Public Health England

Protecting and improving the nation's health

Evaluating detection of SARS-CoV-2 antibodies

EDSAB-HOME study: details, research protocol and outputs

Background

The EDSAB-HOME study is a study aiming to evaluate the detection of SARS-CoV-2 antibodies using home testing kits detecting antibodies against the SARS-CoV-2 virus. These kits are called lateral flow immunoassays, appear similar to a pregnancy test kit, and analyse a small amount of blood obtained from a finger prick. The study is being run by Public Health England (PHE) at the request of the Department of Health and Social Care.

Recruitment has now ceased, but the study is ongoing. More details, including the full study protocol, are below.

Over 3,100 people volunteered for the EDSAB-HOME study, and over 2,800 individuals attended study clinics in June 2020. We are very grateful for their contribution, following which various pieces of work are ongoing.

What we have discovered so far

Publication	Summary
People with higher levels of T cell recognising SARS-CoV-2 are protected from COVID-19 Note: This work is a pre-print, which means it has not yet been peer-reviewed.	T cells are immune cells generated on infection which coordinate the immune system's activities; some T cells specialise in fighting viral infections. About one-quarter of the keyworker population studied had high levels of T cells which recognised SARS-CoV-2 in their blood when they joined the study in June 2020. By 'high levels' we mean levels similar to those seen in people who have had coronavirus (COVID-19) disease. However, about half the people with high levels of T cells in their blood have not had COVID-19, as far as we could tell – the cells were probably there because of previous infection with coronaviruses other than SARS-CoV-2. Importantly, in our study people with higher levels of circulating T cells appeared to be protected from COVID-19 in the 4 months after recruitment in June 2020. This applies both to people who have been previously infected with COVID-19, and to those who had not.
Personal belief in past COVID-19 illness is not necessarily reliable Note: this work has been peer reviewed and published by the Journal of Infection.	Laboratory based antibody tests (Roche Elecsys anti-Nucleoprotein EUROIMMUN anti-Spike S1) detected more than 95% of key workers who had had previous COVID-19 tests. About one-third of keyworkers believed they had had COVID-19. However, of this third, only half had antibodies supporting their belief. The timing of illness, and the nature of the symptoms in this group suggest many had non-COVID illnesses. Self-reported symptoms are not a reliable way of ascertaining past COVID-19 disease.

Dried blood spot testing is substantially less sensitive than testing on liquid blood samples Note: this work has been peer reviewed and published by the Journal of Clinical Virology.	One way of doing antibody testing involves dropping blood onto a filter paper, and drying it. The antibodies in the dried blood can subsequently be washed out and analysed. We showed it was feasible to do this, but the technique could not detect low levels of antibodies. Dried blood spot based tests will not find as many people with previous COVID-19 as doing tests on liquid blood samples.
Lateral flow immunoassays (LFIAs) can deliver results rapidly and at scale, but have widely varying accuracy Note: this work has been peer reviewed and published by EBioMedicine.	SARS-CoV-2 antibody tests are used for population surveillance and might have a future role in individual risk assessment. In a laboratory setting, 4 LFIAs were compared using blood samples from key workers and pre-pandemic blood donors to determine how well the devices correctly detect individuals with antibodies (sensitivity) and those without antibodies (specificity). There was a clear trade-off between sensitivity and specificity across the 4 devices. All 4 devices showed higher sensitivity at higher antibody concentrations, but this varied by device.
Sensitivity of UK-RTC "AbC-19 Rapid Test" lateral flow immunoassay (LFIA) was higher when antibody concentrations were higher Note: this work has been peer reviewed and published by the British Medical Journal.	In a laboratory setting, performance of one LFIA bought by the government (AbC-19 Rapid Test) for population surveillance was compared to laboratory based tests using blood samples from key workers and pre-pandemic blood donors to determine how well the devices correctly detect individuals with antibodies (sensitivity) and those without antibodies (specificity). The device had higher sensitivity when antibody levels were higher (for example, people who had had a more severe previous SARS-CoV-2 infection).

Study details

Study protocol	The protocol for the EDSAB-HOME study
Patient information sheet	The patient information sheet for the EDSAB-HOME study
Laboratory SOP	EDSAB-HOME study: details, research protocol and outputs
Research ethics approvals	NHS Research Ethics Committee 20/NE/0166 (Health Research Authority, IRAS 284980) 2 June 2020; PHE Research Ethics and Governance Group (REGG) NR0198, 21 May 2020
Funding	Public Health England
Clinical trials registration	ISRCTN56609224
Study status	Recruitment completed; follow ongoing

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, research, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

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