**Study contacts:**

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| --- | --- |
| **Study Co-ordinator:** Jenny Riga**Tel:** 01865 617959**E-mail:** jenny.riga@phc.ox.ac.uk | **Primary Care Research Facilitator:** **Mobile: 07920531253****Email: Jennifer.lee@warwick.ac.uk****CCG’s :** Herefordshire |

**Research Information Sheet for Practices**

**PACE**

*CSP: 159928*

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**Principal Investigator:** Chris Butler

**Host Institution**: University of Oxford

**Funded By:** NIHR HTA

The Study

**Study Title**: Primary Care use of a C-Reactive Protein (CRP) Point of Care Test (POCT) to help target antibiotic prescribing to patients with Acute Exacerbations of Chronic Obstructive Pulmonary Disease (AECOPD) who are most likely to benefit.

**Aim of study:** To determine whether the addition of a CRP POCT (with training on test use and interpretation) to current best practice based on NICE guideline for managing an AECOPD leads to a reduction in antibiotic consumption for the exacerbation within four weeks post index consultation without negatively impacting on COPD health status (measured at two weeks post index consultation), compared with current best practice alone.

**Number of patients per practice screened:** ~5000

**Number of patients per practice invited:** 90

**Number of patients per practice recruited:** 11-12

**Number of practices in West Midlands:** 5-6

**Study recruitment period:** Sept 2015 – 31 January 2017 (16 months)

Inclusion/Exclusion Criteria (Summary)

**Inclusion Criteria (summary):**

* Has a current AECOPD with presence of at least one of the following features: Increased dyspnoea; increased sputum volume; increased sputum purulence.
* The acute exacerbation has lasted for at least 24 hours and no longer than 21 days.
* 40 years of age or more.
* Able to provide informed consent.
* Patient should be able to provide the primary outcome data at 2 and 4 weeks within the expected windows.

**Exclusion Criteria:**

* The responsible clinician feels urgent referral to hospital is necessary.
* Severe illness (e.g. suspected pneumonia, tachypnoea >30 breaths per minute, respiratory failure).
* Concurrent infection at another site (e.g. cellulitis) that is likely to produce a systemic response.
* Past history of respiratory failure or mechanical ventilation.
* Currently on antibiotics or has had antibiotics for this acute exacerbation.
* Active inflammatory condition (e.g. flare of rheumatoid arthritis, gout or polymyalgia rheumatica).
* Has cystic fibrosis, a current tracheostomy or bronchiectasis.
* Immunocompromised (e.g. AIDS, taking immunosuppressive therapy or is receiving anti-cancer radiotherapy or chemotherapy).
* Currently pregnant.
* Previously been recruited into the PACE study.

Practice Involvement in the Study – Summary

**By clinicians / practice:**

* Prior to recruiting patients: -
attend study training (approx 1 hour), CRP training (approx. 2 hours), read study protocol and related materials, sign GP agreement and delegation log, assist with conducting a mail-out to patients on the COPD register.
* When recruiting patients: -
carry out eligibility assessment, obtain informed consent, complete baseline CRF, obtain samples from patient (sputum (if possible) and throat swab), randomise patient, carry out CRP test (depending on randomisation allocation), return CRFs and samples as described in protocol and in study training.
* At week 4: -
face-face consultation with patient, completion of CRF and taking samples. Return CRFs, samples and patient questionnaires (approximate time for this consultation is 15 mins).
* Ensure that any serious adverse events are properly reported and causality assigned.

**By participants:**

* Calls the surgery to make an appointment when experiencing an AECOPD (and brings ‘Potentially eligible for PACE Study” card with them).
* Consult with the GP before taking any rescue medication.
* Provide a throat swab and sputum sample (if possible).
* Week 1 & 2 - Completion of a CCQ and EQ-5D prior to telephone interview
* Week 4 - face to face assessment with GP and throat and sputum sample taken (if possible)
* 6 months - CRQ-SAS & EQ-5D completed and sent back to research team.

**By researchers:**

* Assist GP practices to gain R&D approvals
* Provide training to practices – study specific training (approx. 1 hour) and POCT training (approx. 2 hours). (Training may involve travelling to a central training session)
* Training in use of Docmail (if requested)
* Provide agreement between Sponsor and GP site
* Provide site files and study packs to the practices
* Provide updated documentation throughout study
* Offer general support to the practice to help with the smooth running of the study
* Monitoring
* Advise on study close down and archiving

Reimbursement

Reimbursements have been agreed for the following activities. When the practice is initiated into the study, researchers will discuss the process for claiming these costs.

|  |  |
| --- | --- |
|  | **Received by practice:** |
| **One-off costs:** study set up, database search, manual screening and mail out of study information using DOCMAIL | Approximately £250.00 dependant on numbers invited  |
| **Total per patient:** | £180.00 |

Potential Benefits for the Practice

* Opportunity for developing research at your practice (GCP training available).
* Opportunity for patients to engage in research.

Patient Confidentiality

Participant data will only be accessed upon notification of consent being obtained. Data collected will be securely stored in compliance with all national and local regulations.

If you wish to take part in the study, what happens next?

Please complete the sign-up sheet attached to this RISP and post or fax to: Jenny Lee

Fax Number: 024 76528375

**Thank you for your interest in this study. Please call the Study Co-ordinator if you would like to discuss this study further.**

**If you are willing to take part in this study, please complete the form below and fax, e-mail or send to Jenny Lee (address below):**

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**Study Title:**

**PACE**

*CSP: 159928*

**Name:**

**Signature:**

**Date**

**Practice Address:**

**Telephone Number:**

**Fax Number:**

**Email address:**

**Please post, fax or e-mail to:**

Jenny Lee

Research Facilitator

Jennifer.lee@warwick.ac.uk

NIHR Clinical Research Network: West Midlands