HEALTH INNOVATION
North West Coast

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Acute respiratory infection: a test and treat community pathway

A MIXED METHOD REAL WORLD EVALUATION BY HEALTH INNOVATION NORTH WEST COAST

HEALTH INNOVATION North West Coast

NHS England

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1 EXECUTIVE SUMMARY

Innovative community pathways can reduce winter pressures, boost antimicrobial stewardship and improve patient experience in primary care. Winter pressures faced by the NHS are often exacerbated by a surge in cases of acute respiratory diseases such as influenza, respiratory syncytial virus (RSV) and, more recently, coronavirus.[1]

Although most people recover within a week without requiring medical attention, acute respiratory infections can lead to severe illness, hospitalisation and death. Older adults, infants, pregnant women, overweight individuals, and individuals with chronic medical conditions are particularly at risk, with England having among the highest mortality rates from respiratory disease in Europe.[2]

These infections can also lead to a strain on healthcare services, including an increase in GP appointments and hospital admissions, with the average cost of a non-elective hospital spell currently at £5237.[3]

With these factors in mind, Health Innovation North West Coast (HINWC) has worked with regional clinicians to co-design an innovative test and treat community pathway for acute respiratory infections. Eligible patients could access testing at a local GP practice. Primary care-based point of care testing aims to improve diagnostic certainty, enabling GPs to provide the most appropriate advice and care, and to make well-informed decisions on the prescription of antibiotics and antivirals. Currently, anti-virals must be prescribed within 48 from the onset of symptoms and as such have a time-limited window of opportunity to improve patient outcomes.[4]

The pathway was designed to be test agnostic as there are several validated tests suitable for use in a community setting. The efficacy, specificity and sensitivity of the tests was not under review. Polymerase Chain Reaction (PCR) tests were selected as the best fit for the community test and treat pathway as they identify patients within the efficacy timeframe for anti-viral medications.

This report describes the pathway model and findings from the accompanying evaluation. Despite some limitations from a short flu season and smaller than intended testing numbers, the findings offer valuable insights into the key drivers and barriers to further spread of community testing and its impact on patients, general practice, and the wider system. It has shown that providing a point-of-care test in primary care setting is acceptable to staf and patients. Clinical staff acknowledge its potential to improve antimicrobial stewardship if test results are timely enough to influence prescribing decisions without significant delays.

If successfully implemented, community test and treat pathways have the potential to deliver system and patient benefits, including admission avoidance and hospital-based deconditioning. Future pathway development and evaluation should not be limited to acute respiratory infections but include other pathways where there can be better use of antibiotics.

The project was supported financially through a joint working agreement with Cepheid, a diagnostics company, and managed by the HINWC team to ensure independence.

[1] Quantifying the direct secondary health care cost of seasonal influenza in England | BMC Public Health | Full Text (biomedcentral.com) (www.england.nhs.uk/wp-content/uploads/2023/01/monitor-ara-21-22.pdf

[2] United Kingdom - England | Institute for Health Metrics and Evaluation (healthdata.org)

[3] Cost based on the mean cost across the range of complexities and levels of interventions, code DZ11, 23/25 NHS Payment scheme.

[4] https://bnf.nice.org.uk/treatment-summaries/influenza/

Method

This was a collaborative project between HINWC, Moreton and Meols Primary Care Network (PCN), Wirral Teaching Hospital NHS Foundation Trust, Liverpool University Hospitals NHS Foundation Trust and Marine Lake Medical Practice.

All partners co-designed the new pathway to test for acute respiratory infections at the point of initial care when patients first presented at their local practice. Eligible patients were the same as those who met the 2023 influenza vaccine criteria.3 The test screened for three acute respiratory infections: influenza A/B, RSV and coronavirus (SARS-CoV-2).

Moreton and Meols PCN on the Wirral implemented testing from 29 January 2024 until 16 April 2024. Marine Lake Medical Practice, also on the Wirral, acted as a comparator site. While not offering testing, they followed up a matched cohort of patients to track outcomes, strengthening the data for analysis.

A **"mixed methods"** evaluation was undertaken:

- **A qualitative analysis was conducted in alignment with the Consolidation Framework for Implementation Research (CFIR)[6] to understand the complex factors influencing the implementation and sustainability of pathway change projects,**
- **clinical acceptability of acute respiratory testing in a primary care setting was established using the theoretical framework of acceptability,[7]**
- **patient experience of the new pathway was measured through a questionnaire.**

Quantitative data was collected on total test numbers, positive and negative test results, and antiviral and antibiotic prescribing. Patients were followed up at 7 and 28 days to track patient impact through A&E admissions, hospitalisations and deaths.

Qualitative results

Clinician acceptability

All 14 clinicians who responded to the acceptability evaluation agreed that community test and treat for acute respiratory infections was acceptable. Clinical staff acknowledge its potential to improve antimicrobial stewardship if test results are timely enough to influence prescribing decisions without significant delays.

Most of these same clinicians agreed that testing was fair to all patients and could:

- **improve patient outcomes**
- **improve clinical work behaviours and**
- **improve antimicrobial stewardship.**

However, not all clinicians were confident about delivering community testing and concerns remained about workflow, workload, conflicting priorities, and time to receive test results.

[5] National flu immunisation programme 2023 to 2024 letter - GOV.UK (www.gov.uk)

[6] Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50

[7] Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework | BMC Health Services Research | Full Text (biomedcentral.com)

Implementation barriers and facilitators

Qualitative evaluation included ten in-depth, semi-structured interviews with frontline and operational staff. These interviews surfaced considerations across nine themes; funding, centralised co-ordination, pandemic preparedness, antimicrobial resistance, training and education, governance and IT integration, testing location and setup, staffing and workflow, pathway design and test selection.

Patient experience

All patient responders agreed that community test and treat for acute respiratory infections was a positive way to deliver care and would recommend the pathway. Patients felt that rapid point of care testing led to the correct treatment for their symptoms, and it made them feel reassured about their care.

Quantitative results

Moreton and Meols PCN tested 26 patients for influenza A/B, RSV and coronavirus . There were five positive tests in these patients: two for influenza A, none for RSV and three for coronavirus. Testing rates were lower than anticipated due to a short flu season, with infection rates in the region remaining low overall in line with national data (as reported by the UK Health Security Agency).

One patient with coronavirus was prescribed an antiviral, and 14 others were prescribed antibiotics. In the absence of testing for bacterial infections, antibiotics were prescribed when the GP suspected bacterial infection to be present, with or without the confirmed presence of an additional viral infection.

Follow up revealed one patient was admitted to hospital and another unfortunately passed away. Neither had tested positive for influenza A/B, RSV or coronavirus.

At Marine Lake Medical Practice, 44 eligible patients presented with acute respiratory infection symptoms. Of those, none were prescribed antivirals and 38 were prescribed antibiotics. By the seven-day follow up, two patients had visited A&E and were admitted. By the 28-day follow up, two additional patients had visited A&E but there were no further hospitalisations.

Recommendations

This evaluation focused on understanding implementation enablers and barriers and has highlighted system wide action as the key facilitator of the successful implementation of primary care based testing and treatment of acute respiratory infections. HINWC therefore recommends centralised co-ordination, planning and communication for future community testing activities. This will reduce duplication of effort, offer efficiencies, allow for optimal integrated IT systems, and strengthen pandemic preparedness. Pathology support and governance is recognised as an important component of coordinated pathway change in primary care.

Further work is required to optimise the pathway and the accompanying workflow to maximise the impact of point of care testing on prescribing behaviour and patient outcomes.

Testing and evaluation on a broader scale is recommended next flu season. To date, community testing has focused on high-risk patients to aid rapid patient management and any testing of a wider population needs further analysis to isolate any benefits. Further evaluation should also include more testing locations, matched with comparator sites and use a wider variety of laboratoryapproved diagnostic technologies.

To build on current knowledge and implement an improved pathway next winter, joined up financial planning across the integrated care system is recommended to address investment challenges and test reimbursement systems.

2 BACKGROUND

Both primary and secondary care struggle with winter pressures but historically incentives have not been aligned to secure the best outcomes for patients and taxpayers. Integrated care systems provide an opportunity to align incentives and implement new 'test and treat' pathways with the potential to significantly reduce pressures on hospitals, optimise resource use across the healthcare system, improve outcomes for patients and improve antimicrobial stewardship.

In line with the emergence of integrated care systems, policy and governance frameworks are evolving outside of traditional boundaries and there is greater acceptance of, and the need for, real world evaluations to inform strategic recommendations and decision making.

During and following the pandemic, the demand for services due to acute respiratory infections have increased. There were, on average, 66,800 A&E attendances per day in 2021/22, compared to 47,800 in 2020/21. Emergency admissions via A&E were 12% higher in 2021/22 when compared to 2020/21 with the average cost of a non-elective hospital spell currently at £5237. The 2021/22 winter period (November to February) was particularly pressured as services responded to the end of the Delta variant wave and the subsequent Omicron variant wave. In winter 2021, ambulance services faced unprecedented demand, notably in December with a record number of ambulance call outs. Ambulances responded to 82,000 highest category calls, an average of one every 33 seconds.According to UK Health Security Agency data, during winter 2023/24 it is estimated there were 1,240 GP consultations a day for flu-like illnesses in England. 2023/24 was a relative mild year for flu-like illnesses in comparison to previous years which have peaked to over 2,500 GP consultations a day. These figures show that flu-like illnesses are still a burden for GP surgeries in England.[8]

In this context, innovative interventions and pathways have great potential to reduce winter pressures and improve patient outcomes.

This project builds on work happening in the north west since 2021. Previous projects include an initial proof of concept test of a flu testing pathway in winter 2022/23. This pilot also included the clinicians in the co-design process and featured influenza A/B testing only with the Roche LIAT PCR test.

The test used at Moreton and Meols was the Xpert Xpress SARS-CoV-2/Flu/RSV test, which is an automated in vitro diagnostic test for qualitative detection and differentiation of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus. The Xpert Xpress SARS-CoV-2/Flu/RSV test is performed on GeneXpert Instrument Systems.

Influenza

Influenza is an acute infectious viral respiratory disease that causes annual epidemics and occasionally pandemics.[9, 10, 11]

[8] www.england.nhs.uk/wp-content/uploads/2023/01/monitor-ara-21-22.pdf

[9] 1. Paules C., Subbarao K. Influenza. Lancet. 2017;390(10095):697–708. doi: 10.1016/s0140-6736(17)30129-0. [PubMed] [CrossRef] [Google Scholar]

[10] World Health Organization. Influenza (Seasonal). 2018; Available from: https://www.who.int/news-room/fact-sheets/detail/influenza-(seasonal). Accessed: 17 July 2019

[11] Hayward A.C., Fragaszy E.B., Bermingham A., Wang L., Copas A., Edmunds W.J., et al. Comparative community burden and severity of seasonal and pandemic influenza: results of the Flu Watch cohort study. Lancet Respir Med. 2014;2(6):445–454. doi: 10.1016/S2213-2600(14)70034-7. [PMC free article] [PubMed] [CrossRef] [Google Scholar]

Although most people recover within a week without requiring medical attention, influenza can lead to severe illness, hospitalisation and death. Older adults, infants, pregnant women, overweight individuals, and individuals with chronic medical conditions are particularly at risk.

Coronavirus

SARS-CoV-2 is the virus that causes COVID-19, a type of coronavirus. While the long-term impact of coronavirus is still unknown, a systematic review and meta-analysis found that there were over 191 million confirmed cases, including 4.1 million deaths as of 21 July 2021. Emerging data on 'long covid' also suggests the infection can cause persistent issues long after the onset of illness.[12, 13]

Respiratory syncytial virus (RSV)

The pathway also included testing for respiratory syncytial virus (RSV). To date, less information is published on RSV, despite the growing recognition of a potentially considerable disease burden.[14]

Recent modelling indicates RSV is associated with a substantial disease burden in adults comparable to influenza, with most of the hospitalisation and mortality burden in the elderly. Treatment options and measures to prevent RSV could have a major impact on the burden of RSV respiratory disease in adults, especially the over 65s and vulnerable population.[15]

12 Sanchez-Ramirez DC, Normand K, Zhaoyun Y, Torres-Castro R. Long-Term Impact of COVID-19: A Systematic Review of the Literature and Meta-Analysis. Biomedicines. 2021 Jul 27;9(8):900. doi: 10.3390/biomedicines9080900. PMID: 34440104; PMCID: PMC8389585

13 COVID-19: Symptoms, incubation, prevention, and more (medicalnewstoday.com)

14 Wilkinson T, Beaver S, Macartney M, McArthur E, Yadav V, Lied-Lied A. Burden of respiratory syncytial virus in adults in the United Kingdom: A systematic literature review and gap analysis. Influenza Other Respir Viruses. 2023 Sep 21;17(9):e13188. doi: 10.1111/irv.13188. PMID: 37744994; PMCID: PMC10511839

15 Modelling estimates of the burden of Respiratory Syncytial virus infection in adults and the elderly in the United Kingdom - PubMed (nih.gov)

3 PATHWAY DESIGN AND IMPLEMENTATION

The community test and treat pathway was designed collaboratively by stakeholders in primary and secondary care, primarily in Merseyside.

Moreton and Meols PCN implemented the pathway with governance support from Wirral Teaching Hospital NHS Foundation Trust and Liverpool University Hospitals NHS Foundation Trust. There was one testing location for the PCN, with four GP practices implementing the pathway and testing eligible patients at the central location. The PCN has mixed demographics.

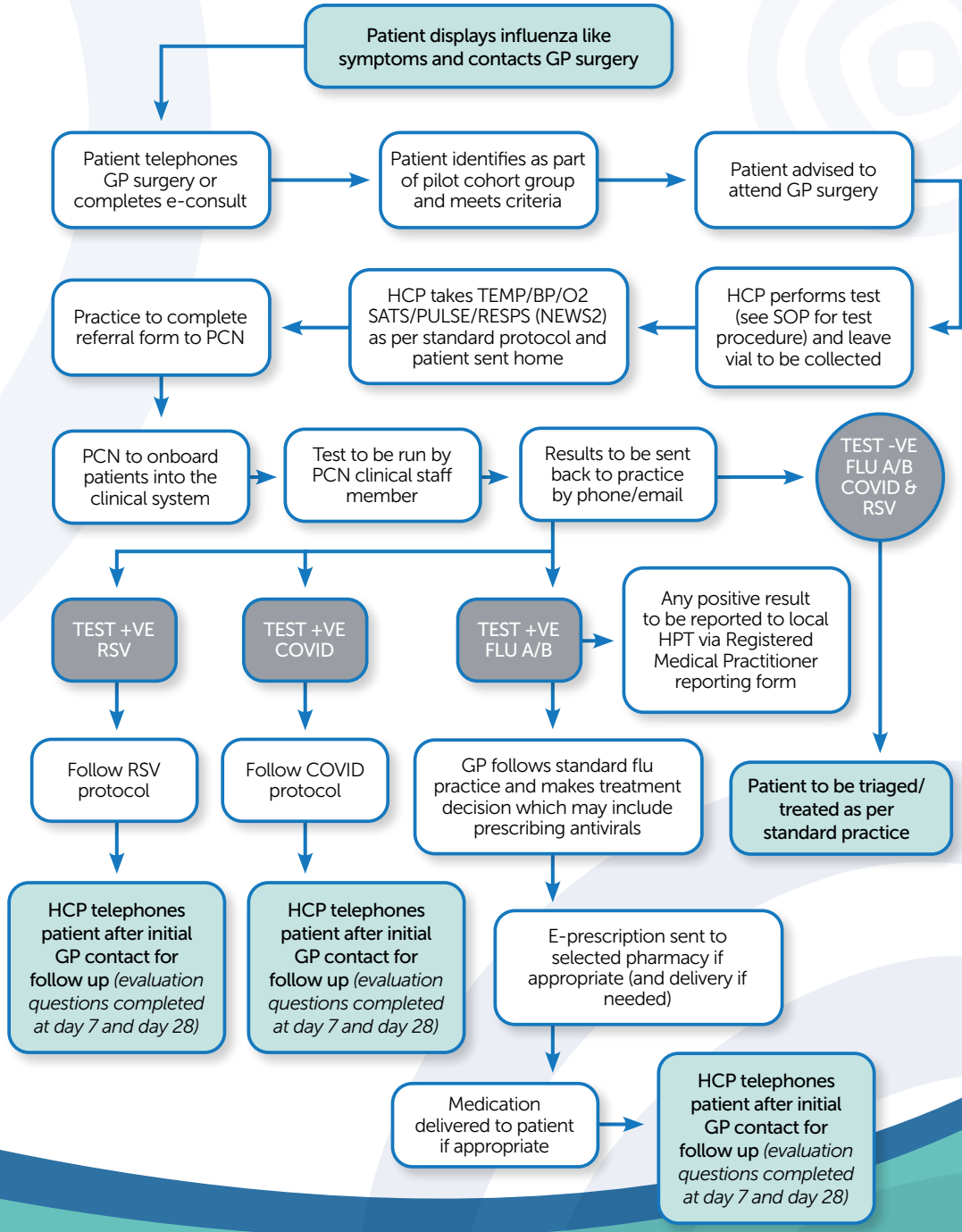


Figure 1. Patient pathway

Before pathway implementation, a robust standard operating procedure (SOP) was developed in conjunction with the two local acute trusts. The full SOP can be found in the appendix.

Marine Lake Medical Practice also participated as a comparator site, enabling the follow up of their matched eligible patients with flu-like symptoms.

HINWC supported the pathway implementation and led the evaluation of this project. HINWC works in partnership with the local health and care system to both improve the health of its population and to boost economic growth, both regionally and nationally.

The pathway implementation was triggered by the annual letter from the Chief Medical Officer and Chief Pharmaceutical Officer at the Department of Health and Social Care, which signals that certain antivirals may be used in response to rising levels of influenza circulating in the UK population.[16]

Patients who were eligible for the test were adults who met the eligibility criteria for the 2023 influenza vaccine.[17]

Eligible patients with flu-like symptoms were invited for testing.

Eligible patients were anyone 65 years old or older, or anyone who:

- **is in care, or long stay residential care**
- **is immunocompromised or living with someone who is immunocompromised**
- **has a respiratory condition like asthma or COPD**
- **has diabetes**
- **has liver, heart or chronic kidney disease**
- **has a BMI of 40 or more**
- **has a neurological condition**
- **has a learning disability**
- **has problems with spleen**
- **is a frontline health or social care worker.**

Symptoms of flu-like illness include:

- **temperature greater than or equal to 38C**
- **aching body**
- **dry cough**
- **sore throat**
- **headache**
- **difficulty sleeping**
- **loss of appetite**
- **diarrhoea or stomach pain**
- **feeling or being sick.**

Test results were integrated into patient records and enabled for consultant clinical virologist oversight, in line with the SOP.

Due to a lack of existing digital infrastructure, an independent NHS owned digital solution (Healthcall) was commissioned. Healthcall provided training for the testing site and also supported the team with the set-up of the most efficient workflow and data collection. Healthcall provided HINWC with anonymised testing data for analysis.[18]

16 Based on UKHSA data. CEM_CMO_2023-003.pdf
17 National flu immunisation programme 2023 to 2024 letter - GOV.UK (www.gov.uk)
18 Home | Health Call | Digital Health Solutions Health Call (nhshealthcall.co.uk)

A step-by-step process map for implementation is available in the appendix for teams wishing to replicate community test and treat of acute respiratory infections.

4 DIAGNOSTIC TECHNOLOGY

Several diagnostic technologies are available to detect and differentiate the most common acute respiratory infections. Polymerase Chain Reaction (PCR) tests have higher sensitivity and specificity for detecting the cause of a person's acute respiratory illness symptoms than antigen tests[19]. PCR tests can provide greater diagnostic certainty to inform clinical decisions about patient management and treatment. Due to the lower sensitivity and specificity of antigen tests they introduce greater diagnostic uncertainty.

The intended use case should be considered when deciding on the diagnostic technology to adopt. The patient cohort needs to have a reliable and rapid diagnosis to ensure that appropriate antimicrobials can be prescribed immediately while still efficacious. Evidence published by the UK Health Security Agency[20] showed that PCR tests can identify patients with COVID-19 while antigen tests were only able to identify patients that were infectious.

Based on this evidence, PCR tests are more likely to detect an acute respiratory infection in symptomatic patients in the earliest phase of an infection. Due to the vulnerable patient group of focus for this pathway and the need to prescribe antiviral treatments within the first 48 hours from the onset of symptoms PCR tests have been selected for use in the community test and treat pathway.[21]

Although PCR tests were selected, antigen tests still have a place in testing. Antigen tests can quickly identify easy-to-find surface markers on the outside of a virus. A person can collect samples easily by swabbing the nose or throat, where the virus tends to replicate and gather in large numbers. Antigen tests produce results within minutes, meaning a trade-off between speed and accuracy may be required when selecting the best fit test for each situation.

The test that was selected for use in winter 2023/24 was manufactured and provided by Cepheid, within the terms of a joint working agreement. The Xpert Xpress SARS-CoV-2/Flu/RSV test is an automated in vitro diagnostic test for qualitative detection and differentiation of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus. The Xpert Xpress SARS-CoV-2/Flu/RSV test is performed on GeneXpert instrument systems.

Cepheid's tests and machines have a robust evidence base into their safety and efficacy. Any further evaluation of the efficacy of Cepheid's tests was out of scope with this evaluation which focused on the implementation of agnostic testing in a community setting.[22]

19 The sensitivity and specificity of PCR varies between manufacturers products

20 www.gov.uk/government/publications/lateral-flow-device-performance-data/performance-of-lateral-flow-devices-during-the-covid-19-pandemic

21 Scenario: Treating influenza | Management | Influenza - seasonal | CKS | NICE

22 Xpert® Xpress CoV-2/Flu/RSV plus (cepheid.com)

5 EVALUATION METHODOLOGY

5.1 THEORY OF CHANGE

The acute respiratory infection point-of-care test and treat pathway is a new model of care in a complex real world setting with multiple external influences.

The Medical Research Council recognises complex intervention research and evaluation goes beyond asking whether an intervention works in the sense of achieving its intended outcome to asking a broader range of questions that identify other impacts, theorise how it works and takes account of how it interacts with the context in which it is implemented.[23] Understanding how a new pathway contributes to system change, and how the evidence can be used to support real world decision making requires a trade-off between precise unbiased answers to narrow questions and more uncertain answers to broader, more complex questions that are most useful to decision makers.

Theory based evaluation, beginning with the co-production of a theory of change, is explicitly concerned with both the extent of the change and why the change occurs and is therefore an appropriate choice of methodology for this evaluation.[24]

HINWC convened a theory of change workshop and brought together key stakeholders from across the north west coast. Stakeholders worked in primary care and secondary care microbiology, virology and point-of-care testing coordination. They agreed the proposed new pathway and co-designed the evaluation aims and methodology. Clinicians involved in the 2022/23 influenza season pilot were also invited.

5.2 EVALUATION AIMS

The primary aim of the quantitative analysis was to understand the impact of testing and the subsequent diagnostic certainty on prescribing. The secondary aim was to measure impact on patients, such as A&E admissions, hospitalisations and deaths.

In-depth qualitative evaluation was carried out to measure clinician acceptability, barriers and drivers to implementation and patient experience. The qualitative analysis consisted of three workstreams: a participant survey, a patient survey and participant semi-structured interviews.

5.3 CLINICIAN ACCEPTABILITY

Clinician acceptability was evaluated using a mixed method theory-informed questionnaire based on the theoretical framework of acceptability.[25] Clinician acceptability data was collected at baseline and at the end of the implementation period when flu season was over. All stakeholders at the testing PCN and the comparator PCN were invited to participate. Lead virologists, microbiologists and point-of-care testing leads at three trusts also participated (Wirral Teaching Hospital NHS Foundation Trust, Liverpool University

[23] A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance | The BMJ

[24] Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions - PMC (nih.gov) (Mary J De Silva), 2014

[25] Development of a theory-informed questionnaire to assess the acceptability of healthcare interventions | BMC Health Services Research | Full Text (biomedcentral.com)

Hospitals NHS Foundation Trust and Lancashire Teaching Hospital NHS Trust).

5.4 QUALITATIVE EVALUATION USING THE CONSOLIDATED FRAMEWORK FOR IMPLEMENTATION RESEARCH (CFIR)

The Consolidated Framework for Implementation Research (CFIR) was used to construct questions for a series of semi-structured interviews.[26]

This framework has five domains: intervention characteristics, outer setting (e.g., population needs and system resources), inner setting (e.g., implementation climate), individuals involved (e.g., knowledge and beliefs of the intervention) and implementation process (e.g., reflecting and evaluating). These domains have 39 underlying constructs designed to assess factors influencing successful implementation of healthcare interventions. Use of CFIR fosters understanding of the complexities of the real world implementation of interventions and identifies specific factors requiring improvement for future implementation.[27]

The interview participants were sampled to select the most informative individuals (purposive), and included frontline and operational staff at the testing site, clinical and operational staff at the comparator site and leads in microbiology, virology and point-of-care testing at the two local trust sites, and a regional point-of-care testing lead at Lancashire Teaching Hospital NHS Trust.

Representatives from the comparator site and an out-of-area point of care expert who weren't directly involved in the pathway design were interviewed to ensure bias was minimised. All those with an understanding of the pathway implementation project were interviewed, therefore a larger sample was unlikely to yield greater insights.

The interviews were conducted via online video calls. These meetings were recorded and transcribed using the inbuilt software, transcripts were cleaned and reviewed manually by the evaluation team. Using the six step reflexive approach.[28]

5.5 PATIENT EXPERIENCE

Patients were asked to complete a patient survey (online or on paper) after their test and consultation. The survey was developed by the Patient and Public Involvement team at Health Innovation North West Coast.

The full set of patient experience questions can be found in the appendix, along with the clinician

[26] Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50

[27] Muddu M, Tusubira AK, Nakirya B, Nalwoga R, Semitala FC, Akiteng AR, et al. Exploring barriers and facilitators to integrated hypertension-HIV management in Ugandan HIV clinics using the Consolidated Framework for Implementation Research (CFIR). Implement Sci Commun. 2020;1:45

[28] Naeem, M., Ozuem, W., Howell, K., & Ranfagni, S. (2023). A Step-by-Step Process of Thematic Analysis to Develop a Conceptual Model in Qualitative Research. International Journal of Qualitative Methods, 22. https://doi.org/10.1177/16094069231205789) the transcripts were then thematically analysed and mapped in accordance with CFIR

acceptability questions and the CFIR aligned interview questions.

5.6 QUANTITATIVE EVALUATION

Quantitative data was collected on the total number of tests, test results, and antiviral and antibiotic prescribing. Patients were followed up at 7 and 28 days and data was collected on A&E admissions, hospitalisations and deaths.

Rates of antibiotic and antiviral prescribing were compared with rates at the comparator site to understand the impact of diagnostic certainty on antimicrobial stewardship.

Testing site patients who presented to their GP with flu-like symptoms and were tested for influenza A and B, RSV and Sars-CoV-2 had their results recorded either through an online portal or directly into the patient record. Data submitted through the online portal was pseudonymised for analysis.

The pseudonymised code for each patient who tested positive was retained by the testing site to allow follow-up data to be collected. Follow-ups were conducted between 7-9 days and 28-30 days after the test to record the patient's health status and use of healthcare services. The practice management team collected this information via telephone.

A second PCN was selected to act as a comparator site to strengthen the data. The comparator site participated in both qualitative and quantitative data collection.

6 EVALUATION RESULTS

The testing period ran from 29 January 2024 until 16 April 2024. Testing ended once the levels of flu in circulation dropped, known as the end of the flu season, and reported as such by the UK Health Security Agency (UKHSA). Coronavirus treatment remained available.[29]

6.1 QUANTITATIVE RESULTS

Quantitative data was collected on patient demographics, total test numbers, test results, and antiviral and antibiotic prescribing. Patients were followed up at 7 and 28 days to track A&E admissions, hospitalisations and deaths.

6.1.1 NUMBER OF TESTS

Moreton & Meols PCN tested a total of 26 patients over the testing period for influenza A/B, RSV and coronavirus (SARS-CoV-2).

6.1.2 TEST RESULTS AND PRESCRIBING

Table 2: Number of positive tests and prescribing data

Positive tests	Number of patients	Prescribed nothing	Prescribed antibiotics	Prescribed antivirals	Unknown
Positive for Influenza A	2		2		
Positive for Influenza B	0				
Positive for RSV	0				
Positive for Coronavirus	3	1	1	1	
Negative for All	21	8	11		2

6.1.3 PATIENT FOLLOW UP DATA

After the follow up of this cohort, one patient was admitted to hospital and one patient unfortunately passed away. Neither of these two patients had tested positive for influenza A/B, RSV or coronavirus.

At Marine Lake Medical Practice, 44 eligible patients presented with acute respiratory infection symptoms. Of those, none were prescribed antivirals and 38 were prescribed antibiotics. By the seven-day follow

[29] assets.publishing.service.gov.uk/media/6620e6d077a30aa0c4757d87/Weekly_flu_and_COVID-19_report_w16.pdf

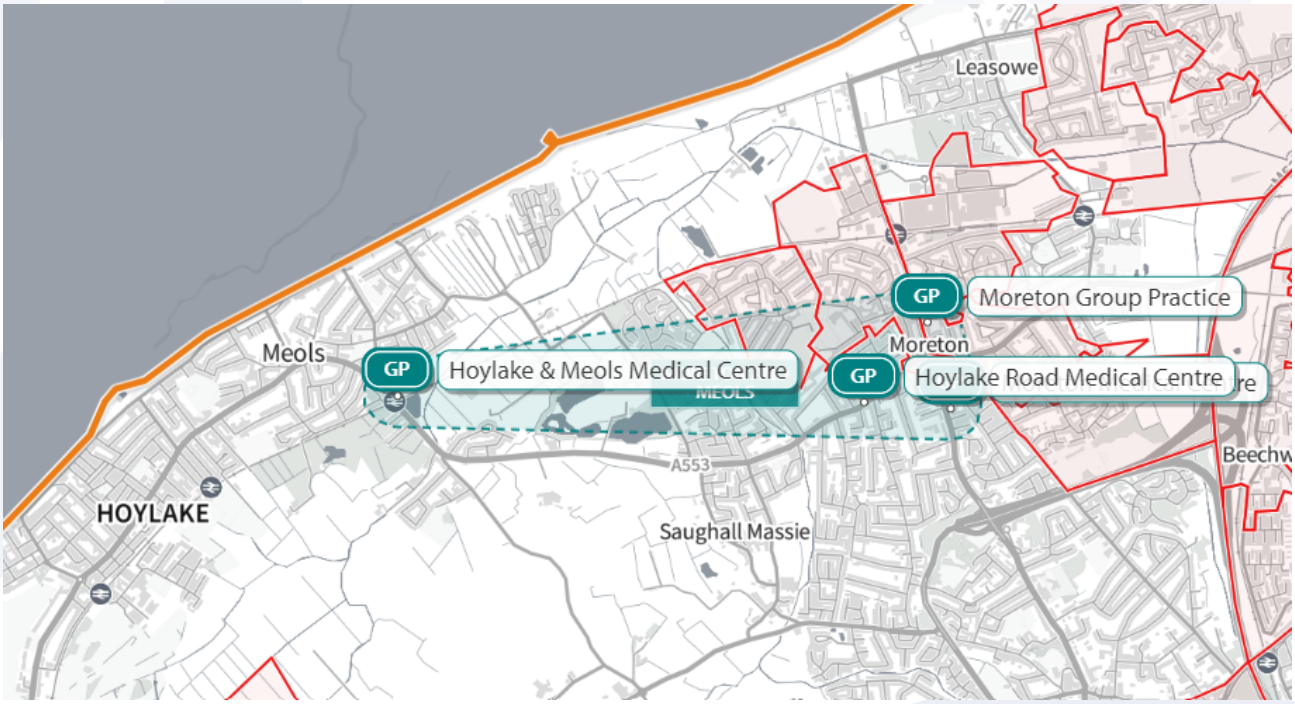
up, two patients had visited A&E and were admitted. By the 28-day follow up, two additional patients had visited A&E but there were no further hospitalisations.

6.1.4 PATIENT DEMOGRAPHICS

HINWC reviewed the demographics of the region and of the patients registered at the participating practices prior to commencing testing. The sample size was ultimately too small to apply this information to any analysis. For context, the ethnicity of the patients who received tests is reported in table 1 and is reflective of the ethnicity percentages across the Wirral according to the 2021 Census for England and Wales.[30]

Ethnicity	Number of patients	Percentage
White	21	80.8%
Mixed / multiple	4	15.4%
Asian (Indian)	1	3.8%

The English Indices of Deprivation measure relative levels of deprivation and the Index of Multiple Deprivation (IMD) is the official measure of relative deprivation in England. Wirral has a diverse population with some areas of relatively high levels of deprivation, shown in red on the map in figure 2.



30 2021 Census - Census of Population - Data Sources - home - Nomis - Official Census and Labour Market Statistics (nomisweb.co.uk)

6.2 CLINICIAN ACCEPTABILITY RESULTS

Clinician acceptability was assessed with a mixed method questionnaire at the end of the testing period and yielded the following results:

1. How comfortable do you feel about community test and treat of ARIs?

Baseline response:	
Very uncomfortable	1
Uncomfortable	0
No opinion	0
Comfortable	8
Very comfortable	5

End of testing period response:	
Very uncomfortable	2
Uncomfortable	0
No opinion	0
Comfortable	3
Very comfortable	1

A mixed response, some participants are comfortable, and some are uncomfortable with community testing at both time points.

2. How much effort will it take you to carry out ARI diagnosis at your primary care?

Baseline response:	
Huge effort	1
A lot of effort	5
No opinion	1
A little effort	7
No effort at all	0

End of testing period response:	
Huge effort	0
A lot of effort	3
No opinion	1
A little effort	0
No effort at all	2

Another mixed response, for some participants it created extra effort but for some participants no extra

effort at all.

3. There are moral or ethical consequences to engage with community test and treat of ARIs?

Baseline response:	
Strongly disagree	0
Disagree	2
No opinion	5
Agree	6
Strongly agree	1

End of testing period response:	
Strongly disagree	1
Disagree	0
No opinion	3
Agree	2
Strongly agree	0

The comments that accompanied the scoring implied these concerns around ethicality came from a delay in obtaining results, which could lead to a delay in prescribing.

4. How fair is the community test and treat for patients with ARIs?

Baseline response:	
Very unfair	0
Unfair	0
No opinion	3
Fair	10
Very fair	1

End of testing period response:	
Very unfair	0
Unfair	0
No opinion	1
Fair	3
Very fair	2

None of the participants felt that community testing was unfair or very unfair at either stage.

5. Community test and treat of ARIs will improve diagnostic certainty

Baseline response:	
Strongly disagree	0
Disagree	0
No opinion	1
Agree	7
Strongly agree	5

End of testing period response:	
Strongly disagree	1
Disagree	0
No opinion	0
Agree	2
Strongly agree	3

Only one participant disagreed that community testing would improve diagnostic certainty.

6. Community test and treat of ARIs will improve antimicrobial stewardship

Baseline response:	
Strongly disagree	0
Disagree	0
No opinion	1
Agree	6
Strongly agree	6

End of testing period response:	
Strongly disagree	1
Disagree	0
No opinion	0
Agree	1
Strongly agree	4

Only one participant disagreed that community testing would improve antimicrobial stewardship.

7. Community test and treat of ARIs will improve patient outcomes

Baseline response:	
Strongly disagree	0
Disagree	0
No opinion	1
Agree	7
Strongly agree	5

End of testing period response:	
Strongly disagree	1
Disagree	0
No opinion	0
Agree	3
Strongly agree	2

Only one participant disagreed that community testing would improve patient outcomes.

8. It is clear to me how community test and treat of ARIs will help improve my work behaviour

Baseline response:	
Strongly disagree	0
Disagree	0
No opinion	2
Agree	7
Strongly agree	4

End of testing period response:	
Strongly disagree	0
Disagree	1
No opinion	1
Agree	2
Strongly agree	2

Participants commented that testing would improve their work behaviour if the results were available quickly (within one to two hours) and was timely enough to influence prescribing and decision making

before they discharged their patient.

9. How confident do you feel about participating in community test and treat of ARIs in primary care?

Baseline response:	
Very unconfident	0
Unconfident	1
No opinion	0
Confident	9
Very confident	3

End of testing period response:	
Very unconfident	2
Unconfident	0
No opinion	0
Confident	3
Very confident	1

Not all participants were confident with community testing.

10. Engaging in community test and treat in primary care will interfere with my other priorities.

Baseline response:	
Strongly disagree	1
Disagree	2
No opinion	2
Agree	7
Strongly agree	1

End of testing period response:	
Strongly disagree	0
Disagree	2
No opinion	0
Agree	4
Strongly agree	0

Participants commented that community testing required effective workflows and time management to prevent interference with other priorities. A streamlined process with minimal form filling and delays is necessary.

11. How acceptable is community test and treat of ARIs to you?

Baseline response:	
Completely unacceptable	0
Unacceptable	0
No opinion	0
Acceptable	11
Completely acceptable	2

End of testing period response:	
Completely unacceptable	0
Unacceptable	0
No opinion	0
Acceptable	4
Completely acceptable	2

All participants found testing to be acceptable or completely acceptable.

6.2.1 POINT-OF-CARE TESTING LEADS ACCEPTABILITY

A questionnaire on acceptability of community test and treat of ARIs was sent to point of care testing (POCT) leads in the Northwest region and yielded the following responses:

1. How comfortable do you feel about community test and treat of ARIs?

Very uncomfortable	0
Uncomfortable	0
No opinion	0
Comfortable	2
Very comfortable	1

The 3 POCT Leads all responded that they were comfortable about the community test and treat of ARIs.

2. How much effort will it take you to carry out ARI diagnosis at your primary care?

Huge effort	0
A lot of effort	3
No opinion	0
A little effort	0
No effort at all	0

The POCT leads all agreed that ARI diagnosis in primary care will require a lot of effort to carry out effectively.

3. There are moral or ethical consequences to engage with community test and treat of ARIs?

Strongly disagree	1
Disagree	0
No opinion	1
Agree	1
Strongly agree	0

One POCT lead commented that "We have an ethical responsibility to provide the best care for our patients, as well as to evaluate the impact on patient treatment vs resources and care required for set up, maintenance and oversight".

Another said "It is patient focused. The patient doesn't care about a GPs title. The patient has come in sick, and we as a system must help the patient get better. It doesn't matter how we get on. The patient sees a system, and we've got to behave as a system rather than individuals or individual buildings or structures. We are the NHS system. So absolutely, we need to do more. There's a moral or ethical issue if we don't do anything".

4. How fair is the community test and treat for patients with ARIs?

Very unfair	0
Unfair	0
No opinion	2
Fair	0
Very fair	1

5. Community test and treat of ARIs will improve diagnostic certainty

Strongly disagree	0
Disagree	0
No opinion	1
Agree	2
Strongly agree	0

Two of the POCT leads agreed that community test and treat of ARIs will improve diagnostic certainty.

6. Community test and treat of ARIs will improve antimicrobial stewardship

Strongly disagree	0
Disagree	0
No opinion	0
Agree	2
Strongly agree	1

The 3 POCT leads agreed that testing and treatment of ARIs in the community will improve antimicrobial stewardship.

7. Community test and treat of ARIs will improve patient outcomes

Strongly disagree	0
Disagree	0
No opinion	0
Agree	2
Strongly agree	1

The 3 POCT leads agreed that testing and treatment of ARIs in the community will improve outcomes of patients.

8. It is clear to me how community test and treat of ARIs will help improve my work behaviour

Strongly disagree	0
Disagree	0
No opinion	2
Agree	1
Strongly agree	0

One of the POCT leads commented that "We are a system, so it will improve my work behaviour because I will help reach out and support the laboratory."

9. How confident do you feel about participating in community test and treat of ARIs in primary care?

Very unconfident	0
Unconfident	1
No opinion	1
Confident	0
Very confident	1

Not all participants were confident with community testing.

10. Engaging in community test and treat in primary care will interfere with my other priorities.

Strongly disagree	0
Disagree	0
No opinion	1
Agree	2
Strongly agree	0

The POCT leads commented that: "It will, I am always busy. To say setting up a new system will have no impact on what people do is naive. It is a matter of getting that balance and understanding what those gaps are".

"From my own perspective as a hospital based POCT lead, there are inadequate human resources in the region for trust-based POCT subject matter experts to engage with and support community POCT to the extent that it needs. I have personally flagged this as a risk to the ICB diagnostic board".

"I believe that extending well supervised diagnostics into community will improve both community and hospital care".

11. How acceptable is community test and treat of ARIs to you?

Completely unacceptable	0
Unacceptable	0
No opinion	0
Acceptable	2
Completely acceptable	1

All 3 POCT Leads concluded that testing and treatment of ARIs in the community is acceptable to them.

6.3 QUALITATIVE RESULTS

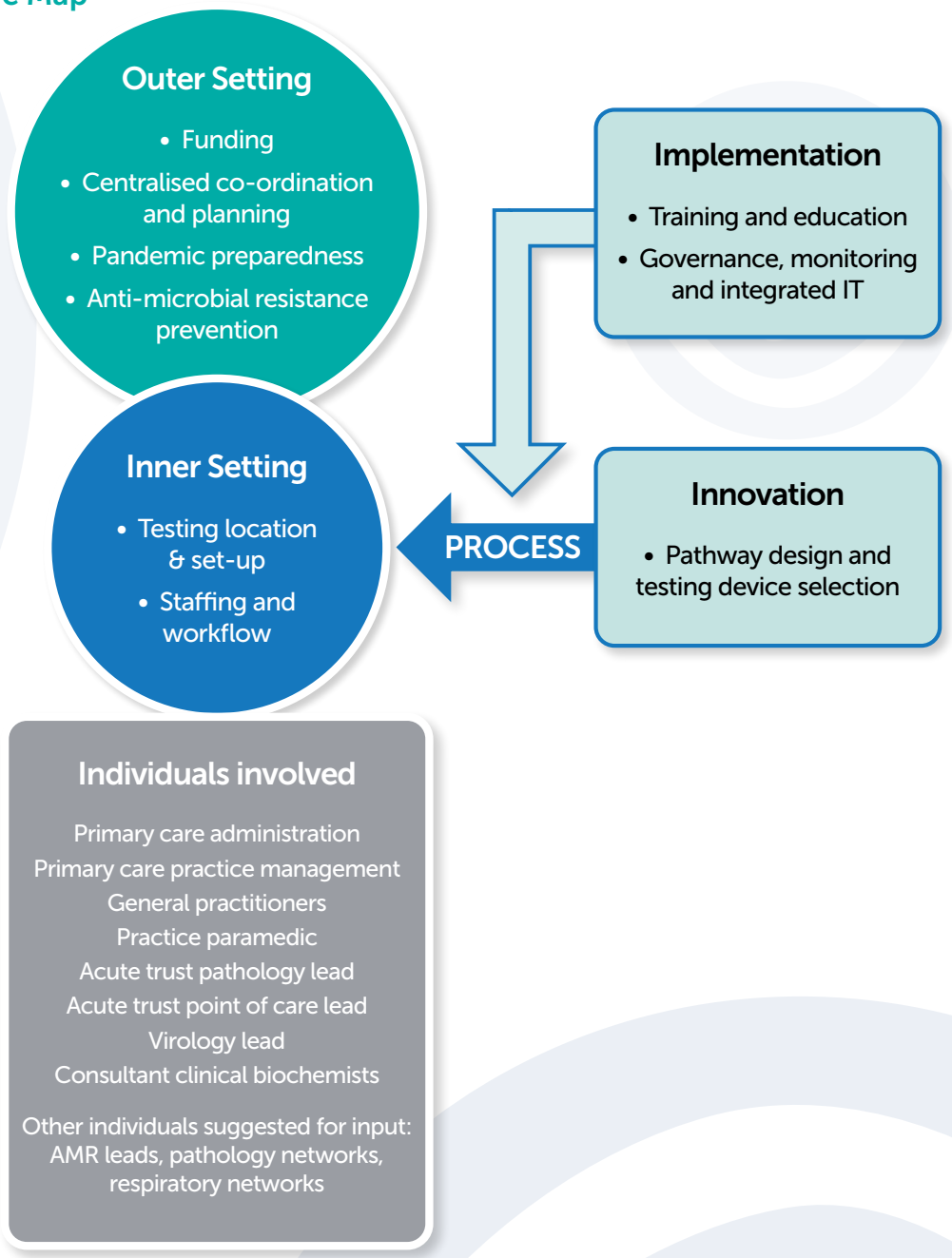
6.3.1 QUALITATIVE EVALUATION USING THE CONSOLIDATED FRAMEWORK FOR IMPLEMENTATION RESEARCH (CFIR)

A total of 10 in-depth, semi-structured interviews were conducted with frontline and operational staff at the testing site, clinical and operational staff at the comparator site and leads in microbiology, virology and point-of-care testing at the two local trust sites. Interviews ranged from 35 to 70 minutes.

Findings from the qualitative evaluation are organised into nine themes displayed in the thematic map (Figure 3). The themes relate to five key domains of the CFIR framework:

- **Characteristics of the intervention**
- **Individuals involved**
- **Inner setting (e.g., at the practice or PCN level)**
- **Outer setting (wider system and national stakeholders)**
- **Implementation process (CFIR domains as per the concepts developed by Damschroder et al, 2009).[31]**

Figure 3. Thematic Map



[31] Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50

Interviewees commented on barriers and facilitators to future spread, which have been assigned to both themes and domains, enabling recommendations to be made on the best ways to drive change and how to further develop the pathway for future spread.

Theme 1 - Training and education

The main CFIR domain was identified as **Implementation** indicating training and education needs to be a priority within any successful implementation plan.

Education, confidence and knowledge for clinical staff was identified as pivotal. Primary care clinical staff require training to boost their knowledge and confidence in delivering test and treat in the community. Clear patient information is also required to explain the testing process, the benefits to testing and the implication of any medications prescribed. With good quality information and communication, engagement with the process is more likely. Communication from a national level to clinicians at the community level will also need to be improved to ensure all clinicians receive the directive to prescribe antivirals if needed.

Facilitators

Intervention domain: Good quality pathway and product information. Clinicians should be provided with information on the performance of the machine from the local acute trusts for reassurance on test quality.

Inner domain: Practice or PCN level information sharing, communications, troubleshooting and support.

Barriers

Outer domain: System level guidance (e.g., MHRA), information and governance. This is currently a barrier and needs to be implemented to facilitate spread.

Patient awareness of the need for and the benefits of community testing is another current barrier to successful community testing. Most patients with respiratory symptoms don't contact their GPs until they have tried to treat themselves at home for some days, by which time their condition might have deteriorated and it would be too late to prescribe antiviral medication.

Theme 2 - Testing location and set-up

The main CFIR Domain was identified as the **Inner setting** indicating it is a priority for the practice or PCN to set up testing in the best-fit location.

There are efficiency and workflow considerations when selecting practice level testing instead of PCN or a place level hubs. Point of care testing hubs that test for a wider range of infections than just acute respiratory infections may offer further efficiencies. Hubs should be able to flex their approach to include care homes and patients in more rural settings. Testing buses were suggested as an alternative way to reach more patients. Practice-based testing requires staff trained to triage, collect samples, and run the tests. This workflow will need to be well-thought out within each practice to avoid disrupting the existing work processes of clinical staff, particularly accounting for seasonal variation.

Facilitators

Implementation domain: PCN or place level hubs represent streamlining for centralised or regional POCT governance and training.

Individuals domain: Community hub point of care testing is more accessible for patients, locating it closer to home. Testing patients in a hub would free up appointments from acute respiratory patients for use by other patients. The level of resource -reallocation needs careful planning.

Barriers

Inner domain: Vulnerable patients should not be in close contact with acute respiratory patients in hub waiting rooms. It is safer for patients with respiratory symptoms to access separate rooms within a hub to reduce the spread of infections. Patients selected for testing must be from the correct cohort and exhibit flu-like symptoms.

Patients prefer to access care as close to home as possible. The bigger the distance from home and more difficult to get to, the greater the risk of them exacerbating health inequalities.

Theme 3 - Primary care staffing and workflow

The Main CFIR Domain was identified as the **Inner Setting** (practice or PCN), representing another area for careful consideration by primary care teams.

Refining the pathway design to facilitate an optimal service will be critical. The pathway implemented and evaluated in this report is unlikely to be optimal due to the time taken to receive results for all patients tested, which interrupted the workflow. A more rapid test would lead to a greater behaviour change. More accurate but slower tests could still be hugely beneficial for some patients.

Efficiently staffing segregated hubs with seasonal fluctuation in demand is challenging.

Facilitators

Intervention domain: The time taken from testing swab until obtaining the results is critical to manage workflow in the community. A two-tiered approach could be considered to improve flow, offering rapid tests as a first line to rule a viral or bacterial infection in or out. More sensitive tests could be offered as a second line option when further information is required to make an accurate diagnosis and treatment decision.

Individuals' domain: Tests can be conducted by a range of clinical staff helping to ease workforce pressures. With robust training from local pathology labs, nurses, paramedics, healthcare assistants and other clinical staff could collect samples and perform the test. This offers a more efficient model than a GP delivered model, however additional funding will still be required. The primary care staff interviewed were all willing to participate and saw the benefit in community testing (both comparator and testing site).

Barriers

Successful community testing will require additional time and effort from an already stretched workforce for administration, implementation and delivery. External support will be required to drive behaviour change in these strained conditions, where there are competing demands on staff time and an opportunity cost.

Theme 4 - Governance, monitoring and integrated IT systems

The Main CFIR domain was identified as the **outer setting** indicating that a system wide, centralised approach is required for governance, monitoring and integrated technology.

A system wide mechanism to share best practice on pathway design and implementation is welcomed. National and regional communication must be strengthened, especially regarding outbreaks, antiviral prescribing and changes in guidance. An integrated IT system is required to enable secondary care oversight of test results for provision of timely advice and governance.

System level monitoring and quality control should operate in line with MHRA requirements. Funded guidance and oversight from the local secondary care pathology leads could facilitate this.

Facilitators

Inner setting domain: Development of standard operating procedures, quality control mechanisms, and reporting guidelines. Regular performance and competency tests conducted on the devices to ensure the results are accurate and reliable, plus local verification and validation.

Characteristics of Intervention: Use of devices with straightforward recalibration and maintenance, well supported by technical and commercial teams.

Barriers

Outer setting domain: Investment must be made into an integrated IT system that feeds directly into patient records and allows for secondary care oversight. There are existing middleware systems in place in secondary care, but currently no POCT connectivity infrastructure in place in the community. A centrally funded system for all point of care testing would enable full integration.

Inner setting domain: Procurement of individual IT systems, maintenance and quality control materials to safely and accurately manage testing would be prohibitively expensive.

Theme 5 - Antimicrobial stewardship and patient outcomes

Main CFIR domain was identified as the **outer setting**, indicating wider system and population level impact.

Point of care testing has evolved, offering faster and more accurate tests suitable for use in the community. Antivirals are available, with more in the pipeline, creating the opportunity to significantly impact patient outcomes with timely prescribing. Reduced prophylactic antibiotic prescribing and increased appropriate antiviral prescribing will lead to better antimicrobial stewardship.

Facilitators

Outer domain: Population level benefits from a reduction of inappropriate antibiotic prescribing. Viruses are well managed early, reducing spread and preventing hospitalisation.

Individuals' domain: Diagnostic certainty empowers clinicians and provides reassurance of the correct diagnosis and response.

Barriers

Implementation domain: The level of diagnostic certainty is dependent on the test or combination of tests used.

A major barrier is the trade-off between breadth and accuracy of tests, and speed and cost with associated workflow implications.

The current low level of antiviral prescribing is another barrier. Clinicians need raised awareness of the benefits of rapid prescribing of antivirals once authorisation is received from the Chief Medical Officer. Patients must also present in a timely manner. Many patients with flu-like symptoms don't contact their GPs until they have tried to treat themselves at home for several days, by which time their condition might have deteriorated and it's too late to prescribe antivirals.

Theme 6 - Pathway and testing device selection

Main CFIR domain was identified as the **innovation**, indicating the impact of device selection on the effectiveness of the pathway model.

A wide range of tests exist, with varying sensitivity and specificity, cost, time to results and ease of use. It was widely understood that the pathway needs to be tailored to suit staff workflows and the setting, and that the selection of tests and devices must fit into the optimal pathway model.

It is possible that a two-tier approach to testing will emerge as a more flexible and efficient model (e.g.,) rapid antigen testing to rule the most common acute respiratory infections in or out, with a subsequent test with a broader window of detection and greater specificity to include bacterial infections, as required.

Facilitators

A broad range of tests are now available and in use across secondary care. Point of care specialists have a good understanding of the best fit of tests for each setting and scenario.

Barriers

More real world evidence is required in a community setting for other pathway models such as hubs or a tiered flexible model.

Theme 7 – Funding for primary care delivery and pathology support

Main CFIR domain was identified as the **outer setting**, again indicating system level action and coordination is necessary.

Secondary care clinicians are overwhelmed with patients with acute respiratory infections in the winter. Primary care testing is anticipated to reduce demand on acute services but needs to be funded.

Facilitators

Inner domain: Funding must increase for primary care to deliver extra workload. Funding is also needed for specialist pathology support.

Barriers

Whilst funding is a facilitator, it is presently one of the primary barriers. Tests and devices are expensive. Workforce and staff costs increase with community testing. Infrastructure, IT and building costs may also increase, especially if a new site is required for a hub. Maintenance, governance, training and oversight all carry costs. Central funding and coordination, whilst potentially the most effective does not currently exist.

Theme 8 – Pandemic preparedness

The main CFIR domain was identified as the **outer setting**, indicating wider system and population level impact.

It is highly desirable to the specialist pathologists, virologists and POCT leads that we have system level infrastructure that can be mobilised to address any outbreak. An established system of community testing can also be used for infection surveillance, with the ability to roll out any test at speed if the infrastructure is already in place.

Facilitators

Individuals' domain: Skilled workforce ready to respond to pandemics and outbreaks. Urgent mobilisation of skilled staff is a key element in pandemic preparedness.

Theme 9 - Centralised co-ordination and planning

The main CFIR domain was identified as the **outer setting**, indicating wider system and population level impact.

Centralised planning and coordination are important to drive the system change needed to facilitate community ARI test and treat. Key system stakeholder involvement will improve the likelihood that any system-wide change can be sustained and optimised. Key stakeholders include, but are not limited to, POCT leads in acute trusts, virology leads, antimicrobial resistance leads, respiratory networks, pathology networks and primary care.

6.3.2 PATIENT EXPERIENCE

A total of 8 patients completed a patient feedback survey following their consultation. The survey consisted of 8 questions in total. The responses are as follow:

1. Was the test done in a place that was easy for you to get to?

Yes	8
No	0
Other	0

All patients who completed the survey agreed that the ARI test, carried out in local practice, was done in a place that was easy for them to get to.

2. On a scale of 1 to 5, with 1 being low and 5 being high, did you feel more reassured by having this flu test?

Five	6
Four	2
Three	0
Two	0
One	0

All patients surveyed felt either reassured or highly reassured by having the ARI test. A patient said they felt reassured because it helped them to know what they had, while another patient said it was clearly explained to them.

3. On a scale of 1 to 5, with 1 being low and 5 being high, do you think the test you had is a good thing for people with flu-like symptoms?

Five	7
Four	1
Three	0
Two	0
One	0

All patients surveyed agreed that having the test done was a good thing for people with flu-like symptoms.

4. On a scale of 1 to 5, with 1 being low and 5 being high, did the results from the test make you feel that you would get the right treatment for your flu-like symptoms?

Five	8
Four	0
Three	0
Two	0
One	0

All 8 patients responded that the test results made them feel they would get the right treatment for their flu-like symptoms.

5. Would you recommend this new way of testing and treating flu symptoms to others?

Yes	8
No	0
Other	0

All patients surveyed responded that they would recommend this new way of testing and treating flu symptoms to others.

6. How would you feel about doing a simple home test (similar to a COVID test) yourself in the future?

Very unhappy	0
Unhappy	0
No preference	0
Happy	0
Very happy	8
Other	0

All 8 patients responded that they would be very happy to do a simple test by themselves at home in the future.

7. In the future, would you like flu testing to be available in any of these places? (Tick all those that work for you)

In a community centre or health centre	2
At your home address	6
At a GP surgery	4
Community Pharmacy	4
Other	0

All 8 patients selected multiple options: 2 patients said they would like flu test to be available in a community centre; 6 wanted it available at their home addresses; 4 at their GP surgeries; and 4 at community pharmacies.

8. Can you think of anything that could have been done better? Or that you would have liked to be done differently when seeking help for your flu symptoms?

Only one patient responded to this question, and the response was 'No'.

7 DISCUSSION

The findings from this evaluation point to a need for point-of-care testing in the community to improve patient outcomes and relieve pressure on acute services. The community testing-pathway was found to be acceptable to heath care professionals and patients, with the primary concerns being workflow challenges and testing delays impacting treatment or clinical decision making.

The most appropriate test for community use will likely depend on multiple factors, such as space and site set-up, workflow and staffing, patient cohorts and disease prevalence. A faster lateral flow test that is cheaper and easier to use and that rules in viral or bacterial infection could embed more easily into existing workflow without the need for additional appointments or a treatment delay, which is particularly pertinent for antiviral prescribing.

However, this faster approach means pathogens would be tested with less sensitivity. For patients identified as having a virus with an initial test, they could then be sent onwards to an acute testing hub (on the same day) for a more accurate diagnosis and an appropriate prescription of an antiviral or other medication, if needed. Consideration should be given to the cost-effectiveness of out-of-practice acute hubs. Use of existing facilities and infrastructure will reduce operational costs. Testing for more than acute respiratory infections could soften the peaks and troughs of seasonal demand variation.

If patients are appropriately tested and treated in primary care, based on these findings and previous work in winter 2022/23, we can reason that it will prevent deterioration and possibly secondary infections, which would lead to hospital admissions. Point-of-care testing at A&E potentially has less impact on antimicrobial stewardship as patients are more unwell and less likely to be prescribed antivirals only. The challenge for system leaders is how to invest in test and treat in the community when the financial benefit is felt in the impact on hospital admissions. The identified facilitators of central coordination, pathology governance and support, integrated IT and quality training and education needs investment. Patient education and communication is integral to this as patients must be made aware of the opportunities for, and benefit of, community testing. Without this awareness they may wait until they are very unwell and then head straight for A&E, denying primary the care the chance to have a positive impact on both patient outcomes and winter pressures.

Antimicrobial stewardship (AMS) is a growing priority that can't be ignored. The recently published antimicrobial resistance (AMR) action plan for 2024-2029 outlines the key requirements to combat and deliver AMS.[32] Improved diagnostic certainty through testing is one of the ways antibiotics use can be optimised, and testing in a primary care setting has more potential impact than in secondary care.[33] Pathology involvement has been invaluable. Pathology expertise can help primary care select the most appropriate tests and devices for their budget and workflow. They also have strong purchasing power that can lead to more cost-effective service delivery. Pathology networks can support learning and communities of practice, aiding primary care to avoid the pitfalls and challenges of testing outside laboratory settings.

[32] Confronting antimicrobial resistance 2024 to 2029 - GOV.UK (www.gov.uk)

[33] www.gov.uk/government/publications/antimicrobial-prescribing-and-stewardship-competencies/antimicrobial-prescribing-and-stewardship-competency-framework

8 EVALUATION LIMITATIONS

Due to financial limitations and the need for a time commitment from over stretched primary care staff, only one active testing PCN and one comparator site was secured. More testing sites would have strengthened the data sets. Governance and SOP development took longer than anticipated and led to a delayed start to later in the flu season. The implementation guide and the SOP are available in the appendix as a resource to speed up future implementation.

Timely set-up of testing pathways well in advance of winter flu season is essential to maximise testing opportunities and patient benefit. This year's flu season was shorter than previous years, further limiting opportunities for testing.

Earlier provision of antivirals should reduce the proportion of people who deteriorate and require subsequent hospitalisation. Due to low testing numbers, it wasn't possible to conduct an intended cost-benefit analysis with this set of data.

HINWC consulted with colleagues and collaborators at expert health economics organisation, Unity Insights, who concluded that continuation with quantitative analysis would not add meaningful value to the study or its findings. The combined factors of a low volume of data and the lack of routine antiviral prescribing would have meant that any quantitative analysis of this dataset would likely reveal tenuous and statistically insignificant results. Further, any observed difference would not be due to the key hypothesis of early provision of antivirals, but due to confounding factors.

The mixed method study design yielded in depth insights into the barriers and facilitators for further spread. However, decisions should not be made on the findings of this study alone but incorporate knowledge from other studies such as the influenza test and treat work by HINWC in 2022/23.[34] Some of the identified limitations of that study have been addressed with this project, such as the lack of a comparator site and the testing being limited to influenza only.

A larger scale randomised trial would improve understanding into the impact of community-based testing on health outcomes and would increase confidence in the selection of the most appropriate testing devices in each situation.

[34] www.healthinnovationnwc.nhs.uk/media/News/2023/Flu%20Test%20and%20Treat%20case%20report%20May%202023.pdf.

9 RECOMMENDATIONS

The application of the consolidated framework for implementation research has highlighted the importance of outer setting, or system wide, action as the key facilitator of the successful implementation of primary care-based testing and treatment of acute respiratory infections.

Central co-ordination, planning and communication is highly recommended. A coordinated approach will reduce duplication of effort, offer efficiencies, allow for optimal integrated IT systems and strengthen pandemic preparedness. Further alignment of primary care into the wider integrated care system (ICS) is required to better align activity and priorities. It is clear from the clinician feedback that direct impact on primary care workflows is front of mind, rather than alignment to ICS level drivers and priorities.

There is a requirement for resourcing for primary care integration, delivery and education, and for pathology governance, support, co-ordination and digital reporting. Resource and support will also be needed to change manage a shift in prescribing behaviour in response to rapid diagnostic certainty.

Community test and treat could be spread in a sustainable manner through reimbursement within the GP contract. The pathway needs further development and evaluation to meet the evidence requirements of such a reimbursement decision.

Further evaluation should include multiple testing devices to understand the points of compromise between the tests, device cost-effectiveness and the best-fit options for each setting. It is possible that more than one type of test and device, or a 'two tiered' approach is most sustainable for primary care workflow. The two stages could test for bacterial or viral infection (using lateral flow), followed by a more sophisticated panel at any second line testing hub when necessary (using PCR). Adding a bacterial testing panel in addition to the viral panel could support rapid identification of targeted antibiotics, further boosting antimicrobial stewardship.

Testing and evaluation on a broader scale is recommended next winter season, with more testing locations, matched with comparator sites, and the use of a larger variety of laboratory-approved diagnostic technologies. Settings should include GP practices, a PCN hub, place-based acute respiratory infection hubs and place-based universal testing hubs to build understanding of the most efficient set up.

Standard metrics and data collection techniques should be employed across the settings for improved quantitative data. The cost benefit analysis conducted in winter 2023/24 should be expanded to incorporate RSV and coronavirus, pathology input costs and updated data on acute admissions. Deploying additional clinician acceptability analysis at each setting is recommended.

To build on current knowledge and implement an improved pathway next winter season, joined up financial planning across the integrated care system is recommended to address investment challenges. HINWC have instigated planning discussions with the regional NHSE team and regional stakeholders.

Education was identified as a key theme through the qualitative analysis. Robust education and communication is recommended for:

- **patients in appropriate cohorts to raise awareness of earlier reporting of symptoms and availability of appropriate antiviral treatments**
- **clinicians, to highlight the availability of: appropriate treatment options, pathway models, implementation toolkits and resources, and support available from local pathology services.**

The findings of this evaluation are in line with national policy on antimicrobial resistance (AMR). The AMR action plan sets out ways to address the challenge of AMR, including further testing of community pathways to support the appropriate use of antibiotics.[35]

A policy framework would be an enabler of system-wide progression, allowing pathology services and primary care to co-develop incentives to drive earlier intervention into acute infectious disease pathways.

Linkage to respiratory virtual wards is recommended to develop appropriate and safe escalation routes for patients identified in primary care (e.g., additional support for patients with secondary bacterial infections).

If successfully implemented, community test and treat pathways promise to deliver patient benefit, including admissions avoidance and hospital-based deconditioning. Future pathway development and evaluation should not be limited to acute respiratory infections but include other pathways where more appropriate use of antibiotics is desirable, such as urinary tract infections.

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Disclaimer

This report presents the findings of an independent evaluation of the acute respiratory infection test and treat community pathway. The findings of this independent evaluation are those of the authors and do not necessarily represent the views of the participating local teams.

Declaration of interest statement

Health Innovation North West Coast (HINWC) supports innovators to bring their innovations to the NHS as well as provide evaluation services. This evaluation was funded by a joint working agreement between Cepheid and HINWC. The methodology and recommendations are independent of Cepheid and represent the views of HINWC.

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[35] Confronting antimicrobial resistance 2024 to 2029 - GOV.UK (www.gov.uk)

10 APPENDICES

The following process map should act as a step-by-step implementation guide for teams wishing to replicate community test and treat of acute respiratory infections:

Set up process map

- Establish needs for acute respiratory testing for your population. Consider which tests are required (e.g.,) influenza A/B, Sar-Cov2 and RSV.
- Consider the best operating model (e.g.,) central hub site, local PCN model, urgent treatment centre. Think through the maximum test turnaround time that could be tolerated and the best fit tests and diagnostic partners to work with.
- Ensure that data collection can be provided through current systems or whether a bespoke solution will need to be developed and commissioned.
- Engage local pathology network and microbiology teams at the local acute trusts. Co-create a standard operation procedure (SOP) that will ensure safety, compliance, governance and support.
- Sign contract with diagnostic partner(s).
- Agree the set up and training requirement of the diagnostics partner(s). Consider which tests and point of care testing machines will be provided, and where and how they will be set up and maintained.
- Confirm the eligible patient cohort, the patient pathway and the workflow changes in collaboration with the testing site. Agree the final setting for the diagnostics machine and referral process if a hub approach is adopted.
- Finalise any information governance agreements and the SOP.
- Distribute point of care testing machines and deliver the required training. Local validation & verification by acute local pathology/microbiology team.
- Complete any required technology integration and ensure any additional software to collect test results sends the data into patient records. Sign contract with the software company if required. Ensure the microbiology team can readily review the test results (e.g.,) via pdf attachment to the health record or a printout.
- Agree which staff will be responsible for onboarding patients on the software and deliver training.
- Ensure any additional equipment, such as nasoparyngeal swabs and viral media transport tubes, are ordered and available.
- Ensure a re-ordering mechanism is in place for further supplies (tests, swabs and viral media transport tubes).
- Invite eligible patients for testing.
- Ongoing communications to let eligible patients know to contact their GP at the onset of respiratory symptoms.

COMMUNITY MOLECULAR DETECTION OF SARS-COV-2, INFLUENZA A, INFLUENZA B AND RSV (CEPHEID GENEXPERT)

COPY 1

LOCATION OF COPIES 1. Health Innovation North West Coast ARI Sharepoint

Revision history

Revision	Change details	Section(s)	Page(s)	Made by	Approved by	Active date
2	Full Review	All	All	BJE/BNFD	BDB	12.07.2023
3	Full Review	All	All	MT	MT	05.12.2023
4	Full Review	All	All	DB	MT	18.12.23
5	Full Review	All	All	AS	MT	18.01.24

This is a new SOP for Community Point of Care

10.1 PROCESS MAP

Before carrying out any molecular procedure, please read the following document: **Good Molecular Laboratory Practice**

10.1.1 Specimens for testing

Nose/Throat swabs can be tested on the GeneXpert every day.

Run time is 36 minutes.

10.1.2 Specimen booking-in

All swabs/samples should have the patients NHS number.

Refer to **Bench Guide for booking in samples on the GeneXpert.**

Refer to **Bench guide Use of Cepheid GeneXpert for guidance on how to use the Cepheid GeneXpert analyser.**

10.1.3 Sample storage and further work

- **Store all positive samples at -80oC for a minimum of 2 months by sending to Liverpool Clinical Laboratories for the attention of Dr Anna Smielewska.**
- **Refer influenza A positive samples to MRI for typing if requested by the CMM.**

10.2 STANDARD OPERATING PROCEDURE INTRODUCTION

10.2.1 Health & Safety Summary

- **Specimens must be processed in a safe clean working environment using appropriate PPE (Masks, aprons and gloves) due to the potential risk of working with SARS-CoV-2, influenza and RSV.**
- **See Local Waste Management Procedures for safe disposal of potentially infectious waste including that containing amplified molecular products (yellow bin for sharps, and yellow bag for potentially infected waste).**
- **Disinfect benches daily with 2% Chemgene[36] and keep working areas clean and tidy.**
- **Follow the daily, weekly and monthly cleaning protocols.**
- **Disposable gowns must be worn at all times. Disposable gowns must be removed before leaving the room.**
- **Disposable gloves must be worn throughout molecular procedures and must be removed before leaving the room.**
- **Carefully dispose of all waste in yellow burn bins.**
- **Post-amplification molecular waste must be disposed of in yellow burn bins placed in the lockable bins outside the lab for collection for disposal off site in accordance with local policy.**

10.2.2 COSHH/Risk Assessment

Sypol reference no.	Material	Hazard(s)	Risk rating
DOC1842	Hazard Group 2 Orgs	Biohazard	Very low
DOC1861	Hazard Group 3 Orgs	Biohazard	Low
DOC1868	Chemgene concentrate	Chemical	Low
DOC1869	2% Chemgene	Chemical	Low
DOC4704	Distel concentrate		
(used at CoCH only)	Chemical	Low controlled acute/ chronic risk	
DOC4717	10% Distel		
(used at CoCH only)	Chemical	Low controlled acute/ chronic risk	
DOC4720	Xpert Xpress SARS-CoV-2 FLU RSV kit	Chemical/Biological	Low controlled acute/ chronic risk

Refer to Chester and Wirral Microbiology Service QPulse for summary of COSHH Assessment

[36] 10% Distel used at CoCH.

Risk assessment reference no.	Activity/situation	Hazard(s)	Risk rating
DOC1421	Specimen Reception / Handling	Biohazard / Chemical / Physical / Clinical	Low
DOC1441	Spillage, Disinfection and Waste Disposal	Biohazard / Chemical / Electrical / Physical	Low
DOC1416	Molecular Procedures	Biohazard / Chemical / Electrical / Physical / Clinical	Low

Refer to QPulse for full details of Risk Assessment

10.2.3 Scope and purpose

Molecular detection of transmissible organisms aids the rapid identification of potential sources of outbreaks. This helps Infection Control teams rapidly identify those patients who need to be isolated or cohorted in order to prevent the spread of infection.

This document describes the detection of SARS-CoV-2, Influenza A, influenza B and RSV viral RNA using the Cepheid Xpert Xpress kit on the GeneXpert platform.

This same test is performed in the Microbiology laboratories at the Countess of Chester Hospital (COCH) and Arrowe Park. Testing there is managed under Chester and Wirral Microbiology Service (CWMS) governance.

10.2.4 Principles of procedure

The Xpert Xpress SARS-CoV-2/Flu/RSV test is an automated in vitro diagnostic test for qualitative detection and differentiation of RNA from Flu A, Flu B, RSV and SARS-CoV-2 virus. The Xpert Xpress SARS-CoV-2/Flu/RSV test is performed on GeneXpert Instrument Systems.

The GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR and RT-PCR assays. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single use disposable cartridges that hold the RT-PCR reagents and host the RT-PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized.

The Xpert Xpress SARS-CoV-2/Flu/RSV test includes reagents for the detection of RNA from Flu A, Flu B, RSV and SARS CoV- 2 virus in nasopharyngeal swab, nasal swab, or nasal wash/ aspirate specimens. A Sample Processing Control (SPC) and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert instrument.

The nasal swab, or nasal wash/ aspirate specimen is collected and placed into a transport tube containing 3 mL of viral transport medium or 3 mL of saline. The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the sample is transferred to the sample chamber of the Xpert Xpress SARS-CoV-2/Flu/RSV cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time RT-PCR for detection of viral RNA.

10.2.5 Specimen requirements

Specimens can be collected following standard procedures and placed into Viral Transport Medium (3mL or 1mL tube with transport medium). Specimens should be transported at 2–8 °C. Specimens can be stored at room temperature (15–30 °C) for up to 24 hours and refrigerated (2–8 °C) up to seven days until testing is performed on the GeneXpert.

Proper specimen collection, storage, and transport are critical to the performance of this test.

Please send specimens on the next available transport (same day or keep until the next day) and then send to Liverpool Clinical Laboratories (LCL) for attention of Dr Anna Smielewska in the large padded transport bags provided by WUHFT pathology. Include print out of sample results in bag (following Instructions on screen to print out).

10.2.6 Training requirements

- **Only health care professionals who have been fully trained in molecular procedures can prepare and load samples onto the Cepheid GeneXpert.**
- **Negative results, and positive results within a specified Ct range, will auto-validate with no further intervention required by staff.**
- **Only HCPC registered BMS staff who have been fully trained in molecular procedures can evaluate and validate POSITIVE end point PCR results that don't auto-validate. Please refer any such samples to Dr Anna Smielewska.**
- **Specific training is required for the following:**
  - Use of equipment
  - Basic Trouble Shooting
  - Health & Safety procedures
- **A complete and up-to-date record of training is required for all staff.**

10.2.7 Equipment & Materials

10.2.7.1 Larger items of equipment

- Cepheid GeneXpert
- Microbiological Safety Cabinet

10.2.7.2 Disposable equipment

- Remel M4RT collection kits
- 300 µL Transfer Pipettes

The Xpert Xpress SARS-CoV-2 Flu/RSV Assay kit contains sufficient reagents to process 10 specimens or quality control samples. The kit contains the following:

Xpert Xpress SARS-CoV-2 Flu/RSV Assay Cartridges with Integrated Reaction Tubes 10

- Bead 1, Bead 2, and Bead 3 (freeze-dried) 1 of each per cartridge
- Lysis Reagent (Guanidinium thiocyanate) 1.5 mL per cartridge
- Binding Reagent 1.5 mL per cartridge
- Elution Reagent 3.0 mL per cartridge

Store the Xpert Xpress SARS-CoV-2 Flu/RSV Assay cartridges at 2–28 °C.

10.2.8 Limitations of procedure

- **Erroneous test results might occur from improper specimen collection; failure to follow the recommended sample collection, handling, and storage procedures; technical error; sample mix-up; or because the number of organisms in the specimen is too low to be detected by the test. Careful compliance with the instructions in this insert is necessary to avoid erroneous results.**
- **False negative results may occur if virus is present at levels below the analytical limit of detection.**
- **Negative results do not preclude SARS-CoV-2, influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions.**
- **Results from analytical studies with contrived co-infected samples showed potential for competitive interference when SARS-CoV-2, influenza or RSV was present at 1X LoD levels.**
- **Results from the Xpert Xpress SARS-CoV-2 Flu/RSV Assay should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.**
- **Viral nucleic acid may persist in vivo, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious or are the causative agents for clinical symptoms.**
- **If the virus mutates in the target region, SARS-CoV-2, influenza virus and/or RSV may not be detected, or may be detected less predictably.**
- **As the Xpert Xpress SARS-CoV-2/Flu/RSV test does not differentiate between the N2 and E gene targets, the presence of other coronaviruses in the B lineage, Betacoronavirus genus, including SARS-CoV-1 may cause a false positive result. None of these other coronaviruses is known to currently circulate in the human population.**

10.2.9 Reference range reported, alert & critical values

The manufacturer stated that test is a qualitative test and does not provide the quantitative value of detected organism present.

10.2.10 Quality assurance

- **Samples are subject to IQA through repeat sample processing on a monthly schedule.**
- **For the Internal Quality Assessment procedure, including the measurement of uncertainty, please refer to Microbiology for advice on this.**
- **Molecular assays are validated by the manufacturer but each batch/shipment of kits must be acceptance tested for performance in-house before they are put into use. A Zeptometrix positive sample is used to verify the performance of the assay before the batch is put into use. Refer to Internal Quality Control and Acceptance Testing.**
- **Chester and Wirral Microbiology Service participates in EQA from QCMD for molecular procedures. This enables this laboratory to be compared with other laboratories to ensure equivalence of performance.**

It is essential that the EQA results are reported to the laboratory from individual machines.

Built in quality controls

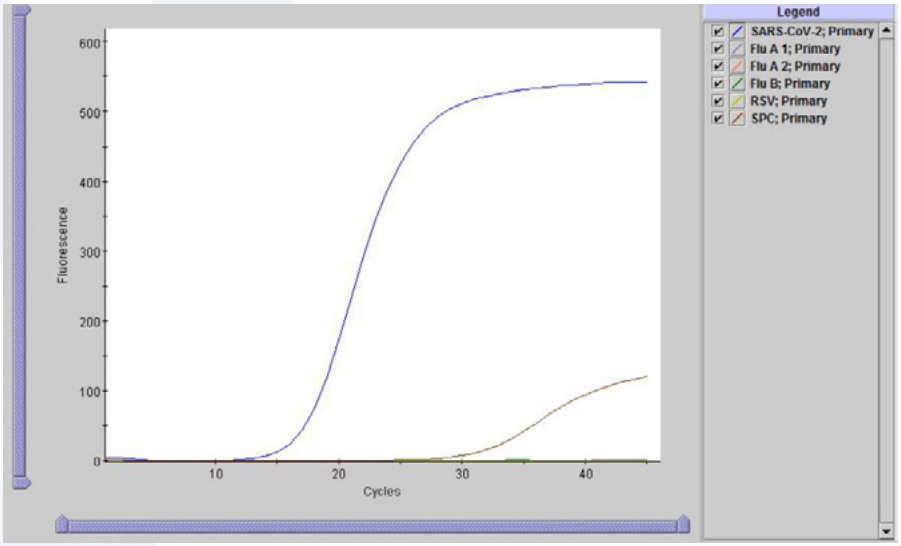
Each test includes a Sample Processing Control (SPC) and Probe Check Control (PCC).

- **Sample Processing Control (SPC) - Ensures that the sample was processed correctly. The SPC verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR assay, ensures that the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria.**
- **Probe Check Control - Before the start of the PCR reaction, the GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. The PCC passes if it meets the validated acceptance criteria.**

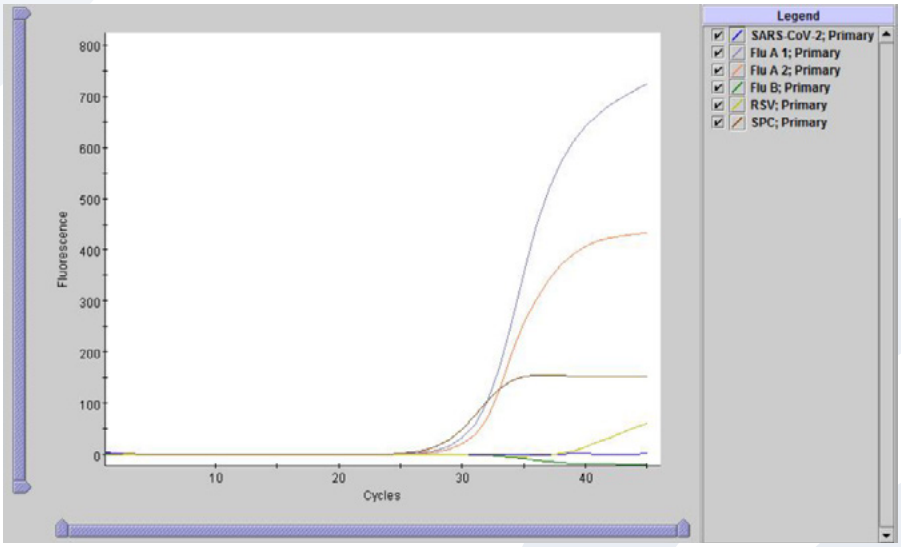
10.2.11 Equipment calibration

This will be performed by Cepheid Field Service Support.

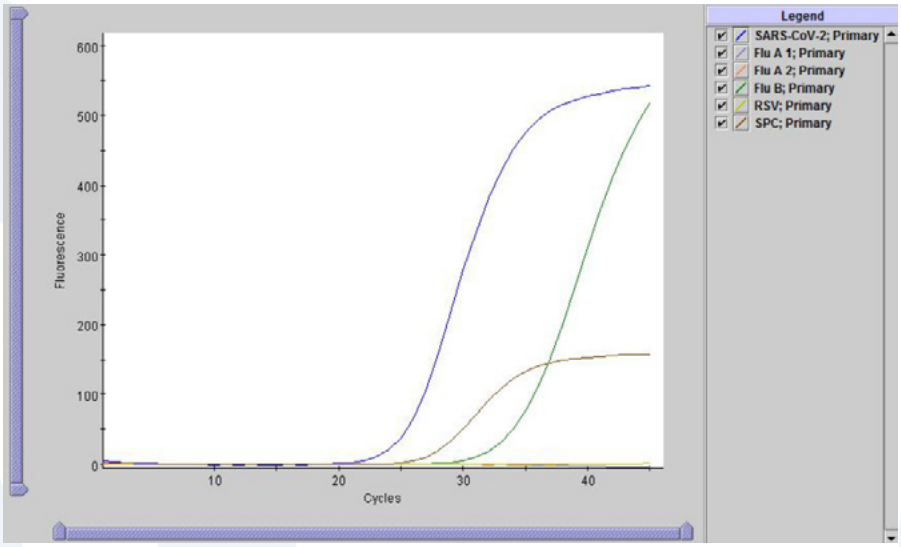
10.3 REPORTING GUIDELINES



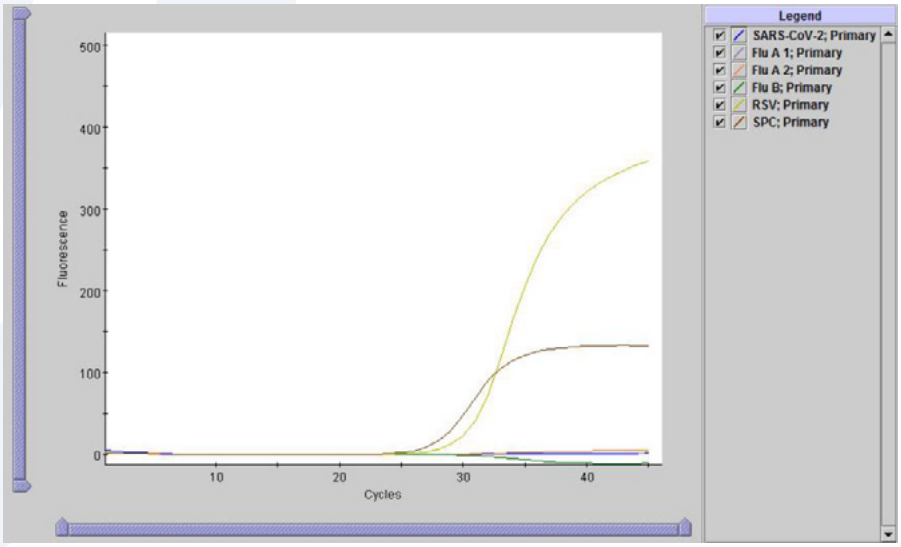
Example of a Positive Result for SARS-CoV-2



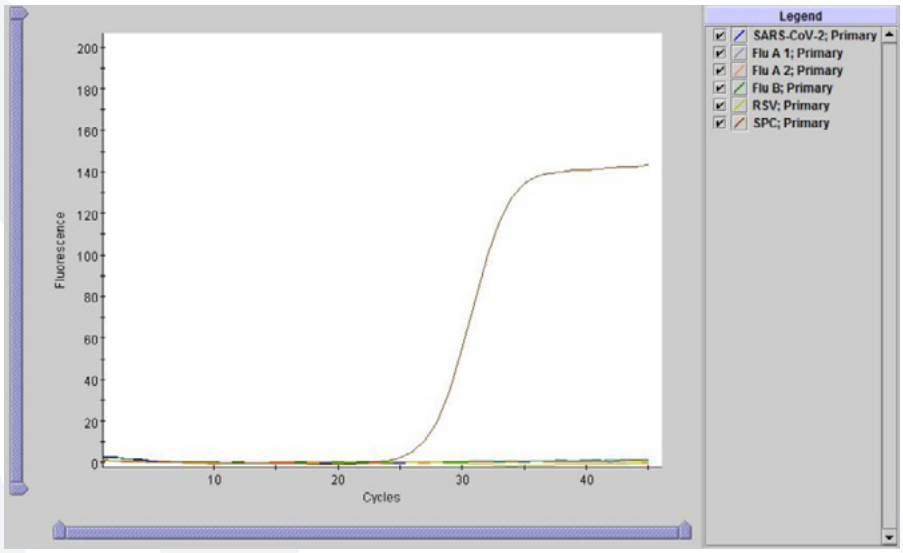
Example of a Positive Result for SARS-CoV-2 and FLU A (1; primary)



An Example of a Positive Result for RSV



An Example of a Negative Result for SARS-CoV-2, Flu A, Flu B, and RSV



Example of an Invalid Result (SPC does not meet acceptance criteria)

Refer to the Healthcall guide for recording results and tracking patients for this service evaluation

Examples of results graphs:

10.3.1 Reporting Flu/RSV PCR Results on HealthCall

All results for SARS-CoV-2, Flu A, Flu B and RSV gene targets will auto-validate.

Invalid results must be identified by the AHCP/BMS processing the assay on the GeneXpert. These samples should be referred to LCL.

Results should be recorded on the Health Call software in line with training. Please see Health Call training manual.

10.3.2 Validation/Authorisation of Reports

Results that autovalidate can be reported on the Health Call app and will be transferred into the primary care patient record. Please include a copy of the results printout with the sample and send to Liverpool Clinical Laboratories for the attention of Dr Anna Smielewska

Results that fail autovalidation should be repeated once. If the second run also fails autovalidation please refer the sample to LCL, and send a print out copy of the GeneXpert results with the sample.

Note: All results need to be viewable [via hardcopy print out or 360 software] for laboratory professional review.

This is to ensure that the machine and tests are producing valid results, and to allow laboratory professionals to provide appropriate advice and guidance to PCN team should the need arise.

10.4 DEVICE REFERENCES

Access to all Xpert Xpress SARS-CoV-2/Flu/RSV documentation is available online at **Cepheid.com/coronavirus-resources**

Cepheid Instructions For Use (IFU)

www.gov.uk/government/publications/smi-q-4-good-laboratory-practice-when-performing-molecular-amplification-assays

Related Documents

- **Use of Cepheid GeneXpert benchguide**
- **Cepheid GeneXpert Batch acceptance testing Benchguide**
- **Cepheid GeneXpert SARS-CoV-2 Flu RSV Sample Preparation for POC**
- **Environmental Monitoring SARS-CoV-2 POC**
- **Use of Healthcall software Guide**

10.5 DATA COLLECTION MATERIALS

Interview Topics and Questions	CFIR Domain
Introductions • Explain purpose of the interview (recap Participant Information Sheet). • Re-affirm verbal consent for participation and use of audio recorder.	
Participant demographic information: • Role and length of service	Inner setting
Which diagnostic test machine are you using at your site?	Characteristics of the intervention
Can you give me an overview of how the service is set up and how it works in practice? • *Prompts:* Can you tell me about your role in the service? Who performs the test? Do you find it easy? What are the challenges? How is the machine set up and cleaned? What training is required? • What information is collected at each visit and how/where is it recorded? What do you think would improve the way this information is collected and recorded?	Characteristics of the intervention
ARI test set-up location Is the test set up in the GP practice or in a hub? If it is in a hub, what are the pros and cons of the test location?	Inner and outer setting
What information and training do staff receive before setting up the service? • *Prompts:* Who provides the training, what format, when received, what does it cover, etc. What do you consider good about this? What do you believe could be improved?	Characteristics of the intervention

Interview Topics and Questions	CFIR Domain
What information is given to patients about the service? • *Prompts:* Who provides it, what format, when received, what does it cover, etc? What was good about this support? What other information or support needs to be in place?	Individuals involved, outer setting
Who is involved in the service? • *Prompts:* Which members of staff is involved? What grade are they? Who selects the patients, using the eligibility criteria? Who informs the patient that they will have the test, and what is involved? Who is doing the follow up phone calls? • For the set up and coordination of the project, please explain: - the number of coordinators involved - number of hours per week in total spent on testing - the number of weeks (this might only be 2 weeks initial set up or they maybe involved throughout the whole project) and their AfC band (required for the cost benefit analysis) • For administering the tests: - What the split is in terms of personnel administering the test (looking for % split between e.g. HCA, nurse, Nurse specialist, GP, such that total adds up to 100%) - Amount of time in minutes it takes to conduct the test including loading patient up on HealthCall app, administering tests and submitting results. - If a non-prescriber administers the test, - which role(s) (include % split of more than one role) review and prescribe? - Amount of time in minutes to review/prescribe.	Inner setting, Implementation process
What do you think has been the main challenges and barriers to implement and deliver the ARI test and treat service? • *Prompts:* Relationship with the team in LUHFT, virologists and microbiologists who will be reviewing the tests, how does it work in practice? Any challenges and barriers with governance and transfer of data?	Inner setting, outer setting and individuals involved
What do you consider to be good practice in terms of how the service is provided? • *Prompts:* Explore in relation to staff and patients. Equipment and technology that would enable good practice	Implementation process
As an aim of this study is to understand the merits and unintended consequences of implementing this new ARI pathway in primary care – what points or issues do you think we need to consider?	Implementation process
How has the testing changed your behaviour? **Do you think it will lead to a change in prescribing?** **Do you think having diagnostic certainty will change the way you work?**	Inner setting,

Interview Topics and Questions	CFIR Domain
Opportunity cost • *Prompts:* While the staff are doing the ARI test, do you think care will suffer elsewhere? What are the implications? • What other unintended consequences do you think could happen?	Characteristics of the intervention
Is there extra time involved in delivering the new pathway? If yes, how much? • *Prompt:* Are there perceived additional costs other than staff time? The extra time, where is it from and what is the grade of the member of staff? What is the cost?	Characteristics of the intervention
What IT infrastructures and hardware are needed? • *Prompts:* Is the ARI test and treat service compatible with and does it fit it in with existing workflow and systems Is your preference a laptop or touch screen device? What could we use instead of the healthcall app, would we need a bespoke software solution?	Inner setting, Characteristics of the intervention
Scale and spread Do you think its sufficiently adaptable to different locations (urban and rural), different settings (care home, general practice, etc.), and scalable? • *Prompts:* What resources or strategies may be necessary for a widespread roll-out? • What are the key aspects which must be retained, and which key differences in implementation are required across locations and settings?	Outer setting, implementation process
Monitoring How does your behaviour change if a patient has positive ARI diagnosis? How do you manage the patient?	Inner setting, Individuals involved
What is in it for the GP? How does it affect you as an individual, the way you do your work and how you feel about your job	Inner setting
Priority How important is the pathway for you to try? Does it fit in with other priorities	Inner setting
Any other thoughts or reflections?	

Interview Questions – Comparator Site

Interview Topics and Questions	CFIR Domain
Introductions • Explain purpose of the interview (recap Participant Information Sheet). • Re-affirm verbal consent for participation and use of audio recorder.	
Participant demographic information: • Role and length of service	Inner setting
Which diagnostic test machine are you using at your site? (should be none)	Characteristics of the intervention
Have you reviewed the proposed pathway changes? • *Prompts*: What are your thoughts about how practical it would be to implement? • How would it be set up in practice?	Characteristics of the intervention
ARI test set-up location Should the test be set up in the GP practice or in a hub? If it is in a hub, what are the pros and cons of the test location?	Inner and outer setting
What information and training would staff need to receive before setting up the service? • *Prompts*: Who should provide the training, what format, when received, what does it cover, etc.	Characteristics of the intervention
What information needs to be given to patients about the service? • *Prompts*: Who would provide it, what format, when received, what should it cover, etc? What do you think is good about this support? What other information or support needs to be in place?	Individuals involved, outer setting
Who would be involved in delivering the service? • *Prompts*: Which members of staff? What grade are they? Who would select the patients, using the eligibility criteria? Who would inform the patients that they will have the test, and what is involved? Who would do the follow up phone calls?	Inner setting, Implementation process
What do you think would be the main challenges and barriers to implement and deliver the ARI test and treat service? • *Prompts*: Relationship with the virologists and microbiologists who will be reviewing the tests, how would it work in practice? Any challenges and barriers with governance and transfer of data?	Inner setting, outer setting and individuals involved

Interview Topics and Questions	CFIR Domain
What do you consider to be good practice in terms of how the service would be provided? • *Prompts*: Explore in relation to staff and patients. Equipment and technology that would enable good practice	Implementation process
As an aim of this study is to understand the merits and unintended consequences of implementing this new ARI pathway in primary care – what points or issues do you think we need to consider?	Implementation process
How would testing and an accurate diagnosis change your behaviour? **Do you think it will lead to a change in prescribing?** **Do you think having diagnostic certainty will change the way you work?**	Inner setting
Opportunity cost • *Prompt*: While the staff are doing the ARI test, do you think care will suffer elsewhere? What are the implications? • What other unintended consequences do you think could happen?	Characteristics of the intervention
Would extra time be needed in delivering the new pathway? If yes, how much do you think would be required? • *Prompt*: Are there perceived additional costs other than staff time? The extra time, where would it come from and what is the grade of the member of staff? What is the cost?	Characteristics of the intervention
What IT infrastructures are needed to capture the data? • *Prompt*: Is the ARI test and treat service compatible with and does it fit it in with existing workflow and systems	Inner setting, Characteristics of the intervention
Monitoring How would your behaviour change if a patient had positive ARI diagnosis? How would you manage the patient?	Inner setting, Individuals involved
What is in it for the GP? How do you expect it to affect you as an individual, the way you do your work and how you feel about your job?	Inner setting
Scale and spread Do you think it would be sufficiently adaptable to different locations (urban and rural), different settings (care home, general practice, etc.), and scalable? • *Prompts*: What resources or strategies may be necessary for a widespread roll-out? • What are the key aspects which must be retained, and which key differences in implementation are required across locations and settings?	Outer setting, implementation process

Interview Topics and Questions	CFIR Domain
Priority How important is the pathway for you to try? Would it fit in with other priorities	Inner setting
Any other thoughts or reflections?	Inner setting

Clinician Acceptability Questionnaire

Theoretical Framework of Acceptability (TFA) Construct	Questionnaire Item				
Affective attitude How clinicians feel about Community Test and Treat of ARIs	How comfortable do you feel about Community Test and Treat of ARIs?				
	Very uncomfortable	Uncomfortable	No opinion	Comfortable	Very comfortable
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Burden The amount of effort required to participate in Community Test and Treat of ARIs	How much effort will it take you to carry out ARI diagnosis at your primary care?				
	No effort at all	A little effort	No opinion	A lot of effort	Huge effort
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Ethicality The extent to which Community Test & Treat of ARIs has good fit with clinician's value system	**Ethical consequences:** There are moral or ethical consequences to engage with community test & treat of ARIs				
	Strongly disagree	Disagree	No opinion	Agree	Strongly Agree
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
	How fair is the community test and treat for patients with ARIs?				
	Very unfair	Unfair	No opinion	Fair	Very fair
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

Theoretical Framework of Acceptability (TFA) Construct	Questionnaire Item				
Perceived effectiveness The extent to which Community Test & Treat has achieved its purpose	Community test & treat of ARIs will improve diagnostic certainty				
	Strongly disagree	Disagree	No opinion	Agree	Strongly Agree
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
	Community test & treat of ARIs will improve antimicrobial stewardship				
	Strongly disagree	Disagree	No opinion	Agree	Strongly Agree
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
	Community test & treat of ARIs will improve patient outcomes				
	Strongly disagree	Disagree	No opinion	Agree	Strongly Agree
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
Intervention coherence The extent to which the clinicians understand how Community Test & Treat works	It is clear to me how Community Test & Treat of ARIs will help improve my work behaviour				
	Strongly disagree	Disagree	No opinion	Agree	Strongly Agree
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐
	Please tell us more about your view: Click or tap here to enter text.				
Self-efficacy The clinician's confidence that they can perform behaviour(s) required to participate in the Community Test & Treat of ARIs	How confident do you feel about participating in Community Test & Treat of ARIs in primary care				
	Very unconfident	Unconfident	No opinion	Confident	Very confident
	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐

<table>
<tr><th>Theoretical Framework of Acceptability (TFA) Construct</th><th colspan="5">Questionnaire Item</th></tr>
<tr><td rowspan="3">Opportunity costs
The benefits, profits or values that were given up to engage in Community Test & Treat</td><td colspan="5">Engaging in Community Test & Treat in primary care will interfere with my other priorities</td></tr>
<tr><td>Strongly disagree</td><td>Disagree</td><td>No opinion</td><td>Agree</td><td>Strongly Agree</td></tr>
<tr><td>1 ☐</td><td>2 ☐</td><td>3 ☐</td><td>4 ☐</td><td>5 ☐</td></tr>
<tr><td rowspan="3">General acceptability</td><td colspan="5">How acceptable is Community Test & Treat of ARIs to you?</td></tr>
<tr><td>Completely unacceptable</td><td>Unacceptable</td><td>No opinion</td><td>Acceptable</td><td>Completely acceptable</td></tr>
<tr><td>1 ☐</td><td>2 ☐</td><td>3 ☐</td><td>4 ☐</td><td>5 ☐</td></tr>
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Please tell us more about your view: Click or tap here to enter text.

ACUTE RESPIRATORY INFECTIONS COMMUNITY TEST & TREAT CONSENT FORM

FOR THOSE ABLE TO CONSENT, THEIR FAMILY MEMBERS OR LEGAL REPRESENTATIVES

WINTER 2023/24

What is this test and why are we doing it?

We are taking part in a community project this winter [2023-2024]. This has involved the design and implementation of a community acute respiratory infection patient pathway using a diagnostic test for Flu, COVID or another respiratory virus (RSV). The test involves taking a nasal swab and the results will be known within the hour. We believe this test will enable prompt diagnosis and appropriate treatment for our patients, we are seeking consent from patients for taking the test.

A clinician will review the test results which may involve prescribing appropriate treatment if a patient tests positive for Flu, COVID or another respiratory virus (RSV).

We believe that testing and treating patients more quickly in the community could improve the outcome for those who test positive for Flu, COVID or other respiratory viruses (RSV) and may reduce unnecessary hospital admissions.

Patient Details (may be completed by health care assistant)

Full Name: Date of Birth:

Gender (circle as appropriate): Male / Female / Other / Prefer not to say

Address and Postcode:

GP Practice Name, Address and Postcode:

Consent from Patient, Relative, Attorney, Advocate

I consent as/on behalf of the person named in the previous section, to a nasal swab being taken and tested for seasonal Flu, COVID and another respiratory virus (RSV) and understand that the results of this test will be used to inform the clinician's treatment options. I understand that information relating to the test, its results and following treatment decisions, may be used as part of a project to help improve the detection and understanding of seasonal Flu, COVID and RSV and to improve treatment options and processes.

Name:

Signature:

Date:

Underline as appropriate:
I am completing this form for myself / I am completing this form for my relative / I am the above individual's Attorney / I am the above individual's advocate and am completing this form on their behalf.

Date of preparation: December 2023

HEALTH INNOVATION North West Coast

NHS England

PATIENT FEEDBACK SURVEY

1. **Was the test done in a place that was easy for you to get to?**

   Yes ☐ No ☐

2. **If you answered No to the last question, can you think of another place that would have been better for you?**

_____

3. **On a scale of 1 to 5, with 1 being low and 5 being high. Did you feel more reassured by having this flu test?**

   1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

4. **Why did you give this score?**

_____

5. **On a scale of 1 to 5, with 1 being low and 5 being high. Do you think the test you had is a good thing for people with flu-like symptoms?**

   1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

6. **On a scale of 1 to 5, with 1 being low and 5 being high. Did the results from the test make you feel that you would get the right treatment for your flu-like symptoms?**

   1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

7. **Would you recommend this new way of testing and treating flu symptoms to others.**

   Yes ☐ No ☐

8. **On a scale of 1 to 5, with 1 being Very Unhappy and 5 being Very Happy. How would you feel about doing a simple home test (similar to a COVID test) yourself in the future?**

   1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

9. **In the future, would you like flu testing to be available in any of these places?** (indicate all that work for you)

   ☐ In a community or health centre
   ☐ At your home address
   ☐ At GP surgery
   ☐ Community Pharmacy

10. **Can you think of anything that could have been done better? Or that you would have liked to be done differently when seeking help for your flu symptoms?**

_____

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HEALTH INNOVATION
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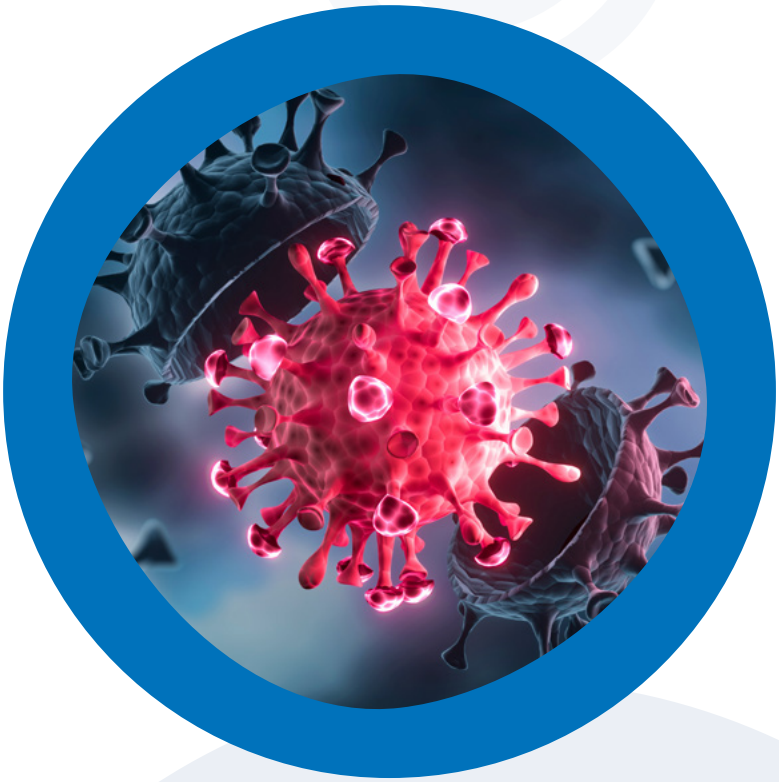

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