Prioritisation and evaluation of novel coronavirus diagnostic in the UK

15 July 2020
COVID-19 New Test Triage and Evaluation System

Mike Messenger, Scientific Advisor to COVID-19 Testing Programme (New Tests)

13 07 2020
The five pillars of the national testing strategy announced by the Secretary of State on April 2 2020

‘Pillar 1’: Scaling up NHS swab testing for those with a medical need and, where possible, the most critical key workers

‘Pillar 2’: Mass-swab testing for critical key workers in the NHS, social care and other sectors

‘Pillar 3’: Mass-antibody testing to help determine if people have immunity to coronavirus

‘Pillar 4’: Surveillance testing to learn more about the disease and help develop new tests and treatments

‘Pillar 5’: Spearheading a Diagnostics National Effort to build a mass-testing capacity at a completely new scale
## Innovation priorities

<table>
<thead>
<tr>
<th>In scope</th>
<th>Out of scope</th>
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</thead>
<tbody>
<tr>
<td><strong>Point of care or rapid turn around time tests which:</strong></td>
<td>• The UK currently has a strong stock and supply chain of laboratory based RT-PCR</td>
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<tr>
<td>• Use a simple hand held or desktop-based (ie non lab based) machine to analyse samples AND/OR</td>
<td></td>
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<tr>
<td>• Do not have a RNA extraction step or have an innovative approach to RNA extraction not demonstrated by products in the UK market AND/OR</td>
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<tr>
<td>• Use an innovative and non-invasive sampling technique i.e. Saliva, sputum, urine, finger prick (capillary) blood, sweat, interstitial fluid, tears, breath AND/OR</td>
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<tr>
<td>• Deliver a quick turnaround (e.g. &lt;30 mins) AND/OR</td>
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<tr>
<td>• Low cost and can be scaled to increase volume AND/OR</td>
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<tr>
<td>• Multiplexes with other pathogens</td>
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</tbody>
</table>
Potential use cases

- Increase hospital lab capacity
- A&E triage
- Hospital admissions (urgent and non urgent)
- NHS staff testing
- Out of hospital testing
- Test and trace
Validation process overview

### Offers received


### Offers triaged

**Desktop triage**

Desktop review of the form for completeness and adherence to Initial Triage criteria or Target Product Profiles.

Outcomes may include: reject, defer and request additional information, or progress to Advisory Group Validation.

### Advisory group validation

Advisory group discuss initial triage review assessment and agrees decision for each offer.

Outcomes may include: progress to evaluation, refer to other group, defer (if offer doesn’t meet need) or request additional information.

### Offers evaluated

**Technical evaluation (TE)**


**Clinical evaluation (in context) (CE)**

Depending on the use case of the test, a clinical evaluation may be required.

Offers that have satisfactorily passed TE and CE will be recommended.

### Offers Referred out

**Referral to other working group**

Offers that appear promising but either not mature enough, or not within our scope are referred to other support working groups, such as The Diagnostics Innovation Team.

### Products procured

Following recommendation from the Validation Programme, DHSC’s procurement and commercial teams will contact the developer or supplier to discuss the terms under which such a roll-out may occur.
Validation process for viral POC tests

VTAG: Initial ‘Desk based’ triage and assessment against TPP

Stage Gate 1a: LoD analysis done by NML using INSTAND materials
Stage Gate 1b: Initial test accuracy assessment
Stage Gate 1c: Usability and safety assessment

Is further analysis on stored/contrived samples possible?

Yes: Initial lab based assessment
No: CONDOR assessment using prospective patients

VTAG: Consideration of data and assessment against TPP

Stage Gate 2: Clinical evaluation (CONDOR)

VTAG: Final review and recommendation from VTAG
Next steps and contacts for Industry

• Please read our guidance on helping the government increase testing: https://www.gov.uk/guidance/help-the-government-increase-coronavirus-covid-19-testing-capacity#how-to-help

• If you think you meet the TPP, or if your test does not match the specifications TPP but looks promising, please consider submitting your proposal via the DHSC portal: https://consultations.dhsc.gov.uk/Full-Test-Kit-Covid19

• If you have enquiries about the DHSC portal or process, please contact 0800 915 9965 or covid19triageservice@nhsbsa.nhs.uk.
CONDOR
COVID-19 National Diagnostic Evaluation & Research Platform

PROF RICK BODY
## Diagnostic Pipeline

A timeline of the COVID-19 pandemic

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>JAN 10TH</td>
<td>SARS-CoV-2 genome sequenced &amp; published</td>
</tr>
<tr>
<td>JAN 17TH</td>
<td>First RT-PCR assay for SARS-CoV-2 reported online</td>
</tr>
<tr>
<td>FEB 4TH</td>
<td>1st FDA emergency approval for RT-PCR assay</td>
</tr>
<tr>
<td>MAR 17TH</td>
<td>1st point of care test receives emergency FDA authorization</td>
</tr>
<tr>
<td>APR 4TH</td>
<td>1st antibody test receives emergency FDA authorisation</td>
</tr>
<tr>
<td>MAY 2020</td>
<td>FindDx lists 247 CE marked assays relating to COVID-19</td>
</tr>
</tbody>
</table>
COVID-19 National DiagnOstic Research and Evaluation Platform

- CARE PATHWAY ANALYSIS & TARGET PRODUCT PROFILES
- IN-CONTEXT CLINICAL VALIDATION
- ANALYTICAL VALIDATION
- HUMAN FACTORS EVALUATION

NIHR | National Institute for Health Research
CONDOR PATHWAY

1. Test submitted using DHSC online portal
2. Referral made to CONDOR
3. Booking form completed. Call arranged
4. Steering committee identify evaluation needs
5. Evaluation completed
6. Feedback to DHSC, company, NICE, journals
Lateral flow test

RAPID RESULTS
SIMPLE TO USE
MAY BE LESS SENSITIVE

Self-testing
GP surgery
Airports
Bench top instrument

RAPID RESULTS
NEEDS SOME PROFESSIONAL EXPERTISE
RELATIVELY SLOW THROUGHPUT
OTHER IMPORTANT CONSIDERATIONS

- BIOSAFETY
- INSTRUMENT AVAILABILITY
- USE CASE-SPECIFIC TARGET PRODUCT PROFILES
WHY WORK WITH CONDOR?

Strong methodology
- Designed by an extensive national network of methodologists
- Subjected to robust peer review

National scale
- NIHR Urgent Public Health status
- Multiple sites
- Multiple contexts

One-stop shop
- Coherent approach with the DHSC, NICE, MHRA

Funded by NIHR National Institute for Health Research
Testing is crucial to inform our emergence from the COVID-19 pandemic.

Our work will ensure that our testing strategy can be informed by the most rigorous science possible.
Care Pathway Analysis

CONDOR Cross Cutting Workstream
The Methodology Subgroup
Care Pathway

The journey of patients with a certain medical condition during an episode of healthcare.
Care pathway analysis

- Allows visualisation of all clinical decisions
- Models the outcomes of the decisions
- Allows assessment of clinical needs
- Informs health economic modelling of the new technology
Workstream aims

- To characterise **unmet clinical need** and **optimal placement** for COVID-19 diagnostic tests

- To inform development of the MHRA **target product profiles** (TPPs)

- To inform the **appropriate design** of CONDOR clinical evaluations

- To inform **NICE economic modelling**

- To identify **evidence gaps**
Progress

National survey of health and social care professionals
- Prioritisation of clinical settings and use cases
- Identification of availability of testing and clinical needs

Care pathway analysis
- Interviews in hospitals and care homes
- Mapping of the pathways
Exploratory economic modelling of SARS-CoV-2 viral detection point of care tests and serology tests

Rebecca Albrow
Associate Director
Diagnostics Assessment Programme
Rationale for this project

To undertake exploratory economic modelling of hypothetical SARS-CoV-2 viral detection point-of-care (POC) tests and serology tests

• To identify the parameters that are most influential on cost-effectiveness modelling results
• Establish priorities for future research and highlight where data are absent
• Establish which use cases are likely to be cost-effective

Characteristics of tests modelled will be based on the Medicines and Healthcare products Regulatory Agency’s (MHRA) target product profiles
2 decision questions

What is the clinical and cost-effectiveness of the point-of-care testing to help detect SARS-CoV-2?

What is the clinical and cost-effectiveness of antibody serology testing?
A range of use cases

<table>
<thead>
<tr>
<th>Setting</th>
<th>Use cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>A test for:</td>
</tr>
<tr>
<td></td>
<td>• Symptomatic patients presenting to a hospital</td>
</tr>
<tr>
<td></td>
<td>• Symptomatic staff</td>
</tr>
<tr>
<td></td>
<td>• In-patients who develop new clinical features of COVID-19 during their</td>
</tr>
<tr>
<td></td>
<td>hospital stay</td>
</tr>
<tr>
<td>Care home</td>
<td>A test for:</td>
</tr>
<tr>
<td></td>
<td>• Newly admitted residents to prevent transmission to existing residents</td>
</tr>
<tr>
<td></td>
<td>• Symptomatic care home residents</td>
</tr>
<tr>
<td></td>
<td>• Symptomatic staff</td>
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Timelines

- Report for stakeholders on hospital and care home setting by October.
- Process designed to be responsive to changes in health system and government priorities.
- May be subject to change to allow NICE to respond as rapidly as possible.
NIHR: Industry Offer

Dr Peter Sargent,
Head of Business Development, NOCRI
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July 2020
Supporting IVD down the road to market

Invention

Prototype (Preclinical Evaluation, Manufacturing Process, Quality)

Evaluation

Care Pathway Impact Assessment

Qualify Analytical and Clinical Validity

Evaluate Clinical Utility

Evaluate Cost Effectiveness

Output Report

Adoption

Patient and Economic Benefit

Diffusion

Healthcare System Impact

Support of Innovation at Technology Readiness Level 3 to 9

NIHR Support

Wider UK research and health system (i.e. DHSC, DIT, OLS, MedCity, NHSA, ATN, UKRI, AAC)

MHRA, HRA, NICE

Connect you to adopters and disseminators (i.e. CCGs, NHSE, AHSNs)
NIHR Offer to Industry

• The NIHR supports life science companies translate their new innovations into the clinic and then onto market.

• We can provide a full range of offers to support innovators throughout their clinical pathway, from early stage translational research through to later stage clinical trials in the NHS and social care settings.

• Connect you to the wider UK infrastructure and Government (i.e. DHSC, OLS, DIT, Trade Associations and Clusters)

Free Service
Offers of Support:
CONDOR:
https://consultations.dhsc.gov.uk/Full-Test-Kit-Covid19

Broader Support:
NIHR Office for Clinical Research Infrastructure
nocri@nihr.ac.uk
www.nihr.ac.uk