UKHSA Evaluation of Effectiveness of National testing for SARS-CoV-2 in England
ORDER REFERENCE: C80260/PRO5331

Order Schedule 20 (Order Specification)

This Schedule sets out the characteristics of the Deliverables that the Supplier will be required to make to the Buyers under this Order Contract

The key purpose of this evaluation is to contribute to the evidence base for the use of testing in any future pandemic response; this is in addition to understanding what did and did not work in relation to testing during the COVID-19 pandemic.

As a guide, the national testing programme includes the following services and delivery channels: Universities, Schools, Adult Social Care, Elective Care, Healthcare, Under-represented Groups, Public Sector, Private Sector, Events, Pharmacies, Home Direct and Targeted Community Testing.

It should be noted that the testing programme was a key component of the Test, Trace & Isolate strategy, and that testing cannot be evaluated without a clear understanding of its relationship to self-isolation of infected individuals and tracing of contacts.

EVALUATION OF ACTIVITIES DELIVERED BY THE NATIONAL TESTING SERVICES

The aim of this project is to evaluate (1) the public health impact and (2) the cost effectiveness of the testing activities of NHS Test and Trace delivered in several settings and through multiple channels (referred to here as 'the services'). The over-riding purpose of this is to contribute to a body of evidence that will inform testing approaches in any future pandemics.

These activities (referred collectively here as 'the intervention') were implemented with the aim of reducing the risk of transmission of SARS-CoV-2 (COVID-19) in the population.

Each individual testing service was required to be clear about its public health objectives and any other objectives it may have, and to have an evaluation planned to address those. An evaluation framework and toolkit were developed in Autumn 2020 to support the planning of evaluations.

REQUIREMENT FOR AN INDEPENDENT NATIONAL EVALUATION

This is an independent evaluation of effectiveness of national testing services to answer the key questions of what worked, for whom and why, to inform both current and future plans for national testing, and to learn lessons for future pandemics. The Public Health impact of the testing programme should be the primary focus, with cost effectiveness as a secondary focus.

UKHSA expect that the evaluation will be conducted closely with relevant stakeholders and experts.

a) This is <u>not</u> a commission of an economic evaluation of the cost effectiveness of NHS Test and Trace or UKHSA as an organisation. Our interest in cost effectiveness is entirely from a Public Health perspective and is limited to the relative costs of different testing interventions and technologies in the context of the service in which they were used and the stage in the pandemic in which they were implemented.
b) <u>nor</u> is the Supplier seeking a critique of government policy, but the evaluation should focus on implementation of policy and success in delivering policy objectives.

SCOPE OF WORK

a) The evaluation should cover the following areas with a common thread throughout of understanding the services' effectiveness (noting that questions here are given as examples, and are not intended to be exhaustive):

Public health benefit – what impact does this intervention have on reducing chains of transmission? Are there observable impacts on prevalence? Are there other public health benefits?

Wider societal and economic benefit – what are the effects and costs of this programme more widely? Are there benefits to individuals and communities? How can these be measured? What has been the impact at a national level?

Disbenefits and shortcomings – it is important to also capture the downside of testing. What were the barriers to testing? Did testing bring about negative consequences for communities and individuals?

b) The evaluation should cover as far as possible the activities delivered to the following services and channels, and their respective target populations:
   i. Services (target populations)
      - Adult Social Care (staff, residents, visitors, visiting professionals)
      - Elective Care (patients)
      - Events (staff, people attending)
      - Healthcare (all staff)
      - Private Sector (employees)
      - Public Sector (employees)
      - Schools (staff and pupils)
      - Targeted Community Testing (Public, specific groups)
      - Universities (students, staff)
   ii. Channels (delivery mechanisms for testing of the general public)
      - In person testing (public regional testing sites, local testing sites, mobile testing units)
      - Pharmacies (public)
      - Home Direct (critical workers for PCR, public for PCR and LFD)

c) The evaluation should take into account the context of changing prevalence, adaptations to national and local testing policies, the end of national lockdown, the increasing coverage of vaccination, and other relevant events.

ROLE OF THE SUPPLIER

a) Build and manage relationships with the services and internal analytics/research teams such that their work is supported and enhanced
b) Provide an assessment of the process used by UKHSA and system partners to design and implement testing services
c) Define testing services' outcomes, and provide an objective analysis of these; this is likely to involve defining one or more counterfactuals
d) Synthesise the data and intelligence from the services to provide practical lessons that could be used to inform implementation of testing services for future pandemics
e) Propose an evaluation framework with tools (forms, templates, basic references, scripts in software packages, etc) that could be used in future evaluations

DESIGN, METHODOLOGY AND DATA

Some non-exhaustive guidance approach to study design and data handling is given here.

a. Definition of impact

Impact here is defined as beneficial or deleterious changes that occurred because of (or attributed to) the implementation of the intervention in the population of these services. The primary analyses will be on the changes in the health status, measured against a set of defined indicators. Impact can also be measured in terms of allowing activities to take place, such as continuity of critical infrastructure, enabling key workers to be in their workplaces, attendance of children at school, etc.

b. Intervention

For this project, the activities under investigation involve the diagnosis of COVID-19 infection in asymptomatic and symptomatic people, followed by the isolation of those with positive results and, where relevant, isolation &/or testing of contacts of positive cases.

These tests can involve:

i. Different sampling methods, e.g. throat and nose swab, saliva
ii. Different technology to detect the virus, e.g. rapid lateral flow antigen immunoassay, quantitative reverse transcription-polymerase chain reaction (qRT-PCR), loop-mediated isothermal amplification (LAMP)
iii. Different regimes, e.g. technology mix and frequency
iv. Different delivery channels
v. Different settings

This project will require a primary analysis of these activities as a single intervention instead of estimating the effect of each different component (isolation of the positive cases vs. isolation of the contacts, different techniques to detect the virus,

etc). Separate analyses (secondary analyses) may be conducted depending on the availability of data and time.

c. **Overview of methodology and design**

Impact implies causal inference[1], which in this project will rely on analysis of observational data and use of a number of other different approaches[2]. These approaches will depend on the nature and availability of data. Potential examples (but not limited to) include:

i. counterfactual reasoning: the number of people detected through testing as a potential infectious case would correspond to the number of people who would not have been identified without the intervention
ii. triangulation: results from different analyses dealing with different sources of biases and assumptions
iii. economic analysis and modelling: for example, the Canna model: Assessing the impact of NHS Test and Trace on COVID-19 transmission, 2021, UK Health Security Agency[3].

A methodological challenge is the overlap of effects resulting from other interventions implemented in the same settings and populations, such as social distancing, vaccination, mask-wearing, etc. As a limitation, it will not always be possible to separate in the analysis the contribution of each one, resulting in varying levels of strength of causal inference. Where causality cannot be proven, the Supplier expects a clear presentation of the nature of the association of the findings.

The Supplier does not want to over-specify the design. However, the Suplier does expect a multi-disciplinary approach that uses some or all of the following:

i. Literature and wider evidence review to learn from international approaches
ii. Systems mapping, logic modelling, service design, economics, user journeys and/or other techniques to understand and communicate complexity
iii. Data science or other advanced quantitative methods
iv. Behavioural science techniques to assess motivation, attitude and human responses
v. Theory-based approaches to impact evaluation that consider wider context and systems
vi. Evidence synthesis and modelling to combine findings into pragmatic policy and programme recommendations that can be easily communicated

The evaluation approach is likely to need to flex to reflect the changing historical policy environment over the course of the pandemic's various phases. It will use rigorous and scientifically sound approaches while remaining pragmatic and focused on policy stakeholder needs.

i. The national evaluation will analyse national datasets available and potentially identify other datasets that could be acquired to assist the evaluation.

ii. The evaluation should take into account existing evidence, frameworks and tools used by and developed by government and partners such as SAGE, SPI-M and SPI-B.
iii. The evaluation approach should be aligned with the Magenta Book[4].

d. **Evaluation questions**

The evaluation approach should address the following areas:

i. Process and descriptive: for example, what was the number of LFD tests conducted in time x and the trends over time? How many people acted appropriately on their test result (self-isolation, tracing)? How many contacts were traced and then acted appropriately? [NB avoid requirement for new data collection] Suppliers should note that this data and much analysis already exists and this will be provided to the successful bidder on request.
ii. Process and normative: for example, what was the proportion of individuals that were tested according to the recommendations (e.g. twice a week)?
iii. Impact related to outcomes defined by the results of the tests: for example, did the occurrence of outbreaks in institutional settings decrease in the course of time since the implementation of the intervention (accounting for local and national prevalence trends)?
iv. Impact related to other outcomes: for example, what was the trend in the indicators of health care utilisation in the community where schools were located, among individuals aged 12-18 years since the implementation of the intervention in schools? (health care utilisation here refers to, for example, amount of call/access to NHS 111 for COVID-19)

e. **Data**

The data to be used will depend on the availability in different settings and will be in relation to:

i. Testing (e.g. number of tests, results, date of the test, frequency)
ii. People tested (e.g. age, sex, staff, students, etc)
iii. Population eligible (number of staff, residents, students, etc)
iv. Context (e.g. covid-19 case rate in local areas where the services are located)

GOVERNANCE, OVERSIGHT AND ADVISORY ARRANGEMENTS

a) Although this evaluation needs to be independently delivered, UKHSA is not just a recipient but a key stakeholder; the output report will have direct utility for learning how to manage future pandemics. It is likely that other independent evaluations will be commissioned in due course, and that these will focus on use of public money to fund NHS Test and Trace in 2020-22, rather than providing an evidence base for the future.
b) The oversight arrangements for this evaluation will be:

i. A secretariat to support the successful bidder and manage day-to-day and week-to week queries and issues; this will include provision of correct data sets, provision of context including prevailing policies, previous evaluation outcomes, responding to general questions, management of risks, etc
ii. An advisory group which comprises a combination of experts nominated by both the supplier and UKHSA to provide assurance on methodology; this group will give expert opinion on methodological questions and their outcomes (including questions related to historical context); this group will be the mechanism through which UKHSA receives assurance on the objectivity of the evaluation; an Open Science approach to publicising the evaluation protocol is expected
iii. A liaison board [name tbc] which comprises senior officers from UKHSA and possibly also from other government departments [membership tbc]. This will be the senior oversight group which will:
   - provide internal assurance to UKHSA that the spend on evaluation is being used appropriately
   - manage relevant relationships with other government departments (at process and outcome stages)
   - ensure that UKHSA pays due attention to the findings of the evaluation and lessons are learned
   - ensure that the evaluation findings are submitted in evidence to the Public Enquiry
   - to note, the Liaison Board will not have the power to direct (or re-direct) the outcomes of the evaluation, but will work with the supplier to ensure that the report is in a format to which government can respond

TRANSPARENCY AND STANDARDS

a) Day-to-day management of this research will be provided by the principal investigator.
b) Ethics approval where appropriate. All research involving National Health Service (NHS) and adult social care users, carers, staff, data and/or premises must be approved by the appropriate research ethics committee (REC) or social care research ethics committee (SCREC). For further information on RECs, please visit the National Research Ethics Service.
c) The successful evaluation team must adhere to the GDPR (2018), Data Protection Act (1998) and the Freedom of Information Act (2000). Effective security management and ensuring personal information and assessment data are kept secure, will be essential. In particular:
   i. The evaluation team shall, at all times, be responsible for ensuring that data (including data in any electronic format) are stored securely. The evaluation team shall take appropriate measures to ensure the security of such data, and guard against unauthorised access thereto, disclosure thereof, or loss or destruction while in its custody.
   ii. Personal data shall not be made available to anyone other than those employed directly on the project by the evaluation team, to the extent

that they need access to such information for the performance of their duties. A higher level of security clearance may be needed. In any event, the evaluation team will work alongside an UKHSA data science team who will be able to provide anonymised and pseudonymised data (as appropriate).

d) Equality, Diversity and Inclusion: due consideration must be given to the impact of the evaluation on potentially vulnerable participants.
   a. Academic publication: The Supplier expects that successful evaluation team will want to publish all or some of their work in peer-reviewed journals and other academic platforms. This will require at least 28 days' notice to UKHSA so that feedback maybe sought and given on accuracy, and amendments made as appropriate. In this instance, 'publication' concerns any presentation, paper, press release, report or other output for public dissemination arising from this funding. There is no time limit to this provision and research contractors remain under an obligation to provide notice even after the contract has ended. Publication of UKHSA-commissioned research is subject to prior consent of the DHSC Secretary of State.
   b. Advisory group members are expected to collaborate as named authors on academic papers if they are appropriately involved in the evaluation design and implementation
   c. Freedom of Information (FOI) etc to be answered by UKHSA
   d. In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information on the transparency agenda is at:

https://www.gov.uk/government/publications/procurement-and-contracting-transparency-requirements-guidance.

DELIVERABLES

a) The supplier is required to prepare an evaluation protocol which will go through a peer review process[5] in early September 2022; once approved, this is expected to be published on an Open Science platform.
b) The supplier will be expected to submit concise written progress reports monthly in which they will indicate any significant risks or proposed changes to the agreed protocol, as well as setting down milestones for the next month, giving an update emerging analysis and other outputs.
c) A draft evaluation report, will be required by the end of January 2023. The draft report will be peer reviewed and circulated to policy-makers in UKHSA.
d) A final report of the evaluation, with an accessible executive summary, will be required by the end of February 2023. For the purposes of the tender response, suppliers should assume that the final report(s) from this evaluation will be prepared and published by their own organisation, while also being appropriately put into the public domain by government.
e) Ways of working: the supplier should demonstrate how they will work with nominated officials in UKHSA and partner government departments. Key documents including for example research protocols, research instruments and reports must be provided to UKHSA in draft form allowing sufficient time for

review. The supplier is expected to work with the authority on a “no-surprises” basis. The supplier is also expected to produce an engagement plan and delivery schedule, and a weekly activity summary and forward look; these engagement management tools will be shared with the authority’s nominated project lead.

f) All data (raw and analysed) from the evaluation will be expected to be transferred to UKHSA as soon as possible and by 15th March 2023 at the latest.
g) Acceptance criteria:
    a. EY will submit interim drafts of a Deliverable to UKHSA for review. UKHSA shall review and provide any feedback on each interim draft within ten (10) business days of receiving it from EY,
    b. UKHSA will notify EY in writing within the timeframes described in this section, either stating that the final Deliverable is accepted in the form delivered by EY or describing in reasonable detail substantive deficiencies that must be corrected prior to acceptance.
    c. EY will correct the described deficiencies within ten (10) business days, at which time EY shall submit corrected final Deliverable to UKHSA for review in accordance with the procedures set forth immediately above.
    d. If UKHSA does not provide a response within ten (10) working days from submission, then the Deliverable will be deemed accepted.
    e. Any beneficial use of the Deliverables by UKHSA before any feedback is submitted shall deem the deliverable immediately accepted by UKHSA.
    f. Deliverables acceptance will not be unreasonably withheld by UKHSA.

ASSUMPTIONS

a) The Buyer is solely responsible for ensuring the scope of the project is sufficient for its purpose.
b) Should the Buyer fail to fulfil their obligations and responsibilities set out in the SOW the Supplier will not be responsible for any delay in the timetable for providing the Services, any failure to provide the Services and any failure to provide the quality of Services set out in this SOW.
c) The Supplier reserves the right to charge the Buyer for any additional resources or time required as a result of a failure to fulfil their obligations and responsibilities, to complete the performance of the Services.
d) Specific obligations on the Buyer’s part underpinning our approach and anticipated quality of outcome are:
    a. The Buyer will provide access to stakeholders to support meetings, discussions, workshops and other points of engagement as will be mutually agreed;
    b. The Buyer will provide access to appropriate data as required;
    c. The Buyer will respond promptly to queries as they may arise;
    d. The Buyer will provide timely notification to a nominated representative (Gulsen Yenidogan) of information that will or may reasonably be expected to impede project activities, delivery of the Services or of the

Deliverables. For this purpose, timely shall mean within one business day of becoming aware of such information;

e. The Buyer will nominate and assign a qualified person to oversee the Services;
f. The Buyer is responsible for all management decisions relating to the Services.

e) The Supplier will rely on Client Information made available to us and, unless the Supplier expressly agrees otherwise, will have no responsibility to evaluate or verify it.
f) The Buyer will endeavour to make all data and information needed for us to fulfil our obligations available to us in a timely manner and notify us in a timely fashion if this data should not be available.

RISK MANAGEMENT

a) Once appointed, the successful bidder is expected to maintain a risk register for delivery of the evaluation.

FUNDING

a) The evaluation contract will be funded from UKHSA on a fixed price contract, with staged milestones
b) Costings can include up to **100% full economic costing (FEC)** but should **exclude output VAT**. Applicants are advised that value for money is a key criterion that Procurement Panel will consider when assessing applications.
c) The budget will not exceed £3.5m excluding VAT

BASE LOCATION

Remote working with a degree of flexibility to meet onsite at London office at the request and express permission of UKHSA.

PAYMENT

The Supplier shall submit an invoice at the end of each month detailing effort employed and progress against the Key Milestones.

Invoices will be paid monthly in arrears by BACs or alternative payment method as agreed between the Buyer and the Supplier.

KEY MILESTONES

The provider should note the following project milestones that the Authority will measure the quality of delivery against.

Other interim milestones to be agreed as part of Milestone one – this may include workshops and other activities to support the delivery of the evaluation and creation of the final report.

Milestone	Description	Delivery date
One	Stand up delivery team, be ready to proceed, delivery and acceptance of implementation plan.	26 August 2022
Two	Evaluation protocol is agreed and can be made public on an Open Science platform	23 September 2022
Three	Acceptance of monthly written progress reports	August 2022 - February 2023 (end of each month)
Four	Draft final report(s) submitted	31 January 2023
Five	Final report submitted, suitable to be published	28 February 2023
Six	All information (including raw and analysed data) from the evaluation transferred to UKHSA	15 March 2023