covers the period of the 1st lockdown, the summer period of viral remission and the second wave in autumn/winter 2020. Here we present our preliminary results between April and October 2020.

Methods: Asymptomatic staff working across 14 centres are tested weekly and cancer patients are tested at specific intervals depending on their treatment plan. The COVID-ATP testing program is complemented by staff and patient adherence to infection prevention control (IPC) procedures, social distancing, clinic spacing, virtual clinics, intense cleaning routines and appropriate Personal Protective Equipment (PPE) use.

Results: 204 healthcare workers and 21 patients are tested on average each week. The prevalence of asymptomatic staff infection was 0.8% shortly after the first lockdown in April/May 2020, reduced to 0% between June/July 2020, increased to 1% in August/September and was 0.8% in September/October 2020. Two asymptomatic patients tested positive on routine testing, towards the end of the 1st lockdown.

Conclusions: This is the first longitudinal study in a UK private healthcare group, who applied a systematic testing program to assess the prevalence of asymptomatic COVID-19 in healthcare workers and patients. The prevalence of asymptomatic COVID-19 in staff is similar to the community prevalence in England at the time of testing and the temporal prevalence reflects the community prevalence trends. The protective measures taken within centres and the self-isolation of staff testing positive, resulted in lack of viral spread.

Keywords: COVID-19 RT-PCR; Infection Prevention Control; SARS-CoV-2

Abbreviations

ATP	:	Antigen Testing Program
COVID-ATP (COVID-ATP)	:	SARS-CoV-2 Antigen Testing Program
IPC	:	Infection Prevention Control
MDT	:	Multidisciplinary Team
NHS	:	National Health Service
PPE	:	Personal Protective Equipment
RT-PCR	:	real time polymerase chain reaction

What this study adds

- The prevalence of asymptomatic COVID-19 in staff is similar to the community prevalence between April and October 2020 (0-1%).
- Asymptomatic staff infections started to drop after April/May 2020, leading to an apparent remission in viral spread.
- The relaxation of lockdown measures with people travelling during the summer has resulted in a rise of the prevalence of asymptomatic infections in September/October 2020 with the highest being 1% in August – September 2020.
- IPC and social distance measures should always be followed so that cancer patients can safely receive their life saving treatments.

Introduction

The World Health Organization (WHO) declared COVID-19 outbreak as a worldwide pandemic on the 12th of March 2020. Since then, more than 6.59 million cases with more than 388.000 human deaths have been reported in more than 200 countries and territories. Due to the limited testing in many geographical regions, it is clear that the total number of actual COVID-19 cases is much higher than the number of confirmed ones [1].

Given the lack of approved treatment for COVID-19, the focus has been on individualizing treatments, particularly in cancer centres, taking risks of infection and benefits of treatment into account. Cancer clinics should consider routine testing of staff and patients in order to ensure that they remain COVID-free, whilst they continue to deliver life-saving cancer treatments. People infected with COVID-19 can have very mild or no symptoms, but can still transmit the virus, acting as super spreaders.

Diagnosis of suspected cases is confirmed by the detection of viral RNA using real-time Polymerase Chain Reaction (RT-PCR) on respiratory samples. The number of people testing positive without symptoms or mild symptoms can range between 10 and 35% [2]. Because of the unprecedented disruption in health care services caused by COVID-19 pandemic, it is important to know how many asymptomatic staff and patients are infected with SARS-CoV-2, so as to understand the magnitude of spread and apply protecting and preventive measures.

Methods

This is a prospective multicenter longitudinal study designed for the purpose of evaluating the implementation of the SARS-CoV-2 RT-PCR test across a 14 centered healthcare group, which involved testing asymptomatic staff and patients systematically. The SARS-CoV-2 Antigen Testing Program (COVID-ATP) involves the use of the nationally recognized RT-PCR test [3] to identify staff and patients who are infected and asymptomatic and who can therefore act as super spreaders.

The SARS-CoV-2 RT-PCR nasopharyngeal swab test is the nationally approved test used in the National Health Service (NHS) for symptomatic and asymptomatic patients and staff. Our proposed testing schedule is nationally endorsed by the Royal College of Radiologists [3]. Ethics Committee approval was deemed unnecessary given that the test is used routinely in the NHS for patients undergoing cancer treatment and prior to clinical procedures. There is no consenting for testing staff and patients in the NHS. However, we decided to obtain written consent from staff once and at the beginning of the recruitment process (April 2020). We also chose to verbally consent patients prior to testing and document this in their electronic medical record.

Objectives

Primary endpoint

To evaluate the prevalence of asymptomatic COVID-19 in our healthcare workforce and patients.

Secondary endpoints

- To evaluate the protective and preventive measures that our organisation has implemented to stop viral spread.
- To draw epidemiological data and benchmark with community data.

The study enabled the rapid identification and isolation of asymptomatic and infected health-care workers, so as to protect patients and the wider community [4].

Inclusion criteria

The SARS-CoV-2 Antigen Testing Program (COVID-ATP) is offered to all asymptomatic staff and patients.

Exclusion criteria

- Patients and staff who decline to be tested (they are risk assessed instead)
- Patients with nasal and/or oral tumours/deformities
- Patients with thrombocytopenia at the discretion of the responsible clinician

Test Collection Methodology

The RT-PCR nasopharyngeal swab test is collected according to the vendor instructions (The Doctors Laboratory). The chosen assay has a minimum sensitivity of 98% and a specificity of 100%, with no cross-reactivity with other viruses. All centre managers keep adequate amount of testing kits every week. Trained members of staff, either radiographers or nurses, take the role of testing other people after being tested negative themselves.

The collection takes place within a dedicated area in the centres or in the car park, for patients who come from home to be tested. Specimen collection includes a nasal and throat swab for PCR viral RNA testing. Complete PPE is used during testing, including FFP2 masks, surgical gown, goggles and gloves [5]. Patients and staff are advised to follow IPC measures at all times, including social distancing even if they test negative. RT-PCR swab samples are labelled with the following information: Employee/Patient Full Name, Date of Birth, Date and time sample was taken. After completing the laboratory request forms with all the required information, the samples are put into a sealed plastic bag with the request form. A courier collects the samples and takes them to the laboratory for processing.

Interventions

Pre-Testing

Participation of staff and patients is voluntary but strongly recommended. Staff provide written consent once, valid for the whole period of testing (30th of April - 30th December 2020). Patients are verbally consented before they start chemotherapy, radiotherapy and theranostics and prior to attending for minor interventional procedures. Verbal consent from patients is taken by a trained radiographer or nurse and is recorded in the electronic medical record. Patients are given an information sheet before they consent, which explains the purpose of testing, the testing procedure and reminds them that they can opt out the testing program at any time.

Asymptomatic patient testing pathway

Patients are tested 48h-72h prior to starting chemotherapy or theranostics and at the time of their pre-treatment blood test. They are also tested prior to every treatment cycle. Radiotherapy patients are tested before fraction 1, at the time of their CT planning scan and then weekly in case of protracted treatments (beyond 5 days). Patients attending for outpatient procedures are tested 48h-72h prior to the procedure. Patients attend on agreed dates and get tested by the tester wearing full PPE. Patients who have to wait more than 5 days between testing and starting treatment are advised to minimise social contact and adhere to social distancing.

On average, 21 patients per week are tested in our centres using the COVID-ATP protocol (figure 1). The turn-around time for the RT-PCR test results is 2 days. All results are extracted from a secure laboratory portal accessible to the clinical teams only. These results are transcribed anonymously onto a Microsoft Teams secure database, which constitutes the asymptomatic COVID-19 prevalence database. Patient results are also uploaded to their electronic medical record.

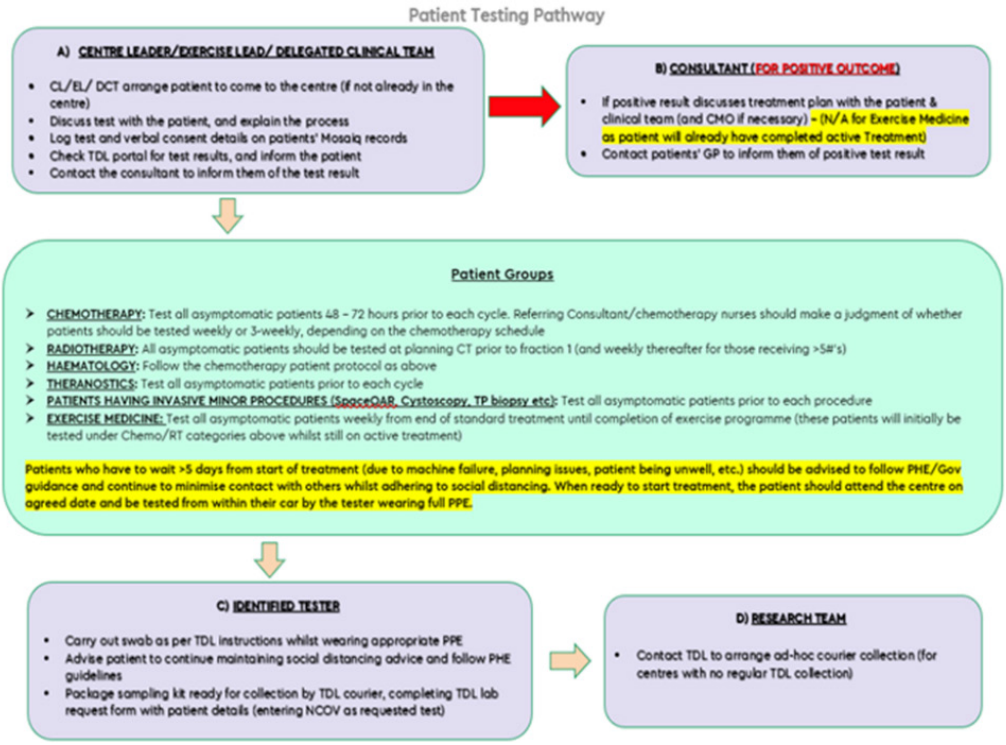

Figure 1: COVID-19 Asymptomatic patient testing pathway.

A member of the clinical team informs patients of their test results. The referring clinician discusses the treatment plan with the clinical team and the patient in case of positive patient results. It is the lab's responsibility to inform Public Health England of any positive test results. Patients may be advised to self-isolate for 10 days before they start or continue their treatment (figure 2). If patients need to continue treatment regardless of the positive test, treatment is delivered at the end of day, with staff wearing full PPE. Appropriate decontamination procedures take place after such treatments.

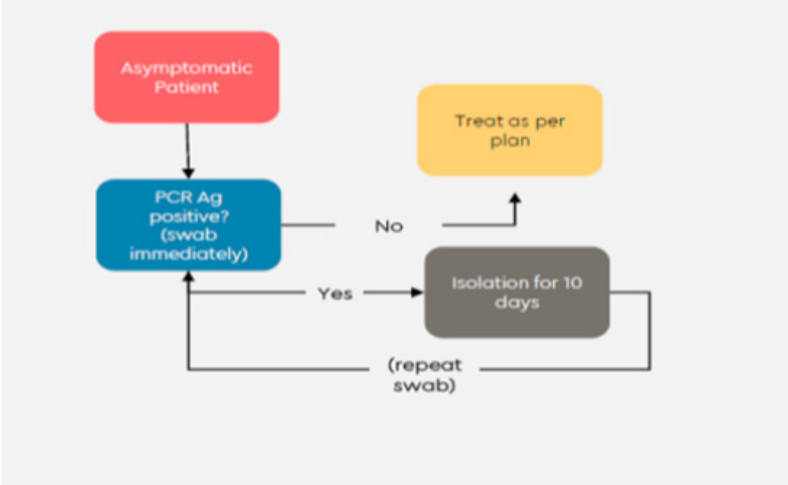

Figure 2: Asymptomatic patient testing and decision-making.

Asymptomatic staff testing pathway

The RT-PCR swab test is performed weekly on staff (figure 1). On average, 204 staff members are tested on a weekly basis and asymptomatic staff continue to work as normal while waiting for the results.

If staff develop COVID-19 symptoms at any time or they test positive for COVID-19 on RT-PCR, they self-isolate for 10 days. After 10 days, if they still have a temperature, they continue to self-isolate and seek medical advice [6]. There is no need for self-isolation after 10 days if they only have a cough or loss of sense of smell or taste, as these symptoms can last for several weeks after the infection has gone [6]. If the repeat swab test is negative, staff continue to work as normal and weekly testing resumes, but if still positive, they continue to self-isolate for another 10 days after which they are re-tested.

Symptomatic staff testing pathway

Staff need to self-isolate for 10 days if symptomatic, regardless of the RT-PCR result. If the swab test is negative, the swab is repeated at the end of the 10th day of isolation. If the second swab is negative and the employee is no longer showing any symptoms, except maybe for cough or loss of sense of smell or taste, they may work as normal and the weekly testing resumes. If the PCR swab test is positive at any time, individuals are isolated for 10 days and the swab test is repeated after 10 days.

Symptomatic patient testing pathway

If patients on treatment develop symptoms and/or test positive on RT-PCR, a discussion is held with their referring clinician regarding treatment continuation. A joint decision between the clinician, patient and centre staff is made which may mean treating patient at the end of the day with staff on full PPE.

Statistical Analysis and Results Evaluation

Sample size

This study will test on average 204 healthcare workers and 21 patients per week for 8 months and aims at evaluating the asymptomatic prevalence of COVID-19 in the healthcare worker and patient population.

Test Results for Employees

All staff test results are communicated to the Director of Operations, Director of People and Culture and respective centre managers in order to make workforce plans. Results are saved in a Microsoft teams secure database. When results are positive, staff are informed and are advised to report to their GP for continuity of care.

Test Results for Patients

All test results are available via the secure laboratory portal and are accessed only by the clinical teams. A trained clinical team member immediately informs both the patient and their referring clinician of the result. Where positive results are identified, a virtual Multi-Disciplinary Meeting (MDT) may be arranged to enable decision-making about patient treatment continuation. This MDT includes the referring clinician, the respective centre leader and the company's Chief Medical Officer.

Results Evaluation

Depending on the results of the swab test, there are actions taken for staff and patients as shown in Table 1.

Swab RT-PCR test for SARS-CoV-2	Actions for staff and patients
Positive	Individual must self-isolate for 10 days as results indicate individual is likely to be shedding. Re-swab in 10 days. Staff can return to work if RT-PCR is negative then, but if still positive need to isolate for a further 10 days. Patients may need to have their treatment postponed or diagnostic test delayed until they can safely receive it. If patient treatment benefits outweigh the risks of COVID-19 infection, a decision to proceed with treatment may be made by the MDT.
Negative	If staff member is asymptomatic, can carry on working. Continue weekly testing for staff. Patients can continue with treatment if asymptomatic.
Void	Re-test as soon as possible and isolate if symptomatic whilst awaiting swab results.

Table 1: RT-PCR result explanation.

Ethical Considerations

Test information and Consent

Patients are provided with an information leaflet explaining that swab testing is part of their treatment schedule. They are given the opportunity to ask questions and their verbal consent is obtained prior to any tests being carried out. Verbal consent is documented in the patient electronic health record. Asymptomatic patients have the right to decline being tested without this compromising their treatment rights. They would still be screened for COVID-19 symptoms and have their temperature checked as per the company's standard operating procedures. However, they would be considered to be of medium risk than other patients who are tested negative (low risk) and appropriate PPE will be considered for staff and patients.

Test Result Management and analysis

Patient test results are read by a trained member of the clinical team and no identifiable data is shared outside the clinical team. The research team has only access to anonymised data for analysis. Staff test results are read by the centre manager, Director of Operations and Director of People and Culture. They are saved on a separate database to the patients' one and only anonymised data are accessed by the research team for analysis.

Data Protection

All information provided by both staff and patients is treated as strictly confidential. All staff have up to date information governance training and research staff have up to date Good Clinical Practice training.

Results

A systematic weekly SARS-CoV-2 antigen testing program was introduced at GenesisCare UK on the 27th of April (week 1). Initially, only 3 out of 14 centres were involved in order to ensure business continuity in case of an unexpected rise of asymptomatic positive staff who needed to self-isolate. Between week 4 and week 25 all staff members from the 14 centres have been tested on a weekly basis (table 2, figure 3). On average, 204 staff members were tested weekly between end of April and mid-October (25 weeks) and recruitment continues until December the 30th.

	staff tested	staff positive	patients tested	patients positive
week 1	57	0	21	0
week 2	140	0	18	0
week 3	148	0	23	0
week 4	291	2	34	0
week 5	214	0	18	1
week 6	226	0	25	0
week 7	214	0	21	0
week 8	219	0	41	1
week 9	235	0	25	0
week 10	225	0	21	0
week 11	204	0	21	0
week 12	202	0	14	0
week 13	189	0	14	0
week 14	190	0	15	0
week 15	184	0	10	0
week 16	179	0	11	0
week 17	192	0	13	0
week 18	188	1	18	0
week 19	207	1	20	0
week 20	211	0	20	0
week 21	225	0	25	0
week 22	240	0	28	0
week 23	227	0	30	0
week 24	251	0	20	0
week 25	249	2	21	0

Table 2: Weekly staff and patient testing.

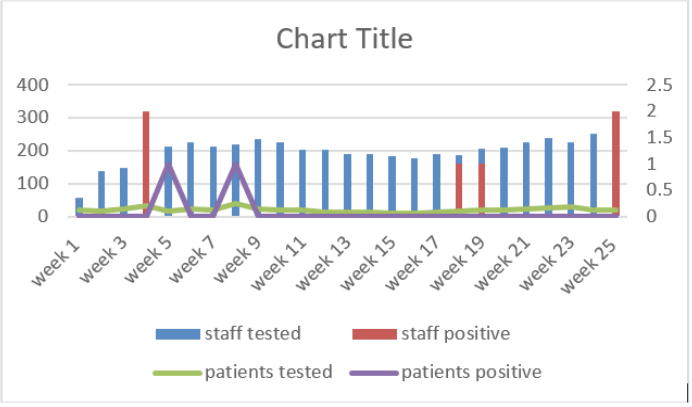

Figure 3: Number tested vs Numbers positive.

We saw no positive tests the first 3 weeks, two members of staff tested positive at week 4 with two patients testing positive week 5 and week 8 (figure 3). The 2 staff members belonged to the same centre but worked in different departments so not in close contact, were asymptomatic and were immediately isolated at home for 14 days. Both returned to work after a negative swab test two weeks later. The rest of the centre staff tested negative on the weekly testing. The positive patient cases belonged to two different centres and were both asymptomatic. Their treatment was delayed until after their self-isolation period and a second negative RT-PCR test.

We saw no positive staff or patient cases between late June, July and early August. Subsequently, there was one staff member testing positive at the end of August and one at the beginning of September and both belonged to the same centre, were asymptomatic and they self-isolated for 10 days (figure 3). They had both recently returned from holidays abroad. Finally, two asymptomatic staff members have been tested positive at the beginning of October from a single centre and they were both isolated for 10 days.

The prevalence of the disease in this closed healthcare

worker population was 0.8% between April/May 2020, reduced to 0% June/July, increased to 1% August/September 2020 and so far has been 0.8% in September/October 2020 (figure 4). All centres continue to apply robust IPC procedures resulting in low prevalence of asymptomatic illness in their healthcare workers and patients with all centres remaining in business.

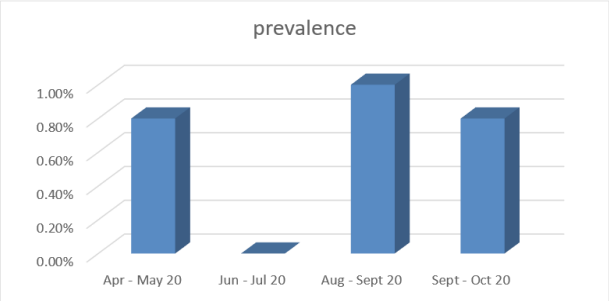

Figure 4: Prevalence of COVID-19 in healthcare workers in our organization.

Discussion

The COVID-19 pandemic has been a great challenge for health systems around the world. One of the biggest challenges is the detection of COVID-19 prevalence in asymptomatic patients and staff, who could act as super spreaders. The purpose of any testing program should be to limit the spread of infection and protect staff and patients from harm.

The molecular test of choice in UK for detecting SARS-CoV-2 infection is the nasopharyngeal RT-PCR test [7], which is highly specific for SARS-CoV-2 and does not become positive when exposed to the nucleic acid of other common viruses [2,8,9].

The purpose of our study is the use of RT-PCR swab test within a routine testing program for asymptomatic staff and patients in a 14-centred healthcare group, in order to assure the safety of patients and workforce while maintaining essential cancer services. The study has reported its preliminary results on the prevalence of COVID-19 in asymptomatic healthcare workers from a closed healthcare population spread across England (figure 4). The 14 cancer centres are spread across a large geographical area, including East and West Midlands, East Anglia, London, Kent, Oxfordshire, the South coast and Somerset. Our prevalence of asymptomatic infections is very similar to the REACT-1 study [10] with 1 in 170 people-testing positive for the virus, a prevalence of 0.5%. This prevalence is higher in certain parts of England, depends on age and ethnicity and ranges between 0.5% and 1% [10,11].

The higher prevalence of asymptomatic infection in April/May 2020 corresponds to the 1st lockdown and is similar to what has been previously recorded [10,11]. The low prevalence during summer follows the strict lockdown measures, but once those measures were relaxed and people started to travel for holidays, we saw an increasing prevalence end August and early September which continues through to October. We aim to observe this pattern closely over the next few weeks and report our final prevalence outcomes in January 2021.

Despite the higher prevalence of asymptomatic infections April/May and September/October 2020, the centres remained opened due to case isolation and other IPC measures. Only two patients were tested positive in May/June time, likely community acquired rather than from the centres, as they belonged to two different centres with no positive staff members. We strongly believe that the rigorous IPC measures, social distancing, virtual consultations, adequate PPE stock for staff and patients and decontamination procedures have resulted in the containment of infection to single individuals only, as reported elsewhere [12].

Reusken (2020) [13] published their results on 1097 healthcare workers with mild respiratory symptoms in the Netherlands and found that 4.1% of them were tested positive for SARS-CoV-2, a lot higher than our recorded prevalence. Keeley (2020) [14] reported on over 1,533 asymptomatic staff who were tested with RT-PCR at Sheffield Teaching Hospitals NHS, with 18% of those testing positive. Hunter (2020) [15] at the Newcastle upon Tyne Hospitals NHS, performed 1666 RT-PCR tests in 1654 asymptomatic staff, with an overall 14% positivity. The prevalence of asymptomatic infections is high in those healthcare worker populations, which reflect the acute nature of the NHS Trusts unlike our non-acute facilities. The prevalence of asymptomatic COVID-19 infection in our healthcare worker population more closely resembles the community prevalence.

Unlike other authors [13-15], we consider two main strengths in our study. First, we have a very close control both of patients and staff population testing. Testing is available routinely for everyone regardless of symptoms, instead just the symptomatic people, which has been considered as a limitation by those authors [13-15]. Our study is well powered as we test on average 204 healthcare workers and 21 patients each week from 14 different centers, which are geographically spread across England. The final prevalence outcomes which are due to be reported in January 2021 will cover the whole pandemic period, from the 1st UK lockdown, to the post lockdown period and the second wave during autumn/winter 2020. Our results will inform about the prevalence of COVID-19 in closed healthcare environments and the positive impact of IPC measures in preventing viral spread [12].

A study limitation is the rigorousness of the testing program and the risk of dropping out for staff and patients. This is mitigated through raising awareness of its importance in keeping staff and patients safe.

Declarations

Acknowledgements

Not applicable

Funding

GenesisCare (the organisation) pays for the testing of patients and staff.

Author details and contributions

The authors are in order of contribution: PK designed the testing program and wrote the protocol, CH supported the protocol writing, KR and AS acted as the clinical advisors, JP performed swab testing, BL and JC reported on weekly results, EMO, EL, JGF and DR shared insights from another country and edited protocol, SL led the global quality agenda for the organisation and all authors have read and approved the manuscript.

Ethics Committee approval

Ethics Committee approval was deemed unnecessary as the test is used routinely in the NHS for staff and patients undergoing cancer treatment and prior to clinical procedures (see text).

Availability of data and materials

The datasets generated are not publicly available and the consent process does not include sharing data publicly. Only anonymised data are reported in this study and future final manuscript. Participant recruitment is ongoing.

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