

**Point of Care C-reactive protein (POC CRP) testing in
community pharmacy for interventions in Respiratory
Tract Infections (RTIs)**

Pilot study

Run by

Total Health and Wellbeing Ltd,

and

North Staffs & Stoke Local Pharmaceutical Committee

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Point of Care C-reactive protein (POC CRP) testing in community pharmacy for interventions in Respiratory Tract Infections (RTIs)

1.Introduction

Antimicrobial resistance (AMR) is a global healthcare and economic problem. Respiratory Tract Infections (RTIs) are the most common infections in patients presenting to GPs and most patients presenting to a GP with a simple RTI still receive an antibiotic, with many doctors and patients believing that this is the 'right thing' to do. However, it is well known that;

- most RTIs are viral
- there is only limited evidence to support the use of antibiotics in acute bronchitis, sore throat, sinusitis and otitis media, and
- evidence suggests little benefit is achieved from the prescription of antibiotics.

Normally, blood contains only trace amounts of CRP. The liver rapidly increases CRP production following infection or injury. CRP binds to phosphocholine, which is found in bacterial and fungal polysaccharides and most cell membranes. This 'tags' infective or injured cells, and helps the immune system recognise and remove pathogens and damaged host cells.

Signs and symptoms of an upper RTI generally peak between days 3-5. Therefore, CRP tends to be highest when patients experience the most severe symptoms. A viral infection commonly causes moderately elevated CRP (10-60mg/l) after less than 7 days of symptoms, peaking on days 2-4. CRP that remains elevated after 7 days suggests secondary bacterial infection.

Overall, CRP POCT used alongside history taking and evaluation of signs and symptoms could reduce antibiotic prescribing without producing a clinically significant increase in the risk of complications or missed diagnoses. This service has been developed to give your customers access to the right advice and treatment for non-complex RTI infections. The service will help identify the cause of the customer's RTI and allow you to give the right advice and access to the right treatment options.

2.Aims of the scheme

To evaluate a CRP test in community pharmacy and to assess the acceptability of point of care CRP testing in community pharmacy. To demonstrate the reduction in GP appointments for non- LRTI and antibiotic prescribing.

3. Eligibility for the Scheme

3.1 Patient eligibility

First consultation of current episode of acute cough duration <4 weeks considered to be caused by lower respiratory tract infections (LRTI).

At time of consultation at least one of the following 4 symptoms

- shortness of breath:
- wheezing:
- chest pain;
- Auscultation abnormalities

At time of consultation at least one of the following 5 symptoms

- Fever according patient history or measurement > 38C;
- perspiring;
- headache;
- myalgia;
- feeling generally unwell

3.2 exclusion criteria

- Children
- Pregnant or breastfeeding women
- Customers who have been experiencing symptoms for less than 3 days (72 hours)
- Customers who have been experiencing symptoms for 3 weeks or more
- Patients with inflammatory conditions (CRP will already be raised)
- Any customers presenting with severe symptoms or any symptoms of concern, should be referred immediately to the appropriate healthcare professional.

4. Scheme Requirements

4.1 Who can provide the pilot?

Four pharmacies have been selected to take part in this pilot. Each of the pharmacies must have;

- All Pharmacists and appropriately trained pharmacy staff working that are clinically competent in the management and treatment of common respiratory tract complaints.
- an approved consultation area which meets the requirements set out in the CPCF for Advanced Services. All consultations must take place in a confidential environment.
- a Standard Operating Procedure (SOP) in place for the service.
- Safeguarding Children and Vulnerable Adults training from the CPPE
- Attend and successfully complete a Point of Care C-reactive protein face-to-face training session

4.2 Participating Pharmacies

Patients can access the pilot at any participating pharmacy, and the service must be available during all hours that the pharmacy is open. Only in exceptional circumstances should a patient be signposted to another provider if unable to provide the service at a particular time, and the local practice(s) should also be notified.

Four pharmacies will be providing the pilot and a list of these pharmacies available to GP practices and other healthcare providers. Therefore, if for any reason the pharmacy wishes to withdraw from the service North Staffs & Stoke LPC will need to be informed immediately.

5. Referral into the Scheme

Patients can access the scheme in four ways;

5.1 Referred by a GP practice to a participating pharmacy

Patients presenting at a GP practice with one of the symptoms listed in section 3.1, may be advised of the pilot and how to access it. Surgeries in close proximity to participating pharmacies will be briefed by the pharmacist about the scheme, in the hope that the surgery can direct patients into the service.

5.2 Referral by pharmacist or pharmacy staff

Patients can be referred into the pilot if they present with one of the symptoms listed and seek advice on the management and treatment of those symptoms.

5.3 Self-referral at participating pharmacies

Patients who are aware of the pilot can self-refer into it if they present with one or more of the common symptoms listed. The decision to carry out a CRP test remains with the pharmacist in charge.

5.4 Referral by other healthcare professionals

Patients can be referred into the service by an Out of Hours provider or NHS 111 where telephone triage identifies a possible respiratory infection which can be checked as part of this pilot. If appropriate, staff from Walk-In Centres and Accident and Emergency Departments can also refer.

6. Duties of the community pharmacist

6.1 Checking GP registration

Before proceeding to carry out the CRP test under the pilot, the patient **MUST** be asked to confirm that they are registered with a GP practice contracted to NHS England (NHSE S&S).

This may be done by:

- checking the patient's PMR, if the patient is already collecting prescriptions from that pharmacy;
- asking the patient to show the repeat prescription slip;
- knowing the patient to be registered with the GP practice;
- medical card

Confirmation of the patient's registration at an eligible GP practice is required if the above documentation is not available or if it is felt that a patient may be attempting to fraudulently use the pilot. Staff may telephone the patient's GP practice for confirmation of registration with the consent of the patient. They should offer the patient's details i.e. name, date of birth, and postcode or address, and merely ask the practice to confirm 'yes' or 'no' whether the patient is registered with them. The pharmacy should not expect the GP practice to offer any other patient information as they should already be in receipt of this from the patient.

6.2 Consultation

Stage one

The first conversation with the customer prior to any discussion about the service should include the WWHAM questions, as with any other customer presenting with symptoms in the pharmacy. Answers the patient provides to the WWHAM will mean that any queries regarding warning symptoms or customers on other medication will be referred to the pharmacist. WWHAM will be able to use identify the length of time the customer has had symptoms for. If the length of time is greater than 3 days, they should be referred to the pharmacists with the view to potential undertaking a test Point of Care C-reactive protein test.

Stage two

The second part of the consultation will be the hand over from the MCA to the pharmacist. This conversation will take place in the consultation room and the customer should always be offered a chaperone as per the chaperone policy. This part of the consultation should be recorded onto PharmOutcomes. The pharmacist will then be required to ask the customer some questions in order to understand if they can proceed with the service or require referral to another healthcare professional.

This stage is to check on the symptoms and to rate the severity. Each of these are rated by the patient as a likert scale where 1 is minimal symptoms and 5 is maximum symptoms.

- shortness of breath:
- wheezing:
- chest pain;
- Auscultation abnormalities
- Fever according patient history or measurement > 38C;
- perspiring;
- headache;
- myalgia;
- feeling generally unwell

There are some general “red flag” signs and symptoms which will always need referral such as

- Symptoms lasting for 3 weeks more

- Rash
- Muffled voice
- noisy breathing, high-pitched sound during breathing or difficulty breathing
- Difficulty swallowing, or is not able to swallow enough fluids
- Signs of blood in sputum
- Signs or symptoms of any other infection or serious illness
- The customer has already taken antibiotics for this RTI

Please refer to NICE Pneumonia in adults: diagnosis and Management cg191

Please note that these lists are not exhaustive. You must use your professional judgement to determine whether a customer's symptoms warrant referral.

Stage three

The third part of the consultation is the actual test. Please refer to separate paper work of how to use the machine for Point of Care C-reactive protein testing

Appendix 1 gives a table of readings from the Point of Care C-reactive protein test and the recommended course of action

6.3 Follow up consultation

Stage four

Patients should be advised that they will be followed up 3 days and 7 days after the initial consultation. This follow up is to check on the symptoms and whether there is any change that may need referral or not. Questions that will be asked are the same as in the initial consultation. For example

- shortness of breath;
- wheezing;
- chest pain;
- Auscultation abnormalities
- Fever according to patient history or measurement > 38C;
- perspiring;
- headache;
- myalgia;

- feeling generally unwell

Each of these are rated by the patient as a likert scale where 1 is minimal symptoms and 5 is maximum symptoms.

6.4 Self-care advice for those patients not requiring the Point of Care C-reactive protein test

Customers should be advised that RTI are generally self-limiting with most people recovering after a week, with or without antibiotics. Over the counter treatments can be used to relieve the symptoms of RTI. Regular use of analgesics such as ibuprofen or paracetamol can help reduce a high temperature (fever) and to ease any aches, pains and headaches. SIGN guidelines recommend a dose of 400mg three times daily for the relief of fever, headache and throat pain for those who can take ibuprofen. For those who are unable to take ibuprofen, you should recommend paracetamol at a dose of two tablets four times a day.

Having plenty to drink if you have a fever, to prevent mild lack of fluid in the body (dehydration). As long as you do not have a fever, there is no evidence that drinking more fluid than usual makes a difference. **Steam inhalation.** There is not very much evidence that this helps; however, some people find it useful. It is very important to be careful to avoid burns and scalds, particularly with children. A safe way of inhaling steam is to sit in the bathroom with the door closed, while running a hot shower to make the room steamy. **Vapour rubs.** Vapour rubs can be bought in pharmacies and supermarkets. Some people find they help with a stuffy nose. Rub the vapour on to the chest and/or back of the person with the cold, but avoid the area under the nose. Sucking **sore throat lozenges** (available from pharmacies and supermarkets) or boiled sweets may help ease a sore throat. **Warm drinks with honey and lemon** may help to ease a sore throat. (Do not give honey to babies less than 1 year old as it is not known if this is safe.) **Salt (saline) nose drops.** These are nose drops made of a salty solution, which may help clear a blocked nose. They are sometimes helpful for babies who are having difficulty breathing through a blocked nose as they feed. They can be bought from a pharmacy.

6.5 Consultation record

It is a requirement of the service that all consultations are recorded on PharmOutcomes. This is a web-based system that is used for the invoicing and management of locally

commissioned pharmacy services. This information should be recorded at the time of the consultation or by the end of the next working day at the latest.

6.6 Referral to GP or other Healthcare Professional

In a situation where a patient presents with a symptom(s) that requires referral to their GP or other healthcare professional (urgent or otherwise), the Pharmacist must complete the 'Referral from Community Pharmacy' (Appendix 2) with the patient's details, reasons for the referral including assessment of urgency, and details of the Pharmacist referring. This information will also need to be recorded within PharmOutcomes. The patient must confirm that they understand the urgency with which they need to seek healthcare support, and take a copy of the referral form with them.

If the patient's GP practice is closed and/or the symptoms are sufficiently severe to warrant a referral to a doctor, the patient must be advised to contact the Out-of-Hours service or attend A&E immediately. A referral form should still be completed in these cases, unless symptoms appear life-threatening, in which case the Pharmacist must dial 999 and provide the attending Paramedics with any relevant information.

Please refer to NICE Pneumonia in adults: diagnosis and Management cg191

6.7 Make an OTC sale rather than referral

OTC treatment(s) can be supplied to patients who do not meet the eligibility criteria as set out in Section 3, and subject to the clinical and professional judgement of the Pharmacist/trained pharmacy staff undertaking the consultation.

6.8 Professional judgement

Pharmacists may use their professional judgement to exclude patients from receiving a CRP test under the pilot when signs and symptoms suggest that a referral to a GP or other healthcare professional is required, including those not explicitly covered within the protocols.

6.9 Record keeping

In addition to the consultation data recorded on PharmOutcomes, it is best practice to make a separate record on the patients PMR.

All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements. Recommendations for the retention of pharmacy records for minor clinical interventions is 2 years.

6.10 confidentiality

During the course of delivering services, as in every other aspect of pharmacy, you and your team will be given or come across confidential or sensitive information. It is therefore important to remember that all team members involved in a service should conduct any conversations with customers in the strictest of confidence and use a sensitive approach. Information held about any individual (whether a customer or employee) is covered under the Data Protection Act. As with all confidential information, you must not disclose this information, other than in the proper performance of your duties and within the scope of the service, either during employment or afterwards. Information acquired during or as a result of work should not be disclosed or discussed. In particular, disclosing a customer's personal information, medical conditions, test results or diagnosis will be treated as gross misconduct.

7. Service evaluation

Pharmacies that participate in the pilot will be expected to facilitate the evaluation of the pilot by participating in patient satisfaction surveys or audit. This data, combined with analysis from PharmOutcomes, will enable commissioners (Total Health and Wellbeing Ltd) along with the LPC to evaluate the efficacy of the scheme.

8. Complaints and incident reporting

Pharmacies will be expected to follow standard operating procedures for complaints that are in accordance with NHS policy.

Any significant incidents or issues that arise during provision of the pilot should be recorded as part of the pharmacy's clinical governance procedures, and notified to the Primary Care Team of NHS England North Midlands (Staffordshire and Shropshire Area).

The pharmacy may also wish to notify Total Health and Wellbeing Ltd, The Orchards, Fenny Bentley DE6 1LB and North Staffs & Stoke LPC of any incidents with regard to this service.

9. Duties of the GP practice

One of the aims of the scheme is to reduce the demand for GP appointments for acute common respiratory complaints that do not need antibiotics, thereby allowing patients with more complex medical needs to be seen more quickly.

GP practices, adjacent to participating pharmacies will therefore be encouraged to display posters advertising the pilot, and have leaflets available for patients which explain the pilot in more detail. Practices may also choose to include information about the pilot in their answerphone messages and on display screens within patient waiting areas.

GP practices will also be expected to refer patients directly into the scheme where it is deemed appropriate to do so and with the agreement of the patient. It is envisaged that reception staff who book appointments for patients will be ideally placed to offer referral into the pilot and will therefore need to have an understanding of, and access to, pilot details in order to do so appropriately.

GP practices may also encounter patients who have been referred back to them by a Community Pharmacist following a consultation under the pilot. These patients will have been provided with a referral form which will include an assessment of the urgency with which the Pharmacist felt the patient needed to be seen, and therefore practice staff should use this information when arranging an appointment. The decision for how quickly a patient needs to be seen though will remain at the practice's discretion.

10. Funding and payment procedures

10.1 Payments

Reimbursement for the scheme will consist of a consultation fee of £20.00. The consultation fee is rated as Exempt for VAT purposes.

There will be a cap of **25 tests per pharmacy**

There will be no fee if a Point of Care C-reactive protein (POC CRP) test is not carried out.

Payments will be made on a monthly basis, and this will be done as a BACs payment to the pharmacy bank account. The reference on the BACs will be;

CRP followed by the month. For example, payments for the service delivered in March will be shown on the bank statement as **CRP03**

All payments will be made at the end of the month following that to which the payment relates.

Claims must be submitted via PharmOutcomes by the 5th of each month

10.2 PharmOutcomes

It is a requirement of the service that all consultations are recorded on PharmOutcomes for invoicing and audit purposes. Upon receipt of this signed Service Level Agreement, the pharmacy will be accredited on PharmOutcomes, and staff will have access to the module.

All pharmacies will require an individual login to access the module, and these are provided separately by PharmOutcomes directly. Most pharmacies will already have these login details for other services accessed via this platform, but if not please contact your Local Pharmaceutical Committee (LPC) who can provide the relevant information.

Patient registration will require the following information to be recorded;

Patients name

- Address including postcode
- Date of birth Page
- NHS number
- Ethnicity
- GP practice with which the patient is registered

Once registration is complete, consultation data can be entered.

As part of your role and responsibility during a consultation you will need to gain informed consent from a customer, for example to perform the Point of Care C-reactive protein (POC CRP) testing. In order to gain informed consent effectively, all the information needed must be given to the customer so they can make a decision to grant their consent and any questions must be answered fully by you. Customers must be able to always provide their consent freely which means that it must not be given under the influence of anyone else, including you. To facilitate this before each conversation, the customer should be provided with an overview of the service any tests that may need to be performed by you. The customer must make their own decision as to whether they would like to proceed with this service or not.

When using PharmOutcomes you will need to obtain verbal consent, if you are using the paper proforma at the time of testing then written consent should be given by the patient signing the paperwork.

All information relating to the consultation should be recorded at the time of the consultation by inputting the information directly onto PharmOutcomes. However it is recognised that some pharmacies do not have access to a computer in their consultation room, and therefore the information can initially be recorded on a paper based proforma (Appendix 3 and 4), but this information must be entered onto PharmOutcomes immediately, or by the end of the next working day at the latest. Failure to do so may lead to payments being withheld, or the contract being terminated.

11. Chaperone Policy

The customer should be made aware of the Chaperone Policy, which allows the customer to have someone (e.g. team member/family member) with them in the consultation room while you provide a service.

12. Contract period

This agreement is for the period 1st March 2017 to 1st June 2017 subject to budgetary constraints.

13. Termination of pilot/service

Any participating pharmacy that has signed this Service Level Agreement (SLA) and is participating in the pilot may terminate the agreement by giving written notice of their intention at least 28 days before cessation. No reason needs to be given for termination of the agreement.

Total Health and Wellbeing Ltd terminate the Pilot by giving written notice to all participating pharmacies. A minimum of 28 days written notice will be provided.

Total Health and Wellbeing Ltd, a responsibility to ensure that all participating pharmacies deliver the scheme in accordance with the Service Level Agreement. If it is found that a Contractor fails to meet any of the obligations of this agreement, they will be notified in

writing of the nature of the breach. Where the breach is not remedied within appropriate time-frames or the LPC deems it is not capable of remedy, LPC will be entitled to terminate this agreement with immediate effect.

14. Indemnity

The Contractor shall maintain adequate insurance for public liability and professional indemnity against any claims which may arise out of the terms and conditions of this agreement.

Any litigation resulting from an accident or negligence on behalf of the Contractor is the responsibility of the Contractor who will meet the costs and any claims for compensation, at no cost to any other body, including the LPC.

15. Data protection

Both parties shall adhere to the requirements of the Data Protection Act 1988 and the Freedom of Information Act 2000.

16. Completion of signed agreement

In order to participate in the service, each participating pharmacy must complete the signed agreement (Appendix 5), and return to Tania Cork as indicated. Once received, the pharmacy will be accredited for the POC-CRP pilot module on PharmOutcomes, and delivery of the service can commence.

A patient journey has been given in appendix 6

Appendix 1

Point of Care C-reactive protein testing score	meaning	Action to be taken
CRP > 100mg/l	infection	Refer to GP to offer antibiotic therapy if the C-reactive protein concentration is greater than 100 mg/litre.
CRP between 20 and 100mg/l	Possible infection	Watch and wait. Consider a delayed antibiotic prescription (a prescription for use at a later date if symptoms worsen) if the C-reactive protein concentration is between 20 mg/litre and 100 mg/litre
CRP <20mg/ml	No infection	Reassure patient and recommend self-care. Do not routinely offer antibiotic therapy

Referral from Community Pharmacy

Patient's name:.....

Patient's D.O.B:.....

Patient's address:.....

.....

The patient named above has accessed the Pharmacy First for Common Ailment's Scheme and following assessment by the pharmacist on duty a referral has been recommended based on the following information;

Pharmacist's comments:.....

.....

.....

Indication of urgency (please tick):

Accident and Emergency

Contact GP or other HCP within 24 hours

Contact GP within days if symptoms do not resolve

Pharmacist's name (PRINT).....

Pharmacy telephone number.....

Pharmacy address.....

.....

Date and time.....

Pharmacist signature.....

Please ensure that this form is given to your GP or other Healthcare Professional

Appendix 3

PharmOutcomes proforma

Surname.....forename.....

Address.....

Postcode.....

DoB.....

GP and surgery

NHS no. if known.....

Presenting symptoms

- shortness of breath: likert scale 1-5
- wheezing: likert scale 1-5
- chest pain; likert scale 1-5
- Auscultation abnormalities
- Fever according patient history or measurement > 38C;
- perspiring; likert scale 1-5
- headache; likert scale 1-5
- myalgia; likert scale 1-5
- feeling generally unwell likert scale 1-5
- **others (please state)**.....

any red flag symptoms

- Symptoms lasting for 3 weeks more
- Rash
- Muffled voice
- noisy breathing, high-pitched sound during breathing or difficulty breathing
- Difficulty swallowing, or is not able to swallow enough fluids
- Signs of blood in sputum
- Signs or symptoms of any other infection or serious illness
- The customer has already taken antibiotics for this RTI
- **others (please state)**.....

course of action

- recommended self-care
- referral to another healthcare professional (please state).....
- undertake CRP test

patients consent.....

Test results

- 100mg/ml
- Between 20-100mg/ml
- <20mg/ml

Action in view of test results

- Referral to GP
- Watch and wait
- Self-care

Appendix 4

PharmOutcomes module for follow up consultation

Surname.....forename.....
Address.....
Postcode.....
DoB.....
GP and surgery
NHS no. if known.....

3 day follow up

- shortness of breath: likert scale 1-5
- wheezing: likert scale 1-5
- chest pain; likert scale 1-5
- Auscultation abnormalities
- Fever according patient history or measurement > 38C;
- perspiring; likert scale 1-5
- headache; likert scale 1-5
- myalgia; likert scale 1-5
- feeling generally unwell likert scale 1-5
- **others (please state)**.....

7 day follow up

- shortness of breath: likert scale 1-5
- wheezing: likert scale 1-5
- chest pain; likert scale 1-5
- Auscultation abnormalities
- Fever according patient history or measurement > 38C;
- perspiring; likert scale 1-5
- headache; likert scale 1-5
- myalgia; likert scale 1-5
- feeling generally unwell likert scale 1-5
- **others (please state)**.....

Appendix 5

SIGNED AGREEMENT

On behalf of (Pharmacy Name and Address)

.....
.....

Contractor Code (FCode).....

I have read and understood the terms in this service specification and agree to provide the standard of service specified.

Signature.....

Print name.....

Designation.....

Date.....

Signature (Total Health and Wellbeing Ltd, The Orchards, Fenny Bentley DE6 1LB).....

Print name.....
.....

Date.....

Please return a signed copy of this form by email to taniacork@northstafflpc.co.uk or by fax to 01782 503672

Appendix 6

Patient flow

